National Center for Mental Health

Research Ethics Committee

SOP

Standard Operating Procedure

Version no. 7

June 19, 2023

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Version no. 7		
Authored by:	National Center for Mental Health – Research Ethics Committee	
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Approval Date:	June 16, 2023	

NATIONAL CENTER FOR MENTAL HEALTH

VISION

"The NCMH is an internationally recognized Mental Health Reference Center leading the advancement of mental well-being for all."

MISSION

"To lead the country in providing comprehensive mental healthcare services through integrated clinical practice, training and research."

CORE VALUES

Integrity | Commitment | Excellence | Inclusivity

NCMH – RESEARCH ETHICS COMMITTEE

VISION

"The NCMH-REC aims to be the premier research ethics committee that advances the mental health and well-being, the rights and interest of every participant and soon to be the reference center of research in terms of mental health."

MISSION

"To protect the Rights, Safety, Welfare, and Confidentiality of Human Research participants through efficient and effective review process by upholding the highest Ethical Standards in Research."

ORGANIZATIONAL CHART

Ethical Framework of National Center for Mental Health-Research Ethics Committee

A. Specific Objectives

1. To uphold ethical standards in research in compliance with provisions of the WHO Operational Guidelines/CIOMS Guidelines and the National Ethical Guidelines;

2. To protect the safety, welfare, rights and dignity of research participants based on the Declaration of Helsinki 2013;

3. To facilitate efficient and effective review process by the preparation of research documents and logistics, delineation of the workflow with detailed description of procedures and allocation of specific forms used in the activity.

B. Governing Principles and Ethical Obligations

The NCMH-REC as mandated by the MCC as an independent body task to review, give recommendations, and final evaluation of research papers in conformation to the ethical principles in the Belmont Report of 1979 as follows:

1. **Respect of Person** – which states that individuals should be treated as autonomous agents, and persons with diminished autonomy are entitled to protection.
2. **Beneficence** – principle that requires investigators to protect participants from harm and secure their well-being.
3. **Justice** – principle that refers to the sense of "fairness in distribution" and "what is deserved."

a. The NCMH-REC is guided by the ethical principles and procedures as expressed in the following International Guidelines:

- Declaration of Helsinki (2013 and subsequent revisions)
- International Conference on the Harmonization of Good Clinical Practice (ICH-GCP), current step 4 version dated November 09, 2016
- CIOMS 2016
- Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants (2011) by the World Health Organization (WHO)
- Guideline on Good Pharmacovigilance Practice (GVP)
- Guidelines for Good Phamacoepidemiology (GPP)
- International Ethical Guidelines for Epidemiological Studies (2008)
- The Nuremberg Code

b. The NCMH-REC functions in accordance with National laws, Regulations, and Guidelines.

- National Ethical Guidelines for Research Involving Human Participants (NEGRIHP 2022)
- Administrative Orders from DOH, Philippine FDA and relevant agencies

c. The NCMH-REC Standard Operating Procedures (SOP) is an amalgamation of the following:

- Operational Guidelines for Ethics Committees that Review Biomedical Research (2000) by the World Health Organization (WHO)
- DOH-REC SOP Template
- FERCAP SOP Templates
- 2020 PHREB SOP Workbook

The NCMH-REC adherence to National and International ethical standards. Protocols approved have been reviewed and approved by other ethics committees including the Multi-Site Research Ethics Board (MREB) prior to their implementation in specific sites.

d. In evaluating protocols and ethical issues, the NCMH-REC is cognizant of the diversity of laws, cultures and practices governing health research in various local sites/countries around the world.

e. NCMH REC updates regularly, of the regulations and requirements of sponsor countries conducting global protocols in the Philippines; and of the requirements and conditions of various localities where a proposed National Center for Mental Health research is being considered.

f. The NCMH-REC is regularly informed, by current state-of-the-art researches and publications that it has approved.

