

# Ethics for Public Health Research in Africa



Social Science Academy of Nigeria

# Ethics for Public Health Research in Africa

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## Preface

While researchers increasingly recognise the need to protect the participants that are targeted in social and behavioural research in public health, available literature is bereft of ample examination of the key ethical issues and challenges most especially in largely non-literate populations in Africa. Thus, the need for sound frameworks in ethical research practice at the global level most especially in developing countries is at the top of the agenda of health promotion and research today.

The existence of viable and active ethical review committees in developing countries is a prerequisite for investment in research. Developing countries must appreciate and establish a system that ensures that the participants in research are protected from potential exploitation, injuries, and harm in order to attract investment in research as well as derive its benefits.

The commitment to the promotion and investment in health research on HIV/AIDS, Tuberculosis, Malaria, and Reproductive Health in developing countries prompted the establishment of Nigeria's National Health Research Ethics Committees and/or other mechanisms that would ensure a sound system for promoting and ensuring the protection of human subjects in research. Several countries have developed their codes of ethics for health research.

Nigeria is one of the leaders in health research in Africa and it is in furtherance of its leadership role and commitment to health research that the Federal Ministry of Health established Nigeria's National Health Research Ethics Committee (NHREC). The Nigerian Code has been developed while NHREC is currently training the members of ethics committees in our institutions. The Committee is about to register institutional ethics committees in order to ensure standardisation and a common understanding in the application of the Code. Finally, NHREC will classify the country's ethics committees according to type and the complexity of the research that they are permitted to review.

The Federal Ministry of Health is aware of the significant gap in the knowledge and application of sound ethical principles among researchers which is affecting their ability to attract funds from international funding agencies for otherwise well conceived and written research proposals.

The Social Science Academy of Nigeria (SSAN) organised a capacity building workshop for Nigerians and others from the West African sub-Region on ethics and codes in applied social and behavioural research in public health. The inclusion of participants from countries in West African is in accordance with Nigeria's commitment towards the promotion of health in the ECOWAS sub-region.

Our sincere gratitude to the Tropical Diseases Research Programme of the World Health Organisation (TDR/WHO) for providing a substantial part of the funds for the workshop and also to the local and international collaborators for assisting to build the capacity of African scientists. It is also a delight to collaborate again with Professor Layi Erinsho with whom we have had a long history of combining efforts to promote health research, policy, and programmes in Nigeria.

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The very important area of ethics in research involving human subjects is often mentioned and discussed in research proposals by African scholars in Africa. But the discussions are often superficial because token attention is paid to its imperatives and requirements by applied social scientists, particularly those that are working in public health in Africa.

The ever evolving codes and ethics in this area are least understood and appreciated by Africa's researchers working in many of Africa's institutions. This lack of appreciation is connected to the contexts where research is undertaken; - contexts that appear not to be as strict and as demanding as those in high income countries whose ethical codes are well articulated.

This weakness is also reflected in what is taught to students who are being prepared for careers that include research. Consequently, most researchers in Africa particularly those who apply social science knowledge to public health lack the capacity to handle ethical requirements in proposals. The Social Science Academy of Nigeria is aware of, and concerned with this problem and is determined to improve the situation. The workshop provided a window of opportunity to enhance the competence of researchers in this critical area.

Founded as the Social Science Council of Nigeria in 1983, the Academy is mandated to harness and develop the capacity of Nigerian social scientists; promote the advancement of social science knowledge; and engender cross-disciplinary discourse.

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# Introduction

*Olayiwola Erinosh*

## Introduction

Ethics, the science of morality, has always loomed large in the various time-honoured professions such as law, priesthood, medicine, and the military. However, globalization has invigorated interest in ethics and it now transcends all human endeavours. Ethics is now taken seriously in governance, business, academia, and other walks of life.

But concepts like ethics, democracy, justice, and freedom have different meanings in different contexts and cultures. What is ethical in a culture might be unethical in others. For example, traditional healers in Africa could be paid in kind by their clients rather than cash (*e.g.*, marriage, or farm products *etc.*). This sort of exchange for professional services is unethical in western-style medicine and/or societies.

The on-going “strife” between the West and sections of the Arab population and/or countries over the meaning of freedom, democracy, and/or human rights can also be cited as an example. There is remarkable diversity across cultures, religions, national boundaries, ethnicity on the meaning of these concepts. For instance, quite a number of theocratic Arab/Muslim states that draw inspiration from the Holy Qur’an differ from Europeans on their meanings. Consequently, the challenge facing humankind is to share a common understanding of these cherished human values.

The challenge is equally evident in the context of health care research in which individuals, groups, and communities are targeted. As an example, the right and proper way in which animals are handled in Euro-American societies is not necessarily the case in other contexts such as Nigeria where animal *rights* are not recognised. Similarly, patriarchy which is the foundation of social structure in most parts of Africa is a significant determinant of social relationship between researchers and their targeted communities and respondents.

Oral cultures such as those in various parts of Africa attach importance to personal social relation in contrast to literate and technologically developed ones where relations are impersonal, highly segmented, and formal. The requirement of informed consent in writing does not go down very well in African societies that are still steeped in oral tradition unlike in European contexts where this is embraced and/or demanded.

There is therefore a divergence between the technologically developed and developing countries on the importance of ethics in socio-medical research. While the former have established effective mechanisms for reviewing and implementing research projects on human/animal subjects, the latter especially in Africa are just about doing so. As a result, many researchers in Africa always have a hard time getting approval for their protocols from international ethical review boards due to their failure to address sticking ethical issues in their protocols.

Support for foregoing assertion lies in a recent study of 670 researchers in developing countries

which concluded that 44 per cent of their projects were not reviewed by their Institutional Review

Boards (IRBs) even though a third of the studies was funded by United States organisations. The study also found that the IRBs in US institutions raised questions on consent forms in local languages and the protection of confidentiality than the IRBs in the host countries (Hyder *et. al.*, (2004).

Another survey of fourteen African countries found most of them in transition. Quite a number are just establishing the mechanisms for ethical clearance while the National Ethical Committees in many contexts are either not functioning or not abreast of their responsibilities (NEBRA, 2006).

One of the tasks facing African countries is to put in place effective structure and process for ethical review and implementation of research protocols and/or projects and also ensure that any system that is put in place is functioning optimally. It is also vital to enhance the capacity of scholars to show appreciation for ethics in the implementation of their research projects.

The significance of research code in extant methods in the social, behavioural, and clinical sciences cannot also be ignored. Research code is about adherence to the rules of engagement in scientific research. As readers may well know, scientific inquiry is about observation, objectivity, rigorous interrogation, analysis, and interpretation of data on the basis of probability theory. Testable propositions are expected to be confirmed and/or refuted on the basis of carefully assembled verifiable facts. Every outcome of scientific enquiry has a character of hypothesis because today's outcomes are refutable tomorrow if newly discovered facts indicate otherwise.

Scientists are expected to be detached in the course of their study of human behaviour (*i.e.*, value-free) as well as display *open* rather a *closed mind* to the outcomes of their studies. Outcomes could be modified or rejected depending on new facts and data. These core principles in science methodology transcend all human societies.

The quest to strengthen the capacity of Africa's researchers in Africa on ethics and research code is recognised by the WHO and other bodies that have committed significant resources to their training with commendable success. But one or two capacity building workshops are too few to achieve the desired impact in a continent that boasts of a vibrant community of scholars that are spread all over the more than three hundred and fifty universities and research institutions.

A regional workshop on ethics and research code in the social and behavioural aspects of public health research was organised to:

1. outline ethics in scientific research;
2. examine the ethical dilemmas and challenges in social and behavioural research in public health in non-literate populations;
3. analyse the factors which act as barriers to accessing grants with particular reference to ethics and code for research;
4. develop capacity on ethics and code in social and behavioural research in public health in largely non-literate populations, and
5. document and disseminate the outcomes of the meeting.

## **Participants**

The participants were drawn from English speaking countries in the West and Central Africa sub-region, notably, Nigeria, Ghana, and Cameroons with most of them from Nigeria for understandable reasons while the resource persons were recruited from Cameroons, United Kingdom, India, and the World Health Organisation.

It was conceived as a Trainer of Trainers' (TOT) workshop because the organisers believed that the mostly senior level participants could in turn organise in-house capacity enhancement workshops on ethics and research code in their respective institutions after training.

Forty-three senior and mid-career scholars in the legal, social, biological, and clinical sciences including others in the field of public health were selected to participate in the workshop from about one hundred and fifty (150) applicants.

## **Workshop Format**

The workshop was interactive and participatory. Scientific sessions at which the resource persons presented papers preceded small group discussions, followed by plenary sessions at which the groups tabled their respective reports and recommendations for discussion.

## **Presentations**

Ten papers that are grouped under four thematic issues were presented. The first of papers focus historical and conceptual issues. Adebamowo provides a historical overview of ethics from the general (*i.e.*, at the global level) to the specific with reference to Nigeria, tracing as well the evolution of the work of Nigeria's National Committee on Ethics and Research Code. The authors argue that the Nigeria experience could be a template for other countries in Africa. Adejumo on the hand outlines the key issues in ethics in scientific work.

Chapters 4,5, and 6 are about consent seeking in diverse contexts, - social, behavioural and clinical research. Falusi's contribution which is about consent seeking and the principles of distributive justice in laboratory projects highlights the key challenges especially when those that are targeted are non-literate. Further discussion of consent seeking from the social and behavioural science research standpoint is by Jegede while Alabi's examines the ethical challenges in study design in social and behavioural research in vaccine testing in Africa.

The usual targets in social science research are individuals, groups, and communities. But social scientists collaborate with experts in public health and/or clinicians in various projects. There is however, little evidence that ethics is given as much emphasis in the training of social scientists as in the animal and human sciences. The outcomes of the pre- and post evaluation of the workshop which are discussed later on bear testimony to this assertion because most of the participants who previously received training on ethics and research code are in the fields of public health, biological and clinical sciences rather than in the social. The data also indicate that nearly all faculties with the exception of the social science faculties had established the mechanisms including the structure (*i.e.*, ethics review committee) for reviewing research proposals.

Erinosho (see Chapter 7) outlines the sticking ethical issues in quantitative and qualitative social research methods, using ample examples in this regard while the paper by Nkwi in Chapter 8 complements the former. Here the author examines ethics in the context of ethnographic studies.

One of the two case reports in Chapter 10 highlights ethical challenges in applied research in non-literate communities while the other focuses on ethical dilemmas around the HIV/AIDS epidemic in Nigeria. Osotimehin argues that there are no easy answers especially where there is conflict over the concern for "public good" (*i.e.*, where the aim is to protect the well-being of next of kin and the public at large) *vis-à-vis* the protection of individual rights on the debate on voluntary versus compulsory testing for HIV/AIDS (see Chapter 10). Similarly, the dilemmas which Nigerian researchers faced during the implementation of USAID supported applied research projects are

amply examined in Chapter 9 by Ewoigbokhan. The writer argues that the critical issue is the pull between local mores and demands and those of the sponsors of research in Africa. The key point is that developing country researchers are caught in this web and they are unable to by-pass internationally stipulated rules and regulations on ethics in public health research.

Finally, Saxena sheds considerable light in Chapter 11 on the queries on social science protocols that are submitted to the World Health Organisation for ethical review and approval. The author concludes that social scientists that are working in public health often take a lot for granted in their write-ups.

## **Evaluation**

Pre- and post evaluation surveys were conducted in order to provide insight into knowledge and the state of ethics and research code among the participants prior to workshop as well as assess the impact of training on them. About 67 per cent of them had never participated in capacity enhancement training workshop/programme on ethics code in health research. More than fifty per cent of them were from institutions with no functioning ethical review committees. Although 61 per cent are aware of Nigeria's national code, only a third of them (27.3 per cent) previously processed their protocols through the national review board. Only 58 per cent said that their institutions offer formal courses on ethics. Nearly all of those who made this claim are from the faculties of science, public health, and medicine in contrast to those from the social sciences whose faculties had not introduced formal courses on ethics.

The outcomes of evaluation at the end of training indicate unanimous support for the introduction of formal courses on ethics and training programme for researchers across Nigeria and the West Africa sub-region. There is evidence from the responses that the participants benefited greatly from the presentations and the ample materials that were provided.

The participants proffered the following observations and recommendations:

### **Observations**

1. The key ethical issues in quantitative and qualitative research are privacy, confidentiality, consent, gender sensitivity, feedback, and response to cultural specificities.
2. Informed consent in writing is viewed with deep suspicion in oral societies due to past experiences dating back to the colonial era.
3. Many institutions lack functioning ethical review boards.
4. Exploitation is distinguishable from inducement. While incentives for participants are not illegal, manipulative inducements are unethical.
5. Effective communication between researchers and largely non-literate participants is always a problem.
6. Ethical issues are not given adequate consideration in proposals and they are as such poorly articulated, indicating that researchers are not sufficiently skilled in proposal writing. There is also limited opportunity for guidance on project development.
7. Although IRBs are constituted, they do not function effectively because they lack the expertise to review and monitor ethical lapses in research proposals.
8. There is conflict between the cultural perspectives of the members of national ethics committees and the presumably superior viewpoints of the international funders of research that are inclined to perceive local cultures as 'bad'. For example, international funding agencies/IRBs are not inclined to take local cultures into consideration in ethical issues concerning consent seeking.

9. Drug companies work with those who do not know their rights or those who have the capacity to negotiate appropriate long-term benefits for their communities in comparison to the risks that are involved. The sponsors and collaborators often times promise to make the products that are tested and found efficacious available to the community but later abandon such ideas.
10. There is generally a poor grasp of statistical methods and the calculation of sample size.
11. The handling, processing, and analysis of qualitative social science data in parts of Africa are weak/poor.
12. Researchers hardly extend the benefits of research to the targeted participants/communities in Africa. Neither do they share the outcomes of their work with them.
13. Field laboratory assistants in Africa are not well remunerated.
14. International organisations that are conducting drug trials are not fully monitored to ensure that they comply with standard operating procedures.
15. Lip service is paid to the translation of questionnaires into local languages that are administered in studies in Africa.
16. There are currently no effective and functional regulatory and monitoring policies that oversee appropriate storage and disposal of micro-organisms and biohazard waste in most parts of Africa.

## **Recommendations**

1. National and institutional committees that monitor the activities of ethical review boards and researchers should be constituted and made to function effectively.
2. National ethical guidelines and code should be developed and adhered to.
3. There is a need for capacity building programmes for ethical review committees in order for them to function effectively.
4. Investigators should be equipped with the knowledge and skills on proposal/project writing such that the recognition and adoption of local and ethical guidelines are integrated into protocols.
5. Feedback should be given to researchers whose proposals are turned down in order for them to have further insight into reasons for the decision and also to be able to improve their work.
6. Local IRBs should ensure that the protocols that are approved by foreign IRBs should be reviewed by them in order to ensure the practicability of the studies and the extent to which they recognise/address socio-cultural implications.
7. Local researchers should be empowered to negotiate their needs and the benefits to local situation, especially where the validity of the results will be affected by the conditions that are advocated by donor agencies..
8. IRBs should be interdisciplinary in order to protect participants from issues that may be culturally and emotionally damaging. In addition, proposals should be sent to more than one expert representing the various disciplines for inputs.
9. The degree of risks in research should be commensurate to their benefits.
10. There is need to design curriculum for training in ethics in social and behavioural research in higher institutions.
11. There is also a need to build capacity of ethics review committees to review social science research.
12. Institutional ethical review committees for social and behavioural research issues should be constituted where none are currently in place.
13. There is need to operationalise consent seeking in view of the compelling cultural realities in Africa.

14. African researchers should be trained to be aware of the fact that they can influence research.
15. Local culture and traditions should be recognised in study design.
16. International agencies that are conducting drug trials should be monitored to ensure that the standard operating procedures are followed.
17. National and institutional ethical committees should protect the population by putting clause that makes it mandatory for the benefits of research to be available and affordable to their targeted participants and communities.
18. Proper agreement should be made from the beginning of research. Patent should be part of agreement prior to testing.
19. There is need to make concepts easier for the participants to understand (*e.g.*, the concept of placebo) so that they can willingly participate in research.
20. There is need to demystify the belief that doctors are all-knowing and require absolute submission on issues of health in Africa.
21. Education and proper dissemination of information to communities are essential.
22. Every institution should have the mechanisms for the storage and disposal of their waste.
23. Each institution should have bio-safety officers.
24. High level risk research should be restricted to institutions that have the capacity to handle them. Such institutions must comply with the policies of the environmental impact agencies (*i.e.*, the EIAs).
25. There is need for capacity building on the handling of toxic wastes *etc.* in laboratories.

## Conclusion

There is ample evidence from the deliberations/recommendations at the Abuja (Nigeria) workshop that much more could be done to develop the capacity of scholars in the Africa sub-region on ethics and research code. Many scholars in the continent are at the receiving end because they are inclined to seek funding for their projects from well-endowed Euro-America funding and other multi-lateral and bilateral agencies. Yet obtaining support for worthwhile projects depends on meeting the stringent conditions for approval and showing how ethics will be effectively addressed in project implementation. It is undeniable that these issues cannot be effectively addressed unless researchers are competent on research code and also know how to handle their animal and human subjects.

