Promoting Ethics and Integrity in Research and Innovation for Development in Africa:

The role of Africa's Science Granting Councils

A Discussion Paper Prepared for the Science Granting Councils Initiative (SGCI) Master Class of 2021

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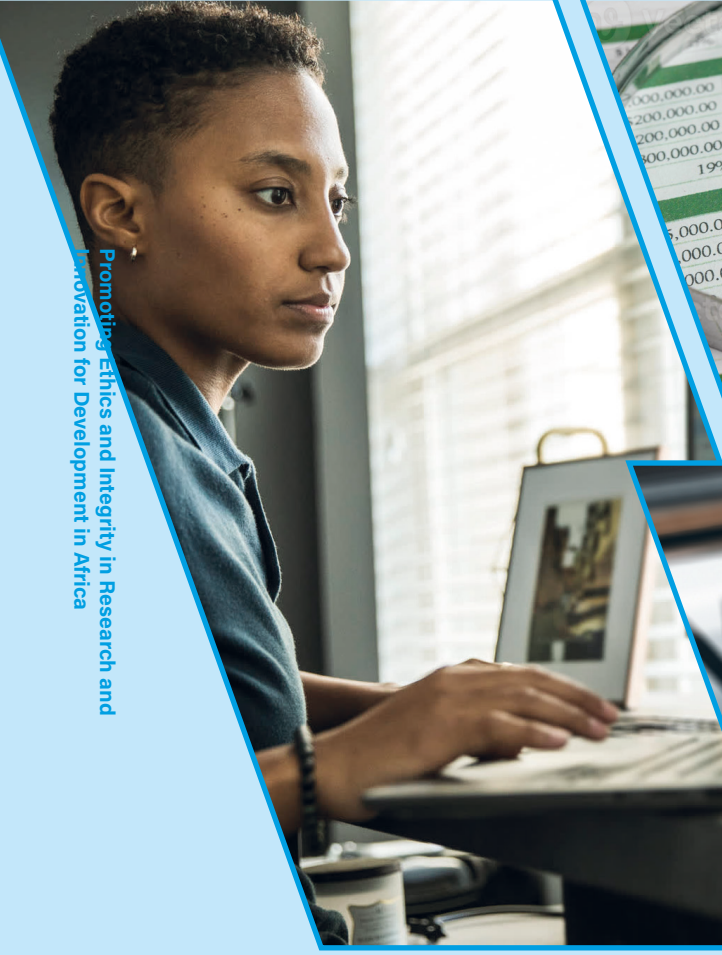

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ACKNOWLEDGEMENTS:

Each year, the SGCI convenes a Masterclass that brings together the Initiative's participating Councils from the 15 African countries and other key stakeholders around the world to deliberate and develop interventions in strategic areas of interest to the Councils and the wider science, technology and innovation (STI) community. To facilitate sharing of lessons and good practices, the SGCI commissions a state-of-the-art paper on a topic of interest for Africa's development to inform the Masterclass. The 2021 theme is *"Ethics and Integrity in Research and Innovation for Development".* This paper was prepared specifically for discussion during the Masterclass.

The work leading to this paper was commissioned by the Scinnovent Centre under the Science Granting Councils Initiative (SGCI) for Sub-Saharan Africa. The authors acknowledge the support of the 15 SGCs who cooperated and provided data upon request. The authors also acknowledge the following individuals who contributed towards the collection of data in the 15 SGCI countries: Awa Keita; Nicholas Phiri; Irene Tsey; Limbanazo Matandika; Mwifadhi Mrisho; Jean Larmarck; Antonio Machava, Claude Kirimuhuzya; Dudu Jankie; Tiwonge Mtandwe; Joyce Ikungura; Mpho Mogodi; Samba Corr; Solomon Abay; Betselot Yirsaw and Sithembile Ruzario.

KEY MESSAGES:

- The main message from this paper is that participating SGCs need to enhance ethics and integrity activities and roles as part of their responsibilities for supporting ethical conduct of research and innovation.
- All partner countries have operational Research Ethics Committees (RECs) and these RECs operate in different ways and at different capacities. The majority of countries have legislations that support and empower RECs.
- In the majority of countries, the development of RECs has been greatly influenced by demands from the health/medical research sector. Research from other sectors is not required to pass through RECs in some of the countries although relevant government Ministries or Departments may grant research permits or permission to conduct research.
- Some of the participating SGCs are closely connected to RECs with some playing some supervisory roles. The majority of RECs clearly require that proposals be reviewed by a recognized REC before funding can be released.
- Semi-autonomous SGCs are implementing more ethics and integrity related activities and roles as compared to SGCs that are based in government Ministries.
- The Science Granting Councils Initiative should formally establish a program for strengthening SGC capacities in ethics and integrity. The programme should include an assessment of changes in capacities at the end of the implementation phase. This would ensure mainstreaming of ethics and integrity in SGCs, funding proposals and programs.
- SGCs should play a leading role in facilitating or influencing the development or revision of Research policies to ensure that they address ethics and integrity issues.
- SGCs should play a catalytic or facilitative role in facilitating the strengthening of ethics and integrity in beneficiary institutions. They can achieve this by placing some requirements on beneficiary institutions for policies and structures for addressing ethics and integrity, providing financial support and training REC members as well as sensitizing all research stakeholders about ethics and research integrity.
- The rapid review of research during emergencies is an area that is currently receiving attention through World Health Organisation (WHO). SGCs can contribute towards the ongoing initiatives by initiating discussions at country level and checking with RECs if they already have SOPs that facilitate rapid reviews of research.
- Gender inequality in research is a subject that is not being addressed optimally in the majority of SGCs. There are various strategies that the SGCs can employ in this regard including initiation of special research and capacity building programs as well as increasing the representation of women on boards and panels.

- The ethical inclusion of minorities and other vulnerable populations in research is a subject that is not being addressed optimally and there are various strategies that the SGCs can employ in promoting the inclusion of underrepresented minorities in research.
- SGCs in the selected African countries can learn lessons from each other, from funder SGCs and from other non-partner countries on best practices in ethics and integrity in research and innovation through collaboration and networking
- Oversight for research involving use of animals as well as chemicals and hazardous materials is still weak or non-existent in the majority of SGC countries.

SGCs in the selected African countries can learn lessons from each other, from funder SGCs and from other non-partner countries on best practices in ethics and integrity in research and innovation through collaboration and networking

1.0 INTRODUCTION:

This paper on Ethics and integrity in research and innovation for development in Africa is based on the tenet that research and innovation in Africa, can only succeed in driving sustainable economic and social development if it is implemented using highest ethical and professional standards. The paper seeks to take stock of the activities and roles of SGCs (Science Granting Councils) in promoting ethics and integrity in research, identify some best practices from SGCs as well as other players; and to put forward recommendations on enhancing the involvement of SGCs in strengthening ethics and integrity in research and innovation. Internationally, the ethics and integrity landscape has continued to evolve and African SGCs are expected to take continuous steps towards best global standards and practices. Numerous reports confirm that Africa has not been spared from questionable practices in research and innovation. Several papers have described various cases involving unethical research in Africa (Annas & Grodin, 1998; Egharevba & Atkinson, 2016; Barsdorf & Wassenaar, 2005; Bayer, 1998; Chima, 2006; Geissler & Pool, 2006; Kilama, 2005, 2010; Lurie & Wolfe, 1997; Ndebele et al, 2014; Nwabueze, 2003; Okonta, 2014).

The African research enterprise has also fallen victim to the increase in reports on unprofessional behaviors, which include research misconduct and other misdemeanors (Ana et al, 2013; Kombe et al, 2014: Van Zyl et al, 2019; Ana et al, 2013; Ballyram & Nienaber, 2019; Horn, 2016, 2017; Kingori and Gerrets, 2016; Padayachee, 2019; Rohwer, 2018; Singh & Remenyi, 2016). Reports of questionable practices in research and innovation not only tarnish the images of the scientists involved as well as their colleagues, but negatively impacts on the images of the countries as well as the SGCs which serve as beacons of light on matters relating to research and innovation in the countries. Such practices also impact negatively on the knowledge generated from the research and public trust in research. The African science enterprise through the SGCs, needs to adapt to the growing concerns and realities if it is to remain relevant. The Science Granting Initiative (SGCI), by bringing together selected science granting councils from across Africa and other parts of the world, presents an opportunity for collaboration among SGCs worldwide and specifically for African SGCs, it presents an opportunity to learn best practices in promoting ethically conducted research and innovation.

At the global scene, the past few decades have seen an increasing emphasis on ethics and integrity in research and innovation as evidenced by numerous international legal and guidance documents namely the Universal Declaration on Human Rights (1948), the Declaration of Helsinki (2013), the CIOMS Guidelines (2016), the Good Clinical Practice Guidelines (GCP) (1996), the Singapore Statement on Research Integrity (2010) among others. The first three documents were a response to abuses of human beings in medical research during the Second World

War and GCP guidelines were established as a way of creating a basic universal standard aimed at ensuring credibility of research data as well as protection of research participants (the International Conference on harmonization (ICH), 1996, 2010). The Singapore Statement on Research Integrity is a recent development and was established as an important step towards promoting ethical conduct among scientists around the world. The crafters of the statement included scientists, journal editors, academic and industry leaders, and representatives from government funding agencies and publishers from over 51 countries (Kleinert, 2010; Resnik and Shamoo, 2011). Some of these international documents have been translated into national regulations, policies and codes in some of the African countries that address either research ethics issues or research integrity issues or both.

Science granting councils by their nature are supposed to contribute towards social and economic development by playing a critical role in supporting countries' national research and innovation systems. They play this role through their coordination of research funding, which is aimed at increasing research and innovation. While SGCs are government agencies, they also represent the interests of the scientific community as they play an important role in both prioritizing research as well as in mobilizing financial resources that can be directed into areas of national priorities. They also coordinate research capacity building through various activities and initiatives including stimulating the establishment of training institutions and programs, coordinating training programs and directly supporting training of manpower in areas of need.

As the main coordinating units on science, technology and innovation (STI), SGCs also coordinate the development of policies and legislations that support research and innovation and additionally manage bilateral and multilateral science and technology initiatives including agreements with international and technical partners. As part of their research and innovation activities, they also promote both the dissemination and utilization of findings from research that is funded using public funds (Steneck, 2007).

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Research and innovation mainly rely on public funding, and society expects responsible conduct on the part of both researchers as well as organizations that coordinate, manage and promote research (Steneck, 2007). The responsibility for ensuring that the funds and research facilities and resources are utilized optimally without any misconduct rests primarily with the SGCs that serve as funding organizations. This calls for the development of policies that address the ethical conduct for utilization of these funds appropriately. It is therefore important that every SGC should have a research policy which sets down the broad principles of responsible and accountable research practice addressing both ethics and integrity issues. The policies should clearly identify the responsibilities of main the parties involved in the research process, namely institutions and researchers. Policies need to address areas such as data and record management, publication of findings, authorship, conflict of interest, supervision of students and research trainees and the handling of utilization of funds (Mandal et al, 2012). Of late there are also discussions around the issue of benefit sharing from research and innovations (Dauda & Dierickx, 2013; Schroeder, 2007; Lairumbi et al., 2011,2012).

A scoping exercise implemented in 15 African Countries with SGCs that are part of SGCI-2 phase to understand SGCs individual research and capacity strengthening interests and priorities, identified Research Ethics as a high priority training need. The exercise covered Kenya, Rwanda, Uganda, Tanzania, Ethiopia, Côte d'Ivoire, Botswana, Burkina Faso, Senegal, Ghana, Zambia, Mozambique, Malawi, Namibia, and Zimbabwe. The study concluded that the SGCs in sub Saharan Africa (SSA) are at a low level of maturity in terms of developing, implementing and enforcing research ethics practices (Mouton, Gaillard and van Lil, 2014). This important finding is reinforced by various studies that have been conducted in Africa to understand research ethics and research oversight capabilities of SSA countries and institutions in response to the significant growth in volume and complexity of international collaborative research conducted in African countries and funded by developed countries in recent decades (Ndebele et al., 2014).

