STANDARD OPERATING PROCEDURES

Institutional Review Board of Noguchi Memorial Institute for Medical Research ('NMIMR-IRB')
First Edition: 2001
Revision Date(s): 2008, 2010, 2012, 2015
Approved By: The entire board members

In Accordance with:
The Declaration of Helsinki
(1996) The ICH GCP (E6)
Guidelines CIOMS
Belmont Report
Office for Human Research Protection (OHRP)
The Applicable Laws and Statutory Regulations of Ghana

CONTENT

CHAPTER 1

INTRODUCTION

1. The Noguchi Memorial Institute for Medical Research Institutional Review Board (NMIMR-IRB) encourages and supports the scholarly endeavors of students and research scientists.

2. The pursuit of scholarly work and research may involve the use of human participants for data collection and analysis.

3. The NMIMR-IRB reviews human participants' research proposals to ensure that:

    3.1 The rights and welfare of human participants used in research studies are protected.

    3.2 Risks have been considered and minimized.

    3.3 The potential for benefit has been identified and maximized.

    3.4 All human participants only volunteer to participate in research after going through the consent process.

    3.5 Research is conducted in an ethical manner and in compliance with established standards.

4. Those individuals seeking to conduct such research may not solicit participant participation or begin data collection until they have obtained ethical clearance from NMIMR-IRB.

5. The NMIMR-IRB is authorized to review, approve, require modifications in, or disapprove research activities conducted by researchers using human participants.

6. The NMIMR-IRB shall evaluate the science and ethics of the proposed study

CHAPTER 2

MISSION OF NMIMR-IRB

7. The NMIMR-IRB has the fundamental mission of protecting the rights and welfare of human participants in research studies from the following:

    7.1 N M I M R

    7.2 University of Ghana

    7.3 Collaborative research study with affiliation from the NMIMR, University of Ghana

    7.4 Other research studies to be determined by the board.

8. To achieve this mission, the NMIMR-IRB shall:

    8.1 Offer advice to investigators in designing their research studies in a manner to minimize potential harm to human participants.

    8.2 Review all planned research involving human participants prior to initiation of the research.

    8.3 Approve research that meets established criteria for protection of human participants.

    8.4 Monitor approved research to ascertain that human participants are adequately protected.

    8.5 The NMIMR-IRB is to assist NMIMR, the entire university body and its researchers on ethical and procedural issues relating to the use of human participants.

CHAPTER 3

INSTITUTIONAL AUTHORITY

9. These Standard Operating Procedures establish and empower the Noguchi Memorial Institute for Medical Research Institutional Review Board (NMIMR-IRB) which is currently registered with the Federal Office for Human Research Protections (OHRP) in the United States of America with FWA No 00001824 and IRB Number 00001276. This board is hereinafter referred to as "NMIMR-IRB."

10. The authority conveyed to the NMIMR IRB includes the following:

    10.1 To review all research projects involving human participants.

    10.2 To require from investigators revision in research proposals and informed consent documents as a condition for initial or continual approval.

    10.3 To approve the initiation of a new research project.

    10.4 To monitor the activities in approved projects, in any way deemed necessary, including yearly scheduled continuing review and verification of compliance with approved research protocols and informed consent.

    10.5 To ensure prompt reporting of any adverse events occurring in approved projects, or in other related projects.

    10.6 To suspend or terminate a previously approved project

CHAPTER 4

THE ROLE OF NMIMR-IRB IN ETHICAL REVIEW

11. Guided by the principles set forth in the Belmont Report, Council for International Organization of Medical Sciences (CIOMS), the World Medical Association's Declaration of Helsinki, Nuremberg Code and other internationally recognized principles of human rights, the NMIMR- IRB ensures that:

    11.1 Risks to participants are minimized and are reasonable in relation to the anticipated benefits.

    11.2 Selection of participants is equitable.

    11.3 Informed consent is obtained from each prospective participant or the participants' legal guardian or healthcare decision-maker.

    11.4 Informed consent is appropriately documented.

    11.5 Provisions are made for the protection of the privacy of participants and that confidentiality of data is maintained

    11.6 Provisions are made for monitoring the data collected to ensure safety of participants.

    11.7 Safeguards are included to protect members of vulnerable population groups

    11.8 Researchers act in the full interest of actual or potential research participants and communities.

CHAPTER 5

NMIMR-IRB MEMBERSHIP

12. The NMIMR-IRB shall be multidisciplinary and multi- sectoral in composition, including persons with relevant but diverse scientific expertise, balanced age and gender distribution, who have the qualifications and experience to review and evaluate scientific and medical ethics aspects of research protocol.

13. The representation of the IRB includes but not limited to the following:

    13.1 NMIMR Director

    13.2 Bioethicist

    13.3 NMIMR Staff

    13.4 Medical Doctor (2-3)

    13.5 Research Scientist (2)

    13.6 Social Scientists (3)

    13.7 Journalist/Communication Specialist (1)

    13.8 Representative from a Religious Body (2)

    13.9 Legal representative (1)

    13.10 Representative from Ghana Health Service

Terms/Conditions of Appointment

14. The IRB shall have at least a seven (7) member quorum. Five (5) of whom must have the qualification and experience to review and evaluate the science, and ethics of the research protocols

15. The NMIMR-IRB members shall be required to submit their curriculum vitae to the Administrator after nomination.

16. A nominated person shall consent in writing to appointment as a board member.

Termination of membership

17. The IRB shall request for a replacement of any member under the following circumstances:

    17.1 If a member is suffering from chronic incapacitating illness that significantly reduces his or her ability to process information and make rational independent decisions Persistent absenteeism of a member without reasonable cause for six consecutive meeting.

    17.2 Death of a Member

    17.3 Voluntary termination by a member who has written a resignation letter to the appointing authority through the IRB Chairperson.

