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An Ethical Framework for Global Governance for Health Research

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AN ETHICAL FRAMEWORK FOR GLOBAL GOVERNANCE FOR HEALTH RESEARCH

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ABSTRACT

AN ETHICAL FRAMEWORK FOR GLOBAL GOVERNANCE FOR HEALTH RESEARCH

By

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May 2017

Dissertation supervised by Professor Henk ten Have, MD, PhD

Global Governance is the way by which various affairs of human social life at the global scale are governed in the absence of a global governance. This field is composed of complex networks of role players. Global Health Governance is a branch of Global Governance that governs the health-related affairs. An important branch of this huge complex of networks that has not been analyzed sufficiently in the scholarly literature yet is Global Governance for Health Research. Global health research, although it is a part of global health affairs, has its own features and conditions that bring about its specific issues and challenges at the global scale. Therefore, Global Governance for Health Research, although is generally a part of Global Health Governance, has major differences (along with similarities and overlaps) with it in different aspect, including the

major role-players, ethical authorities and institutions, and the main issues and challenges.

This dissertation classifies the major role players of Global Governance for Health Research into the state and non-state role players. The major state role-players of Global Health Governance are intergovernmental organizations such as the World Health Organization (WHO), the World Bank, and UNESCO. The non-state organizations include the World Medical Association (WMA) and numerous other civil society and philanthropic organizations and corporations. The WHO and the World Bank, although important in the realm of global research, have not been the most influential role-payers in Global Governance for Health Research. Since the Global Governance for Health Research has mainly been materialized through internationally recognized frameworks and guidelines, the organizations that created, adopted, and promulgated these instruments have been the most influential role-players in the realm of Global Governance for Health Research, among them being the UNESCO, WMA, and CIOMS.

Global Governance for Health Research has its own challenges that are discussed in chapter 3 and studied through cases in chapter 4 of this dissertation. Challenges such as exploitation and helicopter research, double standards, bilateralism, the impact of bio-politics, ethical imperialism and colonialism, and the problem of data sharing and big data. The framework of gaps is also relevant to this field and the knowledge, normative, policy, institutional, and compliance gaps show themselves in Global Governance for Health Research. The cases discussed in this dissertation include the Zika Pandemic, the Research integrity in Iran, HIV/AIDS Research in Africa, Sending Biological Specimens Abroad (the problem of Bio-piracy), Research on Pre-Implantation Human Embryo, and

Local and International Alternative Medicines. Each of these cases portrays a specific set of challenges and gaps in the current situation of Global Governance for Health Research. In addition, it has been shown that most of the challenges in this area are of ethical nature. Therefore, there is a need to a systematic and comprehensive ethical framework in this arena.

This dissertation suggests an ethical framework for Global Governance for Health Research that is composed of three main elements. A virtue-based element/layer that encompasses three moral virtues of empathy, compassion, and care. These virtues are the most basic moral attributes of physicians/health researchers and underlie their ethical behavior and their compliance to the principles. A two-layered principle-based element that encompasses a layer of fundamental principles, i.e. Human Dignity, Human Rights, and Non-Exploitation and a layer of more specific or practical principles that mostly adopted from the UNESCO Declaration of Bioethics and Human Rights to have a comprehensive and universal approach and from the NIH framework to have a research-oriented systematic approach. And the last element of the suggested framework is inspired by particularism or situation ethics that demands establishing, empowering, and strengthening networks of oversight and review committees/boards to guarantee the continual and comprehensive case-by-case ethical review and oversight and monitoring all over the gigantic networks involved in global health research enterprise.

Despite the existing challenging trends such as neoliberalism, isolationism, and protectionism in the Western countries and fundamentalism in some developing countries it seems that the suggested framework can be helpful in shedding ethical light on the challenges of Global Governance for Health Research and in filling its various gaps. This

study is a small step in filling the knowledge gap. The suggested framework can fill part of the normative gap, this framework can be an ethical basis for policies that may fill the policy gap, the situation-ethics element of the framework is concerning the necessity and the ethical way for filling the institutional gap and finally, removing or alleviating the moral barriers is one of the ways for filling the compliance gap. Filling these gaps is not a one-time mission, instead, the process of developing and filling these gaps is continuous and will continue as long as the Global Governance for Health research is a reality on the global scene. In the final part of this dissertation, a number of practical and research recommendations and suggestions are provided.

DEDICATION

Dedicated with love to:

Mitra and Parastoo, The loves of my life,

And to all the people who took part in Women's March on January 21, 2017,

And chanted:

"Love, not hate

Makes us great!"

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Chapter One - Definition, Conceptual Analysis, and History

The first step for understanding and analyzing the situation, challenges, and ethical aspects of global governance for health research is understanding its key related concepts. These concepts are involved in shaping the main conceptual frameworks within them all the discussions and arguments develop and proceed. Therefore, in this beginning chapter of this dissertation, providing a comprehensive conceptual analysis of the involved key concepts seems to be not only helpful but necessary. Having a clarified set of concepts at the beginning of a theoretical endeavor helps the participants to grasp a more vivid understanding of the content and the flow of arguments and prevents the unnecessary ambiguities and misunderstandings that are just the results of uncertainty and disagreement on the exact meaning of the concepts.

The main concepts that are described in this chapter include Governance, Global Governance, Global Health Governance, and Global Governance of Research. These main concepts are used in shaping the theoretical frameworks of the discussions and arguments throughout this dissertation. Many other concepts are used in other parts of this dissertation, such as research integrity, civil society, evidence-based medicine, etc. each of them defined in the respective parts. On the other hand, there are other concepts that are very important and crucial, but are not defined here or anywhere else in this dissertation just because their definitions are considered consensual and a part of common knowledge. These "common knowledge" terms and concepts include (but are not limited to) research, biomedicine, health, government, state, organization, politics, society, etc. Therefore, just four above-mentioned main and essential concepts are defined and discussed in this chapter and neither described within the next parts of this

dissertation, nor are obvious, consensual, well-defined, and self-evident (or so are considered here).

In addition to the conceptual analysis, a brief history of the theoretical development of each one of the above-mentioned concepts has been provided under each respective title, along with a conceptual definition. As well, in the last part of this chapter, a brief history of the international/global research enterprise and its main developments and historical milestones is depicted. A specific part, research integrity, has been explored in more details because it provides a more explicit example and has also been separately discussed in the next parts of this dissertation (in chapter three as a case study).

This historical perspective is needed for acquiring a better comprehension of the nature and importance of the existing challenges and their ethical nature, dimensions, and possible solutions. Exploring the historical perspectives is an integral part of any theoretical work (at least in the field of health humanities) since the best way for finding a comprehensive and realistic picture of the conceptual challenges is looking at them in the mirror of their emergence, developments, variations, and transformations through the courses of their histories.

i. Governance

Governance, in its traditional sense, can be simply defined as "the process of governing." It is important, however, to notice that this term not only refers to the process of governing by governments but also to the process of governance in the absence of a specific government. The latter denotes the more dynamic, sophisticated, and sometimes subtle processes of governing by various interacting role players in the social/collective human life. Therefore, governance can be defined as the sum of a wide variety of means

and processes used by various individuals and institutions to manage their various affairs in the collective human life.[1]

Before proceeding in defining governance, four different notions need to be defined in more details: institution, organization, state, and nation. Although the terms institution and organization and the terms nation and state can be (and frequently have been) used interchangeably, as in some instances in this dissertation they are so, in a closer look they have different extent of meanings and connotations:

(1) Institutions are "social conventions" or "rules of the game", therefore, marriage, market, church, and democracy are examples of institutions. (2) Organizations, however, are "material entities" having physical locations (or seats), and other organs such as office, employees, equipment, and budget." Therefore, entities such as the World Health Organization and National Institutes of Health are among the examples of organizations (although in the name of National Institutes of Health one can readily see the interchangeability of institution and organization). (3) states are "governmental-territorial entities". A governmental-territorial entity means a specific territory defined and confined by its borders that is formally under sovereign governance of a government. This definition is equal to the formal definition of nation-state (this is the reason behind this fact that the terms nation and state are commonly being used interchangeably). The examples of states are clear and abundant: The United States of America, the United Kingdom, Russia, China, Iran, and other members of the United Nations are among the states. (4) Nations, however, can be defined as "communities with share identities", or in other words, "groups of persons professing solidarity based on and around of their respective unifying items, such as language, religion, ethnicity, history, or other bonding

elements."[2] Although nations and states usually coincide, they are not identical. There are nations such as Kurds or Palestinians who are not represented by a single state, and there are states, such as Switzerland and former Yugoslavia, that contain (or contained) different nations. In addition, some nations are (or have been) divided between separate states, such as former East and West Germany, South and North Korea, and South and North Sudan.[3]

The role players in governance include (but are not limited to) corporations, organizations, professions, religious bodies, media, pressure groups, lobbyists, coalitions, civil society actors, activists, and other formal and non-formal role players. In this sense, governance encompasses all the processes of social organization and social coordination. This function is provided not only by governments (or intergovernmental institutions such as organizations, coalitions, treaties, etc.), but also by other social institutions and civil arrangements that work in the forms of markets or networks. Therefore, in one sense, the forms of governance can be broadly categorized into hierarchies (including states), markets, and networks, the last one being the most sophisticated form that shapes the main platform of global governance.[4]

Governance, in various forms, exists in different fields of collective human life, including organizations, activities, and outcomes; and in any level of it, including family, team, tribe, community, nation-state, and globe. Therefore, there are countless types of governance mentioned and described in the literature, for example, public governance, organizational governance, corporate governance, global governance, non-profit governance, project governance, environmental governance, health governance, and information technology governance.[5]

The origin of the word *governance* is the Greek word *κυβερνάω (kubernáo)* that means *to steer*. Governance with the meaning of *the process of governing* has been used in different English texts such as the book titled *The Governance of England* by *Charles Plummer* that was published in 1885. The meaning of governance had always been linked with the functions of governments until the last decades of the twentieth century. In those decades, a conceptual shift occurred and this world became a fashionable term in the academic and political discourse that equated almost solely with the concept of governance without a government or beyond single government(s).[6] In other words, the term, governance, with its current definition has become popular and viral in political, social, economic, and ethical discourses and in the academic literature, since not sooner than the early 1990s (see below).

The newly-emerging ubiquity of the term of governance in the scholarly and political literature is an obvious phenomenon at the beginning of the twenty first century. This ubiquity is especially noticeable in the field of global affairs. Two main trends have led to this abundant reliance on the concept of governance (governing without a government) for describing and understanding the current state of global affair:

First, the ever-increasing complexity of human collective life and emergence of new patterns of social interactions and social life that had brought up new challenges and problems (e.g. global warming, pandemics, cybersecurity) that cannot be solved or managed within the borders of single sovereign states. In other words, in the absence of a single government or a single hierarchical order in the global scene, a system of governance without government is (or in some cases should be) in place to deal with such supranational and transnational challenges and issues.

Second, the emergence of numerous non-state and non-governmental and non-intergovernmental role-players on the scene has changed the scene of global affairs from the one once dominated by Intergovernmental Organizations to the current one that is mostly governed by other role payers, such as non-governmental organizations, transnational enterprises, and civil society organizations (see chapter 2).[7] In other words, in the absence of a single global government, the sophisticated and intertwined network of various role players are in charge of managing different transnational and global affairs. This system is best described by "governing without a government" or governance.

The concept of governance, in general, had almost always been accompanied by questions about the criteria of good governance, or on the other words, this very question that what makes a form of governance a good one. Historically speaking, however, a newly-emerged emphasis on the concept of good governance and its theoretical and practical components, have arisen over the last decades of the twentieth century through the processes originated in the World Bank and International Monetary Fund. They developed criteria for good governance to guide the process of financial support for developing countries.

Mark Bevir in his book titled *Governance: A Very Short Introduction*, holds that governance plans deal with issues of efficiency, development, capacity, accountability, and legitimacy. They try to combine practical effectiveness with ethical values. This obviously shows that the adjective good is a strongly value-ridden one. The values overarching these plans have been mainly inspired by liberal democratic theories, that means that they aimed to develop representative, accountable, transparent, responsible,

and at the same time, stable and sustainable forms of governance,[8] although they have also been accused of imposing the Western liberal values (or neoliberal values) to other countries and lack of respect for cultural diversity and sovereignty of the low and middle income societies and countries. Later in this dissertation these accusations are described and explored in more details.

The collapse of the Soviet Union and many other dictatorships in the developing countries in the final years of 1980s and over the 1990s, led to the appearance of numerous new democracies on the global sense with a common feature that was their desperate need for financial support for reconstructing their infrastructures and for developing modern political, social, and economical systems. This need resulted an upsurge of new demands for financial support from international organizations such as the World Bank and the International Monetary Fund. These financial organizations, in turn, needed to make sure that their financial support would produce their desired/anticipated developments and changes in the recipient countries.

The need to ensure the efficiency of their lending activities (compatible with their accounts of development), led the international funding bodies to create a set of criteria for good governance as the prerequisites of their financial support.[9] They clearly understood that without a desired governance in place, all the financial supports would vanish very fast in a web of corrupted politicians and swamp of ineffective systems. Therefore, these intergovernmental financial institutions began to put an emphasis on exploring the pitfalls and strengthening the institution of governance in the receiving countries. For example, a report published by the world bank in 1989, titled *Sub-Saharan Africa: From Crisis to Sustainable Growth*, argued that the "crisis of governance" is a

major obstacle for development of African countries. Consequently, the World Bank started to add the term "good governance" to its technical vocabulary dealing with technical issues and civil society and aiming to improve the functions of governance in the receiving low and middle income countries.[10]

As mentioned above, the criteria set by intergovernmental organizations for good governance - because of their inevitable value-ridden nature - have raised concerns on and accusations of imposing liberal or neoliberal ideas and ideals to the developing countries.[11] Although in the historical experience, setting neoliberal prerequisites and requirements for financial support has failed in producing sustainable development in the developing countries, this question on what entails a good governance still exists. In the following chapters of this dissertation, the role of bioethics in dealing with this quest is discussed.

Because of the bioethical nature of many of the supranational and transnational problems and their trajectories, trends, implications, and solutions, especially in the global health sector (including health-related research enterprise), bioethics is of a special relevance to global governance.[12] In this sense, two topics of "governance through bioethics" and "governance of bioethics" can be separately discussed. The former topic covers the discussions about the role of bioethics in global governance for health and the latter one covers the governance of theoretical developments of bioethics itself on the global scene.[13]

As a matter of fact, the current state of global health and global bioethics, and their theoretical and practical specifics, developments, and challenges, cannot be comprehensively understood and analyzed without taking the concept of global

governance into serious theoretical consideration. On the other hand, global bioethics is the field or platform in which an ethical framework for setting global criteria for good governance is to be sought.

ii. Global governance

Global governance can be defined as the way in which different role-players in the regional or global spheres exert different sorts of power to manage various affairs at the international level.[14] In is also defined as:

"…the sum of the informal and formal values, norms, procedures, and institutions that help all actors – states, intergovernmental organizations […], civil society, transnational corporations […], and individuals – to identify, understand, and address trans-boundary problems.[15]"

This is obvious that power-relation is a central concept in global governance.[16] In other words, one can say that global governance, as a concept and as a subject of study, provides the overall picture of a sophisticated network of different kinds of power relations that play role in creating or managing supranational and transnational affairs in the contemporary globalized world.

In a historic perspective, the concept of global governance had two predecessors:

(1) international relations and (2) the world order. A theoretical and historical review of these two preceding concepts can shed light on the current standing and characteristics of the concept of global governance.

1- International Relations: Collaboration among nation-states in the modern world has been the subject of international relations studies. The broad range of the forms with which the relations among nation-states are being materialized (intergovernmental

organizations, bilateral or multilateral coalitions and treaties, international soft or hard laws, etc.) has been the subject of this interdisciplinary field of study. The key point has been (1) the centrality of sovereign nation states as the supreme role players on the global scene and (2) dealing with supranational issues (such as global trade, pandemics, war and peace, environmental issues, and humanitarian aids or interventions) through the international organizations, treaties, coalitions, or other kinds of collaboration between nation states.[17]

2- The World Order: After the end of the cold war, in many of the scholarly works on global affairs, the concept of international relations was replaced by the concept of world order.[18] The central element of this notion has been the centrality of a hierarchical order of power and affluence on the global scene that defines the role and influence of each role player, at the top being the United States and Western industrialized democracies. The theories that relied on this concept tried to provide a realistic portray of the realities of the way global affairs were being approached and managed. The concept of world order, however, was criticized as being top-down and static. Therefore, the concept of world order was soon substituted by the more dynamic and describing concept of global governance.[19]

The above concepts were gradually replaced by the concept of global governance through the last decade of the twentieth century and the first decade of the twenty first century. The reasons behind the emergence of the concept of global governance were as follow:

1- The ever-increasing occurrence of some problems with a global nature that could not be solved without a globally coordinated operation. For example, the

phenomenon of climate change is not limited to any geographic area or national borders and cannot be dealt with effectively in the absence of globally coordinated action plans. As another instance, pandemics and outbreaks, such as the recent outburst of Ebola virus disease in West Africa, demand highly coordinated global reactions. The local governments usually are not able to implement effective measures in a timely manner. International organizations and foreign aid providers need to be coordinated to act effectively and with abidance to a well-planed road map. Coordinating all these resources and reactions is done through global governance.[20]

2- The above-mentioned increasing appearance of global problems has been coupled with the exponential increase of non-state role players who are influential in dealing with such problems, in some times, even more than intergovernmental organizations who are formally considered in charge of them. In other words, the emergence of non-governmental role-players and their influential input in governing global affairs, in addition to the relative shortcoming and stumbling of formal international organizations in the same areas(see below), led to the emergence of a new understanding of the way by which the global affairs are being governed(Also see above, under the topic of governance).[21]

3- The state role players started to act beyond of and apart from the previously established intergovernmental organizations. Instead of originating their actions through the programs formulated and conducted within the established intergovernmental organizations, they started to launch unilateral or bilateral programs acting in parallel with the intergovernmental organizations. The health sector, especially in the cases of

pandemics such as HIV/AIDS, is a well-discussed example of such an increased emergence of bilateralism instead of multilateral organizations.[22]

4- At the same time, at least in some serious world problems, such as the recent Ebola outbreak, the formal intergovernmental organizations proved weak and lagged behind the other role-players.[23] The important role of non-state actors (and the state-originated interventions beyond the intergovernmental organizations) in managing such crises showed that instead of intergovernmental (international) organizations, there is a sophisticated form of global governance in place, with various actors and numerous ways of action, that shapes the global approach to such crises and global emergencies.[24]

In sum, through the past decades, as a result of (1) the fundamental changes in the composition of global role-players in addition of (2) the drastic changes in the nature and extend of global issues, and (3) the need for developing and adopting a concept without a top-down and unwanted hierarchical nature in the related scholarly and political discourse, the concepts of "international relations" and "world order" have gradually been replaced by the concept of "global governance".[25] This new concept achieved acceptance and ubiquity in the relevant literature very fast, in a way that nowadays seems to be an essential conceptual tool for understanding, describing, analyzing, and discussion the issues, problems, and phenomena that have transnational, supranational, or cross-national nature or element(s).

As mentioned above, in the emergence of the concept of global governance and replacing the previously ruling concepts such as international relations and world order, the health sector and the health-related issues have not been the exceptions. The transnational and supranational nature, extend, and solutions of many of health issues

(e.g. pandemics, health implications of global trends such as climate change, global collaborations in the areas of healthcare and health research, etc.) in addition to the development of unilateral and bilateral health-related programs beyond the intergovernmental organizations, and the abundance of newly-emerged non-state role players on the global scene has led to the appearance and prominence of the notion of global health governance (also called global governance for health) that is discussed in the following part of this chapter.

iii. Global health governance

The newly shaped conceptual and practical profile of global governance is impeccably mirrored and exemplified in global health governance. As historically and theoretically depicted above, global governance entails collective efforts of various role-payers and has been practiced in numerous ways.[26] The health sector has never been an exception. The same scene of numerous role players and numerous ways of role playing exist in the health sector. These role players and their actions along with the existing problems and challenges, take shape to what we know as the global health governance or global governance for health.

The various means and models of realization of global health governance in the contemporary globalized world include (but are not limited to): Promulgating health or healthcare ethics-related international instruments, including binding and non-binding guidelines, decelerations, resolutions, rules, and regulations; forming bilateral or multilateral coalitions and collaborations on heath affairs; establishing and running international health-related organizations, including regional and global ones; funding health-related program in other countries; conducting international biomedical research;

and providing healthcare or emergency interventions in crises in other countries/regions.[27]

Each of the main categories of actors in global health governance (states, IOs and NGOs) encompasses a various array of role players.[28] Sometimes, an international organization, officially takes the leading role in one of the global affairs, for example, the WHO is the organization in charge of global health issues.[29] Such international organizations, including the WHO, work based on consensus among almost all the member states. Although managing everything according to broad consensus seems to be the most democratic way of managing global affairs, there are some instances where more powerful or wealthy members of such international organizations decide to play unilateral roles.[30]

When a nation state decides to play a role beyond its borders and intervene in the international sphere, that nation state is playing a role in global governance. For instance, launching health related initiatives and programs in other countries for fighting outbreaks or preventing diseases in an international level is part of global health governance.[31] These efforts raise the problem of bilateralism that sometimes is considered as a threat to multilateral global health governance.

Many countries, mostly in the developing world, cannot afford the healthcare needed by their people. In the case of disasters, like outbreaks, famine, or drought, this gap becomes wider.[32] These countries usually depend on international sources, like the helps provided by wealthier countries to provide even basic healthcare for their people. According to the WHO's estimate, 23 countries of the world receive more than 30 percent of their health budgets from sources outside their borders.[33] This monetary aid

usually comes with price tags, least of them is the power bestowed to the wealthier countries to govern health affairs in developing help-receiving countries. Having financial leverage, either in international organizations or in bilateral relations with other countries, makes it possible for richer and more powerful countries to play their own role in global health governance.[34]

Historically speaking, the international coalitions for global health governance, however, are dated back to the 19th century. The pandemics and epidemics of various infectious diseases, like cholera, yellow fever, smallpox, and typhus, parallel with revolutionary scientific discoveries like the germ theory of disease, ended up to some international meetings aimed to establish international institutions and guidelines for preventing the spread of such diseases[35].

The first international conference on health was held in Paris in 1851, with participation of 12 European countries. Establishing uniform procedures and regulations for quarantine and founding an international sanitary board to oversee maritime activities were the main subjects of discussions. Although historical in being the first international meeting on health, this conference ended up as a failure in the terms of application, international cooperation, and implementation. Although the conference produced a convention with 11 articles and 137 regulations covering major disease with adverse influence on trade, such as cholera, plague, and yellow fever, only three governments eventually ratified the convention, two of them, later retracted their ratification. [36]

Two main reasons for this failure were as follow:

First, different participant countries, depending on their geographical locations and other factors, had different and conflicting interests in tightening or softening the

quarantine measures, for example, while nations with significant trading interests showed resistance against tough quarantine measures, countries bordering the Mediterranean Sea sought more strict quarantine measures.[37]

Second, there were no consensus on the cause of communicable diseases like cholera, plague, and yellow fever. Some delegates (e.g. British officials) attributed cholera to environmental factors and bad air, therefore, they insisted on establishing sanitary measures instead of quarantine. Others attributed cholera to an infectious agent. These countries, like Spain, Greece, and Russia were in favor of quarantine. Although in these countries, sometimes the quarantine measures were used to isolate certain social groups like Jews or foreigners. The third theory, for example maintained by Austria, was the supernatural theory that attributed such diseases to the displeasure of God and considered them as divine punishment, therefore, they insisted on religious measures as the only way to contain cholera and other outbreaks.[38]

The next five conferences held between 1859 and 1885 (1- Second Sanitary Conference in Paris, 1859; 2- Third Sanitary Conference in Istanbul, 1866; 3-Fourth Sanitary conference in Vienna; 4- Fifth Sanitary Conference in Washington, 1881; 5-Sixth Sanitary Conference in Rome, 1885). These conferences, also, did not generate any substantive agreement.

It was after Robert Koch's work on cholera -which established a scientific consensus on the cause and treatment of cholera-that the first international agreement was successfully created at 1892's International Sanitary Conference in Venice. This agreement was titled the International Sanitary Convention (ISC) and allowed for very limited quarantine practices for ships passing through the Suez Canal carrying pilgrims to

and from Mecca. Although of limited scope, it was the first successful international effort for global health governance.[39]

Over the next 58 years and through the next conferences (e.g. Eighth Sanitary Conference in Dresden, 1893; Ninth Sanitary Conference in Paris, 1894; Tenth Sanitary Conference in Venice, 1897; Liquor Traffic in Africa in Brussels, 1906; Opium in Shanghai, 1909; Twelfth Sanitary Conference in Paris, 1911; Opium in The Hague, 1911; and (15) Opium in The Hague in 1913[40]), the ISC was revised and expanded in various terms including the number of diseases it covered. This is noteworthy that the main purpose of the ISC was not establishing new quarantine measures; instead, it was mainly aimed at removing the unnecessary and burdensome practices and limit the allowable quarantine practice under the international law to the effective ones without unnecessary impeding or obstructing the flow of commerce and travelers across the borders. [41]

The ISC needed an organizational structure to coordinate the efforts of different states and facilitate the communications and surveillance. For this purpose, the first international health organizations were founded in the first decade of the twentieth century. These organizations were the International Sanitary Bureau (ISB) that later changed its name to the Pan American Sanitary Bureau and then to the Pan American Health Organization; and the Office International d'Hygiene Publique (OIHP). [42]

The trend of establishing organizations for global heath governance consequently continued by appearance of other major role players in the scene. Organizations such as the International Health Division (IHD) of the Rockefeller Foundation (RF), founded in 1913, and the Health Organization of the League of Nations (HOLN), created in 1922.[43] The importance of the IHD was partly in this fact that it was the first noteworthy

appearance of a philanthropic organization belonging to the private sector in global health governance.

After the WWII and establishment of the United Nation, the World Health Organization was founded as the most prominent international organization in the global health governance.[44] Around the time of establishment of WHO as the United Nations (UN) specialized agency for health, other international organizations contributing to health were as follow: The UN Relief and Rehabilitation Administration (UNRRA) established in 1943; UN International Children's Emergency Fund (UNICEF) founded in 1946; and UN High Commissioner for Refugees (UNHCR) founded in 1949[45].

However, in the second half of the 20th century, WHO remained the most important institution and focal point of global health governance[46]. Now it is obvious that it is losing its leading role in the global health governance and needs reforms to regain and preserve its leading role[47].

In sum, global health governance can be understood as a merging point of two major trends: (1) the trend of the change in the composition of global role players in a way that international relations gradually transformed into global governance, and (2) the trend of globalization in health sector, e.g. pandemics, migration of healthcare professionals, need for global surveillance systems, the global distribution of pharmaceutical products, and the effects of global patterns such and the climate change and global inequality on health. The health research enterprise has not been an exception for any of these two major trends. The following part of this chapter takes a closer look at the convergence of globalization and health-related research, that has taken shape to global governance for health research.

iv. Global Governance for Health Research

Health research enterprise encompasses all research activities that are related to human health, including biomedical, epidemiological, and ecological research. Research, as described in details below in this chapter, has developed into a global and cross border enterprise with various role players from states to corporates and from intergovernmental organizations to non-for-benefit ones. Therefore, research activities with transnational and supranational nature are subject to global health governance. This branch of global health governance, although has not been studies like the branches dealing with pandemics or disasters, play an influential role in the health and welfare of human societies all over the globe.

Taking a historical look reveals that the distinct separation between research and therapeutic clinical practice in health sciences, is a recent phenomenon, dates back to the first decades of the twentieth century. Before that time, for centuries, experimenting new treatments or interventions was considered as a part of the routine practice of physicians and was supposed to be aimed at providing the best health for the patient. It was in the twenties century that health-related research enterprise experienced an exponential growth, was recognized as separated from clinical therapeutic practice, and in the second half of that century international and multicenter research projects began to sprout and grow.[48]

Just like other global enterprises, the international health-related research established its own system of global governance.[49] The global governance for health-related research has mainly been established in the following ways: First, the international declarations, codes, and guidelines developed for setting global ethical

standards for health-related research; second, the national rules and regulations made by the countries that host the main funding bodies and institutions on international research; and third, the internal regulations, standards, and guidelines of the various sorts of organizations that fund international research.[50] Therefore, for sketching a realistic portrait of the history of global governance for biomedical research, the best way is taking a look at the developments in the above-mentioned means of implementing global governance for biomedical research and its main concepts and theories.[51]

The recent programs funded by Fogarty International Center (FIC) to establish research ethics capacity in developing countries is a noteworthy example.[52] This program is aimed to transfer the research oversight and review capacity to the low and middle income countries. It has been accused to trying to impose Western values to developing countries. The FIC tried to nullify these accusations by emphasis on including local moral teachings in the curricula and planning for transferring the capacity (both educational and oversight) to the local participant institutions over the period of the programs.

In an attempt for analyzing the theoretical aspects of global governance for health research, Wahlberg et al. introduced four spheres (or layers) of ethical governance for health research as follow: deliberation, regulation, oversight, and interaction . Some countries have established organized processes for national ethical deliberations. This national debate can produce ethical awareness and help to develop a democratic process of problem-solving in the ethical governance of biomedical research enterprise. In addition, ethical regulations at both national and global levels have been developed and shaped another layer of ethical governance for health research. The regulations pave the way for the next sphere or layer that is ethical oversight. As it is discussed in the

following chapters, establishing independent oversight for health research has been one of the major achievements and at the same time challenges of governance for health research. The last sphere or layer is interaction among the role players in research including researchers and research participants. [53] This four-layer model although seems helpful in portraying the existing models of governance for health research, does not shed light on the specific ethical challenges ahead of global governance for heath and cannot contribute in providing new answers and solutions for the existing problems.

v. **A Historical Perspective**

The historical developments of the above-mentioned concepts have been depicted under each topic. The history of conceptual development of the modern notion of governance partly dates back to the 1970s when Michel Foucault transformed this concept.[54] Concepts such as governmentality and biopolitics that were coined or redefined by this French philosopher have been influential in the academic and intellectual discourse on governance. His intellectual role and its critical assessment have been provided in chapter three under the topic of biopolitics vs. bioethics. In this part, the developments of global research enterprise have been portrayed (see below).

In the very beginning of the twentieth century, for the first time in a research that can be called an international research in some senses, American researcher Walter Reed, obtained written informed consent for healthy volunteers in his yellow fever experiment in Cuba.[55] At that time, obtaining informed consent had not been established as a standard of practice in clinical research. However, international reflections on the unethical behaviors in research began from the same years. For example, at an 1898 medical meeting, William Osler, one of the giants in the history of medicine, condemned

the experiment presented by an Italian researcher. That researcher, who worked on yellow fever in 1897, declared that he had injected a bacillus to five people and produced yellow fever in them. William Osler's reflection was frankly that to deliberately inject a poison like that into human subjects of research without their previous consent is criminal.[56]

The first known regulations governing research with human subjects were publicized in the first year of the twentieth century. These Prussian regulations were followed by a code in German in 1931 issued by the Reich Minister of the Interior.[57] In the later decades of that century, the increasing awareness toward biomedical ethics and disclosure of some infamous instances of violation against human dignity and human rights in research projects, led to national, and then international endeavors aimed at establishing a set of ethical standards for health-related research.[58]

The first international code on health-related research ethics was developed and announced in the wake of WWII and in the response to disclosure of unethical behaviors of Nazi doctors on their human subjects during their experiments through the world war II.[59] The most well-known and internationally embraced instrument in the field of health-related research ethics, however, is the declaration of Helsinki. First adopted by the World Medical Association (WMA) in 1964, this declaration was subject to several revisions and amendments. These revisions and amendments kept this instrument updated and reliable until now.[60] The declaration of Helsinki is a brilliant example of using soft law in the global governance .

In addition to the international instruments, some scholarly works and national laws, guidelines, and codes have had great influence on the global governance for

biomedical research ethics. The development of four principles of biomedical ethics by Beauchamp and Childress and the Belmont Report, both in the 1970s, were mammoth steps in establishing the ethical frameworks for global governance for biomedical research.[61]

As said above, the first known national regulations for governance of research enterprise have been developed in Germany in early 1900s, however, what happened in Germany in the following decades proved that just having well-written regulations is not enough to prevent unethical behaviors. As a matter of fact, the same story was repeated in other countries who hosted an established research sector. The most well-known stories happened in the United States. The ones that proved the crucial role of whistleblowers and the need to establish independent ethical oversight for research.

In June 1966, Henry K. Beecher published an article titled *Ethics and Clinical Research* in New England Journal of Medicine. He introduced 22 cases of unethical clinical research on human subjects Drawn from the immediate postwar period from 1948 to 1965 protocols from leading investigators in leading institutions, working on some of the most important questions in medicine, and published in the most reputable medical journals. Examples included purposeful infection with hepatitis of residents at the Willowbrook State School for the Retarded; injection of cancer cells into elderly and senile patients in which the subjects were merely told they would be receiving some cells; and insertion of a special needle through a bronchus into the left atrium of the heart of patients and healthy subjects. And suturing a mercury-filled resistance gauge to the surfaces of the left ventricles of the subjects. Beecher's revelations caused a shift from

Researcher Paternalism to Regulatory Protection; Utilitarianism to Principlism; and Relying on researcher judgment to IRB review and informed consent.[62]

Ezekiel J. Emanuel and Christine Grady, in their article and then book chapter, titled *Four Paradigms of Clinical Research and Research Oversight* explained four distinct paradigms that the research enterprise and research oversight has passed through during the last eight decades in the United States of America, namely: *Researcher Paternalism, Regulatory Protectionism, Participant Access,* and *Community Partnership*.[63] Some other studies show the comparable historical trends occurring in the biomedical research enterprise in other countries.[64]

According to Emanuel and Grady, in the late 1980s and early 1990s, a paradigm change from *regulatory protectionism* to *participant access* occurred in the United States. Before that time, the conception of clinical trial participant was a vulnerable patient that needs protection provided by oversight/regulatory bodies and institutions such as the Institutional Review Board (IRB) reviews and informed consent. This perspective/paradigm was based on a historical experience of abused and exploitation of research subjects of researchers that were exposed and led to establishment of oversight legislations and institutions.[65]

However, in the late 1980s and early 1990s some events triggered a paradigm change. Two important ones among them were the AIDS epidemics and the breast cancer movement. In these cases, the patients advocate groups demanded earlier access of dying patients to experimental drugs.[66] This was a dramatic change. The patients/research subjects had no longer been considered as vulnerable persons to be protected against unnecessary enrolment in clinical trials, instead, the protection was against unfair access

to the clinical trials as the only hope for survival in front of patients who had no other curative or therapeutic choice.[67]

Therefore, through a paradigm change, (1) the key protection changed from IRB review and individual informed consent to individual autonomy; (2) the conception of clinical trial participant changed from a vulnerable patient to an informed consumer, (3) the role of research and healthcare changed from research priorities being seen as threat to clinical care to clinical trials being viewed as best, cutting-edge clinical care; (4) the underlying philosophy of research oversight changed from principlism to individual rights-based theories ; and (5) the highlighted ethical principle changed from independent review to informed consent.[68]

The demand of HIV/AIDS patient for informal access to experimental drugs also was mirrored in the laws and regulations. The informal access to experimental drugs was made possible through legislations that passed in 1987 and was revised in 2009 (see below for details).[69]

Similar changes occurred on the global scene. A prominent example of demanding compassionate use of experimental drugs occurred during the Ebola outbreak in West Africa. Although Ebola infection has no proven curative treatment, some experimental medicines have been used hoping to save patients who otherwise would be likely to die. The long process of approving experimental drugs for using in standard clinical practice has always been a subject to criticism. During the HIV/AIDS epidemics, sometimes there were competitions among potential participants (patients/infected people) for entering the clinical trials because they looked those clinical trials as the last resort and beacon of hope for receiving an effective treatment. In the case of Ebola infection, however, the

clinical trials were being conducted thousands of miles away from the foci of outbreak. Delivery of experimental drugs to those patients was not part of any research study or clinical trial. As a matter of fact, considering the especial context of chaos and shortage of healthcare workers and facilities, it was impossible to conducts sufficiently well designed and well-conducted clinical trial in those areas. Providing experimental drugs for those patients hoping to be effective in relieving their suffering and even saving their lives was an act out of compassion/philanthropy.[70]

The most important development in the realm of global governance for research ethics occurred in the past two decades. These developments are as follow:

1- The rapid growth of research enterprise in the Low and Middle Income Countries (LMICs) that made the health-related research and research ethics a global subject to concern and debate.[71]

2- The significant increase in the number and size of international and multi-center research projects that also brought global attention and international concerns into the health-related research enterprise.[72] The issues raised by these multi-center research collaborations can be classified into two major categories:

2.1. The issues raised by the collaborations between centers from developed countries with centers from developing (low and middle income) countries. The power and knowledge imbalance in these collaborations have raised concerns on the exploitative nature of them or imposing ethical standards by the powerful counterparts. Examples of the issues that can be located within this category are double standards in clinical trials and the lack of benefit sharing in research activities funded by developed countries and

executed in the low and middle income countries. These concerns have been discussed in details in chapter three.

2.2. The issues raised by the collaboration in which all the counterparts belong to the developed countries and no power imbalance exists. Even in these kinds of collaborations, emergence of new sources of ethical concern has been proved to be unenviable. Working on big data, large scale biobanks, and the relation between research sector and medical tourism are among the examples of this category. These concerns, as well, have been discussed in more details in chapter three.

The ethical issues related to health research can be classified into several categories. Each category of health research ethics or each part of health research enterprise has its own history of developing a national and then global oversight or network of governance. The historical overview is not complete without a brief discussion on at least one of the examples that shows how ethical debates proceed in each of these categories or parts. For this purpose, research integrity can be a suitable choice. Research integrity, as a topic discussed in more detail later in this dissertation, also has its own history that can be depicted in more details and serve as an example on the above-mentioned historical courses and backgrounds:

Some aspects of research integrity, such as avoiding plagiarism, are as old as the written history, itself. However, the notion of research integrity in its current dimensions and characteristics is a relatively new notion. For example, in the United States, research integrity became a public issue in 1981. In that year, a congressman named Albert Gore, Jr. who was the chairman of the Investigations and Oversight Subcommittee of the House Science and Technology Committee, held the first hearing that was provoked by the

public disclosure of certain research misconduct cases. Those cases had occurred at four major research centers in the previous year. About twelve cases of research misconduct were revealed in the US between 1974 and 1981. The attention of the US Congress to the issues related to research integrity was continued throughout the 1980s because of some added accusations of research misconduct and reports that the NIH, universities, and other research institutions were unsatisfactorily reacting to those accusations.[73]

In 1985, the Congress of the United States passed the Health Research Extension Act. This Act required the Secretary of Health and Human Services to issue a regulation requiring applicant or awardee institutions to establish "an administrative process to review reports of scientific fraud" and "report to the Secretary any investigation of alleged scientific fraud, which appears substantial."[74]

In March 1989, the PHS created the Office of Scientific Integrity (OSI) in the Office of the Director, NIH, and the Office of Scientific Integrity Review (OSIR) in the Office of the Assistant Secretary for Health (OASH). The reason behind foundation of these offices was to deal with research misconduct.

The establishment of OSIR also began the course of detaching responsibility for research misconduct from the funding organizations. In May 1992, OSI and OSIR were combined into the Office of Research Integrity (ORI) in the OASH.

As the prominent examples of its activities, ORI published the ORI Introduction to the Responsible Conduct of Research in 2004 and began the RCR Program for Graduate Schools in collaboration with the Council of Graduate Schools to institutionalize RCR education in graduate training.[75]

The above examples show the process of legislative and regulatory attention to the issues of research integrity and research misconduct in other countries and in the global scene: First, some cases of violation of research integrity gain public attention, then gradually the related rules and regulations are passed in the legislative bodies and executive offices take shape to enforce those rules and regulations. The global governance for research needs the same process to take shape at the global scale to deal with the issues of research misconduct and research integrity through global governance for research ethics.

In sum, the concept of global governance for research has two parallel lines of history: First, the history of the concepts of governance, global governance, and global governance for heath, as depicted under their respective titles above in this chapter. An overall look at this history shows that globalization along with the dramatic changes in the composition of role players on the global scene has resulted the development of these conceptual tools to be used in analyzing and solving the issues with global nature. The course of development of the concepts and their emergence out of their predecessors (e.g. international relations and world order) shows the significance and influence of values (i.e. moral theories and value systems) in their theoretical make and nature. These concepts have always emerged, used, and developed within ethical frameworks. Therefore, any scholarly and analytic discussion on them is deeply value-ridden and proceeds within specific ethical frameworks. As shown in the next chapters of this dissertation, the existing challenges and issues, also, are mainly of significant ethical nature or have major ethical components. And the best way to approaching them is seeing them within the respective ethical frameworks. Before taking a deeper look at the existing

issues, it is necessary to examine the exact composition of these role players in more details. This detailed examination can be found in the following chapter.

