National Code of Health Research Ethics

2006

National Health Research Ethics Committee of Nigeria (NHREC)

FEDERAL MINISTRY OF HEALTH

DEPARTMENT OF HEALTH PLANNING AND RESEARCH

2006 National Health Research Ethics Committee
Federal Ministry of Health
Federal Secretariat Complex
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Foreword

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Statutory Authority

Federal Government of Nigeria National Health Bill 2004

96. Establishment, Composition, Tenure and Functions of National Health Research Ethics Committee

(1) There is hereby established the National Health Research Ethics Committee.

(2) The National Health Research Ethics Committee shall consist of not more than 15 persons who shall include –

(a) Chairman to be appointed by the Minister;

(b) A Medical Doctor

(c) A Legal Practitioner

(d) A Pharmacist

(e) A Nurse

(f) At least two Religious Leaders

(g) A Community Health Worker

(h) One Researcher in the Medical Field

(i) One Researcher in the Pharmaceutical Field

(j) Three other persons who in the opinion of the Minister are of unquestionable integrity.

(3) A member of the National Health Research Ethics Committee shall be appointed for a term of three years in the first instance and may be reappointed for

another term of 3 years and no more under such terms and conditions as may be specified.

(4) A member of the National Health Research Ethics Committee shall vacate his office if he resigns or is requested in the public interest by the Minister to resign.

(5) If a member of the National Health Research Ethics Committee vacates office or dies, the Minister may fill the vacancy by appointing a person in accordance with subsection (2) for the unexpired portion of the term of office of his predecessor.

(6) The National Health Research Ethics Committee shall:-

(a) Determine guidelines for the functioning of health research ethics committees;

(b) Register and audit health research ethics committees;

(c) Set norms and standards for conducting research on humans and animals, including norms and standards for conducting clinical trials;

(d) Adjudicate in complaints about the functioning of health research ethics committees and hear any complaint by a researcher who believes that he has been discriminated against by a health research ethics committee;

(e) Refer to the relevant statutory health professional council matters involving the violation or potential violation of an ethical or professional rule by a health care provider;

(f) 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

(g) Advise the Federal Ministry of Health and State Ministries on any ethical issues concerning research.

(7) For the purposes of subsection (6) *(c)*, ‘‘clinical trials’’ means a systematic study, involving human subjects that aims to answer specific questions about the safety or efficacy of a medicine or method of treatment.

97. Establishment and Functions of Health Research Ethics Committees

(1) Every institution, health agency and health establishment at which health research is conducted, shall establish or have access to a health research ethics committee, which is registered with the National Health Research Ethics Committee.

(2) A health research ethics committee shall:-

(a) Review research proposals and protocols in order to ensure that research conducted by the relevant institution, agency or establishment will promote health, contribute to the prevention of communicable or non-communicable diseases or disability or result in cures for communicable or non-communicable diseases; and

(b) Grant approval for research by the relevant institution, agency or establishment in instances where research proposals and protocol meet the ethical standards of that health research ethics committee.

Other relevant sections

53. Health Services for Experimental or Research Purposes

(1) Subject to sub-section (2) of this section, before a health establishment provides a health service for experimental or research purposes to any user, the health establishment shall inform the user in the prescribed manner that the health

service is for experimental or research purposes or part of an experimental or research project.

(2) A health establishment may not provide any health service to a user for a purpose under subsection (1) of this section unless the user, the health care provider primarily responsible for the user's treatment, the head of the health establishment in question and the relevant health research ethics committee, or any other person to whom that authority has been delegated, has given prior written authorization for the provision of the health service in question.

58. Access to Health Records by Health Care Provider

(1) A health care provider may examine a user's health records for the purposes of:-

(a) Treatment with the authorisation of the user; and

(b) Study, teaching or research with the authorisation of the user, head of the health establishment concerned and the relevant health research ethics committee.

(2) If the study, teaching or research under subsection (1)*(b) of this section* reflects or obtains no information as to the identity of the user concerned, it is not necessary to obtain the authorisations contemplated in that subsection.

102. Regulations

(1) The Minister, after consultation with the National Council, shall make regulations with regard to:-

(a) Anything which may or shall be prescribed under this Act; and

(b) Generally, any other matter which it is necessary or expedient to prescribe in order to implement or administer this Act.

(2) The Minister may, in any regulation made under this Act:-

(a) designate as authoritative any methodology, procedure, practice or standard that is recognised as authoritative by internationally recognised health bodies within the relevant profession; and

(b) require any person or body to comply with the designated methodology, procedure, practice or standard.

(3) *(a)* The Minister shall publish all regulations proposed to be made under this Act in the *Gazette* for comment at least three months before the date stated for their commencement.

(b) If the Minister alters the draft regulations substantially, as a result of any comment, he shall publish those alterations before making the regulations.

(c) The Minister may, if circumstances necessitate the immediate publication of a regulation, publish that regulation without the consultation stated in paragraph *(a)*.

103. Minister may Appoint Committees

(1) The Minister may, after consultation with the National Council, establish such number of advisory and technical committees as may be necessary to achieve the objects of this Act.

(2) When establishing an advisory or technical committee, the Minister may determine by notice or circular:-

(a) its composition, functions and working procedure; and

(b) any incidental matters relating to that advisory or technical committee.

104. Assignment of Duties and Delegation of Powers

(1) The Minister may assign any duty and delegate any power imposed or conferred upon him by this Act, except the power to make regulations to:-

(a) any person in the employ of the State; or

(b) any council, board or committee established in terms of this Act.

(2) A Commissioner may assign any duty and delegate any power imposed or conferred upon him or her by this Act, except the power to make regulations to any officer in the relevant State Ministry or any Council, Board or Committee established in terms of this Act.

(3) The Permanent Secretary of the Federal Ministry may assign any duty and delegate any power imposed or conferred upon him or her by this Act to any official in the Federal Ministry; and

(4) The Permanent Secretary of a State Ministry may assign any duty and delegate any power imposed or conferred upon him or her in terms of this Act to any official of that State Ministry of Health.

105. Savings and Transitional Provision

(1) Anything done before the commencement of this Act under a provision of any other relevant Act or regulation which could have been done under a provision of this Act shall be regarded as having been done under the corresponding provision of this Act.

(2) The Minister may prescribe such further transitional arrangements as may be necessary in the circumstance.