The foregoing recommendations indicate that there is a window of opportunity for training African scholars on research ethics and code. However, one or two workshops will not do in view of the large community of scholars on the continent. Consequently, it is desirable to sustain the momentum of the Abuja workshop by funding several workshops in order to ensure that as many scholars as possible grasp the essence of research code and ethics. It is being proposed the World Health Organisation and responsible national authorities should support such workshops.

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## 2

# Developing Ethical Oversight of Research in Developing Countries: Case Study of Nigeria

*Clement A. Adebamowo, Margaret A. Mafe, Aminu A. Yakubu, Julie M. Adekeye, and  
Jonathan Y. Jiya*

### **Introduction**

In recent decades, there has been an increase in research and programmatic intervention to combat diseases that are prevalent in developing countries. With this rise have come increased reports of unethical research and scientific misconduct. These allegations highlight limited development and reach of programmes that are designed to ensure ethical oversight of health research in developing countries. We consider the creation of a national ethics regulatory infrastructure one of the necessary responses to address current and future health research ethics issues such as those already reported. In this paper, we use Nigeria as a case study for the development of such regulatory infrastructure and opine that the Nigerian examples may be suitable for other countries with a significant level of existing research ethics activities. To this end, we outline the history and development of the Nigerian Code for Health Research Ethics (NCHRE) and its successes, problems, and prospects. We suggest that the public-private partnership model that was used in Nigeria based on an innovation systems approach should be more widely adopted despite its limitations of greater cost and slower rollout of activities. The benefits of such as institutionalisation of research ethics, potentially greater impact and sustainability outweigh these limitations.

Nigeria is the most populous country in Africa. With a population of 140 million people, Nigeria is home to every 4 Africans. The health profile of Nigeria is characterised by twin epidemics of communicable diseases such as malaria, tuberculosis and HIV/AIDS and non-communicable diseases like obesity, hypertension, diabetes, cancers, and mental health disorders. In this respect, it is similar to most other developing countries.<sup>1,2</sup> In the past decade, there has been increased funding of the health sector from the government, donor agencies, and development partners such as the WHO, the United Nations and its agencies, the Roll Back Malaria project, President Bush's emergency Plan for AIDS Relief and the William J. Clinton Presidential Foundation. These have either provided or increased funding for treatment of diseases, particularly HIV/AIDS, tuberculosis, and malaria.<sup>3,4</sup>

Additionally, health research in Nigeria is increasing in response to the needs of the population. This is being driven by the need to find more effective treatments and public health interventions for persistent infectious diseases epidemics.<sup>5</sup> The emergence of old diseases like tuberculosis and leprosy in ever more virulent forms is also driving the need for increased research.<sup>6</sup> With the completion of the Human Genome and the International Haplotype Mapping Projects,<sup>7</sup> researchers have been conducting research in Africa in order to better understand the genomic basis of diseases and human history<sup>8</sup> as well as differential responses to drug treatments.<sup>9</sup> Furthermore, more clinical trials are being conducted in order to take advantage of the low-cost, poorly regulated and less litigious health research environment.<sup>10</sup>

This growth in research activities is desirable and is to be encouraged. Research and clinical trials have the potential to improve the quality of health care services that are offered to the population. Research also increases countries' abilities to participate in international research enterprise, thereby enhancing their potential to contribute to economic development and growth by providing employment, equipment, training and income for local researchers and their institutions. It transfers skills and helps to retain talented individuals who otherwise may be tempted to join the brain drain and leave developing countries.<sup>11</sup>

However, the increase in treatment and research programmes has revealed the dearth of functioning ethics committees in most developing countries, including Nigeria. Programmes to effectively protect research participants are nonexistent, weak or non-functional.<sup>12-14</sup> In response, local and international organisations have sought to strengthen health research ethics in developing countries. International organisations like the WHO<sup>15</sup> and UNESCO<sup>16</sup> have developed guidelines for the functioning of ethics committees while the European and Developing Countries Clinical Trials Partnership (EDCTP)<sup>17</sup> and the United Nations Institutes of Health (NIH)<sup>18</sup> have awarded grants to support training of members of research ethics committees and biomedical researchers. In addition, researchers within countries have also increased interest and are demanding ethics regulatory infrastructure to augment these internationally funded activities.

In general, these programmes have functioned as stand-alone training programmes that equip individuals with the ability to function effectively as members of ethics' committees, as ethically aware members of the research team, or as individuals who are capable of teaching or conducting research in bioethics. In countries that already have a relatively strong tradition of research ethics, this model works by training members of ethics committees who return to fit into existing structures.<sup>19</sup> However, in most African countries where ethics regulatory bodies (if they exist at all) are of more recent origin, this model may not work.<sup>20</sup> Studies of ethics review committees in Africa have shown that besides training, political commitment and funding are the most serious challenges that they face.<sup>21-22</sup> Trainees may therefore return to environments where their ability to practice their skills is severely compromised by institutional and infrastructural limitations.

In view of these realities, we believe the development of national ethics regulatory infrastructure should occur alongside increased training. Such bodies will:

1. set legally enforceable norms and guidelines for ethical review of protocols;
2. set training standards for members of health research ethics committees, and
3. develop strategies for adequately funding them.

In this paper, we describe how the Nigerian system is being set up; its successes and challenges. We propose this model for other African countries intent on developing ethics regulatory infrastructure.

## **History of National Health Research Ethics Regulation in Nigeria**

The earliest attempts to set up a national ethics regulatory infrastructure in Nigeria took place in 1980. However, this effort faltered largely because of lack of sustained interest and funding. Subsequent attempts were also unsuccessful because the decades of the 1980s and 1990s were marked by military misrule and socio-economic dislocation. The advent of civilian democracy in Nigeria in 1999 coincided with a period of increased international attention to the problems of unethical health research that occurred particularly in developing countries.<sup>23</sup> By 2004, several Nigerians had graduated from the older U.S. National Institutes of Health/Fogarty International Centre (NIH/FIC) funded international research ethics training programmes in the United States, Canada, and South Africa, and they increased pressure on their institutions to set up ethics



committees where there were none and strengthen existing ones even as they started to provide local bioethics training. These efforts gathered momentum such that during a 2006 Presidential Retreat on the Health of Nigerians, the fact that Nigeria needed an ethics regulatory infrastructure for health research to meet its United Nations Millennium Development Goals targets, was strongly highlighted.

In response, the Federal Government of Nigeria reconstituted and strengthened the National Health Research Ethics Committee (NHREC)<sup>24</sup> and backed it with legislation to:

1. Determine guidelines for the functioning of health research ethics committees (HREC) in Nigeria;
2. Register and audit HRECs;
3. Set norms and standards for conducting research on humans and animals, and for conducting clinical trials;
4. Adjudicate in complaints about the functioning of HRECs and hear any complaint by a researcher who believes that he has been discriminated against by HREC;
5. Refer to the relevant statutory health professional council, matters involving the violation or potential violation of an ethical or a professional rule by a health care provider;
6. Institute such disciplinary action as may be prescribed against any person found to be in violation of any norms and standards, or guidelines, set for the conduct of research under this Act, and
7. Advise the Federal and State Ministries of Health on any ethical issues concerning research.

In order to expeditiously pursue these objectives, the Federal Ministry of Health signed a technical cooperation agreement with the West African Bioethics Training Programme (WAB),<sup>25</sup> a United States NIH/FIC funded programme located in Nigeria with a mission to train biomedical researchers and train bioethics in Nigeria and West Africa. The terms of the technical agreement included the provision of training and support for members of the National Health Research Ethics Committee and relevant members of staff of the Federal Ministry of Health. The WAB was also to help the Ministry to draft a national code for health research ethics, develop standard operating procedures for ethics committees, and other relevant documents and activities with the aim of strengthening health research ethics in Nigeria.

In fulfilment of the terms of this technical agreement, the WAB set up a multidisciplinary, multi-institutional technical consultation committee comprising individuals with backgrounds in health and social sciences in addition to postgraduate training in bioethics. This committee was charged with the responsibility for reviewing current research ethics codes and developing an appropriate code for Nigeria that takes account of the existing guidelines and recent developments in international health research ethics. In doing its work, the committee was enjoined to take account of the Nigerian Constitution and the Federal structure of the country, other relevant laws, the history of research and research ethics in Nigeria as well as the needs of local and international researchers. Previous bioethics needs' assessment studies had indicated that the potential for bureaucratic delays, corruption, and obstructionism were the most important concerns that biomedical researchers in Nigeria have about a national ethics committee. The committee was therefore asked to keep these concerns in mind as it develops the guidelines.

The draft code developed by the committee was submitted to NHREC in 2006 and it was adopted after amendments. The Code was then published on the NHREC website and disseminated within and outside the country for consultation and comments by the research community and stakeholders. Appropriate comments, suggestions and corrections that were received were incorporated by NHREC into the code after which it was submitted to the government for adoption

as the first domestic legal regulation establishing ethical review of research in Nigeria. The Code has now been released for implementation by Nigeria HRECs and biomedical researchers. It sets the norms and standards that must be applied for the ethical review of research in Nigeria.

### **Enforcement of Ethics Regulations**

Prior to the development of the National Code in Nigeria, interested parties and institutions in Nigeria set up ethical committees according to institutional and international guidelines. There was therefore the lack of uniformity and minimum standards. There was also no coordinating and legally binding enforcement mechanism. More recently, largely in response to increased research funding from foreign governments and organisations, institutions have either established or remodelled their committees after the U.S. institutional review boards systems and in accordance with the U. S. Common Rule.<sup>26</sup> This often occurred at the behest of international collaborators who needed to satisfy their home countries' regulatory agencies.<sup>22</sup> While such collaborative studies underwent ethical oversight, the same was often not true of locally funded and local-investigator led domestic research. Therefore, much undocumented unethical research continues to be conducted in Nigeria as in other developing countries, outside the purview of ethics committees. In addition, there was no systematic and sustained development of a culture of ethical health research in national institutions.

Where research is conducted with foreign funds, non-compliance with ethical standards can lead to the withdrawal of funding and the debarment of researchers from receiving additional funds from such sources in the future. Given that there is little international cooperation in enforcement of ethical conduct of research, such researchers may be able to access other research funds and, in the absence of domestic legal regulation of ethical research, there are few or no sanctions available against non-compliance with ethical standards. Litigation as a method of enforcing ethical standards has not been uniformly successful. This is partly because of weak judicial systems, the absence of enabling laws, and unenforceability of international guidelines such as the Nuremberg Code, Belmont principles, Helsinki Declaration, and CIOMS guidelines. The latter have been described as non-legally binding declarative statements that lack the specificity required for legal action.<sup>27</sup> They are therefore not legally enforceable and their contravention in developing countries carries minimal risk to researchers.

### **Highlights of the Nigerian Code for Health Research Ethics**

The Nigerian Code for Health Research Ethics resembles most of the current international health research ethics guidelines, but it differs from them in some important aspects. In order to ensure minimum standards in ethical evaluation of research, the Code requires all ethics committees in the country to be registered. This registration is renewable every two years and gives the NHREC the opportunity to conduct oversight over institutional ethics committees. Institutions setting up ethics committees are also expected to agree to provide equipment, office space and personnel for these committees, otherwise they risk losing their registration.<sup>28</sup> Ethics committee members and biomedical researchers are also mandated to undergo at least biennial NHREC-approved training in informed consent.<sup>29</sup> The Code requires institutions to appoint HREC administrators, an essential role that has hitherto been largely ignored in many of the efforts to promote health research ethics in developing countries.<sup>30</sup> While HREC members are often rotated, administrators remain the backbone of sustainable ethics committees by ensuring continuity and providing support. A system of categorisation of committees has also been created so that institutions are motivated to support their HREC and improve them in order to maintain their status or attain a higher one. Categories are also linked to the types of research that institutions' committees can approve and, by implication, the types of research that can be conducted in institutions.

The Code allows institutions to have more than one ethics committee but limits the authority of the ethics committees to their geographical location or the research activities of the institution's permanent staff only. This is to prevent "ethics committee shopping" by researchers seeking to avoid rigorous ethical oversight.<sup>31</sup> In view of the high cost of setting up ethics committees and the need for there to be a steady stream of research proposals in order for a committee to acquire competence and experience in protocol review, the Code assumes that there may be institutions that cannot sustain the establishment and continual functioning of ethics committees. In order for research to be conducted in such institutions, the Code provides for the establishment of cooperative agreements between institutions that have and those that do not have ethics committees so that ethical oversight in the latter institutions is possible.

Central and regional review of protocols has been widely discussed in the research community as a method of providing ethical oversight of multicentre studies in a timely and an efficient manner. This avoids duplication of effort and discordant outcomes of multiple ethics committees' review of same protocols.<sup>32, 33</sup> The Code provides opportunities for principal investigators to seek central review of their protocol by the National Ethics Committee at their own discretion or upon referral from their local ethics committees. This is recommended where the research involves multiple centres or is taking place in institutions or localities where there is no ethics committee. The ethics committee of an institution may also refer research to the National Committee for review, if, for example, the research is of such sophistication that no one institution in Nigeria has all the relevant expertise to adequately review and provide oversight function for it.

Individual researchers may also petition the National Committee to review a study where there has been inordinate delay or dispute with the institutional ethics committee. In such instances, the National Committee may assign the protocol to any institutional committee to review the protocol on its behalf as the "Committee of Record" after which local institutional committees provide continuing ethical oversight if the protocol is approved. Additionally, the National Committee may set up an ad hoc ethics committee made-up of experts from different institutions within Nigeria or the National Committee can constitute itself into a reviewing ethics committee and exercise all the authorities therein. Institutional ethics committees were preferred to regional ones. Though the latter are likely to be more efficient, they carry the risk that ethical review will not be seen as part of the cultural fabric of institutional research programmes and may not adequately support the growth of an ethical research environment within institutions.<sup>33</sup>

In order to monitor the transfer of biological materials and protect the interests of local researchers in international collaborative research that exploits local bio-diversity and resources, the Code requires a Materials Transfer Agreement between collaborating researchers, monitored by the institutional ethics committee and recorded at the National Committee. Where appropriate, other agreements such as Clinical Trials Agreements, Community Assent, Community Benefits Agreements or Intellectual Property Rights Agreements, may also be required by the institutional ethics committees before studies are approved. Ethics committees are encouraged to consult each other when reviewing multicentre studies and researchers must submit ethics review of protocols from different sites to their institutional HREAC for resolution, particularly where outcome of review is discordant. The Code also outlines clear processes for ethics committees to provide continuing ethics oversight of studies, suspend studies, resolve concerns and issues arising from ethics oversight and recommend termination of studies to the National Committee. There are also procedures for the investigators to appeal to the local institutional ethics committees and independently to the National Committee in cases of disputes with the institutional committee.

Several studies have shown that funding is the most important limitation facing ethical committees in developing countries.<sup>34, 35</sup> Several options have been suggested to resolve this problem including charging for review of protocols, institutional or government support, external funding, or grant support. The NHREC took the view that while ethical review of protocols is a public good that should be supported by the government, this is not a viable option for governments still struggling to meet their commitment to the provision of basic healthcare.<sup>36</sup> Dependence on external grants alone was not considered a sustainable long-term option for funding ethics committees. Institutional ethics committees are therefore permitted to charge fees commensurate with the sophistication of the research protocol, source of research funds, and the expected amount of work that would need to be done in order to provide satisfactory ethics oversight. These fees can vary according to availability of additional support provided by institutions and other sources to the institutional ethics committees.<sup>35</sup>

Ethics committees and independent ethicists can conduct both ethics consultations and ethics training programmes taking due care to avoid conflicts of interest. For quality assurance purposes, ethics education programmes must submit their curriculum and a list of lecturers/resource persons, and their qualifications to the NHREC for vetting to ensure that these meet the minimum requirements for education in research ethics that is mandated for members of ethics committees and biomedical researchers in the National Code at least once every two years.

Existing ethics guidelines have been criticised as having arisen partly or wholly in response to research ethics crises. For example, the Nuremberg Code was a result of the trial of doctors and scientists that conducted unethical research during the Second World War. They are also believed to be unbalanced because they accord excessive weight to the principle of autonomy and fail to meet current challenges in research ethics such as community concerns, use of placebos, conflicts about standard of care, resource availability when research is over, and quality of an adequate informed consent process.<sup>37-39</sup> The Nigerian Code reflects these new paradigms in ethics guidelines and includes explicit information about protecting communities and their interests as well as the application of the ICH-GCP guidelines in clinical trials.<sup>38-40</sup>

The National Committee believes that biomedical researchers and ethics committees' adherence to the code and other guidelines will depend on the provision of educational programmes as well as enforcement of compliance by the National Committee. This will wean ethics committee members off the guidelines and processes with which they are already familiar. Many members of ethics committees lack adequate foundation in modern research ethics and this may explain the common complaints about the quality of ethics review, the types of issues that ethics committee members raise, and their concentration on minutiae of the informed consent form to the neglect of other prospects of research protocols. The National Committee therefore charged the WAB to continue to provide education for members of ethics committees in Nigeria on a continuing basis.