C. Scope

The National Center for Mental Health - Research Ethics Committee review researches involving human participants conducted by:

1. NCMH Staff (Consultants / Fellows / Residents / Nurses and other allied personnel)
2. Pharmaceutically sponsored researches wherein the Primary Investigators are NCMH Staff
3. Non-NCMH Staff who will conduct research at NCMH
4. In special cases, NCMH-REC may conduct research ethics review and approval of researches in other institutions as requested.

This SOP provides the Terms of Reference (TOR) that describe the framework for the constitution of the NCMH-REC, the responsibilities and activities of its officers, members, and Staff.

D. Responsibilities

NCMH Medical Center Chief

1. It is the responsibility of NCMH Medical Center Chief to constitute and establish the NCMH-REC.
2. It is the responsibility of the Medical Center Chief to formally appoint the NCMH-REC Officers, Members, Independent consultant and Staff of the NCMH-REC after due consultation with the current Officers and Members of the NCMH-REC.

NCMH-REC Chair

1. Ensures that all REC Members receive orientation and undergo basic Research Ethics training immediately after their appointment and continuing education thereafter.
2. The NCMH-REC Chair shall enjoin NCMH-REC members and staff to attend trainings/seminars/workshops as needed, and ensure that adequate resources are provided for continuing professional development. Therefore NCMH is responsible for allocating an annual budget for specific trainings and other educational activities for NCMH-REC member and staff.
3. Obtains administrative and logistics support for the sustained operations of the REC.
4. Approves the agenda and presides over REC review meetings (If Chairperson has Conflict of Interest relative to the protocol for deliberation s/he designates the Member-Secretary or any designated Member to preside over the meeting
5. Classifies type of review of a particular research protocol as to Expedited or Full Board review or Exempt from Review.
6. Selects suitable (somebody with related expertise) Member / Independent Consultant to be the Primary Reviewer of a protocol whether by Full board or Expedited review, and ensures that aforementioned member does not have conflict of interest.
7. Manages complaints from study participants, authorities or the general public.
8. Designates a Member or group of members to investigate in cases of complaints or report of major non-compliance. Ensures that the REC is perceived as fair and impartial, and complies with Institutional, National and International standards.

9. Provides updates on relevant and contemporary issues related to ethics in health research, as well as relevant literature to the REC members.
10. Represents the REC in various Local, National and International meetings and conferences.
11. Prepares the Annual Work Financial Plan (WFP) and the Project Procurement Management Plan (PPMP) and approved by the Medical Center Chief.
12. Ensure adherence to quality standards to maintain the accreditation status.

NCMH-REC Vice-Chair

1. Presides over meetings in the absence of the Chair.
2. Performs other duties as designated by the Chair.
3. Serve as Primary Reviewer for research protocol documents within area of expertise, and as General Reviewer for all researches discussed at convened meetings of the REC.
4. Conduct Expedited / Full Board review of protocols assigned by the REC Chair.
5. Submit within seven (7) days to the Staff the completed Protocol Assessment form when designated as Primary Reviewer
6. Perform Post-Approval review procedures of protocol-related documents within seven (7) days.
7. Conform at all times with the legal and ethical principles accepted by the REC.
8. Attend all regularly scheduled REC meetings (i.e. monthly meeting every 1st Tuesday of the month) as well as basic and continuing education on Research Ethics at least once a year.
9. Update Curriculum Vitae and Training Record every time appointment is renewed.

NCMH-REC Member-Secretary

1. Supervises the REC Staff related to good REC office management.
2. Prepares and finalizes the meeting agenda of Full board meeting after consultation with the Chairperson.
3. Collects and reviews the assessment forms submitted by the Primary Reviewers before the meeting.
4. Classifies type of review of a particular research protocol as to Expedited or Full Board review or Exempt from Review upon approval of REC Chairperson.
5. Appoints or designates the primary reviewer for such particular review upon approval of REC Chairperson.

