

▶ **O64**
Bioética

- ▶ **Carlos Victor Montefusco-Pereira***
- ▶ **Nora Ney Almeida Rodrigues****
- ▶ **Ademarina Teixeira Cardoso*****
- ▶ **Fátima Maria da Costa Castro******

DESARROLLANDO UN COMITÉ DE
ÉTICA DE INVESTIGACIÓN: EL CASO
DEL SISTEMA DE SALUD DE MANAUS

DESENVOLVIMENTO DE UM COMITÊ
DE ÉTICA DA INVESTIGAÇÃO: O CASO
DO SISTEMA DA SAÚDE DE MANAUS

Developing a Research Ethics Committee the case of Manaus Health System

▶ Fecha de recepción: 10 de enero de 2013

▶ Fecha de evaluación: 29 de mayo de 2013

▶ Fecha de aceptación: 26 de junio de 2013

* Pharmacist. Health Assistant at Manaus Health City Office (Secretaria Municipal de Saúde de Manaus — Address: Gerência de Educação na Saúde, Secretaria Municipal de Saúde de Manaus. Avenida Mário Ypiranga, 1695, Adrianópolis, 69057-002, Manaus, Brasil—). Administrative assistant at the Research Ethics Commission. E-mail: cmontefusco@gmail.com.

** Pharmacist. Health Specialist. Coordinator of the Research Ethics Commission. E-mail: nora.rodrigues@pmm.am.gov.br.

*** Social Assistant. Health Specialist. Chief of the Sector of Health Education. E-mail: ademarina.cardoso@pmm.am.gov.br.

**** Social Assistant. Health Specialist. Chief of the Sector of Health Education. Member of the Research Ethics Commission. E-mail: fatima.castro@pmm.am.gov.br.

RESUMEN

La creciente complejidad de la investigación biomédica con seres humanos genera muchos conflictos éticos que se suman a la dificultad de cumplir con todos los requisitos impuestos por una legislación en bioética. La Secretaría Municipal de Salud de Manaus (MHCO, en inglés), en la Región Norte de Brasil, ya tenía un intercambio con universidades locales que no era gestionado por ningún sector en específico, por lo que los proyectos de investigación se autorizaban sin análisis de viabilidad o relevancia y sin ningún seguimiento de acciones dentro del sistema de salud local. En 2008, la MHCO creó la Comisión de Ética de la Investigación (RECO, en inglés). Entonces, ¿constituye la MHCO un campo para la investigación? Hay que decir que sí en el sentido de que, del sistema local de salud, parten temas y servicios que caracterizan por completo a la salud y a la ciudad en sí. Entre 2008 y 2011, el total de proyectos presentados para trabajar dentro de los establecimientos de salud asciende a 282, relacionados con trabajos de pregrado y postgrado. La MHCO representa una acción del gobierno local para supervisar las actividades de investigación en el sistema local de salud y, al mismo tiempo, atrae la atención de los empleados públicos como investigadores de su propio entorno laboral. Dicha acción contribuye a identificar problemas a nivel interno y revela la forma en que la sociedad de Manaus ve al sistema de salud. Artículo de reflexión.

Palabras Clave

Bioética, Gobierno, Investigación en humanos, Comités de Ética, Asistencia Sanitaria.

SUMMARY

The growing complexity of biomedical investigation with human beings generates many conflicts regarding ethical values that add up to the difficulty of fulfilling all the requirements imposed by the legislation on bioethics. Manaus Health City Office (MHCO), in North Brazil, had already had a long time exchange program with local universities which was not managed by a specific sector, so research projects were authorized without further analysis of feasibility, relevance, or a follow-up of its actions within the local health system. In 2008, MHCO created the Research Ethics Commission (RECO). So, is MHCO a field for research? We ought to say yes inasmuch as from the local health system stem subjects and services completely characterizing the health and the city itself. From 2008 to 2011, the number of submitted projects intended to be implemented inside the health establishments was 282, concerning undergraduate and graduate papers. MHCO represents an action of the local government in monitoring research activity in the local health system and, at the same time, catches the attention of public employees as researchers of their own environment of work. This action helps to identify internal problems and shows the impression Manaus society has in relation to the health system.

