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Analyze of the survey

**Annex 15 : Nigeria – Preparatory text
for the future National Committee**

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Draft National Ethical and Operational guidelines for research on human subjects, Nigeria

Proposal Prepared

By

National Ethics Review Board (NERB), Nigeria

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DRAFT FORMAT, NATIONAL ETHICS AND OPERATIONAL GUIDELINES

OF THE NATIONAL ETHICS REVIEW SYSTEM IN NIGERIA

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Chairman
National Ethics Review Board

1.0 RESEARCH BIOETHICS IN NIGERIA

1.1 Introduction

Nigeria is a democratic state where human dignity, the achievement of equality and advancement of human rights are respected and protected under the 1999 constitution. Specifically, Chapter II section 17 (2) (a) states that “every citizen shall have equality of rights, obligations, and opportunities before the law;” (b), “the sanctity of the human person shall be recognized and human dignity shall be maintained and enhanced;” (d) “exploitation of human or natural resources in any form whatsoever for reasons, other than the good of the community shall be prevented”

All health research on both animals and human participants must be scientifically sound to be ethical. If clinical research is to be properly done in humans, the scientific merit of the project must be matched with the ethical merit of the work. According to the Council for International Organisations of Medical Sciences (CIOMS) guidelines, scientifically unsound research on human subjects is *ipso facto* unethical in that it may expose subjects to risks or inconvenience to no purpose¹. This means that the study plan or protocol must be methodologically rigorous, scientifically sound (in purpose and design), valid and feasible. Without validity, the research cannot generate the intended knowledge, cannot produce any benefit, and cannot justify exposing subjects to burdens or risks.² Therefore, the ethical and scientific rigour of all research projects to be conducted in Nigeria must be reviewed by a Nigeria based ethical review committee.

The onus is on the local Institutional Review Boards/ Ethical Review Committees (IRB/ERCs) to ensure human protection in clinical trials and other studies involving humans, by evaluating study plans vis a vis the presumed/claimed values of the interventions before approval. It is also possible through the IRB/ERC data safety and monitoring committee (DSMC) to arrest harm as soon as it is noticed during the course of research. The ethical review process is therefore a very crucial step in human subjects' research. A sound ethical review would ensure that trial participants are protected from harm before and during the trials. A competent IRB/ERC made up of well trained members would ensure that there are measures in the design of the study that would include precautions, safeguards and alternatives that would reduce the probability of harm. It is the duty of the ERC to listen to complaints and address issues immediately. IRB/ERC reviews assure members of society that people who enroll in trials will be treated ethically and that some segments of the society will not benefit from the misuse of others.

In view of the above, the ethical principles and guidelines outlined in this document were developed for the following purposes:

- i). To promote respect for autonomy in research by ensuring that all researches involving human subjects in Nigeria are done based on ethically sound procedures and principles.**
- ii). To protect and promote the rights of participants, and to encourage researchers, Institutions and organizations to respect participants' rights and needs.**
- iii). To specify areas of potential conflict and prescribe ways of resolving them.**
- iv). To improve the quality, legitimacy and credibility of research on human subjects by ensuring that only competent persons are allowed to handle and participate in research.**

It must be noted that the document in its present form may not resolve all ethical issues but would serve as a template and minimum standards for making ethical judgments.

1.2 Specific Objectives

The main objective of a national review system would be to promote ethics in scientific research, monitor and ensure compliance with the relevant legislation, regulations, ethical guidelines and standards. Specifically, the programme should lead to the development of:

- national policies that will support training and funding to cover IRB/ERC activities and teaching of bioethics locally.
- minimum standard and accreditation mechanism for IRB/ERC members.
- specific rules and procedures to guide the constitution of IRB/ERC in Nigeria with built in methods of validation, which will ensure balanced representation and competence.
- local capacity which would make ethics more appropriate within the context of the local environment.

¹Constitution of the Federal Republic of Nigeria 1999.

³ Beecher H.K. Ethics and clinical research. *New England Journal of Medicine* 1966;274:1354-1360

²Council for International Organisations of Medical Sciences. *International Guidelines for Biomedical Research Involving Human Subjects*. Geneva, Switzerland: CIOMS; 1998

⁴ Leine R.J. *Ethics and Regulation of Clinical Research*. 2nd ed. New Haven, Conn: Yale University Press; 1988

- simple guidance document for IRB/ERC in Nigeria, which will spell out what is meant by good science and good ethics in the environment.

The system is designed based on a cooperative and educative model for appraising the work of IRB/ERCs, being concerned with ensuring that good ethical standards are maintained in research and that the review of practices is a learning process.

2.0 GUIDING PRINCIPLES

The purpose of these guiding ethical principles for health research in Nigeria is to help to identify what is good, desirable or acceptable conduct. The primary purpose of this statement of principles and values is to protect the welfare and rights of research participants, and reflect the basic ethical values of respect for persons, beneficence and justice. Both national and international accords and texts outlined under legal empowerment of this document guide these principles and values. The following guiding ethical principles and values must underscore all health research activities in Nigeria. All health researchers are expected to conform to these principles.

2.1. Core ethical principles

Four well-known moral principles constitute the basis for ethics in research and they apply in Nigeria. They are:

(i) The Principle of Non-maleficence:

Research must not cause harm to the participants in particular and to people in general. Any pain, suffering or discomfort must be minimized, carefully justified and accurately described to the participants, the patients and the people in general.

(ii) The Principle of Beneficence:

Research should also make a positive contribution towards the welfare of people. Research should make a positive or potentially positive contribution towards the health and welfare of the participants or to the good of future patients.

(iii) The Principle of Autonomy:

Research must respect and protect the rights and dignity of participants. This is in accordance with Section 17(2)b, 34(1), 35(1)37, and 38(1) of the Nigerian constitution.³

(iv) The Principle of Justice:

The benefits and risks of research should be fairly distributed among people. Those who bear the burdens of research must not be denied the benefits. This is clearly stated in Section 17(1), 17(2)b of the Nigerian constitution.