Tenure of board members and Staff

18. The voting members shall serve a minimum of 5 years renewable for two (2) terms.

19. The maximum term of office shall be ten years.

20. The tenure of permanently employed Administrators is unlimited provided they are still employed.

Payment to IRB Members

21. An honorarium shall be paid to members to members who participate in the review process.

22. Payment must not be related to or dependent upon a favorable decision relating to application for review.

23. Board Members who are NMIMR Staff shall not be paid for participating in the review process.

Confidentiality and Protocol

24. Board members must be willing to sign and abide by the confidential agreement regarding:

    24.1 Meeting deliberations applications, protocol submissions, information on research participants,

    24.2 Related matters which they have had the privilege to have as a result of being members of the IRB.

Declaration of Conflict of interest

25. Board members shall declare conflict of interest at each meeting.

Co-opted Reviewers

26. The NMIMR-IRB at its discretion may invite scientists or non-scientists from within or outside NMIMR who are not members of the IRB but have expertise to function as co-opted reviewers of a project application to assist the NMIMR IRB in its review process.

27. A co-opted reviewer shall have access to all documents submitted to the board relevant to the specific project under review.

28. A co-opted reviewer may participate in meeting deliberations and make recommendation on the project.

29. A co-opted reviewer shall not vote at the NMIMR IRB meeting.

30. A co-opted reviewer shall sign confidentiality forms.

CHAPTER 6

NMIMR-IRB ADMINISTRATION AND FUNCTIONS

NMIMR- IRB Secretariat

31. The IRB shall have a permanent secretariat at NMIMR headed by the IRB Administrator.

32. NMIMR shall provide the necessary funding for the operations of the NMIMR-IRB.

33. The officers of the secretariat shall comprise an Administrator and two Administrative Assistants.

Responsibilities of the Chairperson

34. The NMIMR-IRB Chairperson shall:

    34.1 Facilitate the provision of training and educational programs to IRB members, and the greater science community at NMIMR. The training shall include but not limited to programs about the basic principles of human participant protection, current literature, regulations and guidelines affecting the IRB and NMIMR.

    34.2 Review and accept revisions that were made per committee recommendation pending protocol approval.

    34.3 Determine submissions that are exempt from review, and notify the IRB and the submitting investigator of such exemptions.

    34.4 Perform expedited review of research that meets the expedited review criteria.

    34.5 Assign responsibilities and duties to the Vice Chairperson or to other members.

    34.6 Supervise the IRB administrator.

    34.7 Be available for and attend to any study site investigations by the Board.

35. The Vice chairperson's responsibility shall be the same as the Chairperson.

Chairperson's Term of office

36. A member shall be elected as the Chairperson or Vice Chairperson by a majority vote.

37. The Chairperson and Vice Chairperson shall serve a renewable term of 3 years each.

Responsibilities of NMIMR-IRB Members

38. The NMIMR-IRB shall:

    38.1 Review research protocols to safeguard the rights and well-being of study participants.

    38.2 Support the secretariat in the discharge of their duties when called upon.

    38.3 Undertake duties assigned to them by the Chairperson or Vice Chairperson.

    38.4 Members shall study documents submitted to them before meetings.

    38.5 Members are obliged to keep IRB documents given to them secure, private and confidential.

    38.6 Attend meetings regularly and participate actively during deliberations.

    38.7 Participate in continuing education.

Responsibilities of NMIMR-IRB Administrator

39. The Administrator shall be responsible for the following:

    39.1 Perform a pre-review of each application to the IRB to ensure

adherence to administrative requirements.

39.2 Undertake all administrative procedure in providing training and educational programs to IRB members and the greater science community.

39.3 Support the Chair in preparing and providing a statement of assurance when required by the regulations guiding the establishment of the IRB.

39.4 Design and disseminate formats for IRB application documents, including research protocols, informed consent materials, agreements, and periodic and final reports.

39.5 Design and maintain a system for collecting and filing all IRB documents, including meeting minutes, member qualifications, protocol submission versions, deviations from approval protocol, and periodic and final reports.

39.6 Assist the appointing authority to recruit new IRB member.

39.7 Accept, verify and distribute all submitted items to the appropriate members for IRB review. Ensure that all required materials for a submission are provided and complete.

39.8 Prepare and submit annual IRB operational budget and plan to the NMIMR management in consultation with the Chairperson.

39.9 Create and distribute meeting agendas, and arrange meeting logistics.

39.10 Attend IRB meetings, take minutes during the meetings, and verify and distribute minutes in a timely manner.

39.11 Correspond with all submitting researchers at all times throughout the submission and review process.

39.12 Advise submitting investigators on the preparation and submission of protocols for review according to Standard Operating Procedures (SOPs)

39.13 Distribute and keep records of all correspondence

39.14 Assist the Chairperson in the conduct of IRB meetings.

39.15 Continually study and update staff about IRB operational regulations.

39.16 Attend any outside investigations or audits of the Board.

39.17 Manage IRB documents, records and archives.

40. The Administrative Assistants shall assist the Administrator.

CHAPTER 7

NMIMR-IRB MEETINGS

41. The NMIMR-IRB shall meet once every two months and also whenever practicable; to review submitted research project applications submitted for approval.

42. The NMIMR-IRB shall have an agenda for each meeting. The agenda will include listing and identifiers for all research project applications awaiting action by the NMIMR-IRB.

43. The IRB Administrator shall notify all IRB members of an upcoming meeting at least two week in advance by e-mail and mail.

44. The notification shall include:
    - 44.1 Meeting agenda, which shall outline all protocol and related research submissions for consideration in the meeting,
    - 44.2 Meeting minutes
    - 44.3 Copies of research protocols,
    - 44.4 Continuing and final reports, safety reports, amendments and any other necessary documents.

45. In the case where the Administrator is unsuccessful in distributing the materials to the IRB members, the Administrator shall at least notify the member(s) of the occurrence of the meeting, and shall arrange for alternative means of material distribution.

46. Whenever possible, the Administrator shall distribute the materials electronically.

47. The Administrator shall notify all IRB members of any changes in meeting time, date or agenda as soon as possible.

48. With the exception of applications eligible for expedited review the NMIMR-IRB will determine the outcome of its review of research project applications at meetings, where a quorum has been established.