Kruger et al. (2014) in their contribution to a book on 'Research Ethics in Africa' mapped the status of research oversight systems and practices in Africa and reported that the growth in research in Africa had not been complemented by necessary advances in health research oversight systems and functional ethical review committees. A growth in research quantity and complexity requires commensurate growth in ethics review structures and functions in the form of effective and efficient Research Ethics Committees (RECs) as well as supporting policies and regulations. The past decade has seen some initiatives aimed at strengthening the capacity of research ethics committees in Africa. These include funding initiatives like the Fogarty International Center at the National Institutes of Health and the European and Developing Counties Partnerships (EDCTP). However, challenges still persist, thereby leaving the African continent and its citizens vulnerable to exploitative and harmful research (Ndebele

Funding challenges have also been noted elsewhere. Milford et al. (2006) noted that RECs are mainly funded by well-resourced developed countries which allows them to dictate their terms regarding regulatory guidelines as well as oversight requirements.

et al, 2014; Noor, 2009). Some challenges facing RECs in SSA countries include poor resource availability and lack of capacity (Kasule at al., 2016, IJsselmuiden .et.al, 2012). Other studies that have looked at research ethics systems capabilities in African countries have focused on the needs of RECs . These studies have identified various challenges including the shortage of personnel trained in research ethics, and lack of adequate resources to support the work of RECs (Benatar, 2004; Isaakidis et al., 2002; Rugemalila & Kilama, 2001; Singer & Benatar, 2001. Kass et al., 2007; Mielke & Ndebele, 2004; Ikingura, Kruger & Zeleke, 2007; Nyika et al., 2009a,b).

In a programme aimed at mapping RECs in Africa, IJsselmuiden et al (2012), managed to map about 170 RECs across Africa and the majority of the RECs indicated training in research ethics as one of their major needs. This study also recommended that more research was needed focusing on best practices in the funding of African RECs to ensure their sustainability and autonomy from funding arrangements. In 2011, about 40 REC administrators (RECAs) from 21 African countries established the Association of African Research Ethics Committee Administrators (AARECA) during a meeting hosted by COHRED at Kasane, in Botswana (26th - 28th September, 2011). During this meeting, it was noted that the profession of REC administration was still a new one in Africa and there was need for courses that are specifically relevant for the needs of RECAs (COHRED, 2011; Kasule et al.l, 2016).

Funding challenges have also been noted elsewhere. Milford et al. (2006) noted that RECs are mainly funded by well-resourced developed countries which allows them to dictate their terms regarding regulatory guidelines as well as oversight requirements. This is likely to introduce bias in the ethical review process as REC members may have to apply oversight guidelines that are foreign to them in complex environments that have great diversity in culture and traditions, religion, social-economic status and demographic distribution foreign to the funders. Another key area identified was the need to enable all RECs in Africa to acquire online research management systems to bridge the digital divide between the collaborators' RECs and African RECs. This would improve the quality and efficiency of ethics reviews as well as refute the current mentality by the research community that ethical reviews hinder research (IJsselmuiden et al., 2012)

In recognition of the important role that quality and timely ethical review of research plays in safeguarding the dignity, rights, safety and well-being of all actual and potential human research participants and minimizing exploitation, various partners have contributed towards the establishment and capacity strengthening of ethical reviews in Africa. The past two decades have witnessed an increase in the number of graduates trained in research ethics. For example, to date, there have been more than 10 Fogarty International Center (FIC) funded Programs that have specifically targeted research ethics trainees from SSA. By 2012, the various FIC funded programmes had trained a total of about 275 long-term trainees. Interestingly, of the 275 trainees, 72 (26%) were from Nigeria while 76 (27%) were from South Africa. About 160 of the 275 were males as compared to 115 female trainees, showing gender imbalance and the difficulties that women face in terms of taking time off from family and work to pursue further studies (Ndebele et al, 2014). The fact that the majority of trainees from FIC funded programmes were mainly from 2 countries (South Africa and Nigeria), coupled with the fact that there are still RECs and even countries with no trainees, implies that the number of trainees still remains inadequate. To ensure sustainable development, country ownership and collaboration among external partners' ethics and regulatory functions in SSA , the European and Developing Counties Partnerships (EDCTP) has dedicated its efforts to ensure that SSA countries hosting clinical trials have functional , effective ethics and regulatory review structures at institutional, national and regional levels since 2005 to date. There is therefore need for additional training opportunities to be availed for those countries and institutions that still do not have trained personnel.

Specifically, regarding integrity in research and innovation, very llittle is known about the prevalence of, and reasons why research misconduct is occurring in Africa. Except for countries like South Africa (Bedi, 2004), majority of African countries still do not have national policies, guidelines or structures to promote research integrity. The perspectives from African scholars are largely missing in international debates and research on research integrity (Kombe et al, 2014). During the past

few years, there has been an increase in interest in issues around research integrity mainly focusing on research misconduct and how it can be avoided (Adeleye & Adebamowo, 2012; Adesanya, 2020; Van Zyl, 2019; Kombe et al., 2014; Okonta and Rossouw, 2014; Rossouw, Van Zyl & Pope, 2014; Were, Kaguiri & Kipligat, 2020). There have also been a number of reports on research misconduct and other unacceptable practices in Africa including retractions of published papers. Most of these reports centre on fabrication, falsification and plagiarism (Ana et al, 2013; Ballyram & Nienaber, 2019; Horn, 2016, 2017; Kingori and Gerrets, 2016; Mulenga, Jordaan & Mandebvu, 2021; Ngemu et al., 2014; Rohwer, 2018; Singh & Remenyi, 2016). Interestingly, most of the reports are from South Africa. This perhaps can be explained by the fact that South Africa is one of the few countries in Africa with research misconduct policies and research integrity systems at national level (Bedi, 2014; Kanyile et al., 2006).

While performing their various functions, the African SGCs confront a number of ethical and integrity challenges that require attention if they are to meaningfully contribute towards promotion of ethics and integrity in research. The SGCs are major players in the area of research and are well placed to influence ethics and integrity at both national and institutional levels due to the amount of power they hold as government research funding agencies. Against this backdrop, there is the need to strengthen ethics and integrity in research and innovation through strengthening the capacity of the SGCs to ensure adherence to national and international laws and guidelines.

The study which was conducted in preparation for this paper, sought to identify various roles and activities of the SGCs in the implementation of research ethics and integrity in the African context. The lessons from this study may be useful in refining and strengthening ethics and integrity in research and innovation across Africa.

2.0. ETHICAL AND INTEGRITY CHALLENGES FACED BY SGCS:

Among the challenges that the SGCs face includes the ideological conflicts in academic enterprise. The academic enterprise has traditionally treated scientific knowledge as a "public good" since science is mainly funded using public funds (Cervantes & Meissner, 2014;, Downie, 2005; Hensley, Galilee-Belfer & Lee, 2013; Martin & Tang, 2007; Schmiemann & Durvy, 2003). On the other hand, the opposing commercial/ business culture which is growing immensely, treats scientific knowledge as a "private good" that should be used for creating new products and services that can generate profits for the institutions. Globally, a large number of academic organizations have established Research and Commercialization Departments or Units responsible for commercializing research findings. This raises a dilemma for the SGCs since they use government/public funds to support research. Public good advocates are quick to point out that any knowledge so generated should benefit the whole society and that all members of society should have the right to access that knowledge. Organizations and researchers are not spared by the ethical dilemma. The need to commercialize findings negatively impacts on the freedom to publish research findings. It also affects the decisions on the nature of partnerships that organizations and researchers can get into as well as the need for complex contractual agreements that require legal expertise and take time to negotiate.

On the global scene, there have been calls for and adoption of open access publications and open science more generally. Open science has been defined as a set of practices that increase the transparency and accessibility of scientific research (van der Zee & Reich, 2018). Open science aims to bolster scientific research in part by testing the reproducibility and replicability of findings. Open Science is has been touted as having many advantages including reducing delays in the re-use of the results of scientific research including articles and datasets by firms and individuals, and promote a swifter path from research to innovation to produce new products and services. Open science goes against the culture of research and commercialization which promotes secrecy in science (Crüwell et al., 2019; Foster & Deardorff, 2017; Tijssen, 2004). Open science presents various disadvantages for majority of African research organizations that do not have adequate capacities to speed up research. Additionally, Africa's SGCs and researchers and organizations mainly rely on funding from Western funders that are driving the agenda for open science. In some establishments, however, there is still preference for and practice of secrecy in scientific research and innovation.

Regarding the relationship between the SGCs and grantees, the question on controlling the content and dissemination of research products by the former might be raised as a concern (Miller, Moore & Strang, 2006). The

degree to which funding bodies can and do exert control on dissemination of research findings, raises important issues which need to be openly debated by research stakeholders. Current policies relating to censorship and other means of controlling research topics or outputs need to be examined. Some have argued that the regulation of research by funding bodies contravenes the scientific ideal of freedom of information and open access to knowledge (Miller, Moore & Strang, 2006). They have argued that regulation raises concerns in relation to the ethical principle of beneficence, which is embodied in all international ethics guidance documents.

Regarding the relations between the academy and private sector, while some researchers are working for academic institutions that are funded by the SGCs, some of them develop or maintain links with the private sector that may end up diverting or commercializing knowledge gained through publicly funded research for their own benefit (DeAngelis, 2000; Martin & Tang, 2007; Schmiemann & Durvy, 2003). Private companies commonly offer attractive financial rewards to academics in the form of consultancy fees, royalties, equities and others and this in itself creates potential conflicts of interest and commitment. Conflict of interest and commitment policies are now the norm in academic organizations as a way of trying to manage such conflicts (Annane et al., 2019; Bandari et al., 2020). Additionally, the involvement of private sector actors in university business either through faculty positions (adjuncts) or as members in university boards (Councils/ Senate) may lead to demands for reciprocal favours from both sides that may lead to unethical or unprofessional practices in research and innovation (Scinnovent, 2020).

Globally, there are ongoing discussions on ensuring that underrepresented populations are not unnecessarily excluded from research. Marginalization may results from gender, cultural affiliation, race, linguistic group, location, disability or some other characteristics which may be individual or group based (Castillo-Mancilla et al., 2014; Erves et al., 2017; Heller et al., 2014; Kraft & Doerr, 2018; Rogers & Lange, 2013). Women, sexual minorities and minority tribes are often underrepresented in research and innovation in Africa and the world over. The decision to incorporate marginalized groups in society is an ethical question that the SGCs have to grapple with as they promote research. The SGCs should take steps to ensure that the needs of minority groups are prioritized, that members of minority groups participate in research as well as in decisions on research and also that they benefit from research findings. In view of the above challenges, this paper focuses on the role and activities of the SGCs in matters related to ethics and integrity in research and innovation.

3.0. DEFINING ETHICS IN RESEARCH AND INNOVATION:

Research ethics are based on four basic principles: respect for persons, beneficence, nonmaleficence and justice

The advancements in knowledge and technology are a direct result of growth in research and innovation. Some of this research has relied on human beings and animals as participants and subjects, respectively. The use of chemicals and hazardous materials that have negative effects on human being and the environment has also led to expression of concerns. In the past century,

society has become increasingly sensitive to ethical issues associated with research involving human subjects, and especially the risks that research participants are exposed to during the conduct of the research. Particularly, society has become very sensitive to the potential exploitation of research volunteers who make sacrifices by agreeing to participate in research and being placed at the risk of harm for the good of society (Ndebele, 2011). Ethical requirements have therefore been developed to minimize exploitation and harm by ensuring that research participants are not merely used as a means to an end but treated with respect while contributing to the social good. Several events in history have led to the development of these ethical requirements as well as the current drive towards the conduct of ethical research in general (Boulton, 2009; Beauchamp & Childress, 2001). When one discusses the ethical requirements that have been developed by society especially during the past century in

response to the abuses of fellow humans, they are delving into the area of Research Ethics (Steneck, 2007).

Research ethics can be defined as norms for conduct that distinguish between acceptable and unacceptable behaviours in research (Boulton, 2009; Beauchamp & Childress, 2001). Research ethics is about the rights and wrongs in research, values of science and expected standards of conduct in science. Law and ethics are not the same things, although they can overlap. What is demanded or forbidden by law may not be by ethical standards. Morality relates to the rightness or wrongness of behaviours and is based on society or communities' beliefs that some behaviours are right while some are wrong. Many people use the terms ethics and morality interchangeably as they both have to do with the right or wrongness of an action. The difference between morality and ethics is that morality is something that's normative, while ethics defines standards or rules that determine what is "good and bad" for a particular community, group, organisation or social setting. In this module, research ethics refers to standards set for and that apply to the research community.