## **Problems and Prospects**

Domesticating international research ethics guidelines, backing them with legislation, and setting up a national ethics regulatory body are necessary to advance the cause of ethical research in developing countries. Developing countries cannot develop modern research programmes or host health research conducted by international companies and organisations without transparent and effective research ethics regulatory infrastructure. In its absence, attempts to ensure compliance with ethics regulations are likely to remain superficial and falter over time. The exact mode for developing such an infrastructure will vary from country to country depending on constitutional arrangements, historical, social, economic, and educational factors, as well as the size of its

research and ethics community.<sup>41</sup> The Nigerian experience demonstrates the value of working with the government using a public-private partnership model.

Using a dynamically interactive systems approach, Nigeria has developed an in-country partnership between the public service and a private initiative to set up an ethics regulatory infrastructure that advances the objective of all partners. The government benefits from expertise that is not readily available within the public service and obtains support for the training of staff and the provision of books, computers, and electronic documents while providing the legal authority and institutional support for the framework. The private partner is able to further the objective of providing training in bioethics and producing graduates who will have opportunities to deploy their skills effectively within the system. We believe that this approach enhances the capacity of the country to have a sustainable ethics programme in the long run. This innovations systems concept for capacity development has been used in other areas of science and technology in Africa.<sup>42</sup>

The systems approach to capacity building requires a shift in conceptualisation of partnerships from just producing personnel to the development of systems of interactive actors that are able to generate and apply knowledge needed within their local environment. This slows down the process and requires greater investment of time and effort because of the need to build a team, debate and resolve competing priorities, and mobilise resources. Trust must be built and barriers to partnership gently lowered.<sup>42</sup> Demand for services must also be stimulated in consonance with development of delivery systems. This approach is eminently suitable for the bioethics expertise in developing countries because while the principles of biomedical ethics are global, their application is local and requires local knowledge and expertise. Training programmes that produce personnel without taking account of the environment and infrastructural requirements for effective functioning are not likely to have sustainable impact in the long run.

The model we have used is probably more suited to large countries with several research institutes and universities, some of which may already have health research ethics programs.<sup>43</sup> Other countries have used other models. For example, some developing countries have centralised all ethics review and located it in the Health Ministry. This provides the Ministry the ability to monitor all research on-going in the country, negotiate with research partners, and allow only those studies that the Ministry considers relevant to the health needs of the population. There is no systematic evidence that this model is more efficient than alternative models. Rather, anecdotal reports suggest that it is plagued by delays in approval, political interference in scientific research, and bureaucracy. Yet this model may be suitable for small countries with few research institutions and limited resources.

## **Conclusion**

There is nothing substantially unethical about research that are conducted in developing countries; in fact, efforts to discourage research in developing countries are themselves inherently unethical because, among other factors, they deny the citizens of these countries a potential benefit on account of uncertain risks. Ethics development programmes need to move beyond the mere training of individuals towards a systems approach that takes account of the eventual working environment of their trainees. Programmes should extend their activities to include a closer working relationship with national authorities in order to institutionalise the ethics review process. Where they do not exist, development of legal instruments within countries to support ethics review of all research, whether sponsored or local-investigator led should be considered an urgent task. Existing codes and guidelines represent a distillate of current standards that can be modified and gradually built upon. There is also a need for international cooperation in monitoring health research ethics given the globalisation of health research. While the recent ruling by the United States Office for Public

Health and Science, Department of Health and Human Services stating that non-U.S. institutions must satisfy its regulations as it has not found any that is equivalent to the common rule is understandable, there is a need to move beyond this and consider development of common minimum standards and compliance procedures accompanied by greater cooperation between ethics regulatory agencies throughout the world.

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# 3

## Ethical Issues in Scientific Research

*Adebayo O Adejumo*

### **Introduction**

Scientists use the scientific method to explain the relationship between cause and effect in nature. Such investigations could be conducted in all aspects of human life - clinical, social, and technology sciences. Scientists ask questions; construct and test hypotheses; conduct experiment; analyse data; draw conclusions; and disseminate the outcomes of their studies.

The challenges facing humankind make the need for scientific enquiry imperative. Considerable efforts are therefore made to subdue human and environmental problems which have resulted in tremendous improvement in the quality of life in various societies (Lenhard, Lawrence, and Makenna, 1995).

The process of conducting scientific research is guided by regulations (Slutsman, Buchanan, and Grady, 2007). But quite a number of studies have, by historical accounts, resulted in harm to those that are targeted. As an example, the method of recruiting those who will participate in studies including the research process could be coercive and exploitative (Barry, 1988). All of these and others have necessitated the development of the various ethical codes that guide scientific studies today.

### **Historical Overview**

The history of research ethics could be traced to the tragic abuse by Nazi doctors during World War II. Sixteen German physicians conducted unethical medical experiments, using Jews, gypsies, and political prisoners. Out of these horrors came the Nuremberg Code and other international codes of ethics written to protect the participants in research. The Nazi doctors were convicted of crimes against humanity under this Code. The trial introduced standards, part of which underscores voluntary participation in research and the avoidance of risks (Katz, 1996).

The scandal over the 40 year Tuskegee Syphilis Study by the US Public Health Service in Macon County (Alabama) which came to light in 1932 is another milestone in the study of research ethics. The American Government promised 400 African American men free treatment for “bad blood” which had become an epidemic in the county. However, the government did not provide the standard treatment for them despite the fact that penicillin was available in the course of the study. The participants were also not fully briefed on the research design and the possible risks to them.

There is also the experiment by Milgram (1961) on the conflict between obedience to authority and one’s personal conviction. The researcher examined the justification for acts of genocide by those who were accused at the post-world war II Nuremberg trials who claimed that they acted under orders from their superiors (Jones, 1981).



Thirdly, a group of children with mental retardation who lived at Willowbrook State Hospital in Staten Island in New York were made to participate in the “Willowbrook Study” between 1963 and 1966. These innocent children/subjects were fed with extracts of stools from infected individuals and later injected with more purified virus preparations. The children were deliberately infected with the hepatitis virus. However, the researchers claimed in defense of their investigation that the vast majority of them would have in any case acquired the infection while at Willowbrook, and it was better for them to be infected under carefully controlled research conditions (Rothman, 1991; Katz, 1972).

Humphreys, a sociologist, conducted a research tagged "Tearoom Sex" study in the mid-1960s. He hypothesised that the public and the law enforcement agents and agencies held stereotypical beliefs about men who committed impersonal sexual acts with one another in public restrooms. "Tearoom sex", as fellatio in public restrooms, accounted for majority of homosexual arrests in the US. Humphreys argued that it was important for society to gain a better understanding of the identity of the men as well as what motivated them to seek quick impersonal sexual gratification. He set out to answer this question by the methods of participant/observation and structured interviews. Humphreys stationed himself in "tearooms" and offered to serve as a "watchqueen". The "watchqueen" had the duty to be on the lookout for law enforcement agents or deliberately cough if strangers were approaching the area.

During the study, he observed hundreds of acts of “tea-room sex” and gained the confidence of some of the men he observed. He disclosed his role as a scientist and persuaded them to tell him about their personal lives and motives. To avoid bias, Humphreys secretly followed some men and recorded the license numbers on their vehicles. A year later, Humphreys showed up at their private homes and claimed to be a health service interviewer. He asked them questions about their marital status, race, job, and other personal questions (Seiber, 2001).

Humphreys’ findings destroyed many stereotypes. He found that 54 per cent of the men were married and 38 per cent were neither bisexual nor homosexual. Most of the men were successful, well educated, economically stable, and highly praised in the community. Only 14 per cent of the men that he observed were homosexuals and part of the gay community. Humphrey’s research was carried out in the mid-1960's before the existence of Institutional Review Boards (IRB).

These studies led to the creation of the Belmont Report and the Institutional Review Board (IRB) for the protection of human subjects that are targeted in research.

## **Ethical Issues in Scientific Research**

Virtually every scandal in research involving humans has been followed by attempts to codify the rules that should govern research. Whereas human experimentations can be traced back to several centuries, organised efforts to protect human subjects who participate in experiments started only 60 years ago (Caballero, 2002).

Emanuel *et. al.*, (2000) identified the benchmarks for determining the ethical validity of research. Considerations were given to:

1. socio-cultural value;
2. contributions to science;
3. informed consent process;
4. ethical review process, and
5. risk-benefits ratio.

But Nigeria's National Code for Health Research (NCHR) offers a more practical and culturally adaptive dimension. Section F of the Code contains a detailed analysis of what clinical investigators should consider when conducting human research (Federal Ministry of Health, 2007). The guidelines are readily applicable in social science research. The document stresses that ethical research must have social or scientific value to the:

- participants;
- population they represent;
- local community, and
- host country or the world in order to justify the use of finite resources and avoid exposing the participants to harm.

### ***Key Issues***

1. Research should evaluate issues that lead to improvements in the socio-psychological and health conditions of participants and the research community. It must also contribute meaningfully to knowledge. Such knowledge should be disseminated to all the relevant stakeholders during and after research. Research that lacks the following is unethical:
  - clear scientific objective(s);
  - valid methodology;
  - equipoise (in clinical studies);
  - adequate operational plans within the context of the environment where research is to be conducted;
  - plausible data analysis plan (including a specific role for a Data and Safety Monitoring Board [DSMB] in clinical trials), and
  - unbiased measurement(s) of outcome(s).
2. There must be fairness in the selection of participants, based on the scientific objective(s) of the research while minimising risks. This requirement refers to those who are included/excluded and the strategies for recruiting participants (including the choice of research sites and communities). Regardless of this requirement, participants who are at excessively increased risk of harm should be excluded. Children, pregnant women, socially, culturally, economically, politically, educationally, physically and psychologically disadvantaged sub-groups or those with constrained autonomy and other vulnerable subgroups in the populations should not be excluded from research without explicit reasons for doing so from studies that can advance their health and wellbeing. However, specific safeguards should be included to protect the vulnerable appropriate to degree of risks. Groups, communities, participants, and researchers who bear the burden of research should share in the benefits
3. Effort must be made to minimise risks and maximise health related benefits. Harm can be defined as both physical and psychological. There are two standards that are applied in order to protect the privacy of research participants: confidentiality and anonymity. Researchers must assure that information that identifies the subject is not made available to anyone who is not directly involved in the study. Anonymity implies that the participant will remain anonymous throughout the study in order to guarantee the privacy of participants. This is sometimes difficult to accomplish in situations where participants are seen at multiple time points (*e.g.*, a pre-post study).
4. Protocol/project must undergo independent review. A research ethics committee or independent review board is a panel of persons who reviews grant proposals with respect to ethical implications and decides whether additional actions should be taken to assure the safety and rights of the participants. By reviewing proposals for research, the committee

protects the organisation and the researcher against potential legal implications of neglecting important ethical issues.

5. Informed consent which provides adequate information at an educational level that is not higher than that of individuals with at most 9 years of education is required. Essentially, this means that prospective research participants must be fully briefed about the procedures and the risks that are involved in research and must also give their consent to participate.
6. Respect for potential and enrolled participants should be guaranteed. This is related to informed consent. It requires that participants should not be coerced to participate in studies. This is especially relevant where researchers previously relied on 'captive audiences' for their subjects (*e.g.*, prisons, universities).
7. A trust relationship between investigator(s) and potential participants should be assured. This necessitates transparency in all matters relating to the research enterprise including a clear description of the goals, risks, benefits, alternatives to participation and voluntariness. This trust principle encourages the engagement of individual participants and communities, respect for local socio-cultural values, and it also encourages the provision of relevant and timely feedback to communities.
8. The interest of participants, researchers, communities, and sponsors must be accommodated. This is to ensure that the research has lasting impact; transfers technology where appropriate; contributes to capacity building; and demonstrates respect for socio-cultural and other differences. Risks, benefits, and the responsibilities of research must be shared during the development, planning, conduct, and the dissemination of results. Intellectual property, indigenous knowledge and the contributions of all parties must be taken into consideration, adequately protected, and compensated.
9. It is vital to conduct research in accordance with the principles of good clinical and laboratory practices. These are international standards for designing, conducting, and reporting clinical trials that involve human subjects. Compliance with these standards is additional assurance that the rights, safety, and well-being of participants are protected in a manner that is consistent with the highest ethical and scientific standards.

## Conclusion

Research is the pivot for elucidating information otherwise not obtainable (Lefor, 2003). It is relevant because it helps to describe, explain, predict and control interventions and practices in science. Concurrent with the rapid growth of scientific research in many regions of the world, there are unending reports of lapses and challenges that are related to ethical, cultural, and social concerns as exemplified by the activities of Nazi physicians between 1935 and 1945 (Pace and Sullivan-Fowler, 1996). Studying and understanding these issues will promote the science and ethics of planning, implementing, and utilisation of scientific research. With these, the research enterprise will contribute to generalisable knowledge with which the bio-psychosocial challenges of man and his environment can be surmounted. Added to these, scientific investigations will minimise their potential adverse impacts on those who participate in them irrespective of the setting, race, or status if researchers give adequate attention to local and international ethical standards.

The nuances of researchers as well as conflicts of interest are often explicated in their dual roles as service providers and researchers (Levine, 1986). The usual power imbalance between researchers and the resource limited members of the society that are targeted in research heightens the potential vulnerability of the latter and could compromise their autonomy in decision making.

It is vital for researchers to adhere to ethical standards in their relationship with the less advantaged members of the society. This becomes imperative due to the growing appreciation of the rights of

patients and the global quest for the protection of human subjects who are included in investigative procedures. Without these, the gains that are already recorded in the growth of science would be reversed. Research activities in whichever discipline and professional practice that do not adhere to ethical standards amount to mere exploitation of the less-advantaged fellow human beings as was the case in the days of the Tuskegee syphilis study.

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## Consent Seeking and the Principles of Distributive Justice in Field Laboratory Health Projects in Non-Literate Societies

*Adeyinka Falusi*

### Introduction

Research ethics deals with the application of moral rules and professional codes of conduct in the collection, collation, analysis, reporting, and dissemination of information on research subjects (whether they are individuals or groups) as regards the right to privacy, confidentiality, and informed consent. The literature is replete with reports on unethical practices in health research. Among the major ones are the: Tuskegee Syphilis experiments (1932); Nazi experiments (1930-45); Leary and Richard Alpert Hallucinogenics (1960-63); Jewish Cancer Research Experiments (1963); Mississippi Appendectomies (1907-1941) and the Pfizer Trovan Drug Trial involving children in Kano, Nigeria in 2001 (Falusi, 2004). The abuses in these studies created public perception that researchers cannot be trusted with the safety of research participants. They also undermined the integrity of the scientific community.

The following research ethics are now formulated to guide the conduct of research worldwide: Nuremberg Code (1964); Belmont Report (1978); Helsinki Declaration (1964); 45 CFR 46 – Federal Oversight FWA; and the WHO/TDR Operational Guidelines for Biomedical Ethics Committees (2001) which led to the derivation of the three key principles of autonomy (i.e. respect for persons), beneficence/non-maleficence, and distributive justice. All the foregoing now guide research in the clinical, social, engineering, veterinary, and physical sciences that are committed to the well-being of humankind.

Respect for persons is about giving research subjects the freedom to decide whether or not to take part. Comprehending the consent process is key to participation. Special regulations are also put in place for vulnerable subgroups like pregnant women/foetuses/neonates, prisoners, children and others in the population who might be decisionally impaired including the poor, non-literates, employees, and students (Delvin, 2001).

Beneficence must be maximised while maleficence is minimised. In other words, research should benefit individual participants, their class, community or society. Research should also enhance the capacity of the targeted communities. It must also be clearly stated whether the participants will have access to proven research benefits after the study. Overall, research is expected to be responsive to local needs.

The third which is distributive justice is aimed at tackling the following questions:

1. “Is justice done? and if so, is it distributive?”
2. Are the benefits of research likely to accrue to those bearing its burdens?”
3. Is there fairness to individual participants, their class, and/or the community?”

### Informed Consent

The consent process spells out the responsibilities of investigators, sponsors, and participants. Informed consent is about the decision to participate in research, taken by a competent individual who has received the necessary, and adequately understands the information; and who after considering the information arrives at a decision (voluntarily) without being subjected to coercion or undue influence or intimidation (CIOMS, 2002). Understanding and voluntary decision are essential components of the informed consent process. A written consent is normally required in internationally funded projects while a verbal or tape recorded consent is admissible in country studies. Studies on minors require parental or surrogate consent.

There is minimal risk and no need for informed consent in studies on the review of medical record and decisionally impaired and/or unconscious patients. But the permission of those who keep records must be obtained and assurance must be given that their records will not be disclosed to third parties. The data that emanate should be properly stored and only shared with the members of the research team and other relevant authorities to the benefit of participants.