106. Interpretation

In this Act, unless the context otherwise requires:-

"**Appropriate authority**" means any other authority apart from the Minister,

Commissioner, Executive Secretary, Chairmen of Boards or Chairman of Agency;

‘‘**blood product**’’ means any product derived or produced from blood, including circulating progenitor cells, bone marrow progenitor cells and umbilical cord progenitor cells;

‘‘**certificate of need and standards**’’ means a certificate under section 61;

‘‘**Commissioner**’’ means the Commissioner of a State responsible for health;

‘‘**communicable disease**’’ means a disease resulting from an infection due to pathogenic agents or toxins generated by the infection, following the direct or indirect transmission of the agents from the source to the host;

‘‘**Constitution**’’ means the Constitution of the Federal Republic of Nigeria, 1999;

‘‘**death**’’ means brain death;

‘‘**embryo**’’ means a human offspring in the first eight weeks from conception;

‘‘**Federal Ministry**’’ means the Federal Ministry of Health;

“**guaranteed minimum package**” means the set of health services as may be prescribed from time to time by the Minister after consultation with the National Council on Health;

‘‘**gamete**’’ means either of the two generative cells essential for human reproduction;

‘‘**gonad**’’ means a human testis or human ovary;

‘‘**health agency**’’ means any person other than a health establishment:-

(a) whose business involves the supply of health care personnel to users or health establishments;

(b) who employs health care personnel for the purpose of providing health services; or

(b) who procures health care personnel or health services for the benefit of a user, and includes a temporary employment service involving health workers or health care providers;

‘‘**health care personnel**’’ means health care providers and health workers;

‘‘**health care provider**’’ means a person providing health services under Act of Law;

‘‘**health establishment**’’ means the whole or part of a public or private institution, facility, building or place, whether for profit or not, that is operated or designed to provide inpatient or outpatient treatment, diagnostic or therapeutic interventions, nursing, rehabilitative, palliative, convalescent, preventative or other health services under section 60;

‘‘**health research**’’ includes any research which contributes to knowledge of:-

(a) the biological, clinical, psychological or social processes in human beings;

(b) improved methods for the provision of health services;

(c) human pathology;

(d) the causes of disease;

(e) the effects of the environment on the human body;

(a) the development or new application of pharmaceuticals, medicines and related substances; and

(g) the development of new applications of health technology;

‘‘**health research ethics committee**’’ means any committee registered under section 93;

‘‘**health services**’’ means health care services that are preventive, protective, promotive, curative and rehabilitative in respect of physical mental and social well being;

‘‘**health technology**’’ means machinery or equipment that is used in the provision of health services, but does not include medicine as defined in the Drugs and Related Products Registration etc Act. No. 19 of 1993;

‘‘**health worker**’’ means any person who is involved in the provision of health services to a user, but does not include a health care provider;

‘‘**hospital**’’ means a health establishment which is classified as a hospital by the Minister under section 60;

‘‘**Local Government Health Authority**’’ means any authority established under section 29;

‘‘**Minister**’’ means the Minister charged with responsibility for matters relating to health;

‘‘**National Council on Health**’’ means the Council established by section 7:

‘‘**national health policy**’’ means all policies relating to issues of national health as approved by the Federal Executive Council on the advice of the National Council on Health through the Minister;

‘‘**National Health Research Committee**’’ means the Committee established under section 89;

‘‘**National Health Research Ethics Committee**’’ means the Committee established under section 92;

‘‘N**ational health system**’’ means the system within the Federal Republic of Nigeria, whether in the public or private sector, concerned with the financing, provision or delivery and regulation of health services;

‘‘**non-communicable disease**’’ means a disease or health condition that cannot be contracted from another person, an animal or directly from the environment;

‘‘**norm**’’ means a statistical normative rate of provision or measurable target outcome over a specified period of time;

“**NPHCDA**” means the National Primary Health Care Development Agency established under section 21;

‘‘**Office of Standards Compliance**’’ means the Office established under section 13(4);

‘‘**oocyte**’’ means a developing human egg cell;

‘‘**organ**’’ means any part of the human body adapted by its structure to perform any particular vital function, including the eye and its accessories, but does not include skin and appendages, flesh, bone, bone marrow, body fluid, blood or a gamete;

‘‘**Permanent Secretary**’’ means the administrative head of the Federal Ministry of Health or a State Ministry of Health;

‘‘**premises**’’ means any building, structure or tent together with the land on which it is situated and the adjoining land used in connection with it and includes any land without any building, structure or tent and any vehicle, conveyance or ship;

‘‘**prescribed**’’ means prescribed by regulation made under section 98;

‘‘**primary health care services**’’ means such health services as may be prescribed by the Minister to be primary health care services;

‘‘**private health establishment** ’’means a health establishment that is not owned or controlled by an organ of state;

‘‘**public health establishment**’’ means a health establishment that is owned or controlled by a government body;

‘‘**rehabilitation**’’ means a goal-orientated and time-limited process aimed at enabling impaired persons to reach an optimum mental, physical or social functional level;

‘‘**State Ministry**’’ means any State Ministry responsible for health;

‘‘**Statutory Health Professional Council**’’ means a professional regulatory body established by an Act or Law,

“Technical Committee” means the committee under section 9;

‘‘**tertiary hospital**’’ means a public or private hospital approved by the Minister to provide health services at a tertiary specialist level of care;

‘‘**this Act**’’ includes any regulation made thereunder;

‘‘**tissue**’’ means human tissue, and includes flesh, bone, a gland, an organ, skin, bone marrow or body fluid, but excludes blood or a gamete;

‘‘**use**’’, in relation to tissue, includes preserve or dissect;

‘‘**user**’’ means the person receiving treatment in a health establishment, including receiving blood or blood products, or using a health service, and if the person receiving treatment or using a health service is—

(a) below the majority age, ‘‘user’’ includes the person’s parent or guardian or another person authorised by law to act on the first mentioned person’s behalf; or incapable of taking decisions, ‘‘user’’ includes the person’s spouse or, in the

(b) absence of such spouse, the person's parent, grandparent, adult child, brother, sister, or another

(c) person authorised by law to act on the first mentioned person's behalf;

"Ward Health System" means the organisation and delivery of primary health care services at the Ward and village levels;

''**zygote**'' means the product of the union of a male and a female gamete.

107. Short Title

This Act may be cited as the National Health Act, 2004.

To whom does this code apply?

This code applies to all health research involving human participants, conducted, supported or otherwise subject to regulation by any institution in Nigeria.

Definition of Research and Coverage of Code:

Research here is defined as systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this code, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Health research that is conducted anywhere in Nigeria must comply with all sections of this code.

Exemption

Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this code:

(a) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

(1) Research on regular and special education instructional strategies, or

(2) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(b) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behaviour, unless:

(1) Information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and

(2) Any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.