Research ethics are based on four basic principles: respect for persons, beneficence, nonmaleficence and justice (Boulton, 2009; Beauchamp & Childress, 2001; FHI360, n.d.). In the context of human research, the principle of Respect for Persons incorporates two elements that deal with respecting individuals. The first one requires that people should be treated as autonomous. The term autonomous means that a person should be free to make his or her own decisions about whether to participate in research or not. Researchers are expected to recognize that individuals have the right to make their own decisions about whether to enroll in research or not. In order to ensure that individuals make autonomous decisions, they should be provided with complete and relevant information about a study and decide on their own whether or not to enroll. The second element requires that people with diminished autonomy should be protected. Some people in society do not have the capacity to make fully informed decisions about what they do or what happens to them. This could include young children, those with mental problems, people who are very ill, or those with other social challenges. In such cases, these people should be protected and only be included in research under specific circumstances, since they cannot make a true informed decision on their own. The principle of respect for persons is operationalized through seeking and obtaining of informed consent before involving human beings in research.

The principle of beneficence requires researchers to engage in action that is done for the benefit of research participants and others. The principle of nonmaleficence is simply the opposite of the principle of beneficence and dictates that researchers should do no harm and also remove harm wherever possible (Boulton, 2009; Beauchamp & Childress, 2001). Research should at all times be held for the purpose of discovering new information that would be useful to society. Research should never be performed with the purpose of harming anyone or discovering new information at the expense of other people. In putting these two

principles into practice researchers should seek to maximize benefits for participants and minimize risks for the same participants. Different types of studies presents differing levels of risks or harms to participants and communities. This means that in all research, participants may be exposed to some harms or risks. While it is the primary responsibility for researchers to maximize benefits and minimize harms, research ethics committee (RECs) should check on this during the review of research proposals and continue to monitor the research while it is being implemented.

The principle of justice deals with the concept of fairness. Researchers designing studies should consider what is fair in terms of recruitment of participants and choice of location to conduct a trial (Boulton, 2009; Beauchamp & Childress, 2001). This encompasses issues related to who benefits from research and who bears the risks of research and innovation. This principle provides the framework for thinking about these decisions in ways that are fair and equitable. People who are included in research should not be included merely because they are a population that is easy to access, available, or perhaps vulnerable and less able to refuse participating. The principle of justice also indicates that questions being asked in trials should be of relevance to the communities participating in the study.

While a lot of focus is placed on the use of fellow human beings in research, the area of research ethics also focuses on the welfare of animals that are involved in research. For example, in the drug development process, different types of animals are often used to test new products for safety before introducing these products to humans (Steneck, 2007). Researchers, therefore, need to appreciate the critical role that animals play by handling them humanely, minimising their suffering and using other means of acquiring data on safety. Researchers need to develop new models for safety evaluation that can be used instead of animals. Numerous countries have organisations and laws that address the handling of animals and provide for penalties to individuals and organisations that treat animals with cruelty. Additionally, the area of research ethics has been extended to protection of the environment from harms that can occur as a result of research (Steneck, 2007). Globally, concerns are being expressed regarding the use of materials in research and procedures that are harmful to the environment and to human health, including harmful chemicals and biological organisms. Concerns relate to the potential for such materials to harm staff members working in research laboratories, research participants, the public as well as the general environment. It is crucial for hazardous materials to be handled and used appropriately to ensure that they do not cause harm to the environment, human beings and animals.

4.0. DEFINING INTEGRITY IN RESEARCH AND INNOVATION:

Research integrity touches on the ethos of science and is guided by the rules imposed on the research community by itself. Research integrity is a topic that addresses adherence to ethical principles, national laws, institutional policies and professional standards. All these components are important building blocks for the responsible conduct of research and can be traced back to the past six decades (Ndebele, 2015). Research integrity as a topic mainly gained prominence due to concerns being raised about research misconduct in academic and research institutions as a result of the increased competition in the area of science due to increased government support and the growing need to publish research findings among academics as a way of earning recognition (Ndebele, 2015). Before World War II, little public funding was provided for research and society did not expect much accountability from researchers. However, after the War, public funding increased in America and Europe, and then the public through the elected officials began to pay more attention to the way research was practised. Concerns were raised that some scientists were engaging in fabrication, falsifying data and abusing of research participants in efforts to cut corners during conduct of research.

Concurrently, the atrocities committed by Nazi physicians during the War also resulted in a

Before World War II, little public funding was provided for research and society did not expect much accountability from researchers. However, after the War, public funding increased in America and Europe, and then the public through the elected officials began to pay more attention to the way research was practised.

global call for regulation of research. Concerns about the handling of human and animal subjects emerged, and later issues about research misconduct practices were identified. This led to the development of government regulations and standards.

Research integrity as a discipline, aims at providing a comprehensive framework for scientists on how to how to carry out their work within accepted ethical frameworks as well as following good scientific practice (Steneck, 2007). Research integrity is an essential quality for scientific excellence and sustaining the public's trust of the research enterprise and draws from international guidelines, government regulations, institutional policies, scientific standards and professional codes. In general, it is recognised that there are different cultural and national standards for scientific research, and yet there are certain basic standards and principles which are universally applicable. These are articulated in four basic principles: Honesty in all stages of research; Accountability in all stages of research; Respect for fellow professionals through courtesy and fairness in working with others; and Stewardship in research (Resnik and Shamoo, 2011). Funders (SGCs) and research institutions play a critical role in creating and maintaining a culture that supports research integrity. This is through providing a research environment for promoting responsible conduct of research.

The confidence of society in and the support of research is largely based on public trust and the honesty of the individual researchers and research institutions. Researchers are accountable to society and have the responsibility for creating and fostering research environments that promote integrity in the conduct of research. This also requires the promotion of high ethical and scientific standards and commitment to the continual professional development of researchers. The topic of research integrity discusses the use of honest and verifiable methods in preparing research proposals, conducting research and handling research data. Research integrity also encourages truthfulness in reporting research results and emphasises on adherence to rules, regulations, guidelines, and following commonly accepted professional standards. Research integrity is all about the trustworthiness of research due to its emphasis on the soundness of research methods and the honesty and accuracy of research findings. Responsible conduct of research (RCR) is defined as the practice of scientific research with integrity. For research institutions, integrity is about safeguarding the commitment to creating an environment that promotes responsible behaviour by embracing the standards of excellence, trustworthiness, and justice in the conduct of research by staff and all members associated with an institution. The term 'responsible conduct of research' (RCR) is often used interchangeably with research integrity to refer to a wide range of areas of research compliance, professional conduct, and personal responsibility (Steneck, 2007).

As a result of the immense growth in international collaborative research, research integrity has taken on a global dimension over the past three decades. Furthermore, the research enterprise has become more interdisciplinary and transdisciplinary. It is

common for collaborative research projects to involve investigators, laboratories, and institutions in different countries. Researchers are therefore expected to adhere to international standards that have been developed over the past years to guide research with human and animal subjects (Van Zyl and Rossouw, 2014). These include the Nuremberg Code, the Helsinki Declaration, and the Council for International

Organizations of Medical Sciences guidelines and ICH Good Clinical Practice (ICH-GCP) guidelines (CIOMS, 2016, WMA, 2013, ICH, 1996). These documents have guided the laws, regulations, and guidelines adopted by various countries' research institutions, industries and funding agencies. Another recent international guidance document is the Singapore Statement on research Integrity which is now being used as a template for shaping national and institutional regulations and policies for research integrity

As a result of the immense growth in international collaborative research, research integrity has taken on a global dimension over the past three decades.

5.0. METHODOLOGY:

This paper is based on extensive review and examination of documents such as national policies and regulations as well as SGCs' websites. The document review was complemented by review of peer-reviewed literature on ethics and integrity in research as well as international guidance documents. Online and telephone interviews were also held with SGC representatives and focal persons; individual interviews were held with a few respondents representing target populations and vulnerable groups; Observations were made and anecdotal data collected and used as appropriate. The study was designed to understand the role of the SGCs in promoting ethics and integrity in research in SSA countries that are participating in SGCI-2 namely Kenya, Rwanda, Uganda, Tanzania, Ethiopia, Côte d'Ivoire, Botswana, Burkina Faso, Senegal, Ghana, Zambia, Mozambique, Malawi, Namibia, and Zimbabwe. The paper also includes perspectives from Europe, North America as well as non-SGCI countries (South Africa and Nigeria) as points of comparison and sources of lessons for the SGCI.

6.0.KEY QUESTIONS ADDRESSED IN THIS PAPER:

In order to enhance the role of the SGCs in ethics and integrity in research and innovation, and in support of the STISA 2024, the Science Granting Councils Initiative commissioned this paper to explore issues related to ethics and integrity in research and innovation and to propose good practices from around the world. In particular, the study on which this paper was based, sought to address the following key questions:

- At the national/ Councils level, what are the guidelines for ethics and integrity in research and innovation? Do the Councils have ethical guidelines for their grantees? How do such guidelines (where they exist) address the key ethics and integrity issues? How are these guidelines aligned (or not) with national research and STI policies?
- Are there specific ethics and integrity issues that are peculiar to collaborative research (collaborations with private sector, cross-country collaborations? How are these issues managed?
- At the funders level how do the policies and guidelines on ethics and integrity affect their relationships with grantees?
- What can the Councils learn from the funders "good practices" and experiences?
- At the research level, how are issues of ethics and integrity captured and implemented? What are the practical experiences SGCI managers in handling ethics and integrity issues?
- How are the institutional policies on research, innovation, commercialization and valorization facilitated or hindered by practical requirements of ethics and integrity?

- What are the views, perspectives and experiences of individual researchers and grantees? How do the issues affect their promotions and career opportunities; freedoms and choices on publications, innovation, networks etc.?
- What are the experiences of the business community and implications for public – private partnerships (PPPs). How do the issues affect technology transfer and knowledge exchange; participation in university programmes such as boards of management; faculty appointments; course accreditation etc.?
- How are issues relating to ethics and integrity handled for rapid research? Are there guidelines? Are there any lessons that can be gleaned from funding research during the covid-19 pandemic?
- What are perspectives of SGCs on gender and other marginalized/excluded groups? How could the Councils ensure more direct and intentional approaches to gender and inclusivity in research and innovation?

7.0. KEY FINDINGS ON THE STATUS OF ETHICS AND INTEGRITY IN RESEARCH AND INNOVATION:

The scoping exercise that was implemented has revealed variations among the 15 SGCs in terms of how involved they are in promoting ethics and integrity in research. Several factors may contribute to these variations including how each SGC was established. We observed that SGCs that were established as semi-autonomous entities have more research ethics and integrity related activities compared to those that operate within government ministries or Departments. Where SGCs operate as semi-autonomous bodies, they have more control on research related activities and have a more holistic picture of the research and innovation enterprise compared to those which are based in government departments and hence give attention to issues relating to ethics and integrity. The availability of officers/ staff or board members with expertise in the areas of Research Ethics and Integrity also matters. SGCs with officers or board members who have received training in research ethics and integrity are more likely to engage in more ethics and integrity activities.

Overall, from the review of the 15 SGCs, SGCI funders and various regional initiatives, we were able to identify various

activities and strategies aimed at promoting research ethics and integrity in research and innovation. Here we describe some of these strategies and activities:

Research Ethics: In all 15 countries under review, there are structures that address research ethics as evidenced by the existence of RECs in all 15 countries and regulations as well as national guidance documents in some. The development of RECs is at varying levels with some having complex accreditation systems while others have unregulated RECs. In Appendix 1, we present a list of national regulations and guidelines from the 15 SGCI countries. On the African continent, Nigeria and South Africa serve as role models as they have regulations that require the establishment and accreditation/registration of RECs in institutions that conduct human research. Across Africa in general, the research ethics landscape has been driven and shaped by developments in the area of health research. There is more attention to ethical issues for health/medical research than is the case with other forms of research (e.g. humanities, business, psychology, agriculture, engineering, social science among others). This is however not the case with a few countries that require that all human research be reviewed by a recognized REC. Examples include Malawi and South Africa.

Some SGCs have policies and guidelines that specifically address research ethics while others address research ethics issues in general research policies. In some of the policies and guidelines, some of the SGCs clearly endorse international guidance documents such as Declaration of Helsinki, CIOMS and GCP. Some SGCs such as those from Malawi, Uganda and Zimbabwe, are directly responsible for providing oversight over the RECs in those countries and work closely with the RECs including accreditation/registration. Some SGCs include research ethics content in their calls for proposals and they have clearly stated that proof of ethics approval is required before release of funding. Some have reviewers' checklists that address ethics issues such as benefits for participants, reducing harms and informed consent and justice in selection of participants and communities. Some SGCs provide proposal templates that capture some content on research ethics issues. Some SGCs require that an individual who has received recognized training in Research ethics (often referred to as ethicists) be part of the review process. Other funding agencies have RECs that review grant applications after initial review by Scientific Review Committees. The SGCI funders could serve as role models as they have advanced activities and structures related to research ethics and integrity.

