# AFRICAN HISTORY OF RESEARCH ETHICS VIOLATIONS:

## LESSONS FOR THE FUTURE

## ADVOCACY REPORT

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# AFRICAN HISTORY OF RESEARCH ETHICS VIOLATIONS: LESSONS FOR THE FUTURE

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## Research Ethics in Africa

The history of colonialism, as well as the internationalisation of research over the past decades, have significantly influenced research ethics standards in African countries. (Kruger et al, 2014). Historically, developments of guidelines in research ethics, and ethics review processes, have often been reactive responses to critical events (i.e. ethics breaches) in medical research practice.

According to Global Policy Forum - GPF (2014), Africa is a continent endowed with immense natural and human resources as well as great cultural, ecological and economic diversity but remains underdeveloped. World Population Review places Africa as the least-developed continent outside of Antarctica, with many of its countries still mired in issues including poverty, government corruption, and armed conflict (2022). Health is considered as a basis of development, therefore "good health is a cornerstone of economic progress, a multiplier of society's human resources, and, ultimately, the primary objective of development" (Chen & Berlinguer, 2001), especially in developing countries. The capacity to develop local guidelines in developing countries may either not exist or be deemed unnecessary given the plethora of international guidelines. Despite such guidelines, there are limitations as to the extent to which they can be applied to research that involves human subjects. Research in developing countries creates a greater risk of exploitation as individuals or communities in developing countries assume the risks of research, whereas most of the benefits may accrue to people in developed countries (Wertheimer, 1999).

## The genesis of research ethics

Research ethics as a branch of applied ethics has well-established rules and guidelines that define their conduct where researchers ought to protect the dignity of their subjects and properly publish the information that is researched (Fouka & Mantzorou, 2011). Decisions about health and other interventions must be based on scientific evidence.

The context for research ethics and clinical practice changes continually owing to developments in technology and medical procedures including genetics and robotics. (Knight, 2019).

The determination of embracing research ethics is premised in the field of biomedical research which arose from the need to use human beings in research. (Emanuel, et al, 2004). This development dates back even before the 18th century although the need to develop guidelines governing research ethics was seriously taken into consideration in the wake of the events during the Second World War, where widespread atrocities were committed by Nazi scientists and physicians under the guise of medical experimentation (Shuster, 1997 & Kour, 2014).

There was a global outcry resulting from these atrocities which necessitated the need for a code of conduct for human research, such as the Nuremberg Code (Shuster, 1997), and the introduction of professional codes and laws to prevent the abuse of human subjects and protection of human rights in research (Oddi & Cassidy, 1990; Fouka and Mantzorou, 2011).

The Nuremberg code stressed the need to observe informed voluntary consent, liberty of withdrawal from research, protection from physical and mental harm or suffering and death with particular emphasis on the risk-benefit balance (Burns, 2005). The Helsinki declaration of 1964 highlighted the need for non-therapeutic research emphasizing the protection of subjects by noting that the well-being of individuals is more important than scientific or social needs (Oddi & Cassidy, 1990). More declarations on research ethics were made, however, these guidelines were largely physician oriented and did not directly address the issue of research in developing countries. The Council for International Organization of Medical Sciences (CIOMS) finally addressed the issues in developing countries in collaboration with the World Health Organization (WHO) and proposed guidelines for international research which were further amended in 1993 and are presently undergoing further revisions.

These guidelines are not legally binding on nation-states, however, they provide moral validity and influence research policy guiding research ethics in much of the developing world.

## History of research ethics violations

There exist wide disparities in economic development, in the burden of disease, and in health outcomes in Africa (Evans et al, 2001), the trajectory towards globalization, without the basic safeguards and protection of human rights, will only worsen these health inequalities.