Informed consent is about the protection of the well-being and safety of participants. It deals with the risks and benefits of the trial, their rights as participants, and their choice on whether or not to participate. However, the citizens of many communities in developing countries are very much unaware of the notion of informed consent. Informed consent process has often been evaded while a large pool of uninformed participants is enrolled for research in these countries.

Violating informed consent process is complete disregard for the value of human life and the inherent rights of the participants in research. The governments of developing countries usually look the other way as the informed consent process is regularly evaded because research projects are perceived as the only way to obtain otherwise unaffordable benefits for their communities.

### **Consent Seeking and Its Challenges in Non-Literate Societies**

The challenges in consent seeking in developing countries include poor the handling of:

1. the informed consent process;
2. confidentiality;
3. conflict of interest issues;
4. the standard of care;
5. reporting of data, and
6. the handling of misconduct and plagiarism offences.

Moreover, the professional competence of researchers might not be adequate at the onset of projects. Finally, the selection of subjects and choice of sites could be flawed while the benefit to the research communities might not be clearly stated.

Sometimes, the perception is that it is a waste of time because the researchers or their assistants in developing countries are under pressure to recruit as many study participants as possible within a short period of time and are not inclined to spend sufficient time on the consent process with participants and their community leaders. They also believe that the study populations do not know their rights and therefore need not be unduly worried. There is also the perception that researchers are doing the targeted individuals a favour especially if health care is a component in their project.

Voluntary decision is a challenge in research settings in developing countries. Sometimes medical doctors and other researchers are regarded as little '*gods*' and there is lack of will to challenge or question their authority. Physicians have credibility and great influence over patients because of the

belief that a doctor will always “*do good*” for his/her patient. Furthermore, the innocent participants are gullible and are inclined to comply with any terms for participation. The distinction between care and research might also not be clearly spelt out when the physician is also a researcher. Finally, the poverty along with undue pressure to bring participants into research are also important factors.

### **Stages in Consent Seeking in Non-Literate Societies**

Consent seeking involves various gatekeepers in communities like chiefs, participants’ husbands, parents, and in-laws whose consent counts prior to individual consent. Abuses occur in the process of reaching these key players in research.

### **Literacy and Culture as a Challenge**

While it is imperative to present all the necessary information in order to ensure that a potential participant makes an informed decision, non-literate participants in developing countries may have difficulty comprehending and retaining lengthy and often complicated research protocols. The translation of scientific terms like genes, recombinant DNA *etc.* into several local languages are also challenging.

Africa’s customs relegate women to the background and they are usually not in a position to take unilateral decisions without the covering approval of their spouse and/or parents. Poverty wears a female face, hence the tripartite relationship of poverty, child labour, and daily struggle does not augur well for confidentiality or individual consent by women (World Bank, 2004). This notwithstanding, many studies are targeted at women and children. Besides, many Nigerians/Africans are usually skeptical or wary of written documents for a variety of reasons and would prefer to give verbal rather than written consent. Yet, internationally funded research projects insist on informed consent in writing by participants.

### **Confidentiality as a Challenge**

Confidentiality is about full disclosure of the goals of research and the protection of data that are gathered. The researcher is expected to dialogue with participants and community. The participating individuals and communities should not be exposed to unnecessary risks. Nor should their access to other beneficial opportunities be jeopardised.

Confidentiality is usually conveyed in writing. It is a categorical statement and indeed a legally binding one concerning the fact that the information that is obtained will not be disclosed to third parties *only* in exceptional circumstances. But can confidentiality be effective or sincere in communities where women are rated as second class citizens or in context in which they can only be approached through a third party (e.g., spouse or parents) as earlier discussed?

### **Conflict of Interest**

Conflict of interest can be defined as situations where the primary professional judgment on patient care or scientific knowledge in research is unduly influenced by secondary interest of financial and/or other personal gains/benefits such as promotion or publications or academic recognition. Conflict of interest could occur in all research processes including consent seeking. Conflict of interest between sponsors and researchers on the one hand and between the researcher and the community on the other should be avoided. The effect of poverty in developing countries

sometimes makes researchers and communities to *jump* at all manners of research without giving much thought to conflict of interest.

### **Researchers' Responsibilities**

The professional competence of researchers must be adequately addressed. There must be honest reporting data while misconduct and plagiarism should be discouraged through stiff and deterrent disciplinary measures whenever they occur.

Researchers should target appropriate participants bearing in mind the inclusion and exclusion criteria in order to maximally benefit participants. The targeted individuals and communities should be given the opportunity to decline or withdraw from study. Moreover, researchers should report adverse events in their locality within 48 hours of occurrence to the Research Ethics Committee (REC) to their sponsors in order to facilitate appropriate steps that will minimise further risks to participants. But what is likely to happen in a system where communication is almost non-existent like rural and inner city communities and/or where large numbers of non-literate individuals are targeted? This constitutes a great challenge.

### **Access to Research Communities**

Entering “communities” for health research requires special skills if research is to be conducted in an ethically sound manner. The problems that researchers face differ from one community to another. There are different types of communities – some are easy to reach (*e.g.*, students) while others are hard to (*e.g.*, drug users). Factors like social organisation, political system, and worldview shape mode of access. There are other factors like belief-system, gender, family structure, and social networking. Overall, the extent to which the targeted individuals and communities comprehend perceived benefits and harm including the researcher's, and/or sponsor's reputation as well as institutional integrity play a role in access to community and procurement of consent.

### **Other Challenges**

Who pays the piper? What motivates the sponsors of research? Who sets the priorities for research? These are reasonable questions to sort out in pursuance of research in poor and non-literate societies. Africans communities are suspicious of documentation because of their low literacy level and the fear that the information that is gathered could be used for tax purposes in view of their previous experiences during colonial era. They therefore prefer verbal consent which is non-committal.

Researchers in developing countries have to be mindful of these factors and assist the sponsors of research from the North to optimise best practices in spite of these challenges and fears. Harmonising ethics across disciplines and diverse populations of the world is not easy. As mentioned above, there are grey areas that ought to be addressed (Plattner, 2002).

### **Way Forward**

It is unacceptable to embark on research without initially identifying efficacious interventions that are locally available to the control group. Consequently, the following are proposed:

1. Developing countries researchers must secure post-trial access to effective interventions for the benefits of participants in all clinical trials.



2. Negotiation on the introduction and sustenance of successful treatment regimen for the wider benefit of communities should be outlined prior to research and also discussed at the ethical review stage.
3. Researchers and sponsors should provide ample justification of their claims to RECs prior to the commencement of research.
4. It is vital to monitor research in order to ensure that ethics are not breached. This should be the responsibility of REC and sponsors most especially in developing countries that lack functional RECs (NEBRA, 2005). Developing countries should therefore establish National and the Institutional Research Ethics Boards/Committees (RECs) that are active and functional (Falusi *et. al.*, 2007). These Committees should be empowered to adopt basic ethical principles and universal minimum standards of care in research.
5. The governments of developing countries should train and empower their researchers in their respective institutions. The active participation of the Legislative and Executive arms of governments in the identification and selection of relevant projects in developing countries should be encouraged.
6. The complementary role of RECs in developing appropriate consent process for research in developing countries cannot be overemphasized (EDCTP, 2007).
7. Field and laboratory health projects in non-literate societies can only be successfully implemented if logistical issues in research are adequately addressed.

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# Consent Seeking in Social and Behavioural Research in Non-Literate Communities

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## Introduction

Consent seeking in social and behavioural health research is a difficult task in non-literate societies for three reasons. Firstly, unlike in biomedical research, studies in social and behavioural science do not demonstrate immediate material benefits in the form of therapeutic services or the provision of infrastructures for the targeted participants and communities. Yet, the participants in such studies would like to know direct or indirect benefits of such research to them. Secondly, it involves questioning participants on issues that invade their privacy which they would ordinarily not like to discuss. Lastly, the participants exist in communal contexts where the autonomy of the individual is understood in a wider context of layers of social relationships as indicated, - “*we are persons through other persons*” (Ayantayo, n.d). The communal system of living in non-literate societies protects the interest of people and raises the question concerning the autonomy of an individual in decision-making.

This paper examines the ethical challenges in consent seeking in social and behavioural studies in largely non-literate communities.

## Ethical Challenges

The ethical challenges in doing social and behavioural research in non-literate communities revolve around:

1. respect for persons;
2. sharing of benefits of research;
3. fairness in Sample Selection;
4. technical inaccuracies;
5. privacy of the individual;
6. community exploitation;
7. deception, and
8. competence of field assistants.

## Respect for Persons

The respect for, and the protection of autonomy, rights and dignity of participants is a major ethical challenge in patriarchal societies with large numbers of non-literate persons. Patriarchy undermines voluntary decision-making in such societies in two ways. In the first place there is imbalance in the power relation between the male and female gender in largely non-literate patriarchal societies. Females cannot give informed consent on important issues without the consent of their husbands (in the case of married women) and fathers in the case of unmarried girls. Consequently, it is difficult to obtain consent from a woman whether married or single. Fathers and/or husbands could influence girls and/or women which in turn implies that the researcher are merely obtaining involuntary consent.

Importance is attached to age and authority usually flows from the top (*i.e.*, older age groups) to the bottom (*i.e.*, lower ones) in patriarchal societies and this is obvious in non-literate settings. Consequently, respect is the basis of social relation in parts of Africa. Age grade is an important determinant social status and authority in these societies. Those who are born about the same time bound together, move up the social ladder together, and they also exercise considerable influence over those in the lower age grades. Important issues or decisions are delayed in order to obtain the consent of elders who are the custodians of wisdom or the sources of authority. Getting consent from a community member could therefore be difficult where the elderly members are present and/or not around to give their assent.

Paradoxically, research that involves human subjects must not only respect but also protect the autonomy, rights, and the dignity of all participants. The participation of the targeted individuals must be voluntary and based on informed consent which is often required in writing. How this can be achieved in patriarchal societies where the female gender is not expected by tradition to make informed decision that is independent of their fathers (*viz.*, if unmarried) and husbands (if they are married) is a challenge. Also, how the decision-making role of elders can be addressed in this context because age is the basis of social relations and source of authority is another challenge to researchers. Generally, individual autonomy is at stake in this context and this could mar the research process if the autonomy of the individual most especially of the vulnerable subgroups in the population such as women is required.

### **Sharing of Benefits**

The sharing of benefits is an important aspect of the research enterprise. Communities are interested in the outcomes of the research that is conducted in their milieus (Fernandez *et. al.*, 2003b, 2005, 2007; Schulz *et. al.*, 2003; Fong *et. al.*, 2004; Moutel *et. al.*, 2005; Dinnett *et. al.*, 2006). Non-literate communities may not enjoy the benefits of research that is conducted in their settings due to lack of proper negotiation because of the wide socio-economic gap between the researcher and the targeted participants. Benefit sharing may not be a fair process in such communities where there is no level playing field.

### **Fairness in Sample Selection**

Fairness in the selection of the participants in research could be difficult in non-literate communities. For instance, people might not know their age since record keeping is a major problem in non-literate communities. Although age could be estimated through important symbols or historical events in their communities, such estimates are not always accurate. Bias could be introduced if participants are not randomly selected. For instance, the over-representation of highly placed or older people in the sample could influence decisions on the underprivileged.

### **Technical Inaccuracies**

Technical inaccuracies are major issues in social and behavioural research in non-literate communities. Research designs could exclude communities' contextual knowledge, and observations including the local knowledge and experiences that are reported by community members. This can lead to inadequate information about diet, lifestyle, and other important details especially in cross-cultural communities that have different subsistence patterns (Frohberg, 1999).

## **Privacy of the Individual**

The privacy of participants is another ethical challenge in consent seeking in social and behavioural research in non-literate communities. It is often difficult to manage the principle of confidentiality in non-literate communities because researchers are sometimes inclined to use interpreters or are forced to cope with next of kin and significant others who cannot be easily kept at a distance during interview sessions. The result is that researchers are forced to deal with third parties in the course of their interaction with respondents in non-literate settings.

## **Community Exploitation**

The exploitation of communities and inducement of participants to participate in studies are important ethical challenges in consent seeking in social and behavioural research in non-literate communities. Socio-economic inequalities between researchers and participants play a coercive role in the recruitment of participants (Benatar, 1998; Lindegger and Richter, 2000). This often leads to difficulty in applying the widely recommended bioethics principles (Loue, Okello, and Kawama, 1996). For instance, the participants in poor-resource settings might not have adequate information on the subject matter of the research once they are given what amounts to generous incentives. Although incentives are allowed in research, they could be unethical if they influence judgment in a manner that undermines the autonomy and worth of participants. Resource-poor societies are confronted with the problem of choosing between informed knowledge of the subject matter of research and the incentives that are offered by researchers. The targeted individuals are mostly blinded by incentives and are inclined to overlook many things or even struggle to participate because of the incentives that are offered to them.

Consequently, community exploitation is also a possible factor in consent seeking in social and behavioural research in non-literate communities due to the divergence between the socio-economic statuses of researchers *vis-à-vis* the targeted individuals. Usually, researchers have economic advantage and the power of scientific knowledge over participants. Researchers could use these to their advantage by manipulating non-literate communities to open their gates to hazardous social and behavioural studies. Researchers may fail to compensate communities appropriately once they are able to gain the support of gatekeepers. The gatekeepers could in turn open the 'gate' of their communities on the basis of monetary reward that is not commensurate with the magnitude of research activities. Or they could sell out their communities through deals with researchers. The participants may be induced to give their consent to participate in a study through financial compensation that is more than what they could earn in their daily economic activities or in the form of material things that look precious to them.

## **Deception**

Deception is another critical issue in consent seeking in social and behavioural research in non-literate communities. Researchers might not provide complete information on the subject matter of their research if it will hinder them from getting the consent of participants (Varmus, 1997). In such circumstances, participants are deceived to give their consent to harmful studies. For instance, certain cultural practices may be difficult to study due to taboos surrounding them or their beliefs could deter them from responding to questions on such issues. Some researchers may willingly apply the 'cover' approach which is permitted in social and behavioural research where it is not necessary in order to get their work done quickly and easily at a little cost.

## Competence of Field Assistants

The capacity of field assistants to work in an ethical manner is another challenge. The field assistants have the same ethical responsibilities as investigators. But do they in practice have adequate skill in research ethics in such settings? Although they are expected to be trained on how to adhere to ethical details in research, it is doubtful if they can satisfy this requirement as members of the same community where they are collecting data without using their personal influence to coerce participants to give their consent to participate in a study.

## The Way Forward

Conducting social and behavioural research in non-literate communities requires proper skill and monitoring. Training in ethical reasoning is the first step in addressing this issue in order to ensure that things are done correctly. Knowledge and skill on ethical practice are currently low among social scientists in developing countries even though research ethics is taught as a topic or two in research methods classes. The following steps must be taken in order to tackle the foregoing lapses.

First, the social science disciplines should incorporate ethics into their curricula. This should be taught as a required course at the undergraduate and postgraduate levels. Second, all social and behavioural researchers should be trained in research ethics. Evidence of this training should be a condition for research grant and approval for any protocol. Third, public educational programmes should be promoted in order to close the gap in knowledge between researchers and communities. Researchers should not only collect data and leave communities, they should share their experiences with them because this will build trust and also ensure support for future research (Richards *et al.*, 2003; Partridge *et al.*, 2003; 2005; Hoeyer *et al.*, 2004; Dixon-Woods *et al.*, 2006; Wendler *et al.*, 2007; Shalowitz and Miller, 2008). Fourth, verbal consent should be permitted in non-literate communities. This can be recorded in video for record purposes. Asking participants to sign informed consent form in non-literate communities may be taxing while the use of thumb printing could be demeaning. An alternative is to accept verbal consent.

Finally, research protocols should be translated into the local languages of the research communities and used in communication during data collection. This will make it possible for participants to have adequate understanding of what it takes to participate in research.

## Conclusion

The paper has highlighted the reasons for increased knowledge in ethics in health research in developing countries. It has also identified and outlined the ethical challenges in consent seeking in studies in non-literate communities. An important consideration for social and behavioural research in non-literate communities is the understanding of the socio-economic and cultural contexts. Non-literate communities are vulnerable. They face severe socio-economic problems and are at the risk of research atrocities. We can therefore not assume that researchers will always do the right thing while working in non-literate communities.

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## Ethical Challenges and Code in Study Design in Social and Behavioural Research in Vaccine Testing in Non-Literate Communities

*Abraham Alabi*

### **Introduction**

Vaccine testing through clinical trials poses ethical challenges even in literate communities but the problem is compounded in the non-literate due to ignorance, cultural beliefs, and lack of proper understanding of the concept of vaccine.