Keywords

Bioethics, Government, Human Research, Ethics Committee, Healthcare.

RESUMO

A crescente complexidade da pesquisa biomédica com seres humanos gera muitos conflitos éticos que contribuem para a dificuldade de satisfazer todas as exigências impostas pela legislação sobre bioética. A Secretaria Municipal de Saúde de Manaus, na região norte do Brasil, já tinha um intercâmbio com universidades locais que não eram geridos por qualquer sector específico, para que os projectos de investigação foram autorizados sem análise de viabilidade ou de relevância e de quaisquer acções de acompanhamento no âmbito do sistema de saúde local. Em 2008, a Secretaria criou o Comitê de ética da pesquisa. E ben, ¿constitui o Secretariado um campo de pesquisa? Deve ser dito que sí, por causa do sistema de saúde local partem assuntos e serviços que caracterizam completamente para a saúde e para a cidade. Entre 2008 e 2011, o número total de projetos apresentados para o trabalho em estabelecimentos de saúde foi 282, do trabalho de graduação e pós-graduação. A Secretaria representa a ação do governo local para monitorar as atividades de pesquisa no sistema de saúde local e, ao mesmo tempo, atrai a atenção dos funcionários públicos, como os pesquisadores em seu próprio ambiente de trabalho. Esta ação ajuda a identificar problemas internamente e revela a maneira em que a sociedade de Manaus vê o sistema de saúde.

Palavras-Chave

Bioética, governo, pesquisa em seres humanos, Comitê de Ética, assistência à saúde.

O65

INTRODUCTION

At a self-implemented survey conducted among 1110 medical staff recruited from Shanghai's 22 psychiatric hospitals, only 11% and 16,6% of them knew about the Nuremberg Code and the Declaration of Helsinki respectively. This affirmation reflects the current situation not only in China, but all over the world. It would be likely to find similar numbers not only in psychiatric hospital staff, but also in that belonging to hospitals for children, women, general and infectious diseases ones which have inexperienced professionals in the matter of Bioethics regarding human research.

According to SANMUKHANI, ethical guidelines in various parts of the world were formulated only after the discovery of inhumane behavior towards participants during research experiments. In the pre-World War II era, most of the research experiments were carried on the own self or on one's own patients. World War II led the states to take more interest in science and research resulting in the initiation of larger, systematic clinical investigations to gain knowledge for better treatment of patients, especially soldiers. Most of the studies were carried out through defense efforts and mainly used the prisoners without concern for their consent and well-being. The experiments by the Nazi doctors in their concentration camps were the cruelest of all of them. In some of the most dreadful of these experiments, they kept the prisoners in compression chambers, freezing water, generated gunshot wounds and even transplanted grafts among twins to see the body's response in such adverse situations. Death was the end point in most of the experiments and, when it was not so, the doctors did *antemortum* dissection to study changes in the body.

Nowadays, economic incentives in medical practice and research have exacerbated the potential for conflicts of interest, which can undermine ethical relations between medical professionals and researchers, drug companies or other research supporters, patients who become research participants, and even the regulatory agencies whose mandate is to protect participants' safety.

Bioethics, reaching 40 years in 2011, has been focusing on questions involving vulnerability and the possible exploration of susceptible population, concerning socioeconomic and cultural reasons or for mental/physical health issues. SCHRAMM describes Bioethics proposing a theoretical and practical tool concerning the tasks of:

- Understand the conflicts;
- Generate proposed solutions (and, when possible, to integrate them);
- Protect the involved individuals and population;

Bioethics, from a *stricto sensu* manner, concerns about ethics applied to human actions that may have negative long-lasting effects over men and women; and following the *lato sensu* manner, it is understood as a planetary ethics, that is, an ethics worried with accountability, in short and long term, for the harmful effects resulting from the human acts over the individual, social and cultural human life, the biosphere and ecosphere in general.

In Brazil, Resolution No. 196/96 that determines guidelines and regulatory rules, according to the item II.14, stipulates, by every institute that performs research on humans, the formation of Research Ethics Committee (REC) – interdisciplinary and independent collegiate, with *munus publicus*, of advisory, deliberative and educational character, created to defend the interest of research subjects in their integrity and dignity, contributing with research development attending the ethical standards. Those committees must evaluate every project involving humans; these can be conducted only after careful analysis and approval.