2.2. Other ethical principles for research

Other relevant ethical principles that are equally of paramount (additions which further explains to the above principles more clearly) include:

(v) Scientific integrity:

In addition to demonstrating a need and value for the research, the research proposed must demonstrate sound methodology and a high probability for providing answers to the specific research question posed. The research protocol must show knowledge of the relevant literature, derived where possible from a systematic review of that literature, including where appropriate, laboratory and animal studies. Moreover, research methods and results should be open to peer- review and scrutiny.

(vi) Relevance (Essentiality):

Researchers in Nigeria have a moral and ethical responsibility to ensure that the research that they conduct is relevant both to the broad health and development needs of the country and to the real needs of those who are affected by the diseases and concerns under study. The findings of the research must be translatable into mechanisms for improving the health status of Nigerians.

(vii) Investigator competence:

The study must be conducted by a suitably qualified individual. The investigator's competence is assessed by technical competence. Technical competence, which includes research competence, is assessed by education, knowledge, certification and experience. Compassion and empathy are also

³ Constitution of the Federal Republic of Nigeria 1999.

required characteristics of a technically competent researcher. A proper clinical and research environment, encompassing good research mentoring provides this. In all cases, a local principal investigator must be a Nigerian. Sincere commitment to research in general and to the relevant subject in particular and readiness to acquire adequate knowledge, ability and skill for undertaking particular research are essential prerequisites for good ethical research.

(viii) Accountability and transparency:

The conduct of research must be fair, honest and transparent. It is desirable that institutions and researchers are amenable to social and financial review of their research by an appropriate and responsible body. They should also make appropriate arrangements for the preservation of research records for a reasonable period of time.

(ix) Respect and protection of autonomy, rights and dignity of participants:

Respect for dignity of person, and their well being including safety and advancement of health of the patient, should be the primary concern of the health research involving human participants. As such, culture, language, beliefs, perceptions, and customs must all be considered. The respect for participants' dignity and rights must first manifest in voluntary recruitment based on the participants' understood voluntary informed consent. It is the responsibility of the researcher not to coerce participants into research studies. Use of undue incentives to coerce participants is exploitative and does not respect the autonomy and voluntariness of participation/patients. Participants must be informed of their right to refuse to participate in studies (if they so wish) and must be told that such refusals would not cause them to suffer any consequences or disadvantage.

(x) Informed consent:

informed consent should only be sought after the purpose and nature of the study, identity of the researchers, duration, estimated risks and benefits and appropriate alternatives, possible benefits to participants, researchers and others, funding, mechanisms to protect confidentiality within the confines of what is possible and the law, what would be done with the results, who to contact if there are questions, and the extent of the consent explained to the participants in the local language(s) of the community where the research should be done. Efforts must be taken to ensure that the participants understand the notion of consent before consent is received. It is the responsibility of the researchers, institutions and funding agencies to ensure that the people understand and can cognitively consider the information given for the consent.

Both written and verbal informed consent must be obtained, unless there are good reasons to the contrary (such as situations of coma, emergency, or mental capacity). Prior approval of the ethics committee must be obtained in all situations in which it is justifiable to initiate research without informed consent of the participant. Verbal consent where the participant is illiterate should be obtained in the presence of and countersigned by a literate witness.

Consents should be obtained without duress and coercion. The incentives to be given should not constitute coercion by being too tempting for the people to risk the study without appropriately considering the risks and the benefits of the study. Researchers must take cognizance of the vulnerability of many of the Nigerian populace in terms of service access and education levels. As such, research details must be provided in a clear, simple and culturally appropriate manner. If a participant lacks capacity to exercise an informed voluntary choice to participate, an appropriate person to make the choice for them must be identified.

(xi). Where community consent may be required:

Possession of the community consent through the recognized channels would not remove the requirement to obtain individual consent for studies and it is the responsibility of the researcher to obtain this. This does not override the necessity to preserve and respect individual privacy, confidentiality and autonomy of community members who participate or refuse to participate in research.

(xii) Feedback on research findings:

It is the responsibility of the researcher to ensure that participants who or communities that participated in a research are given a feedback on their research findings if they so desire. This does not preclude that the need not to disclose the identity of the participants and or community in which the research took place when reporting findings. The need to respect the pact on confidentiality must be observed.

(xiii) Non-exploitation:

Research must not unnecessarily consume the time of participants or make them incur undue loss of resources and income. It should not expose them to risks due to participation in the research. The

relationship within the research team, including student and junior members, should be based on the principle of non-exploitation. Contribution of each member of the research team should be properly acknowledged and recognized.

(xiv) Privacy, anonymity and confidentiality:

In its simplest form privacy is concerned with access to personal records, whilst confidentiality refers to use and release of personal information once it has been disclosed. Participants' right to both privacy and confidentiality must be protected. The researcher must therefore ensure that, "where personal information about research participants or a community is collected, stored, used or destroyed, it should be done in ways that respect the privacy or confidentiality of the participants or the community and any agreements made with the participants or community". Except in situations when information becomes public domain property, all information and records provided by participants and/or obtained indirectly on the participants/patients must be kept confidential. It is the responsibility of the researcher to ensure that strict confidentiality of participants/patients private information is maintained as such. It is the responsibility of the researcher to assure the participants that their privacy and confidentiality can be preserved before enrolment in studies. Studies that may compromise the security and safety of participants may require that the researcher(s) obtain certificate of confidentiality to protect participants from subsequent litigious use of study findings against them and they should be firmly assured of this when and where feasible. Release of any identifying information may only be done as required by law and/or with the expressed permission of the participants/patients.

(xv) Full release of necessary information about the study:

The participants must be given all necessary information (as determined by the properly constituted body for the protection of human participants in research, participants advocate or the local review boards) about the nature of the study, the extent of consent given, the duration of the study, the expected risks, intended use of the information and plans of a subsequent release to a third party and benefits of participation in the studies. Participating members must be informed about their contribution to studies at the recruiting stage.