Africa has not been immune to human research abuses, with numerous reports having documented unethical experimentation and unethical clinical trials in Africa. An example like the interventional studies conducted on 500 patients in Zimbabwe in the 1990s, of whom the majority were indigenous Africans using new drugs and anaesthetics, without the approval of the National Drugs Authority, and without the knowledge of the patients resulting in up to six deaths (Edlin, 1993); British Medical Journal, 1995). Another research testing for the efficacy of breast cancer chemotherapy on South African women was conducted without either research ethics approval or individual informed consent. (Weiss et al, 2000)

In yet another incident in 1996, Pfizer tested Trovan, an experimental drug on nearly 200 children during a meningitis outbreak. Children in the control arm allegedly received Ceftriaxone at an inadequate dose and eleven died, while some survivors suffered permanent brain damage and paralysis. It was later revealed that the clinical trial had not been approved by a local research ethics committee and that the families concerned were not adequately informed that their children were research participants in a study. (Washington, 2006; Macklin, 2003).

Whereas in 2001 in Nigeria, Pfizer pharmaceutical company was sued by 30 families over trials of Trovan antibiotic that was intended to treat meningitis.

These most likely represent a small number of research violations that occur in Africa, as other cases might go unreported due to various reasons. Research in the developing world such as African countries may be deliberately conducted in these contexts due to the existence of weak regulatory systems and a relatively litigation-free environment, compared with western countries (Bhutta, 2002). Concerns have been raised regarding access to treatment, standards of care, the voluntariness of informed consent practices, control of tissue samples, cultural values, justice, exploitation in general (Resnik, 1998; Lurie, 1997; Gisselquist, 2009) "reasonable availability" of interventions that are proven to be useful during the course of research trials (Connor, 1994; Lurie, 1999; Angell, 1997; Wilfert, 1999; Omene, 1999).

Reasonable availability refers to the agreements and assurances about the benefits of research products to the host community. CIOMS guidelines 8 and 15 explicitly state that "As a general rule, the sponsoring agency should agree in advance of the research that any product developed through such research will be made reasonably available, (Bhutta, 2002) to the inhabitants of the host community or country at the completion of the successful testing, however, the most recent revisions of the Helsinki Declaration, takes a less stringent position, stating that "Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research."

These issues are particularly relevant to the developing world where consideration of risk, vulnerability and coercion are important historically (Benatar, 2002) since wider issues of power, privilege, gender, race and corruption also influence researcher–participant relationships.

Yet, even if research carried out in Africa is locally relevant, the benefits from any studies might not be reasonably available locally. These cases of human research abuses in Africa call for the strengthening of research oversight protections and systems so as to ensure the protection of vulnerable populations and research participants.

It must however be noted that events that happened in other parts of the world have played a significant role in directing the development of the research ethics environment in Africa. A majority of African countries have some kind of system in place for the ethical review of health research. In some countries, the systems are supported by legislation, whereas they are still informal in others. (Ndebele et al., 2014).

It is argued that clinical trials conducted in Africa are done by pharmaceutical companies, research institutions etc. with little or no consideration for ethics, or for the relevance of the drugs to the needs and pathology of the trial subjects involved, (Cleaton-Jones, 2000). Therefore it is critical for Africa to embrace a robust research oversight system as researchers and research staff might disregard ethical principles, national laws and international guidelines, either inadvertently or deliberately.

It goes without saying that health research plays a pivotal role in addressing inequities in health and human development, but to achieve these objectives the research must be based on sound scientific and ethical principles. (Bhutta, 2002).

## Keys to avoiding research ethics violations

Specific issues in the ethical conduct of research in developing countries include:

- **Advocacy and safety** where a researcher should design a project which will not infringe on the rights and safety of the interviewees or respondents. (Blumberg et al, 2005);
- **Anonymity, confidentiality and privacy**: Researchers have the ethical responsibility of protecting the privacy of human subjects while collecting, analyzing, and reporting data. (Mugenda, 2003).
- **Beneficence** refers to "doing good" (Churchill, 1995) and ethics in research is to serve and promote the welfare of people and avoid bias or deception.
- **Deception**: When conducting research, participants should be told the truth (Blumberg, et al 2005).
- **Non-maleficence**: Beneficence asserts the usefulness of the study while non- maleficence expresses the potential risks of participation and focuses on avoiding harm. (Akaranga & Makau, 2016). It emphasizes what constitutes harm which could be physiological, emotional, social or even economic in nature (Burns & Grove, 2005).
- **Voluntary and informed consent**: This is one of the major ethical issues in conducting research which implies the fact that "a person knowingly, voluntarily, intelligently, and clearly gives his or her consent" (Arminger, 1997, p.330). Informed consent also emphasizes the respondent's right to autonomy which according to Beauchamp & Childress (2001) is the ability for self-determination in action
- **Community participation**: Research needs to respond to community needs and national priorities, and the development of a national research agenda in developing countries must be firmly grounded in a process of priority setting.
- **Benefits of research**: Medical research is only justified if there is a reasonable likelihood that the populations in which the research is carried out stand to benefit from the results of the research in Article 20 of the Declaration of Helsinki (World Medical Association, 2013)
- **Inadequate cultural sensitivity**: Sensitivity to cultural perspectives and practices is necessary for appropriate informed consent, as in the case of community assent. In some cultures, it is most uncommon for people to say no directly, even when they oppose a proposal. In most African countries, there often exists a paternalistic power imbalance, which is seen in research where potential participants may not feel empowered to ask questions (Knight et al., 2018).
- **Lack of feedback/study results dissemination**: Feedback of research findings to local participants is the most basic aspect of benefit-sharing practice in research (Schroeder & Cook Lucas, 2013; the Declaration of Helsinki (Article 26) whether they are positive or negative.
- **Standard of care and the use of placebos**: The issues surrounding the standard of care highlight the wide disparities that exist in health and economics globally. (Bhutta, 2002). A major issue is the use of the placebo arm instead of the study drug. The recent revisions of the Helsinki Declaration clearly stated in Section 29 that "the benefits, risk, burdens and effectiveness of a new method should be tested against those of the best current prophylactic, diagnostic and therapeutic methods. This does not exclude the use of placebo, or no treatment, in studies where no proven prophylactic, diagnostic or therapeutic method exists."
- **Fair Subject Selection**: Historically, populations that were poor, uneducated, or powerless to defend their own interests were targeted for high-risk research, whereas promising research

was preferentially offered to more -privileged individuals. Emanuel et al (2004) posit that scientific considerations alone will usually under-determine which community or individuals are selected.

- **Ethics dumping**: Ethics dumping is the practice of undertaking research in a low- or middle-income setting which would not be permitted, or would be severely restricted, in a high-income setting (Chatfield et al, 2021), where ethical review processes, compliance structures and follow-up mechanisms might not be as well-resourced or supported (NovoaHeckel et al., 2017; Schroeder et al., 2018, 2019).

Given the limited resources for research in most developing countries, stringent application of different criteria and guidelines might make it almost impossible to provide such long-term assurances of protections and benefits. It is notable that none of the existing national and international ethics guidelines explicitly consider all the factors discussed here.

## The current state of research in Africa

Some African countries have either established, or have remodelled their research oversight systems and committees emulating the Western institutional review boards system, or in accordance with the World Health Organisation (WHO) guidelines on the operations of research ethics committees (RECs). (Kass NE, Hyder AA, Ajuwon A, Appiah-Poku J, Barsdorf N, Dya Eldin Elsayed DE et al. 2007). Nonetheless, many African RECs are faced with a scarcity of resources, insufficient training of members, inadequate capacity to review and monitor approved studies and a lack of national ethics guidelines and accreditation (Silaigwana and Wassenaar, 2015).

While Africa carries about 20% of the global burden of disease, its scientific output represents less than 1% of the world.

Africans represent the oldest and most diverse genome in the world. Studies of African diseases and public health are critical not just to improve the mortality and morbidity of Africans themselves but also to shed light on the diseases in question. Inequities within and among populations and between genders result in much potential talent being lost to science productivity in general and home-based scientific productivity in particular. There is continued exploitation by commercial enterprises that regard the African continent as a source of large populations for clinical trials to develop innovative preventions and treatments that will serve more prosperous populations elsewhere in the world, with weaker policy and human protections such as informed consent and intellectual property. (Marincola, & Kariuki, 2020).