(c) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are *publicly available* (note that this refers to availability of data and not the status of the custodian of the information/data) or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(d) Studies that are meant to evaluate the outcome of procedures, programs and services are exempt because they are designed to produce information leading to improvement in delivery of procedures, programs and services. Such studies usually evaluate measures that are already in use and considered part of standard practice. They may include collection and analysis of data or collection of new data but they do not involve allocation into groups or randomisation.

(e) Studies that are designed to evaluate/assessment of quality of services, programs and procedures and formulate guidelines leading to their improvement are exempt. Such studies may involve the collection and analysis of some data.

(f) Innovative or non-validated medical treatment – treatment that is designed solely for the benefit of the patient but in which the ability of the treatment to result in the desired result is to some degree not proven. Such activities are exempt while recommending that they should be subjected to research in order to generate information about their efficacy as soon as possible.

(g) Clinical audit, where the study is designed and conducted solely to define or judge only current care, without reference to a standard. It may involve the collection and analysis of data but there is no allocation to intervention groups or randomisation and the services have been delivered before the audit is initiated.

Who determines exemption?

All exemptions shall be determined by the Health Research Ethics Committee (HREC) - *vide infra*. In summary, applicants requesting exemption shall submit the proposal or a written summary that contains enough information for judgement to be made, to the HREC. The HREC Chairperson or his designee, in consultation with HREC Administrative Officer – where one exists, shall decide whether the research is exempt. Where the Chairperson is uncertain and the uncertainty is unresolved after request for and provision of more information by the applicant, the proposal or summary should be referred to HREC. All applications for exemption must be brought to the notice of HREC at its regular meeting for discussion as may be deemed necessary by members of HREC.

Registration of Health Research Ethics Committees

In order for an institution to be able to conduct health research, the institution must have a registered health research ethics committee (HREC). The following are the guidelines for registration:

(a) Registration with National Health Research Ethics Committee (NHREC) shall require:

(1) An application by the authorized head of the institution or their authorized designee which among other things should include that the line of reporting authority of the Chairman of the HREC is directly to the Chief Executive of the proposing institution.

(2) A list of members of the proposed health research ethics committee identified by:

i. Name

ii. Qualifications

iii. Representative capacity

iv. Indications of experience such as trainings, certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to HREC deliberations

v. Any employment or any other relationships (including stock ownership, receipt of grants, honorariums or support from potential research sponsors) that may be construed as conflict of interest within the context of membership of the HREC.

(3) All members of the proposed HREC must have completed NHREC approved training programs in research ethics, research methodology and research

administration. Copies of the certificates of completion of such programs must be submitted along with the application. The institution setting up the HREC must provide resources for such training.

(4) Statement of agreement to comply with the Nigerian Code of Health Research Ethics subsequently referred to as the code, governing HREC in the discharge of its responsibilities for protecting the rights and welfare of human participants of research conducted at or sponsored by the institution

(5) Statement of commitment to provide meeting space of sufficient quality, office and storage space, sufficient staff and funds to support the HREC's review and recordkeeping duties in order to guarantee that these duties can be accomplished with sensitivity and confidentiality.

(6) A statement of commitment to take full responsibility for all actions of each member of HREC in the course of performance of duties related to membership. The institution shall provide coverage for any liability of any member arising from service on HRECs.

(b) The lifespan of any HREC shall be two years, after which the institution shall apply for re-registration. The application for re-registration must be submitted within the last 6 months of the expiry of the current registration. During the re-registration process, the institution shall submit

(1) A current list of members of the health research ethics committee identified by:

i. Name

ii. Qualifications

iii. Representative capacity

iv. Indications of experience such as trainings, certifications, licenses, etc., sufficient to describe each member's chief anticipated contributions to HREC deliberations

v. Any employment or any other relationships (including stock ownership, receipt of grants, honorariums or support from potential research sponsors) that may be construed as conflict of interest within the context of membership of the HREC.

(2) Certificates of completion of National Health Research Ethics Committee approved training programs in research ethics, research methodology and research administration within 6 months of the expected start date of the registration of the HREC. Copies of the certificates of completion of such programs must be submitted along with the application.

(3) Copy of the primary statement of agreement to comply with the Nigerian Code of Health Research Ethics previously endorsed by the institution and the NHREC.

(4) Report of fulfilment of previously stated commitment to provide infrastructure and logistics to support the HREC's review and recordkeeping duties.

(5) Complete record of the activities of the committee, including financial records, attendance register at statutory meetings, complaints, litigations, number, and titles of protocols received, reviewed, approved, rejected and pending, and the mean time from protocol submission to approval in each of the preceding 2 years.

(c) Where a registered HREC does not apply for re-registration during the life of its current registration, the HREC shall be considered de-registered and may apply anew to NHREC. No research may be conducted in the institution during this period of de-registration.

(d) Institutions may propose to have more than one HREC. In such instances, the jurisdiction of each of the HRECs should be clearly defined and there should be open channels of communications between them that will allow transfer of proposals to the HREC with appropriate expertise. Researchers must not submit the same protocol simultaneously to more than one HREC within or without the institution.

(e) The authority of HREC shall be within the bounds of the proposing institution unless otherwise specified by the NHREC.

(f) In lieu of an institution being able to constitute a health research ethics committee and where such institution desires to engage in research

(1) Such institution shall establish a cooperative agreement with a registered HREC located within the same state of the federation as the institution.

(2) Where there is no registered HREC within the same state of the federation, agreement can be established with any HREC within the same geopolitical zone of the country.

(3) In the eventuality that there is no registered HREC within the same geopolitical zone, the institution should consult the NHREC for guidance.

(4) The registered HREC shall agree to review all proposals emanating from the applicant institution only during the period covered by the collaborative agreement which cannot extend beyond the period of registration of the HREC by the NHREC.

(5) Institutions seeking to establish collaborative agreements on health research ethics review must submit an application to the NHREC

(6) The reviewing HREC must be currently registered and must attest that it will maintain its registration status for the period covered by the proposed collaborative agreement

(7) The applicant institution can have collaborative agreement with only one HREC while the reviewing HREC can have multiple collaborative agreements subject to NHREC approval

(g) Categories of HREC

(1) NHREC shall establish categories of HRECs.

(2) NHREC shall outline from time to time, the criteria for this categorization

(3) NHREC shall outline the types of research that different categories of HREC shall review

HREC membership

(a) The authority to establish a HREC and the procedure of selecting members is vested in the Headship of the proposing institution.