6. Serve as Primary Reviewer for research protocol documents within area of expertise.
7. Conduct Expedited / Full Board review of protocols assigned by the REC Chair.
8. Submit within seven (7) days to the Staff the completed Protocol Assessment form when designated as Primary Reviewer
9. Perform Post-Approval review procedures of protocol-related documents within seven (7) days.
10. Ensures that the Members completely fill out necessary forms used for the review of protocol or protocol related submissions.
11. Supervises the REC Staff in the preparation of the meeting agenda and minutes.
12. Supervises the REC Staff in the preparation of the annual report of the REC to be submitted to the Medical Center Chief, DOH, PHREB and other bodies.
13. Ensures good REC documentation and archiving.
14. Ensures overall REC compliance with Good Clinical Practice.
15. Ensures good financial management of REC resources.

NCMH-REC Staff

The NCMH-REC Staff is composed of the Committee Secretary, and the Administrative Staff who are employees of the Hospital.

The Staff shall have the following functions:

1. Organize an effective and efficient tracking procedure for each proposal received.
2. Prepare, maintain and distribute study files.
3. Organize REC meetings regularly.
4. Prepare meeting agenda and minutes.
5. Maintain good REC documentation and archiving procedures.
6. Communicate with the REC members and Investigators.
7. Arrange training for personnel and REC Members.
8. Organize the preparation, review, revision and distribution of SOPs and guidelines.
9. Provide the necessary administrative support for REC-related activities to the Chair of the REC.
10. Maintain a library of research files, relevant resource materials and reference.

It is the responsibility of the NCMH-REC Officers, Members and Staff to study, comprehend, comply and respect the procedures and guidelines set forth by the NCMH-REC.

Responsibility of newly appointed NCMH-REC Members and Staff to undergo training during the course of his appointment. The existing NCMH-REC member and staff should continuously update themselves and train on relevant knowledge and skills.

It is the responsibility of the NCMH-REC Members to nominate and approve the name/s of the Independent Consultants to be endorsed by the REC Chairperson to the Medical Center Chief.

It is the responsibility of the newly appointed NCMH-REC Officers, Members to read, understand, respect, and sign the required appointment forms at the start of their appointment or reappointment to the REC. Refusal of any members to sign such agreement may be ground for his/her disqualification from the Committee.

1. **Responsibilities of REC Member, as follows:**

- Serve as Primary Reviewer for research protocol documents within area of expertise, and as General Reviewer for all researches discussed at convened meetings of the REC.
- Conduct Expedited / Full Board review of protocols assigned by the REC Chair.
- Submit within seven (7) calendar days to the Staff the completed Protocol Assessment form when designated as Primary Reviewer.
- Perform Post-Approval review procedures of protocol-related documents within seven (7) calendar days.
- Conform at all times with the legal and ethical principles accepted by the REC.
- Attend all regularly scheduled REC meetings (i.e. monthly meeting every 1st Tuesday of the month) as well as basic and continuing education on Research Ethics at least once a year.
- Update Curriculum Vitae and Training Record every time appointment is renewed.
- Perform other tasks requested by the REC Chair.

2. **Non-Medical / Non-Scientific Member of the REC responsibilities as follows:**

- Non-Scientific or Non-Medical / Layperson will be responsible for the review of Informed consent form and shall focus on the human subject / participant concerns to ensure adequate and proper application of International and National principles and guidelines
- Conduct Expedited / Full Board review of protocols assigned by the REC Chair
- Submit within seven (7) calendar days to the Staff the completed Protocol Assessment form when designated as Primary Reviewer
- Perform post-approval review procedures of protocol-related documents within seven (7) calendar days
- Conform at all times with the legal and ethical principles accepted by the REC
- Attend all regularly scheduled REC meetings (i.e. monthly meeting every 1st Tuesday of the month) as well as basic and continuing education on Research Ethics at least once a year.
- Update Curriculum Vitae and Training Record every time appointment is renewed.
- Perform other tasks requested by the REC Chair.