49. All new protocols must be submitted for full board review/approval.

NMIMR-IRB meeting procedures

50. The Chairperson, the Vice Chairperson or, in their absence, a member of the NMIMR-IRB will chair the meetings.

51. Whenever a research project application is being reviewed, in which a member of the NMIMR-IRB may have a conflict of interest, that member will leave the NMIMR-IRB meeting for the duration of the review of that application, and will not vote on the application.

52. The members attending the IRB meeting shall discuss a protocol an either vote or by general consensus approve, disapprove, or defer and decision until revisions are implemented, additional information is provided, or further expert review is obtained.

53. Investigators may be invited to describe their proposed study and to answer any questions posed by members of the IRB when necessary.

54. If minor revisions to the submitted documents are required or a missing document of minor importance is to be obtained, the NMIMR-IRB may delegate the Chairperson or any competent member to subsequently approve a project which requires revision.

NMIMR-IRB Meeting Minutes

55. The Administrator of NMIMR-IRB shall prepare minutes of each meeting.

56. The minutes will be in sufficient detail, and will include the following:

    56.1 Date and venue of the meeting.

    56.2 Attendance and absence.

    56.3 Decisions reached on each research project application reviewed.

    56.4 Reasons for requiring changes in a project, or disapproving, suspending or terminating a project.

    56.5 Summary of the discussion of disputed issues and their

resolution if possible.

56.6 Date of next scheduled continuing review of a project, and the perceived level of risk on which the time of next review was based.

56.7 The minutes will be made available for review by email and posted to the Board Members.

Communicating IRB decisions to applicants

57. Upon completion of the review of a research project application, the Administrator will prepare a notification letter or electronic mail, to inform the applicant or principal investigator of the outcome of the review. Such notification should include the following information:

57.1 The outcome of the review by the NMIMR- IRB, and the date the decision was reached for approved projects, the date of next scheduled continuation review (one year from the date of approval), and the reporting requirements for the principal investigator.

57.2 For disapproved, suspended or terminated projects, the reasons for these decisions should be communicated to the researcher.

58. Decisions regarding submitted protocols should be officially communicated, in writing, to the applicant within 5 working days of the meeting that made the decisions. The details shall include the following:

58.1 The name, title and address of the applicant

58.2 The exact title of the proposal reviewed

58.3 The names and identification numbers (versions Numbers/dates) of the reviewed documents (if applicable)

58.4 A clear statement of the decision reached by NMIMR-IRB

58.5 The date of the decision and signature Chairperson/Vice Chairperson.

58.6 In case of a conditional decision, any requirements by NMIMRIRB, including suggestion for revisions should be

clearly explained in writing to the applicant.

58.7 In case of a positive decision, a statement of responsibilities of the applicant and any requirements as stipulated in the decision by the board.

58.8 The validity period of the approval

59. The final ethical clearance shall be signed by the Chairperson/Vice Chairperson or any other member nominated by the Chairperson.

CHAPTER 8

THE USE OF HUMAN PARTICIPANTS FOR RESEARCH

60. The focus of activities of the NMIMR-IRB will be on human participants who are involved in research.

61. Interventions in human participants include physical procedures by which data are gathered, and manipulations of the participant or the participant's environment for research purposes.

62. Interactions with human participants include communications or interpersonal contacts conducted for research purposes.

63. Private information includes:

63.1 Information collected under circumstances the participant can reasonably expect that no observation or recording is taking place.

63.2 Information that the participant can reasonably expect will not be made public in a manner exposing the identity of the participant.

63.3 Sensitive information includes but is not limited to information:

63.1.1 Relating to sexual attitudes, preferences, or practices.

63.1.2 Relating to the use of addictive products

63.1.3 Pertaining to illegal conduct.

63.1.4 Information that if released could reasonably be damaging to an individual's financial standing, employability, or reputation within the community.

63.1.5 Information that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination.

63.1.6 Information pertaining to an individual's

psychological well being or mental health.

Vulnerable populations

64. Vulnerable participants shall not be included in research unless:

    64.1 The research is necessary to promote the health of the study population represented.

    64.2 The research cannot be performed on other less vulnerable participants.

    64.3 The justification for their inclusion, and adequacy of special precautions taken to minimize risks.

65. The NMIMR-IRB will consider certain groups of human participants to be particularly vulnerable to coercion or undue influence in a research setting to include:

    65.1 Children and infants

    65.2 Fetuses and human in vitro fertilization.

    65.3 Pregnant and lactating women

    65.4 Mentally ill

    65.5 Intellectually disabled

    65.6 Cognitively impaired persons

    65.7 Prisoners and economically or educationally disadvantaged persons

66. The special needs of the economically and medically disadvantaged must also be recognized.

67. If participants are compensated, the amount and method of compensation should not cause undue influence on the participants.

68. In reviewing research studies, the NMIMR-IRB shall scrutinize those involving these vulnerable groups, to ascertain that their use is adequately justified, and additional safeguards are implemented to minimize risks unique to each group.

69. The NMIMR-IRB will consider for approval of research projects involving vulnerable populations, if one of the following conditions is met:

    69.1 The research does not involve more than minimal risk to the participant.

    69.2 The research is likely to benefit the participant directly, even if the risks are considered to be more than minimal.

    69.3 Requests for approval of any research that exposes

70. Vulnerable populations to risks significantly greater than minimal, without providing obvious direct benefit to the participant, will have been sent to all members of the NMIMR-IRB for review and approval.

CHAPTER 9

INFORMED CONSENT

71. Respect for persons requires that participants, to the degree that they are capable, are given the opportunity to choose what shall or shall not happen to them; the informed consent process is the instrument to provide this opportunity.

72. The NMIMR-IRB will ascertain that the investigators of a research project will obtain from human participants or their witness a legally valid informed consent.

73. In obtaining informed consent, the investigator shall:

    73.1 Give the participant (or representative) sufficient information about the study and how the study may affect the participant.