Clinical trials are far cheaper to conduct in the developing world and epidemics of HIV/AIDS, malaria and TB predominantly occur overseas, and they are receiving more attention from wealthier countries. Increasingly, US-sponsored research is carried out abroad, raising numerous challenges for Institutional Review Boards (IRBs) and Research Ethics Committees (RECs) in both sponsor and host countries. These US IRBs often know little about local contexts, regulations, and standards for care, and struggle with the understandings of other cultures' differing views of autonomy, risks, and benefits of daily life. This contact with the real situation can be assessed by local institutions as universities and the government, in which specialized professionals can discuss the best case scenario in a case of multinational research.

Along this paper, we want to show how Manaus health system is a field for academic research (in the most diverse science fields). At the same time, how can a research-potential environment deal with projects which involve users, employees and health services in different conditions? How can be evaluated the need and the correspondence that a project can have related to the Brazilian bioethical legislation?

MANAUS HEALTH CITY OFFICE (MHCO)⁸

Manaus is a Brazilian city, capital of the state of Amazonas and the main financial, corporative, and economical center of the North Brazilian region. It is a historical and portside city, located at the center of the biggest tropical forest in the world. It is also located in the confluence of the rivers Negro and Solimões. It is geographically located 3.490 kilometers away from Brazil's capital, Brasília, and the most inhabited city of Amazonas state as well as of the Amazonian region with a population of 1.832.423 inhabitants, according to the Brazilian Institute of Geography and Statistics in 2011, what makes it the seventh more populated Brazilian capital and the 131st from the world.

As MCHO webpage describes, in a way to provide better services to the population of Manaus, the City Hall, by Law No. 1.094 from October 21st of 1970, established directions to the Administrative Reform in which the Development Secretary (*Secretaria de Desenvolvimento – Sedeco*), in the health sector, would develop preventive actions in general and of Epidemiologic Vigilance. The increasing of population numbers and the complex problematic that followed demanded from the Public Power to adequate the structures of service providers to reach the aims of its propositions. That is why, through Law No. 1240 from November 20th 1975, it was created the Manaus Health City Office, a first level sector of the City Administration. In its structure, the Division of Public Health was entrusted with specific activities, including Sanitary Inspection and the Direction of Urgency Help in the level of service providers. Due to the amplitude of MCHO actions, it was practically restricted to the field of its activities, and, once the difficult was recognized, it was established a new organizational structure by Decree No. 1686 from December 17th 1979, allowing a larger flexibility.

To ensure the provision of promotion, protection and recuperation of health, Manaus City Administration has 9.299 employees from Manaus Health City Office, with a city net composed by 1 Maternity, 1 Central for the Mobile Service of Urgency with eight decentralized bases (18 ambulances of basic care, 5 of advanced support and 2 ambulance-boats of advanced care), 1 program named Social SOS (transportation of patients during chemotherapy, radiotherapy, physical therapy, hemodialysis, transplanted, paraplegic), 7 Services of Emergency Care,

8 Polyclinics, 1 Reference Center of Workers Health, 1 Service of Physical Therapy, 3 Centers of Dentistry Specialty, 2 Centers of Diagnostic Support in each District of Health, 1 Laboratory of Cytopathology, 1 Laboratory of Health Surveillance, 1 Center of Zoonoses Control, 1 Central of Medications, 46 Basic Units of Health, 3 Modules of Family Health, 20 Stations of Rural Health and 158 Basic Units of Family Health, all distributed in health districts (North, South, West, East and Rural). All those units act in an axis of Primary and Specialized Attention, building a rich environment for investigations in diverse areas, from familiar health to urgency attention, passing through multidisciplinary fields in an enough way to gather more professional categories in a correct performance of its activities.

MCHO has the task to represent one the biggest capitals of Brazil in a cultural and traditional context of the Amazon region, bringing reflected peculiarities in its way of treating, dealing with, and approaching a capable health system, for instance, in the support to the rural and riverside area of Manaus city, facing challenges as challenging as transportation in Amazon state's roads/rivers.