Clinical trials that lacked appropriate scientific basis and ethical justification were conducted predominantly on the disadvantaged, usually non-literate subgroups at different times in past century. For instance, the Nazi doctors conducted gruesome medical experiments in German concentration camps during the Second World War. Similarly, some 400 poor black men in the rural south of USA who were diagnosed with syphilis were left untreated as part of a study that was designed to observe the natural course of untreated syphilis in the Tuskegee syphilis study that came to light in the 1970s (Jones, 1981). Such trials which were deliberately designed to exploit the ignorance of participants were accompanied by serious injuries, permanent disability, and the death of the research subjects.

The establishment of internationally recognised ethical codes and standards for conducting clinical trials on human subjects was as a result of public outcry and condemnation and as part of the concerted efforts of the scientific community to prevent future occurrence. A few examples of codes and regulatory frameworks that are conceived to prevent occurrence are the: Nuremberg Code (1949), International Ethical Guidelines for Biomedical Research Involving Human Subjects (CIOMS, 1993), World Medical Association Declaration of Helsinki (2000; 1964), and Belmont Report (1979).

This paper will attempt to outline main ethical challenges in study design in vaccine testing in non-literate communities and/or resource-limited settings in Africa.

### **Study Design**

Non-literate communities are unique settings in which the concept of vaccine testing or trials could easily be misunderstood or misinterpreted at any stage of the process. Hence the study design must be simple with in-built mechanisms for monitoring, dissemination of outcomes, investigator-community interaction, and conflict resolution. Other important factors that must be carefully considered in the design of a vaccine trial in non-literate communities are the objectives of the trial; the Phase (whether Phase I, II, or III); mode of delivery; cold-chain requirements; data analysis; cultural beliefs; leadership structures; confidentiality; and community mobilisation (*i.e.*, how to communicate effectively with all strata in a given community). It is important to pay attention to post-trial events such as plan for the dissemination of results and how the tested vaccine will be made available to the participating communities if successful.

Ethical codes in vaccine testing consist of a set of clear guidelines for community-based vaccine trials in accordance with internationally acceptable standards. This is without prejudice to the type

of community, (*i.e.*, literate or non-literate) because ethical codes should not be based on social or educational status. However, special efforts must be made to ensure that the ethical codes are simple and unambiguous when vaccine trial is conducted in non-literate communities. In addition, the codes should be translated into local languages and clearly explained to staff in a way that they understand the rules and procedures that guide the conduct of trials if they are to be directly involved (*i.e.*, as field workers or interpreters).

Ethical codes in vaccine trials must provide guidance to all staff on the likely ethical issues that may arise in the course of trial. These will include respect for participants and the cultural values of the participating communities; informed consent; enrollment of volunteers; procurement of vaccine; storage and transportation; recommended dosage and the route of administration; health and safety (*i.e.*, the favourable risk/benefit ratio); sample and data collection procedures; analysis and dissemination of results; including independent ethical review of protocols. All professional staff such as doctors and nurses must comply with the ethical codes of their professional bodies throughout trials.

### **Ethical Challenges in Vaccine Testing in Non-Literate Communities**

The guidelines for ethics in scientific research involving human subjects are informed by the principles of:

- a. respect for persons;
- b. beneficence/non-maleficence, and
- c. justice (Marshall, 2007).

While these ethical guidelines are now widely publicised, their implementation and acceptance has remained largely voluntary (Bhutta, 2002). This is true in many developing countries where the regulatory bodies and institutions that are charged with the responsibility of ensuring compliance with international standards lack the capacity to do so. However, many of these countries are now making effort to have functional National Ethics Review Committees (NERCs) and Institutional Review Boards (IRBs) with the support of funding agencies.

Carrying out vaccine trials in non-literate communities often involves an act of balancing universally recognised ethical standards for research with the local. Marshall (2007) concluded that the disconnection between ideal standards and their application in the real world of structural imperfections and social, political, and economic inequities contributes to the moral complexity that surrounds research design and implementation in resource-poor settings. It is desirable to adapt ethical requirements to the reality in non-literate communities without compromising internationally acceptable standards. The main ethical challenges in vaccine trials in non-literate communities are as follows:

### **Informed Consent**

The concept of informed consent is crucial to the credibility of any vaccine trial. The participants in trials should voluntarily agree to participate after they are given all relevant information pertaining to the trial; (*i.e.*, they have well-informed knowledge upon which they can independently take a decision to participate without any fear of intimidation or denial of any potential benefits of the trial).

But the challenges in non-literate communities include:

- how to explain the concept of informed consent to non-literates to sufficiently understand and make informed decisions;
- how independent is the decision to participate in a vaccine trial (*i.e.*, autonomy);
- the motive for participation, and
- whether the head of a household or community can give consent on behalf of members of his/her household or community.

Therefore well-informed consent is a challenge. The question is: “how informed is informed consent among non-literate respondents?”

In a study of informed consent in an influenza vaccine trial among children in The Gambia, Leach *et. al.*, (1999) reported that, although 90 per cent of the 189 consenting parents knew that the aim of the vaccine was to prevent disease, only 10 per cent understood the placebo in the control design. Similarly, Pace *et. al.*, (2005) found that even though most respondents in their study of comprehension of consent in a randomised drug trial among HIV-positive individuals in Thailand said that they were well informed, only one third correctly reported that half of the participants would receive the experimental therapy. Finding words in local languages to explain scientific terms such as placebo, randomisation, and confidentiality without distorting their meanings is also a great challenge.

## **Community Consultation and Mobilisation**

Recognised heads/leaders (*i.e.*, traditional rulers, village heads, chiefs, etc) wield enormous powers in non-literate communities and securing their support is essential to achieving a successful vaccine trial in their communities because they enjoy substantial respect and followership. The challenge is how best to approach these leaders to make them buy into the idea that participating in a vaccine trial is good for their communities. The support of such community leaders is also vital in resolving potential misconceptions or conflicts during trials. For instance, The Medical Research Council (MRC) has been operating in The Gambia for over sixty years with good and mutually beneficial relationship with Gambians and their Government. This cordial relationship has been very useful in resolving misconceptions about research activities. Consequently, community involvement should be an ongoing process in which the community is kept abreast of research activities and findings (Marshall and Rotimi, 2001).

## **Conclusion**

Internationally recognised ethical codes and standards are well-established for scientific research involving human subjects. Social and behavioural research must always uphold mutual respect and trust between participants and investigators and also adhere to the principles of beneficence and non-maleficence (do no harm). Ethical code must strike a balance in the obligations to study participants, professionalism, funding agencies, and the society at large.

The debate goes on whether ethical codes and standards should be universally sacrosanct and followed strictly by the letter irrespective of the location of a study. While strongly arguing against promoting double standards under any guise, it is advisable to adapt ethical codes and standards to the need and practical realities of the different communities across the globe.

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# Ethical Issues and Research Code in Social Science Methodology in Africa

*Olayiwola Erinosh*

## Introduction

Scientific inquiry is about observation, objectivity, rigorous interrogation, analysis, and interpretation of data on the basis of probability theory. Testable propositions may be confirmed or refuted on the basis of carefully assembled verifiable facts. Every outcome of scientific enquiry has a character of hypothesis. As such, today's outcomes may be refuted tomorrow if newly discovered facts indicate otherwise. The core principles underlying science methodology transcend all human societies regardless of their colour, creed, or spatial location.

Pioneer social scientists also shared the epistemological standpoint of biological and physical scientists in the production of knowledge. Social scientists are therefore expected to be detached in the study of human behaviour (*i.e.*, value –free) as well as display an *open* rather a *closed mind* on outcomes. Outcomes may be modified or dismissed depending on new facts/data.

The orientation of the founders of the social sciences was eclectic because they were inclined to utilise wide ranging strategies severally and collectively in data collection. They recognised a holistic approach to the production of grand scientific theories. Positivism was not strictly defined in terms of the quantitative method, or by simply quantifying data/information but in a broad inclusive way. They reasoned that grand theories could only enjoy scientific credence *if all possible useful and relevant techniques* are used in data collection in the study of social problems and society.

The classical works of pioneer social scientists bear testimony to this orientation. Works by Smith's (1776), Comte's (1776), Durkheim (1951), Weber (1958), and Marx (1906) underscore an eclectic orientation in social research because both the quantitative and qualitative including the historical methods were used by these writers to gather data that are required to support their paradigms.

The pioneer social anthropologists invented the participatory/observational method in order to understand/analyse human behaviour/communities. They lived, ate, drank, played, worked etc with groups/communities. They studied the local languages before they embarked on research. It is painstaking because researchers are required to spend several months or years observing and taking notes before analysing and interpreting what they observe. This enables them to understand the history, social life and structure of the groups/communities were (or are being still) studied.

This paper will attempt to provide an overview of the ethical issues and research code including challenges/dilemmas in social science research projects in largely non-literate societies in Africa.

## Ethics and Code in Social Science Research

Ethics and research code are extremely important in the work of social scientists because the rights of human beings that are targeted in their studies must be respected. It is desirable for them to:

- obtain informed consent from participants prior to the studies that focus on them;
- handle them with dignity during study;
- assure confidentiality of the information, most which might be personal, that is obtained from them;
- provide feedback to them on the completion of study, and
- ameliorate their conditions if possible (Nuffield Council on Bioethics, 2002; Marshall, 2007).

One of the practical ways of highlighting what is proper in the context of social research is to focus on methods of social investigation which include:

- survey research (*viz.*, which may be retrospective, cross-sectional or longitudinal);
- experimental;
- quasi-experimental;
- participatory/observational;
- non-participatory/observational;
- focus group discussion;
- In-depth interviews;
- case study, and
- documents/records.

Informed consent is required in order to access documents/records in retrospective surveys and in the procurement of information from respondents that are targeted in all manners of social research. Written permission is required while respondents and organisations are free to participate or opt out from studies. Permission provides the covering approval for data collection on a wide range of issues including those that are of personal and/or sensitive nature. Also, the respondents that are targeted must be given adequate information on the objectives of the study.

The permission to ask any question or obtain any record including the opportunity to use the precious time of respondents is a *privilege* and not a *right*. As such, researchers are expected to seek their cooperation before embarking on their study.

Entry into organisations and/or small communities can be facilitated if permission is sought and obtained from their heads/elders. The heads/elders of organisations are the gatekeepers of records/documents, their co-operation will facilitate data gathering. Researchers should give assurance that on keeping the information that is provided confidential. It is also necessary to enlighten respondents/communities on the risks and benefits of their studies. Finally, they should express their gratitude to them on the completion of interviews/studies.

Researchers were inclined in the past to report the outcomes of their studies in journals/books which are usually not accessible to their respondents or the organisations that are targeted for study. But sharing outcomes through policy briefs and/or workshops with respondents/organisations that are targeted for study is vital for two reasons. Firstly, it gives them an insight into outcomes and also ample opportunity to make input into them (*i.e.*, the outcomes) even when researchers are unable to solve the problems of respondents and communities. Information sharing also reassures the targeted respondents/organisations/subgroups that they are not merely used and dumped by researchers. Finally, feedback clear the way for prospective researchers in same group/community/organisation in the future.

It is vital to draw attention to ethical issues in participatory/observational studies of sensitive groups such as cults or secret societies etc. While such groups could grant researchers the

permission to study their activities, they might not take kindly to the dissemination of what they do in secret to the public at large (Brink, 1993). This implies that those who work on sensitive issues ought to seek clarification before disseminating the outcomes of their studies.

### **Research Code in Social Research**

Studies must be conducted in accordance with extant guidelines/rules in scientific work. Among the extant guidelines are to:

- select adequate/representative sample;
- maintain affective neutrality;
- apply appropriate statistical techniques where required;
- interpret outcomes dispassionately, and
- draw reasonable conclusions based on facts.

Researchers should recognise the limitations in the use of records and documents that are kept by those that do not have the researchers in mind. Secondly, records/documents are not necessarily sufficiently rich for the analyses that social researchers envisage. Thirdly, they might have been deliberately distorted by their recorders/keepers. Fourthly, records and documents provide an eye bird view of issues/problems (*e.g.*, hospital records or crime records) and are therefore not sufficiently comprehensive. These and other shortcomings should be recognised in retrospective surveys based on records and documents.

Researchers ought to exercise caution in the interpretation of findings, bearing in mind that there are chance errors. Besides, they ought to be honest and transparent in their work as well as acknowledge the contributions of co-authors, field workers, and other collaborating institutions in the implementation of their studies.

### **Ethical Challenges and Dilemmas in Non-literate Communities**

One of the major challenges facing researchers in non-literate communities is how to obtain *informed consent in writing* as demanded by international ethical review boards. Non-literate respondents are always unwilling to append their signature to, or thumb print consent form because of its legal implications. However, they are inclined to give oral consent. The key issue is whether oral consent is adequate for ethical clearance by boards that are not acquainted with the socio-cultural context of research in Africa. A solution that is worth considering is to procure oral consent on tapes provided it is with the permission of respondents.

Another challenge revolves around entry into communities. Communities are now becoming hostile to researchers and are also equally inclined to demand some sort of monetary gratifications before collaborating with them. The participants in focus group discussions would like to be reimbursed for money spent to travel to the venue of discussions and/or for abandoning their sources of livelihood in order to take part in discussions. Chiefs would like to be *settled in cash or in kind up front* before garnering the support of members of their communities. Some areas or sub-regions like the Niger Delta in Nigeria are proving dangerous for research work

There is now a loud and demand from the public for the benefits of research in view of the failure to use the outcomes from past studies to improve lives. A certain degree of cynicism has crept in and this is accounting for blackmail and/or outright hostility toward social research and researchers. But researchers usually lack the funds for dissemination seminars/workshops at the end of their study.

## Research Code and Its Challenges in Non-Literate Communities

There are misconceptions about social science methodology in Africa's institutions of higher learning resulting in a situation in which students tenaciously hold to the viewpoint that the quantitative is the most effective and important method. Teachers and students appear to be incapable of showing appreciation for developing and/or acquiring appropriate skill in qualitative including the historical methods that can yield the data that enrich quantitative studies. There is an erroneous but widely shared view that social science work cannot really be regarded as scientific or earn respect unless:

- questionnaires are designed and administered;
- data are processed using computers, and
- mathematical models/equations and other sophisticated statistics are flaunted with commendable ease.

This orientation presumably explains why the dominant social science methodology among scholars obfuscates the understanding/analysis of Africa's problems.

Africa is still largely rural and noted for oral tradition and large numbers in the population are still non-literate. Surveys in which questionnaires are administered among largely non-literate respondents in Africa often fail to uncover critical aspects of behaviour patterns, resulting in superficial analysis, interpretation, and recommendations. Although researchers usually indicate that they intend to gather qualitative data through focus group discussions or in-depth interviews, they hardly make use of them in the final analysis.

The importance of an eclectic orientation in social science methodology in the understanding of Africa's problems cannot be glossed over in view of the outcomes from recent HIV/AIDS studies. African countries are still carrying a heavy burden of the disease in view of the pervasiveness of high risk behaviours despite the efforts that have been made to understand the factors that account for its spread. Two studies, one from East Africa (Soma-Net, 2006) and the other from Malawi (Tawfik & Watkins, 2007) in which the researchers used the participatory/observational and community dialogue methods in their investigation of behaviour patterns that are conducive to the spread of HIV/AIDS. are however providing significant insights. These studies demonstrate the need to bring a fruitful approach to the study of social problems in Africa.

The challenges in field research at the macro standpoint can be briefly examined in the context of the study of sensitive problems like secret societies or sexuality or reproductive health matters most especially among non-literate or Muslim subgroups and bland/ non-sensitive ones (*e.g.*, job satisfaction and motivation or use of health facilities *etc*). Researchers are likely to face more difficulties or taxing challenges in the studies on the sensitive than in those that are not.

The design of instrument for field studies in multi-ethnic and largely non-literate societies could be challenging because they (*i.e.*, the instruments) are expected to be translated into local languages/dialects by experts who are also acquainted with commonly used words and/or inoffensive concepts (*e.g.*, studies on sensitive issues/subgroups). Back and forward translations could be problematic and is also are the recoding of responses by field workers. Field assistants must be well trained to administer the instrument in the most effective way. They must also possess the capacity to relate in an accustomed way to respondents/communities. For instance, accessing women who live in Purdah in Muslim communities in surveys is by no means an easy task because the permission of their husbands must be sought and obtained. The husbands of these women could



also insist on being around while the interview is taking place. Getting such women to participate in focus group discussions away from their homes could also pose a problem to researchers.

Another dilemma facing researchers is how to compensate participants during data collection without paying them. Respondents are nowadays unwilling to participate in studies unless they are compensated in one way or another partly because the:

- societies have become materialistic;
- respondents are wary of researchers who tend to breeze in and out and take their cooperation and support for granted, and
- cynicism over the possible benefits of research to them/communities.

Consequently, everyone is anxious to know what is in the research for them which they would like to collect “up front”.

Data like age is difficult to gather in non-literate populations. The National Population Commission in Nigeria has devised the means of estimating age during national censuses by using important historical events. Occupation is another variable that defies reliable classificatory scheme because it is difficult to distinguish trader from business man or woman. Another is income and researchers are forced to estimate or use proxies.