Second, the history of health research itself. The other line of history that collides with the history of global health governance and takes shape to the concept of global governance for health research, is the history of health research. As a modern enterprise, as depicted above, health research is young, aging less than 100 years. However, over its relatively short lifespan, this enterprise has changed the way human beings give birth, live, die, and perceive themselves. Like any other intentional deed of human being, health research is a subject of ethical analyze and assessment. It is also true about the part of this enterprise that goes beyond and across the national borders and take shape to another facet of what is called globalization. Health research on the global scene has been an enormous source of ethical challenges and debates. Dealing with these challenges on the global scene and at the global level needs the respective ethical framework, that the next chapters of this dissertation are aimed to provide.

Chapter Two - Situation Analysis

This chapter explores the existing situation and portrays the map of Global Governance for Health Research in the contemporary world. For this purpose, this chapter firstly provides a detailed description of the major role players, including institutions and instruments, and secondly, depicts a scheme of the global network through with the Global Governance for Health Research operates.

The role players on the scene of Global Health Governance have generally been classified into two major categories: (1) States and Intergovernmental Organizations, and (2) Non-State actors.[76] The same classification seems to work for classifying the role-players of Global Governance for Health Research, although as it looks obvious through this chapter, there are two major differences: (1) major role players on the scene of Global Governance for Research are not the same as the ones in Global Health governance, and (2) The more important part of Global Governance for Health Research is the international soft law rather that the existing organizations.

As discussed in chapter one, the terms nation and state and the terms institution and organization can be used interchangeably. However, they also bear different meanings and connotations (see above). In this chapter, the term “international organizations” have been used with its current connotation in the political discourse that equates with intergovernmental organizations, however encompasses some significant exceptions, including the World Medical Association (WMA) that is an international, but not intergovernmental organization. A more detailed description can be found later in this chapter.

An important fact reveals itself through examining different role players in this chapter. This fact is that the most significant part of Global Governance for Research in the contemporary world is the body of the existing soft international laws. This body has been created by the involved organizations and has gradually found its place in the international discourse. The process through which the soft law gains popularity and acceptance and becomes hard law, such as what occurred for the Universal Declaration of Human Rights, is beyond the scope of this chapter, although it provides a good example by introducing the bioethical documents that have gone through the same process.

Although there is no overseeing and governing organization for global research, the standards, values, principles, and guidelines that are developed, and delineated through the aforementioned instruments have been used as the normative and theoretical grounds and educational resources for local and regional governing bodies to develop their own systems of research regulation and oversight. Therefore, a significant part of the situation analysis of Global Governance for Health Research consists of examining the codes, declarations, and guidelines and their exceptional role in shaping the current situation and their potential to be used in developing a comprehensive and consensual ethical framework for Global Governance for Health Research. The same endeavor has been previously done by Emmanuel and Grady for creating an ethical framework for clinical research.[77]

After describing the role players within each of the aforementioned two main categories, this chapter discusses the characteristics and mechanisms of the global network through with the Global Governance for Health Research operates. This part connotes the interrelated, sophisticated, and, in some senses, convoluted nature of this

network. The truth is that there is not such a thing as a defined and coherent network to oversee the Global Governance for Research. Instead, different parties with different scopes, agendas, interests, and extends of influence take part in governing the existing asymmetrical collection of activities that can be considered international research projects throughout the world. At the end of this part, an example of creating a comprehensive and systematic ethical framework with reliance on the extant guidance is provided. This example sheds light on the way ahead of normative scholarly work in the field and its general characteristics.

The situation analysis and map in this chapter also provides a basis for portraying the most relevant challenges and obstacles in the field that are discussed in the following chapters of this dissertation. Having a good knowledge of the situation and its main challenges lead this dissertation to its next chapters to discuss the ethical framework for good governance in this field.

i. States and Intergovernmental Organizations

In this part, three major intergovernmental organizations involved in Global Governance for Research Ethics are discussed: The World Health Organization (WHO), the World Bank, and the United Nation's Educational Scientific and Cultural Organization (UNESCO). Then, other forms of the involvement of states in the global governance for research are discussed that include the role of the United States and the Council of Europe.

This part shows that the significance and influence of these role players in Global Governance for Health Research is different from their significance and influence on Global Health Governance. While WHO is formally supposed to adopt the leading and

central role in Global Health Governance, it seems that its role in Global Governance for Health Research is more peripheral and tangential. On the other hand, UNESCO has played a more significant role in shaping the ethical frameworks for biomedical research and its governance at the global scale. In sum, while WHO has been mostly involved in the technical aspects of health promotion and Global Health Governance and the World Bank has exerted its impact in funding global projects and developing the concept of Good Governance at the political level, UNESCO has developed the most comprehensive and cultural-sensitive ethical instruments to be used in shaping an ethical framework for Global Governance for Health Research.

WHO: In some cases in the scene of global governance after the WWII, an international organization, officially takes the leading role in one of the global affairs.[78] For example, the World Health Organization (WHO) is the organization in charge for global health issues.[79] Such international organizations, including the WHO, work based on consensus among almost all the member states.[80] In addition to WHO, the World Bank plays a major role in Global Health Governance (see below). Also, there are other United Nations agencies focusing on the international health issues. However, WHO is still, at least formally, the United Nation's major body in dealing with Global Health Governance.[81]

To act as the leading organization in international health-related affairs, the WHO was founded in the wake of the World War II in 1948.[82] Its constitutional ratification meeting was held in New York City in 1946 and the first meeting of the body was held in Geneva in 1948.[83] WHO has been the most important institution and focal point of global health governance in the 20th century.[84]

The highest decision-making body for WHO is the World Health Assembly. In the World Health Assembly, delegations of the 194 member states convene each year, generally in Geneva, Switzerland. The World Health Assembly appoints the Director General, governs the budgetary and financial affairs, and decides on its missions and main directions. The Executive Board, consisting of 34 members who are experts in health is in charge of giving effect to the decisions and policies of the World Health Assembly and provide it's needed expertise and technical support and advice.[85] The secretariat, the main administrative and technical part of WHO, operates as the third element of the governance of this organization. Finally, the picture of the governing bodies of WHO becomes completed by adding it's six regional offices that enjoy degrees of autonomy and perform much of the programmatic work of this organization. These regions include: Africa, the Americas, the Eastern Mediterranean, Europe, South-East Asia, and the Western Pacific.[86]

Although WHO was originally founded to take a leading role in global health governance, its leadership has always been a subject of fluctuations and criticism. This leadership or lack of leadership, however, have usually been pertaining to the public health issues. The role of WHO in governing the ethical aspects of the health research enterprise has mostly been tangential and not substantive. Research is relevant to the WHO's constitutional roles, functions, and objectives in two ways:

1- Research is essential for WHO to perform its health-related roles and functions and achieve its constitutional main objective that is "the attainment by all people of the highest possible level of health." The health-related policies and practices should be in accordance and resulted from valid and reliable scientific knowledge which, in turn, is

only achievable through well-designed and well-conducted health research. WHO has a good grasp of this mandate. For example, at the Ministerial Summit on Health that was held in 2004 in Mexico City, the participants (including the health ministers) asserted that health policy, public health, and health service delivery should be grounded in reliable evidence derived from high quality research.[87]

2- The WHO's constitution specified a research function of this organization: "to promote and conduct research in the field of research". Therefore, WHO established its first Advisory Committee on Medical Research in 1959 (renamed to the Advisory Committee on Health Research in 1986) and afterwards the regional advisory committees were founded. In addition, the Sixty-Third World Health Assembly (held in May 2010) approved WHO's strategy on research for health. This strategy was approved by the 193 Member States of WHO.[88] One of the six core functions of WHO, as listed in *The Eleventh General Program of Work* is "shaping the research agenda and stimulating the generation, translation, and dissemination of valuable Knowledge." Research in WHO, however, focuses mainly on "secondary and commissioned research" with a focus on health systems, health policy, and health advocacy.[89]

Therefore, WHO pays attention to conducting and promoting research as the basis for evidence-based for healthcare (encompassing all its elements from prevention to treatment and rehabilitation) and for policy making for health (for example, in its 2013 report, WHO emphasized on the crucial role of research for universal health coverage).[90] Consequently, observing the ethical standards in research is important to WHO, although it was usually limited to the research inside or under direct supervision of WHO and has

not made this organization a world leader in shaping ethical frameworks for health research.

The WHO Strategy on Research for Health lists three main principles as the guiding principles for the type of research it supports: (1) Quality: WHO holds a commitment to high-quality research. High-quality research means being "ethical, expertly reviewed, efficient, effective, accessible to all, and carefully monitored and evaluated.[91]" (2) Impact: This principle implies that WHO prioritize research based on its potential consequences and achievements for health. (3) Inclusiveness: Adopting a multisectoral approach and collaborating with communities and civil society and collaboration among state members and stakeholders consist the meaning of inclusiveness to WHO.[92]

In 2011, WHO published the *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants*. This document is aimed at providing guidance for Research Ethics Committees for reviewing the health-related research projects with human subjects. However, this document does not include guidance on how to approach and resolve ethical challenges in research ethics and is not intended to substitute ethical guidelines.[93]

WHO has also published the *International Ethical Guidelines for Biomedical Research Involving Human Subjects* and the *International Ethical Guidelines for Epidemiological Studies* in collaboration with the *Council for International Organizations of Medical Sciences* (CIOMS) that are discussed below in the part dedicated to discussing the role of CIOMS.

The World Bank: The World Bank has started funding global health-related programs from a few decades ago and became a major role-player in global health

governance.[94] Since the 1980s the World Bank has become the largest financial supporter of global heath projects.[95] Although the main role of the WHO and World Bank is in providing healthcare for in-need societies and dealing with global public health issues such as outbreaks and pandemics, they both fund health-related research projects and develop ethical guidelines for research activities.[96]

Formally established in December 1945, this organization is based in Washington DC. The World Bank works like a cooperative and has 189 member countries. The highest policymakers at the World Bank are the representatives of the member states who convene at the Board of Governors that convenes once a year (Annual Meetings). The Executive Directors (appointed by the five largest stakeholders of the bank) who work at the Bank receive their specific duties from the Board of Governors. The World Bank Group President (selected by the Board of Directors for 5-year periods) chairs the meetings of the Board of Directors.[97] The highest official of the World Bank is the president who has always been a US-citizen. This is among the facts that shows the high influence of the United States in this intergovernmental organization.

The World Bank Group consists of five major financial organizations as follow: (1) International Bank for Reconstruction and Development (IBRD), (2) International Development Association (IDA), (3) International Finance Corporation (IFC), (4) Multilateral Investment Guarantee Agency (MIGA) (5) International Centre for the Settlement of Investment Disputes (ICSID).[98]

The World Bank has been among the main sponsors of some impactful health-related research projects, one of the most well-known among them being the project of Global Burden of Diseases. This project has invented a health economics unit for measuring

utility in health, named Disability-Adjusted Life Years (DALYs). This project, although it has gained vast acceptance in the world and has been useful in providing more reliable assessments of the burden of diseases (for example, providing a single measure for calculating premature deaths and disabilities), has also been criticized for many aspects of it such as putting economic value on human life, entailing sex or age discrimination, and not being cross-cultural.[99] These ethical debates show the numerous ethical concerns that exist in the way of creating measures for health measurement in different communities and providing fair estimates of the health needs and priorities and comparing them between different counties and communities.

The World Bank has taken some steps in developing a guideline for research, however, no guidelines have been announced or adopted yet.[100] Therefore, this organization, although very influential in Global Health governance and in raising ethical debates, has not contributed in Global Governance for Research Ethics by taking part in shaping the existing body of the related soft law.

UNESCO: The United Nation's Educational Scientific and Cultural Organization (UNESCO) though not considered directly related to the technical aspects of health issues, has had a noteworthy contribution in developing ethical standards and norms for global bioethics and healthcare ethics and accordingly, UNESCO has made a major contribution in global governance for biomedical research. The most prominent step taken by UNESCO for this purpose, has been developing, adopting, and disseminating the *UNESCO Universal Declaration of Bioethics and Human Rights* .[101] The General Conference of UNESCO in its 33rd meeting on 19 October 2005, unanimously adopted this declaration.[102]

As one of the UN organizations, UNESCO is in charge of coordinating international collaborations in education, science, culture, and communication.[103] The constitution of UNESCO ratified in November 1945 at the end of United Nations Conference aimed at stablishing an educational and cultural organization convened to create an organization to promote a culture of peace and intellectual and moral solidarity among human beings. Consequently, the first General Conference of UNESCO convened in Paris in November and December, 1946 with representations from 30 countries.[104]

The governing bodies of UNESCO include the General Conference that consists of the representatives of the State Members (with participation of Member States, Associate Members, and observers from Non-Member States and intergovernmental and non-governmental organizations) and meets every two years. The General Conference is the supreme governing body of UNESCO that determines its policies and missions, set its programs and budget, and elect its Director General and members of the Executive Board.[105]

UNESCO operates through five major programs: education, natural sciences, social/human sciences, culture, and communication/information. As the specialized UN organization with a mission on science, including the life sciences, UNESCO has always focused on ethics in science and technology, including bioethics. Accordingly, since 1993, it has been hosting the International Bioethics Committee (IBC) and has dedicated part of its budget to pursuing specific objectives in the field of ethics in science and technology. In 1998, UNESCO established the World Commission on the Ethics of Scientific Knowledge and Technology to cover other areas of applied ethics and the Intergovernmental Bioethics Committee (IGBC) to fulfil the respect for cultural

diversity and geographic representation in its bioethical operations. As an international organization affiliated to the UN, part of the objectives that UNESCO defined for itself in the field of bioethics has been setting globally consensual standards. In the General Conference, held in 2001, ethics of science and technology was included among the five top priorities of UNESCO, confirming the organization's leading role in bioethics. The same meeting of the General Conference invited the Director-General to examine the possibility of setting and adopting universal norms on bioethics. This was the practical starting point of a series of endeavors that ended to creating and adopting the *UNESCO Universal Declaration of Bioethics and Human Rights* in 2005.[106]

The *UNESCO Universal Declaration of Bioethics and Human Rights* consists of an introduction and 28 articles organized under the following titles and subtitles:(1) Scope; (2) Aims; (3) Principles: Human Dignity and Human Rights; Benefit and Harm; Autonomy and Individual Responsibility; Consent; Persons without the Capacity to Consent; Respect for Human Vulnerability and Personal Integrity; Privacy and Confidentiality; Equity, Justice, and Equity; Non-Discrimination and Non-Stigmatization; Respect for Cultural Diversity and Pluralism; Solidarity and Cooperation; Social Responsibility and Health; Sharing of Benefits; Protecting Future Generations; Protection of the Environment, the Biosphere, and Biodiversity; (4) Application of the Principles: Decision-Making and Addressing Bioethical Issues; Ethics Committees; Risk Assessment and Management; Transnational Practices; (5) Promotion of the Declaration: Role of States; Bioethics Education, Training, and Information; International Cooperation; Follow-up Action by UNESCO; (6) Final Provisions: Interrelation and Complementarity of the Principles; Limitations on the Application of the Principles;

Denial of Acts Contrary to Human Rights, Fundamental Freedoms, and Human Dignity.[107]

Some of the characteristics of this declaration that are relevant to global governance for health research are as follow:

(1) This declaration provides the first and only universally and consensually created set of norms and principles for governing bioethics, including research ethics. The unanimous approval of all the members of UNESCO is one of the important features of this declaration. Therefore, this declaration provides another great example (like what was said about the Declaration of Helsinki) of the role of soft law in global governance, at all, and in global governance for health research, in particular.[108]

(2) All the principles of the classic set created and adopted by the Belmont report and the Beauchamp and Childress's four principles of biomedical ethics, which are the columns of principlism in bioethics, are included among the principles of this declaration. However, other principles are added to make it more comprehensive, inclusive, and global. Adding these principles expands the scope and view of these principles from a Western-oriented one to a globally and transculturally recognized set of principles. Therefore, these principles can also be called a part of the common intellectual heritage of mankind.[109]

(3) UNESCO is one of the UN organizations, therefore, in creating ethical instruments, it should observe and consider the norms and principles once promulgated through *The Declaration of Human Rights*. The *UNESCO Universal Declaration of Bioethics and Human Rights* has been successful in keeping the necessary abidance to this great predecessor, and at the same time, encompass and observe other important

values such as cultural diversity, with this important caveat that no principle (including respect for cultural diversity) should be interpreted in a way that is contrary with human rights and fundamental freedoms.[110]

In sum, one of the features that differentiate global governance for health research from global health governance is its strong relation with bioethics and medical humanities. Therefore, the relevance of UNESCO to global governance for health research seems to be even stronger that WHO's, even if WHO is the main international organization in charge of global health governance, formally speaking. In the next chapters of this dissertation, the principles introduced and adopted by the *UNESCO Universal Declaration of Bioethics and Human Rights* are used for developing an ethical framework for the global governance for biomedical research.

The United States of America: The contribution of the United States of America (USA) in Global Governance for Health Research actualize in three main ways: (1) developing theories and domestic guidelines and legislations that are pioneer, groundbreaking, standard-setting, and serve as prototypes and models for other countries and institutions; (2) influential participation and playing a unique role in international organizations and coalitions; (3) hosting the most prominent funding bodies for international health research both in the governmental and private sectors. Below, brief discussions on each of these roles are provided:

1.Over the past decades, the US has always hosted the pioneer institutions and scholars in the field of biomedical ethics, including research ethics. One of the major developments, was the whistleblower article of Henry Beecher that showed that in health research it is not enough to rely on the personal virtues, respected characters, and good

intentions of researchers and their hosting institutions, because even in the most prestigious institutions and under supervision and leadership of the most reputable physician/researchers this is quite possible that extreme violations of the rights of human subjects take place. [111] Therefore, independent oversight backed by legislations grounded in solid principles and values are necessary for governance of health research enterprise.[112]

In 1974, the National Research Act was passed and the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research was established. Consequently, according to the act and within the framework of the principles of the Belmont Report (see below), the federal regulations for protection of human subjects were developed and adopted by the Department of Health, Education, and Welfare. This name of this department was later change to its current name, the Department of Health and Human Services. These regulations are process-oriented; therefore, they look less relevant to the subject of developing an ethical framework for Global Governance for Health Research.[113]

In 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research published a short but influential document delineating the moral principles for biomedical research that is called after its birthplace, the Belmont Report. It was in the Belmont Report that for the first time, a framework of general principles for biomedical research ethics (also known as the Belmont Principles) were introduced. These principles include: Respect for Person (applies to informed consent), Beneficence (applies to risk-benefit assessment, and Justice (applies to selection of research participants). Displaying such a close and obvious relevance between the

abstract moral principles and the practical ethical aspects of research ethics is one of the main features of Belmont Report. The principles of Belmont Report were not developed by referring to certain philosophical works or schools, but they were included in the report based on their widely acceptance in the cultural tradition or in other words, based on Social morality. [114]

Consequently, in 1978, Beauchamp and Childress introduced their four principle of biomedical ethics as follow: Respect for Autonomy, Beneficence, Non-Maleficence, and Justice. The differences between these two frameworks, although trivial, were grounded on some criticisms on the Belmont Report. For example: Respect for Person implies respect for all the persons, regardless of their possession or lack of autonomy, while the informed consent is developed to protect the subjects who are autonomous and for the subjects with reduced autonomy, the principles of beneficence and non-maleficence look more relevant. As another example, the concerns about using utilitarian justifications to endanger the human subjects of research (like what had occurred in a group or scandalous research projects revealed by Beecher) led Beauchamp and Childress in include Non-Maleficence as a separate principle in their framework. [115] These principles were consequently included in the more comprehensive and global framework provided in The *UNESCO Universal Declaration of Bioethics and Human Right.*[116]

2.The USA is an important member of almost all international organizations with noteworthy role in the Global Health Governance and Global Governance for Health Research (including intergovernmental organizations such as WHO and international nongovernmental organizations such as WMA). In addition, the USA has not limited its participation in Global Health Management to its role in international organizations.

Instead, this country has initiated a number of large unilateral and bilateral programs to promote global health that have been accused of weakening multilateralism in Global Health Governance.

3.The USA is the most important state-funder of health research, including international health research in the world. This funding occurs in two major ways: (1) through for-profit organizations such as corporates, or non-profit organizations such as philanthropic institutions, that is discussed elsewhere in this dissertation; and (2) through the federal budget by government in the for of the projects funded by the National Institutes of Health (NIH). Therefore, the regulations overseeing the practice of US-based parties in these research projects are important parts of Global Governance for Health Research. Since these regulation are mostly grounded in the Belmont principles (see above), there is no need to examine them in more details in this part of this dissertation.

The Council of Europe

The Council of Europe had been a major role-player in Global Governance for Health Research in the past decades by its role in shaping the soft law. This organization should not be confused with the European Union although all the members of the European Union are also members of the Council of Europe. The Council of Europe was founded in 1949 and is an intergovernmental organization having 46 members. One of more than 200 multilateral conventions created by the Council of Europe over its history is *The Convention on Human Rights and Biomedicine*. [117]

The Convention on Human Rights and Biomedicine (its full title being: The Convention for the Protection of Human Rights and Dignity of Human Being with regard to the Application of Biology and Medicine) is the first international agreement created

regarding the newly emerged biomedical technologies. This convention is the first legally-binding international biomedical law and ethics document that considers human dignity a central concept and creates a legal framework for communities with various cultural and normative backgrounds.[118]

This convention is a good example of international hard law that contains values such as human dignity that do not belong to a specific cultural or philosophical context, but belong to the common heritage of mankind.[119] Another example that is made by this convention is the methodology through which a group of countries join a convention and then, the group expands by joining other members and adopting it as their on legally-binding law. Although the recent trends of isolationism and protectionism augmented by political phenomena such as Brexit and the recent election of Donald Trump as the president of the United States might shadow the efforts toward globalization in international law, the need to strengthen global governance in areas of research and the will of human kind to preserve and prevail its common moral heritage, such and human rights and human dignity, will finally overcome these temporary retreats and shape the future of global governance.

ii. Non-State Role Players

Civil society and private sector organizations are among the most important role players in the scene of global governance for biomedical research and in protecting the vulnerable groups in research.[120] Their contribution can be divided into three main categories: philanthropic organizations, civil society, and for-profit organizations. In sum, the non-state role players participate in Global Governance for Health Research in two ways: First, by supporting, conduction, and promoting international research all over the

world. Second, by taking part in ethical regulation and oversight for research. Some international organizations that belong to civil society has taken important parts in this realm, e.g. the World Medical Association (WMA) that crated the Declaration of Helsinki and The Council for International Organizations of Medical Sciences (CIOMS) with the *International Ethical Guidelines for Biomedical Research Involving Human Subjects.* The Non-State organizations show that how globalization has changed the scene of global power relations in a way that the states are not the only major role players, but in some areas, they even lag behind the non-state role players in the governance of global affairs.

1- **Philanthropic organizations**: This category includes all the organizations established to serve the public in the field of global health.[121] These organizations either provide health-related support for in need societies around the globe or support activities that are in service of common good. The constitution of the WHO explicitly recognizes the potential contribution of civil society organizations in global health affairs. Part of the mission of these organizations is protecting vulnerable populations both inside and outside of research. Bill & Melinda Gates Foundation is an example of this category of organizations.

Among the private organizations, the Bill & Melinda Gates Foundation is a noteworthy example. This foundation has been a major contributor to global health with profound influence on international health policy and the design of global health programs and initiatives. Although the foundation's contribution to global health is a publicly recognized fact, its grant-making program may be less known even by the professionals. Between January 1998, and December 2007 the total value of these grants

was US$8. 95 billion. A wide range of global health organizations, such as WHO, the World Bank, the Global Fund to Fight AIDS, Tuberculosis and Malaria, prominent universities, and non-governmental organizations received grants. The share of supranational organizations was $3·62 billion (40% of all funding). Just the share allocated to research and development (mainly for vaccines and microbicides) or to basic science research was over a third ($3·27 billions) of funding.[122]

This should be mentioned that a major part of global health governance is conducted through partnership between public and private sectors . Among the most prominent examples of such collaborations are the Albendazole Donation Program, Medicine for Malaria Venture, and International AIDS Vaccine Initiative. These partnerships are effective in protecting vulnerable groups and are sometimes more efficient that the more bureaucratic international organizations.[123] It has been claimed that the concept of building collaborative partnerships with business is a central view of the United Nations (UN) organizations on the governance of globalization.[124]

Private philanthropies have always been subject of criticisms. For instance, Bill & Melinda Gates Foundation is criticized because of its global agenda. The critiques argue that this foundation is too focused on technology and disease that shapes the vertical approaches that are easily quantifiable, while does not pay enough attention to horizontal approaches that focus on improving health systems.[125]

2- **Civil Society**: Civil society that encompasses Non-Governmental Organizations, community movements, and other institutions that arise in the communities and act as non-governmental actors, are among the major role players in Global Health Governance.[126] Professional associations are among the civil society actors. In the field of

global health research ethics, the World Medical Association (WMA) and the Council for International Organizations of Medical Sciences (CIOMS) have been one of the most influential role players in the past decades. This importance has mostly been because of the Declaration of Helsinki and the *International Ethical Guidelines for Health-related Research involving Humans*.

The WMA: World Medical Association is a confederation of medical professional associations with members from 112 countries. Professional associations typically are independent institutions and are not part of or subordinate to any governments. Therefore, the WMA is an international organization, but not an intergovernmental one. The mission of the WMA, as stated on its website, is: "…to serve humanity by endeavoring to achieve the highest international standards in Medical Education, Medical Science, Medical Art and Medical Ethics, and Health Care for all people in the world."[127]

The first General Assembly of the WMA was held in Paris, September 1947.[128] Being established in the wake of WWII and the shocking revelation of the violations against human rights occurred during the research experiments of Nazi physicians, the WMA was founded with a deep concern about human rights and the rope of physicians in safeguarding and promoting them.[129]

Driven by the concerns about human rights and attending to its nature as an institution originated from civil society, from the very beginning, the WMA emphasized on the professional independence of medicine, and in delineating, declaring, and preserving ethical standards for medical professions.[130]

What has made the WMA very special in the relevance with global governance for health research is the Declaration of Helsinki. Adopted by the WMA at its General

Assembly in Helsinki in 1964, the Declaration of Helsinki of the WMA has been the most influential and well-known international ethical guideline for health research in the past decades. [131] This declaration, created and adopted by a confederation of professional associations, provides a great example of the roles of independent institutions of civil society and their created international soft laws in global governance. The Declaration of Helsinki was lucky to be followed by the Beecher's revelations in 1966 that showed the necessity of and the need for such an instrument in the research enterprise.[132]

Being undergone multiple revisions and amendments until the last one in 2013, the current version of the Declaration of Helsinki consists of 37 articles organized under 12 topics as follow: (1) Preamble; (2) General Principles; (3) Risks, Burdens, and Benefits; (4) Vulnerable Groups and Individuals; (5) Scientific Requirements and Research Protocols; (6) Research Ethics Committees; (7) Privacy and Confidentiality; (8) Informed Consent; (9) Use of Placebo; (10) Post-Trial Provisions; (11) Research Registration and Publication and Dissemination of Results; and (12) Unproven Interventions in Clinical Practice.[133]

Of 37 articles of the Declaration of Helsinki, 12 of them depict "general principles". These principles start with a recall of two mandated for physicians, one of them included in the Declaration of Geneva of the WMA as parts of a professional oath for them, as follow: "The health of my patient will be my first consideration," and another one asserted in the international Code of Medical Ethics, as follow: "A physician shall act in the patient's best interest when providing medical care".[134]

The next articles in the "general Principles" part of the declaration, other main values are asserted, such as (and not limited to): (1) the primary purpose of medical research

with human subjects being “to understand the causes, development, and effects of diseases and improve preventive, diagnostic, and therapeutic interventions” ;(2) the duty of physicians “to promote and safeguard the health, well-being, and rights of patients,” including the research participants; (3 the priority of rights and interests of individual research human subjects to the ultimate purpose of research; (4) the necessity of the appropriate scientific and ethical credentials and qualifications as the prerequisites for conducting research projects; and the necessity of compensating the harms resulted by research activities.[135]

The main claimed weakness of Declaration of Helsinki is its belonging and adherence to just one side of the parts involved in research. In other words, the Declaration of Helsinki is created and adopted physicians and addresses them, while for a comprehensive ethical guidance for research, the voice of other parts such as the participants and communities should be heard through their active participation in developing the guidance. It has also been claimed that the Declaration of Helsinki has taken a partial position in favor of physicians/researchers by loosening the tight criteria of informed consent that was included in its predecessor, the Nuremburg Code.[136]

The CIOMS: The Council for International Organizations of Medical Sciences (CIOMS) is another example of the international nongovernmental organizations that ultimately belong to the global civil society and play a significant role in Global Governance for Health Research. Established jointly by WHO and UNESCO in 1949, and located in Geneva, CIOMS is dedicated to the international biomedical scientific affairs and coordination among the major role players in this area, e.g. UN, WHO, and UNESCO.[137]

One of the noteworthy features of the CIOM on the map of the existing situation of Global Governance for Health Research is its being a civil society organization (in the category of international non-governmental organizations) established by two major intergovernmental organizations. CIOMS represents the global health-related scientific community through having a large number or organizations among its members. In 2016, 13 international organizations, 12 national organizations (USA not being among them), and 19 associate member organizations were among the members of CIOMS. [138] Therefore, CIOMS represent many scientific and biomedical professions and disciplines in various countries.

One of four CIOM's main long-term programs is the bioethics program. Through its mission on bioethics, one of the CIOM's functions has been developing and promulgating ethical guidelines for health research. In 1993, CIOMS published its influential guidelines titled *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. The last version of this guideline is published in 2002 and has recently undergone a new round of revisions and the 2016 has been published under the slightly modified title of the *International Ethical Guidelines for Health-related Research involving Humans*.[139] In addition, in 2008, CIOMS published the *International Ethical Guidelines for Epidemiological Studies.* This guideline was published as a book with a slightly modified title of *International Ethical Guidelines on Epidemiological Studies* in 2009. [140]

These two documents (*International Ethical Guidelines for Health-related Research involving Humans* and *International Ethical Guidelines on Epidemiological Studies*) are substantial and well-known parts of the existing global soft law on health-related research

ethics and shape the significant contribution of CIOMS in Global Governance for Health Research. In shaping the soft law of Global Governance for Health Research, these two documents are complementary additions to the *WMA's Declaration of Helsinki* and *The UNESCO Universal Declaration of Bioethics and Human Rights.*

3- **For-profit organizations**: For profit organizations are involved in the global governance for biomedical research, mainly by funding the international research.[141] Their supranational activities have raised ethical concerns regarding the vulnerable populations,[142] even some scandals have occurred. However, they have also contributed to correcting the ethical flaws of their performance and developing ethical norms and standards for their research activities. In this way, they have contributed in the global governance for biomedical research and to the protecting of vulnerable human research subjects.[143]

The ethical network for Global Governance for Research will not be successful, unless the private sector regards ethics as a competitive privilege. The reputation of these companies should be contingent to their observance for ethical standards. This shows the important role of media in overseeing the role-players in the global research enterprise and naming and shaming the ones who are not observant for ethical standards. Also, the role of civil society in convincing people and states to ban and boycott non-ethical corporations.

In sum, without active contribution of the private sector, this will be futile to develop ethical standards for global research enterprise. And the private sector will participate just when it finds this participation a competitive privilege in the market.

iii. A Global Network

Organizations vs. Instruments: The existing map of the global governance for health research can be portrayed based on a Network Model.[144] As is briefly shown above, no single organization has a monopoly on the realm of global health governance. However, different kinds of national and international institutions take part in this interconnected network throughout the world. As a matter of fact, the existing situation of global governance for health research is the sum of all the involved role players who take part in this network.

As mentioned above, although WHO has been considered the leading organization in Global Health Governance, at least in the first decades after its foundation and as its formal and constitutional role, its leadership in the areas of healthcare ethics and research ethics has never been considered undisputable. Instead, other organizations such as UNESCO and WMA has always challenged the leading role of WHO in this ethical guidance of the health sector. In addition to the international organizations, bilateral initiatives, philanthropies, and private sector have been among the role players that put the leadership role of WHO in jeopardy.

When it comes to the health research, although WHO has created and adopted some useful instruments such as guidelines and strategies, the most influential and well-known instruments have been created and adopted by other organizations. The best examples of such instruments are the World Medical Association Declaration of Helsinki and the UNESCO Universal Declaration on Bioethics and Human Rights, both introduced in this chapter.

The role of philanthropic and for-profit role players in global governance for health research is undeniable, as depicted above. However, none of them is, or can be, in the leading position of global governance for research. They are parts of a bigger network that should be guided by a larger and more consensual and global size, reach, and identity. Among the governmental role players, the United States, being the single largest funder and conductor of international research in the world, can take a constructive leading role, however, cannot be the sole and unilateral leader of global governance for health research.

Therefore, the major weakness in the current network of global governance for health research is the lack of a capable and legitimate world leader in the form of a multilateral international (not necessarily intergovernmental) organization. These is no international organization established or considered to be the world leader for health research ethics. Even WHO that once was supposed to lead the global health, neither proved capable to establish a monopoly in this leading role, nor was supposed or considered to be the world leader in the field of health research. In addition, although managing everything in accordance with broad consensuses seems to be the most democratic way of managing global affairs, there are some instances where more powerful or wealthy members of international organizations decide to play unilateral roles.

It seems that the most prominent ways through which Global Governance for Research is operated in the current world are the soft and hard domestic and international laws. The history of international soft laws on health research started with the Nuremburg Code just after the WWII.[145] Afterwards, this primary code was replaced by more comprehensive and realistic ones. Nowadays, the *UNESCO Universal Declaration of*

Bioethics and Human Rights, the CIOM's *International Ethical Guidelines for Health-related Research involving Humans,* and the WMA's *Declaration of Helsinki* are two complementary documents that play the most prominent role in this regard. In addition, the domestic law of the countries that host the major funding bodies for international research (USA and European Union) are impactful.

One important feature of these instruments is that they do not specify one or more certain philosophies as the theoretical bases of their guidelines. Instead, they are generally based on the common accepted norms and values that can be considered the common heritage of mankind regardless of specific philosophical or religious traditions. This feature should be preserved in any ethical framework that will be developed for Global Governance for health Research.

These guidelines and legislations, in addition to providing a legislative basis for Global Governance for Health Research, serve as the educational instruments and resources both for training local experts (including members of Research Ethics Committees and Institutional Review Boards) and for developing local guidelines. These instruments are helpful resources for local experts in developing local legislations and guidelines on health research because they provide them with a basis of globally accepted and scholarly elaborated set of principles and guidelines that can be tailored and modified based on their local needs and cultural sensitivities.

Therefore, in the absence of a single world organization in the leading status, guiding the existing network by a set of principles (or a body of soft laws) can still be considered a pragmatic (and more realistic) solution for the lack of authority in global governance for health research. In other words, instead of a single organization, the global

governance for health research can be realized and exerted by a set of globally consensual principles and norms. The principles and norms that are accepted, adopted, promoted, and safeguarded by various role players in a non-hierarchical network.

A Historical Precedent: The normative framework introduced by Emmanuel and Grady is a noteworthy historical precedent for using the existing instruments for creating a normative network for research. They argue that having a summative deduction from all the existing main "myriad guidance' is helpful because the extant guidance accumulated in the shape of numerous instruments has some flaws, including:

1.many of these instruments have been the results of scandals and revelations that shocked the community and led to creating some reactional guidelines that are not helpfully and comprehensively applicable to all the research projects. For example, the emphasis that the Nuremberg Code put on the absolute necessity of informed voluntary consent, was a conscientious reaction to the revelation of the experiments done by Nazi researchers on the restrained subjects without obtaining their consent. However, this absolute demand for informed voluntary consent made it almost impossible to do research on people with diminished autonomy, while they would benefit from such research addressing their problems and needs. Therefore, this mandate subsequently was modified by other guidelines. In the same way, the Belmont report was a reaction to the revelation the Tuskegee Syphilis studies.[146]

2.Most of the extant instruments lack comprehensiveness. They have either created for a more inclusive or a less comprehensive purpose, such as the UNESCO Declaration of Bioethics and Human Rights or are most focused on procedural purposes, such as the Common Law (45 CFR 46) in the USA, or are developed by just one of the involved

parties, such as the Declaration of Helsinki. Although some of than have tried to be complementary to their predecessors, still the lack of a comprehensive and global research-specific framework is undeniable.[147]

3.In addition to not being comprehensive, none of the extant pile of guidelines is systematic. Instead, they are "tend to be lists of claims or principles."[148] Providing a systematic framework that covers all the phases and steps of research from design to publication with guidelines that can be clearly interpreted, has been another argument behind developing this framework for clinical research.[149]

Therefore, they developed a new framework for clinical research based on the previous guidance. This framework encompasses 8 principles that cover all the phases of clinical research from the very beginning to the end. In addition, each principle is detailed by benchmarks that provide an explicit explanation and interpretation of each principle. In other words, the benchmarks are practical clarifications of what is necessary to actualize each principle. The principles included in this framework are a follow: (1) Collaborative Partnership, (2) Social Value, (3) Scientific Validity, (4) Fair Participant Selection, (5) Favorable Riske-Benefit Ratio, (6) Independent Review, (7) Informed Consent, and (8) Respect for Participants.[150]

In sum, taking all the precedent instruments and framework-making efforts into consideration, it seems that the next major step in Global Governance for Research Ethics, will be developing a comprehensive, systematic, impartial, and cross-cultural ethical framework.

The Crucial Role of Civil Society: In addition to the role of the civil society organizations in Global Governance for Health Research, this is very important to note

that civil society as an infrastructure is fundamental and essential for establishing valid and reliable systems of governance and oversight for research, both at domestic and global levels.

The main concern in development of the basic theories of civil society and research ethics has simply been protecting the less powerful and less privileged in social – and research – transactions.[151] Having an organized and well-developed civil society is the best way to protect and preserve the basic rights and freedoms of vulnerable social groups. In the same manner, having well-established research ethics instruments and institutions safeguards the rights, well-being, and interests of research subjects, and their families, communities, and countries, as the less powerful parties in the related negotiations and transactions.

As a though experiment for realizing the ethical norms and standards of research ethics, imagining one's self on the other side of the table of negotiations will help the researchers to find the most ethical way to behave. This means that the researcher asks herself: "what I would like/do if I was the research subject or the representative of their community or country?" In almost all cases, the answer of this question is compatible with ethical recommendations and requirements.

One of the most important factors in strengthening the ethical quality of research in a sustainable manner is having professional bodies for researchers that develop, announce, support, teach, promote, and enforce the ethical guidelines and regulations for research[152]. Independent professional bodies are a main and major component of civil society. In the absence of civil society, there will be no independent professional organization. And in the absence of independent professional organizations, there will be

no substitute for them to accomplish this important mission. Governmental bodies cannot play this role. Up to down laws and regulations are of limited help in making research practices more ethical because such regulations should emerge out of the consensus among the professionals not as governmental commands or directions.

As a historical perspective, one can argue that in both developed and developing countries, the strengthening of civil society and promoting research ethics follow correlated and interdependent trends. These trends, however, are more complicated and stumbling in developing countries.

In almost all countries hosting research enterprise, research ethics instruments and institutions are thriving and flourishing.[153] Many of these countries have compiled their own research ethics instruments that are in concordance with global values and standards.[154] Developed countries help the developing countries that host collaborative research trials to develop and strengthen their research ethics infrastructures.[155]

Some obstacles, however, have remained. The collective historical experience, shows that just having well-written instruments is not sufficient for preventing violations of ethical standards and basic rights of research subjects, especially the vulnerable groups.[156] The key factor in effective implementation of the values and requirements of such instruments is the existence of independent and non-governmental bodies to do an array of key functions from performing independent review and oversight to advocating for vulnerable groups and research subjects. This is the main problem in some developing countries in them the civil society infrastructures are not established and developed.

As a matter of fact, a strong disbelief toward the values of civil society and resistance against development of independent and non-governmental institutions are the underlying

causes of the lack of such institutions in the field of research ethics in many of developing countries. As a result, the instruments, such as guidelines and even laws are compiled and ratify and announced. In the absence of required civil society infrastructures, however, they don't become fully implemented and are not taken seriously by the involved parties. For instance, in Iran, the research ethics committees are always consisted of the high brass of the related organization and their members are the principal investigators – or their bosses, subordinates, or close colleagues – that prevents them to be effective and make serious barriers against unethical behaviors and abuse of power.

The other main obstacle in developing countries is the lack or underdevelopment of independent organizations including the professional bodies that make and represent the consensus among researchers and the advocate bodies that represent the patients and research subjects. Non-democratic governments do not tolerate independent civil society organizations in their territories[157]. They try to give the ethical role of such professional bodies to governmental ones. However, the governmental bodies, although possess power and wealth, are not able to generate consensus and represent all the parties in the power relations in the research enterprise. Therefore, in the absence of civil society and its resulted independent professional and advocacy bodies, this is impossible to strengthen the ethical quality of research in a sustainable manner.