(xvi) Minimization of risks and maximization of benefits:

All research carries some risk to the participants and to society. It is the responsibility of the researcher and the funding body/agency to minimize, safeguard (take adequate precautions) and mitigate the risks to participants in research undertakings. A risk benefit analysis of the study should precede the conduct of the research itself. Risk-benefit analysis should take full cognizance of benefits and harms beyond the life of the study itself, particularly in the case of chronic life threatening conditions. Alternative ways of providing benefits to the patients might be available without research; thus the distinction between the probability of harm and the possible benefits of the effects must be made. The principal investigator has the ethical duty of excluding participants who are at undue risk.

(xvii) The obligation to compensate for research related injuries and costs:

The responsibility for due observance of all principles of ethics and guidelines devolve on all those directly or indirectly connected with the research. They include institution(s) where the research is conducted, researcher(s), sponsors/funders and those who publish material generated from research. They must be prepared to take care of side effects and dangers to participants and remunerate them or their estates when death and/or incapacitation occur. It is the responsibility of the researcher to bear participants/patients' costs in studies including transportation costs and whatever may result from income lost for participating in studies.

(xviii) Distributive Justice:

Research proposals should provide sufficient information to justify if there is any reasonable likelihood that the population on whom research is to be carried out stand to benefit from the research projects and its results. Selection of participants from groups whom are unlikely to be beneficiaries of subsequent applications of research results should also be justified. Research proposals should indicate whether long-term therapy would be provided to participants after the completion or termination of the study.

The principles outlined above should guide all researches involving both animals and human participants in any discipline relating to health. All IRB/ERCs in Nigeria are encouraged to adopt these principles to guide their efforts in assessing health research projects. All health research in Nigeria, including research undertaken by military and other national bodies should be subject to these guidelines. Those who conduct "secret" research should be held to the same levels of accountability if their work involves human subjects. Compliance with these standards and other international and national scripts provides the public with the assurance that the rights, safety and well-being of study participants are protected.

(xix) Inclusion / Exclusion Criteria:

The selection, recruitment, exclusion and inclusion of research participants in a research project must be just and fair, based on sound scientific and ethical principles. No person must be inappropriately or unjustly excluded on the basis of race, age, sexual orientation, disability, education, religious beliefs, pregnancy, marital status, ethnic or social origin, conscience, belief and language.

(xx) Conflict of Interest:

A researcher must disclose the sources and extent of funding for the research to the research participants and the ethics committee and where appropriate the regulatory authority, and must declare any affiliation or financial interest at the time of proposing and reporting the research.

(xxi) Safety Monitoring:

Safety monitoring on research participants is imperative, particularly in a clinical trial. This involves the prompt reporting of serious adverse events, the appropriate management of such an event and post trial follow up. Safety monitoring should include the possibility of pre and post “test” counseling.

(xxii) Multi-Centered Studies:

There is a need to ensure that designs of multi-centered clinical trials and studies being undertaken in Nigeria are appropriate for the local setting and that particular modifications are made to the local study when required e.g. inclusion / exclusion criteria. It is unacceptable for developed country participants to have better standards of care offered in the study when compared to Nigeria participants. In particular, when Nigeria is chosen for a trial or study, and the trial or study is not undertaken in the country of origin, an explanation should be sought as to why this is the case. In terms of study design, special attention should be paid to the sampling strategy. Other issues in international studies include financing of the study, the appropriateness of incentive packages to research participants and remuneration packages for investigators.

(Need to discuss on the issue of intellectual property transfer and on the issue of use/reuse of materials other than the initial purpose of the study).

(xxiii) Ethical Review:

All health research conducted in Nigeria must be reviewed by an ethics committee and should not commence unless and until approval has been granted. This provides an objective appraisal of the research proposal as it affects the potential participants and the general day-to-day functioning of the health system.

(xxiv) Publication of Results:

Investigators have an obligation to disseminate research results whether positive or negative in a timely and competent manner. This is particularly important in clinical trials, where investigators are duty bound to ensure that study findings are made public for all outcomes assessed. It is however important that the release of research findings is done in an ethical manner, so as to ensure that false expectations are not raised in a vulnerable population. Research results should not be prematurely released, published, or unreasonably delayed. It is advisable that the main results should be disseminated using appropriate communication formats to the participants and other interested members of the communities where the study was conducted.

Results of a study, whether government or industry-sponsored, should always be published if they have scientific merit. Requests to withhold findings, to change or tone down the content of a report are not acceptable to good ethical practice. Sponsors or relevant stakeholders should be afforded the opportunity to provide comment on research findings prior to publication without any entitlement to veto, change the conclusions, or delay publication of results unreasonably.

In collaborative research with pharmaceutical or other companies, the conditions of publication should be spelt out clearly in the protocol. Ethics committee should be satisfied that there is no interference with the right to publish results.

3.0 Rights and Responsibilities of Parties

3.1 Rights of Participants

(i) Relationship with the participants:

Participants must be valued as persons in their own right worthy of protection and respect. They have the right to have their contributions appropriately acknowledged. They must not be used merely as a means to other's end.

Participants have the right to be protected from any significant or unnecessary physical, psychological and social deprivation as a result of research studies. It is the responsibility of the researcher in conjunction with the participants to determine the level of bearable risks, untoward side effects and complications. The researcher's role is to explain the technical details about the risks to the participants and not to make the decisions for the participants. It is also the responsibility of the researchers to provide for the participants comfort during the duration of the studies. Accruable benefits should also be completely divulged to study participants.

Participants have the rights to be protected from discrimination with respect to race, ethnic or class distinction and gender. In the context of research, studies that may endanger the health of women should exclude women only on the basis of clear data and not just on the assumption that the women may be pregnant or breastfeeding. It is unethical to exclude women from participating in research on the basis that they are women.

Research with vulnerable populations should only be taken when it is directly related to their own health and these studies cannot be done with other groups. It is the responsibility of the researcher to protect vulnerable participants in research and their situation should not be exploited in any way.