    73.2 Deliver the information in a comprehensible manner, using a language readily understandable by the participant.

    73.3 Assure voluntary capacity of the participant, by providing sufficient opportunity to consider whether or not to participate, and minimizing the possibility of coercion, undue influence, or harassment.

74. The basic rule of human participant research is that both components of the informed consent process shall be completed. These are:

    74.1 Providing the person, who is being recruited to become a participant of research, or that person's legally authorized representative, with the information necessary to give informed consent.

    74.2 Documenting that informed consent has been obtained by means of a Participant Consent Form.

75. However, in accordance with ICH/ GCP Guideline (E6) and local regulatory requirements (such as FDB), the NMIMR-IRB has the authority to waive the requirement for obtaining or documenting informed consent that has been obtained.

76. The NMIMR-IRB may consider waiving the requirement of obtaining written informed consent from a participant of research, if the nature of the research meets one of the following definitions:

76.1 Is not violative and not invasive, and

76.2 Does not involve risks to the participants that are more than minimal.

77. The following may be considered as eligible for waiver of the written informed consent:

77.1 Research involving collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, in which the investigator records the information in such a manner that participants cannot be identified directly or through identifiers linked to the participants, or if the sources of the information are publicly available.

77.2 Research involving normal educational practices.

77.3 Research involving use of educational tests, survey procedures, interview procedures or observation of public behaviour without revealing participants' identity, placing them at risk of criminal or civil liability, or damaging their financial standing, employability or reputation.

77.4 Research involving sensitive information may include but not limited to:

77.4.1 Information relating to sexual attitudes, preferences, or practices.

77.4.2 Information relating to the use of addictive product

77.4.3 Information pertaining to illegal conduct.

77.4.4 Information that if released could reasonably be damaging to an individual's financial standing, employability, or reputation within the community.

77.4.5 Information that would normally be recorded in a patient's medical record, and the disclosure of which could reasonably lead to social stigmatization or discrimination.

77.4.6 Information pertaining to an individual's

psychological well- being or mental health.

77.4.7 Research that anticipates but lacks definite plans for involvement of human participants, such as institutional-type centre or training grants; any study involving human participants under the umbrella of such grants will have to be reviewed subsequently by the NMIMR-IRB prior to its initiation.

77.4.8 Research that cannot practicably be carried out, if informed consent were to be obtained in advance, provided that the rights and welfare of the participants will not be adversely affected; in this instance, arrangements shall be made to provide pertinent information to the participants after their participation.

78. According to the ICH/GCP Guideline (E6), the Patient/Participant Information Sheet and the Patient/Participant Consent Form should include twenty different aspects of the study (see the ICH/GCP (E6) Guideline or the NMIMR-IRB Patient/Participant Information Sheet template for more information). The consent form should meet the following criteria:

78.1 Explain purpose of study by using language suitable to the potential participants and indicate which aspect of study is experimental.

78.2 Use languages suitable to the intended participants.

78.3 If the proposed study is a clinical trial, the study should explain study details such as nature of intervention, possible use of a placebo, method of assignment, probability of being assigned to different study arms, invasive procedures involved, duration of involvement, sample size, likelihood of premature termination.

78.4 Describe reasonably foreseeable risks or discomforts to participants and fetus/nursing infant if applicable.

78.5 Describe reasonably expected benefits (such as compensation, treatments) to participant or to others.

78.6 Participants shall be updated timely of new information that

may be relevant to his/her willingness to continue participation in study.

78.7 Describe how data will be handled to protect participants' privacy.

78.8 Explain alternatives if participants refuse to participate.

78.9 Assure voluntary participation and right to refuse, withdraw at any time without reprisal.

78.10 Explain possible reasons under which the participant's participation in study may be terminated.

78.11 Explain anticipated expenses for which participants will be reimbursed (when applicable).

78.12 Explain commitment of sponsor(s), study institute(s) and investigators, where appropriate.

78.13 Explain compensation and treatment available for study- related injury.

78.14 Provide information of research institution and investigators.

78.15 Provide contact for queries & adverse event reporting.

78.16 Provide NMIMR-IRB contact information.

78.17 Dated by the person or persons whose signature is required to be obtained.

79. At the start of the study, the informed consent document shall be submitted for approval to the NMIMR-IRB, together with the application for initiation of a new project, or continuation of a previously approved project if there had been changes to the IC.

80. Each copy of the document to be presented to the research participant shall contain a Date of Approval and a Date of Expiration, corresponding to the date of the initial approval of the project by the NMIMR- IRB, and the date the next continuation review has been scheduled by the IRB.

81. The consent document will gain validity only after the approval of its text by the NMIMR-IRB.

82. The NMIMR-IRB requires that the information necessary to give informed consent by the person being recruited as a research participant be given to

that person or the person's legally authorized representative in writing.

83. The written document - Participant Information Sheet - shall include the title of the study, the names of the investigators, and how the investigators can be reached.

84. No informed consent, whether oral or written, may include any exculpatory language through which the participant or the persons legally authorized representative is made to waive or appear to waive any of the participant's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

85. The document shall include at least the basic elements of the Patient/Participant Information Sheet; the use of the NMIMR-IRB template is strongly recommended. In most instances, a single document shall be employed, encompassing all aspects of the research; the information shall not be fragmented.

86. The content shall be easily understandable by a layperson with modest education and written in a language comprehensible to the study participant/ his or her representative.

87. The investigator shall present the written document to the participant or the participant's legally authorized representative, and provide adequate opportunity for them to study the document.

88. At the time of obtaining the consent, the investigator shall provide additional verbal information, as needed, so that the nature and anticipated consequences of the study are sufficiently clear.

89. The act of obtaining consent shall be validated on the written document that contains the information needed to give informed.

90. The validation shall be implemented by the signature of the participant or the participant's legally authorized representative, and by the investigator obtaining the consent.

91. Participants who are unable to write or read shall have the consent explained to them verbally and indicate approval or disapproval by thumbprint and signature of the participants witness / parent. In such circumstances, it is essential to document the method of communication,

the explanation given (and by whom), and the means by which the participant indicated his/her wish.