Therefore, actual establishment and strengthening of research ethics institutions in developing countries depend on prior strengthening of civil society in these countries. Without taking this crucial step, and in the resulted absence of independent oversight, relying on just creating new instruments and training efforts won't do much in preserving

and safeguarding the basic rights and well-being of research subjects that is what research ethics is all about.

In sum, describing the global network - through and within which the Global Governance for Health Research operates - won't be complete without considering the crucial role and importance of civil society. Civil society at both national and global levels provide the infrastructures for implementation any sets of values, norms, and principles. In the absence of civil society, it seems futile to talk about research ethics and ethical governance for research at the institutional level. Therefore, this situation analysis of Global Governance for Health Research entails the crucial role that has already played by civil society organizations and the importance of civil society in the current and future situation of this institution.

Chapter Three - The Main Challenges and their Ethical Nature

In this chapter, the main challenges of Global Governance for Health Research are presented and discussed. In addition, the ethical nature of these problems and/or their underlying ethical causes and roots are evaluated and analyzed. Following the conceptual and situation analyses provided in the previous chapters, shedding light to the main challenges seems to be the next logical step before presenting an ethical framework that will be depicted in the next chapters. For portraying a complete picture of the current situation of the Global Governance for Health Research, complementary to the situation analysis provided in the previous chapter, nothing is more illuminating than portraying its main challenges. The global network for governing health research has developed and took its current shape for solving the global challenges. On the other hand, the existence of challenges at the global level necessitates the existence of such a network for dealing with them. In other words, the frontiers and borders of Global Governance for Health Research has constantly been formed and reformed by the process of encountering these challenges over the past decades. This claim is true for and relevant to all other aspects of Global Health Governance, too.[158]

The challenges that are identified, discussed, and analyzed in this chapter, are mainly resulted from power relations between parties involved in research. Most of these challenges arise when a powerful (wealthier and more informed) party conducts research projects in/on a less powerful party (country, community, or individual) and this power imbalance ends up to the formation of exploitative –or other kinds of ethically wrong – transactions/relations. The challenges for Global Governance for Health Research, however, are not limited to the relations between wealthier and poorer countries and

communities. Even in the relations and transactions that take place among the high-income communities, the power imbalance resulted from the accumulation of data/information at the researchers' side causes problems with ethical nature that needs the governance's attention.

As a result of globalization in research enterprise, over the previous decades, the number of health-related research projects and clinical trials conducted in the low and middle-income countries (LMICs) has significantly increased .[159] Although this can be looked as a kind of scientific growth or transferring science and technology to the LMICs, there are some facts and issues that raise ethical concerns. These ethical concerns need the attention of both the national authorities and the global governance. These ethical concerns include: (1) In some of these interventional studies and in some area in which these studies are conducted, the potential participants are mostly poor and illiterate and lack political power. (2) Due to the poverty of the participants and the weakness of heath infrastructures in their communities and countries, this may be too difficult for potential participants to get access to the modern and quality healthcare outside the research settings .[160] (3) Multinational pharmaceutical companies and research funding institutions in high-income countries (HICs) sponsor most of these health-related research projects .[161] Their focus on their financial interest and competiveness in the market and bearing the most possible amount of profit as the criteria of their success, may lead to undermining ethical responsibilities and moral duties. (4) Many of these research projects are designed in response to the health needs and priorities of the populations of the HICs and the hosting populations in the LMICs won't benefit from the ultimate results and

products of the projects. Instead, the products will be produced and distributed and purchased only in the HICs.[162]

The above ethical concerns that are the results of globalization, need global attention. In other words, they need to be governed globally. In this chapter, the most prominent forms in which the above-mentioned major ethical concerns are being materialized in the contemporary world (on the global scene of the expanding enterprise of international research) are discussed. Through this discussion, the following questions are answered: (1) What are the characteristics and details of the main problems and challenges confronting each aspect/sphere of governance in the Global Governance for Health Research? (2) To what extent the main problems confronting the Global Governance for Health Research are of ethical nature? (3) What are the ethical aspects or elements involved in each of these challenges or helpful in finding their solutions? What are the actual or potential roles of the role-players of global governance (e.g. scientific community, professional organizations, and educational institutions) in creating or solving these challenges?

In this chapter, the following challenges for global governance for health research are recognized to be among the main challenges and depicted in a way that clearly shows the ethical nature or background or elements of them: Exploitation and Helicopter Research; the Problem of Double Standards; Ethical Imperialism and Colonialism; Bilateralism vs. Multilateralism; Biopolitics vs. Bioethics; and the problems associated with Data Sharing, Big Data, and International Collaborations.

Among the above challenges, the first four ones are mostly relevant to research collaborations between developed and developing countries. The fifth one, however, is

more relevant to the collaborations among developed countries, although it is can also be relevant to the collaborations between developed and developing countries and even the collaborations among developing countries.[163]

After analyzing the above-mentioned challenges, this chapter uses a model created by Thomas Weiss, titled the "frameworks of gaps", for further analyzing these challenges in the context of the current theories of global governance. The elements of the above challenges are categorized within a five-fold set of gaps that exist in the following arenas: (1) Knowledge, (2) Norms, (3) Policies, (4) Institutions, and (5) Compliance.[164] All these gaps can be demonstrated in the theoretical and practical elements of the challenges examined in this chapter. Applying the frameworks of gaps as theoretical tool sheds light on different aspects and implications of these challenges, provides a comprehensive and classified understanding of these challenges, and reveals that they should be discussed and their solutions should be sought in the field of Global Governance for Health Research.

At the final part, this chapter provides some conclusive remarks holding that one of the main roots/causes of the existing problems and gaps is the absence of a comprehensive, consensual, and democratically constructed ethical framework. The existing frameworks are difficult to apply and have not been successful in overcoming these challenges, partly because they are top-down.[165] Developing a comprehensive, consensual, and efficient ethical framework in one of the next major tasks/challenges of the Global Governance for Health Research.

i. Exploitation and Helicopter Research

On Exploitation: Exploitation is one of the most important, central, and well-discussed concepts in the field of biomedical research ethics. Although not included as a distinct principle in the canonical set of principles of biomedical ethics, it has been argued that the imperative of "minimize exploitation" has been one of the most prominent (or even the only) moral rationales of these principles.[166] This idea seems even more plausible by looking at the formal birthplace of the modern sets of principles of biomedical ethics that was the Belmont Report, that has been created in direct relation with the biomedical research.[167]

Exploitation can be defined as "taking unfair advantage" of the subject of exploitation. However, with this definition, the ambiguity persists, because this should also be clear that which kinds of relations or transactions entail taking "unfair advantage". For clarifying this concept and introducing an unblemished definition, Wertheimer developed a theoretical framework. Examining Wertheimer's framework show that it includes different theoretical aspects for recognizing and defining exploitation in biomedical research. These aspects can be categorized as follow: (1) essentials of exploitation, (2) differential diagnoses of exploitation, and (3) different types of exploitation.[168] In this part, Wertheimer's framework in provided in more details since this framework is best fitted and tailored for discussing the concept of exploitation in the context of biomedical research ethics. The Kantian and Marxian concepts are also briefly introduced and discussed (see below).

Essentials of Exploitation: First, the exploiter benefits from the relation or transaction that entails exploitation. Without an exploiter-benefactor party, the

relation/transaction falls into other differential categories (see below). Second, the exploitation is mainly about the unfair results rather than defective/unfair processes (e.g. in an exploitative research project, even if the subjects –for any reasons – had given their informed consent, the research project was still exploitative). In other words, regardless of the process and methodology, if unfair advantage is taken, exploitation occurred. Third, being unfair is an essential element of an exploitative transaction, however it is difficult to define "unfairness". A proposed definition is that a transaction is unfair when a party gains more (exploiter) or less (exploitee) than what that party would have gained in a competitive market.[169] In addition, it can be argued that for some transactions, no competitive and fair market can be theoretically imagined. Transactions that are in contrary with human dignity, such as selling organ parts or slavery, are exploitative in nature and such transactions/relations do not have any imaginable counterparts in a fair and competitive market. In other words, the existence of a market for such transactions is equal to exploitation. the Kantian notion is more helpful for differentiation the transactions for them no market is ethically considerable.[170]

There are other well-known notions of exploitation that imply almost the similar set of necessities. According to the Kantian notion, exploitation occurs when a person (or a group of persons) is treated only as a mean. The verb "only" is very important in this definition, because in many ways where humans are treated both as means and as ends, no exploitation exists. In the account provided by Marx, however, exploitation occurs when a person (or a group or persons) does not receive the total and fair worth of their labor. Both the Kantian and Marxist accounts shed light to the concept of exploitation.[171] When it comes to clinical research, they add some significant and useful points to the

account formulated by Wertheimer. Especially the Kantian notion is very illuminating in recognizing the transactions that are exploitative in nature, regardless of their imaginative occurrence in a free market.

On the other hand, there are elements that are not essential to exploitation. One of these elements is vulnerability. Vulnerability is neither essential nor sufficient to prove that exploitation has occurred. For example, if a researcher recruits a patient for a research on a new chemotherapy for cancer patients who are untreatable by the current treatments, and the patient is desperate and vulnerable because there is no other option available to deal with the cancer, no exploitation has occurred as long as the process of recruiting is standard and entail obtaining voluntary informed consent and observing the rights of the subject. As another example in which vulnerability is not a necessary condition for vulnerability, if an employer hires a vulnerable person with reasonable salary and with observance of all laws and rights of the employee, one cannot argue that the employee is exploited because of her vulnerability and having no other choice to make a living.

This is very important to note that although vulnerability is not an essential condition for exploitation, most of exploitative transactions or relations, including in the realm of health research, occur in the context of vulnerability. For example, the most important cases that raised the issue of exploitation in international research in the past decades were about enrolling pregnant women, as vulnerable people, to the HIV-prevention trials in Africa.[172]

Unequal benefits also cannot be considered essential for exploitation. For example, in the case of surgery, the doctor receives some (unfair amount of) money, and the patient

will have her life saved, therefore, the patient has received more and at the same time has been exploited. In addition, legal age or even legal status have not been criteria to limit the attribution of exploitation. For example, even using human embryos for research has been accused of exploitation, since the human embryos (who lack ethical status, at least according to the mainstream secular ethics) are being exploited. These accusations have mainly based on the Kantian concept of exploitation.[173]

One of the issues that looks more relevant to international research is differentiating between "unfair backgrounds that leads to a transaction" and "unfairness of the transaction regardless of the backgrounds." The latter always entails exploitation. The former, however, at least in some cases, may not entail exploitation. For example, when a company plans to conduct a research project in a poor country, in which the potential research subjects live under unjust and unfair conditions of poverty and diminished access to education and healthcare, this does not sound reasonable to argue that recruiting a group of this people for research necessarily entails some degrees of exploitation. Instead, what determines that exploitation has occurred or not, is the fairness of the transaction (the terms and conditions under which they are recruited for the research project, including the potential benefits for their community), itself. There is no need to explanation that the relevance between the unfair backgrounds and exploitation is stronger in the Marxian account.[174] The duties of researchers toward the host community, especially when the research is conducted in developing countries or poorer communities, has always been a subject of debates. Whether the "local conditions' can be influential in shaping these duties largely depends on the theoretical framework that defines exploitation (see below).[175]

Differential Diagnoses of Exploitation: One of the essentials of exploitation, as explained above, is that the exploiter benefits from the exploitative transaction or relation. By taking this essential into consideration, exploitation can be differentiated from discrimination, paternalism, and neglect. In all these types of usually unethical behaviors, there is no exploiter who "benefits" from the relation or transaction, therefore, none of them falls under the title of exploitation.

In discrimination, a person is deprived from a specific right or benefit because of a non-relevant characteristic (e.g. not enrolling black or Jew or Muslim students in public schools); in denial, a person is not provided with something that she entitles to (e.g. not giving the prize to a person who really won it); and in paternalism one tries to benefit somebody by overriding her autonomy (e.g. forcing people to vaccinate their children or forcing a woman to keep her pregnancy against her wish). In these types of behavior, one essential component of exploitation is missing: the benefit to the exploiter. This is one of the important features that relying solely on the Kantian notion might overlook.[176]

Discrimination and denial are almost always unethical, while paternalism can occur in both ethical and unethical forms. Many interventions in public health entail degrees of justified and ethical paternalism.[177] For example, forcing people to fasten their seat belts while driving or avoid driving under the influence of alcohol or drugs are examples of justified paternalism, while forcing a competent patient to enter a research study as a participant (that is believed to be beneficial for his health) without obtaining his informed consent is an example of unethical paternalism.

Types of Exploitation: The exploitation can be mutually beneficial or include harming one or more parties of the relation/transaction (harmful exploitation vs. mutually

advantageous exploitation). Also, the exploitation can be mutually consensual or include coercion, deception, or incompetence (consensual exploitation vs. nonconsensual exploitation). For example, when a surgeon demands and receives an unfair amount of money of a necessary and beneficial surgery, a mutually advantageous (the surgeon takes money and the patient receives the treatment he needs) and consensual exploitation has occurred. Combinations of these types exist, for example in the case of unfair fee for surgery, a mutually advantageous and beneficial exploitation has occurred, because both parties have bene benefited and consented to the transaction ad interaction, and one party, i.e. the surgeon, has taken unfair advantage from another party (the patient). In the case of Nazi experiments, harmful nonconsensual exploitation was in case because the research subjects neither consented nor benefited from the practice.[178]

It is not always an easy task to differentiate a mutually advantageous exploitation from a harmful one. For example, in the cases of selling kidney for transplantation, the seller of the organ is harmed because of the surgery and losing an organ; at the same time and transaction, he is benefited because of the monetary reimbursement he has received. In this case, although the transaction is exploitative (unfair advantage is taken from the organ seller), he has had a net benefit (otherwise, he would not give consent to this operation), therefore, this transaction can be categorized as a mutually advantageous exploitation.[179] As another example, in commercial surrogate motherhood is an example of exploitative transactions, this seems to be difficult to tell whether the surrogate mother is benefited or harmed from the transactions. The problem worsens when the surrogate woman has no actual control on the money she gained through this transaction and the benefits are controlled by his husband.[180]

In addition, the analysis should be *ex ante* (before) rather than *ex post* (after) the transaction. For example, in the case of kidney selling, since at the beginning of the transaction there was a reasonable likelihood that the kidney will be beneficial and work for the receiver, even if it won't work (e.g. the immune system of the receiver rejects the transplanted kidney) one cannot argue that the seller had exploited the receiver.

Examining validity of consent is not always an easy task. A valid consent should be free of coercion and undue inducement. These two terms "coercion" and "undue inducement" are very crucial terms in research ethics literature and have always been subjects of confusion and misunderstanding. Therefore, it seems reasonable to provide a clear definition of them. Coercion occurs when a person threatens another person that if she makes or does not make one or more certain choices, her rights will be violated. This is different from the cases in which the person has no choice other than accepting a certain option. For example, a patient who has just two potions: either accept a surgery or die from the illness, can still give a valid consent to that surgery. Undue inducement, on the other hand, occurs when an offer is too seductive in a way that twists the person's ability to make a sensible choice. An example for undue inducement is offering a large reimbursement for participation of children in a research in a poor community that may lead to the parents entering their children to the research project, while otherwise they did not.[181]

Ethical Grounds for Intervention: Exploitation is unethical. However, knowing that exploitation is ethically wrong is not enough to answer this question that when (or whether) a government – or governance - should intervene to prevent an exploitative transaction to takes place? In other words, if the predictable consequence of the actual

preventing a mutually advantageous and consensual exploitative transaction is that the potential exploiter leaves the transaction (and does not give an alternative fair proposal) and the potential exploitee loses the beneficial option provided by the exploitative transaction (and remain without any other fair or better option), does the governance still have a moral duty to prevent this ethically wrong transaction? For exploring this issue in the field of Global Governance for Health Research, the next part of this article provides a real-world example that has been considered as one of the most noticeable instances of exploitative transactions and most prominent challenges of Global Governance for Health Research in the past few decades.[182]

Helicopter Research: Helicopter medical research entails that "researchers from HIC institutions flying into a LMIC, taking patient specimens and date, and flying out without providing any benefit to the host community ."[183] Helicopter research typically entails exploitation. All the above-mentioned theoretical accounts of exploitation (the ones of Kant, Marx, and Wertheimer) fit with this kind of research.

The significant increase in the number and size of research projects, including clinical trials, conducted in the LMICs in the past decades made the issue of exploiting the local vulnerable populations very considered and debated. It has been claimed that the lower ethical obligations in addition to lower costs of recruiting research subjects and keeping them in research projects have been the main drives of the pharmaceutical companies and other research bodies to conduct many of their clinical trials in the LMICs.[184]

This has also been argued that these research projects are not aimed to respond to the health needs of the hosting countries, even are not aimed to benefit them by its

potential results and products, because these products are too expensive to be purchased and used by the local patients or their countries' health sectors. The so-called 10/90 gap is another explanation of this problem .[185] It has been internationally noticed and recognized that only a small proportion of global spending on biomedical research addresses the major health problems and needs of large vulnerable, marginalized, and disadvantaged populations . [186]

A part of the following chapter of this dissertation, titled "HIV/AIDS Research in Africa" encompass good examples of helicopter research. In this part, however, a more abstract example of helicopter research (using the historical models of HIV/AIDS research) is discussed to show how the theoretical elements of exploitation math these research projects. The overall line of argument is as follow:

1- Helicopter Research entails exploitation and can be substituted with non-exploitative research.

2- Exploitation is ethically wrong and if it can be substituted with better options for the subjects, it should be stopped by the responsible governance.

3- The Global Governance for Health Research should stop helicopter research at the global level.

A paradigm case of helicopter research proceeds as described below. This paradigm case is delineated by a title and center text because the next parts of this chapter (the problem of double standards) also contain references to this case:

A Paradigm Case

1- Researchers from country A that is a HIC go to country B that is a LMCI to conduct a clinical trial that entails examining an experimental medication (or a

medication for a new experimental use or in a new experimental dose) on a group of patients.

2- The researchers deign and practically follow a research protocol in which the rights of the participants are not considered and observed in the extent that is required by law and regulations and standards for potential research participants in domestic research in country A (in terms of risk/benefit analysis, access to ancillary healthcare, respect for research participants, etc.)

3- The researchers argue that they have modified the risks for or benefits to the participants from country B because of local conditions in which they live. For example, they did not provide them with certain types of necessary clinical care that they would provide in research projects in country B, because these types of clinical care are not normally accessible for people in country B. Or they paid less to the research participants from country B. Or they used/examined a sub-optimum experimental dose of the experimental medication, only because to find a less expensive dosage of an already-proven effective medication.

4- If the medication they use/examine prove to be effective, using this medication will not be affordable for the people of country A (or even the research participants in the control group of the trial) and will mainly be marketed and used in country A and countries at the same level of income as country A.

Base on the elements of exploitation explained above, this paradigm case entails exploitation, because: (1) at the smaller scale, the researchers from country A take unfair advantage from their research participants and their host community on Country B. (2) At the larger scale, this paradigm case entails taking unfair advantage from the hosting

community and country by the researchers and the ultimate benefactors of the research, including the pharmaceutical company and country A.

As described above, the responsibility of governance to act to stop exploitation has been conditioned, at least by some philosophers, to having an available substitute for exploitative transaction available to the exploitees. In other words, although exploitation is ethically wrong, if the exploitative transaction is the only beneficial option for the exploitees, this is ethically wrong for governance to stop it. This premise can be subject of criticism, however, in the case of helicopter research, there is no need to discuss this condition, since helicopter research can be replaced by better options if the governance, including local governments, require the research enterprise to comply with ethical standards and avoid exploitation. For example, providing standard healthcare to the research participants or providing the medications, if they trial prove them to be effective, for a certain amount of time to the hosting communities with affordable prices can be included in the binding regulations at both domestic and global levels. The recent additions to the Declaration of Helsinki reflects these considerations.[187]

Global Governance for Health Research has two general ways to deal with helicopter research: First, through international legislations; second, through domestic capacity-building.

1- International Legislation: As described in Chapters 1 and 2, one of the most important instruments available to Global Governance for Health Research is international legislation. International soft and hard law makes and promotes ethical standards for global health research enterprise. Although in the first international codes on research ethics, such as the Nuremburg Code, the issue if international research was

missing, in the following decades, especially in the 1980s and 1990s when the international research enterprise blossomed and its ethical issues received international attention, the very issue of international research found its way into international discourse.[188] Consequently, the international soft law adopted new additions dealing with international research aimed at preventing exploitation in the form of helicopter research.[189]

2- Domestic Capacity-Building: The most important agents that have to be aware of the rights of research participants and hosting communities and protect and preserve them in the negotiations with the research enterprise are the health authorities and officials of the hosting countries, specially their research policy-makers, and research ethics committees. In other words, the hosting communities need well-established research review and oversight bodies that have the essential knowledge, skills, and capacity for protecting the rights of local research participants and communities. In the absence of such review and oversight bodies, the international guidelines cannot be implemented and efficiently used to protect the basic rights of the vulnerable subjects and communities. Therefore, one of the major tasks of Global Governance for Health Research is capacity-building in the countries/communities that host the vulnerable people who have been exploited for research purposes.[190]

The last version of the CIOM's International Ethical Guidelines for Health-related Research Involving Humans explicitly asserts:

"Health-related research often requires international collaboration and some communities lack the capacity to assess or ensure the scientific quality or ethical acceptability of health-related research proposed or carried out in their jurisdictions.

Researchers and sponsors who plan to conduct research in these communities should contribute to capacity-building for research and review. Capacity-building may include, but is not limited to, the following activities: research infrastructure building and strengthening research capacity; strengthening research ethics review and oversight capacity in host communities […]; developing technologies appropriate to health care and health-related research; educating research and health-care personnel and making arrangements to avoid undue displacement of health care personnel; engaging with the community from which research participants will be […]; arranging for joint publication consistent with recognized authorship requirements and data sharing […]; and preparing a benefit-sharing agreement to distribute eventual economic gains from the research."[191]

In the clinical trials conducted in the LMICs there have been many instances of not observing the rights and freedoms of research subjects as asserted in the related laws, regulations, and guidelines. Also, the ethical roots of this problem are common with the problem of helicopter research, however this problem can be discussed more under the title of the next part of this paper: the problem of double standards.

ii. The Problem of Double Standards

Most of the HICs have a recent history of adopting strict regulations and establishing efficient organizations to protect the basic rights and fundamental freedoms of their citizens, especially the vulnerable groups, when they are recruited as research participants. However, it has always been claimed that in dealing with people of other countries, the powerful parties who are from the HICs (who observe all these rights and freedoms inside their national borders and for their own people) are less willing and driven to observe the same profile of rights and freedoms in other countries. This claim

shapes the problem of double standards in a large scale. Part of this problem has showed itself in the research enterprise and international research activities, that is the subject of this part of this dissertation. [192]

The main question is that if the researchers are ethically obliged to observe the same ethical standards when they are dealing with different people with different cultural and geographical contexts and situations? The proponents of "Uniform Care Requirement" have a positive answer for this question. They argue that in the absence of uniform care requirements and if decision-making on the quantity and quality of care is left to the individual agreements between involved parties, then the policy-makers and other research counterparts in LMIC may overlook the rights and benefits of the vulnerable potential research participants.

On the other hand, the proponents of a negative answer to the above question argue that insisting on the uniform care requirements may deprive LMICs from the research projects that otherwise could be carried out and benefit the local patients and communities.[193] For example, in some infamous examples researchers gave placebo to the control arm of their clinical trial while the life-saving treatment did exist in the HICs. Their justification was that in the hosting country that treatment was not available for the patients because of the high costs. Therefore, if their subjects did not participate in the research project, they would not have access to that treatment in contrast to the similar patients in the HICs. Therefore, that treatment is not considered "the standard treatment" given the special satiation of their research subjects and there are not ethically obliged to provide that for their control group.[194]

Others, however, have commented against the above claim, arguing that the researchers are ethically obliged to have a single definition of "standard treatment" especially when it comes to the vital and life-saving treatments. As described below, the global principles set by UNESCO supports this perspective .[195] This perspective is rooted in the principles such as justice and equity. These principles imply that all the people are entitled to the same basic rights and it is ethically unjustified to deprive people from life-saving treatments based on their place of birth or living or their socio-economic status.[196] Therefore, they have to provide the standard treatment based on the standards of their original HIC rather than the realities of their host countries.

In the paradigm case described above (under the title of Helicopter Research) this part is related to the problem of double standards: "The researchers argue that they have modified the risks for or benefits to the participants from country B because of local conditions in which they live." In other words, when the researchers have two (or more) different sets of standards (in terms of the rights of participants and their relatives and their hosting communities) for their research subjects based on the conditions they live in, the problem of double standards arises. The cases of double standards may include or not include exploitation.

Having double standards is ethically wrong because it violates the principles of justice in the canonical Western set of biomedical ethics. In addition, having double standards is a violation to the ethical principles promulgated in the broader and wore global set of principles introduced by the *UNESCO Declaration of Bioethics and Human Rights* such as equity, human dignity, and solidarity. [197]

Whether the governance, including Global Governance for Health Research, should get involved to stop practices that entail double standards, follow the same reasoning as explained for exploitation above. When the practice that entailed double standard can be replaced by another practice that is more beneficial for the research subjects and their communities (the weaker party of the power relation) the governance has aa duty to act against practicing based on double standards. Therefore, in the cases that are similar to the paradigm case described above, this line of reasoning can be applied:

1- These cases entail practicing based on double standards and can be replaced by practices that do not entail double standards and are more beneficial for the research subjects and their hosting communities.

2- Practicing based on double standards is wrong and when can be replaced by practices that do not entail double standards and are more beneficial for the research subjects and their hosting communities, the governance should act to stop it.

3- The Global Governance for Health Research should act to stop the cases that match with the main characteristics of the paradigm case (entail double standards).

The necessity of avoiding double standards had been implicitly or explicitly included in the international soft law for Global Governance for Health Research, including The WMA's Declaration of Helsinki and the CIOMS International Ethical Guidelines. Although the term "ethical standards" has not been defined in the relevant literature and can be considered a part of common knowledge.[198]

Avoiding double standards does not imply ignoring all the contextual necessities and requirements of designing and conducting research projects. The standards that are part of unalienable rights of research participants should be uniformly observed, while

the technical adjustments should be considered based on local contexts. For differentiating the universal ethical standards from technical and contextual requirements, the US National Bioethics Advisory Committee (NBAC) has provided a useful classification that is explained below.

Substantive vs. Procedural ethical requirements: For differentiating between the global standards that are essential to preserving the rights of research participants and the standards that can be subjects of cultural variations (in attempt to avoiding ethical imperialism), the classification provided by the US National Bioethics Advisory Committee can be helpful. The 2000 report of this committee classifies the ethical requirements in international research into the substantive and procedural categories.[199] The substantive ethical requirements entail fundamental ethical principles that are derived from and are necessary to observe the main ethical principles of the Belmont Report: respect for persons, beneficence, and justice. These requirements are global ethical standards that should be observed globally and are not subjects of cultural variation or interpretation. However, the procedural requirements are the ones that depend on the local circumstances and are not essential to preserving fundamental human rights and freedoms. For example, obtaining informed and voluntary consent from each competent subject of a research is a substantive requirement and should be considered a global standard. However, in the communities with hierarchical orders, such as tribes, obtaining a separate collective consent from the local authorities in addition to the individual consents does not violate the ethical standards and can be considered a procedural requirement rooted in the cultural necessities.[200]

In conclusion, the problem of double standards in the field of health research is translated into having double standards of care, double standards for human rights and human dignity, and even double accounts for defining the “standard treatment”. This problem is of a strong ethical nature and having such double standards, as mentioned above in this part, entails obvious violation of the ethical principles of justice, equity, human dignity, and solidarity.

Although having double standards is ethically wrong, adopting sets of universal standards has also been criticized. The critiques argue that the standards and values vary based on the cultural contexts, therefore, adopting or formulating universal standards is nothing but imposing the values and standards of a culture to the others. In a surprising way, two conflicting arguments, one in favor of adopting universal standards and the other one in favor of adopting local and contextual standards, both have presented to preserve the rights of vulnerable research subjects and their communities. The latter argument is explained in more details in the following part of this chapter that deals with the claims of ethical imperialism and colonialism.

iii. Ethical Imperialism and Colonialism

The terms "imperialism" and "colonialism” have been used in order to describe a country’s superiority, domination and influence upon other countries or societies.[201] In the contemporary literature, these words have negative connotations and are usually being used for criticizing the influence of powerful countries on the less wealthy and less powerful societies.

On Colonialism: Colonialism refers to a practice in a certain historical period in which newly-modernized European powers expanded their dominance to the continents,

countries, and communities is Africa, America, and Asia that were less developed. Settlers from the powerful countries formed colonies in the newly "discovered" lands and acquired political power and military dominance. They usually exploited the natural and human resources of host communities and at the same time, exported their cultural norms and ways of life, along with different features of modern civilization such as modern governments, judiciary systems, press, parties, and technical advances such as modern architecture and transportation to the host countries. In addition, a generation of nstive people acquired modern education (by traveling to the colonizing countries or by enrolling in the educational institutions established in the colonized countries) and imported and presented these new and modern ideas and lifestyles into the traditional communities. These developments have always been shocking and confusing for the host communities. Conflicts occurred as a result of the clash of values, traditions, lifestyles, and perspectives and a strong sense of being exploited, dominated, and humiliated conveyed to the colonized communities. The relations between colonizing powers and local people were not based on respect and equality.[202] Many other countries and communities were not formally colonized (e.g. Iran), however, the same effects of confrontation with modern powers occurred within their traditional social institutions and changed almost all the aspects and trends of their collective lives.

Because of the injustice that was generated (or the sense of injustice that was induced) by colonialism, resistances arose in the colonized communities and after years of mostly bloody and violent battles and revolutions, over the last decades of the nineteenth century and the first decades of the twentieth century, all the colonized countries gradually became independent. However, with some exceptions (such as the

United States of America), their conflicting dependence to the former colonizing powers did not disappear, but remained in two major forms. These two major forms shape the characteristics of the post-colonialism era: (1) the new cultural norms and ways of life imported, imposed, and promoted by the colonizing powers attracted layers of local people, especially the elites and people who were educated from Western or Western-style universities. The contrast of the values, norms, and practices of these modern lifestyles fell in contract with traditional beliefs, values, norms, and standards and in some cases these contrasts led to violent confrontations with local authorities and people. (2) the economic and industrial infrastructures of newly independent countries have remained largely dependent to the colonizing countries. Modern developments such as modern educational systems, healthcare systems, industries, and enterprises along with governmental and civil society institutions such as modern judiciary systems, parliaments, and political parties, although significantly improved the life conditions of local people, led to a variety of conditions such as unplanned population growth and urbanization that became major sources of internal instability and dependency to the former colonizing powers.

The moral analysis of colonialism, itself, is a challenging task. Although nowadays, almost nobody justifies colonialism as an acceptable or suggestable practice, assessing this phenomenon in the context in which it occurred, shows that colonialism, along with numerous unwanted effects on the colonized countries, had some positive consequences for them such as modernization and improvements is various areas such as health, industry, and agriculture. In addition, this is not right to judge a historical practice by

today's standards. The moral analysis of colonialism, however, is beyond the scope of this chapter.

The history of colonialism is intertwined with a rise and expansion in the activities of Christian missionaries. New transportation means and geographical discoveries opened the doors of the Christian Europe to the vast lands and large populations in other continents that were not Christians. Christian missionaries had two major effects in their hosting communities. First, the positive effect that was their promoting humane values such as unconditional love and charity. Unforgettable figures such as Albert Schweitzer and Mother Teresa are examples of this effect. Second, the negative sense of threatening local values, traditions, and lifestyles by imposing the new religion. Cases of violent forcing local people to convert to Christianity or exploiting Christian teachings for devaluing local people or traditions (such as what occurred by Spanish conquers in Latin America) were examples of this kind of effect. Ethical colonialism in the form of promoting Western-Christian values without respect and consideration for local cultures and values entails a reminder to the latter negative effects of Christian missionaries in the former colonized communities.

Ethical colonialism, that means imposing the moral standards and values of previously colonizing countries to the previously colonized societies, is a concept that has been used for criticizing the transfer and promulgation of Western ethical values and standards – including the bioethical ones – in the LMICs. This term implies the negative account of colonialism that entails ignoring the local and traditional values, standards, and lifestyles of non-Western countries and undermining their cultural and moral heritage

and imposing alien and conflicting values that are considered superior to the local ones without any justification.

On Imperialism The term "imperialism" has mainly been used in the left and revolutionary discourse throughout the twentieth century. Vladimir Lenin (1870-1924) considered it as the highest and last stage of capitalism.[203] Although the revolutionary forecasts of the Marxist-Leninist doctrine concerning Capitalism and Imperialism proved wrong (and practically harmful), this word did not disappear from the global discourse. It remained as a way of formulating and expressing suspicion and mistrust on the power relations between the wealthy and powerful countries and the poor ones. When it comes to ethical standards, this word is obviously revitalized and viral .[204]

Ethical imperialism is defined as "imposing the ethical values and practices of the West on communities for whom these values were foreign."[205] In the fields of bioethics and biomedical research ethics, these debates have been serious .[206] The endeavors aimed to advocating and teaching the ethical principles as were developed and formulated and expressed by Western scholars and organizations, have been subject of this kind of criticism, a clear example being the NIH's initiative for training health research ethics experts in the LMICs.[207]

Colonialism and Imperialism in Research Ethics: The terms colonialism and imperialism, although different in meanings and implications, have been used with similar connotations and intentions in the discourse of Global Governance for Health Research. As explained above, they both have been used to criticize the efforts aimed at importing and promulgating Western-born standards and values of research ethics to and within the developing non-Western countries and societies. For example, this has been

argued that the mandate of obtaining informed voluntary consent from the competent research participants is a standard that belongs to the individualistic Western societies and may not be applicable to many of Eastern communities in them such decisions are not made by individuals but are made by the families or tribes or the heads of families or tribes. This has been argued that the different notion of "person" in non-Western communities necessitated different notions and practices regarding obtaining informed consent.[208]

This kind of arguments that attribute norms such as voluntary informed consent to the values of Western aliens, in some cases, have also been appealed by local authorities to deprive their subordinates and local vulnerable population from their basic rights and freedoms guaranteed by so-called Western bioethical standards and values. The main challenge is differentiating the values and standards that are really cultural-dependent and belong to Western cultures and ways of life from the values and standards that belong to the humanity as a whole and cannot and should not be considered as belonging to a specific geographical or cultural area or tradition. These values and standards are, as a matter of fact, the common heritage of mankind regardless of their geographical or cultural origins or denominations.

Common Heritage of Mankind: The concept of ethical imperialism is mainly related to the issue of cultural diversity. Respect for cultural diversity is an inalienable part of biomedical research ethics. It is one of the global principles of bioethics set by the UNESCO.[209] However, there are moral standards and principles that cannot be simply considered as Western or Christian. Instead, a certain group of principles as delineated by universal declarations and conventions, are supranational and their legitimacy is beyond

specific cultural or philosophical traditions, but the belong to all the humanity and can be called the common heritage of mankind.[210] The principles delineated in the UN Universal Declaration of Human Rights and UNESCO Declaration of Bioethics and Human Rights can be considered common heritage of mankind. Therefore, the implications of the principle of respect for diversity can be divided into two main and ethically different categories:

1- The cultural practices and behaviors that violate the fundamental human rights and freedoms, such as not allowing women to take informed decisions on their own participation in a research or taking collective informed consent from the local authorities without taking informed and voluntarily consent from each of the human subjects of research. Respect for cultural diversity never justifies these kinds of practice. As a matter of fact, human rights, as a significant part of intellectual common heritage of mankind, are ethically superior to culture-specific local norms and standards .[211]

This is not a sort of ethical imperialism or colonialism because the principles of the Universal Declaration of Human Rights do not belong just to the West. They are the common heritage of the mankind .[212] Violating the rights of vulnerable groups under the title of cultural diversity and accusing the opponents to advocating ethical imperialism is an unacceptable practice and it has explicitly asserted in the UNESCO Universal Declaration of Bioethics and human Rights that no principle of this instrument should be interpreted in a way that violates human basic rights and fundamental freedoms. [213] The United Nations as an international organization and its affiliated organizations, such as WHO, are in charge of protecting the vulnerable groups by strictly observing the principles of human rights and freedoms .[214]

2- the cultural practices and norms that do not contradict the principles of basic rights and fundamental freedoms: This part of local cultures is to be observed according to the principle of respect for cultural diversity. As an example related to research, the researchers can take the agreement and permit of the local authorities such as the chief of the tribe in addition to taking informed voluntary consent from each of their potential research subjects.[215]

According to the above discussion, ethical imperialism, as another challenge for global governance for health research, entails obvious ethical components. Both the proponents and opponents of this theoretical criticism, appeal to ethical reasoning to support their side of discussion. Although this criticism entails some real and noteworthy ethical concerns, it should not be allowed to be misused by the violators of human rights and by local authorities who want to safeguard their illegitimate power over the rights of their subjects.

When it comes to health research, this debate shows itself in some areas, one of the most important of them being the process of obtaining informed consent. The right of giving individual voluntary and informed consent is an inviolable right of every research subject in clinical trials and taking collective consents from the local authorities (e.g. head of tribe or governor of the county) does not override the right of each individual subject.[216]

Therefore, adhering to global ethical standards for health research in the research carried out in developing countries and within local communities is an ethical mandate. At the first look, this can look like ethical imperialism. However, in the absence of universal standards, each local power and authority can set its own standards, appealing

to the local culture and values, in a way that violate the rights and freedoms of vulnerable populations and benefit a part of the community that is intended by that power or authority.[217]

The projects conducted by HICs for capacity-building in LMICs in the fields of research review and oversight, have been criticized to be aimed for promoting Western values and standards and imposing them to the local and host communities.

iv. Bilateralism vs. Multilateralism

International Organizations (IOs) such as the WHO have been established based on the concept of multilaterality.[218] Acting based on consensus among state members guarantees the democratic nature of such organizations. These IOs are also responsible for observing the ethical principles of global bioethics in their instruments and interventions. In recent years, however, some major and powerful players in global health governance have launched bilateral programs. One of the most prominent examples of such bilateral programs is the US Government's Global Health Initiative (previously the President's Emergency Plan for AIDS Relief or PEPFAR) .[219] These bilateral programs, although being so fruitful in fighting serious pandemics like HIV/AIDS, have allegedly weakened the multilateral role players and in the case of global health governance, the threat was mostly pointed to the WHO .[220]

As described above the monetary helps of wealthier nations usually come with their own price tags, least of them being the power granted to the wealthier and more powerful countries to govern health affairs – and use the gained influence in other political matters- in developing countries, which need and receive these helps. Having financial control in bilateral relations with other countries makes it possible for richer and more powerful

countries to play their own role in global health governance. In some cases, the impact of trade agreements worsens this power imbalance. Avoiding the possible abuse of this power in political affairs is another reason behind the existing need to move toward more multilateralism.[221] Multilateralism in global health governance make it possible to make sure that the values of solidarity and benefit sharing (rather than political agendas of powerful countries) rule in managing global health affairs and in practicing global health governance.

Some examples of multilateral programs/institutions are as follow: (1) WHO (that is supposed to assume the leading role), (2) World Bank (in recent decades became a major role player in funding health-related programs), and (3) The Joint United Nations Program on HIV/AIDS (UNAIDS). UNAIDS, itself, is cosponsored by several international/multilateral organizations. Taking a look at the list of these organizations reveals the very multilateral nature of this program. These cosponsoring organizations are as follow: (1) United Nations Children's Fund (UNICEF), (2) World Food Program (WFP), (3) United Nations Development Program (UNDP), (4) United Nations Population Fund (UNFPA), (5) UNESCO, (6) WHO, (7) World Bank, (8) United Nations Office on Drugs and Crimes (UNODC), and (9) International Labor Organization (ILO). Bilateral programs, however, are formed and conducted by an agreement between a powerful/wealthy nation state and a country or a group of countries in need. When it comes to HIV/AIDS the most influential bilateral program has been the US Government's Global Health Initiative (previously the President's Emergency Plan for AIDS Relief or PEPFAR).

As mentioned above, bilateral programs, although sometimes successful and efficient, potentially weaken the role of IOs, in this case WHO, in leading international efforts against pandemics and other heath crises. This weakening may also become extended to ethical principles and norms of global bioethics, which guaranties pluralism as the source of trust and ethical infrastructure for global health interventions. Therefore, there is a need to a comprehensive ethical analysis of bilateralism and its benefits vs. risks for global governance for health. In a comprehensive ethical framework for global governance for health, the bilateral partnerships should be developed and directed in a way that entails minimal risks for consensus-based multilateral mainstream that is in charge of finding and executing fair and unbiased solutions for global health challenges in the future.