Research Integrity – This remains an area of weakness for the majority of the SGCI-2 countries. The following countries were identified as having guidelines that clearly address research integrity issues though mainly focusing on conduct of clinical trials: Botswana, Ghana, Zambia and Zimbabwe. South Africa could serve as a role model as it has regulations that address issues of research misconduct. South Africa's National Research Foundation (NRF) has some guidance as well as policy on research integrity. Specifically,

the NRF endorses the Singapore statement on Research Integrity. The African Academy of Sciences (AAS) could also serve as a role model as it has a clear policy that addresses research integrity and applies to all applying for grants. The policy addresses issues such as research misconduct as well as research non-compliance. Issues of conflict of interest as well as conflict of commitment are being addressed by a few SGCs. This is an area that could benefit from additional attention to avoid scandals.

Gender and inclusion of underrepresented minorities. There were variations in terms of how the SGCs address issues of gender and underrepresented minorities. Some SGCs have appointed significant numbers of women on the SGC boards and within senior staff positions. Others such as the South African NRF, highlight issues of gender and underrepresented minorities in grant calls, application guidance as well as in the checklists that are used for judging research grant applications. In the case of NRF for example, an applicant receives additional points for including black, disabled and tribal minorities as senior team members. Some points are also awarded for plans to groom junior scientists from these underrepresented groups. Some funders and SGCs have also created specific programmes that promote issues affecting women and minority groups. The San people of Southern Africa have taken steps to ensure that they are included in research. In 2017, the San Council, a group of leaders who represent the San peoples in Southern Africa published the San Code of Research Ethics, which requires all researchers intending to engage with San communities to commit to four central values, namely fairness, respect, care and honesty, and to comply with a simple process of community approval. This is the first ethics code developed and launched by an indigenous population in Africa. Key to this achievement were: dedicated San leaders of integrity, supportive NGOs, legal assistance and long-term research collaborations with key individuals who undertook fund-raising and provided strategic support (Schroeder at al., 2019).

Research involving animals: Animal experimentation is common in Africa as evidenced by numerous publications based on research involving animals, and yet the region has not accorded adequate priority towards animal protection (Kimwele, Matheka & Ferdowsian, 2011; Nyika, 2009)). This is an area of weakness for the majority of SGCI countries. In all selected countries, there are established bodies with a mandate to provide oversight over the care of animals. These bodies are however not involved in issues around animal research. South Africa serves as a role model for all other SGCs as it has some regulations that mandate the establishment of animal care and use committees that review animal research before data can be collected from animals (Mohr, 2013). In Zimbabwe and Botswana, these committees are still in their infancy and collaboration with SGCs is yet to be strengthened.

Research that raises biosafety concerns. The 15 countries under review have variations in terms of the development of oversight for research that raises biosafety concerns. Role models include Malawi and Zimbabwe where the SGCs work closely with the national biosafety bodies. In these two countries, the SGCs drove the processes that led to the establishment of the biosafety regulating bodies. These regulators are responsible for reviewing and monitoring research involving genetically modified organisms (GMOs) as well as hazardous materials.

Rapid review of research during infectious diseases outbreaks and emergencies: The coronavirus disease 2019 (COVID-19) outbreak has exposed unique ethical dilemmas in conducting research during infectious diseases outbreaks. In order to develop interventions, all research stakeholders have an ethical obligation to promote swift learning that can enable development of effective health policies, drugs and vaccines through research and ensure that this is done without delay. Protocols can be developed to ensure accelerated ethics review without undermining basic ethical principles of beneficence, respect for persons and justice. There are various initiatives that are aimed at ensuring rapid reviews including African Vaccine Regulatory Forum (AVAREF). By bringing together drug regulators and RECs, AVAREF promotes synchronous review by the two important players in clinical trial oversight. AVAREF has also shared standard operating procedures and other tools for facilitating joint reviews by countries hosting the same trial. One option that has also been proposed is to authorize the advance review of generic protocols for conducting research,

The coronavirus disease 2019 (COVID-19) outbreak has exposed unique ethical dilemmas in conducting research during infectious diseases outbreaks.

which can then be rapidly adapted and reviewed (WHO, 2016). There is need for preparedness policies like harmonized ethics review through collaborations so that research, especially clinical trials, can be done without delay. WHO has issued *"Ethical standards for research during public health emergencies: distilling existing guidance to support COVID-19 research and development (WHO, 2020). WHO is currently supporting efforts aimed at development of "*Recommendations for Ethics Committees (IECs/IRBs) When Reviewing Vaccine Clinical Trials During a Public Health Emergency" (Covid-19 CRC, n.d.). RECs and interested parties are participating in the process of development of these guidelines and representatives from various RECs in the selected countries have provided feedback.

Oversight for international collaborative research: There is variation in how international collaborative research is handled. In Zimbabwe, Uganda, and Malawi, projects involving international collaborations require the approval of the REC as well as that of the SGC. This is the same for Malawi. For Botswana they require the approval of relevant government ministries or departments. The shipment of research specimens in Zimbabwe is also regulated by the SGCs who issue permits.

8.0. SPECIFIC RECOMMENDATIONS FOR KEY ACTORS:

The above main findings have implications for the Science Granting Councils Initiative (SGCI) as a whole as well as for the SGCs as entities participating in the Initiative. Some of the findings have implications for other players including RECs, researchers, research institutions, government ministries and others. Since this paper is focusing on the SGCI, recommendations that are put forward in this paper are confined to SGCI and SGCs.

8.1. SPECIFIC RECOMMENDATIONS FOR THE SGCI:

Based on the above overall findings, the following recommendations that specifically relate to the SGCI, are put forward:

1. SGCI should establish a programme on Ethical and Responsible Research to fund research projects that (1) aim at strengthening research ethics and integrity in countries (2) identify factors that are effective in the formation of ethical researchers and approaches to developing those factors in all fields that SGCs support.
2. The SGCI should commission another study at the end of the program to re-assess the roles and activities of SGCs related to ethics and integrity in research and innovation.
3. AAU and AAS should work with AAU/NEPAD to influence the ethics and integrity landscape across Africa. The two organizations could advocate for the development of model laws on ethics and integrity that can be cascaded to all African countries.

8.2. SPECIFIC RECOMMENDATIONS FOR SGCs:

Based on the above overall findings, the following recommendations that specifically relate to the SGCs, are put forward:

1. In countries where there are no specific laws that mandate ethics review of research, the SGCs should facilitate or influence the development of such laws.
2. The SGCs should facilitate or influence the development or revision of national research policies to ensure that they address the following issues:

- Human research participant's protection: Should focus on the operationalisation of the ethical principles.
- Gender issues – Focusing on ensuring that women and other groups that are adequately represented in research
- Inclusion of minorities and other underrepresented groups in research: Focusing on ensuring unnecessary exclusion and promoting their inclusion.
- Animal welfare: Focusing on improving animal welfare and avoidance of unnecessary suffering.
- Environmental protection: Focusing on preventing damage to the environment
- Publication practices and responsible authorship: Focusing on promoting responsible publication practices and avoiding unacceptable publication practices
- Peer review: Focusing on avoidance or minimisation of bias through the use of peer review processes.
- Collaborative research : Focusing on promoting fair collaborations that represent wins for all parties involved.
- Conflict of interest and commitment: Focusing on disclosure and management of conflicts of interest.
- Mentoring: Focusing on promoting mentoring of junior scientists by seniors
- Data acquisition, management, sharing and ownership: Focusing on confidentiality and fairness in sharing of data.
- Research misconduct: Focusing on steps to prevent and address research misconduct.

3. The SGCs should enhance their roles in promoting ethics and integrity in research and innovation and have the following as part of their efforts:

- Codes and policies on ethics and integrity.
- Specific committees or experts to review protocols/proposals of studies involving humans, biosafety concerns and animals.
- Gender balanced boards/committees and requirements for promoting inclusion of underrepresented minorities.
- Procedures for reporting and investigating allegations of research misconduct.
- Procedures for ensuring that grantees comply with national regulations, policies and international ethical and professional standards in conducting their research.
- Procedures to ensure that grantees follow laboratory safety rules and established practices for the responsible use of hazardous materials are enforced.
- Procedures to ensure that grantees follow accepted international rules and established practices for the responsible use of animals in research are enforced.

- Training for all researchers in ethics and research integrity and mechanisms for ensuring that they are aware of the relevant codes and policies.

4. The SGCs should require that all beneficiary institutions have the above as part of efforts to promote ethics and integrity in research.
5. The SGCs should designate Research Integrity Officers who will be responsible for coordinating ethics and integrity issues.
6. The SGCs should require that all institutions that receive funding from SGCs and other government agencies, designate research integrity officers who will be responsible for coordinating ethics and integrity issues within the institutions. The integrity officers will also serve as contact persons on all matters concerning ethics and integrity including reporting research misconduct and noncompliance issues.
7. The SGCs should update their websites to include documents that are relevant for ethics and integrity in research and innovation. These documents include:

- Copies of institutional research policies and guidance documents
- Links to relevant national government legislations and policies
- Relevant forms and instructions for completion
- Links to ethics and integrity training programmes
- Contact information for relevant personnel that deal with ethics and integrity issues (also commonly referred to as the designated institutional research integrity officer)

8. The SGCs should take concrete steps aimed at addressing gender issues as well as the inclusion of minority groups in research. These steps should be reported to SGCI during annual reporting.
9. 9.The SGCs should play a facilitatory role in promoting harmonization of REC reviews as well as the use of online platforms that allow RECs to continue working even during "stay at home" periods.

9.0 INTERNATIONAL GUIDANCE DOCUMENTS ON ETHICS IN RESEARCH AND INNOVATION:

In this section, a summary is presented of the various international guidance documents that relate to ethics in research and innovation:

Universal Declaration on Human Rights: After the lessons learnt during the Nuremberg Trials, there were numerous responses. One of the major responses was from the United Nations, which came up with the UN Universal Declaration on Human Rights which makes it clear that individuals cannot be forced to participate in research (Govern, 2017).

Declaration of Helsinki: As an additional response, the World Medical Assembly (WMA) decided to come up with a code of ethics to guide medical doctors in their research activities involving their patients. This decision culminated in the Declaration of Helsinki in 1964. The Declaration has undergone several revisions and the current version was issued in 2013 (WMA, 2013).

CIOMS Guidelines: The Council of International Organisations in the Medical Sciences (CIOMS) in collaboration with the World Health Organization (WHO) came up with guidelines for epidemiological research involving human subjects in 1982 as a way of filling the gaps left by the Declaration of Helsinki. The CIOMS Guidelines were meant to cover all kinds of biomedical research and also address the growth in research funded by rich countries and conducted in developing countries (CIOMS, 2016).

ICH-GCP Guidelines: GCP is an international quality assurance standard that was developed by the International Conference on Harmonisation (ICH). The ICH is an international

body that has assumed the responsibility of defining standards, that governments can utilise in developing regulations for clinical trials involving human subjects. The ICH started its work in 1990 as a joint initiative by regulatory authorities in Europe, Japan and the US to develop a single set of guidelines on good practices in clinical trials to ensure that data generated from clinical trials conducted in these countries would be mutually acceptable. Adherence to GCP standards thus enables more efficient licensing of new drugs in countries which endorse and follow the standards. Since 1996 when the first version of GCP was issued, GCP has now grown to be internationally accepted as a global standard that aims for the protection of the safety, rights and welfare of research participants while at the same time assuring quality and credibility of data (ICH-GCP, 1996, 2010).

Good Clinical Practice Guidelines describe standards and processes on how clinical trials should be conducted. It outlines the roles and responsibilities of study sponsors, study investigators, and study monitors. In the drug development industry, monitors are often called Clinical research associates (ICH-GCP, 1996). Over the past years, some governments have adopted GCP into their laws as a way of domesticating GCP requirements to ensure that they become binding to researchers. In addition, there are also other useful guidance documents including Good Laboratory Practice (GLP), which aims at providing guidance relating to laboratory aspects of clinical trials. While GCP guidelines were developed in the context of clinical research, most of the principles are relevant for research in any discipline as they can be generalised. ICH- GCP addresses both issues of ethics and integrity in research and innovation.

Standards and operational guidance for ethics review of health-related research with human participants (WHO, 2012): This document is aimed at providing guidance to research ethics committees and provides guidance on how RECs should be established, how they should operate, how they should review research proposals and how they should provide ongoing oversight of approved projects. The document presents some basic standards, which if followed, can result in improvements in the operations and reviews performed by RECs (WHO, 2012).