(b) Each HREC shall have at least five members and if more, then the total membership must always be an odd number.

(c) The HREC shall be sufficiently qualified through the experience, expertise and diversity of its members, including consideration of age, gender, socio-cultural backgrounds and religion, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of researchers and research participants. Members should have varying academic and professional backgrounds to promote complete and adequate review of health research conducted by the promoting institution.

(d) In addition to possessing the professional competence necessary to review specific research activities, the HREC shall be able to ascertain the acceptability of proposed research in terms of institutional regulations, applicable laws, and standards of professional conduct and practice. The HREC shall therefore include persons knowledgeable in these areas, including a lawyer.

(e) Each HREC shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in non-scientific areas.

(f) Each HREC shall include at least one member who is not affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

(g) No HREC may have a member participate in the HREC's initial or continuing review of any project in which the member has a conflicting interest.

(h) If a HREC regularly reviews research that involves a vulnerable category of participants, such as children, prisoners, pregnant women, physically and mentally challenged persons, the HREC should co-opt one or more individuals who are knowledgeable about and experienced in working with these participants for the review process. These individuals may not vote during the HREC meeting.

(i) Each HREC member must pledge to maintain confidentiality regarding all meetings, deliberations, applications, information on research participants and related matters that shall come to his/her knowledge during service on HREC even after leaving the HREC assignment. There is no time limit for this prohibition.

HREC functions and operations

In order to fulfil the requirements of this code, each HREC shall:

(a) Operate in accordance with the National Code of Health Research Ethics and the Standard Operating Procedure (SOP) issued by the NHREC.

(b) Except when an expedited review procedure is used, research proposals shall be considered at regularly convened ordinary meetings at which a majority of the members of the HREC are present, including at least one member whose primary concerns are in non-scientific areas.

(c) Where a member cannot physically attend a meeting, the member shall be accounted as being present if he/she can participate electronically, for example by teleconferencing for the majority of the duration of the meeting.

(c) Process for regular research approval

(1) HREC shall review prescribed application materials and have authority to approve, require modifications in (to secure approval) or disapprove all health research activities covered by this code.

(2) In order for research to be approved, the decision shall ordinarily be arrived at by discussion and consensus or it shall receive the support of a simple majority of those members present at the meeting.

(3) HREC may, at its own discretion, invite representations from the applicant(s), sponsor(s), institution(s) or any other person(s) that it may consider relevant to provide information pertinent to research during the review process.

(4) HREC shall notify investigator(s) in writing of its decision to approve or disapprove proposed research activity, or of modifications required to secure approval of the research activity.

(6) HREC shall have a maximum of 90 days from the date of receipt of a valid application to give its decision to the applicant.

(7) Where HREC considers an application of such complexity that it cannot conclude the review, the application should be referred to NHREC and the applicant duly informed within the stipulated 90 days.

(8) Where HREC does not conclude its review in 90 days and has not referred the case to the NHREC, the applicant can complain to NHREC with the possibility of re-allocation of the proposal to another HREC and sanction of the concerned HREC

(9) Where HREC decides to disapprove a health research activity, it shall include in its written notification a statement of the reason(s) for its decision and give the applicant an opportunity to respond in person or in writing within 90 days.

(10) Where HREC has received representation from the applicant in response to an existing decision, HREC may decide to uphold or modify its previous decision and shall communicate this decision to the applicant within 90 days.

(11) HREC is mandated to keep all records related to its decision(s) for a minimum of 10 years after completion of the research activity.

(d) Process for continuing oversight of research

(1) HREC shall conduct continuing oversight of research covered by this code at intervals adjudged by HREC as being appropriate to degree of risk involved in participation in the research.

(2) This shall be at least once a year or during the lifetime of the research, whichever is shorter.

(3) HREC shall have authority to observe or cause to be observed on its behalf, the consent process and the research, to ensure compliance with the highest scientific and ethical standards.

(4) HREC shall initiate process of oversight of research in the event of receipt of complaints, information or data relevant to the research from any source.

(e) Process for expedited review

(1) HREC may expedite review of research in either or both of the following circumstances:

(a) Research is found to involve no more than minimal risk

(b) Minor changes in previously approved research during the period for which approval is authorized.

(2) Expedited review may be carried out by the HREC chairperson or his designee from among members of HREC. In reviewing the research, the reviewer(s) shall exercise all of the authorities of HREC except that the reviewer(s) may not disapprove the research.

(3) The Chairman of HREC shall bring all research reviewed expeditiously to the next meeting of HREC for notice, discussion and ratification.

(f) Process for amendment of research

(1) HREC shall require that applicants apply for permission to amend protocols in any of the following circumstances

(a) Where there are changes in any part of the research protocol

(b) Where there are changes in the named members of the team conducting the research

(c) Where there are changes in research sites

(c) Where there are changes in the sponsorship, institutional guidelines, institutional structure, HREC requirements, national laws or exigencies that impact on the ethical conduct of research

(2) HREC shall require that researcher submit an application for original research approval where in its opinion, the proposed amendments are substantial, such as but not limited to, change in inclusion or exclusion criteria, randomization, interventions and outcome measures.

(3) Under no circumstances shall a researcher deviate from approved protocol, except such as is necessary to eliminate immediate hazard to research participants. In all such instances, the researcher shall notify the Chairman of HREC within 24 hours of such changes.

(g) Process for exemption

(1) HREC may grant exemption from review in any of the conditions enumerated earlier (*vide supra*).

(2) Applicants seeking exemption shall submit the proposed research or adequate information about it to the HREC, sufficient in HREC's judgement to make a determination

(3) Exemptions may be granted by the HREC chairperson or his designee from among members of the HREC, in consultation with HREC Administrative Officer – where one exists.

(4) In granting exemption, the reviewer(s) shall exercise all of the authorities of the HREC except that the reviewer(s) may not disapprove the research.

(5) Where the reviewer is uncertain and the uncertainty is unresolved after request for and provision of more information by the applicant, the proposal or summary should be referred to the HREC.

(6) The Chairman of HREC shall bring all exempted research to the next meeting of HREC for notice, discussion and ratification.

(h) Process for suspension of research

(1) HREC shall have authority to suspend research that is not being conducted:

(a) In accordance with HREC's requirements
(b) In accordance with existing legislation
(c) In accordance with existing institutional guidelines; or
(d) Where research is associated with unexpected serious harm to participants.

(2) Any suspension of research shall include a statement of the reason(s) for the HREC's action and shall be reported within 14 days to the researcher(s), institution(s), sponsor(s) and the NHREC.