One of the most important feature that differentiates and recognizes the principles and guidelines promulgated by UNESCO or WMA is their consensual nature and multilateral structures of the organizations that developed, adopted, and announced them. This consensually and multilateralism makes these principles a part of the common heritage of mankind regardless of their historical origins. Otherwise, if the ethical standards and values are imposed, transferred, or dictated in the bilateral relations, they will always remain the subjects of criticisms as ethical imperialism and colonialism (see above).

v. Biopolitics vs. Bioethic

The main question behind the concept of biopolitics is “how bioethics can be independent?” In other words, this concept, since the very time it was coined, has prompted reflecting, exploring, and investigating on the influences of politics on

bioethics. The concerns over the influence of political powers and interests on bioethical discourses is a legitimate concern at both national and international levels. Considering that health has moved from the soft politics to hard politics over the past decades, and the importance of health research, this concern is also valid when it comes to Global Governance for Health research.

In the realm of the history of thoughts and theories, everything started with a lecture series delivered by French philosopher, Michel Foucault (1926-1984), at the Collège de France in 1978 and 1979. The term of biopolitics had been coined before these lecture series, however, its accompaniment by some other key words ended up to a change in the meaning of this term in the political and ethical literature. Below, this chapter provides a closer look to this debate that has played a crucial role in the theoretical evolution if the concepts of governance and bioethics.

The concepts of "governmentality" and consequently, the concepts of "bio power" and "biopolitics" have been coined by Michel Foucault, and then expanded by other thinkers have noteworthy implications in different fields including bioethics and the ethics of global governance and research ethics.[222] Accordingly, political interests and powers influence the decisions in the field of global governance.[223] This influence has the potential of competing and conflicting with bioethics as directed just by ethical norms/principles.[224] Therefore, the influence of political powers and their interests can be considered as another major source of ethical concern in the field of Global Governance for Health Research.[225]

The ethical nature of this concern/issue is not covert. As a matter of fact, the undue influences of political power over biomedical decision-makings have always been

sources of ethical concerns. In the realm of health research, the influence of biopolitics at every level of research from priority setting and funding decisions to development of international collaborations and even the decisions on recruitment of subjects and the methodology of the studies is a subject of ethical concern. For example, prioritizing the health issues for research budget allocation can be influenced by political interests. In some cases, the political attention to specific types of diseases can result unproportioned research budget of effort allocation. On the other hand, ideological interests or even taboos can be influential in the governance of research enterprise. Limitations on conducting certain types of research that might entail results in conflict with dominant ideologies in some countries is an obvious example. At the global level, also, this problem is present. The debates on patent rights of pharmaceutical industry or mass transfer of biological samples from developing countries to developed ones are among the topics that need attention to biopolitics and are discussed in the following chapters of this dissertation.

When it comes to the problems caused by the influence of politics on bioethical decisions, this is self-evident that a top-down world order will never be able to solve these problems. As a matter of fact, this very issue clearly shows how the global governance for health and health research needs to replace its current top-down ethical framework with a new collaborative one with emphasis on global justice, equity, and solidarity.[226]

vi. Data Sharing, Big Data, and International Collaborations

Data sharing has been called “an ethical and scientific imperative.” Numerous evidences and arguments support this claim, for example: (1) The data of previously

published trials may entail new information for the researchers who come afterward and can take a new look and shed a new light to the previously analyses data; as studies show that reanalysis of the data of the previous clinical trials, in a significant proportion of cases, have ended to different interpretation compared with the original studies, although the numbers of studies that entail reanalysis is very small in comparison to 500000 clinical trials that are published in MEDLINE. (2) Data sharing makes meta-analysis studies possible that produce more strong evidences for clinical practice compared with each single study that is included. (3) This is possible that the investigators of the original studies inadvertently were not reported some important findings that may be revealed through the data sharing with other researchers who may take a fresh look at the data and unreported findings. And (4) ethical responsibility to the participants of the clinical trials who put themselves at risk for producing the data that may be beneficial for the society, therefore, the obligation of research community is unearthing the greatest amount of benefit that may be extracted from these data which, for the aforementioned reasons, is achievable through data sharing.[227]

One of the most important features of data obtained for research purposes –and the information resulted from them - is their belonging to the humanity as a whole. In other words, scientific data and information is a part of common heritage of mankind. As explained above (number 4 in the list of arguments that support data sharing) human subjects of research projects put themselves at risk for producing knowledge that benefit all the humanity. This is the basis of a social contract according to which, the scientific community has an ethical obligation to maximize this benefit for all the humanity and this is not possible without making data available to other researchers to extract all the

possible information from it. i.e. data sharing.

In addition, the scientific knowledge (that is used for and increased by analyzing these data) cannot be produced and accumulated without relying on the great resources of common knowledge produced by the previous generations of scientists even in ancient times. Researchers and scientists do not work in isolation or from the scratch. Their ideas, premises, previous knowledge, and supporting evidences are based on the knowledge accumulated through centuries by the collective efforts of scientists from almost allover the world and all the civilizations on earth. Therefore, the research data and scientific knowledge, at least partly, belong to (and produced intended to benefit) all the humanity. Therefore, this is an ethical responsibility of the Global Governance for Health Research to maximize the benefit of all the humankind from the data and knowledge produced by research by (1) making datasets shared and available, and (2) making scientific knowledge accessible for all (as much as possible).

Data sharing, however, brings about a series of ethical concerns. When data sharing occurs among trials that were conducted in different countries, these ethical concerns find their ways to the realm of Global Governance for Health Research. Among these ethical concerns are: (1) Privacy of participants: the shared data mush be deidentified. Through the process of obtaining informed consent, the participant must be informed about this fact that their deidentified data will be shared. (2) Fairness to researchers: considering the intellectual right of the original investigators over the data, some relevant ethical issues are still under the clouds of ambiguity, such as the right to authorship, the time period between the publication of the original study and the reanalysis, and the fair process for handling the requests for access to the shared data. (3) Efficiency of the system of data

sharing: considering the increasing complicated and sophisticated nature of the methodology of clinical trials, having an efficient system for data sharing proves to be more difficult than any previous time. In some cases, the support and assistance of the original investigators in still necessary for reanalyzing the data. Therefore, this mandate should be included in the original contract between the funder(s) and original investigators, or can be requested/purchased from them in other ways.[228]

Other types of international collaborations that involve sharing data or biological material include biobanks. Biobanks collect and store human biological specimens for research purposes. It seems that the international collaborations are eager to accelerate the sharing of genomic and health-related data, including through collaborations with and among biobanks. This practice raises its own ethical issues.[229] Some of these issues, such as privacy of participants and necessity of modifying informed consents are discussed above.

Another issue raised as a result of scientific collaborations and data sharing is the issue of large datasets or "big data". Big data is the product of a group of recent developments such as invention and establishment of electronic health records and formation of national health databases that integrate huge amounts of health-related information, as well as large scale national and international collaborations that produce massive databases and other kinds of data storing means. Creation of these large datasets has been facilitated by new technologies such as the portable computers and mobile devices, large digital data storages, and widely accessible high-speed internet. These technological facilities pave paved the way for international collaborations in data collection and data accumulation. Also, with expansion of digital and electronical

infrastructures and facilities to developing countries, they have gradually joined the large projects that collect and create these big data. Therefore, a large part of the current health-related big data is developed through international collaborations. Accordingly, part of ethical issues raised by them and their solutions are covered by Global Governance for Health Research.

The advantages and benefits of access to big data have been enormous. For example, conducting research projects with larger amounts of data, samples, or subjects can lead to more valid and reliable results. In addition, in the realm of public health, the phenomenon of digital disease detection using electronic data sources and availability of global real-time data have improved the ability of the health sector in dealing with health crises such as outbreaks because they have accelerated detection of outbreaks by digital surveillance channels, as was actualized during the 2014 Ebola virus outbreak in West Africa.[230]

Development of big data, on the other hand, have led to new ethical concerns about privacy, confidentiality, technical efficiency, informed consent of the participants, and the justified uses and users of these "big data" resources. Vayena et al. have classified the ethical challenges of digital disease detection into three categories: First, "Context Sensitivity" that encompasses ethical challenges of differentiating between commercial and public health use of data and include concerns on identification and informed consent; the privacy of uses of electronic means; and the openness of private data into global health-related use; second, the "Nexus of Ethics and Methodology" that entails the concerns on the valid and reliable functioning of the involved technologies and the public use of personal data in aggregated from; and third, the "Legitimacy Requirements"

that encompasses the standards of best practice and existence of a globally shared code of practice, monitoring and response to the inaccuracies and the resulted harms and finally, communication to the public and dealing with general expectations.[231] They have also proposed an ethical framework for dealing with these ethical challenges. Their framework encompasses values such as: "Privacy and Contextual Integrity; Transparency; Global Justice; Risk of Harm; fair use of resources; Trust, Transparency, accountability; Trustworthiness; Justice; and Common Good."[232]

This is also part of the mission of Global Governance for Health Research to establish efficient and ethical regulation and oversight for big data.

vii. The Ethical Nature of the Challenges and Five Major Gaps

The Ethical Nature of the Challenges: This chapter examined some of the most important challenges facing Global Governance for Health Research. A brief look at these challenges show that they have major ethical roots and components. In other words, the major challenges of Global Governance for Health Research are mostly of ethical nature. Therefore, the possible solutions of these main challenges are to be sought in the realm of ethics and its relevant branch to this subject, that is global bioethics. Therefore, the Global Governance for Health Research needs a new and properly constructed ethical framework to deal effectively with these challenges. For depicting the ethical nature of these challenges in more details, some of the ethical concepts that are closely and deeply related with these challenges are discussed below. A comprehensive and more detaild description of the involved ethical principles will be provided in chapter 5. The involved ethical concerns include but are not limited the ones in this list:

Respect for Vulnerability: When it comes to some of the ethical debates, concerns, controversies, and discussions surrounding the Global Governance for Health-related Research, including exploitation and helicopter research, ethical imperialism and colonialism, and double standards, one of the central concepts is vulnerability. The debates are around the vulnerability of weaker parties in the global power relations (and in this case, international research) and the ethical obligation of global governance to protect the vulnerable parties, including countries, populations, communities, and even the future generations. Like other conflicts that involve vulnerability and power relation, these debates are of a clear ethical nature.[233] As stated above in this part, the solutions for the above challenges are to be sought in the realm of healthcare ethics/global bioethics. Establishing an ethical framework for Global Governance for Health Research is the solution that global bioethics can provide for answering the above questions, challenges, and needs.

Human Dignity: The concept of human dignity is the fundamental basis of the human rights and freedoms.[234] Problems such as exploitation and double standards entail explicit violation of this principle. Human dignity as a cross-cultural and universal ethical principle is a certain part of the common moral heritage of mankind and stands beyond the accusations of ethical imperialism and colonialism. Violation human dignity is the root and reason behind moral badness of the research practices that entail using human subjects as mere means. At the same time, human dignity is the basis of a moral framework that can deal effectively with these challenges.

Justice: Justice is another cross-cultural and universal ethical principle that stands behind the global ethical norms and values.[235] Challenges such as helicopter research,

double standards, bilateralism, and even biopolitics involve sorts of violation the principle of justice. As a constant part of all the sets of principles for biomedical ethics, justice is an inseparable part of any type of ethical framework for Global Governance for Health Research.

The Role of Organizations: The involved scientific community and professional organizations have a crucial role in establishing the needed ethical framework. Also, different aspects and levels of ethics education, as a well-developed field, play an important role in bringing the theoretical findings into practice and integrate them with the routine practices of all the role players who are involved in global governance for health. This is a continuous and never-ending process. Similar to the technical knowledge, ethical knowledge is subject of constant change and development. Therefore, ethics education is an endless endeavor. This endless endeavor is also crucial for safeguarding the basic rights of all the parties involved in heath research and ensuring the best performance of global governance for health research.

Although the majority of challenges, which global governance for health faces, have arisen from the ground of HICs-LMICs collaborations, there are other challenges that are pertaining to HICs-HICs collaborations, too. A perfect example of such challenges (big data, data sharing, and international collaborations) has been discussed above in this essay. Therefore, even in the relations between parties of the same power and influence, there are still challenges ahead of Global Governance for Health Research that, as argued in the relevant part in this chapter, demand ethical attention and ethical solutions.

Five Major Gaps: Thomas Weiss, a renowned world scholar in the field of Global Governance has described five major gaps in the current situation of global governance. This analytic framework is helpful in portraying the status and challenges of global governance. In addition, this framework is dynamic because the characteristics of each gap are subjects of evolutions and variations over time. These gaps are in the following areas: (1) Knowledge, (2) Norms, (3) Policies, (4) Institutions, and (5) Compliance. The order of this list is also important in the analytical framework, for example, the gaps in knowledge are partly the roots of the gaps in norms and policies.[236]

This model of gaps is developed for understanding the current situation of global governance in general. In this part, this model is applied specifically to the challenges of Global Governance for Health Research as listed and described in this chapter. Formulating the current situation and challenges in a pre-developed model of gaps will be helpful in developing an ethical framework that is well-situated with the status of the issues and challenges.

1- **Knowledge Gaps**: There is no theoretical agreement on the characteristics and nature of the challenges. This knowledge gap has multiple sources, including (1) the impact of ideologies as was discussed above in this chapter under the title of ethical colonialism and imperialism. The ideological and political suspiciousness to the efforts originated from Western countries in addition to the same kind of intention to undermining values such as human rights and fundamental freedoms in developing countries have led to a part of challenges in Global Governance for Health Research that shows itself in the form of resistance against promotion and promulgation of the universal research ethics norms and standards. (2) the areas of ethical controversy and

lack of consensus such as the exact definition of standard treatment as discussed above under the title of double standards is also a major source of knowledge gap that takes part in creating the main challenges ahead of Global Governance for Health Research. Another example of such controversies as shown in the discussion of the challenges is on the meaning of exploitation and the need of action through governance to prevent it. The existing variation among the ethical guidance provided by different declarations and guidelines is a feature of this knowledge gap. (3) the emergence of new concerns and challenges are the result of gradual shaping or filling of the existing or new knowledge gaps. The same is true for global governance at the larger scale. For example, the population problem in the 1970s and the global warming in the last decades of the twenties century were the results of new scientific knowledge that was created and crossed the lines of deniability. The historical predecessors of this issue in global health governance is discussed in chapter 1, such as the resistance against the proposed European sanitary regulations because of the lack of belief to the germ theory and reliance on the alternative, even superstitious, theories for disease and outbreaks. This knowledge gap sometimes is the manifestation of underlying ideological, religious, or material interests rather than merely difference in knowledge and understanding of the facts.

In the field of Global Governance for Health Research the improvements and updates in the international soft law and guidelines fill the previously existed knowledge gaps in a gradual manner. The new consensuses and consensual declarations are new pieces of knowledge that partly belong to the common intellectual heritage of mankind. At the same time, on the other hand, the new challenges are also being resulted from the

new knowledge on the developments and evolutions of international research enterprise. For example, before revealing the research methods used in HIV prevention trials in African countries, the problems of helicopter research and double standards had not been on the list of major challenges of Global Governance for Health Research. The process of creation and filling of knowledge gaps in Global Governance for Research can be summarized and portrayed through this simplified model:

New Scientific Knowledge/Questions → New Research Methodologies/ Designs → New Ethical Challenges/ Controversies → New Ethical Knowledge → New/Updated Ethical (Governance) Soft and Hard Law

This model shows the continues creation and filling of knowledge gaps in the field of Global Governance for Health Research.

2- **Normative Gaps**: The normative gaps are about the difference between the norms and values and the levels of abidance by the standards and norms among different role players (state and non-state) of Global Governance for Health Research. In the absence of a single global government or global authoritative body, the process of ratifying and enforcing the standards and norms is more complicated in the realm of global governance than in the nation-states. Norms, like knowledge, follow their own cycles of emergence, growth and popularity, globalization, modification, and sometimes fading and elimination. There is a typical trajectory: A group of norms first emerge as local ideals, then find their way into domestic laws and then into international soft law, and after a while, the global consensus paves their ways into taking the shape of international hard law.

The most prominent example of such norms are human dignity and human rights as are embodied in the *Universal Declaration of Human Rights*.[237] The examples of fading norms are the sanctity of state sovereignty that today is questioned by the right of nations to exit the nation-states and join to of form new nation-states. In the realm of Global Governance for Health Research many of the widely accepted norms have passed through the similar trajectories. Informed consent, as an example, was defined and promoted in the form of domestic standards over the first decades of the twenties century. It was in the wake of the WWII that this norm showed itself as a part of international soft law, the Nuremburg Code.[238] The repetition and promulgation of the necessity of obtaining informed consent from competent subjects made it a universally accepted norm that can be considered a piece of the common intellectual heritage of mankind in the realm of research ethics.

3- **Policy Gaps**: Policy is defined as "an interlinked set of governing principles and goals, and agreed programs of action to implement those principles and achieve those goals…. Moreover, at the national level, policy can also be used to refer holistically to the entire package of actions and attitudes."[239] In the realm of Global Governance for Health Research, policies are embodied in the form of research ethics codes, declarations, guidelines, laws, and regulations. The Nuremberg Code, Declaration of Helsinki, the CIOMS guidelines, and the Belmont Report are among the examples of policies that are related to health research.

Who is in charge of global policy-making for research enterprise? This is a major question that reveals the existing policy gaps. Each of the above-mentioned pieces of policy have formulated, adopted, and implemented by a different party involved in

research. As described in chapter 2, the Declaration of Helsinki, as the most well-known and influential international policy regarding international health ethics has been formulated by civil society bodies that represent physicians. In addition, the membership of such organizations that have created such policies (e.g. WMA for Declaration of Helsinki) do not necessarily cover all the involved role-players in the world. For example, there are many medical professional bodies that are not among the members of WMA. On the other hand, one may argue that in the intergovernmental organizations such as WHO and UNESCO, the voice of non-governmental actors is missing.

Therefore, at the current situation, the challenge of the lack of globally legitimate and agreed-upon policy-maker forms a part of policy gaps for the Global Governance for Health Research. The role of experts and networks in influencing the process of policy-making in international bodies is undeniable. The collective efforts of all these role-players have already led to formulation, adoption, and even implementation of a large and valuable body of policies in the realm of Global Governance for Health Research. As a matter of fact, these policies are the far most prominent way through with the Global Governance for Health Research has been actualized in the contemporary world. However, policy-making in this realm still has the gaps resulted from the diversity and incompatibility of the bodies of policy making.

4- **Institutional Gaps**: The weakness of the existing international organizations and institutions in dealing with the challenges ahead of Global Governance for Health Research, or the absence of effective ones with sufficient coverage and authority forms the fourth set of gaps: the institutional gaps. In the previous chapter, in describing the existing situation of international organizations, such as WHO, their weaknesses in taking

the leading role in confronting the challenges of health and health research are discussed.[240] Although some international organizations such as UNESCO, CIOMS, and WMA have been successful in developing soft law for Global Governance for Health Research, there is no single world institution in charge of dealing with the challenges of global research enterprise.

The global trend of weakening of international organizations, as described in chapter 2, shows itself in the field of health research, too. WHO has been supposed to take a leading role in global heath governance. Regardless of its success in taking this important role, this is questioned that whether this supposed leading role can be extended to the governance of health research and research ethics? Are there any differences between the leadership of WHO in technical aspects of global health and leadership in the realm of bioethics? The obvious preeminence of other global organizations such as UNESCO, CIOMS, and WMA in taking part on Global Governance for Health Research shows that the WHO, even in theory, does not have a monopoly in Global Governance for Health Research.

This lack of centrality and divergence of leadership efforts and institutions is a major feature of institutional gaps in Global Governance for Health Research. Accordingly, this can be argued that the institutional gaps in Global Governance for Health Research are deeper and more severe and significant than the same gaps on global governance and global health governance. In developing an ethical framework for Global Governance for Health Research, the existing institutional gap should be noticed and considered.

5- **Compliance Gaps**: In a global order made of sovereign nation-states, the most obvious gaps in the fivefold set of gaps are the gaps in compliance. Since the trials of Nazi doctors after WWII there has never been any serious enforcement of research-related regulations at the international level. Therefore, the compliance to the existing body of the soft and hard laws on research ethics constantly is a subject of doubt and question. The real picture of Global Governance for Health Research consists of a large body of laws in the absence of a global low-enforcement authority.

In the contemporary world, almost all major and international research project is reviewed and monitored by at least one Institutional Review Board (IRB) or Research Ethics Committee (REC). The funding of the projects and publication of the result are highly dependent on the confirmation and ethical clearance provided by these oversight bodies. Therefore, one can argue that the research ethics norms are being enforced in the global research enterprise. However, the frequent revelation of scandals such as the HIV research projects in Africa shows that some other factors such as corporate greed and rivalry may create noteworthy obstacles against complete enforcement of research standards and norms. Therefore, the compliance gaps in some shapes and degrees persist and show themselves.

For overcoming the compliance gaps there is no need to an international court of justice for research. Instead, collective efforts of all role players, including the funders, representatives of research subjects, oversight bodies, and publishers for optimizing the current system of research monitoring and oversight can create an ever-increasing improvement in filling the compliance gaps.

Conclusions: In this chapter, the main challenges of Global Governance for Health Research are discussed and their ethical nature is shown. The discussions provided above about each of the main challenges showed that all these challenges have ethical roots and components. Principles such as human dignity, respect for vulnerability, justice and equity, and respect for cultural diversity are involved in all the discussed challenges. In addition, the possible solutions of these challenges are tied to improvement in the existing ethical frameworks.

After portraying the challenges and their characteristics and ethical roots, this chapter analyzed the challenges using the gaps model created by Thomas Weiss and showed that all the gaps described in that model (Knowledge, Norms, Policies, Institutions, and Compliance) can be traced and depicted in the Global Governance for Health Research. As a matter of fact, the main challenges described in this chapter are various manifestations if these gaps.

This chapter concludes that one of the main roots/causes of the existing problems is the absence of a comprehensive ethical framework. The existing frameworks are difficult to apply because they are top-down. Developing a comprehensive, consensual, and efficient ethical framework in one of the next major tasks/challenges of the Global Governance for Health Research. Consequently, the main question that is to be dealt with in the next steps of this theoretical endeavor is "What would be an appropriate normative framework for global health governance for international health-related research?" For answering this question, in the previous chapter of this dissertation, a conceptual, historical, and situation analysis of Global Governance for Health Research and its major role players is provided. In the following chapters, after providing a detailed examination

of some prominent cases, an ethical framework for Global Governance for Health Research is provided and its possible impacts in the future are analyzed.

Chapter Four: Case Studies of Global Governance for Health Research

In this chapter, some of the historic ethical cases of Global Health Governance and Global Governance for Health Research are introduced and discussed. Exploring real and historical cases is helpful for portraying a realistic picture of the existing situation and problems in Global Governance for Health Research and how an ethical framework can be useful in solving these problems. In other words, each case entails certain lessons to learn. Also, certain ethical principles are relevant to each case (Table 4.1).

For starting with a broader scope, the first case, Zika pandemic is more related to Global Health Governance at the large scale. This part shows how Global Health Governance uses previous experiences to deal with newly-emerged problems. The following parts are pertaining to different aspects of Global Governance for Health Research. Research integrity in Iran describes the problem of local practices on research integrity and how they can affect global research collaborations. HIV/AIDS Research in Africa depicts a well-discussed case of exploitation in research. Sending Biological Specimens Abroad deals with the problem of bio-piracy and how international collaborations may be seen from the weaker sides. Research on Pre-Implantation Human Embryo shows how different religious and seculars perspectives collective take part in shaping ethical grounds for Global Governance for Health Research, and Local and International Alternative Medicines deals with the globalized aspects of science-pseudoscience debate.

By analyzing the above cases, this chapter shows the real and practical need of Global governance for Health to certain elements in the form of principles and regulations that along with other ones will shape a comprehensive and efficient ethical framework. A

general scheme of the topics of lessons and principles of each case is depicted in Table 4.1. The resulted ethical framework will be discussed in chapter 5.

Table 4.1. The cases, the learned lessons, and the involved principles in Global Governance for Health Research

Cases	Topics of Learned Lessons	Involved Principles
Zika Pandemic	• The existence and functioning of Global Health Governance • Need to a comprehensive set of principles • The variety of role-players • Importance of the leading role of international organizations (Multilateralism vs. Bilateralism) • The need for improving healthcare and research infrastructures of developing countries • The importance of local cultural sensitivities • The Compassionate Use of Experimental Medications	Cooperation, Solidarity, Sharing of Benefits, Social Responsibility, and reciprocity, Respect for Cultural Diversity, Compassion as a Virtue
Research Integrity in Iran	• The importance of research integrity in global collaborations • Global consensus on the definition and importance of research integrity • Inconsistency in knowledge, attitude, and practice regarding research integrity among different countries • The role of Global Governance for Health Research in promoting research integrity	Honesty, Research Integrity, Common Heritage of Mankind

	• The importance of ethics education in promoting research integrity	
HIV/AIDS Research in Africa	• The problem of double standards • The problems of exploitation and helicopter research • The problem of inability of poor communities to afford the vital medications • Undue influence of religious or political interests (the problem of bio-politics) • The problem of bilateralism (vs. multilateralism)	Sharing of Benefits, Social Responsibility, Informed Consent, Respect for Cultural Diversity, Respect for Vulnerability Human Dignity, Multilateralism
Sending Biological Specimens Abroad	• The role of bio-politics • The role of bio-economics • An example of hard law that protects vulnerable populations (Nagoya Convention) • The problem of bio-piracy	Respect of Common Heritage of Mankind, Sharing of Benefits, impartiality and independence of global bioethics
Research on Pre-Implantation Human Embryo	• The need for protecting early human life and the responsibility of global governance • The role of religious institutions • The importance of global ethical standards for research • Global consensus on dignity of early human life • The need for hard law for some aspects of health research	Human Dignity, Sanctity of Human Life, Respect for Cultural Diversity, Respect for Vulnerability
Local and International Alternative Medicines	• Scientific medicine vs. pseudoscience and superstitions (Pseudo-medicine)	Safeguarding Scientific Validity, Respect for Scientific Methods as a

	• The problem of Bio-piracy • Alternative and Complementary medicine as a rich resource of therapeutically hypotheses	part of the Common Heritage of Mankind

i. Zika Pandemic

Pandemics are among the health issues that best reflect the necessity, functioning, and effectiveness of Global Health Governance.[241] Global Health Governance can be defined by a two major defining elements: First, the variety of role players, including states, international organizations, and non-state organizations that are involved and shape a global network;[242] second, the issues that are cross-border and raise cross-border concerns and demand cross-border attention and interventions.[243] Therefore, Global Health Governance is a network of the above role-players that deal with cross-border health issues in our globalized world.

Like any other social institution, Global Health Governance uses a body of collective experience and wisdom accumulated through many years of experience in dealing with various health problems. The pandemics are not exceptions. A precious body of collective experience and knowledge has been achieved through fighting different pandemics in various geographic areas and in each case, some valuable lessons are learned and added to the existing body of experience and knowledge. Therefore, this is not surprising to say that Global Health Governance learned from this body of knowledge and experience in dealing with newly emerged pandemics like the Zika virus pandemic.

In this part of this chapter, after explaining the current situation of Zika virus pandemic and a brief description of previous similar experiences in dealing with other

pandemics such as Pandemic Influenza and Ebola, this is argued that the main lessons learned from the previous experiences and applicable to the current efforts in fighting Zika virus pandemic (and the potential future pandemics of other infectious diseases) are as follow: (1) The need to an expanded account of ethical principles that govern the Global Health Governance and Global Governance for Health Research, (2) The need to strengthening the leading role of the World Health Organization (WHO) in Global Heath Governance (that implies the importance of having a leading organization in Global Governance for Health Research) while preserving the "network" nature of global health governance that facilitates the involvement of more role players and wider array of the forms of leadership, that is at the same time, an emphasis on multilateralism as described in the previous chapter as the best model of international collaboration for Global Governance for Health Research; (3) The need to improve the healthcare systems especially in lower and middle-income countries along with research facilities that focus on local health needs and priorities ; (4) The necessity of providing universal health coverage for all (including affordable medications), as a goal for global health governance; (5) The need to empowering the mechanisms of governance from below; and (6) Relying on shared global and cultural sensitive values such as cooperation and solidarity and benefit sharing as the overarching values of Global Health Governance and Global Governance for Health Research.

Situation Analysis: This part of this chapter sketches the main factual characteristics of the recent Zika virus Pandemic. For this purpose, first a brief description of scientific facts regarding this viral infection is provided. Then, the epidemiological situation of the recent pandemic is portrayed and then, the predictions

and expectations on the future trajectory of this pandemic are explained. Having a realistic portrait of the problem is one of the first major steps of each study and helps the researchers to ground their arguments and analysis on a firm and reliable basis.

Scientific Facts: Zika virus is a mosquito-borne virus that belongs to the Genre of Flavivirus. This virus is transmitted through the bite of an infected mosquito from the Aedes genus, mainly Aedes aegypti.[244] These mosquitoes inhabit in tropical regions. They transmit other viral diseases such as dengue, chikungunya and yellow fever, too. Sexual transmission of Zika virus has also been reported. Other types of transmission, including blood transfusion and perinatal transmission have not been proved or rejected.[245]

The mosquito that carries Zika virus bites during the day with higher rates during afternoon hours.[246] The incubation period of Zika virus disease is estimated to be a few days. The signs and symptoms of this viral disease are usually mild and last between 2 and 7 days and include fever, skin rashes, conjunctivitis, muscle and joint pain, headache, and malaise. However, what have caused a large scale of global fear of this viral disease, are its potential neurological and autoimmune complications, the most infamous one among them being microcephaly in babies born to mothers infected with Zika virus.[247]

Diagnosis of infection with Zika virus is based on suspicion according to symptoms and history of recent travel to an area where Zika virus is known to be present and confirmation according to laboratory testing for the presence of Zika virus RNA in the blood or other body fluids, including urine or saliva.[248]

Prevention and control is mostly based on reducing the population of mosquitoes through source reduction and reducing contact between mosquitoes and

human beings. Source reduction means removal and modification of breeding sites of mosquitos. Reducing contact between mosquitoes and human beings can be done by the following methods: regular using insect repellents; wearing clothes that shields as much of the surface of body as possible; installing physical barriers such as window screens in houses; keeping doors and windows closed; and additional personal protection, including sleeping under mosquito nets during the day. In addition, removing mosquito-breeding sites such as water containers, flowerpots, roof gutters, sites of accumulation of still water after rains or in discarded containers and waste materials in and around houses. Special attention and help should be bestowed to those who are less able to protect themselves sufficiently, such as young children, the sick or elderly. In addition, during outbreaks, spraying of insecticides can be helpful and may be suggested by health authorities.[249]

Travelers should observe the essential precautions to protect themselves from mosquito bites. Since sexual transmission is one of the methods of transmission of Zika virus, the infected individuals and their sexual partners should practice safe sex that means using condoms. Especially the sex partners of pregnant women who live in or travel to the areas where local transmission of Zika virus happens, should practice safe sex, wear condoms, or refrain having sex throughout the pregnancy. Individuals who return from areas where local transmission of Zika virus occurs should practice safe sex or abstinence for at least 4 weeks after their return.[250]

The disease resulted by Zika virus is usually mild and does not need any specific treatment. No vaccine has become available yet for Zika virus infection and disease.[251]

Epidemiological Facts and Predictions: Zika virus was first identified in 1947 in rhesus monkeys and then in 1952 in human beings, both in Uganda, a country in east Africa (first identifying in human beings concurrently occurred in the United Republic of Tanzania). Historically, outbreaks of Zika virus have previously occurred in Africa, the Americas, Asia, and the Pacific. Zika virus disease outbreaks were reported for the first time from the Pacific in 2007 and 2013 (Yap and French Polynesia, respectively), and in 2015 from the Americas (Brazil and Colombia) and Africa (Cabo Verde). In total, 64 countries and territories have reported transmission of Zika virus since 1 January 2007.[252]

The recent pandemic that occurred in the Americas and the Pacific began in April 2015 in Brazil and spread throughout most of Americas.[253] The fear from vertical transmission of virus caused several warnings about avoiding pregnancy for women residing in or traveling to the affected areas. Also, restricting traveling to the affected areas and even cancelling events that attract tourists to those areas have been proposed and discussed.[254]

Later, it was claimed that Global Health Governance has showed a kind of "over reaction" to this pandemic. This alleged overreaction was also partly a reaction to claims about late and insufficient response to previous pandemics, especially the recent case of Ebola. Therefore, assessing the approaches of Global Health Governance to those outbreaks and comparing them with the current epidemic of Zika virus, can entail valuable lessons for the future. For this purpose, the next parts of this chapter, after examining the concept of global health governance, will provide a detailed comparison among these world experiences.

Comparison with Previous Pandemics: Pandemics as a major concern of public health have been among the main issues that caused and underpinned a paradigm shift from bioethics to global bioethics and have embodied the nature of globalization in this field of theory and practice.[255] This part of this chapter, assesses and explains the historical experience of global health governance with three major outbreaks: Pandemic Influenza, HIV/AIDS, and Ebola and explores how the lessons learned through these experiences prove useful in approaching the current pandemic of Zika virus.

Pandemic Influenza: There have been about three influenza pandemics in each century for the last 300 years, the most recent one being the 2009 Influenza pandemic. This part of this part of this chapter provides a brief examination of the lessons learned through the approach of global health governance to this pandemic.

One of the issues raises during all pandemics is the issue of surveillance of infectious diseases. Among the first missions of the WHO was governing the international efforts for controlling, and in some cases, finally eradicating infectious diseases. For this purpose, the international community needed a system of surveillance. This system had been in place before the foundation of the WHO, in the form of numerous scattered international conventions. The International Sanitary Regulations (ISR) replaced those conventions with a single internationally agreed upon law with an organization in place to enforce it at the global level. ISR was adopted by the Fourth World Health Assembly of the WHO in 1951 and entered into effect in 1952. Then, in 1969 the ISR were revised and renamed into the International Heath Regulations (IHR).[256]

The process of creation and enforcement of the IHR is noteworthy in assessing the global governance for controlling infectious diseases, including pandemics. This first major global experience showed that: (1) this is feasible and practical to create and enforce a global law, system, and organization for collaboration among different countries with different and conflicting political systems and economical statuses; (2) the IHR proved effective and ended up to some noteworthy successes such as the eradication of small pox; (3) this experience showed that how a health-related international law gets old and reveals its shortcomings through the time and can be revised and updated by the agents of global health governance; and (4) the last revision of the IHR in 2005 showed how the international nature of health governance is transforming into a global nature, i.e. more involvement of non-state actors in the surveillance of infectious diseases in addition to more flexible and liquid definition and determination of key factors such as the list of notifiable diseases.[257]

Isolation, meaning the practices that restrict the free transportation, contact, and social activities of individuals for the purpose of preventing the spread of a pandemic, is another important topic. Therefore, quarantine and compulsory hospitalization are also considered as forms of isolation. One of the first priorities of health systems in controlling pandemics is preventing further spread of the infection. For this purpose, the minimum necessary level of restriction of freedoms is to be executed. However, the principle of reciprocity demands that the individuals, who are subjected by these restrictions, receive reciprocal benefits such as the best possible quality of stay during the quarantine and provisions for substituting the lost possible trips.[258]

As discussed above, the healthcare workers have a duty to provide health services during the times of pandemics. This duty is of moral, professional, contractual, and legal natures.[259] At the same time, the principle of reciprocity implies that the governance provides the best compensation and recognition for their efforts.

At the global level, the principle of cooperation and solidarity requires that even non-involved countries get engaged in controlling the pandemics in the afflicted areas. In the current globalized world, no pandemic remains confined in a certain geographic area for a long time.[260] Therefore, in addition to the moral demand out of solidarity, the national interests of countries, especially the ones that or the major destinations of immigrants and refugees, demand their attention to timely and efficient controlling of pandemics.

Ebola: Although Ebola, as a viral disease, had been identified from the 1970s after its first detected appearance in Central Africa, its 2014 pandemics resulted a new and specific attention to this disease.[261] This specific attention was because of the following facts. These facts also make this pandemic relevant to the subject of this chapter that is the lessons learned by Global Health Governance from this pandemic:(1) the spread and severity of this pandemic was extraordinary. Several African countries were affected and many people died, (2) the spread of this disease to the wealthier/developed countries, specially to the USA, (3) various debates with ethical nature that rose during the Ebola pandemic such as compassionate use of experimental drugs that relates this subject to Global Governance for Health Research, and (4) the struggle of Global Health Governance, especially failure of WHO in effective and timely controlling of the pandemic.

Started in 2013 and traced to a 2-year-old girl in Guinea as the index case (who died from this infectious disease), the outbreak of Ebola virus infection/disease in West Africa in 2014 is the most widespread and persistent outbreak of this viral infection ever recorded since the time of discovery of this virus in 1976.[262] This outbreak has killed thousands of people in West African countries during this outbreak.[263] It also has disrupted the activities and programs of the health sector of those countries (like programs to control Malaria) and imposed huge deals of economic lose to those countries.[264]

Some important features and facts about Ebola outbreak, which are relevant to the subject of this part of this chapter, are as follow:

1- Ebola, like HIV/AIDS, has no curative treatment. Although some antiretroviral drugs have been successfully discovered to be effective[265]. Although not curative, the current available treatment of Ebola virus disease mostly consists of supportive measures like providing adequate nutrition and hydration.[266]

2- The recent pandemic of Ebola first started in Western African countries.[267] Health officials in the United States hoped that by adopting reasonable measures, the infection would not enter inside the borders of the United States. It did. Although this event arose some discussions about the ethical limitations and requirements of quarantine as a public health intervention, but the greater lesson was that in the contemporary globalized world, with this huge network of interconnectedness and huge amount of international travelers, heath crises, especially outbreaks of infectious diseases, don't remain confined within the national borders. Both the experiences with HIV/AIDS and Ebola virus disease simply

shows the global nature of public health crises and the global impact of outbreaks that originate in an area but never remain confined to that geographic area.

3- Occurrence of this outbreak in some developing countries showed the challenges of fighting such outbreaks in regions with people who have various sets of beliefs and different cultural/economical contexts. For example, the very issue of mistrust resulted from long lasting political chaos, civil wars, economical poverty, and political dictatorships in the region is discussed separately in this part of this chapter which shows the importance of contextual issues in public health interventions within the frameworks of Global Heath Governance. The same issues can affect research projects in such areas. The problem that also should be covered by Global Governance for Health Research.

4- Comparing the treatment provided for few cases of Ebola infection in the United States, with the chaotic situation of healthcare for Ebola patients in affected countries in the West Africa, uncovers a bitter reality of the current world: the huge disparity and inequality between these countries in term of health care resources and facilities, both in treatment and research sectors.[268] Equality and justice are among the most emphasized values of global bioethics. If Global Heath Governance does not take measures to fight these unacceptable inequalities, the next pandemics will occur in developing countries and will cause human tragedies again and again.

When this deadly outbreak of Ebola found its way to the inside of borders of the United States, the very important role of Global Health Governance in dealing with health crises showed itself again.[269] Mass media and social networks extensively covered this outbreak and the related ethical issues were being discussed in academic circles, and in the public sphere in the house and days after their causes took place. Several issues

about quarantine, the function and efficiency of governmental bodies like the Center of Disease Control (CDC), and the organizational ethics within the US hospitals have been fiercely discussed inside the United States. There are also other lessons learned from ethical features of this experience, which are more relevant to the very concept of Global Health Governance.

It has been argued that in the recent outbreak of Ebola, an existing and ongoing crisis in global health leadership cost thousands of human lives because of delayed and ineffective emergency responses.[270] At the time of crisis, WHO was not able to exert proportional reaction in timely manner to this public health emergency at international level[271]. Although this inability and late reactions have been attributed to shortage of monetary funds available to WHO, however, regardless of the possible causes, it shows the existing need for strengthening the functionality of this leading global organization.[272]

The problem of double standards in Global Health Governance is explained above, in chapter 3, by discussing the example of double standards in treating human research participants in different parts of the world.[273] This problem also exists and should be dealt with at the level of leadership of Global Health Governance.

The problem of double standard in Global Health Governance, however, has other faces, too. The reaction of mass media to two cases of death from Ebola in the United States was fiery and sweltering! The related governmental bodies like the CDC were criticized for not providing guidelines and facilities for preventing transmission in a timely manner. In addition, the very issue if quarantining of a nurse who had come back forms an infected area became a subject of boiling debates. At the same time, thousands of people were dying from this infection in a few African countries and the coverage by

mass medical and reaction of people and public opinion were dilute comparing with the ones evoked by the relatively tiny domestic events. When thousands of people are dying and other countries do possess facilities for preventing such human tragedy, do they have a kind of social responsibility out of solidarity and cooperation to help them more than what happens currently in the real world? Is it justified for governments and nation states to regard the death and suffering of foreigners less important than their own citizens? And is it ethically accepted to refuse to help desperately needy people who are struggling with a deadly disease in the presence of enough resources and capacities?