Ethical standards for research during public health emergencies (WHO, 2020): By issuing this guidance document, the World Health Organisation (WHO) has acknowledged that there is an ethical imperative to conduct research during public health emergencies, as some research questions can be adequately investigated only in emergency contexts. Based on lessons learned from the 2003 outbreak of the Severe Acute Respiratory Syndrome (SARS), the 2009-2010 H1N1 influenza pandemic, and the 2014-2016 Ebola outbreak in West Africa, WHO has developed some guidance on how to conduct ethical research during emergencies. This new document was issued in 2020 in order to ensure ethical research during the COVID-19 outbreak. The document summarizes the key universal ethical standards that should be adhered to by researchers, review bodies, funders, publishers, and manufacturers during an emergency (WHO, 2020).

10.0 INTERNATIONAL GUIDANCE DOCUMENTS AND INITIATIVES ON INTEGRITY IN RESEARCH AND INNOVATION:

The following international guidance documents as well as initiatives are relevant for SGCs and can serve as basic standards in integrity in research and innovation:

The Singapore Statement on Research Integrity (2010): The Singapore Statement was produced through the second World Congress on Research Integrity, which was held in Singapore in 2010. The statement as well as the principles and responsibilities that it set represents the first international attempt to promote the development of unified guidelines aimed at fostering greater integrity in research globally (Resnik & Shamoo, 2009). About 340 conference participants from about 51 countries participated in the 2nd World Conference on Research Integrity that led to the Singapore Statement. The participants represented various stakeholders including research funders, research managers, scientists, leaders of research institutions (universities and research institutes) and journal editors. The statement was developed through a process involving two stages. A small drafting committee appointed as part of preparations for the conference came up with a draft statement which was then presented to the Conference for consideration. The small committee further refined the draft for release after obtaining endorsement by the conference (World Conference on Research Integrity, 2010).

The Singapore Statement highlights the following expectations concerning researchers and other research players.

- **Integrity in research:** Researchers and research team members are expected to take responsibility for the trustworthiness of their research, inclusive of data collection procedures and results. This translates into good research designs and appropriate data collection and management methods. This expectation aims at ensuring accountability in research.
- **Adherence to regulations:** Researchers and their team members should be aware of and comply with national regulations and institutional policies related to research. This expectation is also applicable to institutional leaders who also need to take steps to ensure that researchers are kept up to date concerning national regulations and institutional policies.
- **Research methods:** Researchers and all members of their teams are expected to adopt appropriate research designs and methods, draw conclusions from critical analysis of the data and report study findings and their interpretations thoroughly and in an objective manner. This expectation is aimed at ensuring that researchers are adequately trained in proposing research,

collecting data, managing data, manuscript writing and other relevant areas.

- **Research records:** Researchers and their team members are expected to keep legible and accurate records of all research activities to allow for verification and reproducibility or replication of their research by others. This expectation is aimed at ensuring that researchers use the right standards when correcting data and have access to adequate record storage facilities. Institutional leaders can play an essential role in ensuring that this requirement is complied with.
- **Research findings:** Researchers and their team members are expected to share data and results in a timely manner promptly, as soon as they secured intellectual property rights. This expectation ensures that research findings are disseminated to the appropriate users and are adopted for the benefit of society. The expectation also seeks to protect the ownership rights of investigators and institutions in accordance with institutional and national requirements.
- **Authorship:** Researchers and their team members are expected to appropriately and fairly assume responsibility for their contributions to all publications, funding proposals, research reports and other presentations of their research. This expectation addresses unacceptable authorship practices. This is an area that is presently receiving attention in academic institutions due to the pressure to publish.
- **Publication acknowledgement:** Investigators should acknowledge in their publications, the names of all those individuals and organisations that who would have made significant contributions to the research, including listing the roles they would have played. These parties may include writers, funders, sponsors, and others, who may not meet authorship criteria. This expectation addresses practices such as ghost and gift authorship which are among some of the unacceptable authorship practices. The expectation addresses the question of who an author should be and who should be acknowledged.
- **Peer review:** Peer reviewers of research are expected to provide fair and rigorous reviews in a timely manner. Peer reviewers are also expected to maintain confidentiality when reviewing other scientists' work. This is important in ensuring that a peer-review process remains fair, objective and useful in strengthening research.
- **Conflict of interest:** Study investigators are expected to disclose financial and other conflicts of interest that have potential to introduce bias which may compromise the trustworthiness of their work, including in research proposals, publications and other outputs. Additionally where conflicts of interest are identified, management plans should be put in place for managing those conflicts.
- **Public communication:** Investigators are required to only comment on research in their areas of expertise when they are engaging in public discussions about the application and importance of research findings. When commenting, researchers should also distinguish clearly their professional comments from opinions that are based on their personal views. Scientists

are expected to maintain professionalism and recognise the limits that are placed on their capabilities by specialising in one area of expertise.

- **Reporting irresponsible research practices:** Scientists and research leaders are expected to report to relevant authorities any suspected research misconduct as well as noncompliance. This includes plagiarism, fabrication, falsification, and other unacceptable research practices that undermine the trustworthiness of research. The reporting of alleged misconduct is an important part of self-regulation of the scientific enterprise by fellow scientists who may serve as whistle-blowers.
- **Responding to irresponsible research practices:** Research institutions, research oversight bodies, journals, professional organisations and research funding agencies should have procedures for timely responding to allegations of misconduct and other unacceptable research practices. These parties should also come up with procedures for ensuring that whistle-blowers who report allegations in good faith are not victimized. Whenever irresponsible practices are confirmed, it is important that appropriate actions are taken speedily, including putting in place corrective measures as well as measures to ensure that similar events do not recur in future. Journal editors and institutional leaders have an important role in addressing allegations of research misconduct.
- **Research environments:** Academic and Research institutions should create and sustain environments that promote research integrity. This can be achieved through relevant policies, training programs, education, and setting of reasonable standards and structures that support research integrity. Institutions provide a home for the scientists and hence they need to provide oversight over as noncompliance and misconduct may tarnish institutional reputations.
- **Societal considerations:** Research institutions and scientists should recognise that they both have an ethical obligation to maximise benefits and minimise harms to individual, society, the environment and animals in their work. This expectation takes cognisance of the fact that research institutions are entrusted with the responsibility of using public funds and that research should be aimed at advancing the public good.

Researchers and their team members are expected to keep legible and accurate records of all research activities to allow for verification and reproducibility or replication of their research by others.

In these expectations, the Singapore Statement addresses various players involved in a research enterprise and lays out the responsibilities of each party (World Conference on Research Integrity, 2010).

Responsible Conduct of Research (RCR): The area of responsible conduct of research covers about ten domains including data management, mentoring of juniors, avoidance of research misconduct, peer review, appropriate handling of animal subjects, appropriate publication and authorship practices, protection of human participants in research, managing conflict of interest, appropriate practices in collaborative research; and environmental health and safety issues"

(Steneck, 2007). Training in RCR is required by major funders including the National Science Foundation as well as the National Institutes of Health (NIH) in USA. Institutions that benefit from funding from these agencies are required to establish some training programmes for their investigators and research team.

11.0 CASE STUDIES: USEFUL LESSONS FROM OTHER NON-AFRICAN ORGANISATIONS:

As part of the study, practices in other organizations involved in funding or coordinating research outside Africa were reviewed and lessons drawn for the purpose of sharing with SGCI partners:

The Case of National Science Foundation (USA): Creation of special programs focusing on Ethics and Integrity: In recognition of the importance of focusing on ethics and integrity in research and innovation, some SGCs from other continents have established special programs focusing on ethics and integrity. For example, the US National Science Foundation has established the Ethical and Responsible Research program (ER2) which funds research projects that identify factors that are effective in the formation of ethical STEM researchers and approaches to developing those factors in all STEM fields that NSF supports. The program solicits proposals for research that explores questions such as what constitutes responsible conduct for research (RCR), and which cultural and institutional contexts promote ethical STEM research and practice and why? Do certain labs have a 'culture of academic integrity? What practices contribute to the establishment and maintenance of ethical cultures and how can these practices be transferred, extended to, and integrated into other research and learning settings? ER2 research projects will use basic research to produce knowledge about what constitutes or promotes responsible or irresponsible conduct of research, and how to best instill this knowledge into researchers and educators at all career stages. In some cases, projects will include the development of interventions to ensure ethical and responsible research conduct. The program also makes specific awards to minority and women's colleges as well as organizations primarily serving persons with disabilities (NSF, n.d.)

The case of UK Economic and Social Research Council: Development of a Research Ethics Framework: The Research Ethics Framework that sets out good practice for social science research, detailing principles and expectations from researchers, research organizations (ROs) and research ethics committees (RECs). It outlines six key principles for ethical research:

- research should aim to maximize benefit for individuals and society and minimize risk and harm;
- the rights and dignity of individuals and groups should be respected
- ▪wherever possible, participation should be voluntary and appropriately informed
- research should be conducted with integrity and transparency
- lines of responsibility and accountability should be clearly defined
- independence of research should be maintained and where conflicts of interest cannot be avoided they should be made explicit.

The framework requires that researchers, research organizations and RECs should consider ethics issues throughout the lifecycle of a research project and promote a culture of ethical reflection, debate and mutual learning. The lifecycle of research includes the planning and research design stage, the period of funding for the project, and all activities that relate to the project up to - and including - the time when funding has ended. This includes knowledge exchange and impact activities, the dissemination process - including reporting and publication - and the archiving, future use, sharing and linking of data. The Framework is complementary to the policy and guidelines for good research conduct of the organization (UKRI, n.d.).

The case of the European Code of Conduct for Research Integrity: As the title suggests, this document specifically serves the European research community as a framework for self-regulation across all scientific and scholarly disciplines and for all research settings. It has been included in this paper in order to demonstrate the possibility of having a region-wide code. The code addresses emerging challenges emanating from technological developments, open science, citizen science and social media, among other areas. The European Commission recognizes the Code as the reference document for research integrity for all EU-funded research projects and as a model for organizations and researchers across Europe. The Code was published originally in English and was translated to all official EU languages. The document describes good research practices in the following contexts: Research Environment, Training, Supervision and Mentoring, Research Procedures, Safeguards, Data Practices and Management, Collaborative Working, Publication and Dissemination, Reviewing, Evaluating and Editing (Allea, 2017).

12.0 CASE STUDIES: SOME LESSONS FROM SGCI FUNDERS ON THEIR ROLES IN PROMOTING ETHICS AND INTEGRITY IN RESEARCH:

There are some lessons on both ethics and integrity that can be gleaned from selected SGCI funders:

The Case of the South African National Research Fund (NRF): :There are numerous lessons that can be learned from the NRF, one of the SGCI funders on ethics and integrity in research and innovation including the following:

- In South Africa, research ethics issues fall under the National Health Research Ethics Council (NHREC) which is a statutory body established under the National Health Act No 61 of 2003. The Act mandates the Minister of Health to establish the Council and it sets out NHREC. One of the main functions of NHREC is to develop guidelines for the conduct of research involving humans and animals. All human research undertaken in South Africa must be reviewed and approved by an REC registered with the National Health Research Ethics Council (NHREC) (Department of Health, South Africa, 2004, 2015).
- NRF has issued a "Statement on Ethical Research and Scholarly Publishing Practices" and the policy is available on the NRF website. The Statement was jointly issued by the Academy of Science of South Africa (ASSAf), the Council for Higher Education (CHE), the National Research Foundation (NRF), the Department of Higher Education and Training (DHET) and Universities South Africa (USAf) in 2019. The Statement endorses the Singapore Statement on Research Integrity in 2010
- Various guidance documents issued by NRF South Africa make it clear that Ethical Clearance is required. Regarding ethical clearance, NRF clearly states that ethical clearance It is the responsibility of the grant holder, in conjunction with the institution, to ensure that all research activities carried out in or outside South Africa comply with the laws and regulations of South Africa and/ or the foreign country in which the research activities are conducted. These include all human and animal subjects, copyright and intellectual property protection, and other regulations or laws, as appropriate. A research ethics committee must review and approve the ethical and academic rigor of all research prior to the commencement of the research and acceptance of the grant. The awarded amount will not be released for payment if a copy of the required ethical clearance certificate, as indicated in the application, is not attached to the Conditions of Grant.
- NRF requires a plan on data management and dissemination as well as utilization of findings as part of the grant application package

- Disability, Race and Gender is factored into the score card and contributes 10%
- There is a research grant scheme available for Blacks through the Black Academics Advancement Programme (BAAP).
- Reviewers sign a confidentiality agreement and conflict of interest form before reviewing any proposals.
- Regarding intellectual property, NRF clearly states that the researchers of each country, particularly the leaders, must take adequate steps to ensure protection and sharing of the intellectual property that could result from the joint projects. (SA NRF, n.d.).
- Institutions that handle funds awarded by NRF, have designated research integrity officers who are responsible for coordinating ethics and integrity issues in research and innovation.