Participants have the right to any help they would require in case of adverse reactions during the course of the study. Participants also have the right to be protected from social or political retaliation for participating in studies. Information that could contribute to the improvement of quality of life of the participants should be passed on to concerned person(s), official(s) or the agencies. That the participants have been made to sign that they would be responsible for adverse reactions as a result of the studies does not relieve the researchers from the responsibility of caring for or compensating them.

There should be equitable distribution of burdens and benefits of research studies. Those who bear the burdens of research should not be denied the benefits of the same. There should be a conscious effort on the part of the researcher to recruit from all classes and groups within the community unless the design of the study dictates otherwise.

(ii) Informed and understood consent:

Informed and understood consent should be obtained from all study participants. Where it is not feasible to obtain informed and understood consent from study participants as in the case of children, the assent of the children (where feasible) should be sought in addition to the permission of the guardians.

After the age of fourteen, children have been known to be able to take some responsible decisions with respect to their health. Permission should be granted to these '*mature, enlightened, emancipated*' children bearing the laws of the land into consideration.

Participants should be informed of their right to refuse to participate and withdraw without their suffering any dire consequences or penalties for such decisions. They should also be informed that they reserve the right to withdraw the permission granted if they object to the use of data gathering equipment such as tape recorder or video cameras pertaining to them at any time in the study.

An agreement received from community leaders to carry out a research in a community should not be taken as individual consents. Despite efforts made to ensure community leaders' agreement to studies within a community, all efforts must be made to receive individual consents for any research bearing in mind the principle of autonomy in research.

The following basic elements must be present in the informed consent

- Basic elements of informed consent
 - State that the study involves research
 - Explanation of the purpose of the research
 - Expected duration of the subjects participation
 - Description of the procedures
 - Identification of any experimental procedures
- A climate conducive to facilitate informed consent, for example appropriateness of language, environment, peer counseling
- Information on qualifications of investigator/s
- Explanation of participants' responsibilities
- Description of foreseeable risks and discomforts
- Description of any benefits to the subject or to others which may be expected including provisions after the study is completed

- Disclosure of alternative procedures or courses of treatment
- Statement describing the extent to which confidentiality will be maintained
- Statement that authorities may inspect records
- Explanation as to whether any compensation will be given
- Explanation as to whether medical treatments are available if injury occurs and what they consist of and where information may be obtained
- Explanation of whom to contact in the event of trial related injury
- Explanation of whom to contact for:
 - Research
 - Research participant's rights
- Statement that participation is voluntary
- Refusal to participate will involve no penalty or loss of benefits
- Participant/s may discontinue without penalty or loss of benefits
- The approximate number of subjects involved in the study
- Trial treatments and possibility of random assignment to each treatment
- Clear explanation of the implications of random assignment to experiment and control groups
- Foreseeable circumstances and/or reasons for termination of participation

When appropriate, one or more of the following elements of informed consent should also be provided:

- Statement that treatment may involve unforeseeable risk
- The investigation may terminate the participant's participation
- Additional costs may occur
- The consequences of a participant's decision to withdraw
- The right of the patient to be informed of new findings
- Statement that a copy of the full informed consent will be given to the participant

All the essential elements of informed consent must be included in the Informed Consent Form, unless an element is not relevant to the study.

Informed consent is a necessary but not sufficient requirement for ethical conduct. The informed consent requirements are not intended to pre-empt any laws, which require additional information to be provided to the participants. The authority of the medical practitioner to provide emergency medical care will not be limited to these requirements.

(iii) Anticipation of findings use:

Possible future use of study findings such as in a database archival research or recordings for educational purposes, tissues and body fluids as well as possible use in unanticipated circumstances like use as secondary data should be made known to participants and prior permission sought unless where the information has become public property; then, such permission may be unnecessary.

(iv) Ethics of research in refugee populations and internally displaced persons:

Internally displaced populations create unique issues that require special attention. Internationally a debate is underway within the relief community about the proper ethical guidelines to apply when researches are carried out in refugee populations and internally displaced persons. Nevertheless several point are clear: -

The eagerness of internally displaced persons and refugees to meet life's daily need (food, shelter and clothing) should not be taken advantage of in recruiting them for research. The provision of these daily needs or the promise of early settlement should not be exploited in enrolling them in studies.

It is unethical to undertake studies that have no bearing on the health and welfare of refugees and internally displaced persons. It would be exploitation to undertake studies that have no bearing on solving their health, physical, social and psychological needs. Studies that can be answered by any other settings should not be undertaken with them.

It is the responsibility of the researcher to impose no further risks to these displaced persons and refugees than is the barest minimum. It is the responsibility of researchers and funders to initiate and maintain procedures that would monitor and minimize both immediate and future risks for participating in studies. The safety, privacy and confidentiality of study participants must be promoted and ensured at all times to the maximum extent possible. Unavoidable limitations that pose serious risks should preclude approval of the proposed research.

Researcher(s) must select study participants on the basis of scientific principles without bias introduced by issues of accessibility, cost or malleability. It is the responsibility of researchers and sponsors to promote the well being, dignity and autonomy of all study participants in all phases of the research study.

The highest feasible standards of obtaining informed and understood consent must be obtained from individuals and where appropriate from clan, family and community heads despite the fact that participants are internally displaced and refugees,

3.2 Rights and Responsibilities of Researchers and Institutions.

(i) Relationships between researchers and institutions:

Researchers have a right to be protected from undue pressure to compromise expected ethical standards in the execution of studies. Institutions have a responsibility to take appropriate steps to protect researchers against pressure inimical to the observance of the ethical guidelines for research in spite of the urge and the necessity to carry out research and make money. The urge to undertake research should not make the researcher or the institutions disregard culturally sensitive issues in communities where they undertake research and in the dissemination of their research findings.

(ii) Protection and promotion of integrity in research:

Researchers have a right and a responsibility to refuse to continue to undertake studies that contravene ethical guidelines, violate the integrity of research and/or compromise their individual autonomy in all stages of research including design right through to implementation and publication stages if their rights are being violated. Researchers should be free to take any course of action compatible with right ethical actions and their conscience.