Responding the abovementioned questions in not easy at all. Different factors like respecting the sovereignty of local states, the responsibility of governments towards their own people, the scarcity of resources, and lack of real trustful collaboration among the major world powers, all should be considered in formulating a response/solution for these ethical questions/problems facing global heath governance. But difficulty of finding a compelling and practicable answer does not shrink the very importance and vitality of these questions and should not cover this very fact that the way the major role players in Global Health Governance respond to these questions is a matter of death and life for thousands and even millions of people in the present and future of human civilization.

Amid the crisis of Ebola infection, when several institutions where working in that area and collaboration with local health officials for controlling the outbreak, one of the most important obstacles against their efforts was the deep mistrust of local people toward any governmental or international agency or intervention. For example, it was reported that in Guinea, panicked residents in a village killed all the members of a team that had been sent to that area to raise awareness about the disease.[274]

The long history of dictatorship and abuse of power in African countries, along with the inevitable side-effects of dictatorship like widespread corruption of police force and their abuse of power, have resulted in the lack of trust, while trust is crucially needed for efficient collaboration among various involved parties and for eliciting people's partnership which is so central and critical in controlling such health-related crises.

Although Ebola infection has no proven curative treatment, some experimental medicines have been used hoping to save patients who otherwise would be likely to die. The long process of approving experimental drugs for using in standard clinical practice has always been a subject of criticism. During the HIV/AIDS epidemics, sometimes there were competitions among potential participants (patients/infected people) for entering the clinical trials. They looked those clinical trials as the last resort and beacon of hope for receiving an effective treatment. In the case of Ebola infection, however, the clinical trials were being conducted thousands of miles away from the foci of outbreak. Delivery of experimental drugs to those patients was not part of any research study or clinical trial. As a matter of fact, considering the especial context of chaos and shortage of healthcare workers and facilities, it was impossible to conducts sufficiently well designed and well-conducted clinical trial in those areas.

Providing experimental drugs for those patients hoping to be effective in relieving their suffering and even saving their lives was an act out of philanthropy. It seems that outlining the regulations and principles under which this kind of premature release of experimental drugs can happen again in the future is part of the duties of the institutions in charge of Global Governance for Health Research. However, it is obvious that the guiding principles of this action are benefit sharing solidarity and cooperation[275].

Ebola pandemic has been called as a failure for Global Heath Governance.[276] However, as explained above, many lessons learned by global health governance that could be applicable to Zika pandemic.

In sum, although Global Health Governance is accused of "over-reacting" in approaching to Zika virus pandemic, this over-reaction that might have saved many lives and prevented births of many defected babies, as a result of previous experiences, such as the criticism of Global Health Governance because of its late and insufficient reaction during Ebola pandemic.

In conclusion, in this part of this chapter, the following lessons learned from the previous pandemics for applying in Zika virus and other future pandemics have been discussed: First, an expanded account of ethical principles (compared with the classical ones) is needed for establishing and shaping an ethical framework for Global Health Governance and Global Governance for Research in dealing with pandemics. This expanded account includes some restrictions to the original principles such ad respect for autonomy and addition of new principles such as cooperation, solidarity, and reciprocity. Second, through discussing more concrete practical concerns, it is depicted that how this modified account of ethical principles can lead and help in dealing with those concerns and show the point of balance among the various and conflicting ethical principles, norms, and obligations. This model needs to be expanded and include other ethical considerations and practical concerns to provide an inclusive and comprehensive ethical framework for global health governance in dealing with pandemics. Third, the above review and comparison shows the need to strengthening the leading role of the World Health Organization (WHO) in Global Heath Governance while preserving the "network"

nature of Global Health Governance and multilateralism on Global Governance for Health Research that facilitates the involvement of more role players and wider array of the forms of leadership. Fourth, the need to improving the healthcare systems and research governance especially in lower and middle-income countries is one of the points that are obvious through the above parts of this part of this chapter. Fifth, the above review and comparison clearly show necessity of providing universal health coverage for all (including affordable medications), as a goal for Global Health Governance in which the research sector can be helpful. Sixth, the need to empowering the mechanisms of governance from below is another point that can be concluded from the above part of this chapter. And seventh, relying on shared global and cultural sensitive values such as cooperation and solidarity and benefit sharing as the overarching values of Global Health Governance and Global Governance for Health Research is the best way for founding an ethical framework for the future of Global Governance for Health Research and its future encounters with pandemics.

ii. Research integrity in Iran

During the second half of the twentieth century, the number of international and multi-central research projects increases with a fast rate.[277] This rate was continued in the first two decades of the next century. This phenomenon is a part of a bigger picture that has been named “globalization”. Globalization in any aspect of social human life necessitates global governance as well as global ethics for that aspect. [278] Research enterprise has not been an exception. Therefore, the governance and ethics of the international research ethics are parts of global health governance and global bioethics, respectively.[279]

Among the different topics of research ethics as it pertains to Global Governance for Health Research, research integrity is one of the most important ones. The reasons of this importance (in addition to the reasons of the importance of research integrity of research in general, that is beyond the scope of this part of this chapter) include:

1- Multinational and multi-central research collaborations are based on the values of honesty and trust. When multiple parties from different parts of the world decide to collaborate in a research project, they have to trust each other's honesty and reliability in following the same methods and standards and in correct and accurate reporting of results, including the possible adverse effects or inabilities to achieve the expected goals or milestones. Therefore, having global ethical norms and regulations that support this mutual trust and a global governance to ensure and promote these norms and regulations will be an integral part of international research enterprise. Otherwise, the high costs of mutual monitoring and verifications will render such research projects too expensive to be practical.

2- Research integrity is among the topics on them it seems possible to achieve a global consensus. When it comes to global consensus on bioethical issues, it is obvious that on some controversial topics (such as abortion or discrimination) it is very hard – if not impossible – to reach to a form of global – and even local - consensus. However, there are certain areas in them it is possible to found a common ethical ground for global ethics. Research ethics is a good source for such grounds. The values that shape the ethical foundations of research include honesty, accuracy, efficiency, and objectivity.[280] These values – at least to the extend they pertain to research – are globally accepted and

justified and can be used as a common ground for founding and ethical framework for Global Governance for Health Research.

Like other areas of practical ethics, historical experiences are the engine that produces force for ethical deliberations, legislations, and enforcement to move forward.[281] Without the bitter experience of human experiments in Nazi Germany, we would not have the Nuremburg Code[282], and without the unpleasant disclosures made by Henry Beecher, we would not have the Belmont Report[283], at least at their current time and place in the history. The same fact is true about research integrity. Historical cases of research misconduct and the related scandals have resulted noteworthy achievements in this area. Therefore, studying, exploring, and analyzing the similar experiences are also valuable in improving research integrity in the future. This part of this chapter is intended to be a step in this direction. Therefore, the main question this part of this chapter deals with is: how the systems of Global Governance for Health Research can learn from the experiences of collaborative/multinational research in countries like Iran for optimizing their approach to the issues related to research integrity?

For answering this question, after a conceptual analysis of the notion of research integrity, and a history review, the concept of global governance for research integrity is introduced and its achievements and shortcomings are explored. Then, some infamous cases are introduced and analyzed. Afterward, a historical review and situation analysis of research integrity in Iran is provided and accordingly, the roots and causes of existing problems and the way ahead are explored. Finally, this part of this chapter concludes that expanding international research collaborations is expected to have beneficial effects in term of improving research integrity in developing countries such as Iran. In addition,

research integrity can be considered an agreed upon basis for developing a part of globally accepted ethical framework for Global Governance for Health Research.

The Concept of Research Integrity: In this part, first, a definition and conceptual analysis of the notion of research integrity is provided, then some of the most important historical landmarks are introduced and discussed.

Definition and Conceptual Analysis: According to the National Institutes of Health, Research integrity includes: "(1) the use of honest and verifiable methods in proposing, performing, and evaluating research, (2) reporting research results with particular attention to adherence to rules, regulations, guidelines, and (3) following commonly accepted professional codes or norms."[284] Therefore, the mandates of research integrity cover all the activities of researchers through all the major phases of thesis development, conducting research/study, drafting and finalizing the report/paper, and publishing the results. Research integrity is very important because of numerous reasons including the following ones asserted by the NIH:

(1) "Researchers rely on trustworthy results of other researchers to make scientific progress."[285] Therefore, research misconduct; including fraud, falsification, and fabrication of data can destroy not only the current but also the subsequent researches that destroy the reliability of science.[286]

(2) "Researchers rely on public support, whether through public investments or their voluntary participation in experiments, to further science."[287] Therefore, violating research integrity can be considered as betrayal against public trust and support and finally can deprive the academic/research society from the support provided by the public, both funding and participating.[288]

(3) “The public relies on scientific progress to better the lives of everyone.’[289] Therefore, scientific misconduct can also gas deteriorating effect on one of the final products and goals of science that is the quality of human life.[290]

(4) “Researchers who are dishonest and act without regards to integrity could actually harm the public.”[291] Therefore, research misconduct is not only a violation of the trust and norms and rights within the professional community, but also is a violation against the public and common good.

All the reasons mentioned above for the importance of research integrity can be defined and mirrored in the global level. The notions of trust, public, and common good can be defined at the global level. In this level, the public encompasses both the community of people of the world and the community of nation-states.[292] For the abovementioned reasons, the notion of research integrity has gained increasing attention in the past decades and should be considered as an integral part of research governance in both local and global levels.

A Historical Review: Some aspects of research integrity, such as avoiding plagiarism, are as old as the written history, itself. However, the notion of research integrity in its current dimensions and characteristics is a relatively new notion. For example, in the United States, research integrity became a public issue in 1981. In that year, a congressman named Albert Gore, Jr. who was the chairman of the Investigations and Oversight Subcommittee of the House Science and Technology Committee, held the first hearing that was provoked by the public disclosure of certain research misconduct cases. Those cases had occurred at four major research centers in the previous year. About twelve cases of research misconduct were revealed in the US between 1974 and

1981. The attention of the US Congress to the issues related to research integrity was continued throughout the 1980s because of some added accusations of research misconduct and reports that the NIH, universities, and other research institutions were unsatisfactorily reacting to those accusations.[293]

In 1985, the Congress of the United States passed the Health Research Extension Act. This Act required the Secretary of Health and Human Services to issue a regulation requiring applicant or awardee institutions to establish "an administrative process to review reports of scientific fraud" and "report to the Secretary any investigation of alleged scientific fraud, which appears substantial."[294] In March 1989, the PHS created the Office of Scientific Integrity (OSI) in the Office of the Director, NIH, and the Office of Scientific Integrity Review (OSIR) in the Office of the Assistant Secretary for Health (OASH). The reason behind foundation of these offices was to deal with research misconduct. The establishment of OSIR also began the course of detaching responsibility for research misconduct from the funding organizations. In May 1992, OSI and OSIR were combined into the Office of Research Integrity (ORI) in the OASH. As the prominent examples of its activities, ORI published the ORI Introduction to the Responsible Conduct of Research in 2004 and began the RCR Program for Graduate Schools in collaboration with the Council of Graduate Schools to institutionalize RCR education in graduate training.[295]

The above examples show the process of legislative and regulatory attention to the issues of research integrity and research misconduct in other countries and in the global scene: First, some cases of violation of research integrity gain public attention, then gradually the related rules and regulations are passed in the legislative bodies and

executive offices take shape to enforce those rules and regulations. The global governance for research needs the same process to take shape at the global scale to deal with the issues of research misconduct and research integrity through global governance for research ethics.

Global Governance for Research Integrity: In this part, a situation analysis of the global governance for research (a general picture) and the global governance for research integrity (with more details and specifics) is provided. Then, an infamous case is portrayed to discuss the lessons learned from them to improve the global governance for research integrity.

Achievements and Shortcomings: Distinct separation between research and therapeutic clinical practice in health sciences, is a recent phenomenon, dating back to the first decades of the twenties century.[296] Before that time, for centuries, experimenting new treatment or interventions was considered as a part of the routine practice of physicians and was supposed to be aimed to providing the best heath interest for the patient.[297] In was in the twenties century that health-related research enterprise experienced an exponential growth, was recognized as separate from clinical therapeutic practice, and in the second half of that century international and multicenter research projects began to sprout and grow.[298]

Just like other global enterprises, the international health-related research established its own system of global governance.[299] The Global Governance for Health-related Research has mainly taken place and been mirrored in the following ways:

First, the international declarations, codes, and guidelines developed for setting global ethical standards for health-related research. Many of these instruments have

specific part pertaining to research integrity, a prominent example being the declaration of Helsinki.[300] Almost all the countries involved in international research collaborations have generally accepted this declaration. Therefore, the standards exerted by this declaration, although they are very concise and brief, consist a major regulation part of global governance for research. In addition, other international instruments such as the *Singapore Statement on Research Integrity* of 2013 have been promulgated in this relevance.[301]

Second, the national rules and regulations made by the countries that host the main funding bodies and institutions on international research, the most prominent one being the United States. There are many law and regulations in this country setting the standards and enforcing them in regard to research integrity.[302] In addition, many of the hosting countries have announced their laws and regulations in this relevance, Iran being an example.[303]

And third, the internal regulations, standards, and guidelines of the various sorts of organizations that fund international research.[304] These funding organizations have their policies and regulations on research integrity. NIH[305] and National Science Foundation[306] (NSF) are two prominent examples.

Therefore, for sketching a realistic portray of the history of global governance for biomedical research, the best way is looking at the developments in the above-mentioned means of implementing global governance for biomedical research.

A Review of an Infamous Case: The case of Hwang Woo-Suk has some noteworthy lessons for global governance for research integrity; therefore, this part of this part of this chapter explores this case with more details. Hwang Woo-Suk, a

professor of theriogenology and biotechnology at the Seoul National University (SNU) was considered a pioneer and ground-breaking researcher in the field of stem cell research up to 2006. In his country, South Korea, he was treated as a national hero. His claimed research achievements including cloning of different mammals got extensive media coverage and made him a public and admired national figure in South Korea.[307]

He invited famous global figures to his team.[308] His works also gained widespread international attention, were published in the highest-ranked journals such as the *Nature* and he appeared in numerous international meetings as an invited lecturer.[309] In two articles appeared in Science in 2004 and 2005 he claimed that he had created human embryonic stem cells by cloning. However, in 2006 it was revealed that his claims were fraudulent and he faked the reported data and results. This was a scandal for him and a big damage to the scientific reputation of North Korea.[310]

He also was convicted for obtaining human eggs for his research through unethical sources that was his female subordinates that raised concerns about coercion.[311] In addition, Gerald Schatten, a professor of cell biology at the University of Pittsburgh, who was one of two corresponding authors of Hwang's second article, was accused of research misconduct, but later a university investigation found that Schatten was not a party to the fabrication of data and was unaware of it. However, it was also reveled that his contribution in the study was not at a level that make him eligible for authorship. In fact, he has also committed research misconduct by accepting a "guest authorship".[312]

The case of Hwang Woo-Suk shows that when a research project or a researcher gains public and political attention, this may have beneficial and adverse effects for him/her. Beneficial in terms of obtaining more research fund and personal/institutional

honor and prestige, and adverse in terms of putting pressure to him/her to have noteworthy results/products and being under the light of media and monitoring bodies. In addition, political support may cause at least temporary immunity of regular scrutiny and inspection that postpones the exposure of research misconduct to a time that it has been worsened and irreversible.

In addition, this case study shows that how detrimental such research misconducts can be in international research collaborations. Such researchers and research projects that gain widespread global attention and work on hot topics of health, science, and technology are very successful in absorbing global funds and collaborations. A case of research misconduct from each party of such collaborations will damage and deteriorate the achievements and reputations of all involved parties. The case of Hwang Woo-Suk is a noteworthy example that shows the importance of research integrity in multinational health research collaborations and the importance of the attention of global governance for research to this subject.

Iran's Experience as a Case Study: This part of this chapter is committed to exploring Iran's experience on research integrity and research misconduct as a case study. After a review and situation analysis, this part will explore and analyze the roots and causes of existing problems and later in this part of this chapter, it will be discussed that how global governance for research and use this experience for promoting research integrity in a global scale.

A Historical Review and Situation Analysis: In the past decades, the health-related research sector in Iran experienced a fast growth.[313] This growth, like other parts of the world, raised some concerns about ethical issues including research integrity.[314] In the

recent years some cases of research misconduct reported from Iranian researchers has led to discussions and debates that shed light to different aspects of research integrity and research misconduct in Iran.[315] This attention was partly because some of the holders of high-ranked offices in the cabinet of previous president, Mahmoud Ahmadinejad were among the people who were accused of research misconduct.[316] In one case, a faculty member tried to answer to the accusations saying that the person who committed the plagiarism was my student and my name in the authorship byline was because I was the instructor/professor and I had not even read the manuscript.[317] This kind of answering just shows deep unawareness of some of these people from the basic mandates of research integrity.

Few empirical studies in this regard have been published. Two studies show that the knowledge and attitude of Iranian students[318] and faculty members[319] toward plagiarism shows there are rooms for more education and improvement. These studies, however, does not reflect a complete picture of the existing situation because they have been conducted in Tehran University of Medical Sciences that hosts the most elite students and faculty members in the country. Also, some papers in this regard have been published by non-Iranian authors, some of them tried to show a darker-than-reality picture of the existing situation in Iran.[320]

In one noteworthy development, a group of Iranian scholars launched a blog named "Professors Against Plagiarism" in which they openly discussed the cases of plagiarism occurred in Iran. They showed that some high-ranked officials of the government have committed some severe cases of plagiarism.[321] The reaction of government is banning (filtering) that blog and accusing them to produce anti-regime propaganda.[322]

In the medical universities of smaller cities, it seems that the rate of research misconduct is higher. Personal experience of the author of this part of this chapter and his colleagues form conducting research ethics workshops and many medical universities throughout Iran and their conversations and discussions with faculty members, students, and researchers who took part in those workshops shows that in some cases, some practices such as guest authorship, ghost authorship, and gift authorship are common. Of course, this high prevalence is mostly occurring in the literature published in Persian. Among the researchers who write and publish in English, research misconduct still occurs but with a lower rate. The reasons of this phenomenon are discussed below in this part of this chapter.

In some parts of larger cities such as Tehran, some private institutions that target graduate students (who are obliged to publish a certain number of ISI-indexed articles for their graduation) advertise for selling research services, including fully-completed dissertations and published articles for certain amounts of money! These businesses have been criticized however have not been removed and continue their marketing and activities.[323]

In one case, the Iranian party of a multinational research project was accused of research misconduct and their contribution was withdrawn from the published results of the study. This case occurred in Isfahan, a central city of Iran and in a prestigious research center. The problem was that the main investigators, as usual, had many academic and administrative jobs and duties, so the work they accepted was being done by a team of junior researchers with insufficient training about research integrity and especially with lower interest and dedication to the project and the integrity of its results.

Therefore, they allegedly committed data fabrication that was reported by a fired employee to the central team of research and they remover Iranian tem from that collaboration.

Roots and Causes of the Existing Problems: With a review of the historical review provided above and a deep look at the related developments and their dynamisms in the past decades, one can explore the roots and causes for the existing problems regarding research integrity in Iran. This part of this part of this chapter discusses some of the most important ones of these roots and causes in more detail and digs deeper in the underlying grounds of the existing problems regarding research integrity in Iran.

The first point is that Iran is not totally different from other countries regarding the causes and drives that may push the researchers and academics towards violating the norms and values of research integrity. These causes and drives include:

1- The need –and sometimes- greed toward achieving higher academic ranks, prestige, money and power in academia.[324]

2- Interpersonal and professional rivalry and competitions that urge people to have more academic achievements.[325]

3- The monetary or academic gain of reaching to significant results in analytical researches that assesse new theories or products.[326]

However, there are some factors that are more relevant to the situation in Iran as explained below.

Iranian academic centers rely on the number of articles published in the journals that are indexed in the directories of the US National Library of Medicine (PubMed) or Institute for Science Information (ISI) for academic ranking and promotion. Therefore,

each academic institution or faculty member has to have a number of articles published in the above journals to achieve academic status, promotion, prestige, or recognition. Otherwise, that person may fall to backwardness in academic rankings and competitions. Therefore, the faculty members and institutions (including research centers, higher education schools, universities, and other academic centers) feel obliged to have a number of such papers in their report card at the end of each year. This system, i.e. relying on the indexing databases such as PubMed and ISI has been extensively criticized. The critiques have mentioned the below weaknesses for this system of ranking and promotion:

1- Some journals are being indexed in these databases/indexing systems while they do not have enough scientific and academic status to be used for this purpose. Some of these journals had been included in the list of the journals indexed by those databases, however before they lost their academic standards. In some cases, these journals accept manuscripts even with a monetary cost. This phenomenon has even led to appearance of some private institutions in Iran that sell the indexed and published articles to their student or faculty costumers!

2- Many valuable and highly ranked academic journals, especially in certain fields such as healthcare ethics, are not being indexed in these databases. Therefore, a student or faculty member who has published an article in one of these journals will gain no or less credits in comparison with a colleague who has published in a very weaker journal that is published in an indexed journal!

3- The credit gained by an article should not be defined and calculated just by the indexing status and Impact Factor of the journal in which that article is accepted or

published. Instead, other factors related to that article such as its scientific value, being innovative or ground breaking, relevance to the real problems of the country of the field of study have to be considered while these factors are foregone in the current system of academic promotion.

On the other hand, the defenders of the current system argue that by using indexing sites such as PubMed and ISI, the academic authorities rely on an objective and impartial source for judging about the scientific value of the articles. Otherwise, if they substitute this system with an internal system in the ministry of health, ministry of science, universities, or departments, they will be alleged to being unfair and partial and may be influenced by the authorities or pressure groups to give unfair value/rank/score to certain papers or authors. Therefore, relying on those foreign-based impartial and agreed-upon websites is the best among the available options.

In addition, the proponents of the current system notice that a significant group of the critiques and opponents of the current system are the scholars who have entered the academia using the rant of political power. They typically are unable to contribute in the current scholarly debates by authoring publishable articles. Instead, they write weak and worthless papers and publish them in domestic journals and websites taking advantage of their power and influence. Therefore, if the reliance on the objective systems of PubMed and ISI is removed, this group will be able to force their institutions to accept their worthless papers as valuable articles and basis for their academic promotion.

The debate on whether to continue the current system of academic ranking and promotion or not is continuing in Iran. Even in one time the Supreme Leader warned about over-relying on the ISI indexing system.[327] However, because of the

abovementioned concerns, this system has not been substituted yet. As regarded to research integrity, the problem with the current system is that many of the Iranian students, researchers, and faculties are not well prepared and trained for doing research and writing scholarly papers, especially in English. The causes of this unpreparedness include:

1- The weakness of English language education in pre-academic and academic educational centers. After the revolution of 1979, the new Islamic government removed the foreign language programs from elementary schools and limited them in the middle and high schools. The weakness of English language education had several causes including (a) the political and ideological challenges and conflicts of the Islamic Republic with Western countries that caused hesitation of the educational system to promote Western languages; (b) the overall weakness of educational system because of the long-lasting Iran-Iraq war and other factors that led to a struggling economical situation; and (c) the isolation of Iranian people from the global community and diminished encountering and transactions with foreign people that necessitate learning a foreign language. The resulted weakness of English language skills among Iranian students and faculty members led to (a) their overall inability or difficulty in contributing in scholarly debates and communicating with their colleagues from other parts of the world, and authoring scholarly papers in English and (b) some kinds of plagiarism in the form of copying the paragraphs of the previously published articles in English and substitute their findings (numerical values, measurements, etc.) with the original ones. Before the recent movements toward improving research integrity in Iran, even some well-recognized

scholar advised their students to use this technic for overcoming their inability in writing in English from the scratch.

2- The weakness in research skills training that begins from as early as the elementary school. The educational system mainly relies on memorizing the content of textbooks and has little room for training innovation and research. Therefore, the students and even faculty members who enter the academia have little previous training on research and research methodology. In the medical schools and during the residency programs, the main emphasis is on memorizing the content of textbooks and learning the skills, not understanding and conducting clinical trials or other kinds of research. However, the system expects its medical residents, PhD students, fellows, and faculty members to write and publish scholarly papers as to fulfill the requirements of graduation or promotion. This pushes them to find fast tracks and short cuts to have enough published articles that are indexed in the ISI to fulfill this requirement.

The other cause of the existing problems had been the lack or scarcity of education, training, and regulations regarding research integrity until recently. Research ethics is a young filed in the world and even younger in Iran.[328] The first national code for publication ethics was promulgated in 2009.[329] Inclusion of current standards of research integrity on formal content of research training courses and workshops has started a few years before that time. Therefore, part of the reason of the cases of research misconduct has been the lack of enough and correct education. For example, during the author's clinical residency in Shiraz University of Medical Sciences (2002-2005), it had been considered a standard that the dissertation is an intellectual property of the instructing

faculty member (the director of thesis/dissertation) and s/he has the right to exclude or include the name of anybody in the byline of the resulted paper(s) as an author!

The other noticeable problem is that many of faculty members hold high-ranked official and governmental offices at the same time. In one case, a faculty member of a medical university in Tehran had at least 18 other executive positions simultaneously. These faculty members try to keep their status in the academic race by relying on their students or other subordinates to write papers and include their names in the authors' list. This phenomenon has sometimes leads to cases and scandals of plagiarism.

When it comes to international research collaborations, the same factors explained above in this part of this chapter, cause the problems. It seems that the rate of research misconduct in international collaborations is lower than the one in the general research sector in Iran, because the researchers who are involved in international research are usually among the best and best trained and experienced researchers who are unlikely to commit research misconducts. However, in some cases factors such as the weakness of management and monitoring in the cases in them the high-ranked officials got the privilege of involvement as a partner in international research projects, such cases and scandals occurred.

The Way Ahead: As mentioned above, in 2010 the Iranian Ministry of Health and Medical Education has promulgated a national guideline for publication ethics.[330] In addition, many courses and workshops have been conducted to make Iranian researchers, students, and faculties more familiar with research integrity.[331] This can be expected that in the predictable future the trend toward higher degrees of research integrity will keep

continuing in Iran, especially in more central and higher ranked institutions and universities that are typically engaged in International research collaborations.[332]

This is also expected that after lifting the economical sanctions, more Iranian centers will get involved in international research collaborations. This phenomenon will result in importing and getting more familiar with the ethical standards of research ethics including research integrity as they exist and are being practiced in the developed countries. The funding institutions, universities, pharmaceutical companies, and other research partners in the developing world demand their partners from the developing world to observe and fulfill certain level of ethical mandates, standards, and requirements. This, per se, will entail some degrees of education and requirement for self-education in this field for Iranian researchers. Therefore, it seems that having international collaborations, per se, will have positive impacts on research ethics and research integrity in the field of health-related research in Iran. Although many ethical problems arose during research collaborations in LMI countries in the previous decades, considering the awareness of research policy-makers and governing bodies in Iran, it is unlikely that those problems, such as exploitation of research subjects, helicopter research, or double standards, will be repeated in future international and multi-central research projects in Iran.[333]

Some organizational changes can also improve the situation in the future, one of them being strengthening internal review systems for academic ranking and promotion to substitute the current system of relying on the quantity of papers indexed in the ISI. Also, not expecting the people who hold executive offices to publish in academic journals unless they had enough time to contribute as an author in producing that paper.

Global application of Iran's Experience: Iran's experience, although has local characteristics and specifics, has also some valuable lessons for global governance for research. This part explores the possibilities and limitations of using Iran's experience at a global level and for improving global governance for research integrity.

Possibilities: Growing international research partnerships is anticipated to have valuable effects in promoting research integrity in developing countries. Iran's experience shows the higher standards of research institutions in the developed world will be transferred to the developing countries through research collaborations and the unfavorable effects such as double standards and exploitation are avoidable through suitable global and local governance for research.

Research integrity can be considered as a field with mostly agreed-upon norms and standards among different cultures, traditions, ideologies, and political systems. According to the NIH, the shared values in scientific research are (1) Honesty that means to convey information truthfully and honoring commitments, (2) Accuracy that means to report findings precisely and take care to avoid errors, (3) Efficacy, that means to use resources wisely and avoid waste, and (4) Objectivity that means to let the facts speak for themselves and avoid improper bias.[334] All these values can be considered cross-cultural and globally acceptable. Therefore, research integrity and research ethics and be considered as a core and first step/chapter for compiling the ethical standards for global governance of heath research.

At sum, Iran's experience shows the importance of research integrity in establishing research partnerships that shape global research network and enterprise. In addition, it shows that how promoting globally accepted ethical standards can help local

and global governances in establishing and maintaining acceptable foundations and practices in the field of research and research integrity.

Limitations: Using a local experience at a global scale always has some limitations. The specific cultural context of Iran makes some of its experiences locally valuable but non-generalizable to other regions. The specific characteristic of health system in Iran, such as the faculties holding high ranked executive offices, are not common in other countries, especially in the developed world.

Also, Iran's relative isolation during the past decades has had specific consequences, such as the relative scarcity of international collaborations that may not be found in many other parts of the world. This is possible that in future, with gradual removing the sanctions, the situation will change in Iran and more international partnerships will be possible, however, still great obstacles remain in front of realization of this development, at least in the near future.

Some other specifics of Iranian universities also contribute in shaping more limitations. For clarifying this source of limitations, one can mention two examples as follow:

(1) The leadership of universities is largely influenced by the political sector. Presidents of universities are appointed by the suggestion of the minister of health or minister of science and technology and approval of the Supreme Council for Cultural Revolution. Therefore, after each election that leans to change in the leadership of the executive branch, the presidents of universities and consequently the heads of schools and sometimes departments change. This instability of academic positions is a source of

some difficulties that do not occur in countries whose academic sector is more independent from the political sector.

(2) In 1988, after the end of Iran-Iraq was, the Islamic parliament passed a legislation according to that, the veterans of the war and the relatives of martyrs of the revolution and war, bestowed with a specific quota (more than 40% of the capacity of universities for admission) for entering the universities.[335] This legislation led to entering a huge number of unqualified students to the universities including medical schools.[336] Many of these students when needed to do research and prepare scholarly works, compensated their inability with purchasing research credit from the black market. This also has been a problem rarely encountered in developed countries.

Conclusions: The main question of this part of this chapter has been: how the systems of Global Governance can learn from the experiences of collaborative/multinational research in countries like Iran for optimizing their approach to the issues related to research integrity?

For answering this question, this part of this chapter first provided a conceptual analysis of the notion of research integrity. Then a historical review showed the main related historical milestones and examples. Afterwards, this part of this chapter introduced the concept of global governance for research integrity and explored its achievements and shortcomings. Then, some infamous cases are introduced and analyzed. In the next part, a historical review and situation analysis of research integrity in Iran is provided and accordingly, the roots and causes of existing problems and the way ahead are explored.

This part of this chapter concludes that:

(1) Expanding international research collaborations is expected to have beneficial effects in term of improving research integrity in developing countries such as Iran. As described above, the higher standards and practices of research institutions in the developed world will be transferred to the LMICs through research collaborations. The adverse effects of such collaborations such as double standards and exploitation are preventable through a good global and local governance of research sector.

(2) Research integrity can be considered an agreed upon basis for developing globally accepted research ethics for global governance for research. In contrast with many other ethical topics (e.g. topics pertaining to the beginning and end of life issues), research integrity can be considered as a field with mostly agreed-upon norms and standards among different cultures, traditions, ideologies, and political systems. Therefore, research integrity and research ethics and also be considered as a core and first step/chapter for compiling the ethical standards for global governance of heath research.

(3) Establishing an effective and efficient global network for health-related research won't be possible without having global standards for research integrity and promoting and training these standards in all the countries that host centers taking part in multinational research projects. There are some international instruments available in this regard. Continuous updating and optimizing these instruments, transforming the soft rule into hard rule, and promoting and enforcing them in the global research network is a crucial and ongoing mission of global governance for research ethics.

iii. HIV/AIDS Research in Africa

In this part, the case of "the experiment of preventing vertical transmission of HIV in Africa" is discussed. The central concept is the problem of double standards and the importance of benefit sharing.

The AIDS research was among the first that attracted a global attention to the global governance for research. The high costs of antiretroviral drugs lead to different debates about the ethics of intellectual property and patent. [337] The high costs made such drugs unavailable for many people who were in desperate need of such drugs. Even people of countries that tolerated the burdens of hosting the clinical trials that resulted in the creation and production of such drugs could not afford those final products while many people in those countries were in desperate and emergent need of them. [338]

HIV/AIDS: First reported in 1981 in the *Morbidity and Mortality Weekly Report* under the title "*Pneumocystis* pneumonia — Los Angeles" denoting a new infectious disease found in a cluster of homosexual men, human immunodeficiency virus infection and acquired immune deficiency syndrome (HIV/AIDS) is a disease spectrum of the human immune system caused by infection with HIV.[339] Soon after its discovery, HIV/AIDS became pandemic with millions of infected people and millions of deaths all around the works with huge cultural, political, and economic impacts. The importance of HIV/AIDS in addition to the size of infected and diseased populations is originated in several factors including:

1- Its perceived relevance to sexuality, especially to homosexuality, which made this disease a taboo in some communities and even a subject of anti-Western propaganda in other countries as explained below. This relevance to sexuality and sex education was

one of the main obstacles for the prevention of this disease in the societies in them speaking about sexual subjects in public, including sexual education for young people, is not permitted by cultural/religious authorities. Because when it is impossible to speak and educate about sex and sexuality, it will be impossible to provide effective education for preventing the sexual transmission of HIV/AIDS. Also, the resulted stigmatization and discrimination (from the communities, families, social partners, and even from the healthcare workers and political systems) against infected people, which instigates a large deal of ethical debates.

2- The lack of effective treatment and 100% case-fatality rate of this disease which exacerbated the panic around the world and resulted sometimes in unnecessary and unfounded fear which acted as an obstacle in fighting this infection/disease.[340]

3- The long latency period which resulted in a relatively long period (medium 10 years) in which an apparently healthy infected person (even may be unaware of his infection) is able to transmit the virus to other people through sexual contact or other means of transmission.[341]

4- Its global feature (being a pandemic that affected almost all the countries around the world) that makes it relevant to Global Health Governance[342]. During the past decades, treatment, prevention, and research on HIV/AIDS arose fierce ethical debates and challenged the existing models and frameworks of Global Heath Governance and Global Governance for Health Research in various technical and ethical ways. The lessons learned from this global experience are useful for enlightening the way ahead of global health governance in fighting inevitable future pandemics.

The pandemic of HIV/AIDS have had a huge impact on different aspects of Global Heath Governance. Different ethical issues arose during the past few decades when the pandemic of HIV/AIDS developed, affected millions of people and several countries and communities, and a huge deal of scientific, political, philanthropic, and economical activities were conducted in dealing and fighting with this deadly infection/disease. Some of the lessons learned from different aspects of this crisis, which are relevant to global health management, are discussed in this part of this dissertation.

Research Activities and Intellectual property: The high costs of antiretroviral drugs lead to different debates about the ethics of intellectual property and patent. The high costs made such drugs unavailable for many people who were in desperate need to such drugs. Even people of countries that suffered the burden of clinical trials ended to production of such drugs could not afford those final products while many people in those countries were in desperate and emergent need to them.[343]

The high costs of medicines and allegedly unfair profit margin of pharmaceutical industry has always been a subject of fierce debates. The so-called HIV/AIDS activism was a social movement appeared in reaction and response to uncovering of such ethical shortcomings and aimed to protection the community and HIV/AIDS patients.[344]

The pandemic of HIV/AIDS alongside with globalization of biomedical research industry added to the heat and extent of this debate. It has been argued that the scandals resulted from uncovering the unethical behavior of biomedical research enterprise in relation to HIV/AIDS has been one of the major causes behind the last paradigm shift in research overview at least in the United States of America. This paradigm shift led to

more emphasis on the very concept of "collaborative partnership". Thank means more involvement of communities is designing of research and setting research goals.[345]

As a matter of fact, collaborative partnership as far as it is related to the subject of ethics in international biomedical research, can be red under the abovementioned principles of the *UNESCO Universal Declaration on Bioethics and Human Rights*, especially respect for cultural diversity and pluralism[346]. Other principles, also, are relevant to this issue like equality, justice, and equity; solidarity and cooperation; Social responsibility and health; and Sharing of benefits.[347]

Bilateralism vs. Multilateralism: Both multilateral and bilateral programs have been efficient in combating the pandemic of HIV/AIDS. Some examples of multilateral programs/institutions are as follow: (1) WHO (that is supposed to assume the leading role); (2) World Bank (in recent decades became a major role player in funding health-related programs); and (3) The Joint United Nations Program on HIV/AIDS (UNAIDS).[348]

UNAIDS, itself, is cosponsored by several international/multilateral organizations. Looking at the list of these organizations reveals the very multilateral nature of this program. These cosponsoring organizations are as follow: (1) United Nations Children's Fund (UNICEF), (2) World Food Program (WFP), (3) United Nations Development Program (UNDP), (4) United Nations Population Fund (UNFPA), (5) UNESCO, (6) WHO, (7) World Bank, (8) United Nations Office on Drugs and Crimes (UNODC), and (9) International Labor Organization (ILO).[349]

Bilateral programs, however, are formed and conducted by an agreement between a powerful/wealthy nation state and a country or a group of countries in need. When it

comes to HIV/AIDS the most influential bilateral program has been the US Government's Global Health Initiative (previously the President's Emergency Plan for AIDS Relief or PEPFAR).[350] As mentioned above, bilateral programs, although sometimes successful and efficient, potentially weaken the role of IOs, in this case WHO, in leading international efforts against pandemics and other heath crises. This weakening may also become extended to ethical principles and norms of global bioethics, which guaranties pluralism as the source of trust and ethical infrastructure for global health interventions.

Politics, religion, and medicine: Respect for cultural diversity is one of the ethical principles, which guide global health governance, and is a separable part of its obligation to plurality.[351] As a sexually transmitted infection/disease, the prevention and control of HIV/AIDS in communities, inevitably faces with cultural/religious conventions, beliefs, taboos, and dogmas, especially in developing countries. To be effective, Global Governance for Health Research has to find a way for dealing with such obstacles. A way, which takes advantage of potentially useful cultural features, like avoiding extramarital high-risk sexual behaviors, and at the same time get rid of obstacles resulted by other sets of such features like resistance against sexual education especially for women and young adults, resistance against availability of preventive measures like condom, stigmatization and discrimination against certain groups like patients and homosexual/transsexual persons.

In some countries such as in Islamic Republic of Iran, The governmental media took advantage from the information about HIV/AIDS outbreak, which was firstly discovered in Western countries and among homosexual males, to claim that this

outbreak is a result of non-obedience to moral norms in Western countries.[352] Consequently, for many years, some high-ranked officials of the Ministry of Health ignored the need to taking preventive measures, including proper education, in the country claiming that this disease is pertaining to immoral Western countries and has nothing to do with the people of Islamic Republic. This resistance and ignorance replaced by an expensive program for controlling HIV/AIDS after the government realized that this disease was spreading with a fast pace in the country[353]. Even now, however, the resistance of the Islamic government and religious leaders against taking some proposed preventive measures like sex education in schools and easy availability of condom for young and unmarried people is part of the reality behind the rising prevalence of this disease in Iran.[354]

An Infamous Case in Africa: One of the paradigm cases of global research ethics that has been very influential in shaping the ethical frameworks for Global Governance for Health Research has been the trial on preventing vertical transmission of HIV virus in Africa. This case drew a large deal of attention and raised ethical concerns on the research in developing countries. Issues such as exploitation and double standards and benefit sharing were discussed seriously after revelation of the ethical concerns of this study.

The effect of oral use of zidovudine in prevention vertical transmission (i.e. transmission of virus from pregnant mother to her future child) was shown in clinical trials in the United States in 1994. Afterwards, the US Public Health Service recommended a regimen containing zidovudine as the standard treatment for pregnant women in the United States. However, the recommended dosage was not affordable for

most affected people in developing countries. Afterwards, several research projects, including 15 placebo-controlled clinical trials were conducted in developing countries, mostly in Africa, most of them funded by US funding bodies and assessing the effects of prescribing lower doses of zidovudine (in some cases, combined with other medications) for pregnant women in preventing the vertical transmission of HIV virus. Two major ethical questions were raised concerning these trials: (1) were these trials ethical? In other words, is this ethical to examine a lower than effective dose of a vital medication, while its efficacy is proven in higher doses, just for financial reasons? (2) Was it ethical to have placebo arms in these trials?[355]

The major ethical concern was that whether the research subjects of these trials and their communities were exploited because of their contextual poverty? Does the poverty as a contextual factor can be ethically relevant in deciding to examine a lower-than-effective dose or having a placebo arm with this justification that these subjects, if not recruited in research, had no access to the standard treatment (the full or even reduced dose of the medication that was proven as standard treatment in JICs)?[356]

This case raises the challenges of double standards and exploitation and can be discussed in the light op principles of human dignity, justice and equity, non-maleficence, and non-discrimination.

iv. Sending Biological Specimens Abroad

Bioethical and Biopolitical Concerns: This part of this chapter deals with the problem of real and imaginary threats and their implications on research policy and research ethics. Research on samples derived from human body and other living organisms (biological samples) and transporting these samples through international

research collaborations has raised its specific ethical concerns. Since the exchange of biological specimens is a frequent and integral part of global research collaborations, the challenges associated with this issue is relevant to Global Governance for Health Research.