**a. History of research ethics committees - RECs**

Research ethics committees - RECs are just one important component in the entire system of human research protections. Countries and institutions have the responsibility of putting in place measures to ensure the protection of research participants. A REC (also known as ethical review board (ERB), ethical review committee (ERC), human research ethics committee (HREC), institutional review board (IRB)) are a group of individuals who undertake the ethical review of research protocols involving humans, applying agreed ethical principles.

The main responsibility of a REC is to protect potential participants in the research while taking into account potential risks and benefits for the community in which the research will be carried out, monitor studies once they have begun and, where relevant, take part in follow-up action and surveillance after the end of the research. Its ultimate goal is to promote high ethical standards in research

for health in accordance with internationally and locally accepted ethical guidelines in African countries. World Health Organization. (2009).

Many African RECs are faced with a scarcity of resources, insufficient training of members, inadequate capacity to review and monitor approved studies and a lack of national ethics guidelines and accreditation (Silaigwana and Wassenaar, 2015). According to Bernstein et al, ethics has received only patchy attention in many "developing" countries with little uniformity in the structure and function of research ethics committees and minimal if any public accountability (2021). Additional shortcomings in some countries include the existence of self-appointed private ethics committees lacking in expertise and culpability, the absence of open-minded dialogue and public deliberation, and possibilities of undeclared conflict of interest between the roles of physicians as carers for patients and as medical researchers that are not adequately addressed nor acknowledged (Emanuel & Steiner, 1995; Spece et al., 1997).

To minimize concerns with regard to researchers' conflicts of interest and to ensure public accountability, an independent ethical review of all clinical research protocols is necessary (Emanuel et al, 2004). Whilst the review must be independent and competent, Emanuel further adds that other regulatory approvals may be necessary for some types of research. (2004). Committees have the authority to approve, reject or stop studies or require modifications to research protocols. They may also perform other functions, such as setting policies or offering opinions on ongoing ethical issues in research. World Health Organization. (2009).

Moreover, the regulatory infrastructures and independent oversight processes that might minimize the risk of exploitation may be less well established, less supported financially, and less effective in developing countries.

**b. What has been done, progress?**

**The Development of Research Ethics Systems in Africa**

Research oversight capacity is critical for the protection of human research participants, as well as to prevent exploitation of African populations, communities, institutions, and countries. RECs have an obligation to safeguard the welfare of research participants. One of the first documented cases of ethical review in African health research was in South Africa (SA). Other African countries afterwards established RECs at varying levels which have continually experienced growth over time in both scope and complexity, with some countries now having well-developed, decentralised ethical review systems, whereas others have centralised systems (Kirigia, 2005; Noor, 2009)

**c. The need for improved ethics guidelines in a changing research landscape**

The ethics of research practices involving human participants are regulated in most African countries through the national government e.g. in South Africa according it's the National Health Research Ethics Council (NHREC), while in Kenya it is the National Commission for Sceince, Technology and Innovation (NACOSTI) and in Ghana it is the Ghana Health Service (GHS). They provide oversight of the conduct and practices of human research and ethics committees set and provide guidelines on the norms and standards for research involving human subjects/participants (and animals) and act as an adjudicating and disciplinary body to handle complaints and research ethics violations.

Globally, ethics guidelines for conducting research involving human subjects have been informed by practices and procedures developed for

and with reference to, medical research. (Pimple, 2002; DuBois, 2004).

**d. Implementing the values of fairness, respect, care and honesty**

Local RECs have a crucial role in highlighting potentially exploitative activities, however, researchers can do more in reducing the burden on RECs by having research proposals imbued with fairness, respect, care and honesty. In this regard, the clearest way to find out what is considered fair and respectful in research is simply to ask those who will be involved or affected. This demonstrates care from the outset.

There is growing recognition of the potential benefits of community engagement in international research settings. Joseph et al. (2016) concluded that effective community engagement holds the key to addressing concerns for research ethics, offering a means to improve equity for vulnerable populations/participants in African countries. Kamuya et al., (2013) further reiterate, the importance of community engagement in terms of their social and cultural norms, values, goals, resources and levels of technological understanding which could be achieved through meetings, gatherings and seminars with the sole purpose of sharing information about potential studies (Chatfield et al., 2018). This will give room for excellence in research where there is a protection of research subjects beyond informed consent.