3. **The Non-affiliated Member** is appointed because of their views that are valuable, and presumably, reflect the concerns of research and the whole society. They are also less affected by the possibility of financial and nonfinancial conflicts of interest, which may arise with someone who works in the institution or is related to an employee of the institution. They may be nominated for appointment by the NCMH-REC Chair or be appointed directly by the head of the institution. They are usually community members who have a general interest in the welfare of human research and should not be related to any employee of the institution. **Responsibilities of Members (Non – Affiliated) are as follows**:

- Serve as Primary Reviewer for research protocol documents within area of expertise, and as General Reviewer for all researches discussed at convened meetings of the REC.

- Non-Scientific or Non-Medical / Layperson will be responsible for the review of Informed consent form and shall focus on the human subject / participant concerns to ensure adequate and proper application of International and National principles and guidelines.
- Conduct Expedited / Full Board review of protocols assigned by the REC Chair in lieu of any absent regular member
- Submit within seven (7) calendar days to the Secretariat the completed Protocol Assessment form when designated as Primary Reviewer in lieu of any absent regular member.
- Perform Post-Approval review procedures of protocol-related documents within seven (7) calendar days in lieu of any absent regular member
- Conform at all times with the legal and ethical principles accepted by the REC.
- Ensure the independence of the REC in its work and decision-making.
- Attend all regularly scheduled REC meetings (i.e. monthly meeting every 1st Tuesday of the month) as well as basic and continuing education on Research Ethics at least once a year.
- Update Curriculum Vitae and Training Record every time appointment is renewed.
- Perform other tasks requested by the REC Chair.

4. Responsibilities of the Independent Consultant, as follows:

1. Serve as primary reviewer in protocols for which there is no expertise in REC.

   Review must focus on:
   - Procedures and research method
   - Risk/benefit assessment
   - Risk mitigation
   - Vulnerability issues
   - Providing updates about the research topic

2. You must complete the assessment form to be reviewed by the REC at the time the study is reviewed.

3. You may attend the NCMH-REC meeting, present your assessment and participate in the discussion. However, you have no voting rights

and will not be part of quorum requirements but your report(s) will become permanent part of the study file.

5. **Conditions of Appointment of Members** : All REC members must be willing to –

- To make public his/her full name, profession, and affiliation as an REC member.
- Disclose all financial accountability, reimbursement for work and expenses, related to their work in the NCMH REC that shall record and publicly disclose its financial records upon request.
- All REC Members shall sign the Conflict of Interest Agreements. The agreement should cover all applications, meeting deliberations, information on research participants and related matters.

6. **Terms of Office**

- The appointment letter should include functions, conditions of appointment, terms of office, and honorarium, if any.
- Members are appointed for a period of three (3) years and renewable for three (3) consecutive terms depending on their performance.
- The REC shall adopt mechanism to enable participation of new Members with fresh outlook and approaches, but it shall also strive to ensure continuity, as well as the development and maintenance of expertise.

E. Statement of Institutional Authority

Pursuant to Hospital Order Number 09, s 1998 paragraph 95 and Hospital Order No. 11, s 1998 paragraph 64 dated September 28, 1998 and November 12, 1998, respectively, the committee shall be named NCMH Institutional Ethics Review Committee/Independent Ethics Committee (IERC/IEC), hereto referred as National Center for Mental Health-Research Ethics Committee (NCMH-REC).

The NCMH-REC was organized as mandated by the Philippine Health Research Ethics Board (PHREB), a national policy-making body on health research ethics; and operates according to the International Conference on Harmonization Good Clinical Practice Guidelines (ICH-GCP) which is embedded in the National Ethical Guidelines for Health Research of the PHREB.

F. Independence of the NCMH-REC

The NCMH-REC is independent and does not answer to individuals, departments, or units that rely on the NCMH-REC for the review of their researches. The REC is the final authority for all decisions regarding the safety, protection and welfare of human participants in research activities. Institutional officials may not approve the research if it has not been approved by the NCMH-REC.

