Eastern Visayas Health Research and Development Consortium-
Ethics Review Committee (EVHRDC-ERC) STANDARD
OPERATING PROCEDURE

GLOSSARY

1. **Active files/ Vertical files** - include protocols that are awaiting schedule for review, protocols that are scheduled for review (full or expedited), protocols for revision, protocols approved for implementation and approved protocols undergoing implementation.

2. **Amendment** - A written description of a change(s) to, or formal clarification of a protocol and changes in any other supporting documentation made from the originally approved protocol by the ERC after the study has begun.

3. **Appeal** - an application in writing to a recognized authority for corroboration, vindication or decision.

4. **Appointing authority** - the institutional official that has the power to designate or appoint individuals to specific offices or roles.

5. **Coding** - a unique number assigned to a protocol indicating the year and series it was received.

6. **Conforme** - acceptance of or agreement to an assignment or designation.

7. **Consensus decision** - a general agreement or unanimity between ERC chair and members.

8. **Conflict of Interest** - a conflict between the private interests and the official responsibilities of a person in a position of trust.

9. **Confidentiality** - Prevention of disclosure, to other than authorized individuals, of a sponsor's proprietary information or of a subject's identity.

10. **Confidentiality agreement** - agreement between two or more parties regarding an unauthorized disclosure of information that could be prejudicial to the national interest.

11. **Conflict of Interest** - Conditions in which professional judgment concerning a primary interest (such as patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain).

12. **Continuing Review Protocol Package** - consists of all the documents in the initial protocol package plus the blank copies of the protocol evaluation forms with the

synopsis of the study protocol and updated informed consent form with the transmittal letter to the primary reviewers.

13. **Decision** - the result of the deliberations of the ERC in the review of a protocol or other submissions.

14. **Disapproved researches** - are research protocols rejected because of ethical and legal concerns.

15. **Document**s - refers to proposals submitted to the ERC for review.

16. **Early Study Termination** - a study approved by the ERC that is being recommended for termination before its scheduled completion.

17. **Ethics Review Committee** - a committee constituted to review the ethical aspects of a research proposal and its possible implementation.

18. **ERC Staff Secretary**- The person providing administrative support to the operations of the ERC.

19. **Exemption from Review** - a decision made by the ERC Chair or designated member of the committee regarding a submitted study proposal based on criteria in the NEGHHR 2017 The Research Ethics Review Process Guideline 3.1.

20. **Expedited Review** - is the ethical evaluation of a research proposal and other protocol related documents, a resubmission and after-approval submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.

21. **Executive Management Committee (ExeCom**) - a policy decision making body of the Eastern Visayas Health Research and Development Consortium consisting of the heads of institution from Department of Health – Eastern Visayas Center for Health Development, Department of Science and Technology VIII, University of the Philippines Manila - School of Health Sciences, Commission on Higher Education VIII, National Economic and Development Authority VIII, St. Scholoasticas' College of Tacloban, and Visayas State University. The ExeCom is authorized to make decisions on behalf of the consortium.

22. **Expertise** - a proficiency, skill or know-how possessed by experts in a certain academic or Professional field.

23. **Full Review** - is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.

24. **General Assembly** - is an annual gathering of the heads of all EVHRDC member institutions or its representatives which is scheduled every November of the year. The

EVHRDC Chair presides over the General Assembly, where the nominees for the ERC are presented and after thorough deliberation, the ERC members are chosen.

25. **Inactive files** - Completed studies and approved by the ERC three (3) years after closure of final report has been done. Also, classified as studies when no further communication has been received by the ERC after three (3) years. This also refers to the studies that underwent early termination upon receipt of relevant information about termination.

26. **Incoming Communications** - these are letters, requests or inquiries coming from other individuals or agencies received in the office.

27. **Independent consultants** - Resource persons who are not members of the Ethics Review Committee, whose expertise is needed in the review of a research protocol/proposal and who may be invited to attend a committee meeting but are non-voting during the deliberations.

28. **Indigenous People** - are people defined in international or national legislation as having a set of specific rights based on their historical ties to a particular territory, and their cultural or historical distinctiveness from other populations that are often politically dominant.

29. **Initial Review** - ethical and technical review conducted on the initially-submitted study documents. It may be expedited or full.