This part of this chapter describes the bioethical and biopolitical challenges of sending biological specimens abroad under two main topics: the biopolitical concerns regarding possible genome mapping and the ethical/economical concerns (can be called bioeconomical concerns) regarding commercial benefits and patents produced by the specimens collected freely from developing countries, the problem that has been also discussed under the title of biopiracy.

Biopolitics of Biological Specimens: In some countries, including Russian Federation and Iran, there have been some concerns about sending biological specimens with human origin that are containing DNA to other countries, especially the Western countries. It is argued that the information that is potentially obtainable from such DNA-containing samples may include sensitive information about the biological characteristics of the people living in those countries that may be used even in producing weapons that target that people in a specific way. In addition, in countries with racial/ethnic tensions such as Iran, the local authorities are sensitive about research on racial/ethnic issues, such as the origin of local ethnic groups. For example, in Iran, governmental authorities including the research officials in the ministry of health are suspicious about any research activity trying to attribute the origin of ethnic groups who live within the national borders of Iran to other countries.

The question is that to what extent these sensitivities are realistic and based on real existing threats in the real world and to what extent they are just imaginary threats raised from their over-suspiciousness towards the Western world? Although no reliable answer can be found for this question in the available literature, the sure thing is that with escalating the tensions among countries and hostile rhetoric from the both sides, this kind of mutual suspiciousness will persist and will act as an obstacle for the research enterprise. Therefore, this can be considered as a biopolitical issue that makes challenges for research and as the interface of biopolitics and Global Governance for Health Research. Although the ultimate solutions of these problems are mainly beyond the scope of bioethics or Global Governance for Health Research, creating and adopting reliable and consensual international guidelines in this regard can be useful to promote trust and facilitate international research collaborations hat entail exchange of biological specimens.

On the other hand, it can be argued that the biological samples are a part of common heritage of mankind and cannot be restrained for political reasons or patented for commercial purposes. This argument can be used to suggest a free and uncontrolled network of sample sharing for non-profit research purposes. This suggestion, although looks humane and remarkable, seems to be far from practicality in the current political and commercial atmosphere of the world.

Bio-economics of Biological Specimens or Bio-piracy: In the recent decades, it has been argued that the companies and research enterprise of developed countries use the natural and genetic resources of developing countries and less powerful communities (e.g. tribes and indigenous people) to make products that are beneficial for the companies

and researchers while the communities that provide the natural resources do not have a share of this benefit.[357] This practice is a violation of the principle of benefit-sharing.[358]It has been claimed that using the natural resources and knowledge of indigenous communities and developing countries without benefit-sharing is a sort of colonialism and can be called bio-piracy. A term coined in the 1990s that became popular in the relevant discourse afterwards.[359]

The result of these debates and arguments was the adoption of *The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity* by 92 UN Member States and the European Union. This protocol was a by-product of the *Convention on Biological Diversity* and was ratified in Nagoya, Japan, therefore it is also known *as the Nagoya Protocol on Access and Benefit Sharing* (ABS). [360] This protocol is a supplement added in 2010 to the 1992 *Convention on Biological Diversity* (CBD) and came fully into force in October 2015 in the form of a treaty. This protocol mandates that any company that uses genetic resources obtained from each of the countries signed this protocol, must have a contract that ensures benefit sharing. Research-related benefits are included.[361]

Although the arguments demanding benefit-sharing have been very strong and even named using the natural resources without adequately benefit-sharing as bio-piracy,[362] as a counterargument, it has been claimed that the insistence on benefiting the source countries from exporting biological specimens may cause delay in producing or inadequacy in coverage of vital medications. For example, each year, the seasonal influenza vaccine is produced based on the prevalent strains of influenza virus of that year determined by a panel of experts that meet twice a year (once ahead of each

hemisphere's winter) through a process conducted by the WHO's Global Influenza Surveillance and Response System (GISRS). Then, the pharmaceutical companies have to produce vaccines against the specified strains and for this purpose they need the biological samples from all over the world. If some countries refrain to deliver the samples or put unreasonable price tags on them or require long negotiations to reach the benefit-sharing agreements, this may undermine the efficiency, timeliness, and coverage of the new vaccines. This problem will cause risk and harm to public health at least in some parts of the world.[363]

Conclusions: Sending biological specimens abroad and the arguments, discussions, and controversies around this issue is another good example of the ethical challenges ahead of Global Governance for Health Research. It seems that there are not enough reliable and consensual international guidelines in this regard available to the countries that express concern on political or military misuses of biological specimens. In addition, the attempts for safeguarding the fair share of the source countries and communities, such ad the Nagoya Protocol have had adverse implications in timely and effective production of vaccines. In the case of sending biological specimens abroad, in addition to explaining the com the complex and complicated nature of the existing issues, the principles of benefit sharing along with solidarity and attention to the concept of common heritage of mankind have been used to provide an ethical framework that has been helpful in approaching and solving this challenge and its related problems.

v. Research on pre-implantation human embryo

The ethical status of human embryo from the time of conception until its implantation in the womb has been among the most controversial topics in the field of biomedical

ethics during the past decades.[364] In this phase, the human embryo can be called Pre-Implantation Human Embryo (PIHE). Various interventions with various purposes, including research, treatment, and enhancement can be done on the PIHE.[365] In some cases, these interventions cause damage, change genetic make-up, or destroy the PIHE. Are these interventions ethically permissible? The answer to this question depends on one's perspective toward ethical status of the PIHE.

The ethical debate on the ethical status of the PIHE is a relatively new and modern one. For many centuries, these phases of human life have been out of reach of scientists and physicians. Although abortion has always been an uptight subject of moral debate, nobody could isolate, create, or manipulate a PIHE; therefore, the artificial creation or in vitro destruction of human embryo has been out of scope of such debates.

In the recent decades, the technology if In Vitro Fertilization (IVF) made it possible for scientists to conduct the fertilization of human gametes and produce human embryos in their labs.[366] This new technology opened the black box for human fertilization and made the PIHE exposed and vulnerable to experimental interventions and manipulations, the most notable among them being stem cell research and human cloning (see below). Now, human being has the power of –even mass- production, manipulation, destruction, and transformation of some of their own in the very earliest stages of their lives.[367]

As described below, different religions and moral schools have different views on ethical status of the PIHE. At one end, some ethical schools totally condemn producing or killing the PIHE in the laboratory. On the other end, there are some who consider the PIHEs as a commodity at full disposal of their owners.

In the contemporary globalized world, where such technologies, their usage, and their consequences cannot be confined within national borders. The people created by these technologies move to other countries and jurisdictions and take the concerns on their identity with themselves; human embryos also can be transferred across the national border; and people who are in desperate need to treatments provided by such research, also, can move across national borders to find allowing jurisdictions and willing providers.[368] Each ethical or legal approach to this subject potentially had global consequences. Therefore, research on PIHE is also a subject for Global Governance for Health Research.

This part of this chapter is composed of three main parts. The first part provides a brief review of scientific facts about research on PIHE. This is necessary to introduce the subject of this ethical analysis, show its importance, and portray the areas of ethical concerns. Then, the second part provides a portrait of ethical perspectives and concerns of three main ethical schools of thoughts regarding this subject. This part shows that there are some significant, well justifies, and almost globally consensual concerns and ethical principles/norms regarding research on early human embryo that can be used as the basis of the ethical framework for Global Governance for Health Research on early human embryo. The third part examines this subject and its ethical controversies in the global scale and on the global scene. This part shows that there are unaddressed ethical concerns and gaps in this regard that need global attention in terms of legislation and enforcement. In other words, research on PIHE needs a global ethical framework. This global ethical framework should be developed, adopted, and implemented by Global Governance for Health Research.

At the end, this part of this chapter argues that: (1) there seems to be a global consensus on the principle of respect for human embryonic life. Therefore, some implications of this principle such as refraining of producing human embryo just for research purposes can be considered as globally accepted standards of practice. These standards can be delineated and enforced as parts of global governance for research on PIHE, and (2) for preventing the noteworthy harmful consequences of unleashed and uncontrolled exploitation of human embryos, the existing soft international laws are not sufficient and there is a need to hard laws that protect early human life from destruction and exploitation.

Genetic Research on PIHE: As explained above, the reason behind arising the furious debates and controversies on the ethical status of PIHE in the previous decades has been the scientific and technological advances that made it possible for scientists to produce in vitro embryos and use them for research purposes. Among these research purposes, the most notable ones have been stem cell research and cloning.

Human reproductive cloning has never been attempted or ethically approved, at least to the public and available knowledge.[369] Research/therapeutic cloning has not been successful on providing real treatments yet, however, is a promising field of research.[370] Stem cell research, however, with use of embryonic cells that destroys PIHEs has been developed, and has raised many promises and hopes for finding cure for some serious and untreated health problems.

In this part of this chapter, a concise description is provided on the scientific aspects of these technologies, their status quo, and their foreseeable future or futurology. This scientific review is useful to grasp a broad perspective of the realities in the field. This

perspective/knowledge is necessary for discussing the ethical importance, implications, and controversies in this field.

A Scientific Review: Stem Cell Research and Cloning: Stem cell research is a promising and expanding field of research in genetics and medicine that has opened doors to new hopes for finding treatments for a group of currently incurable diseases such as Parkinson's disease or Degenerative Heart Failure.[371]

There are two main sources for stem cells: Adult cells and Embryonic Cells. Adult stem cells can generate replacements for the cells and tissues that are lost through injury, disease or normal wear and tear. Adult stem cells are also called somatic stem cells. Adult stem cells usually develop into the same type of cell as the tissue from which they have been extracted. For instance, Stem cells found in muscle tissue normally give rise to new muscle cells. Embryonic stem cells, however, are "starter cells" that can be directed into becoming any of the specialized cells of the body. That's why the embryonic stem cells are called "pluripotent." Embryonic stem cells are derived from human embryos that have been created in the laboratory, not in a woman's body. A new achievement in the field, however, is creation of what are called "Induced-pluripotent stem cells" that are adult stem cells that have been genetically manipulated to behave like embryonic stem cells. At present, they serve a valuable role in research and drug testing.[372]

Creating and using embryonic stem cells through in vitro fertilization and then destroying the PIHEs for retrieving stem cells has been the subject of many controversies as it is apparent in the history of banns and then permissions on such research in the past decades in the United States.[373] The invention of Induced-pluripotent stem cells is a

promising stem toward abandoning the use of human embryos for harvesting stem cells. However, the potential of Induced-pluripotent stem cells for replacing human embryonic stem cells is still a subject of research and uncertainty.[374]

In addition to developed countries those have always been pioneers in advanced scientific and technological developments, some developing countries have also taken noteworthy steps in these fields. For example, Iran has been one of the pioneers in the field of stem cell research. This was partly because of flexibility of the religious authorities in permitting such research as described below.[375]

Futurology: Humane Genetics or a New Brave World: Scientific and technological advances in the field of human genetics have always raised concerns on the potential endangerment of human life or values by them. There have always been deep concerns about the legitimate and ethical boundaries of human science and technology that distinct humane achievements from building a "Brave New World".[376]

As describe above, stem cell research and cloning have been very promising for finding cures for a group of most debilitating and fatal human conditions such as degenerative and congenital diseases. On the other hand, creating, using, manipulation, and destroying PIHEs for this purpose have been subject of furious criticisms, especially from the religious and prolife perspectives.[377]

Although Induced pluripotent stem cells have created a promising perspective of abandoning the use of human embryos for harvesting stem cells, the potential of Induced-pluripotent stem cells for replacing human embryonic stem cells is still a subject of research and uncertainty.[378] Therefore, it seems that in the foreseeable future, the

scientists will need and keep using the PIHE for research purposes that will be a source of ethical controversies about the moral status and inviolability of early human life. [379]

In addition, because of globalization, international and multicenter research projects on PIHE are growing in number and quantity.[380] This means that in the era of globalization, they embryos that are created in one country and jurisdiction can be transported and used on other countries or jurisdictions. This makes the governance of such research a subject of global governance for biomedical research. These facts necessitate the existence of an overarching law to regulate this enterprise and prevent violation of human dignity and the sanctity of early human life.[381]

Ethical Status and Protection of PIHE in Genetic Research: In this part, a perspective is provided toward the current viewpoints on the ethical status of the early human embryo. For this purpose, three of the main and most influential ethical accounts/schools in the contemporary world that have distinct and leading perspectives toward this subject have been selected and discussed. These three schools are: Secularism, Catholicism, and Islam.

Secularism is the basis for legislation in developed countries, also is the basis of international and cross-cultural legislations.[382] An international consensus or legislation, which is needed in global governance, should be based on secular reasoning.[383] Therefore, this is important to shed light on this perspective toward ethical status of embryonic human life.

Catholicism is also a very influential school of thoughts, especially when it comes to protecting the dignity and sanctity of early human life. [384] The formal position of the Catholic Church toward in vitro fertilization (IVF) and research on PIHE has been very

influential and controversial at the same time.[385] It seems that Catholicism has adopted the most conservative approach in defending the ethical status of PIHE; therefore, this perspective should be included in any review of current influential and important perspectives toward the ethical status of human embryo.

Covering at least 10% of all Muslims in the world and making the second largest bough of Islam (After the Sunni branch), the Shiite branch of Islam has its own theological, jurisprudential and ethical schools. Among the Islamic countries, Iran, Iraq, Azerbaijan, Lebanon and Bahrain are Shiite majority ones. In all the aforementioned countries, Shiite jurisprudence and ethics have a great influence on life style of large groups of people, including their decisions about child bearing, using assisted reproduction technologies, or abortion. In Iran, according to the constitution, all the rules and regulation should be in accordance with Shiite jurisprudence.[386] Therefore, the Shiite perspective towards such important issue as the moral status of early human embryo, not only is important as a noteworthy part of religious ethics, but also deserves attention because of its great impact on some vital aspects of lives of more than 200 million people in the world.[387]

Considering the above facts and reasons, in this part of this paper, a review is provided of the perspectives of these influential schools of thoughts, namely Islam, Catholicism, and Secularism, toward the ethical status of PIHE. This critical review is necessary for establishing sound theoretical grounds for global governance for research on the early human embryo.

Secular Perspectives: According to the secular perspectives, in ethical assessment of using human embryos for stem cell research, two ethical duties come into conflict: (1)

The duty to prevent or alleviate suffering and (2) The duty to respect the value of human life.[388] Both of these duties are cross-cultural and can be considered secular and prima-facie. Therefore, the main ethical challenges in front of secular bioethics in dealing with stem cell research on PIHE is weighing these two duties and compare them in the case of PIHE.[389]

For providing a sound answer for the above question, secular bioethics has to determine the ethical status/value of the PIHE. A wide variety of viewpoints in this regard can be defended by secular reasoning, varying from bestowing full ethical status to a fertilized egg to postponing ethical status to even after birth. However, when it comes to collective –international or domestic – agreements in secular societies, it seems that human life in its first 14 days is considered valuable, but not as full human life with ethical status. Therefore, they incline to permit use of human embryos for valuable and scientifically sound purposes, but restrict this use to surplus embryos remained after In-Vitro Fertilization (IVF) procedures.[390]

The secular perspective to the ethical status of human embryo has also been reflected in international soft and hard regulations that have been discussed in a later part of this part of this chapter (see below).

Catholic Perspectives: Catholicism is the largest one, in the size of population, among the denominations of Christianity[391]. In dealing with bioethical debates and issues, Catholicism mostly relies on the discipline of theology[392]. Therefore, the moral debates and deliberations in Catholic bioethics are based on reasoning rather than only the Holy Scripture[393].

Catholic ethics relies on the concept of natural law[394]. According to the theory of natural law, human beings are able to differentiate between right and wrong, morally speaking. They do so by appealing to their reason and life experience, either individual or collective, because God has created them and the universe in a way that makes it possible.[395] In its normative meaning, however, the theory of natural law infers that there are some acts, which are against nature (contra naturam). Accordingly, these acts are intrinsically evil. This concept of being intrinsically evil is an important concept in the approach of Catholic bioethics toward practical issues like terminating an early human life.[396]

According to the Catholic perspective, the human being is created in the image of God. This is the very basis of human dignity and sanctity of life in Catholicism. The human person ordered to God by grace and alienated from God by sin. However this is about their conscious life. The human early life, or the PIHE has not gotten the chance of choosing between grace and sin. This person. However, is protected by human dignity and sanctity of life because he or she is created in the image of God.[397] This is the basis of the sometimes controversial positions of the Catholic Church is safeguarding the early human life and considering it as eually dignified as other stages of human life.[398]

In the Catholic perspective, human embryo is bestowed by ethical status or personhood from the very moment of the infusion of soul into its body. However, no official Catholic Church document specifies an exact age or developmental phase of human embryo as the time of ensoulment. This uncertainty, however, has led to adopting a position that covers all the probable times of ensoulment. In the other words, considering that from the time of conception, the human embryo, even if pre-implanted

and pre-differentiated, constitutes human life and is ready and capable for accepting a human soul, therefore, according to the official Catholic Church documents, should be treated as if it has ethical status and personhood. [399]

The position of Catholic Church on the ethical status of PIHE is based on church doctrine and its interpretation of scientific facts. According to this interpretation, the early human embryo is the earliest form of human life and should be protected by dignity and sanctity of life. The validity of such interpretation, considering the developing nature of current knowledge on human embryo and the existing findings, has also been a subject of controversy and criticism.[400]

Although there are some alternative perspectives among Catholic scholars and some of them argue that the ethical status and personhood starts at the later phases of embryonic life, the official position of Catholic Church is still based on bestowing full ethical status and personhood to human embryo from the time of conception.[401]

Islamic Perspectives:

Early Human Embryo (Nutfah) in the Holy Qur'an: The term "*Nutfah*" by which the semen and early human embryo have been named in the most Islamic classical texts and scriptures, has been repeated 12 times in Holy Qur'an. In some verses, the consecutive stages of embryonic and fetal development are described. For example:

"We created the human from an essence of clay. Then we made him, a drop (Nutfah), in a secure receptacle (the womb). Then we created of the drop, a clot (of congealed blood) and we created the clot into bite size tissue, then we created the bite size tissue into bones, then we clothed the bones with flesh, and then produced it another creation. Blessed is Allah, the best of creators"![402]

And: … and that it is he who created pairs, the male and the female, from an ejaculated drop (Nutfah) and that upon him is the second creation.[403]

Obviously, the term used for referring to early human embryo in the Holy Qur'an and Islamic Holy Scripture is *Nutfah*. Other terms, like *Alghah* (the clot) and *Muzghah* (tissue) that represent the subsequent stages of fetal development, are not covered by this part of this chapter.

According to Holy Qur'an, *Nutfah* is the very first stage of development of an embryo. Whether it is attributed to: (a) the sperm (male gamete) which continues to form an early embryo in the womb (the traditional understanding of embryonic development); Or (b) just to the result of conception which develops in the womb after fertilizing an egg by a sperm (the modern understanding of embryonic development), is not very clear in the verses themselves. However, the commentators, based on their understanding of embryology, have read the text differently.

In some verses, the former interpretation is more obvious, for example:

…was he not a drop of fluid which gushed forth?[404]

While, the proponents of the latter interpretation, refer to the verses which denote a "mixed *Nutfah*" as the very first stage of embryonic development, for example:

Indeed, there came upon the human a period of time when he was an unremembered thing. We have created the human from a drop (Nutfah), a mixture, testing him; we made him to hear and see.[405]

As a matter of fact, in describing natural issues – from the human body to astronomic facts – *Qur'an* never obviously contradicts the knowledge of the era in which the Prophet lived. Therefore, the commentators of *Qur'an*, before the modern era, never understood

the *Qur'an*ic verses describing the growth and development of fetus in contradiction with the Aristotle's or Galen's descriptions of early human life. Accordingly they did not consider any difference between semen and the early human embryo (before 40th day).

Even now, some commentators and jurists utilize this word with ambiguity. Some others, however, clearly recognize the findings of modern science, which show the very difference between sperm (the male gamete) and early embryo (the result of conception in which a male and a female gamete are combined to form a zygote and then the zygote multiplies to form the embryo).[406]

The Importance of Implantation: In their assessment of the tort committed against the fetus, jurists have regarded implantation of the *Nutfah* in the uterus as the beginning point of the sacred embryonic life beyond which any infliction of harm to it requires compensation (*Diah*). Before implantation, destroying the *Nutfah* without any justifiable reason is considered as wrong, but, according to the majority of Shiite scholars, no monetary compensation has been considered for it. The monetary compensation gets higher with growth of the embryo and fetus and reaches its maximum level after 120 days which is the very point of ensoulment.[407]

Ensoulment and its Implications: As mentioned above, the later phases of fetal development, including the one in which ensoulment takes place- is beyond the scope of this part of this chapter. However, because of the important implications of this event on the ethical and legal status of human fetus, it is worth mentioning, albeit briefly. According to Muslim jurists, including the Shiite ones, ensoulment, which is the breathing of divine soul into the human body, takes place after 120 days of embryonic

life after implantation. It does not mean that this is the exact time of ensoulmant, but it means that ensoulment never takes place before 120 days after implantation.

After the very point of ensoulment, the human fetus is considered as a human person entitled to all moral and legal advantages attached to personhood. Before this point, however, the human embryo or fetus (including early human embryo) is not considered as a human person entitled of all legal and ethical rights. Accordingly, killing the human embryo or fetus before ensoulment is forbidden but is permissible under certain circumstances. After ensoulment, however, the fetus is considered as an inviolable human person.

Controversies on Withdrawal: It has been claimed that withdrawal (the pull out method for contraception) is the oldest contraceptive method used by human being. In Shiite jurisprudential scriptures, the legitimacy of this method, which is named *Azl*, has been discussed and different opinions have been expressed. According to the traditional understanding of the very meaning of the term *Nutfah*, this method is a kind of wasting *Nutfah*. Although today we know that during withdrawal it is only semen, not embryo, which is wasted, but Muslim scholars, at least until recent scientific discoveries showed the difference between semen and embryo, considered the semen as the very beginning stage of human development (i.e. Nutfah).

Reviewing the above- mentioned discussions can shed light on the ethical status of early human embryo in Shiite jurisprudence. Some Shiite scholars consider *Azl* as permissible and plausible, provided the consent of wife has been obtained. They refer to the *Sunnah* in which Prophet and Imams considered Azl as permissible. Some of them consider it as permissible even without informing the wife.

Other scholars, however, consider *Azl* as forbidden, as they mostly argued that the purpose of marriage is child bearing and avoid bringing a baby is unacceptable for a Muslim couple. Also they refer to the part of *Sunnah* whose documentation is less valid than the part, which permits *Azl*. Accordingly, we can conclude that both the proponents and opponents of this method did not consider any ethical status for *Nutfah* before entering the womb.

*Pre-Implantation Embryo***:** Bearing in mind that no monetary compensation (*Diah*) is considered for destroying pre-implantation embryo, it seems that there is no ethical relevance and worth for such embryos. Some contraceptive methods like intrauterine device (IUD), which prevents implantation thus destroys the early embryo, have been approved by religious authorities and used widely in contraception clinics in Iran. Most Shiite scholars, however, consider this stage of embryonic life as respectful which means that it should not be wasted or destroyed without having a justifying reason. Medical research and health-related interventions such as contraception or infertility treatment are among such reasons.

In 2003, Iran was the first Muslim country that adopted an act on embryo donation, as a treatment for infertile couples. The act of embryo donation to infertile couples states that the surplus early human embryos, produced by IVF for a legally married couple, can be transferred to the womb of the recipient. This legislation paved the way for numerous infertility clinics in Iran to use this technology, however, raised major ethical concerns that is discussed elsewhere.[408]

As a matter of fact, almost all Shiite religious authorities and scholars, accepted in vitro fertilization (IVF) as a permissible and legitimate mean for treating infertility. Also,

they permitted scientists to conduct stem cell research involving destruction of human embryo, with the purpose of finding new treatments for fatal or chronic diseases. Regarding human embryonic stem cell research, Shiite authorities issued Fatwas and declared it as permitted and legitimate.[409]

Moreover, mostly influenced by the guideline developed in the Western world, the Iranian National Guideline for Research on Human Gamete and Embryo requires researchers to perform research only on surplus embryos remaining after infertility treatment and forbids producing human embryos just for research purposes.[410]

This chapter is inclined to conclude that according to the dominant reading of Shiite jurisprudence, early human embryo, before implantation, does not have any ethical value and can be utilized, manipulated or destructed for justified medical purposes. The ethical value of human embryo is considered and talked about whenever implantation takes place.

Global Governance and Genetic Research on PIHE: As mentioned in the previous chapters of this dissertation, the Global Governance for Health Research has mainly took place and been mirrored in the following ways: First, the international declarations, codes, and guidelines developed for setting global ethical standards for health-related research; second, the national rules and regulations made by the countries that host the main funding bodies and institutions on international research; and third, the internal regulations, standards, and guidelines of the various sorts of organizations that fund international research.[411] In the following parts the approach of global heath governance toward research on human embryo is discussed. First, as an important and integral part of global governance, the related international legislations and guidelines are discussed.

Then, the existing ethical problems and gaps are introduced and at the final part, the possible and practical ways toward an ethical consensus are depicted.

International Legislations and Guidelines: The most well-known and influential international declaration on biomedical research that can be called as the cornerstone of global governance for biomedical research is the World Medical Association's Declaration of Helsinki. The principles of the Declaration of Helsinki will apply to all clinical research in respect to human embryo, including PIHE, as well as all problems that arise out of such clinical research. The World Medical Association recommends that physicians refrain from intervening in the reproduction process for the purpose of making a choice as to the child's sex, unless it is to avoid the transmission of serious sex-linked disease. Also, the World Medical Association expressly condemns any commercialization by which ova, sperm, or embryo is offered for purchase or sale.[412]

In 2005, the United Nations (UN) approved a Declaration on Human Cloning that urged member states to ban all forms of cloning, including therapeutic cloning.[413] In the same year, the *UNESCO Universal Declaration on Bioethics and Human Rights* was approved and promulgated by UNESCO.[414] The perspectives of George W. Bush administration influenced the *UN Declaration on Human Cloning*, therefore, this declaration entailed a total ban on human cloning even for research purposes.[415] The *UNESCO Universal Declaration on Bioethics and Human Rights*, however, does not explicitly mention early human life, but some of its principles/articles are applicable to this subject. These articles are as follow:

(1) human dignity that includes protecting human embryo regardless of considering it as person or not.[416] The principle of human dignity is the cornerstone of the theories that

support the inviolability of early human life. This concept is very important in both secular and religious schools of thoughts.[417]

(2) Respect for Human Vulnerability and Personal Integrity that covers early human life according to Catholicism.[418] The PIHE can be considered among the vulnerable entities that need legal support and protection.[419]

(3) Protecting Future Generations, in a broader understanding of this principle, is also applicable to this debate.[420] Early human embryo is the very beginning of the next generation. Therefore, protecting the future generations implies protecting and safeguarding the early human life and the PIHE.[421]

The Existing Problems and Gaps: From what explained in this part of this chapter, one can conclude that despite the great achievements and promises in the field of research on PIHE, there are some ethical problems and legislative gaps than need the attention of Global Governance for Health Research. These problems and gaps are as follow:

(1) The need to explicit inclusion of the rights of early human life in the international declarations and legislations in the way that the ethical norms on them there is a global consensus (such as forbidding production of human embryos for research purposes) be included in these instruments. An explicit recognition of the ethical status of early human life is a necessity for establishing sound ethical grounds for legislations that will protect early human life through the global health governance.[422] The international organization such as the WMA, WHO, and international treaties can shape the organizational backbone and support for these legislations.[423]

(2) The need to protection early human life by enforcing the related regulations on the global scene. The organizational backbone of global health governance (see

above) should be in charge of enforcing the legislations that protect the early human life.[424] Enforcing the legislation through the mechanisms and power relations within the global heath governance is complicated because in goes beyond and across the authority of sovereign states.[425] Therefore, there is a real need to establishing global and international organizational background to support and enforce the related legislation on the global scene.[426]

The Way towards an Ethical Consensus: Despite the existing conflicts and disagreements among the main schools of ethical thoughts regarding the ethical status of PIHE, as described above, there are some norms that can be considered as the area on consensus among all these major schools. For example, all of these schools are in favor of banning of production of human embryo for research purposes. This common area can be used as a common ground and first step for establishing consensus on broader concepts, also consents on creation global instruments (soft or hard international law) to protect early human life as a function of global health governance.

Moving toward legislation and enforcement in this area is one of the main functions of global health governance.[427] Research enterprise has always been one of the concerns of global health governance.[428] The areas of consensus among the major schools of thoughts have always shaped the bases for developing such soft and hard legislations.[429]

For this purpose, interfaith dialogue can be used as a well-designed and experienced method in the contemporary world.[430] Through interfaith dialogue, different schools of thoughts can explore their similarities and differences in order to found a consensual basis for developing consensual legislations for global governance.[431]

Therefore, one of the most crucial endeavors that can shape the future of such debates and be suggested as a useful mean to achieve consensus on sensitive issues is interfaith dialogue.[432]

This can be suggested that the organizations that are involved in global health governance develop the specific global guidelines and legislations with reliance on the above common and consensual areas and using the well-developed methods such as interfaith dialogue as described above.

Conclusions: This part of this chapter, after a brief review of the scientific facts, provided a critical ethical analysis of different significant and influential schools of thoughts regarding the ethical status of early human life. Then, concluded that this has to be one of the functions of global health governance to provide legislations and safeguard the rights of early human life, at least as far as there is a consensus among different major schools of thoughts. This is also argued that in face, some areas of consensus exist. As a noteworthy example, this part of this chapter presented the currently existing consensus on the necessity of placing a legal ban on producing human embryos for research purposes.

As a more detailed summary, this part of this chapter discussed its subject in these main parts: (1) the first part provided an overview of scientific and factual realities about research on early human embryo. This part showed that for this kind of research, there is real need to using and destroying PIHEs and there is a hope that in the future the embryonic cells will be replaced by manipulated adult cells, however, this promising development has not been able to completely replace the use of embryonic cells yet; (2) the second part of this part of this chapter portrayed the ethical perspectives and concerns

of three major ethical schools of thoughts regarding this subject. This part showed that there are some significant, well justifies, and almost globally consensual concerns and ethical principles/norms regarding research on early human embryo that can be used as a basis for developing a consensual ethical framework for global governance for research on early human embryo; (3) the third part of this part of this chapter examined this subject and its ethical controversies in the global scale and on the global scene. This part of this part of this chapter showed that there are unaddressed ethical concerns and gaps in this regard that need global attention in terms of legislation and enforcement.

Based on the above-mentioned parts, this part of this chapter can list its conclusions, and then limitations and suggestions, as listed below:

Conclusive Remarks: (1) there seems to be a global consensus on the principle of respect for human embryonic life. Therefore, some implications of this principle such as refraining of producing human embryo just for research purposes can be considered as globally accepted standards of practice. These standards can be delineated and enforced as parts of global governance for research on PIHE; (2) For preventing the noteworthy harmful consequences of unleashed and uncontrolled exploitation of human embryos, the existing soft international laws are not sufficient and there is a need to hard laws that protect early human life from destruction and exploitation.

Limitations: The limitation of this study is as follow: This study does not include other influential schools of thoughts those have their perspectives toward the ethical status of early human life, such as Judaism, Buddhism, Zoroastrianism, and others. However, the area of consensus that is provided in this part of this chapter does not seem

to be violated by examining other schools and religions. However, a more comprehensive study can be suggested for the future.

Suggestions: Further studies can be suggested in this area to further clarify the areas of consensus among the major global schools of thought. In addition, further studies are needed to explore the best ways in integrating these consensual norms into the legislations that shape global governance for health. In addition, this part of this chapter suggests more studies on the best and most efficient ways of enforcing the legislations to safeguard early human life and at the same time, to protect and facilitate valuable research and treatments.

As the final conclusion, this part of this chapter shows that in the era of globalization, this is crucial to establish a comprehensive ethical framework for Global Governance for Health Research, so the rights and welfare of the future generations will be protected and safeguarded, even in the very first stages of their human life.

vi. Local and International Alternative Medicines

At the Intersection of Market, Medicine, and Politics: Using different sorts of alternative and complementary medicine have had a growing trend in the USA and in the world during the past decades. Many kinds of practices name themselves as alternative medicine; therefore, there is a wide range of them from herbal/traditional medicines to energy therapy, homeopathy, pressure therapy, and using the ones entail different sorts of verbal or material practices. Efforts to revitalize traditional medicine in some developing countries have also had political backgrounds and connotations. For example, one of the elements of cultural revolution in China at the time of Mao was self-relying and in the field of medicine, this was translated into using traditional Chinese medicine to replace

Western Medicine.[433] In India, establishing new organizations with the mission of safeguarding the traditional medical heritage has been considered and effort to fight against bio-piracy.

Two Accounts of Alternative Medicine: The term "alternative medicine" might be misleading and confusing, even may lead some patients to abandon their conventional therapies and appeal to the unproven methods that present themselves as "alternatives". The cautiousness on using this term, led the NIH to rename its institution from "National Center for Complementary and Alternative Medicine" to "National Center for Complementary and Integrative Health".[434] Research on local traditional medicine aiming at marketing them in the global market has always raised challenging ethical concerns.[435] The existence of real clinical equipoise on some of the clinical trials on alternative medicine is questionable.[436]

Although the above position seems to be prudent and scientific, in the reality of the world of various kinds of alternative and complementary medicines, two different accounts exist: The first account believe that the current modern medicine is just one of the possible paradigms of medicine and there are alternative and rival paradigms to them their respected branch of alternative medicine belongs. Therefore, they are not bound to follow the criteria and methods of modern evidence-based medicine for showing the efficiency and safety of their products or methods. They can just rely on their traditional (and sometimes ancient, mystical, or superstitious) theories to find and prove them. The second account, however, regards the alternative medicine as a resource for potentially useful hypothetical and potentially useful treatments that have to be examined by well-designed clinical trials and be added to the current arsenal of medical treatments if their

efficacy and safety is adequately proved. Each of these accounts implicate a different kind of research. The first account relies on the obsolete –even superstitious -paradigms of science and research and can be categorized as pseudoscience. The second account, however, is useful if governed properly by local authorities and Global Governance for Health Research. Below, a brief analysis of these two accounts and their ethical implications for Global Governance for Health Research is provided.

Alternative Medicine as a Brach of Pseudoscience: Emanuel and Grady in their work on the ethical framework for research explain that scientific validity of research (in the phase of creating research ideas and deigning research projects) is an important ethical necessity.[437] In other words, prior to assessing the rights of potential research subjects, the review and oversight (i.e. governance) systems have to look at the scientific validity of a proposed research. Allowing or conducting a research project that lacks scientific validity is unethical.

Considering scientific validity ad an ethical requirement, the part of alternative medicine described as the first account above, raises serious ethical concerns. The only valid way available to show the efficacy and safety of medical treatments (medications or interventions) is through evidence-based medicine. If a branch of alternative medicine systematically flees from scientific evaluation (i.e. clinical trials), or claims that it relies on theories beyond the regular understanding of science (the fallacy of different paradigms), then there is a serious suspicious that it belongs to the realm of pseudoscience and superstitions.[438]

Complimentary Medicine as a Useful Resource for Research: All the branches of alternative and complementary medicine do not belong to pseudoscience and superstition.

In fact, the branches of alternative medicine, especially the local traditional medicines, that used various kinds of herbal, natural, and body-mind medications and interventions have been practiced for thousands of years and are valuable resources of hypotheses that should be evaluated and screened by evidence-based medicine. In this way, the efficient and safe medications and interventions can be found and added to the local and even global arsenal of medicine. In this way, first it is possible to find more natural, affordable, and trustable means of treatment and health promotion for local communities, and second, it is possible to market the medications found in the natural resources of local communities to the world in a way that they benefit from it. This is a way to prevent and counteract the problem of bio-piracy (see above).

Humoral and Herbal Medicine in Iran and India as a Case Study: Founded and developed by ancient Greek and Roman and Medieval Muslim physicians and philosophers, humoral medicine is based on theories about human anatomy and physiology that nowadays are outdated and obsolete. Founded by Aristotle and Hippocrates and expended and optimized by Galen and Avicenna, humoral medicine is founded on this belief that human body contains four major bodily fluids or humors (yellow bile, black bile, phlegm, and blood) and health is equal to balance among these humors. Each of these humors are correspondent with a temperament. For optimum health, there should be a balance among different temperaments. Indian ancient medicine, Ayurveda, was also founded on a slightly different account of humors and their determinant effects on health. The humoral medicine was closely related with the theory of four elements, per that, all things are made from four basic elements: fire (presented in

yellow bile), water (presented in phlegm), air (presented in blood), and earth (presented in black bile).

Although the humoral theories of medicine are obsolete, some of their methods and medications, especially herbal medicine can still be used as a resource for medical hypotheses. The traditional Iranian and Indian physicians, who practiced based on humoral medicine, often used herbs for creating balance among their patients' humors and temperaments. Some of these herbs can be beneficial, however, their efficacy and safety should be proven by evidence based medicine.

The Case of Pseudoscience: Over the previous decades, a group of Iranian traditional physicians (some of them call themselves *hakim* that is a name for wise physicians in the Medieval era) tried to revive the humoral medicine with its traditional theories.[439] They argue that humoral medicine belongs to a different paradigm from the Western medicine, therefore, does not need to be examined by modern standards of evidence-based medicine. They appeal to conspiracy theory (modern medicine is West's plan to destroy health and good habits in Muslim societies) and religious beliefs (traditional medicine is endorsed by religious figures such as the prophet and holy imams) for promoting their practice. This group of traditional practitioners have also got governmental support because they seem to promote self-reliance and relying on domestic and Islamic resources/knowledge instead of Western ones. The same cause that promoted Chinese traditional medicine at the time of Cultural Revolution. They argue that the traditional medicine follows a different paradigm of knowledge and is not obliged to follow Western standards (i.e. evidence-based medicine). They have taken advantage of the political support and established numerous clinics and medical institutions all over the country and

attract thousands of patients. In some cases, they provide very misleading and even dangerous comments and guidance in the media. The principle of respect for scientific validity urges Global Governance for Health Research not to verify these kinds of practices and insist on the universal standards of evidence-based medicine and medical research that are not Western but are a part of common heritage of mankind.

The Case of Preventing Bio-piracy: On the other hand, a group of politicians and physicians both in Iran and India argue that the herbal medications and regimes of traditional medicine should be examined by modern standards to discover the effective and safe ones before they are discovered and patented by Western pharmaceutical companies (bio-piracy). This is the right and ethical way of using the knowledge of traditional medicine and should be supported by Global Governance for Health Research. For example, in the Bt Brinjal case, the National Biodiversity Authority of India (NBA) sued a US-based transnational company because they had used indigenous varieties of brinjal to create a kind of genetically modified food without prior contract or agreement. Similar claims have been made about numerous produces such as *Curcuma*, *Neem*, and *Basmati Rice*.[440] These legal cases showed the legal legitimacy of claims on bio-piracy. The best wat to fight bio-piracy, however, is not making lawsuits after it occurred. Instead, the best way is trying to conduct research on natural resources and traditional knowledge and patent them before being stolen by bio-pirates. Supporting these efforts by facilitating scientific research on traditional medicines is part of the ethical duties of Global Governance for Health Research.

Conclusions: Scientific validity as an ethical requirement is the first ethical point relevant to the debate on alternative and complementary medicine. Scientific methods for

assessment and evaluation of efficiency and safety of new treatments are a well-established part of medical science all over the world. Therefore, they also can be considered as a part of common heritage of mankind. Abidance to the standards of scientific validity and protecting the patients/consumers/research subjects from the danger of medical pseudoscience and superstitions in an ethical duty for Global Governance for Health Research and should be included in any ethical framework developed for it.

On the other hand, alternative and complementary medicine should be considered as a valuable resource of hypotheses to be evaluated by scientific methods and presented to the communities. In this account, local traditional medicines can be used to find new and more natural, culturally acceptable, and cost-effective treatments to be used for treatment and health promotion in local communities and to be marketed with benefits to local communities so to counteract bio-piracy.

vii. Conclusions

The six cases discussed in this chapter reveal different aspects of the issues and challenges that Global Governance for Health Research faces and the ethical principles that are needed to approach these challenges and issues. A brief depiction of the lessons learned and principles that are needed to approach the ethical issues of each cases in provided in table 4.1.

The variety of the factors involved in the challenges of Global Governance for Health Research is stunning. A broad range from the problems of exploitation and double standard in research in developing countries to the issues of biopolitics and bioeconomics in transferring biological and natural samples, to the problems of honesty and integrity in

research and publication of the results of research, and to the problems of noteworthy role of religious ethics in research on early human embryo. This broadness and variety shows that various ethical principles are needed to develop an ethical framework that is capable to approach these different issues with efficiency and competency.