RESEARCH ETHICS COMMISSION OF MANAUS HEALTH CITY OFFICE

The previous view

To propose a commission of ethics in research inside the Health City Office, there is the intention to monitor the access into the city health system to scientific work, not only regarding the use of its physical structure, but also its personnel. Counting with the fact that this work must be consonant to the city administration policies, there is a need to file and analyze projects that will influence the routine of primary attention and its results on the city' health scenario. This monitoring is necessary to update professionals and students in relation to the respect for the rules of investigation while dealing with human beings, striving for the users' dignity so in consequence the general administration will have the perception of what is happening all over the city net of health units, seeking within those researches good results and new propositions of change in public policies.

Before 2008, Manaus Healthy City Office (MHCO) already had a long time exchange program with local universities that was not managed by a specific sector, so

research projects were authorized without further analysis of feasibility, importance, or follow-up of its actions inside the local health system. This matter then brought up a serious question of safety on knowing how many projects are being developed inside MHCO and mainly how the interaction of researchers, workers, and users from these healthcare units was.

The city of Manaus, nowadays, has 11 (eleven) RECs (Fig. 1) that are properly validated and monitored by the National Council of Ethics in Research as "interdisciplinary and independent collegiate with *munus publicus*". Those collegiate might receive projects of any qualified person with interest in research involving the human being, individual or collective, in a direct or indirect manner, in its total or in parts, including the handling of information or materials.

However, the Unified Health System (UHS, Sistema Único de Saúde, in Portuguese) in its integrality possesses a context and experience as unique as its name in which the related professionals obtain maturity in meeting a specific reality which everyday becomes an object of investigation. This knowledge may have enormous usefulness in the formation and preparation of students from health sciences and related areas; consequently, the partnership between MHCO and universities is an advantage for exposing science and the local health system. Indeed, not only university or hospitals are environments that are requiring a REC.

This REC in Manaus represents the 6th one to be installed in a Brazilian Health City Office, right after main cities that have a high flow of undergoing research as Curitiba, São Paulo, Santo André, Belo Horizonte, and Rio de Janeiro.

The current view of work

About the current eleven RECs, all of them were implemented at research institutes or universities that represent the bigger part of the number of knowledge and science production. So is MHCO a field for research? We ought to say yes in a way that from the local health system there are subjects and services that totally characterize the health and the city. From that point of view, we must implement a REC to help with the development of research in a respectful manner considering the five pillars of bioethics: autonomy, beneficence, non-harmfulness, justice, and dignity of an individual and its collectiveness.

The start of a Research Ethics Commission in February 2008 was a process of reflection about the quality and the ethical approach of research projects that intended to work inside the Establishments of Health Attention (EHA).

In 2008, an articulation of the Division of Human Resources Development (today the current Sector of Education in Health) defined the representation of scientific projects inside MHCO and it created a group in order to gather people and other sectors that would receive students and researchers with the intention of obtaining data or applying questionnaires/interviews to users and/or professional of the UHS.

In the same year, the Order No. 069/2008 from the Secretary Cabinet/MCHO defined and summoned sectors of Administration, Primary Attention, and Surveillance to interact and integrate a Research Ethics Commission (RECO) with the aim of safeguarding the rights and the dignity of the research subjects; contribute to research quality and to the discussion of research roles in the institutional development; to contribute to the researcher positive appreciation acknowledging the value of his/her proposition is ethically adequate. Yet, the mission is divided into two main actions: the guiding of researchers and the analysis of the submitted projects.

Currently, Order No. 339/2012 designates RECO as having 11 (eleven) main members, 9 (nine) surrogates and 1 (one) coordinator, establishing and reassuring that all research work performed inside MCHO, by external or inside researchers, must submit projects to RECO. Also, Order No. 038/2011 approved the Internal Regimen.

Professionals of diverse areas (Medicine, Nursing, Nutrition, Management, Social Service, Pharmacy, Statistics, Physical Therapy, Psychology, Dentistry and Fisheries Engineering) take part in meetings that take place at intervals of 15 days. Those members represent MHCO sectors as the five Health Districts, the City Council of Health, Department of Work Management and Health Education, Department of Primary Health, Department of Auditing, Control, Evaluation and Regulation, Department of Planning, Department of Sanitary Inspection and Department of Epidemiologic and Environmental Surveillance.