The case of International Development Research Centre (IDRC): There are numerous lessons that can be learned from the IDRC, one of the SGCI funders on ethics and integrity in research and innovation including the following (IDRC, n.d.):

- The National Council on Ethics in Human Research (NCEHR) has the mandate extending to all research involving humans. Its mission is the advancement of the protection and well-being of human participants in research and fostering high ethical standards for the conduct of research involving humans.
- In Canada all research involving humans is required to comply with Canada's Tri-Council Policy Statement: Ethical conduct for research involving humans.
- Issues on animal research: One Health Research Initiative on Epidemics was implemented to identify, implement, and assess potential innovations in policies, programs, or practices that can prevent, control, and mitigate the risks of emerging epidemic threats.
- In Calls for proposals regarding research ethics, IDRC states that it is the policy of IDRC that research work involving human participants be carried out in accordance with high ethical standards.
- Prior to commencing research, applicants may need to obtain approval from an official institutional or national research ethics body and will need to comply with the terms and conditions of the Grant agreement.
- In contexts where there is no official institutional or national research ethics body, the application will propose setting up of an ethics committee for the project. After approval of the project by IDRC, successful organizations are expected to submit the ethics and security protocols to IDRC.
- IDRC's Equality Statement IDRC strives for equality in all aspects of its work. We support the generation of knowledge – including by individuals from diverse genders, communities, histories, and experiences – that tackles the systems that perpetuate inequalities on the basis of identity.
- Inclusion and equality: IDRC strives for equality in all aspects of its work. We support the generation of knowledge – including by individuals from diverse genders, communities, histories, and experiences – that tackles the systems that perpetuate inequalities on the basis of identity.

- Inclusion and inequality: IDRC acknowledges that inequalities exist across multiple and intersecting categories of identity, including, but not limited to: gender, sexuality, age, class, race, caste, ethnicity, citizenship status, religion, and ability; taking an intersectional approach to equality recognizes these differences and understands diversity as central to advancing equality. Given that gender inequality is a significant barrier across all dimensions of diversity, IDRC invests specific efforts in ensuring its work promotes gender equality.

- Inclusion and Inequality: Proposals should demonstrate how they will promote diversity and inclusion and adopt an intersectional approach, both in respect to team composition and organizations comprising the research team and the research design, throughout the research process.
- Gender Analysis: IDRC expects a clear integration of gender analysis in the research design, implementation, and analysis of findings, as well as the policy/ program uptake strategy.
- Conflict of interest: In submitting an application, the applicant must avoid any real, apparent or potential conflict of interest and will declare to IDRC any such conflict of interest. If any real, apparent, or potential conflict of interest cannot be resolved to IDRC's satisfaction, IDRC will have the right to immediately reject the applicant from consideration.
- Open access: IDRC's approach to open access is based on the belief that the full social and economic benefits of research in support of development should be available to everyone who can use and build on it to improve people's lives. Applicants must be committed to publishing research findings in the public domain in accordance with IDRC's Open Access Policy.
- Policy/program uptake strategy: Proposals should have clear plans for uptake and capacity to generate program- and policy-relevant outputs in line with the context of the country of study.
- Intellectual property rights agreement: Project inventions resulting from project activities funded by the Centre are governed by the Intellectual Property Rights Agreement signed between IDRC and the recipient. Recipients are obligated to report any inventions to the Centre and must enter into an agreement with IDRC in the event an invention is created.

13.0 CASE STUDIES: REGIONAL INITIATIVES/ ORGANISATIONS PROMOTING ETHICS AND INTEGRITY IN RESEARCH:

Across Africa, there are some initiatives focusing on research ethics and integrity. In this section, we describe a few that are operating in Sub-Saharan Africa with the hope that SGCs and RECs may take full advantage of these initiatives:

European & Developing Countries Clinical Trials Partnership (EDCTP: The European & Developing Countries Clinical Trials Partnership (EDCTP) is a public-public partnership between countries in Europe and sub-Saharan Africa, supported by the European Union. EDCTP was established with the main aim of accelerating the clinical development of new or improved medicinal products for the identification, treatment and prevention of poverty-related infectious diseases, including (re-)emerging diseases. Our approach integrates support for research with the development of clinical research capacity in sub-Saharan Africa. Related to ethics and integrity, EDCTP has to date supported regulatory and ethics review committees drug regulatory authorities. EDCTP has since 2003 awarded 45 grants aimed at building capacity where ethics committee do not exist, improving the efficiency of ethics review by strengthen research oversight, increasing public awareness of research ethics review and regulatory oversight of clinical trials; and improving compliance of legal frameworks for national ethics committee and national regulatory authorities with International Standards. About 14 of the 15 countries represented in SGCI-2 reported have received funding to build ethics and regulatory capacities. Côte d'Ivoire is reported as one country that data on current ethics and regulatory funding could not be established. EDCTP also supported the establishment and maintenance of the Pan Africa Clinical Trials Registry (EDCTP, n.d.).

African Medicines Regulatory Harmonization (AMRH) Initiative: The African Medicines Regulatory Harmonization (AMRH) was established to ensure that African people have access to safe essential medical products and technologies. AMRH was created to provide leadership across Africa in creating an enabling regulatory environment for pharmaceutical sector development in Africa. AMRH is a programme of the African Union (AU) implemented as part of the Pharmaceutical Manufacturing Plan for Africa (PMPA). Under the theme "Strengthening of Health Systems for Equity and Development in Africa", the AU Conference of Health Ministers (AUCHM) in April 2007 responded to the AU Assembly Decision 55 (Assembly/AU/Dec.55 (IV) taken during the Abuja Summit in January 2005 which mandated the African Union Commission (AUC) to develop the PMPA within the framework of the NEPAD. The programme started in 2009 as a response to addressing challenges faced by National

Medicine Regulatory Authorities (NMRAs) in Africa. These challenges include; weak or non-coherent legislative frameworks, redundant/ duplicative processes, sluggish medicine registration processes and subsequent delayed decision, inefficiency and limited technical capacity, among others. The work of AMRH is guided by three focus areas: policy alignment, regional integration and harmonization, and human and institutional capacity development. The programme works in collaboration with the AUC, Pan-African Parliament (PAP), World Health Organization (WHO), Bill and Melinda Gates Foundation, World Bank (WB), UK Department for International Development (DFID) and US Government-PEPFAR and Global Alliance for Vaccines and Immunization (GAVI). The AMRH Strategic Plan defines the strategic direction for the medicines harmonization agenda in Africa and provides direction to advance the development of the pharmaceutical sector and provides guidance in monitoring and evaluation (AUDA-NEPAD, n.d).

ZaZiBoNa Initiative: The Zambia, Zimbabwe, Botswana, Namibia Initiative (ZAZIBONA) is a successful regional work-sharing initiative for drug regulatory authorities in the Southern Africa Region. It was established in 2013 by the four original member countries to strengthen regulatory systems in Africa, including the formation of the African Medicines Registration Harmonisation Initiative (AMRH), which encouraged harmonization of the fragmented regulatory systems in the continent, to reduce differences in regulatory requirements between countries. Currently there are nine (9) of the 14 member SADC states actively participating in ZAZIBONA namely Zambia, Zimbabwe, Botswana, Namibia, Tanzania, Democratic Republic of Congo, Malawi, Mozambique and South Africa. The remaining six (6) of 14 member states do not actively participate in dossier assessment but are involved in training programmes and information sharing on products approved through collaborative procedure. ZaZiBoNa activities include: ZaZiBoNa good manufacturing practices (GMP) inspections, assessments of medicinal products, financing and coordination of the SADC, United Kingdom Department of International Development-funded Southern African Regional Programme on Access to Medicines and Diagnostics (SARPAM), WHO, Bill and Melinda Gates Foundation, African Union Development Agency New Partnership for Africa's Development (AUDA-NEPAD) and the World Bank. Achievements to date include conducting 24 assessment sessions since October 2019; 289 products had been considered under the initiative, 203 have been finalized and 86 are pending; 8 manufacturing sites have been inspected and 19 desk reviews conducted; and build capacity of members countries particularly in the regulation of drug trials (TMDA, n.d.).

Southern Africa Research and Innovation Management Association (SARIMA): SARIMA is an association that brings together research and innovation management practitioners to strengthen these disciplines and institutional capabilities within the SADC region. It operates at institutional, individual and national level. SARIMA initiatives to promote research ethics and integrity include an online course in Research ethics and Integrity in collaboration with the University of Witsland

in South Africa. The course is championed by experts with expertise in Research Ethics and has vast experience in the area of Research Ethics and Integrity. This course helps learners develop the competence to promote, foster, and support research ethics and integrity, compliance, and responsible research conduct to understand the ethical challenges of research work. The course leads to Certification through the Wits University (certificate of competence) and is 8 weeks in duration. The Courses modules include: Module 1: Philosophy and Moral Principles of Ethics; Module 2: Resolving Ethical Problems; Module 3: Research Ethics; Module 4: Scientific Integrity and Publication Ethics; Module 5: Research Protocol Development; Module 6: Research Ethics Committee Admin (SARIMA, n.d.)

African Academy of Sciences (AAS): The African Academy of Sciences (AAS) is a non-aligned, non- political, not-for-profit pan African organisation. The AAS' vision is to see transformed lives on the Africa continent through science. Efforts to promote Research ethics and integrity include a community and public engagement project that aims at Building capacity and training on CPE on all DELTAS grant holders; Training and cross learning of staff among the research consortium; and Clinical trials Community is a programme that aims at increasing the visibility of clinical trial in Africa and making transparent and accessible individual country regulatory and ethics procedures to make informed decisions by sponsors. The AAS has broader reach across the African continent and has policies that address both research ethics and integrity.

The African Academy of Sciences has a Policy on Use of Humans in Research which applies to applicants and co-applicants for the AAS grants. The policy explains AAS positions and expectations on research involving human participants. AAS expects research involving human participants is governed by principles outlined in the Declaration of Helsinki, the Nuremberg Code, the Council for International Organizations of Medical Sciences (CIOMS) and the International Council for Harmonization QESM (Quality, Efficacy, Safety, Multidisciplinary) guidelines, all of which set out requirements about the rights and safety of research participants and standards for research design and conduct. The AAS requires that for AAS-funded research involving human participants, researchers must seek and obtain the relevant regulatory and ethical approvals, and appropriate governance mechanisms before the research begins.

Where research is anticipated to run over a number of years, for example in cohort studies, researchers must ensure measures are in place to maintain continuing appropriate ethical oversight and to monitor and, where necessary, obtain advice on ethical, legal and social issues on an ongoing basis. An example of this would be use of an oversight committee with members who are independent of the research in question. These measures would be additional to ethics review and would provide an additional layer of ethical oversight throughout the lifetime of the research. The AAS may bear the actual direct costs of the ethics review process in resource-poor settings, as part of a grant application. However, this must be done in a way that does

not compromise the independence of the ethical review process. All AAS-funded researchers must have an understanding appropriate to their role of the ethics of research involving human participants. The AAS recommends that all AAS-funded researchers involved in such research undergo training in the ethics of research where appropriate and requires this where there is a need to build capacity in this respect. Ethical concerns will duly be presented to the relevant IRB and Oversight Committee for deliberation and advise. The AAS also provides guidance on informed consent, Research involving vulnerable individuals and children, use of human tissues and data, feedback to participants, compensation for injury, emergency research (AAS, n.d.).

Regarding matters around integrity in research and innovation, the AAS has a policy on non-financial research misconduct. This policy provides guidelines for handling non-financial research misconduct. This policy applies to all AAS funded research and all proposals submitted for research funding. For AAS, research misconduct is considered a breach of grant conditions and dishonest practices that seriously deviate from those that are commonly accepted within the scientific and scholarly community for proposing, conducting, or reporting research. Non- financial research misconduct is the fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting All persons taking part in AAS funded research must affirm and document compliance with the principles and standards outlined in this section and those specified in the statements of undertaking signed by the grant holder.