(3) Researcher(s), institution(s) or sponsor(s) shall be entitled to ask for a reconsideration of the decision of HREC to suspend research within 14 days of receipt of notification**.**

(i) Process for revision of suspension

(1) HREC may reverse its decision to suspend research if the precipitant(s) of the action is resolved to HREC’s satisfaction

(2) The HREC will determine the case at its next regular meeting and may require that the researcher sign an agreement with HREC on its finding(s) and agreed remedial measure(s).

(3) Where HREC allows resumption of research, an oversight review of the research shall be carried out within 180 days.

(j) Process for termination of research

(1) Where HREC, researcher(s), sponsor(s) or institution(s) is unable to offer, enforce or ascertain satisfactory remediation of the precipitant, HREC shall terminate the research.

(2) HREC shall indicate the reason(s) for the termination of research in writing within 14 days to the researcher(s), institution(s), sponsor(s) and the NHREC.

(3) Researcher(s), institution(s) or sponsor(s) shall be entitled to appeal the decision of HREC to terminate research to the NHREC within 14 days of receipt of notification.

(k) Process for appeal of HREC's decision to terminate research

(1) Upon receipt of an appeal of the decision of a HREC to terminate research, NHREC may, at its discretion, take up such an appeal.

(2) Where the appeal is sustained,

a. NHREC may with reasons, direct the HREC to approve the research and provide continuing oversight.
b. NHREC may mandate modifications, which if undertaken, can allow the research to proceed/resume, with the institutional HREC providing continuing oversight.

(3) NHREC may sustain the decision of the HREC and dismiss the appeal.

(l) Process for review of multi-institutional research

In the conduct of multi-institutional research, each institution is responsible for safeguarding the rights and welfare of human participants in its institution and for complying with this code.

(1) Where there are no more than 3 Nigerian research sites:

(a) Each research site may apply to its HREC for review

(b) HREC may adopt the result of review by another HREC rather than conduct a fresh review

(c) Where the outcome of review is discordant, the comments from the HRECs shall be submitted by each applicant to the institutional HRECs.

(d) Where the outcome of review is favourable but different modifications are requested, these outcomes shall be provided to each of the institutional HRECs by the applicants for reconciliation.

(2) Where there are more than 3 Nigerian research sites:

(a) Applicant(s) may follow the steps outlined above.

(b) Applicant(s) may apply to NHREC directly.

(3) In international collaborative research

(a) Only applicant(s) with qualification(s) and background sufficient to serve as principal investigator(s) and based in an institution in Nigeria that is capable of carrying out the research shall apply for review of research.

(b) HREC may adopt the result of review by another HREC rather than conduct a fresh review

(c) Where the outcome of review is discordant, the comments from the HRECs shall be submitted by each applicant to the institutional HRECs.

(d) Where the outcome of review is favourable but different modifications are requested, these outcomes shall be provided to each of the institutional HRECs by the applicants for reconciliation.

(4) Transfer of data, samples and any other materials out of Nigeria shall require signing of a Materials Transfer Agreement (MTA) detailing the type of samples, data and any other materials, the use that they shall be put, the location of storage outside Nigeria, duration of such storage, limitations on use and further transfer and termination of use of such materials subject to any enactment. A copy of the MTA shall be filed with the NHREC and an acknowledgement must be received from NHREC before institutional HREC issues approval for research.

(5) Where there is any change in the MTA, a request for amendment of protocol shall be submitted to HREC and HREC shall consider this in the usual manner used for amendment of protocol.

(6) HREC(s) shall have the authority to communicate with other ethics regulatory agencies and institutions about matters relevant to review of research. In such instances, HREC shall notify researcher(s), sponsor(s) and institution(s) about the communication(s).

(m) Process for NHREC review of research

(1) The NHREC may decide to review a research where:

(a) The research is nation-wide in coverage
(b) The research involves more than 3 sites in Nigeria
(c) The research was referred to NHREC by HREC(s)
(d) There is no HREC in an institution and the institution does not have a HREC cooperative agreement

(2) The NHREC may review research by:

(a) Mandating review by any HREC in the country as a HREC of record.

(b) Constituting itself into a review committee and exercising all the powers applicable therein as outlined for HRECs in this code.

(c) Constituting an *ad hoc* HREC at its discretion.

(3) Where NHREC utilizes any of these methods, it may still assign continuing oversight of research to local HRECs.

(n) HREC may charge fees for any or all of its activities

(o) HREC must protect the rights of researcher(s)

(1) HREC must protect the right of researcher(s) to publish their research.

(2) HREC should protect researchers from exploitation.

(3) HREC must protect researcher(s) from undue pressure from sponsor(s), institution(s), participant(s) or any other source.

Ethical Principles and Guidelines for HREC's approval of research

In order to approve research covered by this code the HREC shall determine a balance between the various principles guiding the ethical conduct of research, some of which are outlined below. Since some of these will inevitably conflict, judgement and consensus is essential in determining whether a research should be conducted.

a. Research must have social or scientific value to either participants, the population they represent, the local community, the host country or the world, in order to justify the use of finite resources and risk exposure of some participants to harm. Research should evaluate issues that lead to improvements in health and contribute to meaningful knowledge. Such knowledge should be disseminated to all relevant stakeholders during and after the conduct of research. In certain instances, for example in some international collaborative studies, research should be integrated with comprehensive capacity building, technology transfer and health care delivery strategies that address significant local health problems.

b. For research to be ethical, it must be have scientific validity. Research lacking clear scientific objective(s); using invalid methodology; that is underpowered; lacks equipoise (for clinical studies); whose operationalizing plans are inadequate within the context of the environment where research would be conducted; lacks plausible data analysis plan (including a specific role for a Data and Safety Monitoring Board [DSMB] in clinical trials) and research with biased measurement(s) of outcome(s) is unethical. This requirement is based on the ethical principle of not exposing participants to needless risk, avoiding waste of finite resources, beneficence, and avoidance of exploitation.

c. Ethical research must ensure fair selection of participants based on the scientific objective(s) of the research while minimizing risk of research. This requirement refers to both who is included and who is excluded from recruitment and the strategies employed for participants' recruitment (including 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, economically, politically and educationally disadvantaged groups and other vulnerable populations should be not be excluded without explicit reasons for doing so, particularly from studies that can advance

their health and well being. However specific safeguards should be included to protect the vulnerable as appropriate to the degree of risk. Groups, communities, participants and researchers who bear the burden of research should share in the benefits. This requirement is under-girded by the ethical principles of equity, justice, non-maleficence and beneficence.