Researchers should anticipate and take into account possible misuse of their studies findings and undesirable and harmful consequences of their research before initiating research. Though researchers cannot control the use of published data, they should be protective of their participants enough to correct any misuse or misrepresentation of their findings.

Researchers, grant awarding agencies and institutions should not compromise the protection and the promotion of the rights of participants and should be sensitive to issues and situations that could compromise their participants' rights.

(iii) Relationship among researchers:

Research assistants, students and co-investigators are subject to the same rules as the principal investigators. They are required to promote, protect and be sensitive to the interests of study participants and the principal investigators are responsible for the conduct of their employees. The principal investigators should also ensure that their employees maintain ethical standards in the conduct of the studies. They may also be held accountable for ethical lapses in their research designs and implementation.

It is the responsibility of the PI to impart adequate training including appropriate ethical conduct during studies to research assistants, juniors, administrative staff and trainees. Assistants should not be given responsibilities or expected to function above their level of training, experience or education.

It is the duty of researchers to protect the privacy and confidentiality of study participants even among their staff and they would be held responsible for the consequences of any breach in patient confidentiality.

(iv) Data sharing, reporting and publication of research results:

Except where an appropriate agreement has been entered into, the researcher(s), institutions and the sponsoring agency have joint ownership of data. Along with this right they have the full responsibility of ensuring that personal identifiers are removed before data is shared with other researchers, all necessary measures must be taken to maintain confidentiality by those researchers with whom data are shared.

Data that could effectively be used for positive changes should be released to the community in understandable forms as soon as available. As far as possible, researchers and institutions should ensure that relevant summary findings of the research are taken back to the research participants taking preservation of confidentiality into consideration and preventing as much as possible other harms that such results may occasion.

Reports should be reported irrespective of whether they support or contradict expected outcome(s). Source(s) of funding should be disclosed in the publications unless there are compelling reasons not to do so. Depending on the outcome of the study, anonymity of the study location as well as of study participants should be maintained in the publications.

Where the researcher(s) is delegating the responsibility of publication to the funding agency, researchers must ensure that the funding agency report or disseminate the findings as accurately as the study shows and the publication must be within a stipulated time.

Authorship and its sequence in case of more than one author should be based on the extent of contributions made in terms of ideas, actual performance of the research, analysis and writing up of the report, the status of the contributor notwithstanding. Gift authorship is unethical and should be discouraged.

Other contributors who have not attained authorship status but contributed to the work should be acknowledged.

Appropriate credits should be given to data or information obtained from other sources in order to avoid plagiarism. Researchers should not falsify, fabricate and practice plagiarism of any form and other unethical practices should be avoided.

It is unethical for researchers to disseminate categorical information from studies that have not been peer-reviewed or published in appropriate journals. In situations where there may be the need to disseminate such findings in view of the urgency of the findings, care must be taken to express that the findings being presented have not been peer-reviewed and the interpretation of the findings should be made unambiguously clear for a person not trained in research methodology to understand.

3.3 Rights and Responsibilities of Peer Reviewers/Referees.

Part of the purpose of peer review and refereeing is to maintain near uniform standard of carrying out and reporting research, improve and advance research and facilitate the observance of ethics in research activities and reporting of results. In most universities and research institutes, the use of peer review journals for reporting research findings is almost mandatory for the majority of the materials to be used for advancement. Researchers should be available for reviewing other materials from peers and should be willing to submit their work for peers to review even when there is no legal necessity or demand for it.

Those called upon to be peer reviewers have an ethical duty to undertake the duty objectively, impartially and constructively. Consideration should be given to ensuring that reviewed articles are returned back on time. Where the reviewer cannot ensure prompt review of manuscripts, such should be made.

Researchers should only accept the role and duties of peer reviewers and referees for research and publication only for the fields they have adequate knowledge and expertise. They must review these materials with appropriate ethical principles for research, care and respect of study participants in mind.

Any actual or potential personal/professional conflicts of interest with any of the materials for review with them must be disclosed in writing to the body that has the materials to them for review or decline to review the publication or study materials. Not all cases of declared conflict of interest should automatically prevent a peer reviewer from reviewing materials in which they have conflicting interest but the depth and extent of the conflict should be determined by the supervising body and appropriate action taken accordingly as to whether or not to send the materials to other reviewers. Not declaring a conflict of interest in a specific study or publication when one ought to do so is unethical.

It is unethical for anyone and especially those called upon to be peer reviewers to plagiarize materials given them to review no matter the time interval.

Reviewers who discover violation and malpractice involving ethical principles have the ethical responsibility of reporting same to the appropriate authorities who are under obligations to report to the constituted disciplinary body for due action.

3.4 Rights and Responsibilities of Editors and Publishers.

It is the responsibility of editors and publishers to ensure that the materials being forwarded for publication receive thorough peer review to meet scientific and ethical standards. They must therefore do everything in their power to keep a well-stocked stable of proven reviewers with expertise and integrity in

fields pertaining to their interests. Non-availability of reviewers should not be enough reason to publish an article without its being peer reviewed and found suitable for publication.

It is the responsibility of the editors and the publishers to ensure that the methodology of studies and statements to be published in their journals adhere to ethical guideline standards and this must be part of their instructions to authors as a standing policy of the journal. Contributors should be informed that the material submitted for publication should carry appropriate credits. Fabricated, falsified or plagiarized information should not be entertained and if published before being discovered, it should be followed with a publicized editorial stand exposing and/disowning it.

3.5 Rights and Responsibilities of Funders and Sponsors.

It is the responsibility of Funders and Sponsors to ensure that the study to be funded by their organization complies with ethical standards and they must insist on written authorization from appropriately constituted Ethical Review Committees (ERCs) and Institutional Review Boards (IRBs) clearing that the study has complied with ethical standards.

Funders and Sponsors of research studies should respect the ethical guidelines for research and should not expect researchers and institutions to conduct research in ways contrary to ethical guidelines.