Researchers are also likely to confront different challenges in urban vis-à-vis rural settings. While entry into rural areas could easily be facilitated by community leaders, this could prove to be difficult in large urban settings that incorporate heterogeneous ethnic groups. Researchers might have to enter urban communities through age grade associations, civil society organisations, faith-based organisations etc. or use the media to educate the public about the impending study in order to secure their support.

## **Concluding Remarks**

This paper has addressed key ethical issues and challenges in social science methodology in the context of Africa. As can be seen from the discussion, African countries are unique in a number of ways. They are multi-religious, multi-cultural, multi-racial, and non-literate. Secondly, vast numbers of their citizens are still non-literate and poor. Thirdly, the gap between researchers and the populace is wide because the former who are literate and ‘westernized’ are inclined to carry patriarchal nuances into their relationship with those that are targeted in research who are largely non-literate and unacquainted with the logic and process in social research. The paper has highlighted the dimensions of ethics in research in such settings.

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## Ethical Issues in Qualitative Research in Public Health in Africa

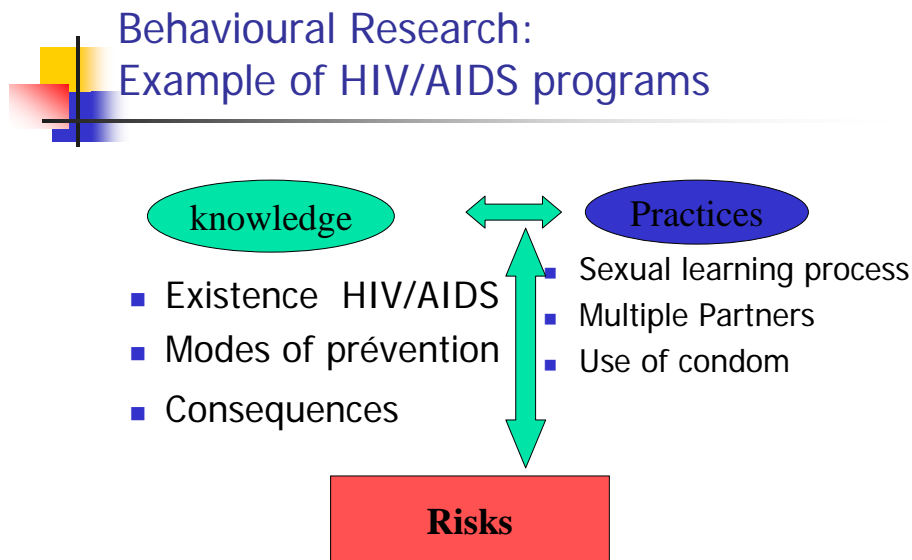
*Paul Nchoji Nkwi*

### Introduction

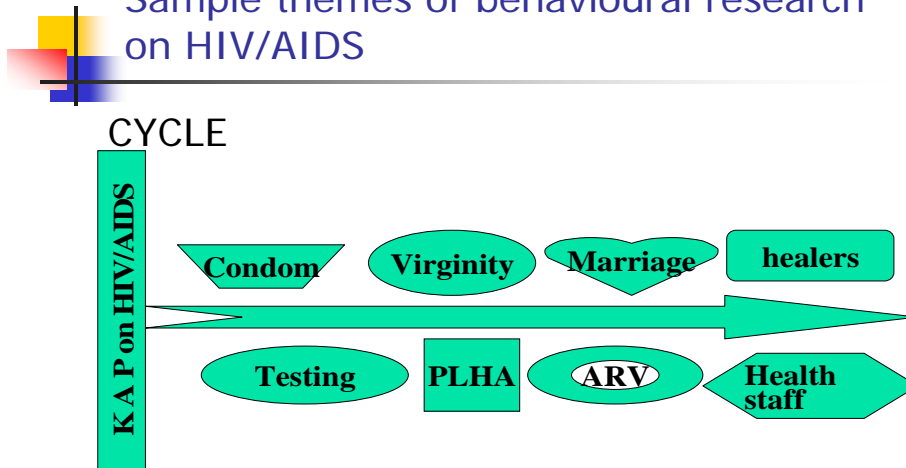
Medical anthropology which seeks to study disease and other health problems as cultural phenomena also pays particular attention to ethical issues. Working with public health specialists often calls for special attention to issues that concern the privacy of patients, confidentiality, conflict of interest, informed consent, beneficence, maleficence, and all ethical issues that focus on cultural concerns. Anthropologists use predominantly qualitative research methods and these ethical issues are part of the process, a process which includes the collection and analysis of data.

The generation or creation of knowledge is often and in most cases the object of research but the practical application of knowledge is often recommended because we seek to improve the quality of health when we deal with health issues. The models below attempt to show how all the ethical issues must be at the back of the mind of researchers as they conduct research.

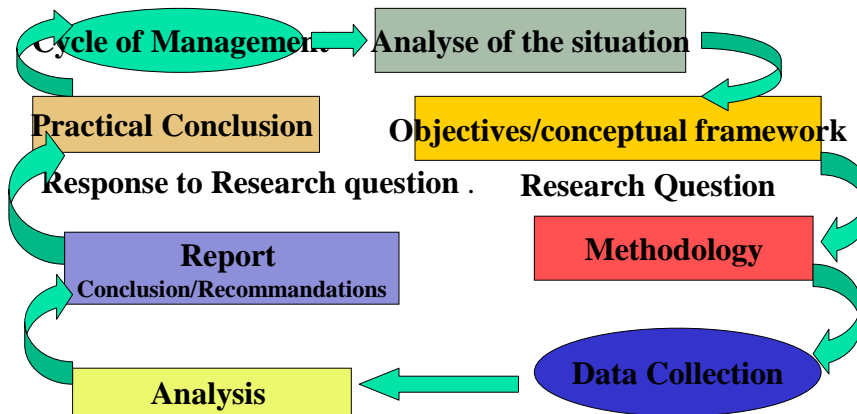
Figure 1



## Sample themes of behavioural research on HIV/AIDS



## Stages of Applied Research



Source: Ndonko and Nkwi, 2004

In order to understand and appreciate qualitative methodology, we will provide answers to the following questions: What is qualitative research? Where do qualitative data come from? What do qualitative researchers in health do? Why use qualitative data?

## What is Qualitative Research?

Qualitative research involves any research that uses data that do not indicate ordinal values. It deals with video, objects, texts, or narratives of a personal life. It could also consist of a list of bars or clubs that are frequented by prostitutes or all articles that mention HIV/AIDS in local newspapers over the last 20 years.

The expression “qualitative research” could be confusing but Bernard (1996) notes that since research consists of data collection and analysis, it is not clear if qualitative research refers to the collection of qualitative data or qualitative data analysis.

## Where Do Qualitative Data Come From?

Qualitative data come from two main sources: non-interviewed-based and interview-based sources. First, we need to distinguish data that already exist in those that are procured through interviews. The non-interview-based data include tangible things (artefacts and documents) and observations. Artefacts include all material objects (archaeological findings, goods and tools, *etc.*). Documents include video (films *etc.*), audio, (music, oral speeches *etc.*), books, personal letters, newspaper articles, *etc.* All human historical records belong to this category

Interview-based data sources can be broken into those that produce free-flowing texts, words and phrases. Interviews that produce free flowing texts can further be distinguished into unstructured (*e.g.*, informal ethnographic materials from participant observation) and the structured (*e.g.*, focus groups). Techniques that produce words and phrases are often referred to as “systematic”. These include free-listing pile sorts, triad tests, paired comparisons, frame substitutions, successive free-listing, ethnographic decision models, face-to-face surveys and questionnaires.

## What Do Qualitative Researchers in Public Health Want to Do?

The choice of methods depends on the (a) aims and goals of research; (b) theoretical and conceptual approaches in a research; and (c) feasibility and ethics of the sampling strategy (Miles and Haberman, 1994). In exploring a subject, a researcher hopes to discover themes and patterns and/or build models. An example is a study on the factors that determine high fertility or the prescribing behaviour of family planning products by providers. In the case of description, the researcher will describe a single case, list typical events as well as exceptional idiosyncrasies. The researcher will describe cases and note how individuals are similar and different from one another. Comparison can be made at the individual and group levels.

## Why Use Qualitative Data?

There are pragmatic and epistemological reasons for using qualitative data. Researchers who study health and population issues might wish to:

- discover or explore new phenomenon;
- identify new concepts and themes;
- describe and understand complex, dynamic, multidimensional phenomena, and
- bring forth people’s experiences.

## The Informant

The informant is to the anthropologist just as the patient is to a medical doctor. Medical ethics imposes on the physician a behaviour pattern or guiding principles that are related to the physician's consultations. The basic values in medical ethics are beneficence, non-maleficence, autonomy, justice, dignity, trustworthiness and honesty. Informed consent is also important.

Informants are the oral sources of information and the repositories of knowledge from which researchers retrieve information which they transcribe into books and monographs. They have special knowledge. They are articulate and full of insight in many areas that are of interest to social scientists. We return to key informants on many occasions in social research and build knowledge on issues that are of interest on such occasions. We document what they say including their names, dates, and settings of interviews. Sometimes we forget to quote them as we quote other authors.

## Interviewing Ethics

Some basic ethical considerations must be respected in order not to cause any emotional or physical harm to informants in the data collection process. The researcher must decide at the initial stage of the interview what kind of data he/she wishes to collect. He/she must protect the identity of informants if the information that is being collected is sensitive. Protection means that the researchers must protect informants from emotional disturbances (Bernard, 1994).

The possible harms to the informants are:

- violation of informant's right to privacy by asking sensitive questions;
- violation of informant's right to privacy by having access without his/her permission to records or files that contain personal and confidential information;
- secretly observing the behaviour of informant;
- disclosure of information from your informant to other persons, and
- failure to observe or respect certain cultural values, traditions, and taboos. (This could occur when the researcher lives in the community).

In order to avoid attitudes that could tarnish the image of a researcher in the community and/or jeopardise the future for others, researchers must:

- obtain the consent of the informant before asking sensitive questions. (This should be obtained before the interview starts);
- respect the informant's privacy;
- ensure that the data are protected against third party, and
- avoid misrepresentation of the information that is obtained from informants (*i.e.*, must be reported verbatim without identifying by name unless this is waived by informants).

Cultural concerns are paramount in all of these. The cultural perceptions of diseases may not necessarily correspond to modern medical ethics. Many cultures have spiritual or cultural theories about the origins of disease which are not in consonance with the germ theory in western medicine. Often researchers have to reconcile the people's beliefs with the tenets of Western medicine but this is often very difficult. Indeed, value judgment must be avoided. That is, researchers should avoid classifying cultural practices as good or bad. Although this could lead us to assert the value of cultural relativity, we cannot judge other cultural practices through our prism.

Consent must be obtained in the collection of qualitative data in which key informants are targeted. The informants should be briefed about the purpose of research and shown why their knowledge

will contribute to this. Informants should know about the risks that they are taking. Informants can choose to make their own health decisions, and only delegate such decision-making authority to another party when culture does permit them to do so. The decision-making tree-model in terms of health reconstruction is generally made on the basis of experiences and cultural norms and values. The value of informed consent is closely related to the value of autonomy and truth telling. An example: in cultures where people's wives cannot be interviewed without their consent, researchers should not attempt to do so.

## **Confidentiality**

This applies to information that is obtained by researchers from informants/patients. Revealing confidential information that is obtained from informants under oath is unethical.

In order to assess the quality of life of people living with HIV/AIDS, we conducted a series of interviews in several treatment centres and found that almost 40 per cent came from other faraway treatment centres. Many of them came to these centres because they wanted anonymity. We had to assure them of total confidentiality in order to collect data from these patients. Revealing HIV/AIDS status without consent is unethical, especially if this information is obtained confidentially.

## **Beneficence**

This is about the concept of doing *good* to community in general. Some interventions or the work that we do can bring about positive outcomes while also potentially doing harm. The problem of "double effect." is possible. Researchers in medical research use experimental drugs for treatment groups while the control groups do not receive treatment. If the experiment proves successful, it will benefit many. During the period of treatment, it is possible that people in the control group may die because of neglect

## **Cultural Concerns**

Use of *emic* and *etic* approaches in the study of health problems in communities is critical in the understanding of how a culture views itself from the inside (*emic*) as well as the outsiders view of it (*etic*). Cultures have different perceptions of medical problems. Some cultures have spiritual theories about the origins of disease. Appreciating these theories and considering them from the standpoint of insiders is the beginning of reconciling these beliefs with Western notions of medicine. Value judgments must be avoided. Although this may lead to asserting the value of cultural relativity, we cannot label other cultural practices as bad. Some cultures believe that female genital mutilation (FGM) has the potential of increasing fertility. Understanding the "internal logic" of FGM will constitute the beginning of leading people to consider the risks that are involved.

## **Studying One's Culture**

Many researchers study their cultures as health providers study their family members. Researchers and health providers who do so must be vigilant not to create conflict of interest or handle issues inappropriately. Studying one's culture usually has a number of advantages, - the mastery of the language(s), knowledge of the basic cultural tenets (values, norms, beliefs) etc. But the researchers can lose objectivity and take many things for granted.

## Conclusion

The anthropology of health which studies diseases and medical problems as cultural phenomena focuses on the individual as the reification of cultural concepts, beliefs, and norms. The individual is not just a patient but a carrier of culture or gatekeeper. The key informant or the ordinary sick person who is seeking to reconstruct his/her health goes to a healer who heals, and to the diviner who diagnoses and also heals. Each culture has its own health system with its own cannons, tenets, and code of ethics. If research has need of information, one of the basic norms is to respect culture, values, and norms. The breaking of these rules can be counterproductive and may constitute a constraint to future researchers.

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## HIV/AIDS in Nigeria and its Ethical Challenges

*Babatunde Osotimehin*

### **Introduction**

Readers might ask: Why the focus on HIV/AIDS? And what makes it so different from other diseases? The true story of the family of Mr. A, a big time cocoa farmer from one of the South Western states of Nigeria, will shed more light on the gravity of the epidemic.

As Mr. A's business boomed, so did his family which comprised four wives and twenty-two children. In the late 90s, Mr. A, a trader operating in Northern Nigeria, took ill and was taken to his ancestral home to receive treatment. Mr. A's illness was protracted, and the family was forced to expend a large proportion of its earnings on its breadwinner. The lorries for his cocoa business were sold. Mr. A's health continued to deteriorate despite the huge amounts that the family spent to look after him.

While Mr. A's health was failing, his second wife took ill. Local herbs and remedies were applied, but her condition worsened. It was detected that she had tuberculosis when the advice of orthodox medical practitioners was sought. Mrs. A was isolated. Her eating utensils (*i.e.*, cups, plates and spoons) were separated from all others in the household. Word spread around that a strange form of witchcraft had befallen the family of Mr. A. Soon after, a gaunt and very sickly Mr. A gave up the ghost. The family mourned the loss of their patriarch. Shortly after his death, Mr. A's first wife also took ill. She lost appetite, complained of nausea and diarrhoea and lost weight very rapidly.

This time around the advice of a close family friend was sought. A formally trained nurse noticed a strange trend in the community. Able bodied men were being brought home "close to death". They presented with symptoms similar to the new and dreaded disease called "AIDS".

Following trainings at workshops, a next of kin volunteered to offer home-based care to those in critical condition as most health care workers were unwilling to touch these patients.

On one of her home care visits, she was informed about the plight of Mrs. A. Based on her experience, she suspected HIV infection. She visited and found two of the wives in critical condition, one dying of tuberculosis and the other losing weight very rapidly. The nurse invited a doctor to their home and offered voluntary counselling and testing services to the wives. Three of the four wives tested HIV positive. Financial support was provided within the dwindling family resources to take care of the sick wives. However, both wives died within a year.

Caring for sick mothers and a father placed a heavy toll on the children's education. Some of the children skipped school in order to take care of their sick mothers. Others took turns to oversee their mothers' petty trading business. As the family income dwindled, so did the prospects of a sound education. Several of their children who ought to sit the West African School Leaving Certificate examination could not do so.

There was simply no money to pay their fees. Others were sent back home as they could no longer afford to pay school fees. The cocoa business gradually crumbled. A once rich family became

impoverished by HIV/AIDS. Word got round that Mr. A's wives were HIV positive. Family and friends were unwilling to associate with the family. The petty trading business also received low patronage as a result of the stigma that is associated with HIV which the family members encountered.

A few 'bold' close relatives offered what they could, but it was insufficient to go round everyone. The nurse who became a regular visitor to the family spoke with a few community leaders and development partners to see if some assistance could be offered.

Mr. A was blessed with several sons and daughters. In an interview with a journalist one of the daughters, a sixteen year old, stated that though she wanted to further her education, she did not have any means to do so and did not know what steps to take. HIV infection had suddenly exposed the teenage girl to the harsh realities of life, thus increasing her vulnerability. If the desired help was not forthcoming, it was left to imagination what the girl could do in order to keep body and soul together and 'make ends meet'. Other children within the family also remained at crossroads. Poverty predisposes HIV and fuels its spread. Mr. A's family story depicts the challenges that HIV/AIDS presents in various spheres of life on a daily basis.