A look at the list of the principles mentioned in table 4.1. show that their number and scope is vaster than the traditional set of four principles of biomedical ethics. In other words, Global Governance for Health Research needs a broader set of ethical principles for approaching its issues and for developing a comprehensive and efficient ethical framework.

Because of the global nature of this field, only cross-cultural principles can be used and relied in developing an efficient ethical framework. Fortunately, three major works have already provided a framework and two sets of principles that have proved cross-cultural and consensual. The framework developed by Emanuel and Grady,[441] the canonical set of four principles of biomedical ethics,[442] and the principles provided by the UNESCO Declaration of Bioethics and Human Rights.[443] In the following chapter of this dissertation, these theoretical works will be relied upon to develop and ethical framework for Global Governance for Health Research.

Chapter Five: A Normative Framework

Adoption of the *Universal Declaration of Human Rights* by the United Nations was actualization of a dream and embodiment of a promise: a global consensus on a framework composed of a set of fundamental ethical principles based on the common and shared understanding of human dignity among all the cultures and communities and inspired by the spirit of cosmopolitanism.[444] This historic event showed that reaching such a framework is not out of reach of humanity. However, what happened afterwards, historically speaking, showed that keeping the promise of human dignity and equity is easier said than done.

When it comes to the realm of global bioethics, the *UNESCO Declaration of Bioethics and Human Rights*, adopted in 2005, is the legitimate and genuine successor of the *Universal Declaration of Human Rights.* Taking a look at the current scene of global research, as depicted in the previous chapters of this dissertation, also shows that keeping the promise embodied in this declaration is not easy either. However, relying on these consensual principles that are an invaluable part of the common heritage of mankind is the only legitimate ground for founding an ethical framework for a global enterprise such as health research, i.e. an ethical framework for Global Governance for Health Research.

In this chapter, the main question of this proposal/dissertation is answered. After a review of the existing approaches, the suggested ethical framework is provided. This ethical framework for Global Governance for Health Research has three main elements: First, a background of personal and subjective virtues that are the merging points of the traditional masculine and modern feminist accounts of virtue ethics; second, a core of principles mainly from the *UNESCO Universal Declaration of Bioethics and Human*

Rights combined with the systematic framework that is named the NIH framework (see below), and third, a place for situation ethics embodied in the crucial role of Research Ethics Committees (RECs) and Institutional Review Boards (IRBs) composed of well-trained experts and lay persons from all the involved parties and communities. A brief scheme of this framework is depicted in Table 5.2.

i. A Systematic Framework:

The necessity of a normative framework for Global Governance for Health Research is shown in the previous chapters of this dissertation through depicting and discussing the existing ethical challenges and examining the cases that show how these challenges affect individuals and communities around the globe (see chapters 3 and 4). Research activities involve and entail power relations. For example, power relations between researchers and research subjects, researchers and communities that host research and research subjects, health policy makers and researchers, corporations and researchers and communities, etc. And wherever there is any kind of power relation, there is a need to ethics and at the larger scale, an ethical framework. Globalization has brought the power relations of research enterprise to a global level. Therefore, it has become a subject for global bioethics that assesses and examines the ethical aspects of power relations at the global scale. This is the gist of the reason behind the need to an ethical framework. The details are provided in the previous chapters.

The NIH Framework: In this part, the framework developed and introduced by Ezekiel J. Emanuel, David Wendler, and Christine Grady is introduced and described. This framework helps to tailor the principle-based approach to the special subject of research ethics and find the most relevant ethical principles included in other, typically

more general, frameworks. Although Emanuel, Wendler, and Grady have not named this framework the NIH framework, since all of these authors had been working at the Department of Bioethics of the Clinical Center of the NIH, and two of them are still working there, and since the current and former heads and the founder of this department are among the authors who developed and created this framework, this chapter names this framework "the NIH Framework".

The NIH framework is the result of the authors' work on the numerous domestic and international research ethics guidelines published during the past 6 decades in different countries or by international organizations. They have provided a list of a selected group of these guidelines as follow: Nuremberg Code, Declaration of Helsinki (WMA), Belmont Report, 45 CFR 46 (Common Rule), International Ethical Guidelines for Biomedical Research Involving Human Subject (CIOMS and WHO), Good Clinical Practice: Consolidated Guideline (International Conference on Harmonization [ICH] of Technical Requirements for Registration of Pharmaceuticals of Human Use), Resolution 196/96: Rules on Research Involving Human Subjects (National Health Council, Brazil), Convention on Human Rights and Biomedicine (Council of Europe), Medical Research Council Guidelines for Good Clinical Practice in Clinical Trials (United Kingdom), Guidelines for the Conduct of Health Research Involving Human Subjects in Uganda (Uganda National Council for Science and Technology), Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (Tri-Council Working Group, Canada), National Statement on Ethical Conduct in Research Involving Humans (National Health and Medical Research Council, Australia), Ethical Guidelines for Biomedical Research on Human Subjects (Indian Council on Medical research), Guidelines on Ethics for

Health Research in Tanzania (Tanzania National Health Research Forum), Guidelines on Ethics in Medical Research: General Principles (Medical research Council of South Africa, Guidelines for Good Clinical Practice in the Conduct of Clinical Trials in Human Participants in South Africa (Department of Health, South Africa).[445] This list shows that they reviewed a variety of influential and pivotal guidelines along with other ones representing different geographical areas.

Emanuel, Wendler, and Grady argue that all these guidelines suffer from a number of common problems such as: they have either created and published in response of a specific scandal (e.g. Nuremberg code in response to the revelation of the experiments done by Nazi researchers and Belmont Report as a reaction to the revelation of the ethical flaws in Tuskegee Syphilis Study) or had an specific practical aim rather than taking a comprehensive approach (e.g. International Conference for Harmonization was held to develop common rules of registration of pharmaceuticals for human use). In addition, to some extent because of their reactional nature, they are mistaken in some of their guidance's (e.g. The Nuremburg Code regards taking voluntary consent as an absolute requirement that makes beneficial research on incompetent and incapacitated people impossible). Therefore, none of these guidelines have created a broad, comprehensive, and systematic ethical framework for research on human subject. They also have overlaps that should be organized into a consistent whole. [446]

For creating a comprehensive and systematic ethical framework that is free of the above-mentioned shortcomings and flaws of previous guidelines and minimizes the possibility of exploitation, Emanuel, Wendler, and Grady developed and published a new framework for clinical research. This framework consists of eight principles and each

principle entails a number of benchmarks that elaborate and explain each principle by providing practical interpretation on the requirements that each principle entails. A characteristic of the principles of this framework is that they are presented in a sequential manner, i.e. orderly from the stage of designing a research project to the stages of conducting and oversighting them. The principles on the NIH ethical framework are as follow:

Collaborative Partnership: The role of communities that host research is incorporated in this principle. This role starts from the very first stages of research, when the research idea and design is shaping and the first drafts of the proposal is being prepared. This principle implies the participation of community representatives in all the stages of research projects, from designing to the dissemination of results. The community representatives as the partners of research team, also hold responsibility in safeguarding the ethical principles and regulations. They also help the research team in abiding with this benchmark of this principle that the values, norms, and cultures of host communities will be respected.[447] The limit of this respect will be the principles implied by human dignity and fundamental human rights as described in the *UNESCO Declaration of Bioethics and Human Rights*.[448] This principle also entails assuring the fair benefit of the community from the research. This is corresponding with UNESCO's principle of Sharing the Benefits.[449] Tangible benefits such as intellectual property and authorship should be considered too. Collaborative partnership is the principle that prevents unethical patterns of research behavior such as helicopter research and is helpful in preventing others such as having double standards. Therefore, the ethical principle of

collaborative partnership is a crucial component of the ethical framework for Global Governance for Health Research.[450]

Social Value: This is an ethical imperative for health research to be beneficial for the society. Otherwise, the resources used for research are wasted and the risk imposed to the research subjects is unethical. Assessing the social value of research should be done – or started- from the first stages of designing and proposal-writing in a prospective way. Although there is no principle in the *UNESCO Declaration of Bioethics and Human Rights* that can be considered exactly equivalent to the principle of social value, some principles of this declaration are partly consistent with the principle of social value, including: Benefit and Harm; Equality, Justice, and Equity; Respect for Cultural Diversity and Pluralism; Solidarity and Cooperation; Social Responsibility and Heath; Sharing of Benefits and Protecting Future Generations.[451]

The benchmarks of the principle of social value entail a number of considerations. For example, determining the group (or groups) of person to whom the research is valuable. In Global Governance for Health Research, this is important to see if the communities from them the research subjects will be recruited is among the potential benefactors of the short-term and long-term results of the research. In addition, the consistency of the research project with the health priorities and needs of the host country is of crucial importance. One of the challenges of Global Governance for Health Research is conducting research in LMICs that are designed to cover the health needs of HICs. This problem was examined in the case of HIV/AIDS research in the previous parts of this dissertation. Another example is Malaria research. Although Malaria is a health problem of LMICs, however, when the exact questions of research are assessed in

relation with the health needs of the host community, new challenges arise. In the case of Malaria, for example, research on medications for preventing Malaria for a short period is more useful for tourists who travel to the Malaria-infested regions, while research on Malaria vaccine is more compatible with the health needs of local people. In addition, provisions for maximizing the social value of research is of ethical importance. Requiring data-sharing, as discussed in Chapter 3, is one of the regulations adopted by Global Governance for Health Research to fulfil this ethical imperative. Also, the burden of research on the healthcare infrastructures of the host community/country is another benchmark derived from the principle of social value.[452]

Scientific Validity: Observing the scientific and methodological standards is an ethical imperative. Any deviation from the generally accepted scientific and methodological standards should be justified. In addition, the research should be designed and conducted in a way that is useful for solving the problem or answering the question for which it was designed and conducted. In other words, to be used for solving the health problems of people. Providing essential healthcare services for research subjects and preventing them from unnecessary or serious harms is another benchmark of this ethical principle.[453] This principle is compatible with the following principles in the *UNESCO Declaration of Bioethics and Human Rights*: Benefit and Harm; Equality, Justice, and Equity; and Social Responsibility and Health. The value of scientific validity, however, is not emphasized in this declaration in the shape of an individual principle.[454]

When it comes to Global Governance for Health Research, respect for scientific validity shows its importance in challenges such as the one described in the case of Alternative and Complementary Medicine (see chapter 4). The lack of scientific validity

causes wasting of resources, harming the subjects, and unwanted promoting of pseudoscience in research enterprise. Only scientifically valid research is useful for promoting health and dealing with health problems in communities. Therefore, Global governance for Health Research should emphasize on the importance of scientific validity through including it in the soft law and require research funding, oversight, and policy-making bodies to consider this important factor in funding, confirming, and monitoring research projects.

Fair Participant Selection: This is the first principle of this framework that mostly pertains to the phases of conducting research projects. This principle requires that the criteria of recruiting human subjects for clinical research be limited to only the ones that necessitate by the research objectives, risks, benefits, and the feasibility of conduction the research. No other factors, such as availability and vulnerability of the potential subjects is ethically justified. The benchmarks of this principle entail that the research population be selected to ensure and maximize the scientific validity and reliability of the data and results based on research objectives and methodological considerations, minimizing risk for the research subjects, and maximizing the social value of research and the benefit of the research project of its individual subjects.[455] This principle is more compatible and consistent with the following principles of the *UNESCO Declaration of Bioethics and Human Rights*: Human Dignity and Human Rights; Benefit and Harm; Respect for Human Vulnerability and Personal Integrity; Equality, Justice, and Equity; Non-Discrimination and Non-Stigmatization; Solidarity and Cooperation; and Social Responsibility and Health.[456]

The importance of this principle for Global Governance for Health Research cannot be overemphasized. Some of the major challenges of Global Governance for Health Research, as explained in chapters 3 and 4, are related to the fairness in recruitment of research subjects. The challenge of double standards entail having unfair double standards in recruiting research subjects in developing countries or poor communities. The vulnerable populations in marginalized and poor communities are at a greater risk of exploitation by research purposes. Other considerations are also important and relevant, for example including the imperative of conducting phases I and II of clinical trails only in developed countries, with the purpose of protecting potential research participants in developing countries, once included in the CIOMS guidelines in 1993, subsequently was removed because of objections made by the representatives of developing countries.[457]

Favorable Riske-Benefit Ratio: Clinical research imposes risk on research participants to produce beneficial knowledge. The risk of research should be assessed and minimized. This is the first benchmark of this important principle. This benchmark entails that the assessment and minimizing the risk should be done based on scientific evidence. In addition, the research should be conducted by qualified researchers. Benefits, on the other hand, should also be assessed, maximized, and enhanced. The benefits of research can be categorized into two groups: first, the benefits for the society that entails the social value of research. Second, the benefits of research for its individual research subjects. The ethically important imperative is that in risk-benefit assessments for justifying a research, only the health benefits of research interventions or medications should be considered and calculated. In other words, although payment to research

subjects for reimbursing their time and efforts is not ethically wrong, and enhancing the health benefits and ancillary care for research subjects, especially in communities that they cannot receive them outside the research setting, is an ethical standard, these secondary gains (e.g. payment or ancillary care) should not be considered as the benefits of research in risk-benefit assessment.[458]

This principle is clearly consistent – and even identical- with the principle of Benefit and Harm in the *UNESCO Declaration of Bioethics and Human Rights*: Human Dignity and Human Rights.[459] Also is consistent with the principles of Sharing the Benefits, and Social Responsibility and Health.[460]

In the perspective of Global Governance for Health; the risk-benefit analysis and the imperative of maximizing the benefit to risk ratio; preventing unnecessary and unjustified harm; and enhancing health benefits for research subjects, especially for vulnerable groups are very relevant to ethical issues in research in developing countries, as explained above under the titles of double standards and helicopter research in chapter 3. The vulnerable populations in developing countries may not be able to assess the risks and benefits and make decisions independently. In addition, politicians and political representatives of such countries may have conflicts of interests and may not be the fairly selected and democratic representatives of local people. Their deals with pharmaceutical companies should be under scrutiny of a sort of governance that takes care of the interests of local and vulnerable populations in risk/benefit analysis of research. For this purpose, having real representatives of local communities and populations in oversight bodies (e.g. Research Ethics Committees and Institutional Review boards) is important and should be emphasized by Global Governance for Health Research. In addition, empowering local

members of Research Ethics Committees and other oversight and policy making bodies for performing efficient and accurate risk-benefit analyses is of crucial importance. As an example, the programs funded by Fogarty International Center (FIC) of the NIH for research ethics education LMICs has been a noteworthy step in this regard. Although accused of ethical imperialism, these programs have empowered local experts to take part in research oversight and monitoring and tried to keep its funded training programs compatible with local cultures and value systems.[461]

Independent Review: Over the first decades after WWII, when utilitarianism was the predominant paradigm in research ethics and research oversight (mostly in the United States as the pioneer in health research and bioethics), it was thought that ethical research is dependent on ethical virtues of researchers. In other words, good and virtuous researchers and doctors necessarily do ethical research. It was believed that the unethical behavior of Nazi doctors in their experiments on human subjects during WWII was because of them being wicked and having unethical ideas and purposes. After the revelations made by Henry Beecher in 1967 that showed that unethical behavior happened in prestigious American universities and institutions and by reputable doctors and researchers, the above perspective changed and the importance of independent review based on ethical principles was proved.[462] Consequently, the importance of establishing Institutional Review boards (IRBs) or Research Ethics Committees (RECs) and independent review as an institution in the governance of research enterprise was emphasized and entered the soft and hard law of research oversight and Global Governance for Health Research.

Independent review is aimed at protecting all parties involved in research, especially the more powerless and vulnerable ones, against the possible conflicts of interests and ensuring "public accountability". The benchmarks of this principle include: establishing regulations for independent research review and oversight by law and regulations and making sure that they are properly followed; ensuring the independence and competency of the IRBs (or RECs); and the decisions of review and oversight bodies being transparent, legitimate, and ethically informed.[463]

The *UNESCO Declaration of Bioethics and Human Rights,* also puts emphasis on the importance of independent review. In article 19, this declaration states that: "independent, multidisciplinary, and pluralistic ethics committees should be established, promoted, and supported at the appropriate level." This imperative is consistent with principles such as: Benefit and Harms; Respect for Human Vulnerability and Personal Integrity; Equality, Justice, and Equity; Respect for Cultural Diversity and Pluralism; Sharing of Benefits; and Protecting Future Generations.[464]

In this part of this ethical framework, again, the importance of empowering local experts and individuals for taking part in independent ethical review of internationally funded research is obvious. In other words, fulfilment of this important part of ethical framework for research and its benchmarks is dependent on having enough expertise and research ethics knowledge to take the role of independent review and represent local people and their interests in reviewing research projects. In sum, this principle has two major implications for Global Governance for Health Research: first, including the necessity and obligation of independent review in the related laws and regulations, and second, empowering MLICs and vulnerable communities/populations to take part in

independent review via their informed, trained, and qualified representatives. The latter implication, again, raises the issues of research ethics training, the duty of HICs to provide this training, the concerns on ethical imperialism and colonialism, and the respect for local cultures and value systems as discussed above under the title of Favorable Risk-Benefit Ratio.[465]

Informed Consent: One of the characteristics of the NIH framework is its accordance with the sequences of research projects. It starts with the considerations mainly relevant to the phase of developing research idea and proposal and continues with the obligations of the phase of subject recruitment and afterwards deals with the ethical concerns that are related with the rights of the people who are selected to be invited to join the research as research subjects, the most important among them being informed consent. Informed consent has been the most discussed topic in research ethics. In other research frameworks, usually informed consent takes the first place in order. Although Beauchamp and Childress assert that their framework of principles does not connote any order or ranking among the four principles, however, in Western culture the principle of respect for autonomy has always taken the utmost priority. In other guidelines and frameworks, such as The Belmont Report, the principle that entails the obligation of taking informed and voluntary consent (respect for person in Belmont Report) is placed at the top.[466] In the *UNESCO Declaration of Bioethics and Human Rights* consent is the fourth in the order of principles, however, human dignity and human rights, as the theoretical background of consent, is the first principle of this declaration.[467]

The benchmarks of this principle entail attention to the sufficiency and adequacy of information provided for the participants in a way that they are nor ambiguous and

inadequate nor too detailed and overwhelming. In addition, considering the surrogate decision making if the subject does not have capacity and taking additional informed consent from local authorities if demanded by local norm and the consistency of the informed consent with the cultural and political contexts in which the subjects are recruited. [468]

The *UNESCO Declaration of Bioethics and Human Rights* incorporates Consent as an individual principle. In addition, the following principles are also in relevance with consent: Human Dignity and Human Rights, Autonomy and Individual Responsibility, Persons without the Capacity to Consent, Respect for Human Vulnerability and Personal Integrity, Non-Discrimination and Non-Stigmatization, and Respect for Cultural Diversity and Pluralism.[469]

Informed consent is one of the most crucial and discussed topics in Global Governance for Health Research. All the competent participants of research, regardless of the contextual factors such as the country of residence or the socioeconomic status, deserve to be respected by obtaining voluntary and informed consent. The contextual factors, such as the cultural issues cannot override this fundamental right. In addition, the content of the informed consent should be compatible with cultural context and conditions, for example, the information should be provided in a language that is understandable for the research participant. In the cases that local authorities demand to be asked for permission for research, their permission can be added to the individualized informed consents but cannot replace them. For example, if a research project needs to recruit subjects from a tribe, the researchers can obtain a consent from the head of tribe

but does not exempt them from the obligation of taking informed consent from each individual research participant from that tribe.

Respect for Participants: The ethical duties of researchers to the participants is not limited to informed consent, but they start with it. The ethical responsibility of researchers toward the participants start when they approach the participants to invite them to join the research project and continues even after the end of the project. The researchers are responsible to continuously do their best to minimize the risk and harm for the participants. The researchers should monitor the health and well-being of the participants all over the study and as long as the effects of the experimental study might persist. Other rights of the participants, including privacy and confidentiality, should be strictly observed. This is also applicable to the data that are kept for a period of time after the research, such as the data that may be shared (see data-sharing in chapter 3) and the samples kept in biobank and big data.[470]

The other benchmark of this principle is the right of the participants to withdraw themselves from the research project without any penalty or adverse effect on their healthcare. During and after the end f trial, the researchers should pay attention to the healthcare of patient. This may include providing ancillary care during the trial and referring to local healthcare providers at the end of research project. Also, paying proper attention to the accidental findings during the research and informing the third parties of their health interest is at stake.[471]

This principle is consistent with the following principles of the *UNESCO Declaration of Bioethics and Human Rights*: Human Dignity and Human Rights; Benefit and Harm; Autonomy and Individual Responsibility; Consent; Persons without Capacity

to Consent; Respect for Human Vulnerability and Personal Integrity; Privacy and Confidentiality; Non-Discrimination and Non-Stigmatization; Respect for Cultural Diversity and Pluralism; Solidarity and Cooperation; Social Responsibility and Health; and Sharing of Benefits.[472]

This principle and its consistent principles in the UNESCO declaration have numerous implications for Global Governance for Health Research. The challenges of double standards, exploitation and helicopter research, and data sharing and big data are in close relevance with this principle. The researchers should take care of both fundamental rights and health needs of their research subjects and their communities and abide to this ethical responsibility with considering the cultural contexts (to provide the best care in a culturally friendly and consistent way) and socioeconomic contexts (to pay attention to the health needs of the participants that cannot be met outside of research) in which the research is being hosted and the participants live and will continue living after the end of the research projects.

The Missing Parts of the NIH Framework: The most notable missing parts of the NIH framework are the principles that would govern research integrity, conflict of interest, and publication ethics. The NIH framework is created to govern clinical research and is focused on the practical/clinical aspects of research and their ethical issues and concerns. This characteristic makes this framework even more relevant to Global Governance for Health Research. A review of the challenges and case studies presented in chapters 3 and 4 of this dissertation shows that the most prominent ethical concerns of global health research are in relation with clinical research. Epidemiological research creates less ethical issues. Research integrity and intellectual property and patenting are

among the prominent ethical issues in global health research and are covered by principles provided by the *UNESCO Declaration of Bioethics and Human Rights* that is appealed in developing an ethical framework for Global Governance for Health Research in this chapter (see below).

ii. Principle-based Approach: Pros and Cons

In this part, the principle-based approach will be analyzed. The pros and cons of this approach will be reviewed trying to answer this question that whether the principle-based approach provides an effective and comprehensive ethical framework for Global Governance for Health Research or not? As described below, the most consistent and comprehensive framework of principles available to be used in formulation and ethical framework for Global Governance for Health Research, is the framework adopted by UNESCO in 2005. As described above and depicted in Table 5.1., Each principle of the systematic framework of the NIH is consistent with a certain number of principles of the *UNESCO Declaration on Bioethics and Human Right*. In this part of this chapter, after a review of the existing sources of ethical principles for Global Governance for Health Research, the comprehensiveness of the UNESCO model is shown and its principles are adopted to be combined with the research-specific and systematic approach of the NIH framework to shape the main element of the ethical framework that this chapter suggests for Global Governance for Health Research.

The Existing Resources of Principles: One of the fundamental ethical principles in research ethics is the principle of non-exploitation.[473] This principle was discussed in detail in chapter 3 of this dissertation. The framework suggested by this chapter for Global Governance for Health Research adopts this principle as one of its fundamental

components along with two other principled, Human Dignity and Human Rights. Other major sources of principles for health research (that are also the main sources of principle-based approach in global bioethics) are the four principles theory of Beauchamp and Childress[474] and the *UNESCO Declaration on Bioethics and Human Right*.[475] In addition, as described above, an ethical framework for health research in developed and another one for developing countries is developed and presented by Emanuel and Grady[476].

The Principle of Non-Exploitation: As explained above, this principle in not among the principles of UNESCO Declaration of Bioethics and Human rights, however it has been argued that the most fundamental concern in research ethics, especially when it comes to clinical research, is avoiding exploitation. It has been argued that non-exploitation is an overarching principle for all the principles and regulations in the field of research ethics, including the most general ones such as respect for person and beneficence.[477] A detailed conceptual analysis of this principle is provided in chapter 3 under the title of Exploitation and Helicopter Research. The accounts provided by Wertheimer, Kant, and Marx are discussed there (see chapter 3).

In clinical research, human subjects are "used" to generate health knowledge, therefore, they are at the risk of exploitation. The same is true about the host communities and countries (see Exploitation and Helicopter Research, above in chapter 3). This risk of exploitation is compatible with both classic Kantian account (using individuals merely as a mean and not simultaneously as an end) and the more recent account presented by Wertheimer (unfair distribution of the benefits and burdens of an interaction) and

explained above in chapter 3. Minimizing exploitation is the fundamental ethical purpose behind the ethical framework of Emanuel, Wendler, and Grady (see above).[478]

The Canonical Set of Four Principles: A set of principles for biomedical ethics had previously been presented at time of drafting *the UNESCO Universal Declaration on Bioethics and Human Rights*. This set of principles presented by Beauchamp and Childress is called the four principles approach (or the Georgetown approach) to biomedical ethics. A version of these principles had previously been developed and published in the Belmont report. Those set of principles includes: (1) Respect for autonomy: This principle demands the healthcare providers to respect the informed decisions made by their patients or their legal representatives. This principle is part of the wider one entitled "respect for person" in Belmont report. (2) Beneficence: This principle denotes that the main purpose of health care should be maximizing good results and outcomes for the patients. This principle in addition to Non-maleficence (the next one) is entitled "beneficence" in Belmont report. (3) Non-maleficence: This principle implies the old motto that says: "first, do not harm" and implies the obligation of health care providers to minimize harms for their patients. (4) Justice: This principle with the same name exists in the Belmont report. This principle can be discussed in different levels from the bedside to the entire heath system of country or even global heath governance.[479]

The above principles are crucial and fundamental. They are relevant to every level and scale of health-related research, from the small projects in local institutions to the large multicenter and internationally collaborative ones. Global governance for

biomedical research, however, needs more principles for dealing with its specific ethical challenges as described above.

The UNESCO Universal Declaration on Bioethics and Human Rights: For portraying the most multilateral and inclusive ethical frameworks for a branch of global governance, as discussed above in this chapter, one should rely on the most consensual sets of such principles/norms. The UNESCO developed this consensual set of principles of global healthcare after long discussions and deliberations of the delegates of almost all of live and large cultural traditions in the world.

The UNESCO Universal Declaration on Bioethics and Human Rights has been compiled and finally adopted by acclamation by the General Conference of the United Nation's Educational, Scientific and Cultural Organization (UNESCO) in October 2005. It is noteworthy that many of the principles presented by this instrument are the ones that were proposed by delegates of developing countries to the previously existed classical sets of principles, which had been developed and introduced by Western bioethicists.[480]

In the *UNESCO Universal Declaration on Bioethics and Human Ri*ghts, all the above principles do exist, but other ones are added which are more relevant to global health governance. Therefore, in discussing this very issue in seems that the UNESCO deceleration provides the best available – and internationally agreed upon – framework of values and norms in the form of a set of principles.

As described above in this chapter and depicted in Table 5.1., among the principles presented by this international instrument, some of them are the most relevant ones to the realm of health research ethics and consequently to the Global Governance for Biomedical Research. These principles that shape a crucial part of the ethical framework

suggested by this dissertation. The list of these principles can be found in Table 5.2. A certain number of the most repeated (see Table 5.1) and referred ones are listed and briefly described below:

human dignity and human rights: This principle, along with non-exploitation that has been called the "fundamental ethical purpose" of the NIH ethical framework for health research,[481] shapes the fundamental/basic layer of principles of the principle-based element of the ethical framework for Global Governance for Health Research. The concept of human dignity, although not fully and exclusively defined yet, and despite the large amount of theoretical debates and controversies that exist on its bases, limits, and implications, is the conceptual basis of fundamental human rights and freedoms as asserted in the *UN Universal Declaration of Human Rights*.[482]

The concept of human dignity and its implications formulated as the fundamental human rights and freedoms are a part of common heritage of mankind and shape the limits and red lines for various interpretations of other principles. In other words, no interpretation or understanding of other principles, including the principle of Respect for Cultural Diversity and Pluralism, is ethically allowed to violate and restrict the principle of Human Dignity and Human Rights.[483] These are the reason behind placing this principle among the ones in the more basic/fundamental layer/level of principles in the suggested framework for Global Governance for Health Research (see Table 5.2).

Respect for Human Vulnerability and Personal Integrity: Vulnerability can be defined as special fragility and susceptibility to confronting with risks and harms. In a broad sense, all human beings are vulnerable. Therefore, research ethics considers this general vulnerability and safeguards different parties of research interactions from

exploitation. However, some groups of people have specific traits and characteristics that make them more vulnerable. In health research, vulnerable groups included infants and children, captive populations, unborn humans, people with mental or physical impairments and disabilities, people who live in poverty, the elderly, among other social and demographic groups. These groups deserve special attention and consideration in all the phases of research. The relevant ethical guidelines should be observed. And the RECs and IRBs should pay attention to safeguarding the rights and safety of these groups of potential research subjects.[484]

Equality, Justice, and Equity: The fundamental equity of all human beings is rooted in the concepts of human dignity and human rights. All human beings, regardless of the sources and sorts of dignity that may acquire or lose throughout their lives, are bestowed with fundamental human dignity that guaranties their fundamental human rights and freedoms. In addition to this basic equity, the concepts of justice, fairness, and equality are crucially relevant to Global Governance for Health Research. Seriously considering the shares and benefit of research participants and the host communities/countries is among the implications of this ethical principle. In all phases of research, from formulating research idea and proposal (considering the social value and avoiding to waste common resources by scientifically invalid designs) to the phase of recruiting the research participants and the phase of distributing the results of research and taking advantage of them (e.g. patents, affordability for people of host communities), the principles of justice and equality are relevant. Therefore, this principle of the UNESCO declaration is included among the principles of the suggested framework for Global Governance for Health Research.[485]

Respect for Cultural Diversity and Pluralism: This principle has numerous implications in global health research. As an instance, the issue of taking consent from local authorities has been previously discussed in this chapter. Although this crucial principle is the backbone of global collaboration and solving the problems such as ethical imperialism and colonialism, it is limited by distinct red lines, that is the fundamental human rights and freedoms. Within the area allowed by these red lines, however, respect for cultural diversity and pluralism brings about social capital and mutual respect and collaboration that is earnestly needed by the global research enterprise.[486]

Solidarity and Cooperation: In a broader perspective than social the ones of social responsibility and sharing of benefits, the concepts of solidarity and cooperation are in consistence with the virtues of empathy, compassion, and care. Human beings ultimately belong to a specie with shared origin, inhabitant, and destiny. Well-being and prosperity for some is meaningless when is accompanied with misery and poor health for others, even in far distances. The historic scandals of global ethics enterprise as described in chapters 3 and 4 have been rooted in the lack or deficit in the sense of solidarity.[487] Virtues such as solidarity and cooperation are antidotes of unethical global trends such as the ones promoted and desired by neoliberalism (see chapter 6).

Social Responsibility and Health: Access to healthcare is among the human rights that guarantee equal opportunities. Health research is not free of responsibility of providing healthcare for the society, either through the results of research activities that should be of social value, or through providing healthcare for research subjects and host communities and considering both the short and long-term benefits of the communities from hosting research projects. In this direction, the duty of research is dealing with the

real and serious health needs of the society. In addition, researchers should not be ignorant to the health needs of their research participants and host communities. Especially about the ancillary and follow-up cares that otherwise they won't afford or have access to them.[488]

Sharing of Benefits: When it comes to Global Governance for Health Research, one of the most cited and appealed ethical principles is sharing of benefits. Research has short-term and long-term benefits. Being of social value is a precondition for health research to be approved and conducted (see above). These benefits, however, are not always distributed fairly. As described through various challenges and cases in chapters 3 and 4, different kinds of exploitation violate the principle of fair benefit sharing. In Global research interactions, this concern has always been raised that the less powerful parties, i.e. research subjects and the poor host communities and countries receive an unfair share of the benefits of research. The challenge of helicopter research and the case of HIV research in Africa are among the examples of the situations that have raised this concern. This principle asserts that the short and long-term benefits of research should be shared in a fair manner.[489] This principle covers multi-central and international research in developing countries and the share of the host communities of the benefits of research (e.g. affordable access to the resulted medications and vaccines) and even the issue of big data and data sharing in the sense that the benefit obtained from imposing risk to research subjects should be shared in the best possible wat through data sharing and fair access to biobanks and big data.[490] The debates on bio-piracy and exploitation of local natural and knowledge resources of developing countries by pharmaceutical companies (see chapter 4) is another example of ethical issues that necessitates the inclusion of the principle of

sharing of benefits in any suggested ethical framework for Global Governance for Health Research.[491]

Protecting Future Generations: Protecting future generations is mostly relevant to the genetic research and research on human gamete, embryo, and fetus (see chapter 4). Although included among the vulnerable groups and covered by the principle of respect for vulnerability (see above) the importance of protecting human gametes and embryos from unethical research interventions (e.g. mass production of human embryos only for research purposes) necessitates another principle to be included in the ethical framework to establish a globally accepted, adopted, and enforced protection of the future generations. Other issues such as inducing and producing permanent genomic changes in germlines and research on human enhancement are among other ethical concerns covered by this principle both in domestic and global research enterprise.[492]

Protection of the Environment: This principle is titled as "Protection of the environment, the Biosphere, and Biodiversity", however, is shortened to "Protection of the Environment" because the other two components were in in the same direct and crucial relation to the ethical issues of Global Governance for Health Research.

All the above principles, including cultural diversity should be accepted and respected within the limits of human rights and fundamental freedoms. This important point is explicitly made in the declaration to prevent any kind of abuse under the name of cultural diversity.[493]

Principles and Ethical Framework: In this part of this chapter, the *UNESCO Universal Declaration on Bioethics and Human Rights* is used to shape the principle-based element of the ethical framework of the Global Governance for Health Research.

The UNESCO framework incorporates other major relevant ethical frameworks such as the ones included in the Universal Declaration of Human Rights and the four-principle framework of Beauchamp and Childress.

These principles and principlistic approach form one of the three major elements of the ethical framework suggested in this chapter. This element is divided into two layers: the more basic/fundamental layer that is consisted of more fundamental principles, including human dignity, human rights, and non-exploitation. The second layer is consisted of other principles that are of crucial importance in the ethical framework for Global Governance for Health research (see Table 5.2).

iii. Particularistic Approach: Pros and Cons

Particularistic approaches that sometimes are called "situation ethics" claim that ethical principles are not useful in determining moral goodness or badness in the real world. Instead, one should rely on the specific context and specifics of each act/situation for moral judgment/decision-making about it This is why this approach to ethics has also been named "situation ethics".[494]

In the fields of global/international health research and Global Governance for Health Research, each situation or problem has its own specifics and characteristics, including the context in which that situation or problem takes place. Situation ethics claims that the principles outlined in the previous part of this proposal are not able to lead the ethicists, researchers, policy makers, or other decision makers toward the ethical solutions/answers. Instead, in each case, those specifics and characteristics compromise the ethically relevant features that should be examined, analyses, and balanced on a case-by-case basis to find the most ethically acceptable/suggestible solutions, answers, or

approached. Situation ethics does not reject the ethical principles as morally acceptable and enlightening thoughts and accepts their role in teaching ethics for students. However, claims that in approaching the real, complex, multifaceted, and complicated ethical cases, these principles are not helpful as described above.[495]

As an example pertaining to the realm of Global Governance for Health Research, the challenge of bio-piracy as explained in chapter 3 is one of the major challenges related to health research. The principles of sharing of benefits led the global community to act. The result was the Nagoya Convention (see above). However, the production of Influenza Vaccine has been adversely affected and delayed because of the obligations made by this principle and the resulted convention (see chapters 3 and 4). Therefore, a generally good and acceptable principle may cause irregularities and adverse implications in its practical application.

Another example is the problem of risk-benefit analysis. In non-therapeutic health research, it has been argued that the risk imposed to the participants (who obviously won't benefit from their participation) should be limited to the standard of "zero risk" that means the risk of normal activities of life. However, considering this double-track assessment (i.e. dividing health research projects into two major groups: therapeutic and non-therapeutic ones and conducting their risk-benefit analyses in two separated tracks) brings about some serious practical problems. For example, the phases I and II of many of clinical trials would be banned if the standard of zero risk was followed. Therefore, instead of adopting the double-track process, the risk-benefit analysis should be done for both therapeutic and non-therapeutic research projects because in some, of course well-

considered and analyzed – cases, the great social benefits can justify some levels of risk for research subjects even in non-therapeutic research.

RECs and IRBs for Situation-Based Practical Approach: The above argument (asserted by the proponents of situation ethics) and examples, show that having a framework of principles is not enough but is just the beginning of the sophisticated process of ethical oversight and governance for research, either domestic or global. The ethical analysis, considering all the ethically relevant items and characteristics and details of each case, should be done by a group of well-trained and ethically and culturally-informed people. This lesson of situation ethics has been the basis of establishment of Research Ethics Committees (RECs) and Institutional Review Boards (IRBs). The RECs and IRBs consider the principles provided by the framework, however, they also examine and analyze each case with specific attention to all its ethically relevant details.

For ethical review and oversight of international research, the RECs and IRBs of the host countries should be involved, because they are well-informed on the cultural specifics of the host community and can safeguard the benefits and interests of research subjects and their communities and countries. Therefore, as described above, one of the ethical imperatives for Global Governance for Health Research is training people in host communities to take part in research monitoring and oversight through RECs and IRBs. In addition, sharing the experiences and ethical wisdom of all people who take part in research monitoring and oversight (i.e. governance) all over the world through shaping and strengthening networks among RECs and IRBs is another ethical imperative for Global Governance for Health Research.

Therefore, in the ethical framework for Global Governance for Health Research provided in this chapter, one of the three major elements is the situation ethics and its practical implication that is assessment and analysis of each research project and research governance system by a network of RECs and IRBs (see Table 5.2).

iv. Virtues as the Subjective Backgrounds

Principles are crucial in shaping a framework and solid knowledge on ethics. However, genuine abidance to the principles and normative frameworks is dependent on personal (internal or subjective) virtues of professionals. In the realm of research ethics and Global Governance for Health, only virtuous researchers genuinely follow the ethical principles and normative frameworks. Otherwise, the abundance of principles, laws, and regulations can never actually minimize the unethical research behaviors, abusive power relations, and exploitation. This part of this chapter belongs to depicting a set of virtues that (1) are grounded in both classical/traditional masculine virtues and feminist virtues, and (2) are crucial in forming a solid subjective/personal background for health researchers. These virtues are empathy, compassion, and care that shape the internal/subjective solid backgrounds of the ethical framework for Global Governance for Health Research. It has been argued that these virtues are the "desired moral attitudes of physicians".[496]

Compassion has been called "the emotional and virtuous core of the desired professional attitude" in medicine.[497] The Ethics Committee of *the American Society of Academic Emergency Medicine* (SAEM) considers compassion "a part of professional competence" which is "perhaps as important as technical competence."[498] These emphasizes on the central role of compassion in the shaping of the professional character

of healthcare providers shows the central importance of this concept in medicine and medical ethics as well as in research ethics at its domestic and global levels.

Compassion is internal/subjective reaction to the suffering of other sentient being(s) and is conjoined with recognition of the suffering, detesting and disapproving that suffering, feeling personal responsibility and engagement with the experience, and tendency to relief the suffering with good intentions toward the sufferer(s).[499] Therefore, one can argue that compassion is always a good trait and there is not such a thing as a "bad compassion" (see below).

From the ancient times, the utmost obligation of physicians has been to alleviate or eliminate human suffering.[500] Daniel Callahan calls this very obligation "a foundation stone of the practice of medicine."[501] Patients' suffering is not limited to pain or other symptoms of their diseases; it also encompasses their mental and social discomfort. This suffering originates from all different sources including their disease, the treatment, their realistic or unrealistic fears and anxieties, their financial and social distresses and all other sorts of discomfort they experience through the courses of their disease, treatment, and recovery.[502]

The broadness and existential importance of the concept of suffering and its importance in the life of a patient, shows how crucial the virtue of compassion is in the practice of medicine and in the pursuit of its goals. Suffering elicits the "impulse of compassion" in almost every normal human being,[503] but it should develop into a virtue in physicians to make them more similar to the ideal ones.

This part of this chapter analyzes the notion of compassion as a common virtue between the traditional/masculine and care/feminine sets of virtues and shows that

compassion as a reunion and merging point of the both sets of human virtues has a crucial role in the pursuing the goals of medicine and healthcare and medical research. This role can be actualized by development and promotion of compassion as an important part of the character of an ideal physician/healthcare provider/health researcher. In addition, this part argues that the notions of empathy, compassion, and care can shed light on some important debates in the contemporary debates on healthcare provider-patient and health researcher-research subject relationships.