Where sponsors and funders also act directly or indirectly as gatekeepers and control access to the participants, researchers should not delegate to the gatekeeper their responsibility to obtain separate and full informed consent from participants and protect all rights of the participants.

3.6 Organisational Mechanism for Ethics.

Since ethical guidelines are not administrative or legal documents, the conscience of researchers may be the best guide for ensuring that ethics are followed in research and clinical practice and for resolving ethical dilemmas. However, there are appropriately constituted bodies at the institutional, local, regional and national levels (Ethical Review Committees and the National Ethics Review Board) to ensure that ethical guidelines are closely followed in the conduct of research and clinical practice. These bodies are mandated to ensure that the researches on human subjects are carried out taken cognisance of the outlined ethics and ethical values. This would entail the review of all proposals for research on human subjects within their jurisdiction and ensure the monitoring and evaluation of such projects.

4.0 THE ROLE OF IRB/ERC

IRB/ERCs are established to provide ethical advice to researchers in order to assist decision-making on the adequacy of proposed research projects regarding the protection of potential and actual human participants. In order to fulfill this role it is essential that **IRB/ERCs** are constituted and perform according to four principles for ethical review: independence, competence, pluralism, and transparency. The *Declaration of Helsinki*, Good Clinical Practice Guidelines, and other international and national instruments require the ethical review of research prior to its commencement. These instruments also require **IRB/ERCs** to perform regular follow-ups to research projects for which they have provided a positive decision. **IRB/ERCs** are responsible for acting in the full interest of potential research participants and concerned communities, taking into cognisance the interests and needs of the researchers and having due regard for the requirements of relevant regulatory agencies and the laws of the country. In their decision-making, **IRB/ERCs** must be independent of the sponsor, the investigator, and any undue influence. **IRB/ERCs** must be appropriately constituted and adopt written standard operating procedures in order to achieve independence and quality in decision-making. It should provide independent, competent and timely review of the ethics of proposed studies in their areas of jurisdictions.

5.0 THE ROLE OF THE NATIONAL ETHICS REVIEW BOARD

The role of the Board would be to 'promote the practice of good ethical practice in Nigerian scientific research, safeguard the dignity, right, safety and well-being of all actual or potential research participants' through the auditing and accreditation of **IRB/ERCs**. In addition to its role of prescription, control and enforcement, the **NERB** would provide guidance, training and support to **IRB/ERCs**. The purpose of auditing and accrediting of ethical review practices is to assist **IRB/ERCs** in reviewing their practices and appraising performance while also providing a means to assure the public that the ethical review of research proposals is carried out according to established standards. This would help to ensure that **IRB/ERCs** comply with the relevant legislation and regulations, ethical guidelines and standards. The survey should establish the basis for an independent evaluation that provides relevant

information to parties having a legitimate interest in the appropriate functioning of an **IRB/ERC**, as defined within the framework of national legislation or mutually agreed to by the surveying entity and the **IRB/ERC**. An independent evaluation should provide an opportunity for an **IRB/ERC** to receive advice on its constitution and operation.

The NERB would be a central body to advise the Federal Ministry of Health on the management of research ethics for Nigeria. The board would not replace existing IRB/ERCs but would serve as a body that sets standards, links with and/or arbitrates on matters of ethics. All ethics committee approving health research in Nigeria will be subjected to the accreditation process and criteria as determined by the board. Continued education and regular auditing of ethics committees will be promoted by the NERB to assist committees in meeting acceptable standards of oversight.

6.0 ESTABLISHMENT AND LEGAL EMPOWERMENT OF THE BOARD

6.1 Authority under which the IRB/ERCs is established

The IRB/ERCs will receive guidance from the NERB. The NERB is to be established in terms of the National health Policy (FMOH; Ref.). The board, with legal empowerment, would make final decisions and the necessary enforcement.

6.2 Relevant laws, regulatory requirements, appropriate national and international guidelines

Constitution of the Federal Republic of Nigeria (Promulgated) in terms of the Federal Republic of Nigeria 1999.

World Medical Association, *Declaration of Helsinki: Ethical Principles for Research Involving Human Subjects*. Adopted by the 18th World Medical Assembly, Helsinki, Finland, June 1964. Amended by the 29th World Medical Assembly, Tokyo, Japan, October 1975; the 35th World Medical Assembly, Venice, Italy, October 1983; the 41st World Medical Assembly, Hong Kong, September 1989; the 48th General Assembly, Somerset West, Republic of South Africa, October 1996; and the 52nd General Assembly, Edinburgh, Scotland, October 2000.

World Health Organization (TDR/WHO). *Surveying and Evaluating Ethical Review Practices a complementary guideline to the Operational Guidelines for Ethics Committees That Review Biomedical Research* Geneva: WHO, 2002.

Council for International Organizations of Medical Sciences (CIOMS), in collaboration with the World Health Organization (WHO). *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. Geneva 1993. Council for International Organizations of Medical Sciences (CIOMS). *International Guidelines for Ethical Review of Epidemiological Studies*. Geneva 1991.

Council of Europe. *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*. European Treaty Series – No. 164. Oviedo, 4 April 1997.

Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. *Official Journal* L121 34-44, 1 May 2001.

European Forum for Good Clinical Practice. *European Guidelines for Auditing Independent Ethics Committees*. Brussels: The EFGCP News, Summer 2001.
European Forum for Good Clinical Practice. *Guidelines and Recommendations for European Ethics Committees*. Revised Edition. Brussels: EFGCP, 1997.

International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH). *Note for Guidance on Good Clinical Practice* (CPMP/ICH/135/95) 1 May 1996.

World Health Organization (WHO). *Guidelines for Good Clinical Practice (GCP) for Trials on Pharmaceutical Products*. Annex 3 of *The Use of Essential Drugs*. Sixth Report of the WHO Expert Committee. Geneva: World Health Organization, 1995: 97-137.

World Health Organization (TDR/WHO). *Operational Guidelines for Ethics Committees That Review Biomedical Research*. Geneva: WHO, 2000.