Issues related to study design, ethical review, and standards of care have received a lot of focus to the detriment of the underlying socioeconomic deprivation and inequities which are largely ignored.

**e. Health emergencies**

The coronavirus disease (COVID-19), which has been characterized as a pandemic by the World Health Organization (WHO), has upended everyone's lives and brought a global health crisis.

The outbreak affected all segments of the population and is particularly detrimental to members of those social groups in the most vulnerable situations. The UN Department of Economic and Social Affairs (UN DESA) notes early evidence that indicates the health and economic impacts of the virus are being borne disproportionately by poor people. As such this increases opportunities for inequality, exclusion, discrimination as seen by health researchers.

Amidst the search for an urgent cure or prevention of the virus, there was a rush by scientists and researchers to test potential treatments for COVID-19 in the wake of the pandemic. This brought about a widespread debate over the use of humans in critical drug trials in Africa. On April 1, two French researchers, Dr Jean-Paul Mira and Camille Locht, (Al Jazeera) suggested on a live television broadcast that trials of a potential vaccine should first take place in Africa. The attitude of these researchers echoes a long, grim history of medical experimentation and exploitation in Africa, where African leaders have colluded with pharmaceutical companies often based in western nations, to conduct trials on the most vulnerable people in society (Lichtenstein, 2020). Scientific and public health research that is bespoke to the many traditions and cultures of Africa is mandatory not just to protect the health of Africans but also to protect world health.

## Research ethics for health equity

According to the World Health Organization, equity is defined as the *"absence of unfair, avoidable or remediable differences among groups of people, whether those groups are defined socially, economically, demographically, or geographically or by other dimensions of inequality"*.

Such dimensions can be defined as ethnic and religious affiliation, sexual orientation, disability, sex, and gender. Therefore, health equity signifies the attainment of full health and wellbeing potential for everyone regardless of the aforementioned variables.

Health equity or its lack thereof depends on the circumstances related to people's birth, growth, work, day-to-day life, as well as their ageing conditions. It can also be heavily influenced by the legal, political, and sociocultural context of the individual since they contribute to the distribution of resources among individuals and populations, as well as to the repartition of power. It is also important to consider the weight of discriminatory practices on the health of people and communities. Discrimination based on sex, gender, race, ethnicity, socioeconomic status and/or sexual orientation can negatively affect the health of individuals, however, if integrated and mainstreamed into institutional processes and procedures, certain groups of the population could face exclusion, marginalization, and under-representation with regard to policy- and decision-making.

**Sex and gender in research ethics**

There is a large body of evidence demonstrating the health disparities between women, men and (to a lesser extent) gender-diverse individuals (CIHR, 2012). These differences can be attributed to sex-related variables, such as the biological differences between females, males and intersex individuals. They could also be attributed to gender inequalities and the different sociocultural expectations, norms, values, and roles attributed to women, men and gender-diverse people by their societies.

Research has shown that sex-related variables can contribute to the vulnerability to certain diseases and can affect the outcome of certain therapeutic regimens.

Furthermore, gender inequalities have been proven to limit women's access to care and health-related decision-making. This can be attributed to the women's lack of autonomy in many regions of the world, in terms of decision-making and freedom of movement. Women are also universally more impoverished than their male counterparts and often find themselves in a state of full or partial financial dependence on male partners or family members, thus hindering their ability to make decisions about their healthcare. (CIHR, 2012)

In the times of COVID-19, significant health disparities and inequities have been highlighted in the African continent. The pandemic, as well as previous health emergencies, have disproportionally affected vulnerable populations such as pregnant women, people with lower socioeconomic levels, ethnic and religious minorities, and sexual and gender minorities. Not to mention how such populations have inequitably been impacted by social isolation, quarantine, and displacement restrictions due to loss of their livelihood and a lack of access to basic healthcare necessities.