The policy also addresses issues of compliance with ethical, legislative and regulatory requirements: Failure to meet ethical, legal and professional standards may also comprise failure to declare competing interests; misrepresentation of involvement or authorship; misrepresentation of interests; breach of confidentiality; lack of informed consent; misuse of personal data; and abuse of research subjects or materials. Improper dealing with allegations of misconduct includes: failure to address possible infringements, including attempts to cover up misconduct or reprisals against whistle-blowers; and/or Failure to deal appropriately with malicious allegations, which should be handled formally as breaches of good conduct. The policy explains the steps for reporting research misconduct (including whistleblowing) as well as investigating allegations and possible actions against those found to have engaged in non- compliance. It also sets procedures for appeal (AAS, 2020)

African Vaccines Regulatory Forum: AVAREF, established by WHO in 2006, is an informal capacity-building platform aimed at improving the regulatory oversight of interventional clinical trials conducted in Africa. Efforts to promote research ethics and integrity include: Development of tools to facilitate the review and monitoring of clinical trials on the continent, the AVAREF technical working group on inspection of good clinical practices (GCP) and clinical trials working group (CTWG).

The training grants are aimed at building capacity of upcoming researchers, training REC members, building infrastructure for REC, as well as conducting research to understand perspectives on research ethics, establishing REC where they do not exist.

AVAREF has coordinated the development and sharing of tools for use by RECS and national drug regulatory authorities including AVAREF Clinical trials application checklist; AVAREF Clinical trials application form; AVAREF Clinical trials assessment form; AVAREF nonclinical assessment form; AVAREF statistical template; and AVAREF GCP Inspection checklist

National Institute of Health (US): The US National Institutes of Health is one of the major players on the African continent when it comes to research ethics capacity building (NIH, n.d.). There are currently 16 active research ethics projects funded by NIH in 8 of the 15 Countries participating in SCGI-2. The Countries with active research ethics grants include; Malawi, Zambia, Zimbabwe, Mozambique, Kenya, Ghana, Ethiopia and Uganda. The countries that registered no active NIH research ethics/ bioethics grants include; Botswana, Rwanda, Tanzania, Côte d'Ivoire, Zambia and Namibia. The training grants are aimed at building capacity of upcoming researchers, training REC members, building infrastructure for REC, as well as conducting research to understand perspectives on research ethics, establishing REC where they do not exist. Training Capacity building programmes are implemented and delivered as short sources, diploma and certificate programmes, master programmes and PhD programmes and the majority of these grants (80%) have been awarded to institution of higher learning and none of the reported are awarded to SGCs. Table 1 below presents a breakdown of research ethics capacity initiatives across Africa.

Table 1 : Current NIH supported research ethics programs in Sub-Saharan Africa

NAME OF PROGRAMME	PRINCIPAL INVESTIGATOR	RESEARCH ETHICS INITIATIVE	INSTITUTION/ COUNTRY
Southern Africa Research Ethics TrainingInitiative (SARETI)	Wassenaar, Douglas R	Master, PhD and Short courses	University of KwaZulu Natal South Africa
MBARARA UNIVERSITY RESEARCH ETHICS EDUCATION PROGRAM (MUREEP)	Kiwanuka, Gertrude	Public Health Masters embedded with Research Ethics Education/ courses	Mbarara University Uganda
Collaborative Research Ethics Education- Mozambique (Formaçao Colaborativa em Etica na Pesquisa, FoCEP)	Moon, D. Troy	Master of Public Health Program and short courses for REC members	Vanderbilt University Medical Center Mozambique
Developing Capacity of Moi Teaching andReferral Hospital / Moi University Institutional Research Ethics Committee (MTRH/MU IREC), Kenya to Prevent and Manage Research Misconduct.	Were, Edwin Onyango	Research Ethics Strengthening and Research Integrity Training	Moi University Kenya
Advancing Research Ethics Training In Southern Africa (ARESA): Leadership Program	Moodley, Keymanthri	Phd, Short Cources	Stellenbosch University Tygerberg Campus. South Africa
Makerere University International Bioethics Research Training Program	Sewankambo, Nelson K	PhD Cource	Makerere University Uganda
Advancing Makerere University Masters of Health Sciences in Bioethics	Sewankambo, Nelson K	Master Level and Short Courses	Makerere University Uganda

Source:https://www.fic.nih.gov/Programs/Pages/bioethics.aspx

NAME OF PROGRAMME	PRINCIPAL INVESTIGATOR	RESEARCH ETHICS INITIATIVE	INSTITUTION/ COUNTRY
CAPACITY BUILDING FOR HEALTH PROFESSION EDUCATION AND RESEARCH IN MALAWI (CHEER-	Prof Nyengo Mkandawire	Research Support Center Research Ethics Committee	University Of Malawi, College Of Medicine Malawi
JHU-AAU Research Ethics Training Program(Ethiopia)	Ali, Joseph	Master Level	Addis Abba University Ethiopia
UZCHS-Promote Excellence in Researchand Faculty Enhanced Career Training (PERFECT Program) Project Number	Hakim, James Gita	Mentoring Researchers in good research practice	College Of Health Sciences, Univ Of Zimbabwe
CBEC-KEMRI BIOETHICS TRAINING INITIATIVE	Bukusi, Elizabeth Anne	Master, Diploma and Short Courses	Kenya Medical Research Institute (Kemri)
Towards eliminating HIV in Uganda by2030; Preparing Ethical Review Committees to support this agenda	-Kibwika, Pauline	Training REC members	Infectious Diseases Institute Uganda
Strengthening Institutional Capacity forResearch Administration in Uganda (SICRA)	Kiweewa, Francis	Research Administration	Makerere University Walter Reed Project
Ethical and Social Issues in informed consent processes in African genomic research	Sabakaki, Erisa Mwaka	Stakeholders perspective study	Makerere University Uganda
Developing Best Practices of Community Engagement for Genomics and Biobanking in Africa - CEBioGEN	Ghansah, Anita	Community engagement initiatives in genomic research	Noguchi Memorial Institute / Medical Res Ghana

14.0 CASE STUDY: COMPARING BETWEEN A SEMI-AUTONOMOUS SGC AND ONE BASED WITHIN A GOVERNMENT MINISTRY

Four of the 15 SGs are directly nested within Government Ministries (Botswana, Ethiopia, Ghana and Senegal) while the rest are set up as semi –autonomous government bodies. In this paper we make a comparison of an SGC which operates as a semi-autonomous body and another one which operates as part of a government Ministry. For the semi-autonomous SGC, Malawi was selected and Senegal was selected as an SGC that is based within a Government Ministry. A comparison of these two SGCs is also interesting in so many other ways: Malawi is in Southern Africa while Senegal is in West Africa. Malawi is part of the English-speaking African countries while Senegal is part of French-Speaking group. The different African regions have different histories and experiences when it comes to research. The National Commission for Science and Technology is the SGC for Malawi while Le Ministère de l'Enseignement supérieur et de la Recherche/ Ministry of Higher Education and Research serves as the SGC for Senegal.

The case of the Malawi SGC: National Commission for Science and Technology:

For the SGC in Malawi, the following have been observed in terms of the various roles and actions related to ethics and integrity in research (NCST, n.d.):

- Accreditation of RECs: The NCST is the registering, auditing and accrediting body for research ethics committees (RECs) in the country under the Science and Technology Act No.16 of 2003. NCST is in the process of developing the National Accreditation Framework for Research Ethics Committee
- REC SOPs: NCST approves standard operating procedures and guidelines for RECs as part of a REC registration process.
- RECs in Malawi: Malawi has currently seven RECs and they all report to NCST, and NCST is represented on the memberships of the RECs. Two RECs operate at a national level. One for biomedical research ethics clearance (National Health Sciences Research Committee) and another for social sciences and humanities research ethics clearance (National Committee on Research Ethics in the Social Sciences and Humanities). These two are centrally established directly by NCST under section 11 of the Science and

Technology Act. The five RECs are institutional RECs registered to operate at institutional level. These are: College of Medicine Research and Ethics Committee; Malawi University of Science and Technology Research Ethics Committee; University of Malawi Research Ethics Committee at Chancellor College; Mzuzu University Research Ethics Committee; and University of Livingstonia Research Ethics Committee.

All institutional RECs operate on delegated authority from NCST. All Research involving humans require approval of an NCST registered REC.

- Gender at SGC: The Board of NCST is made up of 10 individual members and 6 *ex officio* members. 2 of the individual members are women scientists/researchers.
- Regulation of research: The conduct of research in Malawi is promoted, coordinated and regulated by the National Commission for Science and Technology. The Commission sets out regulatory requirements, standards, procedures and guidelines in terms of sections 18 and 48 of the Science and Technology Act No.16 of 2003. Research is approved through the Commission's established and recognized research ethics committees.
- National Bioethics Committee: NCST also established under section 11 of the said Act the National Committee on Bioethics (NACOB) tackles all bioethics advisory issues across all the sectors including the ethics of science and technology. Its Secretariat is the Division of Health, Social Sciences and Humanities within the NCST structure.
- Dissemination of research findings: Biannually, NCST within its function as an SGC organizes a national research dissemination conference to which various stakeholders are invited.
- Commercialization of research findings: The Research and technology transfer Directorate promotes and encourage the patenting and commercialization of research results to farmers, industrialists and entrepreneurs or end users in a manner that enhances economic diversification, competitiveness and employment generation;
- Research Ethics Guidelines: NCST has issued the following regulatory requirements, procedures and guidelines that relate to both ethics and integrity in research and innovation:
  - Human Genetic Research Procedures and Guidelines
  - National Policy Requirement and Guidance for the Provision of Insurance Cover for Research Participants in Clinical Trials in Malawi (December 2012)
  - National Policy Measures and Requirements for the Improvement of Health Research Co-ordination in Malawi (Revised November 2012)
  - Procedures-and-Guidelines-for-Access-and-Collection-of-Plant and Animal Genetic-Resources-in-Malawi
  - The Framework of Requirements and Guidelines for Research in the Social Sciences and Humanities in Malawi, 11th May 2011
  - National Regulatory Checklist for Ethics and Regulatory Affairs for Research Ethics Committees (RECs) in Health, Social Sciences and Humanities (December, 2012)
  - Policy Requirements, Procedures and Guidelines for the Conduct and Review of Human Genetic Research in Malawi (September, 2012)
- Ethics in Calls for proposals: In calls for proposals, NCST clearly states that all proposals require approval of RECs for the disbursement of the research grants.

- Animal Research: NCST is in the process of establishing a national research ethics committee for animal research. NCST is developing standard operating procedures and guidelines for this type of committee. This committee will have its secretariat at NCST
- Biosafety: Research that raises biosafety concerns in Malawi falls under the jurisdiction of National Biosafety Regulatory Committee at the Department of Environmental Affairs and the NCST closely works with the this Department which is a regulatory authority on biosafety.
- Proposal Review Checklist: The research protocols submitted for ethics review are screened for review against a checklist for RECs. The checklist addresses both ethics and integrity issues (minimizing risks, informed consent, etc.
- Research Integrity: Working hand in hand with the Ombudsman and the Office of the President and Cabinet, NCST has an institutional Ethics, Integrity and Accountability Committee whose role is to promote general organizational ethics, integrity and accountability issues at NCST level. It is not a research ethics committee nor is the same as NACOB.

While these attributes apply to Malawi most of them equally apply to similar SGCs such as Uganda, Tanzania and Kenya.

The case of the Senegalese SGC: Ministry of Higher Education and Research:

For the Senegal SGC, the following has been observed in terms of the various roles and activities related to ethics and integrity in research and innovation (Ministère de l'Enseignement supérieur et de la Recherche, n.d.).

- REC review of proposals before funding: The selected protocols must obtain the prior ethical approval of CNERS for funding to be mobilized. The SGC is in contact with the CNERS for all projects in social and human sciences, environmental impact and health.
- ETHICS guidelines for Senegal.
  - National Ethics Committee for Health Research (CNERS) brochure
  - National Ethics Committee for Health Research (CNERS) Researcher's Guide
  - National Ethics Committee for Health Research (CNERS) ICH / BPC
- Cooperation between SGC and REC: The DGRI works with the National Agency for Applied Scientific Research (ANRSA) and the Ministry of Health and Social Action (MSAS) through the Research Division (DR) and the National Ethics Committee for Health Research (CNERS)
- Utilization of research findings: The General Directorate for Research and Innovation (DGRI) is responsible for promoting research and the use of its products for health, economic, social and environmental development.
- Research Commercialization: The Department of Innovation, Promotion, Intellectual Property and Technology Transfer is responsible for promoting the commercialization of research results.
- Biosafety: Research that presents biosafety concerns falls under National Biosafety Agency

- Protection of personal data: Senegal has a Personal Data Protection Commission which is responsible for regulating use of personal data in research.
- Clinical Trials: Directorate of Pharmacy and Medicines
- Calls for proposals: In calls for proposals, the SGC requires compliance with Law 2009-17 on the code of ethics for health research, for example approvals of RECs, informed consent, subscription to an insurance policy if necessary etc. .
- Proposal Review checklist: In the review checklist, the following ethics requirements are included: a consent letter, and the written commitments of each member.
- Biosafety: Biosafety issues are the responsibility of the National Biosafety Committee (CNB). For projects dealing with genetically modified organisms, discharge from the CNB is required. The relationship between DFRSDT and CNB is functional.
- Animal Research: Animal research in Senegal comes under the General Directorate of Research and Innovation which also relies on the various research regulatory bodies.
- Gender issues at SGC: The DFRSDT has 4 agents (2 men and 2 women) gender issues are taken care of in the calls for applications in the form of themes.