92. In the case of a child being recruited as a research participant, an assenting signature of the participant sufficient to comprehend the nature, risks and benefits of the study, shall be obtained on the Participant Consent Form, in addition to the signature of the legally authorized representative.

93. The documentation shall be executed on three copies of the written consent document carrying the participant's name, the hospital case identification number (when necessary), and the date of execution.

    93.1 One copy of the executed document shall be given to the participant or participant's legal guardian.

    93.2 One copy shall be incorporated into the research documents kept by the investigator.

    93.3 One copy shall be placed in the participant's hospital record (when necessary).

94. The approved consent form shall bear the stamp of the NMIMR-IRB with the validity period stated.

95. The NMIMR-IRB may waive the requirement for documentation of the informed consent but not that of obtaining informed consent, under one of the following circumstances:

    95.1 The principal research risk is potential harm resulting from a breach of confidentiality, and the only record linking the subject and the research is the consent document.

    95.2 The research presents no more than minimal risk of harm to participants, and does not include any procedure, for which written consent would be required.

    95.3 In cases where the NMIMR-IRB will waive the requirement for documentation of informed consent, the investigators shall provide the participant with the written Patient/Participant Information Sheet the text of which shall be reviewed and approved by the NMIMR-IRB.

    95.4 The investigator shall obtain oral consent to participate based on this information, but the granting of the consent will not be documented in writing.

CHAPTER 10

CATEGORIES OF RESEARCH PROTOCOL REVIEW

96. An Investigator, who intends to initiate a research project involving human participants, shall be responsible for submitting to the NMIMR-IRB an application for review.

97. Upon receipt of the research protocol for an initial review, the Administrator shall check for completeness of the package and then assign a number to the protocol.

98. The protocol shall then be stamped and entered into the Pro IRB Database.

99. The NMIMR-IRB office shall distribute the application documents to members at least two weeks prior to the meeting.

Initial review of research protocol

100. To apply for an initial review of a new project, the principal investigator shall complete an Initial Review Application Form (FORM A), the template of which can be found on the NMIMR-IRB homepage. All other documents relevant for submission can be found there in an electronic template format.

100.1 The principal investigator shall submit 14 hard copies and the soft copy of the research protocol sent to nirb@noguchi.ug.edu.gh

100.2 The application package shall include the following:

100.2.1 Submission Letter

100.2.2 Investigator's abridged CV

100.2.3 Texts of advertisements for subject recruitment English (where appropriate)

100.2.4 Questionnaires/Interviews – English

100.2.5 Questionnaires/Interviews – local language (where appropriate)

100.2.6 Investigator's Brochure including number and version, (if applicable)

100.2.7 Insurance Policy (if applicable)

100.2.8 Any other relevant document.

101. All new investigational drug trial protocols, including traditional medicine compounds, diagnostic test appliances and devices for which a product license does not exist shall be accompanied by one copy each of

101.1 Insurance policy document

101.2 Study Protocol

101.3 Investigator's Conflict of Interest Declaration Form

101.4 Investigator's Brochure

101.5 FDB Approval

101.6 Any other relevant document that would facilitate a meaningful review.

102. In reviewing a new research project involving human participants for approval, the NMIMR-IRB shall review the application to determine if all of the following criteria are met:

102.1 Study has potential in enhancing health or advancing knowledge.

102.2 Methodology (design, sample size, etc.) is adequate to answer the questions posed.

102.3 Has a favorable risk-benefit ratio based on an adequate assessment.

102.4 Adequate measures to minimize risk and detect adverse events timely.

102.5 If the nature of the research requires repeated assessment of the balance between risks and benefits, there are adequate provisions for such monitoring.

102.6 Participant selection and treatment allocation procedure are fair.

102.7 Recruitment process assures voluntary participation and protects participants from being unduly influenced.

102.8 Participants will be well informed in the consent process.

102.9 How problems resulting from the study will be managed

102.10 Insurance cover and/or indemnity agreement is adequately addressed.

102.11 Participants' privacy and data confidentiality are adequately protected.

102.12 Rights and interests of vulnerable participant, wherever applicable, are adequately protected.

102.13 Payment (amount or method) does not cause undue influence to participant.

102.14 Source of funding is disclosed.

102.15 Potential conflicts of interest of investigators are addressed.

Expedited Review

103. An investigator may apply for an expedited review of previously approved research study.

104. The Administrator in consultation with the Chairperson or Vice Chairperson may choose to process a study for expedited review if the following conditions apply to the research study:

104.1 Does not incur a clinical intervention (drug or invasive procedure) or involves no more than minimal risk to study subjects, and

104.2 Does not include vulnerable participants.

104.3 Does not raise sensitive privacy concerns.

105. Expedited review shall be carried out by the IRB Chairperson, Vice Chairpersons or any NMIMR-IRB member designated by the Chairperson.

106. If the reviewer(s) believe that there is reason for disapproval, or the nature of the project is not suitable for expedited review, the reviewer(s) will defer any decision, and submit the research protocol to a full review board by the NMIMR- IRB.

107. For research studies based on expedited review, the Chairperson shall inform all members advised of research studies that have been approved by expedited review.

108. Information and any observations made by members about a research protocol shall be recorded in the minutes of a meeting.

109. A research study submitted to the NMIMR-IRB for continuing review, amendments, or adverse event reports may be eligible for expedited review depending on the magnitude of the risks to which the research participant will be exposed.

110. Only research studies involving no more than minimal risk will be considered for expedited review.

111. The reviewer(s) shall exercise all the authorities of the NMIMR- IRB, except disapproval, which should be made at a full Board meeting.

112. Examples of research suitable for expedited review are:

112.1 Review of previously approved research for changes without risk implication.

112.2 Surveys by interview or questionnaire on non- sensitive issues.

112.3 Research of data, records and specimens obtained in the usual course of patient management or existing prior to research proposal.

112.4 Collection of blood samples by venipuncture, in amounts not exceeding 450ml in an eight week period and no more often than two times per week from subjects who are 18 years of age and who are not anaemic, in good health and not pregnant.