Specific Aims

- Analyze the feasibility, ethical context, possible subject's vulnerabilities of research projects that interact with users and professionals from the health system
- Reflect about the main knowledge areas stimulated in a government-university-research relation.

Work dynamics

According to Article 21 of Order 038/2011, the “protocols of research” with human beings will be submitted to the Executive Secretary of RECO, in Portuguese, in 2 files, instructed with the following documents:

1. Research Project, following the available model to be downloaded from MCHO website (<http://semsa.manaus.am.gov.br/coep>). Attention to include in the timetable the prediction of sending results to RECO. Attention to include the names of all people involved in the project (students and professors).
2. Institutional Letter of Project Presentation, also expressing the agreement from the university or research institute, with institutional letterhead and director’s signature.
3. Term of Commitment from the Research and Advisor
4. Term of Free and Clarified Consent (TFCC), in the cases of application of questionnaires and/or interviews to users or professionals from MCHO.
5. Curriculum Vitae from the researchers, including educational level and bibliographical sketch.

In case the research being conducted abroad, it is necessary to present an approval document of a REC from the origin country, or a justification. In case the research involves new medicines, vaccines or diagnostic tests, there is a need of preclinical information.

All the signed documents must be scanned and gathered with the other required documents into a 2 CD-ROM or CD-RW. The protocol must be delivered to the administrative staff of RECO that will check all the data. The submission will happen if only there is all the required documentation.

The members from RECO will gather two times per month, from February to December of each year, and extraordinarily for the coordination solicitation. The meetings will happen with the minimum presence of one third of the official members. During the analysis, the following orientation will be respected:

1. Does the title of the study represent the proposed aims of the Project and is it according to them?
2. Are the study’s presentation, introduction, foundation, and justification clear?
3. Will the study add content to the field of approached knowledge?
4. Are the aims clearly written and adequate to the study?
5. Is the research design well presented and clear?

MCHO has the task to represent one the biggest capitals of Brazil in a cultural and traditional context of the Amazon region, bringing reflected peculiarities in its way of treating, dealing with, and approaching a capable health system, for instance, in the support to the rural and riverside area of Manaus city, facing challenges as challenging as transportation in Amazon state’s roads/rivers.

About the current eleven RECs, all of them were implemented at research institutes or universities that represent the bigger part of the number of knowledge and science production. So is MHCO a field for research? We ought to say yes in a way that from the local health system there are subjects and services that totally characterize the health and the city.

6. Are origin, choice, and sample size adequate?
7. Are there inclusion and exclusion criteria, well written, when necessary?
8. Are the main variables well defined (explained)?
9. Are the instruments and procedure to collect data adequate and thoroughly described in the project?
10. Were the ethical questions properly mentioned and correct according to the study?
11. Is the Term of Consent properly written thinking about the target population (the language must be accessible to the research subject)?
12. Is the timetable presenting all the conditions to perform the study included?
13. Is the budget appropriate according to the needs and specificities of the study?
14. Are the references according to the Brazilian Association of Technical Standards?
15. Does the project present the annexes: Term of Commitment from the Research and Advisor, TFCC, Institutional Letter, and Researcher's CV?

The appreciation of each Project will result in one of the following outcomes:

- I. Approved;
- II. Approved with pendency (NO need to return): when the Commission considerate the protocol as acceptable, however there were identified specific problems in the protocol, in the TFCC or both, and it is recommended a specific review or requested a modification or relevant clarification.
- III. Approved with pendency (need to return): when the Commission considerate the protocol as acceptable, however there were identified specific problems in the protocol, in the TFCC or both, and it is recommended a specific review or requested a modification or relevant clarification that must be attended in 15 (fifteen) days to the final appreciation from RECO to be finally approved.
- IV. Withdrawal: by solicitation of the research or when the deadline of pendency will not be attended.
- V. Non-approved.

For the approved and approved with pendency (NO need to return) projects it will be provided a Term of Agreement from MCHO. As RECO is not yet recognized by the National Council of Research Ethics, the same project (but now with the Term of

Agreement from MCHO) will HAVE to be submitted to a validated REC chosen by the research from the 11 RECs available here in Manaus.