Empathy, Compassion, and Care as Virtues: According to Alasdair MacIntyre, a virtue is a developed trait of a human's character that tends to qualify him/here to realize the goals of a certain practice (in our case, medicine and health care) with excellence.[504] Traditionally, according to the Aristotelian understanding of the virtues and virtue ethics, the human virtues have been considered related to masculinity.[505] In recent decades, however, the founders and advocates of the ethics of care described and introduced a set of virtues with feminine nature (see below). This part of this chapter portrays empathy, compassion, and care as the common virtues between these two sets of universal virtues. Both the traditional and feminist theories of virtue ethics emphasize on the importance of these virtues when it comes to healthcare ethics, healthcare provider-patient relationship, and health research ethics. At the end of this part, one can conclude that empathy, compassion, and care as a set of virtues are the merging points of the masculine and feminine virtues in the realm of medicine and health research and are of crucial importance in shaping the character of a virtuous physician/researcher.

Masculine Virtues: *Virtue Ethics*: Andre Comte-Sponville argues that contrary to sympathy, compassion is a virtue.[506] Other scholars have also noticed the difference

between concepts like sympathy, empathy, and pity with the concept of compassion.[507] This differentiation as described briefly below shows how one can consider compassion as a virtue, not a feeling that can be morally good or bad.

Comte-Sponville differentiates sympathy and compassion in this way: Sympathy, which means "fellow feeling", is not a virtue by itself. Its goodness or badness depends on the "feeling" which is being shared between fellows. Having sympathy to malice intents is not good, therefore, sympathy, by itself, can never be a virtue.[508] Compassion, however, is sympathy in suffering and every form of suffering, even the ones originated from wrong causes such as wrongful jealousy or rivalry, deserves sympathy.[509] In addition, compassion encompasses other specifics such as benevolence and inclination to relief the suffering.[510]

Comte-Sponville brings Christ's compassion for his executioners as an example of the goodness of compassion even for evil people who suffer because of their evil and malice acts, intents, and characters.[511] Andre Comte-Sponville argues that compassion, as the same time, is a feeling and a virtue because we can feel it as a feeling and we can want and gain the capacity of being compassionate.[512] In this sense, compassion is similar to love. In the Buddhism, compassion is regarded a great virtue. In Christianity, charity has the same status. However, charity is not identical with compassion. As a matter of fact, the feeling and capacity of empathy, compassion, and care can lead to and resemble charity.[513]

As a set of virtue in its traditional/masculine sense, empathy, compassion, and care are in close relation with biomedical and health research ethics. As mentioned above, alleviation of suffering is a core obligation/goal in medicine and healthcare. The virtue,

which targets suffering, is compassion. Therefore, the pursuit and realizing this main goal of medicine depends on the establishment of this very virtue in healthcare providers/physicians.

Feminine Virtues: *Ethics of Care*: The ethics of care is among the most recently emerged moral theories and attracted a large deal of attention in the recent decades.[514] Its new and innovative approach and viewpoint in dealing with ethical issues has shed light to some formerly dark and overlooked parts of human beings' moral obligations and duties. As a moral theory, ethics of care has its implications and influences on biomedical ethics. Healthcare is one of the most prominent manifestations of care and caring relation in the world of humanity.[515] Therefore, it is obvious that ethics of care has much to say when it comes to health, healthcare, health research and the goals of medicine.

The ethics of care as a distinct moral theory was born inside the feminist ethics. The founders of this theory were feminist philosophers who found the caring nature of femininity of enormous ethical value.[516] As described above, traditionally, in moral theories and even in moral psychology it was considered for granted that ethical virtues are stronger in males.[517] It was because ethical norms and virtues like justice and impartiality were consistent with the role of males as hunters and breadwinners. The role of females, as cares had always been underestimated, morally speaking. According to the founders of the ethics of care, however, this caring nature of female role is of utmost moral superiority and importance and can be considered as a basis for a self-sufficient moral theory. Although some of them believe that the ethics of care is not a sort of virtue ethics, but still it is obvious that this moral theory is founded based on considering care and compassion as unambiguous virtues.

One of the main themes of the ethics of care is considering partiality as a virtue. In the traditional/masculine virtue ethics, justice and impartiality have always been indubitable virtues. However, in the ethics of care, special caring relations come along with obligation of special care and partiality. This is very true in the case of physician-patient and health research-research subject relationships. Medical ethics and research ethics ask physicians and health researchers to always give priority to the health and health needs of their own patients. This priority comes from a relationship: the physician/doctor/healthcare provider-patient relationship. It seems that the typical model of the ethics of care shows itself in this case. Physician should be partial and give priority of his/her patients because of the specific relationship established between them. This partiality shows itself in the form of care and compassion. This care and compassion is aimed to realize the goals of medicine as described below.

Compassion and the Goals of Healthcare: Daniele Callahan specifies the goals of medicine as follow: the prevention of disease and injury and the promotion and safeguarding of health, the relief of all kinds of suffering resulted by maladies, the treatment of disease and providing care for non-curable ones, and the evasion of a premature death and the pursuit of a serene death.[518] It seems that the virtues of empathy, compassion, and care play crucial roles on realizing all these four goals of medicine/healthcare.

Empathy, Compassion, and Care in Researcher-Research Subject Relationship: The root of the word "compassion" is in Latin language where it means "suffering with", equal to the Greek root of the word "sympathy".[519] It is interesting that compassion shares its Latin root with the word "patient" meaning sufferer.[520] This common root

symbolically shows the relation between compassion and caring for parents and relieving their suffering as embodies in the healthcare and medicine. Medicine relies on science but is not merely a sort of science. It also is an art: art of establishing a healing and trustful relationship with the patients. This art depends on certain virtues in physicians, among which is the very crucial one of compassion.

Recent developments in medical technologies along with reliance on science have transformed doctor-patient relationship in the post WWII era.[521] However, these changes and evolutions have not led to elimination of humanistic aspects of doctor-patient relationship and transforming it to a mechanical/machine like relationship. Therefore, still the therapeutic relation depends largely on development of trust and rapport between physician and patient. This trust and rapport take place when patient realize that his/her doctor recognizes his/her suffering and feels for his/him and is intended to alleviate or eliminate his/her suffering. And this is the very definition of compassion as described above in this paper. Therefore, it seems that despite all the evolutions and transformations in the modern medicine, the cornerstone of doctor-patient relationship is still personal virtues and among them, the very important one of compassion.

Taking a look at the history of debates in the contemporary biomedical research ethics clearly shows that no single moral theory has a monopoly on the realm of truth in biomedical research ethics. Instead, in each situation and in analyzing each specific issue of searching for each specific ethical solution, one or more of ethical theories show to be helpful and reliable. In this part, the viewpoint of the virtue ethics has been used and analyzed to shed light on some aspects of biomedical research ethics and to show that empathy, compassion, and care as a set of virtues play a vital role in the pursuit of the

goals of healthcare and medicine in the realm of research, at both the domestic and global levels.

Healthcare, in practice and research activities, involves a great deal of interpersonal involvements and interactions. Therefore, the character of physician/healthcare provider is of crucial importance. This importance paves the way for virtue ethics to play a considerable role in analyzing and problem solving in healthcare provider-patient issues. In this context, compassion, as a virtue, is of extreme importance in pursuing the goals of medicine/healthcare as described above.

Empathy, compassion, and care are common virtues between the traditional/masculine and feminist/feminine theories of virtue ethics and according to the both of them are crucial virtues in biomedical ethics and medical professionalism. The traditional/masculine sense of the virtue of compassion can strengthen the relationship between physician and patient (in this case, researcher and subject) with trust and mutual understanding. In addition, the partiality resulted from this relationship shows itself in the form of giving priority to the one's own patients and is compatible with the feminine account of virtues such as compassion and care. The main goal of medicine is to alleviate or eliminate suffering. Therefore, compassion, along with empathy and care, are the most crucial virtues in pursuing the goals of healthcare and medicine both in practice of medicine and in health research.

Despite the recent technological and scientific transformations in medicine, still the interpersonal relationship between healthcare providers and patients (and researchers and research subjects) play a vital role in pursuing the goals of healthcare and health research. For establishing effective and trustful physician-patient and researcher-subject

relationships, the virtues of empathy, compassion, and care play central roles. These central roles show themselves in ethical issues such as ancillary care and following ethical principles such as sharing of benefits (and in general, the most fundamental ethical principle of Global Governance for Health Research, that is non-exploitation). Making the best decisions in the situations that raise such concerts, depends largely on the trust and rapport which are achievable by virtue of empathy, compassion, and care in the researchers and recognizing this compassion by the patient/subjects and the host communities.

In sum, empathy, compassion, and care can be called the merging and reunion points of the feminine and masculine virtues in pursuing the goals of healthcare and medicine both in practice and in research. Therefore, they shape the virtuous grounds of the ethical framework for Global Governance for Health Research.

v. Global Norms and Cultural Diversity

This part deals with the debate about the potential conflicts between universal norms and cultural/local values. Respect for cultural diversity and the priority of fundamental human rights and freedoms over local ethical variations are discussed above. However, the importance of this subject in global bioethics, especially its relevance to the ethics of health research, demand and necessitate a specific attention to this subject at this part of this dissertation. One of the most famous cases on this kind of conflicts in international health research is the debate over who has to give an informed consent in specific communities, such as tribes in some developing countries, where the traditional authorities overrule the personal right of individuals to give voluntary informed consent.[522]

Since asking for informed consent is one of the fundamental rights of every competent human subject, appealing to cultural diversity is not enough to compromise this basic right and ask for collective consent from the local authorities. Instead, a possible solution would be insisting on obtaining individual informed voluntary consent in addition to the permission of those authorities.

The above case is just an example of cases in which the local cultural norms and traditions come into conflict with universal ethical standards and how the researchers and ethicists can manage to find creative ways to keep adherent to global ethical standards and respectful to cultural diversity and local traditions at the same time.

In sum, this part of this chapter argues that the principles adopted in the *Universal Declaration of Human Rights* and *UNESCO Universal Declaration of Bioethics and Human Rights* are parts of common heritage of mankind and do not belong and are not limited to a specific culture or geographic area. In addition, the principle of respect for cultural diversity, as discussed above, cannot be interpreted in a way that comes with conflict with human dignity and fundamental rights and freedoms. Therefore, the principles that consist the principle-based element of the framework suggested in this chapter are of universal and cross-cultural nature and although they include the important principle of respect for cultural diversity, they are not limited to any culture or nation or geographic region. The limitations of this universal and cosmopolitan approach will be discussed further in chapter 6.

vi. The Global Framework for a Global Network

This part of the dissertation, suggests an ethical framework for global governance for research. This framework is developed to encompasses all the strengths of both principle-

based and particularistic moral approaches. In the light of the above discussions about the existing problems and their ethical nature (chapter 3), and the discussed cases (chapter 4), and the discussions on the theoretical backgrounds provided above in this chapter, this part of this chapter provides a framework that looks to be both comprehensive and systematic.

In addition, the existence of different and sometimes conflicting schools or morality that in some cases are embodied in the various ways of life, is another important point in developing an ethical framework at the global level. The final framework has to show respect for cultural diversity and adherence to global ethical mandates (fundamental human rights and freedoms) at the same time. For this purpose, considering the global norms as the common heritage of humanity (rather than the impositions of ethical colonialism) can be illuminating and helpful.[523]

As described above, the power imbalances among the different parties involved in the global research enterprise raise serious concerns about safeguarding the rights and benefits of the vulnerable people or communities as an ethical mandate. Each ethical framework has to be attentive to this important imbalance in power and its resulted ethical concerns and problems and this truth that one of the most crucial goals of such an ethical framework is dealing with this power imbalance in a way to maximize the benefit and minimize the harm for the most vulnerable parties. In sum, this part of this chapter provides a systematic, comprehensive, and appropriate ethical framework for Global Governance for Health Research.

The Criteria of Appropriateness: The aim of this chapter is providing the "most appropriate" ethical framework for global governance for health research. For this

purpose, this study needs to delineate a set of criteria for appropriateness. The following points are among the ones that should be taken into consideration as the "criteria of appropriateness" for the proposed framework:

1. The suggested framework should be based on and justified by the universal moral values and principles that can be considered part of the common intellectual heritage of mankind. In other words, this framework should observe and include fundamental human rights and freedoms and other cross-cultural norms and values as formulated in international and universal declarations. At the same time, this framework should be cultural sensitive. This means that this framework should make room for respect for pluralism and cultural diversity. One of the main challenges in formulation this network is finding the most appropriate framework for fulfilling both functions (observe universal norms and respect for cultural diversity) without any conflicts or contradictions.

2. This framework is to promote the substitution of governance/globalization from above with the governance from below.[524] The sustainability of global governance and the international research enterprise depends on the extent of its success in this substitution as an ethical mandate or priority.

3. Although no specific government is in charge of global governance, this field is not free of leadership. The ethical framework has to take this important component into consideration. For this purpose, this ethical framework has to promote the network model of leadership and formulate its ethical mandates such as transparency, accountability, representation, and participation.[525]

4. The ethical framework has to cover all the broad range of role-players in the global governance for research. Only a broad and all-encompassing model can solve the complex and complicated problems of global health research. Being inclusive is one of the most important features of an effective model.

5. For refraining unilateral interventions, and providing the best possible cost-utility justification for global heath interventions – including the ones related to heath research – this is suggestible to strengthen the role of WHO as the leader of global heath governance.

6. Human health is inseparable from the health of animals and the ecosystem. The recent experiences of zoonotic pandemics clearly showed that global heath governance for people is in close relation with and dependence on the global health governance for animals, and the nature at all. Global warming and its disastrous impacts on global health is another revealing example. Therefore, having an integrated perspective toward the health of human beings, animals, and the nature as a whole, is crucial for an effective governance for every aspect of health, including health research, in the future.

The framework provided below for Global Governance for Health Research has three main components: (1) the normative cornerstones that appeal to the central concept of human rights as a part of common intellectual heritage of mankind. (2) The systematic approach that appeals to the NIH Framework to implement the principles of universal declarations to the global research enterprise. (3) The situation-based practical approach that incorporates situation ethics into the framework by describing the crucial role of the existing networks especially Research Ethics Committees

consisted of well-trained, culturally informed, and ethically aware members from the participating and hosting communities.

The Normative Cornerstones: Inspired by the Nuremburg Code, the *Universal Declaration of Human Rights* was adopted by the United Nations in 1948. This declaration later shaper the foundation of various ethical and legal declarations, guidelines, conventions, and treaties. Embodied in almost all consensual international and global agreements in the past seven decades, the *Universal Declaration of Human Rights* is a noteworthy and radiant part of the common intellectual heritage of mankind. According to Henk ten Have, this declaration owes this status to its universality and emancipatory force.[526]

Because of the fundamental and globally consensual nature of the articles of *Universal Declaration of Human Rights* the ethical framework for Global Governance for Health Research should adopt them as its normative and moral cornerstone. This declaration has been embodied in the field of global ethics by the *UNESCO Universal Declaration on Bioethics and Human Rights.* he UNESCO declaration provides an unbiased and globally consensual interpretation and expansion of the *Universal Declaration of Human Rights* in the field of global bioethics. Therefore, is applicable and relevant in shaping an ethical framework for Global Governance for Health Research. Therefore, the second step of the normative cornerstone of the ethical framework for Global Governance for Health Research is the *UNESCO Universal Declaration on Bioethics and Human Rights.*

The ethical principle of Non-Exploitation and the ethical virtue of Compassion are also the cornerstones of the ethical framework for Global Governance for Health

Research. The most fundamental ethical concern in health research activities is exploitation. In addition, although relying on the personal virtues of researchers has been supplemented and complemented with other reassuring provisions such as independent review, it does not mean that there is no place for virtues in ethical frameworks. On the contrary, still the most important fundament of ethical behavior is personal commitment of people, especially the ones who are at the more powerful sides of relations and transactions. Therefore, compassion as a personal virtue relevant to the golds of healthcare and health research is one of the cornerstones of Global Governance for Health Research.

Table 5.1. The principles of the NIH framework with their corresponding principles in the UNESCO declaration of Bioethics and Human Rights and their implications on the Ethical Framework for Global Governance for Health Research (GGHR).

The NIH Framework	The UNESCO Principles	Ethical Framework for GGHR
Collaborative Partnership	• Human Dignity and Human Rights • Benefit and Harm • Respect for Human Vulnerability and Personal Integrity • Equality, Justice, and Equity • Non-Discrimination and Non-Stigmatization • Respect for Cultural Diversity and Pluralism • Solidarity and Cooperation • Social Responsibility and Health • Sharing of Benefits • Protecting Future Generations	• Respect for the Role and Participation of Host Communities; Only Limited by Human Dignity and Human Rights • Prevents unethical behaviors such as helicopter research and double standards • Assures the fair benefits of hosting communities
Social Value	• Benefit and Harm • Equality, Justice, and Equity	• Consistency between research questions/aims and the health needs of host societies

	• Respect for Cultural Diversity and Pluralism • Solidarity and Cooperation • Social Responsibility and Heath • Sharing of Benefits • Protecting Future Generations	• Data sharing • Considering the burden of research on health infrastructures of host communities/countries
Scientific Validity	• Benefit and Harm • Equality, Justice, and Equity • Social Responsibility and Health	• The importance of inclusion of scientific validity as a principle in the soft law • Avoiding unwanted promoting pseudoscience and superstitions through invalid and poorly designed research
Fair Participant Selection	• Human Dignity and Human Rights • Benefit and Harm • Respect for Human Vulnerability and Personal Integrity • Equality, Justice, and Equity • Non-Discrimination and Non-Stigmatization • Solidarity and Cooperation • Social Responsibility and Health	• Preventing double standards in international and multi-central research projects • Considering the potential of exploitation of vulnerable populations
Favorable Risk-Benefit Ration	• Risk and Benefit • Sharing of Benefits • Social Responsibility and Health • Protecting the Environment	• Considering the importance of fair and systematic risk-benefit ratios in developing countries and populations that lack the expertise or democratically selected representatives to do so. • The importance of training local experts for risk-benefit analysis • The issue of ethical imperialism and colonialism in research ethics training and the importance of considering local culture and value systems

Independent Review	• Benefit and Harms • Respect for Human Vulnerability and Personal Integrity • Equality, Justice, and Equity • Respect for Cultural Diversity and Pluralism • Sharing of Benefits • Protecting Future Generations	• The importance of inclusion of independent research review in the laws and regulations • The importance of providing research oversight training for LMICs • The issues of ethical imperialism and respect for cultural diversity
Informed Consent	• Human Dignity and Human Rights • Consent • Autonomy and Individual Responsibility • Persons without the Capacity to Consent • Respect for Human Vulnerability and Personal Integrity • Non-Discrimination and Non-Stigmatization • Respect for Cultural Diversity and Pluralism	• Informed and voluntary consent as a right of each competent research participant • Consistency of informed consent with the cultural and political contexts • The need to additional informed consent from the local authorities does not override the obligation of taking consent from each individual research participant

Respect for Participants	• Human Dignity and Human Rights • Benefit and Harm • Autonomy and Individual Responsibility • Consent • Persons without Capacity to Consent • Respect for Human Vulnerability and Personal Integrity • Privacy and Confidentiality • Non-Discrimination and Non-Stigmatization • Respect for Cultural Diversity and Pluralism • Solidarity and Cooperation • Social Responsibility and Health • Sharing of Benefits.	

Conclusions

The ethical framework suggested by this chapter is an interactive combination of three main elements (see Table 5.2):

The first element that shapes the subjective and personal background and support of this framework is adopted from virtue ethics. The merging point of two accounts of virtue ethics: the classic, Aristotelian virtue ethics relying on a set of Masculine ethics and the modern feminist account of virtue ethics adopted by the Ethics of Care. This chapter holds that this merging point in the realm of medicine and health research is embodied in empathy, compassion and care. These virtues (or ethical attitudes/Attributes) are the basis and background of abidance to this – and any other- ethical framework by physicians, healthcare providers, and health researchers.

The second element is consisted of a certain group of principles originated in the concepts of human dignity, human rights, and non-exploitation (as the deeper and fundamental level of principles). These principles are formulated (in the form of an expanded and detailed framework) and adopted by UNESCO through the *UNESCO Declaration of Bioethics and Human Rights*. These principles, because of their consensual, universal, and cultural-sensitive nature can be considered a part of common heritage of mankind. For ensuring their best compatibility with the realm of health research, they are combined with a set of principles provided through the NIH framework in a systematic manner for research, especially for global research.

The third element of this framework is inspired and informed by the schools of situation ethics. The virtues and principles should be applied and implemented into specific situations with innumerable details and characteristics that cannot be summarized or categorized under specific virtues or principles. A group of ethically trained and culturally informed and aware persons are needed to deliberate on each case and appeal and infer to various virtues and principles to formulate the best and most ethical and culturally acceptable way to apply and implement those abstract notions to practical situations. This is the share of situation ethics. This mission is being done by RECs and IRBs all over the world. Without competent and independent IRBs and RECs, no ethical framework can be useful and applicable to solve the challenges, issues, and cases ahead of Global Governance for Health Research.

This framework is not free of limitations. In addition, the current trends in politics show that numerous challenges threaten the integrity of Global Governance for Health

Research. A brief discussion of these challenges is provided in the next chapter of this dissertation.

Table 5.2. A scheme of the elements of the ethical framework for Global Governance for Health Research and their levels and components

Elements	**Component**	
Situation Ethics	The global network of Research Ethics Committees (RECs) and Institutional Review Boards (IRBs)	
Principles	Systematic Approach	Collaborative Partnership, Social Value, Scientific Validity, Fair Participant Selection, Favorable Risk-/Benefit Ration, Independent Review, Informed Consent, Respect for Participants
	Expanded Level	Benefit and Harm; Autonomy and Individual Responsibility; Consent and Persons Without Capacity of Consent; Respect for Human Vulnerability and Personal Integrity; Privacy and Confidentiality; Equality, Equity, and Justice; Non-Discrimination and Non-Stigmatization; Respect for Cultural Diversity and Pluralism; Solidarity and Cooperation; Social Responsibility and Health; Sharing of Benefits; Protecting Future Generations; Protection of the Environment
	Basic Level	Human Dignity, Human Rights, Non-Exploitation
Virtues	Empathy, Compassion, Care	

Chapter Six: Futurology and Conclusions

In this final chapter, a conclusive picture/analysis of the suggested ethical framework for Global Governance for Health Research is provided and its trends and possible developments in the future along with the existing and potential threats and promises are examined and predicted. In addition, some practical and research recommendations are suggested for the future.

Global Governance for Health Research and its ethical norms, principles, and challenges have not been examined sufficiently in the current scholarly literature. Although both the research ethics and the Global Health Governance have been subjects of amazing scholarly works, the interface of these two fields, that is the ethics and ethical framework of Global Governance for Health Research has not been explored by an enough number of scholarly works in the past decades. This study has been an attempt to fill this gap in the current literature.

This part of this chapter, after providing a summary of the content of the previous chapters and some conclusive remarks, tries to depict the predictable future trends of Global Governance for Health Research, provide a number of practical recommendations, and finally, suggest further studies that can be the next scholarly steps in exploring and analyzing this relatively new field of study and research.

i. A Brief Summary and Conclusive Remarks

As described in chapters 1 and 2, Global Governance is composed of sophisticated and crowded networks of role players that govern various affairs of human social life at the global scale. Global Health Governance is a branch of Global Governance that governs the health-related affairs. Although numerous scholarly works have been

published concerning Global Health Governance, an important branch of this gigantic complex of networks has not been analyzed sufficiently yet. This insufficiently examined and analyzed part is global health research enterprise. Global health research, although it is a part of global health affairs, has its own characteristics and situations that bring about its specific issues and challenges at the global scale. Therefore, Global Governance for Health Research, although is generally a part of Global Health Governance, has major differences (along with similarities and overlaps) with it is different aspect, including the major role-players, and main issues and challenges.

The major role-players of Global Health Governance are the WHO, the World Bank, and UNESCO, along with numerous other ones such as UNAIDS and the private and civil society role-players. The WHO and the World Bank, although important in the realm of global research, have not been the most influential role-payers in Global Governance for Health Research. Since the Global Governance for Health Research has mainly been materialized through internationally recognized frameworks and guidelines, the organizations that created, adopted, and promulgated these instruments have been the most influential role-players in the realm of Global Governance for Health Research, among them being the UNESCO, WMA, and CIOMS.

Global Governance for Health Research has its own challenges that are discussed in chapter 3 and studied through cases in chapter 4 of this dissertation. Challenges such as exploitation and helicopter research, double standards, bilateralism, and the impact of bio-politics. The framework of gaps introduced by Weiss is also relevant to this field and the knowledge, normative, policy, institutional, and compliance gaps show themselves in Global Governance for Health Research. The analysis of the challenges in chapter 3

along with detailed case studies in chapter 4 revealed the ethical nature of the existing challenges and shortcomings of this field and the need to a comprehensive and systematic ethical framework. This framework is developed and presented in chapter 5.

The suggested framework for Global Governance for Health Research is composed of three elements. A virtue-based element/layer that encompasses the most basic moral attributes of physicians/health researchers and underlie their ethical behavior and their compliance to the principles. A two-layered principle-based element that encompasses a layer of fundamental principles, i.e. Human Dignity, Human Rights, and Non-Exploitation and a layer of more specific or practical principles that mostly adopted from the UNESCO Declaration of Bioethics and Human Rights to have a comprehensive and universal approach and from the NIH framework to have a research-oriented systematic approach. And the last element of the suggested framework is inspired by particularism or situation ethics that demands establishing, empowering, and strengthening networks of oversight and review committees/boards to guarantee the continual and comprehensive case-by-case ethical review and oversight and monitoring all over the gigantic networks involved in global health research enterprise.

Despite the challenges partly explained below in this chapter, it seems that the suggested framework can be helpful in shedding ethical light on the challenges of Global Governance for Health Research and in filling its various gaps. This study is a small step in filling the knowledge gap. The suggested framework can fill part of the normative gap, this framework can be an ethical basis for policies that may fill the policy gap, the situation-ethics element of the framework is concerning the necessity and the ethical way for filling the institutional gap and finally, removing or alleviating the moral barriers is

one of the ways for filling the compliance gap. By the way, this should be reminded that filling these gaps is not a one-time mission, instead, the process of developing and filling these gaps is continuous and will continue as long as the Global Governance for Health research is a reality on the global scene.

ii. The future of Global Governance and International Research

This part of this chapter consists of two segments. First, the current trends in the realm of politics and economics is discussed. Some threats for implementation and an ethical framework for Global Governance for Health Research are discussed. In developed countries, the trends of neoliberalism and the recent rise of the wave of isolationism and protectionism and in developing countries, the local cultures and authorities that resist against the universality of values such as human rights are discussed as the existing threats against ethical frameworks for global governance, including Global Governance for Health Research.

In the next segment of this part, it is explained and predicted that with implementing the suggested ethical frameworks, what changes would occur in the future of international research and its global governance. Among the items that are discussed in this part are strengthening the role of WHO as the leading organization in global heath governance and adopting an integrated approach to health that include humans, animals, and nature (ecosystems, climate, etc.) and take into consideration the social and political determinants of health, e.g. in setting research priorities.

The challenge of neoliberalism, Populistic Isolationism, and Protectionism in Developed Countries: Donald J. Trump, although is not a classical neoliberalist, is a sort of embodiment of the figure of ground-breaking and rebellious millionaire that was

praised and admired by the prophetic figure of neoliberalism, Friedrich Hayek (1899-1992).[527] His winning the 2016 US presidential election, along with the vote to Brexit (UK's leaving the European Union) in the UK in the same year, and the rise of popularity of populist politicians in the other powerful European countries that have always acted as the engines of globalization, are warning signs for ethical governance of global affairs in all areas, including the global research enterprise.

Neoliberalism: Neoliberalism is a political and economic theory that centers around promoting – or creating – free markets in all areas of human affairs, from ordinary goods and services to the ones that ordinarily are not covered by free market such as healthcare, basic research, and education. This theory regards individual-centered competition as the most ethically (fairly) reliable force for governing human social affairs at both domestic and global levels.[528] Neoliberal attitudes and practices have caused most of challenges for Global Governance for Health Research discussed in chapters 3 and 4 of this dissertation. Focusing on maximizing the material benefit and minimizing the costs even at the expense of harming the community and humanity (the attitude that Donald Trump claimed that makes him 'smart' in one of the US presidential election debates in 2016[529]) has been the direct cause of various kinds of exploitation occurred in the arena of global research, from the exploitation and helicopter research in the cases of HIV/AIDS research in Africa, to having double standards, bilateralism, undue and adverse influence of bio-politics, the problem of bio-piracy, and countless other ethical challenges and cases and scandals.

All the elements of the suggested ethical framework for Global Governance for Health Research imply that the health sector and health research cannot be left in the

hidden hands of free market. The personal virtues that shape the basic layer of this ethical framework implies that the health professionals and health researchers need to put the interests of their patients/subjects/communities ahead of their own interests. Compassion implies sensitivity toward humans' suffering. This sensitivity, when becomes actualized in practice, may limit unleashed greed to maximize the material benefits. Furthermore, the principal-based element of framework encompasses principles such as social responsibility, solidarity, and collaborative partnership that are also in contrast with seeking maximized benefits as might be exemplified by the practice of some pharmaceutical companies. Finally, the situation ethics-based layer/element of the framework insets in empowering local communities in establishing review and oversight bodies that protect the interests of local research participants and their communities. This element also limits profit-seeking in favor of humanity and morality. This is not what can be considered or called "smart" by President Trump or any other greedy entrepreneur in the world.

In his inauguration address, President Trump repeated his slogan: "America First!"[530] This slogan is the gist of the isolationist and protectionist and xenophobic spirit the flies over the Western world and has already embodied in Trump's presidency, the Brexit, and popularity of the National Front in France and Freedom Party in the Netherlands. Isolationism through closed borders and reduced moral and human rights related interventions in the world along with protectionism through putting higher taxes on imported goods and tougher immigration regulations will act as the reverse engines for globalization. Their adverse effect in the realm of Global Governance for Health Research will be (1) less contribution of the Western powers in establishing and

strengthening the ethical frameworks through contribution in setting standards and founding and empowering oversight bodies in developing countries; (2) dominance of neoliberal approach to market and considering health and health research as a part of this wild global market left in the hands of greedy companies and selfish authorities; (3) rise of new globally influential powers such as China and India to use their economic power as a leverage to fill the vacuum of power and governance in the global affairs including healthcare and health research. Some of these rising powers, especially China, have has a history of ambiguous and controversial approach to the fundamental principles of the ethical framework of Global Governance for Health Research, such and human dignity and human rights and even non-exploitation (considering the exploitative nature of some parts of labor market in China and the history of exploitation on other areas such ad organ transplantation). Therefore, the effect of their leadership in global affairs (along with the relative absence of Western powers) on the ethical aspects of global health research enterprise should be expected and monitored cautiously.

The Problem of Universality of Human Right in Developing Countries: It has been claimed that a certain group of concepts are consensual and universal in nature and belong to the common heritage of mankind. These concepts include respect for human dignity and human rights and fundamental freedoms. This universal and consensual nature as asserted in some universal declarations has been one of the theoretical bases of the framework suggested in the previous chapter of this dissertation for Global Governance for Health Research. This universality, however, has not been realized in the real world. Some local cultures do not believe in human rights as they are presented in the *Universal Declaration of Human Rights*. In contrary, they argue that their believed

schools of thoughts (or religions) provide them with different systems and interpretations of human dignity and human rights that is different and sometimes in contrast with the concepts presented in the declarations adopted by the UN or UNESCO. They claim that the concepts of human rights adopted by these international organizations are not universal, but they are rooted in the Western secular and Judo-Christian cultural traditions.

It can be argued that although the values of human dignity and human rights are not absolutely consensual, they are enough consensual to shape the value-based fundaments of ethical frameworks for Global Governance for health Research. When it comes to the health research sector, these values become more agreeable by all the parties. Even countries that have some reservations in adopting conventions on children's right and other sensitive topics, have readily adopted the principles of human dignity and human rights through the declarations on health and health research. Iran, as an example, regardless of domestic controversies and criticized behaviors in the areas of women's rights and freedom of speech, has adopted a series of domestic guidelines for research ethics that are in extreme consistence with international ones.[531] Some other regional authorities that deny human rights, do not have health research sector within their territories.

In sum, it seems that all the countries and jurisdictions that have a sort of health research sector within their boundaries have accepted the fundamental principles of the principle-based element of the ethical framework suggested in this dissertation. Therefore, this dissertation argues that the principles adopted in this framework are globally "enough" consensual and universal.

An Ethical Framework and a Realistic Place for Optimism: Some practical recommendations provided in the following part of this chapter can be helpful in promoting ethical governance in the realm of global health research, including supporting the key and central role of international organizations as the leading institutions in Global Governance for Health Research; embracing integrated approaches to health that not only include humans without any discrimination, but also encompass animals, and the mother nature; and the last but not the least, taking this fact into consideration that social and political determinants of health are important determinants of the health all over the world and they should be included among the global research priorities.

In sum, despite the irregularities, the global trend in the past decades has been toward establishing more ethical and cross-cultural global governance for health research. There have been numerous great achievements, partly described in chapter 2 of this dissertation, including the international declarations and guidelines, consensual adoption of universal values as parts of common heritage of mankind, establishment of international and cross-cultural organizations along with the unprecedented role-playing in the civil society, and the ethics training programs that have empowered local communities to take part in ethical review and oversight for research. The above-mentioned trend and achievements are promising for a future of continual ethical improvements in Global Governance for Health Research.

iii. Practical and Ethical Recommendations

The ethical framework suggested in chapter 5 for Global Governance for Health Research encompasses the normative guidance of three major philosophical approaches to normativity: the virtue-based approach encompassing both classic/masculine and

feminine virtues, the principle-based approach that includes a layer of more fundamental and a layer of more detailed principles, and the particularistic or situation ethics approach. This dissertation argues that implementing this comprehensive model will solve the existing challenges and problems of Global Governance for Health Research (described in chapters 3 and 4 of this dissertation) in a multilateral and comprehensive way. Each virtue and principle included in this framework has its own practical implications. Explaining the practical implications of each component of this framework is beyond the scope of this chapter. However, some general recommendations are provided below to depict how this ethical framework actualize itself in the realm of Global Governance for Health Research:

1- Establishing a governance system from below (instead of the current top-down governance) is one of the most fundamental recommendations concluded from the suggested framework. The appearance of the term of global governance in the political sciences discourse was due to the newly emerged abundance or non-state rope-players in the previous decades that take part in governance of global affairs (see chapter 2). The states, although sovereign and powerful, are limited and sometimes overwhelmed by the political interests of powerful parties and role-players. Therefore, they may not act optimally in dealing with challenges of global governance and protecting the interests of the powerless. The non-state actors are to be the “voice of the voiceless”. As described in chapter 2, many non-state and civil-society role payers act influentially on the sense of Global Governance for Health Research. A major part of the existing body of related soft law (as the main way through which Global Governance for Health Research is embodied and actualized) is created and adopted and promulgated by international civil society role

players, the most prominent example being the Declaration of Helsinki adopted by the WMA. For implementing the suggested ethical framework for Global Governance for Health Research, empowering and encouraging the governance from below by grass root institutions and civil society role players seems to be an imperative of utmost importance. For this purpose, in addition of strengthening civil society, establishing training courses for local people is a major step. Because the ethically knowledgeable and aware people are the only ones who can take the lead in establishing and promoting "from below" governance.

2- Promoting respect for cultural diversity and fundamental human rights as the common heritage of mankind. Actualization of the principle of "Respect for Cultural Diversity" is the best practical way to make disappear ethical Imperialism and Colonialism, and bilateralism. This recommendation combined with establishing a governance system from below will protect the global research enterprise from some major challenges such as helicopter research, exploiting poor countries/communities, double standards, bio-piracy, undue influence of bio-politics at the global scale, and ethical colonialism. The principle of respect for cultural diversity, as explained in chapter 5, is limited with the principles of "Human Dignity and Human Rights". Respect for cultural diversity should be observed to protect the benefits and interests of all the parties involved in or influenced by research, however should not be appealed to justify any violation to the fundamental human rights and freedoms by local authorities.

3- Strengthening the role of the leading organizations in Global Governance for Health Research. The challenge of bilateralism is discussed in chapter 3. The only way for implementing the ethical framework for Global Governance for Health Research is

strengthening multilateralism. This means that international organizations, such as WHO and UNESCO should take the lead in promoting and implementing an ethical framework. Some organizations cannot play this role because of their belonging to just one party of interactions. For example, the WMA, although created the most influential international ethical guideline for research, the Declaration of Helsinki, mostly belongs to physicians. Therefore, it seems that the WHO or UNESCO are the best suited organizations to take this role because of their inclusiveness and their relations with states that have the power and authority needed for implementation and enforcement of ethical guidelines at the domestic and global levels. For instance, the UNESCO Declaration of Bioethics and Human Rights mainly addresses the member states of UNESCO.[532]

4- Adopting an integrated approach to health that includes humans, animals, and nature (ecosystems, climate, etc.). This element is actualized when a comprehensive approach is taken and the local role-players are empowered and involved. The planet Earth is the common habitat of all living organisms. Imposing imbalance and pollution will have backlashes for the health of human beings. Sustainability is a crucial precondition of each governance system. Sustainability that safeguards the harmonic and balanced cohabitation of all the creatures, including the human being. Otherwise, no governance system or developing program will be lasting and sustainable. The Global governance for Health Research is no exception for this rule.

5- Taking into consideration the social and political determinants of health, e.g. in setting research priorities. In every global health crisis (such as the HIV/AIDS pandemic) this question pops up that what the best way for dealing with the health problems is. Is this only a technical and biomedical health problem or other factors such as social and

political structures should also be considered and repaired to achieve satisfactory results?[533] Implementing the ethical framework suggested in chapter 5 necessitates a comprehensive model. In the realm of research ethics, having independent oversight, review, and monitoring bodies is a crucial ethical imperative. Having independent oversight bodies is not possible in the absence of a well-established civil society. The oversight bodies in the absence of civil society will be dominated by powerful authorities.[534] Therefore, implementing this framework is only possible when all aspects of collective human life are considered as relevant to health, including the political power relations and the strength of civil society.

iv. Suggestions for Future Research

Studying Global Governance for Health Research and its ethical challenges and frameworks is just at its beginning steps and has a long road ahead. Both theoretical/normative and empirical studies are needed to fill the knowledge, normative, and policy gaps in this field (see chapter 3). The current threatening and promising trends that are discussed in this chapter also need to be more clarified via further studies. The institutional and compliance gaps also necessitate more research and studies to find the best ways to fill them. The dynamic nature of this field and its gaps continually creates new gaps and new knowledge to fill them.

In the near future, the following topics need to be studied to shed light on the next steps of Global Governance for Health Research and its challenges and ethical frameworks:

1- The current trend of populism along with isolationism and protectionism in the Western countries is a demanding subject of studies. Is this a real and long-lasting trend

with continuous impacts on different aspect of globalization and Global Governance, including Global Governance for Health Research? Or it is just a reactionary period that will end soon and won't have lasting impacts on global affairs? If the former prediction proves right, will there be rising powers among other countries, such as China or India, which try to replace the US and Western countries as the leading powers in Global Governance? What will be the impacts of more involvement of these rising powers in global health research? These questions are to be answered by new studies and research in the coming years and their answer will have definite impacts on the ethical frameworks that Global Governance for Health Research will adopt and comply with in the real world and in practice.

2- The principle-based element of the ethical framework for Global Governance for Health Research will also be a subject of further theoretical studies and debates. What principles can be added to or excluded from the existing sets? Are the principles included in the suggested ethical framework of real universal and consensual nature? Which one of them has been influenced by ethical colonialism and imperialism? What new principles can be added to the framework and considered as a part of common intellectual framework of mankind? The historical course of creation and development of the sets of principles for global research, from the three principles of the Belmont Report to the four principles of biomedical ethics formulated by Beauchamp and Childress, to the UNESCO Universal Declaration of Bioethics and Human Rights, and the NIH Framework, show that over the past decades, many new principles have been added to the existing frameworks. The suggested framework in this dissertation have tried to be a comprehensive one and encompass the previous ones. However, this does not mean that a

final framework is achieved or is achievable. The process of development and evolution of ethical frameworks for Global Governance for Health Research is a never-ending and continuous process fed by incessant chains of studies and research projects on the previous and new principles.

3- As explained above, the framework of gaps in Global Governance and Global Governance for Health Research (see chapter 3) is a dynamic framework. It means that the new gaps continuously appear and are filled with new knowledge and practice that are rooted in research. Evidence based knowledge created by research is the most fundamental need when it comes to filling the gaps in Global Governance. Filling the knowledge gap obviously needs new knowledge. The normative gap demands new normative and ethical research. The policy gap needs evidence-based knowledge to support new policies. The institutional gap needs new research on the situation and weaknesses and strengths of the existing institutions, and compliance gap also needs research-based information and awareness to be filled. Therefore, as a conclusive remark on future research, this chapter holds that the next research projects in this area are needed and should be directed to create evidence-based and normative knowledge to fill the fivefold gaps of Global governance for Health Research.

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