Therefore, taking into account sex and gender in health research can help investigators identify protective and vulnerability-enhancing factors in the acquisition of diseases, differences in adverse effects of medical products and vaccines, and how gender inequalities influence women's and men's health-seeking behaviours, access to healthcare, and treatment adherence. The identification of the aforementioned variables can help formulate recommendations for policy and practice on how to promote health equity through the consideration of sex- and gender-related variables in health.

The scientific community often conflates sex and gender integration in research with the inclusion of

women in research projects that have human participants.

While the systematic inclusion of women in research is a key contributor to the validity and reproducibility of the results, sex- and gender-sensitive research should not only be restricted to that. It should aim to conduct sex- and gender-based analysis as part of its methodology, in order to identify how biological sex and gender interact with the study phenomenon and what health implications could result.

RECs are in a strategic position to halt the conduct of sex- and gender-blind research that does not take into account sex and gender differences, and their impact on individual and population health. As per the universally agreed upon biomedical research ethics principles, namely: Respect for autonomy, Non-maleficence, Beneficence and Justice, it is of the utmost importance for RECs to promote sex- and gender-sensitive research.

When women are able to make an informed decision regarding their participation in experimental research, relying on data from preclinical studies on female specimens that highlight the potential risks and benefits, respect for autonomy is realised, harm is reduced, and the probability of beneficence is augmented. For the principle of justice to be respected in the context of research, equitable selection of participants must occur, with no discrimination based on sex, and keeping in mind that potential risks and benefits of research are to be shared equitably among research participants.

There are available resources for ethics evaluators and researchers alike to help them assess the sex- and gender-sensitivity of their research.

The following are some examples:

- **A Framework for the ethical evaluation of research protocols from a sex and gender perspective during the COVID-19 pandemic and other epidemics**.

This guide was produced in May 2020 by the BCA-WA-ETHICS team from the perspective of health emergencies, particularly, COVID-19. However, it can be applied to other types of research projects. The guide contains a 3-step framework to guide evaluators through a process of sex- and gender-based analysis of several components of the research, namely: the background and justification, the research methodology, and the ethical and societal impact of the research (Nkoum et al., 2020).

- **The ethicist's practical guide to the evaluation of preclinical research from a sex and gender perspective**.

This is a product of the BCA-WA-ETHICS Gender Mainstreaming Secretariat. It aims to provide ethicists with guidance regarding the sex- and gender-based evaluation of preclinical research projects. It contains a three-step framework to evaluate the justification and background of research, its methodology, and its governance and ethical impact. The guide also provides a set of practical exercises for the reader to test their acquired knowledge (Nabil et al., 2021)

- **Harmonization of gender mainstreaming in health research ethics: towards a community of practice.**

This roadmap was produced after the 2nd BCA-WA-ETHICS Scientific Congress on the Regional Harmonization of Gender Mainstreaming. It contains recommendations for ethics practitioners and RECs on the consideration of sex and gender in research ethics and research governance, with emphasis on a harmonized gender practice in the West-African region. (Mbaye & Nabil, 2021)

- **Livre blanc : recommandations pour l'intégration du genre dans les comités nationaux d'éthique de la recherche d'Afrique de l'Ouest**.

This handbook was produced by the BCA-WA-ETHICS Gender Mainstreaming Secretariat in collaboration with the National Health Research Ethics Committee of Benin. It is aimed at Francophone West African National RECs and contains guidelines on gender mainstreaming on an institutional level as well as in the context of research surveillance and evaluation. The book contains tips and recommendations on the design and adaptation of research protocol evaluation tools from a sex and gender perspective. (Ale & Nabil, 2021)

- **Integrating Sex & Gender Checklist – Partnership Development Grants for the Healthy & Productive Work Initiative**.

This checklist was developed by the Canadian Institutes of Health Research's Institute of Gender and Health. It was created for the purpose of aiding evaluators of research grant proposals in their assessment of the gender- and sex-sensitivity of the proposal. It examines the vision, rationale and added value of the research, as well as the quality of its methodology and knowledge translation plan. This checklist helps in appraising the adequacy and diversity of the proposed research team. (CIHR, 2015)

Proper consideration of sex and gender in research ethics, ensures that no potential benefits specific to women or men are overlooked, that the effectiveness of health products and interventions can be equitably applied to men and women, and that sex- and gender-based vulnerabilities are identified and explored in-depth.