### **Nigeria's Response to HIV/AIDS**

Nigeria's journey in addressing HIV/AIDS began when the first case was identified in 1986. There was, however, an initial denial about the infection for four years (*viz.*, 1986 and 1990). HIV infection spread unabated among the 'at risk populations or vulnerable groups' including uniformed men, women, girls, long distance truck drivers, youths, and sex workers during this period. The denial of HIV/AIDS fuelled the spread of the epidemic. The stigma and discrimination faced by the few known HIV+ individuals also drove the infection underground. Slowly and steadily, the number of HIV+ cases grew (NACA, 2002; FGN, 2003; FMOH, 2004).

The first sero-prevalence survey was conducted in 1992 when the national prevalence was 1.8 per cent but this exploded to 5.8 per cent by 2001. However, the last two surveys indicate a decline to 5.0 per cent in 2003 and 4.4 per cent in 2005. We are in the middle of another survey and we expect that it will be less than 4.4 per cent.

General awareness about the infection grew between 1991 and 1998 and Nigeria slowly began to acknowledge the seriousness of the epidemic. But has awareness been translated into action aimed at reducing the spread of the epidemic? No.

It took the death of Fela Anikulapo-Kuti, one of Nigeria's greatest musicians as a result of HIV/AIDS to wake many Nigerians up to the reality of the disease. Fela died in denial of his HIV status. He kept a harem of 27 wives and countless other sex partners. He did not believe in condoms and thought AIDS was a Western invention to discourage sex in Africa, even though his elder brother was Nigeria's renowned Health Minister and notable health care advocate. It took the courage of Professor Olikoye Ransome-Kuti to announce to the whole world that Fela died of AIDS. Fela was the AIDS role model that Nigeria never had.

Fela's death presented an opportunity to drive the HIV/AIDS message home. Unfortunately, that opportunity was not efficiently utilised to drive the AIDS message home. That didn't happen. Eventually, a health sector response to HIV/AIDS was initiated by Professor Olikoye Ransome-Kuti which was energised by the death of his brother.

It became apparent over time that a strictly biomedical approach to HIV/AIDS would not work given the fact that a critical element in tackling this infection was and is still “Behaviour Change”. The need to engage all sectors in the response to the epidemic became paramount, hence the adoption of a multi-sectoral response.

While a multi-sectoral approach has yielded results, it still does not present the ‘magic bullet’ solution to the HIV/AIDS burden that Nigeria bears. We are hopeful but we are not yet there. Several scientific breakthroughs in the past two decades indicate that there is light at the end of the tunnel. Several hurdles lie in way in the attempt to nip the burden of HIV/AIDS in the bud.

Questions abound and there are no easy answers but the author will to raise some of issues in the hope that this paper will stimulate discussions.

### **Voluntary Versus Routine HIV Testing and Ethical Challenges**

Over the past decade, the case for voluntary testing has been promoted by human rights advocates who are of the opinion that an individual should voluntarily undergo HIV test. On presenting at the centre, the individual is counselled and offered the test. He/she could refuse to undergo the test after counselling. It is a purely voluntary issue. Though VCT has been promoted over the years and continues to be promoted by religious leaders, civil society advocates *etc*, a major drawback is that the ‘average man on the street’ has strong reservations about going for HIV test. It takes a lot of courage to go for a test! Yet, those living with HIV do not even know it because they have not gone for test.

There is needless death with the advent of antiretroviral drugs (ARVs) for HIV/AIDS. Many HIV related deaths would have been prevented if the affected persons were aware of their condition and were immediately placed on ARV. Because people often delay, there is the likelihood that they may put their health and that of their loved ones at risk

Routine testing on the contrary implies that HIV tests are done routinely every time persons present themselves at health facilities (*i.e.*, for blood donation, tooth infection, malaria, typhoid *etc*). If the person tests positive, the individual is promptly counselled and placed on treatment for opportunistic infections (O.Is) or ARVs as the case may be.

Proponents of this approach which is now endorsed by the World Health Organisation (WHO) argue that routine testing presents the opportunity to screen a wider range of people for HIV and is beneficial because cases will be detected early. They also argue that given that HIV/AIDS is a public health issue, it is more important to protect the health of the ‘general public’ than to protect an individual’s right. Efforts to protect an individual’s right to privacy, (*i.e.*, through voluntary counselling etc) should not put the health of a population or community in jeopardy. Here lies the ethical dilemma, - do we promote the right of an individual or do we ignore it in order to protect the larger population from harm?

### **Preventing Parent to Child Transmission**

In view of the scientific breakthroughs on HIV, it is now possible for People Living with HIV (PLWH) to marry and bear HIV-children. Several HIV+ women worldwide have through prevention of mother-to- child transmission programmes given birth to healthy children. But it is important that mothers are treated to enable them to take care of their children.

Research indicates that breast milk provides one of the routes for HIV transmission. Consequently, HIV+ mothers are encouraged to avoid breastfeeding: rather, they are to provide infant formula for their newborns. Free infant formulae are provided to HIV+ mothers in some of the tertiary health care facilities under the Federal Government treatment programme in collaboration with its partners. Also, free maternal care and infant formula are available in our culture where breastfeeding is strongly promoted as the best means of nutrition for infants. However, a nursing mother who refuses to breast-feed is viewed with suspicion within the community and may be stigmatised for choosing not to breastfeed. How can HIV-positive nursing mothers in the rural areas preserve the health of their children without incurring the wrath of the custodians of culture/tradition who believe that the ‘mother’s milk is best’?

Should an HIV+ mother in a hard to reach rural community in Nigeria watch her newborn child starve because she cannot afford infant formula? Should she breastfeed her baby and unduly expose the infant to HIV? These are tough decisions for any mother to take and they present another dimension in the debate of what is ethical.

### **The Male Circumcision Debate**

Several cultures in Nigeria and other African countries accept male circumcision as part of socio-cultural and/or religious practices long before the outbreak of HIV/AIDS. Recent research findings on male circumcision that were conducted for HIV prevention among young men in the Kisumu District of Kenya indicate that it could protect them against HIV-1 infection. This was a randomised controlled trial of 2784 men aged 18-24 years aimed at determining the relative risk of HIV incidence in men that were randomly assigned to receive circumcision versus those who did not receive such treatment. The study found that male circumcision significantly reduces the risk of HIV infection among them (Lancet, 2007). It concluded that “where appropriate, voluntary, safe, and affordable circumcision services should be integrated into other HIV preventive interventions and also provided as expeditiously as possible”.

While this can be described as a ‘breakthrough’ in Kenya, such findings need to be cautiously disseminated within Nigeria where men have been circumcised from birth. These findings could also be the subject of several interpretations. The man on the street could interpret them to mean *Because I am circumcised, I am protected against HIV infection*. It means *I can engage in unprotected sex and may not necessarily embrace the ABC of prevention theory*. This could also call into question a woman’s ability to negotiate safe sex as some men might now insist that the research findings are now the gospel truth. Should these findings now take pre-eminence over the use of condoms? Is there sufficient evidence as of now to take the male circumcision trial findings hook, line and sinker? Are the risks to HIV infection lower in men who are circumcised in their youth when compared to men circumcised at birth?

### **Ethical Challenges in New Prevention Technologies in Clinical Trials**

Research on HIV/AIDS that is initiated, designed, and/or funded by agencies that are in high income countries but conducted in those that are poor gives rise to important ethical challenges.

Sub-Saharan Africa continues to bear a disproportionate burden of HIV infection, particularly in the marginalised communities. This implies greater imperative for the development of new strategies and technologies to prevent further spread of HIV and also minimise its impact. The conduct of the much needed research in these communities poses ethical dilemmas that are not easily resolvable.

Although the clinical trials of HIV vaccines began ten years ago in the United States and Europe, an increasing number of them are now conducted or planned in other countries, including several that are considered "developing" countries which have a high HIV incidence.

Safeguarding the rights and welfare of the individuals who are participating as research subjects in developing countries is a priority issue. Researchers are coming under criticism because communities and human rights advocates in the developing countries are concerned about the autonomy and privacy of individuals and respect for their personal, cultural, and social values. This is important in order to maximise the benefits for the targeted participants/communities and also advance the science of HIV prevention in Africa.

Most HIV social and behavioural science investigations are on sensitive issues of prevention on sexual activities (particularly as relates to microbicides), drug use or intervention trials of biomedical technologies that could have unknown physical and psychological outcomes. The ethical requirement for such studies is informed consent from the targeted individuals and communities. But what constitutes "truly" informed consent is a subject of much discussion and disagreement in the scientific community.

The issue is further exacerbated if the targeted participants have little or no formal education, speak different languages from the researchers or have cultural beliefs that do not encourage the questioning medical authority.

The imbalance in the economies among nation-states also widens this divide. Unlike in the high-income countries where their citizens participate in clinical trials for altruistic reasons, those in the low participate in trials because of some form of material 'benefits'. Such benefits include free condoms, free treatment for sexually transmitted infections, transport fare, meal allowance *etc.*

These 'benefits' are the catch or inducements and the would-be participants would rather append their signatures and ignore the details that are contained in the informed consent form provided they are assured of the next meal! Should we then discontinue clinical trials in Nigeria/Africa? No. There will be no rapid scientific breakthroughs without these clinical trials.

Better mechanisms should be put in place to safeguard and protect the rights of participants in clinical trials. Efforts to improve sensitivity in culturally and linguistically appropriate ways are essential in order to provide truly informed consent in HIV prevention studies. Hence, there is need for Community Advisory Boards (CABs), comprising members of the community who can critically review research protocols before they are approved for clinical trials. Trial participants should also be given the opportunity to 'opt out' at any stage of trials.

## **Way Forward**

The opportunity for this presentation before social scientists presents a chance to explore the different ways in which their disciplines can contribute to the understanding of the dynamics of the epidemic and proffer solutions to some of its driving factors.

It is appropriate to suggest that HIV/AIDS and indeed the whole area of sexually transmitted diseases are more of social problems than biomedical ones. We are persuaded that behaviour change is a more effective weapon for fighting the spread of the infection but we sometimes lack the evidence for appropriate messages or interventions that will bring the desired change. Social scientists are challenged to give serious thoughts to the evidence that is required to guide interventions.

New technologies also provide a great opportunity for social scientists. Potentially, there are many products which require acceptance before they are unleashed on the population. Thus, well defined population studies will be required to ensure that Nigerians/Africans are not turned into the guinea pigs of multinational pharmaceutical industries whose sole motive is at times to make ethically unacceptable profits.

Finally it is important for us to appreciate that HIV has provided an opportunity to affect the health and the lives of Nigerians/Africans positively since it brings with it resources which are unprecedented in the annals of infectious disease control. We should seize the moment and make a big difference in our engagement with this development process.

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## Ethical Issues in USAID Applied Health Research in Nigeria

*Stalin Edegba Ewoigbokhan*

### Introduction

Ethics are norms for proper or acceptable conduct. They are also about what is morally right in society. Professions such as medicine and law have ethical codes, deviation from which is considered a misconduct or unethical practice.

Unethical practices in health care research include: manipulation and/or changing research design or methodology to achieve predetermined expectations; altering results that contradict one's previous findings; research that exploits and/or deceives unsuspecting and less privileged subgroups in the population; and falsification of outcomes (Ryan, 2005; Committee on Science, Engineering and Public Policy, 2000). Shamoo and Resnick (2003) describe 29 activities which are deviations from ethical behaviour that are not defined as misconduct by government. Unethical activities can also be due to honest human errors on the part of researchers.

More than 900 codes and declarations have been published around the world (OHRP/USDHHS, 2008). But none of these codes is complete or enjoys universal acceptability or applicability. However, each of the various declarations emerged at different times in history, each aimed at responding to a specific unethical incident. Codes and declarations have no legal status, and to a large extent, serve advisory functions (Nuffield Council on Bioethics, 2004).

Although the Hippocratic Code is regarded as the ground norm for medical practice with its central commandment of *do no harm*, it makes no specific provisions for the protection of human subjects in research. The forerunner of the ethical codes that exist today is the Nuremberg Code (United States Government, 1949). The Code got its name from the German city of Nuremberg where Nazi doctors and scientists were tried in 1947 for carrying out unethical experiments on prisoners in concentration camps during the Second World War (1939-1945).

The Nuremberg Code was the first to make specific declaration on the protection of human subjects in research, declaring among others that the *voluntary consent of human subjects is absolutely necessary*". Also, the World Medical Association (WMA) published the Helsinki Declaration in 1964 (*the Ethical Principles for Medical Research Involving Human Subjects*) which has been amended five times, the latest amendment at Edinburgh, Scotland in 2000 (World Medical Association, 2000).

A series of scandalous experiments in the US such as the: Stanley Milgram's experiment, Willowbrook study, and Tuskegee Syphilis study prompted the enactment of the National Research Act (1974) and also gave rise to the *National Commission for the Protection of Human Subjects in Biomedical and Behavioural Research* that defined the guidelines in the Belmont Report (The National Commission for the Protection of Human Subjects in Behavioural Research, 1979). The Belmont Report established the requirements for Institutional Review Boards (IRBs). The US Department of Health and Human Services (DHSS) sets it out in the code that is known as the Basic Policy for the Protection of Humans Subjects (DHSS, 2005).

## **The Boston University Medical Centre Institutional Review Board (BUMC-IRB)**

The Boston University Institutional Review Board (BUMC-IRB) was established in 1996 in compliance with federal regulations and state laws to protect the rights and welfare of human subjects that are participating in research. It is subject to regulation and inspection by all government regulatory agencies such as the Food and Drug Administration and the Office of Human Research Protection of the Department of Health and Human Services. The BU-IRB applies the principles in the Belmont Report (National Commission for the Protection of Human Subject of Biomedical and Behavioural Research, 1979).

Among the functions of BUMC-IRB is the review and approval of protocols and the consent forms for research that is funded by BUMC. The IRB can approve, defer, or cancel a study if it is convinced that ethical requirements for the protection of the rights of subjects are breached.

## **IRB Registration and Federal Wide Assurance (FWA) Number**

Boston University Ethics Committee requires all the institutions that are participating in studies that are funded by the US Government to have a Federal Wide Assurance (FWA) before research activities can begin (OHRP, 2005). An FWA is an institution's formal commitment to US federal authorities (*i.e.*, the Office of Human Research Protection or OHRP) to protect the rights of subjects.

There are two steps for obtaining an approved assurance from OHRP. First, an application must be submitted for the registration of the institution, followed by the recognition/registration of the IRB of an institution. This is followed by the completion and submission of the assurance application.

The five criteria for registering an Institutional Review Board/Institutional Ethics Committee are:

- membership of at least five;
- at least a member whose primary interest is in the scientific area and at least a member whose primary concern is in the non-scientific area;
- at least a member who is not affiliated to the institution;
- gender balance;
- members are not drawn from a profession, and
- at least a member who should be knowledgeable on ethical issues

IRB provides guidance, review protocols and the consent forms of studies. IRBs have enormous powers but do not necessarily live up to their responsibilities in all cases.

## **The Applied Research on Child Health Project**

The Applied Research on Child Health (ARCH) Project was an international research Initiative, based at the Centre for International Health and Development (CIHD) of the Boston University School of Public Health. The programme supported collaborative research by social and biomedical scientists, aimed at reducing childhood morbidity and mortality in developing countries. It also incorporated training and technical assistance.

The ARCH Project in Nigeria, supported by the United States Agency for International Development (USAID), was designed to:



- generate new knowledge that will contribute directly to the improvement of the health and survival of children;
- build the capacity of individuals and institutions to undertake applied research, and
- disseminate new findings to national and international implementing agencies that are operating in Nigeria.

The goals were pursued through a series of activities and strategies in collaboration with federal and state health authorities, and with USAID partners and contractors working in Nigeria coordinating the project.

A national advisory committee of senior scientists and health professionals based in Nigeria's universities and research institutes provided strategic advice and guidance to the Project.

There were 13 research teams of more than 50 researchers in 8 institutions in 4 groups:

- *Universities:* University of Ibadan, Ahmadu Bello University, University of Ilorin and the University of Nigeria
- *Research Institutes:* Nigeria Institute of Medical Research and Nigerian Institute of Social and Economic Research
- *Non-governmental organisations:* Centre for Economic Development and Conflict Management, Ile-Ife and Centre for Family Health, Ile-Ife, and
- *Government:* the Federal Ministry of Health.

Four teams conducted multi-site studies on congenital malaria, using basic clinical and laboratory procedures while nine teams used the social and behavioural research methods

The topics of research were chosen after a priorities-setting seminar that was organised by the national advisory committee of the Project. The Committee identified six priority areas in child health research and publicly invited proposals in the following areas:

- HIV/AIDS in young children;
- nutrition and feeding in children;
- fever and household decision-making;
- patent medicine sellers and health;
- quality of health care, and
- the effectiveness of traditional medicine sellers.