30. **Initial Submission** - a set of documents consisting of the full proposal and other study-related documents that need to be submitted so that review can be conducted.

31. **Institutional Ethics Review Committee** - An independent body constituted of medical, scientific, and non-scientific members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trial protocol and amendments and of the methods and material to be used in obtaining and documenting informed consent of the trial subjects.

32. **Final Report** - end result of a research.

33. **Full Review** - is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.

34. **Layperson** - non-scientist member who represents the community.

35. **Logbook of Received Documents** - refers to the logbook of received protocol documents.

36. **Major modification** - major changes in the research protocol (ex. study design, major section of the protocol or Informed Consent that affects patient safety and credibility).

37. **Minimal risk** - The probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations.

38. **Minor modification** - minor changes in the research protocol (typographical error, administrative issues, and additional explanations)

39. **Minutes of the Meeting** - detailed notes that serve as an official written record of the ERC regular meeting

40. **Non-Institutional Member/s** - are regular members who are not in the roster of personnel or staff of the Institution. They are not employees of the institution nor do they receive regular salary from the institution.

41. **Multi-site Research** - refers to researches that will be conducted in three or more sites that utilize the same study protocol.

42. **Single Joint Ethics Review** - refers to reviews for the purpose of approving multi-site research that will be conducted in sites within the purview of the Department of Health.

43. **Notice of Meeting** - a document used by ERC which states about a meeting to be held and informs the attendees about the agenda.

44. **Major Modification** - is a recommended revision of significant aspects/s of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data statistical analysis, mitigation of risks, protection of vulnerability, etc.) that impact on potential risks/harms to participants and on the integrity of the research.

45. **Minimal Risk** - term used when the probability and magnitude of harm or discomfort anticipated in a research are not greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.

46. **Minor Modification -** is a recommended revision of particular aspect/s of the study or related documents that do not impact on potential risks/harms to participants and on the integrity of the research, e.g. incomplete documentation, incomplete IC elements, unsatisfactory IC format).

47. **Minutes of the Meeting**- detailed notes that serve as an official written record of the ERC regular meeting.

48. **More than Minimal Risk** - term used when the probability and magnitude of harm or discomfort anticipated in a research are greater, in and of themselves, than those encountered in daily life or during the performance of routine physical or psychological examinations or tests.

49. **NCIP (National Commission on Indigenous People)** - is the agency of the national government of the Philippines that is responsible for protecting the rights of the indigenous peoples of the Philippines.

50. **Noncompliance –** is any deviation from changes of the protocol without agreement of the sponsor and prior review and documented approval from the ERC of an amendment.

51. **Outgoing Communications** - these are decision letters, notification letters, or letters of response prepared by the ERC for other individuals.

52. **Offsite SAEs and SUSARs** - these are SAEs and SUSARs of researches conducted in other participating sites of a clinical trial in which participants are from Region VIII.

53. **Onsite SAEs and SUSARs** - these are SAEs and SUSARs of researches conducted inside Region VIII.

54. **Post-approval Reports** - are accounts of the ongoing implementation of an approved study (e.g., progress report, amendment, safety report, protocol deviation/violation, early termination, final report, or application for continuing review) that are required be submitted by the researcher to the ERC for monitoring purposes.

55. **Primary Reviewers** - a member of the Ethics Review Committee (usually a scientist and a non-scientist) assigned to do an in-depth evaluation of the research-related documents using technical and ethical criteria established by the committee.

56. **Principal Investigator** - the chief or person primarily responsible for the implementation of a research project or clinical trial.

57. **Progress Report** - description of how the implementation of the study is moving forward. This is done by accomplishing the Progress Report Form. The frequency of submission (e.g., quarterly, semi-annually or annually) is determined by the ERC based on the level of risk.

58. **Protocol Amendment** - any minor or major changes in the approved research protocol.

59. **Protocol database** - a roster of file copies of the protocol documents with dates and names of documents.

60. **Protocol Deviation** - non-compliance with the approved protocol that does not increase risk or decrease benefit to participants or does not significantly affect their rights, safety

or welfare or the integrity of data. Example: missed visit, non-submission of a food diary on time.

61. **Protocol File** - is an organized physical or electronic compilation of all documents related to a Protocol.