Following, Evaluation and Monitoring

The research protocols will be registered and classified by chronological order of entry, being distributed to RECO members when they are particularly chosen by the coordinator, according to availability. Each protocol will be sent to at least two members, preferentially to one belonging to the same area of the project or with work experience in a related field.

Even with projects already approved by RECs and validated by the National Council of Research Ethics, we evaluate the context applied to the reality of our local healthy system and to the experience of RECO's members that have been working at MHCO for 5-10 years. If there is no consensus, there will be a decision for a third member during the gathering where it will be properly discussed. RECO can also invite persons or entities that may collaborate with the development of the analysis, where it might create sub-commissions to specific topics, for instance research with indigenous population.

The members must have total independence and no conflict of interest on decision-making process in which there will be secrecy for all the analyzed content, as well as for the consultants that may be frequently required. At any time, there can be consultation of experts to provide clarifying and updated information under a certain issue. There cannot be any pressure, social or political, from hierarchical superiors or by the person/people interested in the research, what includes any attempt of financial involvement or subjugation.

Giving emphasis that the projects must be performed only inside MHCO after the two steps of RECO (Commission, non-validated yet) term of agreement and a posterior approval from a REC (Committee, already validated).

After providing the term of agreement, it will be sent a document after each RECO's meeting to the places in which the research will take place. That action will positively reflect on the reception of a researcher and to the perception of benefit or harm that a research might arise. In summary, our local administrators in each district of health or department will be instructed and notified about the occurrence of projects and the possibility of direct complaint if there is any issue to deal with.

RESULTS OF ITS ACTIONS

From this action, a scenario of bioethics was promoted in order to set out what is the responsibility for a health unit director in accepting a research project without proper care or for a higher chief to grant authorization to projects that are not sufficiently clear.

Having this in mind, we promoted the I Forum of Bioethics in Manaus with the theme "In defense of the citizen's integrity and dignity" (May 12th-13th 2011), in which it was proposed the current Policy of Permanent Education, promoted by the Brazilian Ministry of Health. The event had the aim to supply a discussion of the theme through lectures, round tables and successful case reports, which might expose the good appropriation of resources to help the indispensable task of ethical evaluation of investigation using human beings. With that, there was the offering of a general overview of the theory on Bioethics, the legislation (local and international) that would instruct to analysis and decision. This action contributed to the implementation and strengthening of RECO, aligned with the respect to life, to the valorization of science, and by the ethical and social commitment of improving the health conditions for our population.

RECO now can be seen as a consultation sector, a clearer doubt, giving support on how to receive researchers and investigations that will result on analysis and description of the health scenario inside the city; this process builds up an option to Establishments of Health Attention to have participation in directing the formulation of strategies and to advice how to proceed with research methodology in a way that maybe in the future this action could be installed in each of the five health districts.

As a result, there is an increase of management sector from MHCO to actions from the government-university axis: a higher approximation to university and research institutes, through the contact of the Sector of Health Education in which the researchers and students could be aware of other actions developed by MHCO as the Program of Internship to students from high school, technical degree, bachelor and post-graduation (to mention one, the recent approval of a Residency Program on Family and Community Medicine); as well as specific activities that require the bond of Health Ministry and University as the Program of Education to Health Work.