A technical team in Boston along with the advisory committee in Nigeria assessed the letters of intent and invited fifteen teams to submit full proposals. Eleven proposals that are listed below were funded.

- Dynamics in Household Decision-making on Febrile Illnesses in Children in a Nigerian Rural Community.
- Comparison of Household Decisions for the Treatment of Childhood Fevers in Rural and Urban Communities in Enugu State, South-eastern Nigeria.
- Father's Involvement in Child Health Behaviour in Nigeria: Implications for Child Health Care Delivery.
- Antenatal VCT among Women in Southwest Nigeria: A Case Study of Ijebu North LGA of Ogun State.
- Social Outcomes of HIV/AIDS on Children in Selected States of Southwest Nigeria.

- Feeding and Care of Low Birth Weight Babies in Rural Communities in Ekiti State.
- Feeding and Care of Low Birth Weight Babies in Epe LGA of Lagos State.
- PMS: How important are they in the management of sick children in Kaduna, Northern Nigeria?
- The Role of PMS in Identifying and Treating Childhood Illnesses in Oyo State, Nigeria.
- The Epidemiology of Congenital Malaria Ibadan (A Multi-Site Study in Ibadan, Ilorin , Enugu and Kaduna).
- Introduction to the Study of the Burden of Diseases among Children in Nigeria.

### **Ethical Issues in Nigeria's ARCH Studies**

The ARCH Project provided Nigerian scientists, most especially the junior ones the opportunity to collaborate with scholars and institutions at the international level at a time when research grants were scarce.

The BUMC-IRB ensured adherence and did not hesitate to withdraw grant if ethics were breached. IRB (a) monitored adherence to protocols; (b) facilitated the procurement of Federal Wide Assurance Number (FWA) according to US Code of Federal Regulation (CFR 45 Part 46), and (c) ensured commitment to respect for human subjects (OHRP, 2005).

The IRB regulations underscore:

- **Respect for persons:** the autonomy of the individual.
- **Beneficence:** ensuring that no harm is done to the individual and the maximisation of benefits and minimisation of risks.
- **Justice:** equality of individuals and that the benefits and risks should be distributed fairly.

The applications of these principles are:

- **Informed consent:** subjects must be allowed free choice; consent must be voluntary and based on correct information and a clear understanding of the issues (45 CFR 46.111(a)(4), 21 CFR 56.111(a)(4).
- **Assessment of risks and benefits:** There must be a systematic assessment of benefits and risks to participants (45 CFR 46.111(a)(1), 21 CFR 56.111(a)(1).
- **Selection process:** This entails fairness and no bias in the selection process (45 CFR 46.111(a)(3), 21 CFR 56.111(a)(3).
- It was only after the IRBs/IECs of the grantees' institutions were registered that application could be made for FWA number. Only one of the institutions (the University of Ibadan) had FWA number prior to grant. However, the Project assisted other participating institutions to apply for, and obtain FWA number before funds were released to teams.

### **Deviation from Protocols**

The approval for two studies on HIV/AIDS was delayed by BU-IRB on account of ethical issues. This led to significant revision of the study design. Some studies were also suspended because teams made changes in their study designs without the approval of IRB.

### **Informed Consent**

There is always contention as to who gives consent in an African setting. For example, a community leader might give blanket consent on behalf of members of his community.

The IRB requires an individual to sign the consent form. In some cases, there were threats to stop studies in places where the community leader's approval was not sought. The spouse or older members of the family or household also exercised great influence over approval. Thus, it took a husband to agree or disagree for the wife to give consent.

Signing and/or thumb-printing consent form generated concern among respondents because they were worried about its legal implications and the following clause: *by signing this document it means you have agreed to voluntarily participate in this study...* This aroused suspicion. Many respondents were willing to answer questions but not inclined to sign the consent form. It took persistent persuasion bordering on coercion for them to sign up.

The patent medicine sellers in two studies were uneasy and hesitated to sign the consent form. The process for seeking consent in this group began with advocacy and sensitisation meetings with the officials of their association.

The requirement to sign the consent forms therefore introduced bias because only those who signed. Research assistants were presumably inclined to seek those who they knew would sign up.

A 17 -year old married girl who was enrolled in one of the centres in the multi-centre study on congenital malaria and who gave consent was defined by IRB as a minor because she was under 18 years of age (a child is defined as any person that is below the age of 18 years). She needed the consent of an older member of her family and a child assent form was required.

In the same study and at another site, it was required to determine the level of paracetamia in placenta, thus placentas were harvested for aspiration. But this was a cultural setting where the families of the delivered women go home with placenta. Some women and/or their families objected. Since the placentas were required in the study, investigators faced the added challenge of convincing the family of mothers to allow their placentas to be released to investigators. Some consented while others refused.

Views defer on the necessity for informed consent. Pedroni and Pimples (2001) opined that although the historic basis for seeking informed consent stems from the atrocious experiments in Nazi concentration camps, it is unnecessary to extend consent to "risk free" research such as surveys and interviews. Others share this view and cannot see the risk in answering "a few questions". However, granting interviews and disclosing personal and private information to a complete stranger (researchers) carries certain amount of risk. Some questions could be embarrassing and cause discomfort among respondents. Informed consent has two perspectives: moral and socio-legal (Petroni and Pimples, 2001).

### **Anonymity, Privacy, and Photographs**

Two research teams that studied feeding and care of low birth weight infants in South West Nigeria hit ethical brick walls for different reasons. They first ran into hitches when BUMC-IRB, during the review of their protocols, found listed in the budget, an item for the purchase of cameras and photographic films. A query asking what the cameras and photo films would be used for was posed. The investigators responded that they intended to take the photographs of the environment where low-birth weigh infants and their mothers lived. The IRB differed and reminded the investigators that this was a violation of the privacy of the participants. The grantee was requested to expunge the items from the budget before the IRB allowed the study to proceed.

In an attempt to demonstrate the effects of their intervention and also enrich as well as provide contrast to the readability of their interim report, another team of investigators inserted the before and after photos of low birth weigh babies. Someone spotted the pictures before the report was forwarded to IRB. The pictures were removed because they violated the rules governing the anonymity of research subjects. Furthermore, there was no evidence that the research subjects granted consent for the pictures that were to be taken. A written consent is required for photographs that identify research subjects or patients (American College of Medical Genetics, 2000). The person whose photograph is to be taken should give consent and in the case of children, accent should be given by their parents and guardians. In addition to protecting the rights of individuals that are involved in research, Paulson (2006) expressed the need for more attention to the protection of the privacy of family and community members when genetic or other matters are part of study.

### **Reporting Adverse Events (AE) Involving Research Subjects**

Adverse Event (AE) is defined as any untoward occurrence in research participants. The occurrence need not have clear causal relationship with an individual's participation in research. An AE can be any unfavourable and unintended sign, symptom, event, or occurrence that affects a participant's physical, mental, social, financial, legal, or psychological well-being. Adverse events also take the form of domestic violence, occasioning the forced withdrawal of a subject from a study.

It is the requirement of the Office of Human Research Protection (OHRP) of the Food and Drug Administration (FDA) and the BUMC-IRB to continuously review research. Included in the review is the monitoring of adverse reactions and unexpected events (21 CFR 56.108 and 45 CFR 46.103). Additionally, adverse events can and should be reported at any time during any study. One of the infants in the feeding of low-birth weight infants died but not as a result of being enrolled in the study. This was reported to IRB as part of the review process.

A Voluntary Counselling and Testing (VCT) component in the study was changed to “investigating the knowledge and perception of voluntary HIV and counselling among women attending antenatal care”. The women in the study were to recruit their husbands. The IRB was concerned about confidentiality, anonymity, and the likely adverse events (*e.g.*, domestic violence or divorce) should one or both test positive. A study by Family Health International (2002) found that the women who disclosed their positive HIV status to their husbands after informed consent either were beaten or chased away by them. What are the guarantees that spouses or employers will not have access to the research records as affirmed in the consent form by the investigator?

A woman who opted for HIV test as required of pregnant women who were attending antenatal care in furtherance of the prevention of mother-to-child transmission of HIV at one of the congenital malaria sites was thrown out of the matrimonial home by her husband when she tested positive.

One of the issues raised by the IRB was that a research institution had no FWA number, making it a non-starter because it had no commitment to protecting the participants in the study. The other issues were confidentiality, privacy, and voluntariness. The study was to utilise FGDs. How do you secure confidentiality and anonymity in a group?

## Benefits of Participation in Research

It was stated clearly in the consent form that the individuals would not benefit personally if they participated in the studies, but that the community stood to benefit from their outcomes. One investigator also indicated in the consent form that knowledge of HIV status is a benefit. But BUMC- IRB pointed out that knowledge of HIV status could only be beneficial if she/he was willing to undergo test.

It was customary for community leaders to expect or demand beneficial interventions that were outside the scope and/or budget of the study. The direct benefit to the communities was the recruitment of research assistants from host communities. One of the teams that investigated the role of patent medicine vendors in health care organised feedback seminars for members of their Association.

Consent is required in a case control studies in which participants are made to feel that they were receiving active beneficial ingredients but turns out to placebo (Hill et al., 2008; Wenger and Shapiro, 1997). Such studies are in consonance with the Tuskegee experiments. The benefits that the participants are expecting are really not there.

## Conclusion

The USAID Child Health Research Project was an opportunity for Nigerian scientists to collaborate with international scholars and institutions. It also provided an opportunity for better understanding of ethical issues and the application of universally acceptable ethical standards.

The ethical issues arising from the studies provide useful lessons that will guide future studies. Although all the grantee institutions registered IRBs, their institutions could not provide technical or ethical guidance to their research teams. Consequently, capacity building of IRB members on ethical issues in research is extremely important in Nigeria.

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## Perspective of the WHO Research Ethics Review Committee on Ethical Issues in Socio-Behavioural Research Projects in Public Health

*Abha Saxena*

### **Introduction**

It is increasingly recognised that in order to improve health, the bio-medical approach must be twinned with the socio-behavioural in order to formulate policies that will have a positive impact on health outcomes. WHO has established a Commission on Social Determinants of Health (CSDH) in recognition of the growing importance of the socio-behavioural in public health. The Commission recognises that the social determinants of health (SDH) must be addressed through effective policies based on sound global and local evidence. Though there are abundant global data on the social determinants of health, nonetheless, there is a growing need to generate data for local needs, mainly because data are context-specific, and not easily transferable from one country to another or even within a country from one region to another or one community to another. In recognition of this growing need, various technical departments of the WHO support countries in carrying out socio-behavioural research not only on health care delivery but also tropical diseases. There is also support for studies on reproductive and sexual health, chronic life-style related diseases, child and adolescent related diseases etc. The WHO Research Ethics Review Committee (WHO ERC) is increasingly asked to review research protocols that are either primarily on socio-behavioural or bio-medical projects.

This paper will discuss some of the challenges and issues in socio-behavioural research, based on the experience of WHO ERC. This is not meant to be an exhaustive discussion in relation to socio-behavioural research, but on the common 'problems' that the WHO ERC faces.

### **Insufficient Expertise in Ethics Committees**

Because of the growing demand for socio-behavioural research on health determinants, the ethics committees of many organisations and universities that traditionally review bio-medical research are now challenged to review social science projects or those that have social science components. Traditionally, the social sciences are described as 'soft sciences', because they do not use the rigorous quantitative approach that is used by bio-medical researchers that can be reliably reproduced. The social scientists conventionally use qualitative approaches and also combine quantitative approaches which few bio-medical researchers sometimes (incorrectly) consider 'fuzzy'. Therefore the ethics committees that often have a predominance of medical researchers or no social scientists on their panels, often, misunderstand these projects. It is important that such ethics committees should include social scientists on their panel or at least have them as advisers. Nine of the 26 members of the WHO ERC are social scientists, and the current Chair is a social scientist. This allows the WHO ERC to evaluate most of the social science projects adequately, without having to call in external experts. This was, however, not necessarily the case in the past. We had a paucity of social scientists and were blamed for being too rigid!

## The Research Protocol

The social scientists claim that because they use sufficiently different methodologies as compared to bio-medical scientists, they cannot use the same format for writing their protocols. For example, items like the sample size and inclusion and exclusion criteria cannot be defined in the social sciences. What this really means is that they cannot be defined in precise quantitative terms; however they can be described qualitatively (*e.g.*, that a snowballing technique will be used or that 'enough persons will be selected till a point of saturation is reached' *etc.*). It is the opinion of the WHO ERC that all research protocols can be and should be described using a similar format. This allows for easy reading and review of protocols.

Ethics Committees need to know the details about the way research will be conducted in order to identify the ethical issues in projects. One of the commonest problems that is seen at the WHO ERC is that enough methodological details are not provided in many social science projects. For example, many social science projects just mention that focus group discussions will be conducted in the research communities. The WHO ERC (as should other ERCs) requires information about how many FGDs, with whom, why, where, how *etc.* This type of information is required for all interventions.

*Data analysis* - It may not be enough to say that qualitative approaches will be used to analyse the data, - the analytical tools and methods in the social sciences are sufficiently refined to be described - and should be described, as is done for bio-medical research.

*Adequate peer review* - like any bio-medical research, any socio-behavioural research project must have been reviewed by at least two independent peer reviewers who provide comments on the technical and scientific aspects of projects.

## Risks to Participants

While most socio-behavioural research projects do not have a risk of physical harm (though gender based violence is a definite but an under-estimated risk in many situations), they cannot all be considered as low-risk projects. The potential for harm may be much higher, partly because it may be hidden and unrecognised. It is the responsibility of the ethics committee to be cognizant of such potential risks. In the experience of the WHO ERC, some of the common causes for the potential for harm can occur through:

1. Psychological trauma – discussion of traumatic experiences or private experiences that the participants might not wish to discuss.
2. Breach of confidentiality and privacy.
3. Stigmatisation, either through breach of confidentiality or inadequate attention to gender issues.
4. Increasing vulnerability through inadequate attention to confidentiality and privacy issues.

Socio-behavioural research is often of greater interest in groups of individuals who are already very vulnerable (which is usually the basic premise for studying these individuals) like displaced persons, the impoverished or illiterate population, deviant personalities, those indulging in illegal activities, *etc.* Often, the safeguards for protecting them and their rights are not sufficiently explained in the protocol, and this is of concern to Ethics Review Committees.

Privacy and confidentiality issues are so important that they deserve a special section. The social science methods often include taping interviews, taking photographs, asking intimate questions,



observing practices, and spending long periods of time with research participants thus becoming privy to some very personal and intimate knowledge about them. Often the participants forget that they are engaged in research and the boundaries between the professional and private may become blurred, increasing the risk of breaching confidentiality. These issues deserve more discussion in protocols in order to demonstrate that they have been considered by the investigators, and they are aware of the issues and are taken seriously.

## **Data Ownership**

In the course of conducting social science projects, the investigators may become privy to local knowledge and customs that may have the potential for intellectual property rights (IPR) and be subject to IPR issues (for example collecting information on methods of traditional healing). Who will own the data and who will have IP rights should be a concern raised by the ethics committees.

## **Care Provision in the Context of Socio-Behavioural Health Research**

This is a common issue. While social scientists may not have the professional duty to provide or even make arrangements for health care provision, where it is lacking, but by entering into a collaborative relationship (and sometimes an intimate collaborative relationship with the communities), they do incur a moral obligation to do so. It is not a requirement that they have to take responsibility for improving health care services or provide care and treatment for a disease that they are studying. However, by being in a dominant position, they can make a difference by:

1. providing information;
2. ensuring that research participants have access to counselling;
3. exploring various avenues, and
4. forming networks with civil society organisations and public health officials in order to provide care and treatment *etc.*

Ethics committees (like the WHO ERC) can insist that these moral obligations are fulfilled. It is equally important that these arrangements are discussed with the research communities prior to initiation of research and also ensure that a clear understanding of roles and responsibilities by all concerned.

## **Formative Research**

Increasingly, many bio-medical research projects carry out formative research prior to initiating large-scale clinical trials. Formative research often combine qualitative and quantitative methods, but is often not adequately described in protocols, except to do a lip-service. Very often, the protocols have single sentences mentioning that formative research will be carried out. At least the WHO ERC likes to see greater details on this aspect of the study.

## **Dissemination of Research Results to Communities**

The WHO ERC is increasingly concerned that communities that take part in research study are not always informed about research outcomes. While it may be easier to communicate the outcomes of bio-medical research, one must be more careful in social science research lest the vulnerabilities of individuals are exposed or harm to some families might occur. It is therefore advisable to think carefully on how to disseminate the research results in a responsible and balanced manner.

This is not an exhaustive list of ethical issues that the WHO ERC is concerned about but they are the most frequently encountered ones. I do not think that we are alone in being challenged by these issues. Other ethics committees that review socio-behavioural research projects probably also have similar concerns. Greater communication is required between social scientists and ethics committee members to resolve some of these issues. These problems do not occur due to lack of concern by social scientists but because of lack of the understanding of the requirements of the WHO ethics committee.

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