Therefore, serious transformation is needed in the research field in order to bridge the health disparities gap in Africa.

As established, not everyone shares equal benefits of healthcare. The case of scientific research is no different. Some populations gain more from scientific output than others. This is why considerable efforts have to be made, by researchers and research evaluators alike, to ensure that the research and its eventual dissemination and translation is conducted from a health equity perspective.

**Assessing health equity in research protocols**

Research must take into account health equity, so as to accelerate its achievement. RECs are in a position to integrate health equity impact assessment alongside their routine appraisals of the ethical and scientific dimensions of proposed research (Castillo & Harris, 2021)

During the protocol evaluation sessions, evaluators are recommended to systematically raise the following questions:

- ***Does the research explain the strategies adopted to engage diverse members of the community, especially groups that have been historically marginalized, excluded from or abused in the context of research?***

This engagement of the various community members and stakeholders should comprise the full spectrum of research activities, from needs assessment and research design to the translation and exploitation of the findings.

- ***How will the researchers ensure that all community members benefit equitably from the knowledge translation activities?***

Researchers must take into account the language, cultural, and knowledge-acquisition barriers that may increase and perpetuate inequalities in the communication and dissemination of scientific knowledge.

- ***Do the researchers explain how their recruitment strategies will ensure a study sample that is representative of the community?***

Researchers must not only take into account sex representation, but, also take into account race, ethnicity, religious affiliation, sexual orientation, gender identity, age group, and disability status.

- ***What are the data validation and triangulation mechanisms put in place to avoid misinterpretations of the results?***

The analysis and interpretation of the results should include stakeholders from the local community for better understanding and contextualization of the findings.

- ***How will the research address health and social inequities, especially for vulnerable and under-resourced populations?***

Researchers should be encouraged to reflect on how their research can impact health equity and what benefits it will have for the implicated local communities.

Researchers should also reflect on how their study could have the potential for unintentional augmentation of health inequalities for a specific population.

## Conclusion

The nature of human research in the social sciences and humanities has changed significantly in the last decades, mainly as a consequence of changing technology which has enabled new types of interactions between researchers and participants (Dobrick et al., 2018; Knight, 2019). In order to support health research in developing countries that is both relevant and meaningful, the focus must be on developing health research that promotes equity and on developing local capacity in bioethics. Only through such proactive measures can we address the emerging ethical dilemmas and challenges that globalization and the genomics revolution will bring in their wake (Bhutta, 2002).

One of the ways in improving ethics in health research is through linking health and research issues with equity and focused attention on the needs of African countries and the reduced inequities in health and human rights. It is important to apply bioethical principles in the process of attaining justice, as neither regulations nor guidelines alone can overcome the differences.

Additionally, there is a need for developing local capacity by strengthening models for reviewing the ethics of research, since the capacity for undertaking research must include the capacity to undertake an ethical evaluation of the planned research and its conduct. (Bhutta, 2002). This ought to reduce the possibilities of exploitation in African countries. Although poverty, limited health-care services, illiteracy, cultural and linguistic differences, and limited understanding of the nature of scientific research neither cause nor are necessary for exploitation, they increase the possibility of such exploitation (Wilmshurst, 1997; Glantz et al., 1998; Annas & Grodin, 1998; Shapiro, 2001; Weijer, 2001).

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BCA-WA-ETHICS II

EDCTP

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# BCA-WA-ETHICS II

*Building the capacities of West Africa in research ethics*

**TRAINING**
**NETWORKING**
**REGULATORY SUPPORT**
**COMMUNICATION & DISSEMINATION**

We are a partnership between **Spain**, **Senegal**, **Benin**, and **Mali**.

Our aim is to build capacities in **research ethics** and **gender mainstreaming** in the West African region, with a particular focus on clinical trials during health emergencies.

Our project targets **National Ethics Committees** from the 15 countries of the Economic Community of West African States (ECOWAS).

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