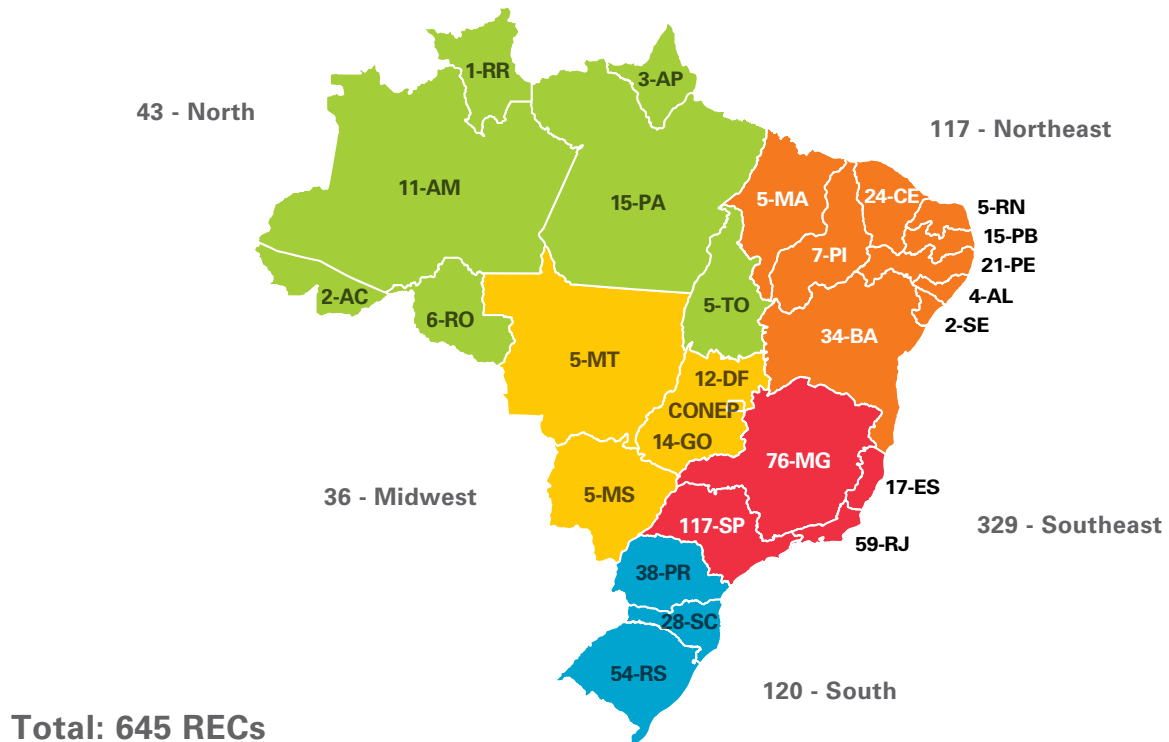


Figure 1. Research Ethics Committees in Brazil (Adapted from BRASIL/CNS/CONEP, 2012⁹)

A second result can be mentioned as the perception of workers' activity on health sciences that a research could reflect, analyze and propose solutions for problematic issues at the current work experience.

For that matter, from 2008 to 2011, the quantity of submitted projects properly approved to be implemented inside the health establishments summed up to a total amount of 282 (two hundred and eighty two), concerning bachelor works, master dissertations and doctorate theses.

CONCLUSION: SPREADING INFLUENCE OF CHANGE

Institutional responsibility for the governance of the research is not limited only to the ethical review by the Human Research Ethics Committee (HREC), but also to the accountability for quality, safety, privacy, risk management, and financial management of research. Despite the development of proposed research

governance frameworks, many institutions do not have such structures correctly established, and rely excessively on HRECs to perform administrative functions that are not their responsibility. That is the case of Australia, but its reflection can be seen in developed and, mainly, in developing economies, like Brazil. Mainly because the size of health systems cannot be monitored only by a centralized administration, the whole organization (government, university, industry) must be aware of what kind of research is happening inside their structure and, of course, how well is it being conducted and how this practice involves the proper ethical guidelines.

Health research initiatives worldwide are growing in scope and complexity, particularly as they move into the developing world. Expanding health research activity in low- and middle-income countries has resulted in a commensurate rise in the need for sound ethical review structures and functions in the form of Research Ethics Committees (RECs). Yet these seem to be lagging behind as a

result of the enormous challenges facing these countries, including poor resource availability and lack of capacity. There is thus an urgent need for ongoing capacity and resource development in these regions in general.

In Africa, since 2009, the Mapping African Research Ethics Capacity (MARC) project is a timely initiative aimed at identifying existing capacity, providing a platform or tool which can be used by RECs in Africa. There are three components to the MARC project: 1) the on-line mapping of research ethics committees, 2) building capacity in research ethics in Africa, and 3) the mapping of medicines regulatory authorities in Africa. Our attempt wants to oversight also international projects and a REC in Manaus health system is an important step in locating and establishing partnership to get involved with, to follow, to give suggestions, to inform foreigners and locals about our health scenario and not only observe research being performed.