62. **Protocol File Index** - a form used to log documents that are filed in the protocol file folder with indicated date of receipt, date forwarded and title of the documents being filed.

63. **Protocol Package** - consists of all the documents in the initial protocol package plus the blank copies of the protocol evaluation forms with the transmittal letter to the primary reviewers.

64. **Protocol-related Documents** - consists of all other documents aside from the proposal/protocol itself that are required to be submitted for review, e.g., Informed Consent Form, Survey Questionnaire, CV of proponent, advertisements, In-depth Interview Guide Questions.

65. **Protocol Violation** - non-compliance with the approved protocol that increases risk or decreases benefit to participants or significantly affects their rights, safety or welfare or the integrity of data. Example: incorrect treatment, non-compliance with inclusion/exclusion criteria.

66. **Quorum** - The number of present members required to act on any motion presented for action during a full board meeting, in addition to types of members required to be present based on international and national guidelines and regulations. A quorum is the presence of half of the total number of members plus 1.

67. **Regular Meeting** - a periodically scheduled assembly of the ERC.

68. **Regular Members** - are members constituting the research ethics committee, who receive official appointments from the institutional authority with specific terms and responsibilities including review of research proposals and attendance of meetings.

69. **Reportable Negative Events (RNE)** - are occurrences in the study site that indicate risks or actual harms to participants and to members of the research team and to integrity of data.

70. **Research Protocol** - is a document that describes the background, rationale, objectives, design, methodology, statistical considerations, and organization of a clinical research project; also alternately referred to as “research study” for purposes of this SOP manual.

71. **Researcher** - is the individual primarily responsible for the conceptualization, planning and implementation of a study.

72. **Resubmissions** - revised study proposals that are submitted after the initial review.

73. **Reviewer** - a regular member of the Ethics Review Committee who is assigned to assess a research protocol, the Informed Consent, and other research-related submissions based on technical and ethical criteria established by the committee.

74. **Risks** - summary of probable negative or unfavorable outcomes ranging from inconvenience, discomfort, or physical harm based on the protocol.

75. **Serious Adverse Event (SAE)** - Any untoward medical occurrence that at any dose results in death, life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or a congenital anomaly/birth defect.

76. **Single Joint Ethics Review** - refers to reviews for the purpose of approving multi-site research that will be conducted in sites within the purview of the Department of Health. For Non-DOH hospitals, participation in this review is voluntary.

77. **Site Visit** - An action taken by ERC members or representatives which involves going to a study site to assess how the investigators are conducting a trial or research and maintaining compliance and proper documentation for an ERC approved protocol.

78. **Site Visiting Team** - members/staff of the ERC (2-4 members) assigned by the ERC Chair to formally go to the research site, meet with the research team and evaluate compliance with the approved protocol and Informed Consent Form and Process, including other related research procedures.

79. **Sudden Unexpected Serious Adverse Reaction (SUSAR)** - refers to an event or reaction that is not listed in the investigator's brochure or is not listed at the specificity or severity that has been observed.

80. **Special meeting** – an assembly of the Committee outside of the regular schedule of meetings for a specific purpose, usually to decide on an urgent matter like selection of officer, approval of a revised or new SOP, report of critical research problem that requires immediate action

81. **Sponsor-** an individual, company, institution or organization which takes responsibility for the initiation, management, and financing of a clinical trial.

82. **Sponsored-Clinical Trials –** are a systematic study on pharmaceutical products in human subjects (including research participants and other volunteers), whose conceptualization, protocol development and support for their conduct are the responsibilities of sponsors who manufactured the products, in compliance with the requirements of regulatory authorities.

83. **Standard Operating Procedures -** are the step-by-step description of the different procedures done to accomplish the objective of an activity. They consist of clear, unambiguous instructions for ethical review to ensure quality and consistency.

84. **Term of office** – the specified length of time that a person serves in a particular designation /role.

85. **Violation/Deviation –** Any change during protocol implementation that does not comply with the ERC approved version.

86. **Voting** – the act of expressing opinions or making choices usually by casting ballots, spoken word or hand raising. The rule is majority wins.

87. **Vulnerable Groups** – participants or potential participants of a research study who may not have the full capacity to protect their interests and may be relatively or absolutely incapable of deciding for themselves whether or not to participate in the research. They may also be at a higher risk of being harmed or to be taken advantage of.