d. All research involve risks; to be ethical therefore, there must be valid attempts to minimize risks and maximize health related benefits (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research or incidental risks or benefits) to participants in order to engender favourable risk benefit ratio within the context of where the research is being conducted. Where the risks outweigh the benefits to the participants, other criteria outlined in this code must justify such risks. This principle should be considered both at the level of individual research participants and that of the community. In research with no apparent benefit to participants, "risk-knowledge calculus" methods may be used to balance group benefits against participants' risk(s). The ethical principles at work here are those of non-maleficence and beneficence.

e. For research to be ethical, it must undergo independent review. Research participants, researcher(s), sponsor(s) and institution(s) have multiple and overlapping interests which can generate conflicts and distort judgements. Independent review, through a system of ethical review and oversight of such systems assures society that reasonable attempts have been made to minimize the potential impacts of these conflicting interests and ensure balanced judgements.

f. Informed consent is a *sine qua non* for ethical conduct of research. In order for consent to be valid, it must have the following components

(1) Adequate information provided at the educational level of individuals with at least 9 years of education.

(2) Design of consent process must be appropriate for the research and the research context

(3) Consent forms shall not be longer than 5 pages in order to ensure comprehensibility, enhance recall of pertinent information, avoidance of verbiage, legalisms, jargons and truth-dumping. The recommended format for each page of the consent form is as follows:

i. Paper size – A4
ii. Font – Times New Roman or similar
iii. Font Size – 12
iv. Spacing – 1.5
v. Margins – 2.5 cm, no gutter

(4) Where indicated, additional information can be provided on information sheets.

(5) The informed consent document shall contain the following aspects:

i. Title of the research
ii. Name(s) and affiliation(s) of researcher(s) of applicant(s)
iii. Sponsor(s) of research
iv. Purpose(s) of research
v. Procedure of the research, including approximate number of participants that would be involved in the research.
vi. Expected duration of research and of participant(s)' involvement
vii. Risk(s)
viii. Benefit(s)
ix. Confidentiality
x. Voluntariness
xi. Alternatives to participation
xii. Due inducement(s)
xiii. Cost to the participants, if any, of joining the research
xiv. Consequences of participants' decision to withdraw from research and procedure for orderly termination of participation.

xv. Action(s) to be taken in case of injury or adverse event(s)
xvi. What happens when the research is over
xvii. Sharing or non-sharing of benefits including commercial, intellectual, property, pecuniary rights and others, among researchers including or excluding research participants.
xviii. Any apparent or potential conflict of interest
xix. Detailed contact information including contact address, telephone, fax, e-mail and any other contact information of researcher(s) and HREC.

(6) Research participants are entitled to retain a copy of the consent form

(7) Where appropriate, researcher(s) may be required to undertake a re-consenting process during the course of research as determined by the HREC.

(8) Where, in ordinary circumstances, participant(s) are unable to provide written consent, researcher(s) must propose a process of consent that adequately records participants' informed decision such as witnessed thumb-printing or witnessed audio recording and the process proposed must be approved by the HREC before the research is commenced.

(9) HREC may require that all or some types of consent process be witnessed.

(10) Researcher(s) must keep all copies of consent form and make them available for examination by participant(s), sponsor(s), institution(s), HREC and NHREC.

(11) Where appropriate, HREC may require researchers to provide translations of consent processes appropriate to the socio-cultural characteristics of the population to be studied.

(12) All consent activities must be documented.

(13) Consent in other situations, including research involving children, persons with diminished autonomy, vulnerable populations and other extraordinary situations,

including waiver of consent, are described in other guidance documents issued by NHREC.

(g) For research to be ethical there must be respect for potential and enrolled participants. This implies that the potential participants be treated with respect from the moment that they are approached to the conclusion of the research should they choose to participate. Their right to privacy may not be needlessly compromised. Participants must know that their involvement is voluntary and that they can withdraw at any time without penalties. However, data, samples, etc. already contributed to the research up to that point may not needlessly be withdrawn as this action may jeopardise the scientific validity of the research, may be unjust to those who remain in the study and all or part of it may have been used or modified into different form(s), including presentation at meetings or publications by the researchers.

Special considerations of voluntariness are needed where participants may be restricted or dependent such as prisoners, staff members, students and members of disciplined forces like the army. Respect also entails that participants must be treated as partners in the research enterprise with every opportunity taken to inform them of the progress of the research and any new finding that may have potential impact on their health and well being, and on their continued participation in the research. Where, for whatever reasons, informed consent documents are modified for example, respect requires that previously enrolled participants shall be re-consented to inform them of the changes in the consent and why those changes were made. Respect also entails protection of the welfare of research participants. The process of research must be carefully monitored to ensure that participants are not exposed to excessive risk. All adverse events must be examined in detail and promptly. They should be reported and efforts made to prevent future occurrences. Full medical care must be provided to participants who have suffered such adverse events and where warranted compensations paid. The requirement to respect both enrolled and potential participants underlies the need for researchers to engage with communities where research is being conducted. In certain instances, community consultation or assent may precede research activities in order to engender community buy-in, respect for the socio-cultural values of the community and its

institutions. It may also be necessary to inform the community from time to time about the progress of the research, pertinent findings that may influence their health and well being, and the outcome of the research. This requirement for respect is justified by the principles of non-maleficence, respect for persons and beneficence.

(h) For research to be ethical, nothing must be done to undermine the trust relationship that is at the heart of the researcher(s)-participant(s) relationships. This requires that there is transparency including clear description of goals and risks, considerations for sharing financial benefits of research, determination of social value, creative approaches for effective representations and involvement of researchers and communities. Strategies of dynamic, reciprocal collaboration that leads to transformation of essential relationships based on reciprocity are also essential. This trust principle encourages the engagement of communities, respect for socio-cultural values, relevant and timely feedback to communities.

(i) For research to be ethical, the interest of participants, researchers, sponsors and communities must be protected in order to ensure that the research has lasting impact, transfers technology where appropriate, contributes to capacity building and demonstrates respect for socio-cultural differences. Risks, benefits and responsibilities of research must be shared during the development, planning, conduct, dissemination of results and sustenance of benefits of research. There must be respect between researchers and between them, participating communities and sponsors that takes account of the values, cultures and practices of all collaborators. Intellectual property, indigenous knowledge, contributions of all parties must be taken into consideration, adequately protected and compensated particularly where research leads to tangible or intangible benefits. Satisfactory parameter(s) that shall determine sharing of commercial and other benefits should be clearly articulated and where indicated, benefit sharing agreements, tissue transfer agreements, patent rights, intellectual property and royalties' distribution agreements should be signed before initiation of research.