Nuremberg Code 1947

Belmont Report 1979

South African draft guideline for audit and accreditation of ethics committees 2000

<http://www.hsph.harvard.edu/bioethics/guidelines/ethical1.html>

7.0 PRACTICES AND PROCEDURES OF ETHICAL REVIEW IN NIGERIA

All research involving human participants conducted in Nigeria must be revised by an ethics committee, and where appropriate by the food and drugs regulatory authority – National Agency for Drug Administration and Control (NAFDAC), and have documentation stating that such approvals/has/have been given prior to the commencement of the research project.

This section therefore outlines the process for gaining approval to conduct a clinical trial in Nigeria.

7.1. Institutional Review Boards and Ethical Review Committees (IRB/ERCs) in Nigeria

The main functions of the Ethics Committee include:

- (a) Reviewing research proposals and protocols to ensure that research conducted will be in the spirit of endeavoring to promote health, and/or prevent disease and/or disability and cure disease;**
- (b) Ensuring that humans involved in research are treated with dignity and that their well-being is not compromised and that animals involved in research are treated compassionately;**
- (c) Ensuring that informed consent is obtained in the case of human subjects; and**
- (d) Granting approval in instances where research proposals and protocols meet ethical standards.**
- (e) Monitoring the process and evaluating the outcome of research it approves to ensure that the guiding ethical principles are adhered to throughout the research process.**

7.2 National Agency for Food and Drug Administration and Control (NAFDAC)

All clinical trials of both non-registered medicinal substances and new indications of registered medicinal substances must be reviewed by NAFDAC. NAFDAC has a statutory obligation to ensure that all packaged food and drugs available in the country fulfill the necessary requirements for safety, quality and efficacy and that the decision to register a drug is in the interests of public health. In the case of an ongoing trial where there are serious breaches of good clinical practice (GCP), NAFDAC can close a trial down. Reference to the regulatory authority in this document refers to NAFDAC.

7.3 Ethics Approval in the Private Sector

A private sector researcher should apply for ethics approval from an established, accredited Nigeria based ethics committee already approving studies with public sector, non-government organization researchers.

7.4. Process For Ethics Approval of Health Research including Clinical Trials in Nigeria

Protocols for all health research involving human participants must be submitted to accredited IRB/ERCs for approval. The following two steps must be taken before a clinical trial involving medicines can be conducted in Nigeria:

- **Ethics Committee Approval**

- **NAFDAC Approval is needed for both non-registered medicinal substances and new indications of registered substances.**

The clinical trial must first be reviewed by the local ethics committee in the institution in which the trial is to take place. When approval is received, from the local IRB/IRC the Principal investigator (PI) must then submit an application to NAFDAC along with the accreditation document received from the local IRB/IRC. Both these reviewing institutions need to approve the project before the study can commence. Principal Investigators should take full responsibility for the scientific and ethical aspects of the study they are directing and should be the channel through which all such issues are passed to the ethics committee during the approval process. Once a study is in progress all reports of adverse events and other management issues dealt with by the sponsoring company should be reported to the ethics committees, ideally through the Principal Investigator who should be fully informed of these issues. To expedite the process, submission of these data could be copied both to the Principal Investigator and to the ethics committee. However, it should be made clear that the Principal Investigator is responsible for the study. In addition a system to ensure monitoring of all research will be set up through the NERB and local ethics committees which will involve each study being issued a national study number and notified in the national database. It is envisaged that ethics committees will be allocated cohorts of notification numbers. When they have allocated a number to a particular project this will be communicated to the NERB for inclusion in their database. A research project cannot commence without a national study number from the local ethics committee. The local ethics committees have the responsibility of ensuring that the NERB receives a full listing of numbers allocated. The information in the national database should be available publicly. The information made publicly available should be restricted to that information that would not jeopardize commercial interests and should reasonably include a listing of:

- Title of research projects;
- Duration of the projects; and
- PI name and affiliation.

A regular update of an anonymous research profile from database may be placed on the FMOH's Website with information such as:

- The number and proportion of studies by type (e.g. trials, non-trials)
- Proportions by study site
- Total sponsorship by type of study and study site.

8.0 CONSTITUTING AN ETHICAL REVIEW COMMITTEE

The Ethical Review Committees should be constituted to ensure the competent review and evaluation of the ethical aspects of the projects they receive and to ensure that their tasks can be executed free from bias and influence that can affect their independence.

They should be multidisciplinary and multisectorial in composition, including relevant scientific expertise, balanced age and gender distribution and lay persons representing the interests and concerns of the community.

The Ethical Review Committees should take into cognisance the values and principles of the community they serve when been set up and when functioning.

The committees should make available to the public they serve, the authority under which they are established, their functions and responsibility, membership, terms of appointment and the location of their secretariat. There is also the need to explain to the public, their internal procedures. These help to ensure transparency in operational procedures. The Ethical Review Committees need to act in accordance with their written operating procedures to ensure accountability.

An annual report of the committee is expected to be submitted to the National Ethics Review Board as stipulated in the letter of accreditation.

8.1 Membership requirements

Clear procedures for recruiting potential members of the Ethical Review Committees should be established. Guidelines should be established as to who or which body makes the appointments; the method for selecting/appointing members; ways to avoid conflict of interest when making appointments.

A system of membership that would ensure continuity, development and maintenance of expertise on the Committee and regular input of fresh ideas and approaches should be considered.

8.2. Terms of appointment

The committee should ensure that the term of appointment of all members should be spelt out. This should include the duration of appointment; the policy for the renewal of an appointment; as well as the disqualification, resignation and replacement procedure.

8.3 Conditions of appointment

The Ethical Review Committees should draw up conditions of appointment of all members. This should include the need to publicly disclose one's identity and the need to sign a confidentiality agreement regarding meetings deliberations, information on research participants and related matters. All expenses for work done for the Committee should be reimbursed and records/receipts kept and made available to the public on request.