112.5 Collection of excreta, external secretions (e.g. urine, sweet, uncannulated saliva), placenta at delivery, amniotic fluid at the time of rupture of membrane, etc.

113. If the research participants include vulnerable populations the study will not be eligible for expedited review, regardless of the risk except research requiring non- sensitive information and /or ordinary clinical management.

114. Research studies which are considered having no more than minimal risk, and not involving children, fetuses, pregnant women, prisoners, mentally ill or cognitive impaired or intellectually disabled persons have been explicitly identified as eligible for expedited review:

114.1 Collection of hair and nail clippings in a non- disfiguring manner; deciduous teeth, and permanent teeth if patient care indicates a need for extraction.

114.2 Recording of data from subjects, using non- invasive procedures routinely employed in clinical practice (including use of physical sensors applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or invasion of the subject's privacy.

114.3 Procedures such as weighing, testing sensory acuity, electrocardiography, thermography, detection of naturally occurring radioactivity, diagnostic echocardiography, and electroretinography, not including exposure to electromagnetic radiation outside the visible range, such as Xrays and microwaves).

114.4 Collection of supra-gingival and sub-gingival dental plaque and calculus provided the procedure is not more invasive than routine prophylactic scaling of the teeth, and is accomplished in accordance with accepted prophylactic techniques.

114.5 Voice recordings made for research purposes, such as investigations of speech defects.

114.6 Moderate exercise by healthy volunteers.

114.7 Study of existing data, documents, records, pathological specimens, or diagnostic specimens.

114.8 Research on individual or group behaviour or characteristics of individuals, such as perception, cognition, game theory, or test development, where the investigator does not manipulate

subjects' behaviour and the research will not involve stress to subjects.

114.9 Research on drugs or devices for which an investigational new drug exemption or investigational device exemption is not required.

115. Research approved previously by expedited review will be considered eligible for expedited review at the time of its regular continuing review, if during the course of the study; the risks of the study have not increased.

116. Amendments to a previously approved research protocol of administrative or logistical nature, revisions in the text of an informed consent document, or corrections in text of documents, all of which are minor in nature and do not increase the risks involved, will be considered eligible for expedited review.

117. Some regulatory agencies recognize certain types of research as having no or negligible risk to the participants, and consider them to be eligible for exemption from review.

118. The NMIMR-IRB will not grant exemption from review for such research, but will consider processing them by expedited review.

CHAPTER 11

MONITORING OF HUMAN PARTICIPANT RESEARCH

119. The NMIMR-IRB shall monitor all active research projects involving human participants, to ascertain that the participants are being protected adequately from research risks and from any other breaches of human rights.

120. Regular monitoring of all previously approved projects shall be in the form of continuing reviews or onsite monitoring scheduled and determined by NMIMR-IRB

121. The frequency of the scheduled continuing reviews will be appropriate to the degree of risk, but not less than once per year, and the schedule of the continuing review will be decided upon approval.

122. The NMIMR IRB shall ensure that the investigators of active research projects carry out the following as a condition of approval of their projects:

122.1 Report to the NMIMR-IRB any planned change in the study, and do not implement any change without receiving prior approval, except to eliminate immediate hazard.

122.2 Report to the NMIMR-IRB any unanticipated problems involving risks to participants.

122.3 Report to the NMIMR-IRB any new information on the project that adversely influences the risk/benefit ratio.

122.4 The investigators will be informed and reminded of these conditions of approval, using the methods of communication stated in Article 33.

123. Every ongoing research study involving human participants shall be subject to continuing review at an interval of one year from the date of approval.

124. The principal investigator of an ongoing research project shall be responsible for submitting to the NMIMR-IRB office an application for continuing review.

125. The NMIMR-IRB shall send a reminder notice, two months in advance of the expiration of the approval period to principal investigators.

126. The investigator is obligated to suspend all participant recruitment and any other activity on the research study if approval for continuation has not been issued by the NMIMR-IRB.

127. To apply for continuing review, the investigator shall complete a' Continuing

128. Review Form - NMIMR-IRB FORM B', which can be found on the NMIMR website.

129. The information to be provided by the investigator in the application form shall include the following:

129.1 Number of participants accrued since last approval.

129.2 Number of participants expected to be recruited in the future.

129.3 Description of adverse events, withdrawal of participants and complaints (if applicable);

129.4 Summary of any amendments or modifications using NMIMRIRB Form C.

129.5 Summary of any reports on multi-centre trials and any other relevant information, especially information about risks associated with the research (if applicable)

129.6 Text of the latest version of informed consent document, and any revisions in the text to accommodate any protocol amendments or adverse events encountered.

129.7 Any changes in study site personnel since last approval.

129.8 Renewed Certificate of Insurance, if the existing one is expired.

129.9 A two page detailed progress report.

130. Investigators may request for amendments to various aspects of the project.

131. The date of approval of an amendment does not change the date by which the regularly scheduled continuing review of the project is to be

completed.

132. A change in the study protocol or investigator's brochure may require a change in the informed consent document.

133. The NMIMR-IRB shall scrutinize the amended documents to determine the degree to which risks to human participants may have changed, if there is any need to revise the consent document, and if changes to the consent document are adequate.

134. A copy of the current or revised informed consent document shall accompany the amendment application.

135. Amendments may include the following:

135.1 Amendment to the study protocol.

135.2 Amendment to the investigator's brochure describing a test article.

135.3 Amendment to the informed consent document.

135.4 Amendment to the Investigators.

136. To apply for an amendment, the investigator:

136.1 Shall complete an Amendment Form - NMIMR-IRB FORM C, which can be found on the NMIMR website.

136.2 Shall submit the original document highlighting the changes being requested for an amendment.

136.3 The investigator may provide all other relevant documents for review.

137. Investigators of a previously approved project are obligated to report to the NMIMR- IRB, without waiting for the next regularly, scheduled continuing review and within the timeframes of Serious Adverse Events (SAE) and Research related incidents.