15.0 CONCLUSIONS:

This paper has described best practices for SGCs in promoting ethics and integrity in research and innovation. The paper has borrowed lessons from all 15 SGCs, from funding SGCs and from other non-partners. From the findings, it is evident that SGCs are implementing different activities and roles related to ethics and integrity in research. From the various lessons shared, it becomes obvious that fostering an environment, which promotes ethics and integrity in research and innovation, is part of the SGCs' accountability to the public. SGCs are responsible for promoting a culture, which is supportive of responsible conduct of research by ensuring that the standards of excellence, trustworthiness, and lawfulness are cultivated. This starts with the development of a vision for the research enterprise and a strategic plan for research that address both ethics and integrity. From the cases presented, it has also become obvious that SGCs can play a facilitator or catalytic role by ensuring that they adequately support research institutions and researchers to fulfil their mandate.

It is necessary for SGCs and research institutions to formally express their commitment to upholding the highest scientific and ethical and professional standards of conduct in research in various ways, including developing and issuing codes of conduct as part of their personnel, academic honesty, research policies and handbooks. SGCs can also develop training programmes that include online as well as face-to-face components for institutions and their researchers. The training ensures that researchers can play an active role by committing to uphold the values of research integrity in their work and their conduct and to adhere to sound scientific practices including

scientific rigor. SGC leaders who show commitment to ethical research conduct can influence institutional conduct. SGC leaders, specifically, need to develop policies, standards and expectations for research institutions and additionally facilitate the provision of education and support in order to promote an environment that is conducive to the responsible conduct of research. SGCs need to ensure that research institutions establish transparent procedures for efficiently and fairly investigating scientific misconduct allegations.

APPENDICES

APPENDIX 1:

Key Research Ethics Players and Research Ethics Regulations and guidelines in SGC Partner Countries

COUNTRY	KEY ORGANIZATIONS	REGULATIONS/LEGISLATIONs	GUIDELINES
Botswana	Ministry of Health, Research and Development Committee: http://www.moh.gov.bw/	Anthropological Research Act 45 (1967):	1. Guidelines for Application for Research Permit (2004) 2. Guide for a Consent Form (2005) 3. Guidelines for the Review of Research Proposals (2005)
	Ministry of Health, Drug Regulatory Unit: http://www.moh.gov.bw/	Drugs and Related Substances Regulations (1993)	1. SADC Guidelines for Regulating Clinical Trials in Human Subjects (2006) 2. Guideline for Regulating the Conduct of Clinical Trials Using Medicines in Human Participants (2012):

Burkina Faso	Ethics Committee for Health Research	Joint Order 2004-147 / MS / MESSE of 11 May 2004 on the Organization and Functioning of the Ethics Committee for Health Research in Burkina Faso	
		Order No. 2010- 292/MS /CAB of 1 October 2010 on the Conditions for Granting Authorizations for Clinical Trials: http://elearning.trree.org/pluginfile.php/34806/mod_folder/content/0/19_Arrete_autorisations_essais_cliniques.pdf?forcedownload=1	
Cote d'Ivoire	National Committee on Ethics and Research	Decree No 317 / SP / DSPH of 14 July 1987 on the Regulation of Drugs Before and After Marketing in Ivory Coast:	
Ethiopia	Ethiopian Science and Technology Commission, Health Department: http://www.most.gov.et/	Proclamation 60/1999, Section 21	National Health Research Ethics Review Guideline, Fourth Edition(2014)

	Food, Medicine, and Health Administration andControl Authority: www. fmhaca.gov.et	Drug Administration and Control Proclamation No. 176/1999, Article 21	
Ghana	Food and Drugs Authority: http:// www.fdagha na.gov.gh	Public Health Act, 2012 Act 851, Sections 150-166:	1.Guidelines for Good Clinical Practice in Ghana (2015): 2.Guidelines for Authorization ofClinical Trials of Medicines, FoodSupplements, Vaccines, and Medical Devices 3. Guidelines for Conduct ofClinical Trials in Pediatric Population 4. Guidelines for Conduct of Clinical Trials During Emergencies (2016):
Kenya	1.National Council for Science and Technology (NCST):http:// www .nacosti.go.ke/ 2.Ministry of Health (MOH):www. health .go.ke/	1.Science and Technology Act(2001) 2.HIV and AIDS Prevention and Control Act, Chapter14(2006)	MOH: National Guidelines for EthicalConduct of Research Involving Human Subjects (2008):

	Pharmacy and Poisons Board: http://www.pharmacyboard-kenya.org /	Pharmacy and Poisons Act, Chapter244 (2009): http://apps.who.int/ medicinedocs/documents/s18245en/s18245en.pdf	MOH: Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines (2005) Guidelines for Applications to Conduct Clinical Trials in Kenya (2014):
Malawi	1.National Commission for Science and Technology (NCST): 2.National Health Sciences Research Committee (NHSRC): 3.College of Medicine Research and Ethics Committee (COMREC): 4.Ministry of Health:	1.Presidential Decree on 30th March 1974 2.Malawi Government Gazette, June 11, 1976, General Notice No. 398 3.Constitution of Malawi, Article 19(5) (1994)	1. The Framework of Guidelines for Research in the Social Sciences and Humanities in Malawi (2011) 2. Policy Requirements, Procedures and Guidelines for the Conduct and Review of Research (2012) 3. National Policy Measures and Requirements for the Improvement of Health ResearchCo-ordination in Malawi(2012) 4.National Policy Requirements and Guidance for the Provision ofInsurance Cover for Research Participants in Clinical Trials in Malawi (2012) NHSRC: 1.Operational Guidelines (2001) 2.Summary Guidelines for Writing Research Proposals (2001) COMREC:General Guidelines on Health Research (2014):
	Pharmacy, Medicines, and Poisons Board of Malawi	1. Pharmacy, Medicines, and Poisons Act, Act 15 of1988: 2. Section 42(1) of PMPB Act,2003 Supplement	
	National Committee on Research in the Social Sciences and Humanities		Framework of Guidelines for Research in the Social Science in Malawi (2011):

Mozambique			Science and Technology Ethics Code (2007):
Namibia			
Rwanda	Ministry of Health, National Ethics Committee: http://www.moh.gov.rw/index.php?id=2		Standard Operating Procedures(2009):
Senegal	National Committee on Health Research Ethics	Law Supporting the Code of Ethics for Health Research (2009)	1. National Ethics Committee for Health Research (CNERS) brochure 2. National Ethics Committee for Health Research (CNERS) Researcher's Guide 3. National Ethics Committee for Health Research (CNERS) ICH /BPC
Tanzania	1.Ministry of Health (MOH) 2.National Institutefor Medical Research (NIMR), National Health Research Ethics Committee(NHREC) : 3.Tanzania Commission for Science and Technology (COSTECH):	1. National Institute for Medical Research, Act of Parliament No.23, of 1979: 2. Tanzania Commission for Science and Technology, Act No.7 of 1986 3. Amendment of NIMR Act1997, Tanzania Government Gazette,No. 675	NIMR: 1.Brochure for Health Researchers in Tanzania (2006) 2.Guidelines on Ethics for HealthResearch in Tanzania (2009): COSTECH: COSTECH Guidelines on Research Permits and Clearance (2006)
	Tanzania Food and Drugs Authority:	Tanzania Food, Drugs, and Cosmetics Act, Sections 61, 66,67, and 69 (2003): Medical Device Act (1988)	
Uganda	Uganda National Council for Science and Technology	Uganda National Council for Science and Technology Act of 1990 (CAP 209):	1.National Guidelines for Research Involving Humans asResearch Participants

			2.Research Registration and Clearance Policy and Guidelines (2016) 3.Research Guidelines and Forms: 4.Accredited Research Ethics Committees:
	National Drug Authority: http://www.nda.or.ug/	Drug Conduct of Clinical Trials Regulation (2014): National Drug Policy and Authority ActRegulations:	1.Human Medicine Guidelines: 2.Clinical Trial Application Forms:3.Guidelines for the Conduct of Drug Related Clinical Trials (2019)
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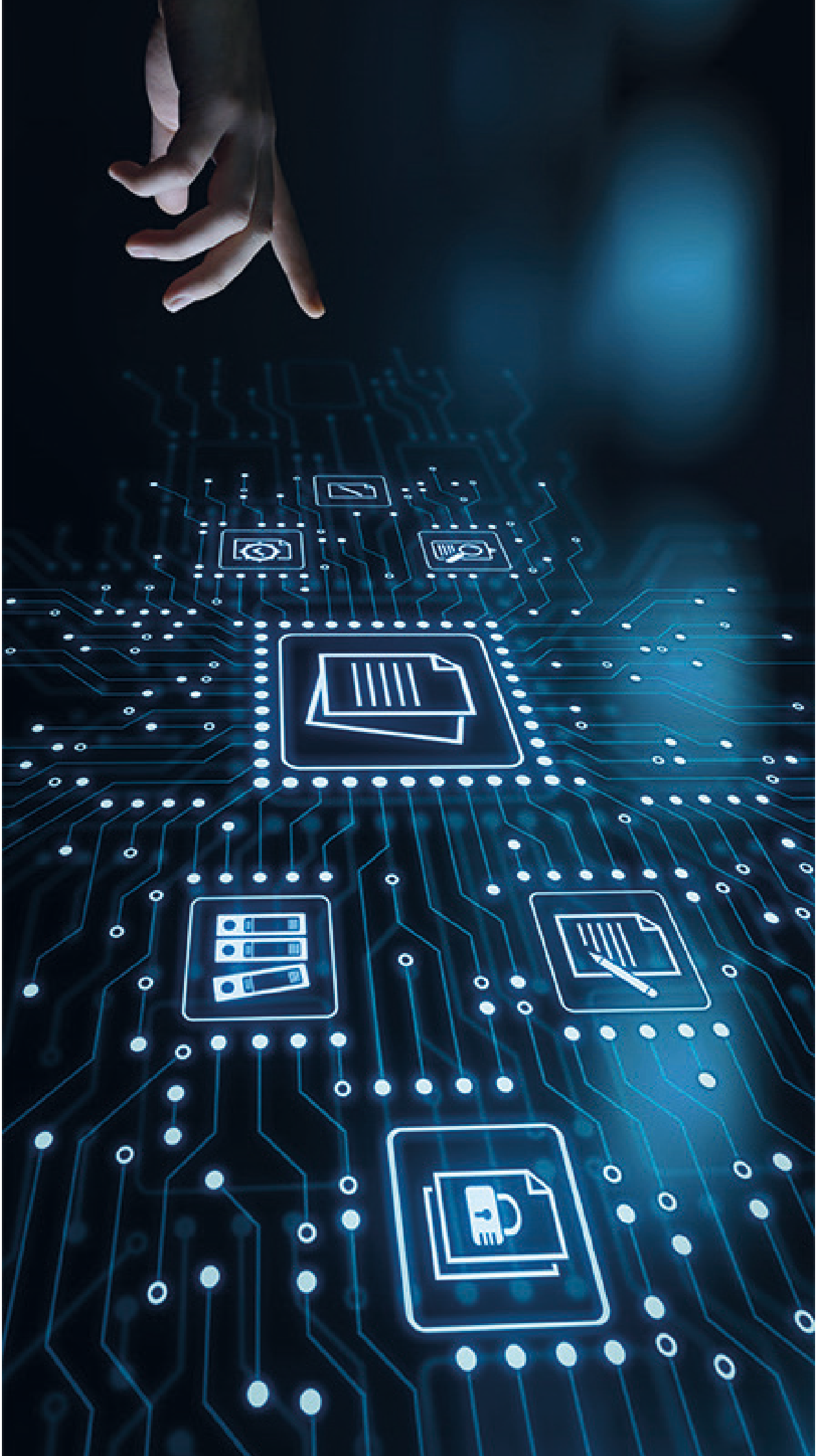


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