8.4 Administration

The Ethical Review Committees should establish clearly defined structures for functioning. The office, responsibilities and functions of the office of the Chairman and the Secretary should be stated. Clear procedures for selecting or appointing officers should be established. The secretariat of The Ethical Review Committees should also have supporting staff for carrying out its routine responsibilities to help ensure efficiency.

8.5 Quorum requirement

The Ethical Review Committees should establish specific quorum requirements for reviewing and deciding on an application. This requirement should include the minimum number of members required to constitute a quorum, the professional qualifications requirements and the distribution of those requirements over the quorum. A quorum should include at least one member whose expertise is in a non-scientific area and one member who is independent of the research/institutional site.

8.6 Independent consultation

The Ethical Review Committees can call upon independent consultants who may provide special expertise to the Committee on proposed research protocols. These consultants may be specialists in their fields of practice whose review may be needed for any aspect of proposals been reviewed. Terms of reference for independent consultants should be established

8.7 Education of the Ethical Review Committees members

The Ethical Review Committees members have a need for initial and continued education regarding the ethics and science of research on human subjects. The committee should ensure that members receive introductory training in the work of an Ethical Review Committee as well as ongoing opportunities for enhancing their capacity for ethical review. This arrangement may be linked with cooperative arrangements with the national body or with other Ethical Review Committees in the country or internationally.

8.8 Submission of an application

The Ethical Review Committees are responsible for establishing well-define requirements for submitting an application for review of a research project with it. The requirements for the submission of a research project for ethical review should clearly describe the application procedure. Oftentimes, it may be easier for the committee to develop an outlined format for application along with an application form to be filled. This enhances uniformity in research protocol presentations as well as enhances the processing and documentation procedure. Information may be needed as to the number of copies of the proposal to be submitted to the committee, deadlines for submissions of applications, method for acknowledging receipt of applications and the expected time for notification of decision following review. The fee structure, if any, for reviewing an application should also be specified as well as the application procedure for amendments to research proposals.

It is the responsibility of the researchers to submit all the required documents as specified by the reviewing committees. This often would include a signed and dated application form, the research protocol along with the supporting documents, investigator(s)'s curriculum vitae, written and or any other form of information for potential research participants in language(s) understood by the potential research participants, informed consent form in language understood by potential participants, description for compensation for study participants, a statement of agreement to comply with ethical guidelines set out by The Ethical Review Committees and all significant previous documents such as decisions of other review committees on the proposal.

8.9 Review

All properly submitted applications should be reviewed in a timely fashion and according to established review procedures. This would be the committee having regular, planned and scheduled meetings. The meetings should be minuted and the minutes adopted. The researcher may be invited to present the proposal or elaborate on specific issues. Independent consultants may also be invited to the meeting or provide written comments subject to applicable confidentiality agreements.

The primary task of The Ethical Review Committees lie in the review of research proposals and their supporting documents with special attention given to the understood consent process, documentation and the suitability and feasibility of the protocol. Cognisance should be taken of the scientific design and conduct of the study; recruitment of research participant; care and protection of research participants including the suitability of the investigator(s)'s qualifications and experience for the proposed study; protection of research participant confidentiality; informed consent process and community considerations.

The Ethical Review Committees may establish procedures for the expedited review of research proposals. These procedures should specify the nature of the applications, amendments and other considerations that will be eligible for expedited review; the quorum requirements for expedited review and the status of decisions (subject to confirmation by full house or not).

8.10. Decision-making

In making decisions on research applications to The Ethical Review Committees, members with conflict of interest should withdraw from the meeting for the decision procedure concerning the application. The conflict of interest should however, be indicated to the chairperson prior to the review of the application and recorded in the minutes. Also, a decision should only be taken when sufficient time has been allowed for review and discussion on the application. Decisions should only be taken at meetings where a quorum is formed and decisions should be reached through predefined methods (by consensus and or by vote).

In case of conditional decisions, clear suggestions for the revision and the procedure for having the application re-reviewed should be specified. A negative decision on an application should be supported by clearly stated reasons.

8.11. Communicating decisions

A decision should be communicated in writing to the applicant according to The Ethical Review Committees' outlined procedures. The communication of the decision should include but not be limited to the exact title of the research proposal reviewed, the identification of the research protocol on which decision was made, the name and title of applicants, the name of the Ethical Review Committee taking the decision, a clear statement of the decision reached and any advice/comments by the Ethical Review Committee. In case of a conditional approval, any requirements by the Ethical Review Committee, including suggestions for revision and the procedure for having a re-review should be included in the communication. In case of a positive decision, the responsibilities of the researcher including submission of a progress reported at stipulated time intervals to enable the monitoring of the research; need to notify the committee in cases of procedural protocol amendments and in the event of serious and unexpected adverse events related to the conduct of the study. Also, there would be a need to report unforeseen circumstances, termination of the study. A final summary and report of the project needs to be submitted to the committee.

8.12. Follow-up

The Ethical Review Committees should establish a follow-up procedure which enables the committee to follow the progress of all studies approved from the time the decision for commencement was taken to the end of the research. There is a need to specify the quorum requirement, the review procedure and the communication procedure for follow-up reviews which may vary with procedures. Each protocol should undergo a follow-up at least once year. These follow-up sessions allow for the monitoring, feedback and evaluation of research procedures.

The decision of a follow-up review should be communicated to the applicant indicating a modification, suspension or termination of Ethical Review Committee's original decision in the view of a breach of research ethics.

In case of a premature suspension/termination of study, the applicant should notify the Ethical Review Committee should be notified of the reasons for the suspension/termination and a summary of the

results obtained in the study prematurely suspended/terminated should be communicated to the Ethical Review Committee.

A copy of the final report of the study should be submitted to the Ethical Review Committee.

8.13. Documentation and archiving

All documentations and communications of the Ethical Review Committees should be dated, filed and archived according to written procedures. Access and retrieval procedures and authorised persons to do so for the various documents, files and archives should also be spelt out. The WHO recommends that documents should be archived for a minimum of three years following the completion of a study. This recommendation has been adopted by the **NERB**.

8.14 Appeal