138. SAEs resulting from the use of an investigational or approved drug, biologic or device observed in an ongoing research study or SAEs occurring at other study sites in a multi-centre study or in other research settings similar to that of the approved project by the NMIMR- IRB.

139. The following minimum timeframes shall be used for reporting SAEs:

139.1 Local drug related, or none drug related SAEs involving human research participants, must be reported **7 days verbally and** 14 **days in writing** from the date the Investigator receives a formal written report of the event(s).

139.2 Overseas reports of drug related or none related SAEs, involving human research participants must be reported **30 days** from the date the Investigator receives a formal written report of the event(s)

140. However, there may be other requirements in a sponsored trial that may have to be followed and the NMIMR IRB reserves the right to request a more stringent requirement.

141. The Chairperson of the NMIMR-IRB or a delegated member shall scrutinize the adverse event and/or other event documents to determine the degree to which risks to human participants may have changed.

142. If there is any need to revise the consent document, a copy of the revised consent document shall accompany the adverse event and/or other event report.

143. Research-Related Incidents includes but not to limited to:

143.1 A procedural error involving a human subject enrolled in the study.

143.2 Physical or emotional harm to the subject during the execution of the experimental protocol.

143.3 A breach of confidentiality or privacy.

144. Active monitoring of approved projects may occur at the discretion of the NMIMR-IRB. This may involve:

144.1 Examinations of research records.

144.2 Verification from sources other than investigators that no material changes in the study have occurred.

145. In targeting research projects to be subjected to these additional monitoring activities, the NMIMR-IRB will consider:

145.1 The level of risks of harm

145.2 The frequency and nature of adverse events

145.3 The vulnerability of the participants of research

145.4 Complaints received from the participants.

146. If the information gained during its monitoring process indicates that human participants of a research project are exposed to unexpected serious harm, or the requirements of the NMIMR IRB are not being met, the NMIMR-IRB shall suspend or terminate the research.

147. In such instances, the NMIMR-IRB shall provide the opportunity of rebuttal for the investigators, either in writing, or by appearing at a meeting of the NMIMR IRB to defend their cases.

148. The following shall be the reasons for monitoring active research projects:

148.1 Oversight visits in response to reports made directly to the ERC or circulating in the community

148.2 Increased frequency of serious adverse events reports.

148.3 Failure to submit progress reports or final report

148.4 Reports of suspected research misconduct

148.5 Researchers who extend their research beyond the approved time frame without formal notification and approval by the ERC.

148.6 Researchers that are suspected to have changed their objectives and design of the study without prior approval.

148.7 Any other reason that the committee feels warrants further follow-up

CHAPTER 12

SAMPLE STORAGE, BANKING AND TRANSFER

149. This chapter outlines procedures on the storage, banking and transfer of samples collected from humans.

150. Consent shall be sought from each human participant prior to the storing of the sample.

151. On the consent form, the following information should be provided:

- 151.1 A question as to whether the participant agrees to the storage of the sample with a yes or no option.
- 151.2 The future study that the sample would be used for.
- 151.3 The institution where the sample would be stored and used in Ghana.
- 151.4 If the samples would be shipped outside Ghana, proper justification should be given and a material transfer agreement should be provided.

152. The material transfer agreement shall contain but not limited to the following:

- 152.1 A description of the human sample
- 152.2 The title of the research to be conducted
- 152.3 Undertaking that the material will not be released to any person other than the signatories of the material transfer agreement except study team working directly under a signatory's supervision.
- 152.4 Undertaking that research results from the samples shall be communicated to both the recipient and provider scientists.
- 152.5 Name of provider scientist and head of the institution
- 152.6 Name of recipient scientist and head of institution

153. If the study would be conducted using existing archived samples, the following should be provided:

- 6.1 A confirmation letter from the authority that gave permission for the storage of the samples or ethical clearance.
- 153.1 The approved consent form that was used to recruit participants in the initial study.
- 153.2 A letter from the institution where the samples have been stored indicating that permission has been granted for the use of those samples.

154. Where the researcher is unable to provide the above information, ethical clearance shall not be granted for the conduct of the study.

CHAPTER 13

USE OF TEST ARTICLES BEYOND THE CONTEXT OF RESEARCH

155. A test article may be made available for use in patients with life threatening or other serious diseases, for which no satisfactory alternative treatments exist.

156. A test article may be administered to a human participant in a life-threatening situation when:

156.1 There is no acceptable standard treatment available.

156.2 The standard treatments have failed.

156.3 The following criteria apply when using a test article:

156.3.1 Must be used by a physician licensed to practice medicine in Ghana

156.3.2 The participant is facing a life-threatening condition, for which there is no conventional treatment, or conventional treatments have failed.

156.3.3 When a licensed physician has legitimate access to a test article, and believes that there is a reasonable likelihood that it may be helpful in the life-threatening condition.

156.3.4 If subsequent use of the test article is contemplated in the same participant or in others, a new project application to the NMIMR- IRB is required in advance of that use.

157. If these criteria are met, a physician may use the test article on a participant, without prior approval of the NMIMR- IRB. In this instance, the physician is required to do the following:

157.1 Obtain written informed consent from the participant or participant's legal representative.

157.2 Enter a description of the procedure in the patients' medical

record and attach a copy of the informed consent document.

157.3 Within five days of using the test article, the investigator shall submit to the NMIMR-IRB the following information in writing:

157.4 Identity and address of the responsible physician.

157.5 Name and hospital case number of the participant.

157.6 Name and source of the test article; investigational new drug/device (IND) number.

157.7 How much, by what route and on what date the test article was administered.

157.8 Information about any adverse events observed.

157.9 Copy of the informed consent document used.

158. NMIMR-IRB will process such notifications as an expedited review and issue an acknowledgement letter.

159. Any subsequent use of the test article will be subject to full review and approval by the NMIMR-IRB.

160. The purpose of the Treatment IND exemption is:

160.1 To facilitate the availability of promising test articles to seriously ill patients.

160.2 To obtain additional data on the test article's safety and effectiveness.

160.3 The Treatment IND protocol is added to an existing IND application, and allows the use of a test article in a group of participants, who are not enrolled in a clinical study testing the safety and efficacy of the test article.