The city of Manaus and its local health system may be represented by RECO to receive, guide and follow research projects inside this scenario, surpassing city limits and accessing other cities with social, demographic, and mainly epidemiologic reasons to gather investigations that might contain ethical and methodological issues to be duly analyzed as its proposition of influence in the local situation and on the research subjects. Therefore, the Manaus City Health Office may already glimpse an action that supports projects inside, not only Manaus, but concerning all the state with its other 61 cities.

This paper introduces to and shows how RECO/MHCO, with almost 5 (five) years of existence, is now looking for physical and human structure to manage the process and in this way the validation from the National Council of Research Ethics is a nearer reality in which there will be reached an autonomy in project analysis, and in the stimuli of the Policy of Permanent Education, and in the execution of scientific work by students, professors and also government employees (including MHCO) inside the Brazilian National System of Health.

The whole action itself represents the local government in monitoring research activity in the local health system and, at the same time, catches the attention of public employees as researchers of their own environment of work. This action helps to identify internal problems and illustrates the impression that Manaus society have concerning the health system. Those impressions, REC's procedure along the time,

international projects, the results from projects follow-up (not only before, but also 'during' and at the end of a project) must be further analyzed in the future so the society can be more engaged not only in science but also in how the procedure must follow ethical rules.

ACKNOWLEDGEMENTS

We would like to thank the *Secretaria Municipal de Saúde de Manaus* (MHCO), the *Gerência de Educação na Saúde* and each one of the 21 members of the Research Ethics Commission that have helped in structuring this action inside Manaus healthcare system. For the Spanish language review, we would like to thank Mrs. Deisy Rocío Duchén Bocangel.



REFERENCES

- SU, L.; HUANG, J.; YANG, W.; LI, H.; SHEN, Y.; XU, Y. (2012). Ethics, patient rights and staff attitudes in Shanghai's psychiatric hospitals. *BMC Med Ethics*, 13 (1), p. 8.
- SANMUKHANI, J.; TRIPATHI, C. B. (2011). Ethics in clinical research: the Indian perspective. *Indian J Pharm Sci*. 73(2), pp. 125-130.
- BRAZ, M.; SCHRAMM, F. R. (2011). Bioética e pesquisa em saúde mental. *Ciênc. Saúde Coletiva*, vol. 16, No. 4, Rio de Janeiro.
- SCHRAMM, F. (2002). A Bioética, seu desenvolvimento e importância para as Ciências da Vida e da Saúde. *Revista Brasileira de Cancerologia*, 48 (4), pp. 609-615.
- BOFF, L. (2002). *Do iceberg à Arca de Noé: o nascimento de uma ética planetária*. Rio de Janeiro: Garamond.
- JORGE, M.; PEGORARO, B.; RIBEIRO, L. (2007). Abrangência de ação do Comitê de Ética em Pesquisa da Universidade Federal de Uberlândia. *Revista Bioética*, 15 (2), pp. 308-16.
- KLINTZMAN, R. L. (2012). US IRBS confronting research in the developing world. *Developing World Bioethics*, Vol. 12, No. 2, pp. 63-73.
- MHCO - Manaus Health City Office (Secretaria Municipal de Saúde de Manaus). (2012). *Nossa História. Manaus, Brazil*. Available at: <http://semsa.manaus.am.gov.br/nossa-historia/> [Accessed 01 Jul 2012].
- Brasil, Conselho Nacional de Saúde, Comissão Nacional de Ética em Pesquisa – CONEP. Mapa CEPs. Available at: http://conselho.saude.gov.br/web_comissoes/conep/aquivos/03_jul_MAPA_CEP_ATUALIZADO.pdf. Accessed in: 7 Jul 2013.
- KRSTEV, Y.; GRIMM, M.; METCALFE, A. (2011). Research governance and change in research ethics practices at a major Australian university. *Monash Bioeth Rev*, 29 (4), pp. 16.1-7.
- IJSSELMUIDEN, C.; MARAIS, D.; WASSENAAR, D.; MOKGATLA-MOIPOLAI, B. (2012). Mapping African ethical review committee activity onto capacity needs: the marc initiative and HRWEB's interactive database of recs in Africa. *Dev World Bioeth*, doi: 10.1111/j.1471-8847.2012.00325.x.