(j) For research to be ethical, it must be conducted in accordance with the principles of good clinical and laboratory practices. These are standards for designing, conducting, and

reporting trials that involve the participation of humans. Compliance with these standards is additional assurance that the rights, safety and well-being of trial subjects are protected consistent with the highest ethical and scientific standards.

HREC's Education and Training Responsibility

(a) HREC shall organise, cause to be organized on its behalf, sponsor, support or associate with training and educational programs for biomedical, social and behavioural sciences researchers.

(b) In order for such programs to be accepted by HRECs as evidence of satisfactory training or educational programs for purposes of research review, they must be certified by the NHREC

(c) Suitable educational programs must contain modules on principles of research ethics, functions of HREC, research integrity and misconduct

(d) HREC shall conduct ethics clinics and consultations at its own discretion and upon payment of fees as it may determine. Such clinics and consultations shall be rigidly separated from the process of ethical review of research and shall not have effect on each other.

HREC Records and Reports

HREC shall prepare and maintain adequate documentation of all its activities, including the following:

(a) All materials pertinent to research review such as:

(1) Copies of all research proposals reviewed

(2) All reviews that accompany the proposals

(3) Approved sample consent documents, including adverts etc

(4) All progress reports submitted by researcher(s), institution(s) and sponsor(s)

(5) All reports of injuries to participants and adverse events.

(6) Attendance at meetings

(7) Date proposals submitted and date approval given

(8) Financial records

(b) Minutes of HREC meetings which shall be in sufficient detail to show:

(1) Attendance at the meetings

(2) Actions taken by the HREC

(3) The vote on these actions including the number of members voting for, against, and abstaining

(4) The basis for requiring changes in or disapproving research

(5) A written summary of the discussion of controversial issues and their resolution.

(c) Records of continuing oversight activities.

(d) Copies of all correspondence between the HREC and applicants, researchers, sponsors, and any other agent consulted in the discharge of its duties.

(e) Statements of complaints or information/data that is used to determine decision(s) on research.

(f) The applicant in applying for ethics review must submit the following

(1) Copy of the research proposal

(2) Copy of all materials to be used for the consent process such as consent forms and advertisements, including but not limited to promotional materials, advertisements, notices in newspapers, trade publications, audio, video and web advertisements.

(3) Copy of curriculum vitae of the principal investigator(s)

(4) Copy of letter(s) of support from co-investigator(s)

(5) Where applicable, letter of sponsorship

(6) One page plain language summary of the research

(7) All questionnaires and instruments

(8) Other ethics committee(s)' review of the study and their decisions

(9) Evidence of informed consent training by applicant and co-investigator(s)

(10) Copies of all agreements such as the MTA etc. where indicated.

(g) Investigator(s) must submit an annual report on their research to HREC within 90 days of expiry of their current research approval. This report shall contain brief summary statistics about the research – number of participants recruited and their breakdown,

number of adverse events, complaints and their resolution, any ongoing investigation or review and copies of any publications, reports or abstracts arising from the research.

(h) All HREC records shall be accessible for inspection and copying by NHREC and through NHREC by other agencies at the discretion of NHREC and in a reasonable manner.

NHREC oversight of HREC functions

NHREC shall exercise oversight of HREC functions in order to promote the health and well being of research participants.

(a) NHREC shall review annual reports of HREC functions including

(1) Record of attendance at HREC meetings to ensure that forums are formed, membership is diverse, outsiders are co-opted as indicated etc.

(2) Record of all materials pertinent to approval of research and their determinations.

(b) NHREC shall review materials from HRECs to ensure that registration status is maintained

(c) NHREC shall review the commitment of institution(s) to provide resources for proper functioning of HREC

(d) NHREC shall, at its own discretion, conduct oversight visits to HRECs.

(e) NHREC shall conduct any other activities in the exercise of its functions as enumerated in the National Health Bill

HREC Compliance and Disciplinary Powers

HREC shall have the power to recommend to NHREC that disciplinary action be taken against researcher(s) who violates the norms, standards and guidelines set out in this code.

(a) Such recommendations shall be made after exhaustion of all steps outlined in this code for resolution of problems identified in research

(b) Such recommendations shall be made after the matter is discussed at a regularly convened ordinary meeting of the HREC

(c) All records pertinent to the matter shall be forwarded to the NHREC within 14 days of the HREC meeting at which the decision is taken and a formal notice shall be issued to the researcher(s), institution(s) and sponsors(s) by the HREC.

(d) Such recommendation shall not preclude the HREC from reporting acts that are clear violations of civil and criminal law such as fraud, assault, battery to constituted authorities or clear violations of institutional rules and guidelines to the institution where the researcher is based.

NHREC Compliance and Disciplinary Powers

(a) NHREC may advertise all cases of research misconduct reported to it, its plan of action and their resolution to the public

(b) NHREC shall recommend disciplinary action against researcher(s) to the institutional authorities

(c) NHREC shall take steps to report cases of fraud, deception, infamous conduct, plagiarism, fabrication, falsification to the appropriate regulatory, the police and other relevant authorities.

(d) NHREC shall bar researchers from conducting research for variable periods of time depending on the severity of findings of misconduct.

(e) In international collaborative research, NHREC shall report its findings of misconduct to the national ethics regulatory agency of the country of origin of the researcher.

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This work was long in gestation but its birth pangs lasted from the 28th of September to the 3rd of October 2006, all days including Saturday, Sunday and the 46th anniversary of our nation's independence inclusive. Like all labours therefore, it was intensive, arduous and difficult. Here is the result.

We owe a debt of gratitude to the many heroes of the bioethics movement, our teachers, mentors, students and friends. In particular, we owe a debt of honour to all those who have compiled national ethical guidelines of different nations because their work served as our template and we borrowed generously from them and their ideas.

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Members of the Technical Consultation Committee

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2. Dr Emmanuel Babatunde Omobowale Ph.D. graduated from the University of Ibadan in 1989 with a Second Class Upper (2.1) Degree in English. He won the Departmental Prize as the best graduating student in the Department of English. He was also awarded the first Heinemann Prize for Literature as the best graduating student, which earned him a nomination for the Faculty of Arts' Prize for the best student in the faculty. In June 2001, Dr Omobowale defended his PhD thesis, which is entitled 'Literature and Medicine: A Study of Selected Works of Nigerian Physician-Writers'. This interdisciplinary oriented thesis is the first in the field of Literature and Medicine not only in Nigeria but also in the whole of sub-Saharan Africa. Following the successful completion of the PhD program, in August 2002, he was awarded an American Fogarty Fellowship to study for an M.A Degree in Bioethics at Case Western Reserve University (Case) in Cleveland. Dr Omobowale is currently a Senior Lecturer in the Department of English, University of Ibadan, Nigeria where he teaches Creative Writing, The Bible as Literature, African Literature, Black Diaspora Literature, with emphasis on Caribbean Literature and African-American Literature, Literature and Medicine as well as Bioethics/Medical Ethics.