160.4 For use in seriously ill patients.

161. There must be sufficient evidence that the test article is safe and effective; usually, such evidence becomes available during Phase III investigations or after all clinical trials have been completed.

162. Whose life is in immediate danger, information available must be sufficient to conclude that the test article may be effective for the intended

use, and would not expose the patient to an unreasonable risk; usually, this information becomes available early in Phase III, or sometimes in Phase II clinical trials.

163. A test article may be used in a single patient:

163.1 With a serious or life-threatening illness, for which all customary treatments has failed, or there is no recognized treatment available.

163.2 When there is a reasonable likelihood on theoretical grounds, or based on anecdotes of success, that the test article may be helpful.

163.3 The physician intending to use the test article will obtain it from its source, and secure IND exemption or submit a treatment IND exemption request with the help of the sponsoring company to the appropriate regulatory authority, for medical reasons.

163.4 An application shall be submitted to the NMIMR-IRB prior to the initiation of the protocol.

163.5 The accompanying consent document shall be particularly explicit with regards to the use of an investigational drug in a health care setting, and the assessment of the risk/benefit relationships.

CHAPTER 14

EDUCATIONAL ACTIVITIES OF NMIMR-IRB

164. The NMIMR-IRB shall disseminate new information on ethical and safety issues involving human participants' research.

165. Resource persons who are experts in the subject matter may be invited from other institutions to take part in these educational activities.

166. The NMIMR-IRB shall educate researchers who have active research projects involving human participants.

CHAPTER 15

RECORDS MANAGEMENT

167. All documents of the NMIMR-IRB shall be dated, filed and archived.

168. Hardcopies will be filed and archived for a minimum period of 3 years following the completion of a study.

169. The following documents will be archived indefinitely:

169.1 The standard operating procedures of the NMIMR-IRB, and regular (annual) reports.

169.2 Member records of the NMIMR-IRB.

169.3 Published guidelines for submission established by the NMIMR-IRB.

169.4 Agendas of the NMIMR-IRB meetings.

169.5 Minutes of the NMIMR-IRB meetings.

169.6 Reports of monitoring of the NMIMR-IRB.

169.7 Correspondence by the NMIMR-IRB members, with applicants or concerned parties regarding application, decision and follow-up.

169.8 A copy of the decision and any advice or requirements sent to an applicant.

169.9 All written documentation received during the follow-up.

169.10 Notification of the completion, premature suspension, or premature termination of a study.

169.11 Research Final Report

169.12 Electronic copies of IRB documents

170. The NMIMR-IRB will maintain an archive of files for all research projects approved by the IRB.

171. Closed study files shall be retained for at least three years after completion of the research.

172. Each project folder will include the following types of documents, as conventional hard copies:

172.1 Initial Review Application Form – FORM A

172.2 Study Protocol.

172.3 Investigator's Brochure (if applicable)

172.4 Participant Consent Form – English.

172.5 Texts of advertisements for participant recruitment – English (where appropriate).

172.6 Questionnaires/Interview Guides – English (where appropriate).

172.7 Investigator's abridged CV.

172.8 Insurance policy document. (If applicable)

172.9 Certification documents from other agencies, as mandated by federal regulatory agencies.

172.10 IRB Approval Certificate

172.11 Research Progress Report Form – FORM B (if applicable)

172.12 Research Final Report

172.13 Protocol Amendment Application

172.14 Statements on significant new findings.

172.15 Correspondence between NMIMR-IRB and investigators of the project.

173. The NMIMRIRB shall maintain a computerized relational database to facilitate tracking of research projects involving human subjects submitted for review. This will involve the use of the ProIRB Database and spreadsheet.

174. NMIMR-IRB member records shall include the term and status of each member, Curriculum Vitae, appointment document and information about training received.

175. Such information should be maintained and updated as necessary and should be retained for at least 3 years after completion of the service of active members of the NMIMR- IRB.

176. The Chairperson of the IRB must review all NMIMR-IRB documents annually or whenever there is a change of IRB Chairperson.

177. The documents are to be reviewed and signed, where appropriate, by the Chairperson.

178. Research investigators shall use the following revised standard forms

when applying for ethics review:

178.1 NMIMR-IRB Initial Submission Form (A)

178.2 NMIMR-IRB Continuing Review FORM (B)

178.3 NMIMR-IRB Amendment Form (C)

178.4 NMIMIR-IRB SAE Form (D)

178.5 NMIMR-IRB Closure Report (E)

178.6 NMIMR-IRB Protocol Deviation Form (F)

178.7 NMIMR-IRB Response Form (G)

178.8 NMIMR-IRB Submission Cover Letter

178.9 NMIMR-IRB Informed Consent Template

178.10 Assent/Parental Consent form

179. All NMIMR IRB members shall use the NMIMR-IRB Review Checklist when reviewing a protocol.

180. The NMIMR-IRB at its own discretion may issue the following documents to investigators:

180.1 Ethical clearance

180.2 Approval letters

180.3 Continuing Review Notification letters

GLOSSARY

Human participant research means a living individual, about whom a professional or student investigator conducting research obtains data through intervention or interaction with the individual, or collects identifiable private information.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

Adverse Event/Serious Adverse Events

An adverse event is any untoward/undesirable experience associated with the use of a medical product in a patient or participant. The event is serious and should be reported to FDA/IRB when the patient outcome is death, life-threatening, hospitalization (initial or prolonged), disability/permanent damage, congenital anomaly/birth defect, required intervention to prevent permanent impairment or damage and other important medical event.

Standard treatment

Treatment that is normally given to people with a given condition

Test article

Any drug, biological product for human use, medical device for human use, human food additive, colour additive, electronic product that is subject to Food and Drugs Board regulation.

Human Sample

Human samples are samples that are collected from human body and consist of or include human cells. This includes blood, urine, stool, etc.

Material Transfer Agreement

This is a document used for the transfer of biological or chemical material.