3. Dr. (Mrs.) Jane Roli Adebusuyi holds a B.Sc degree in Sociology/Anthropology (Ife), Master of Social Work, MSW (Ib) and PhD in Social Welfare (Ib). She has 27yrs experience as a Medical Social Worker and she is currently the Deputy Director of the

Medical Social Services Department of the University College Hospital Ibadan. She is the current National President of the Association of Medical Social Workers of Nigeria (AMSWON). She is an Associate Lecturer at the Social Work Department of the University of Ibadan. As a Medical Social Worker/Counsellor she has been actively involved in Collaborative Counselling Services involving ethical issues. She is an author of 47 academic papers including "Role Conflict as a Dilemma of Bioethics". As a Bioethicist, she is especially interested in Conflict Resolution.

4. Dr. (Mrs.) Bolatito Asiata Lanre-Abass, (PhD Philosophy) is a lecturer in the Department of Philosophy, University of Ibadan, Nigeria. She teaches Ethics, Epistemology and contemporary issues in philosophy both at the undergraduate and postgraduate levels. She has published in the areas of feminist ethics, feminist epistemology, medical ethics and moral philosophy. As a faculty member of West African Bioethics Programme, her contributions to the technical committee includes clarifying ethical concepts and issues on vulnerable individuals such as pregnant women. Her contributions also extend to the area of Islamic bioethical principles in a multi-religious society.

5. Mr. John Oluwole A. Akintayo LL.B (Ibadan); LL.M (Lagos) B.L., is a Legal Practitioner and a Lecturer in the Faculty of Law, University of Ibadan, Ibadan, Nigeria. He is also a Faculty Member of the West African Bioethics Program. He was educated at the Universities of Ibadan and Lagos, Nigeria. His principal areas of research interests include Jurisprudence, Constitutional Law, Administrative Law and Private International Law. As a researcher he has developed keen interest in legislation culminating in the publication of his work on *Legislation in Democratic Governance in Nigeria* in 1999. He participated in the revision of Laws of Oyo State of Nigeria, 1998 -1999 and was a member of the Law Revision Committee of Osun State, 2000-2001. He was General Secretary of the Nigerian Bar Association, Ibadan Branch from 2001 to 2002, and in this capacity he served as a member of the National Executive Committee of the Nigerian Bar Association. He was also a Member of the Advisory Committee on the Prerogative of Mercy in Oyo State.

6. Dr Adebayo Olayiwola Adejumo trained as a general nurse and perioperative nurse before pursuing a BSc. degree in nursing at the University of Ibadan, Ibadan, Nigeria. He thereafter obtained master and doctorate degrees in Psychology at the Department of Psychology from the same University. His interest in bioethics took him to the Joint Centre for Bioethics of the Institute of Medical Science, University of Toronto, Toronto, Canada between 2004 and 2005 under Fogarty Scholarship. During the training, he was a member (under attachment) of the research ethics board of the Centre for Addiction and Mental Health of the University of Toronto, Toronto, Canada. Since then Dr. Adejumo has been involved in clinical and research ethics issues especially among nurses and other health care workers both in Nigeria and in many foreign countries. He has also published on ethical issues in reputable journals. He is currently a lecturer in the Department of Psychology, University of Ibadan, Ibadan, Nigeria with research focus on research and clinical ethics.

7. Dr. Ademola J. Ajuwon received his Bachelors of Science (BSc) Sociology from the University of Lagos in 1984 and the Master of Public Health (MPH) and Doctor of Philosophy (PhD) from the University of Ibadan in 1990 and 2000 respectively. He is currently a Senior Lecturer in the Department of Health Promotion and Education, College of Medicine, University of Ibadan. Dr. Ajuwon's areas of research interests are adolescent sexuality, gender-based violence, and research ethics. He is currently a member of University of Ibadan/University College Hospital Ethics Review Committee. Ademola J. Ajuwon received his Bachelors of Science (BSc) Sociology from the University of Lagos in 1984 and the Master of Public Health (MPH) and Doctor of Philosophy (PhD) from the University of Ibadan in 1990 and 2000 respectively. He is currently a Senior Lecturer in the Department of Health Promotion and Education, College of Medicine, University of Ibadan. Dr. Ajuwon's areas of research interests are adolescent sexuality, gender-based violence, and research ethics. He is currently a member of University of Ibadan/University College Hospital Ethics Review Committee.

8. Professor (Mrs.) Olaitan Soyannwo MBBS, DA, M.Med, WACS, FAS is an academician, past dean of Faculty, researcher and practicing consultant physician for over two decades. She is a Professor of Anaesthesia with special interest in pain

management, the Programme Director of Centre for Palliative Care, Nigeria and currently serves on the Board of African Palliative Care Association (APCA). She also serves on the council of the International Association for the Study of Pain (IASP), West African College of Surgeons and PEPFAR Evaluation Committee, Institute of Medicine of the American Academy of Science. She is an active member of the West African Bioethics Training Programme (WAB). In particular, she was involved in the development of the curriculum on aspects of ethical issues in terminal care, AIDS and Malignancy, Palliative care, death and dying, euthanasia, do not resuscitate orders and surrogate decision making. She has also served as a member of the UI/UCH IRB and attended courses in Bioethics including WHO sponsored ethics in Reproductive Health and at University of Lancaster, End of life Observatory on end of life care.

9. Dr. Ayodele Samuel Jegede received his Bachelors of Science (BSc) in Sociology and Anthropology and a Master of Science (MSc) in Medical Sociology and Anthropology from the Obafemi Awolowo University, Ile-Ife in 1987 and 1989 respectively and Doctor of Philosophy (PhD) in Medical Sociology from the University of Ibadan in 1995. He also received a Master of Health Science (MHSc) degree in Bioethics from the University of Toronto, Canada in 2006. He is currently a Senior Lecturer in the Department of Sociology, University of Ibadan. Dr. Jegede's areas of research interests are culture and health, reproductive health, genomics and biotechnology policy research, priority setting in health care delivery, and international health research. He is currently a member of the University of Ibadan/University College Hospital Ethics Review Committee.

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