G. History of NCMH-REC SOP

The First and Second Versions of NCMH-REC SOP were done in August 12, 2014 and November 3, 2016 respectively, using the DOH template. In August, 2017, the NCMH-REC SOP Revision Team formulated the NCMH-REC SOP Version 3 which adopted the 2017 Department of Health Standard Operating Procedures. The NCMH-REC SOP Revision Team is the following REC members: Dr. Hyacinth Manood, Ms. Epifania Crespo, Mr. Alfredo Torres and Ms. Leticia Dizon. Revisions were made effective February 15, 2021 upon the recommendation of PHREB in line with NCMH-REC application for Level 2 accreditation. Additional revisions were made effective April 21, 2021, July 07, 2021 and November 15, 2021. The New Composition of NCMH-REC has the Real-time revision of SOP during SOP Workshop conducted by PHREB dated October 19-20, 2022. Revisions were finalized effective November 29, 2022. The SOP Team Revisions were made effective March 21, 2023 upon the recommendation of PHREB dated February 6, 2023 in line with NCMH-REC application for accreditation. Additional revisions were made effective May 15, 2023 and June 19, 2023 upon the recommendation of PHREB-CSA, each SOP has a history indicating the changes made.

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres Ms. Leticia Dizon	Adopted the 2017 DOH SOP
2	February 15, 2021	SOP Team	History of SOP: added date of revision
3	April 27, 2021	SOP Team	History of SOP: added date of revision
4	July 07, 2021	Dr. Rommel Mendoza	A. Specific Objectives: rephrased International Guidelines: GVP, GPP, IEGES (2008), added History of SOP: added date of revision
5	November 15, 2021	Dr. Rommel Mendoza	A. Specific Objectives: rephrased B. Governing Principles and Ethical Obligations, first paragraph, rephrased International Guidelines: ICH-GCP, version date, added; The Nuremberg Code, added; National Laws, Regulations and Guidelines: NEGHHR, added SOP: 2020 PHREB SOP Workbook, added

			History of SOP: added date of revision
6	October 19-20, 2022	SOP Team	Real-time Revision during SOP Workshop
7	March 21, 2023	SOP Team	Added NCMH-REC Organizational Chart Added Responsibilities and terms of reference of the NCMH-REC Officers, members and Staff in the Introduction (Recommended by PHREB-CSA)

1.1. Policy Statement

The selection of REC members shall be through a nomination process that ensures representation of different disciplines and sectors, designated as regular members for a period of 3 years and renewable for 3 terms and shall attend meetings whenever called to ensure that meetings are conducted with sufficient members.

1.2. Purpose

Selection and Appointment of REC Members aims to ensure that the composition of the REC complies with the international, national, and institutional guidelines and that appropriate expertise is taken into consideration.

1.3. Scope

This SOP begins with the call for nominations, approval of the MCC and ends with the filing of appointment documents and CVs of REC members in the membership file.

1.4. Process Flow

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Call for nomination	Chair	7 days
2	Receipt of nominations	Staff	3 days
3	Shortlisting of nominees	Chair	3 days
4	Endorsement of shortlisted nominees to Medical Center Chief	Chair	1 day
5	Receipt of Hospital Order of new members	Chair	1 day
6	Forwarding of appointment papers to the new members	Staff	3 days
7	Signing of conforme, conflict of interest disclosure and confidentiality agreement	New Member/s	1 day
8	Filing of appointment documents and CV's in the membership file (see SOP 27 on Managing Active Files)	Staff	1 day

1.5. Detailed Instruction

1.5.1. Call for nomination

The Chair informs the Medical Center Chief through PETRO regarding the need for new member/s. The call for nomination shall be based on qualifications and requirements stated in the international, national and institutional policies. It shall require accomplishment of a nomination and acceptance of nomination form (Form 1.6), and submissions of other documents, e.g CV (form 1.2). The call of nominations is coursed through the heads of units or other entities that the authorities deemed to be concerned.

1.5.2. Receipt of nominations

The nominators submit the nomination and acceptance of nomination form (Form 1.6) and other required documents including CVs to the REC Office. The Staff checks the completeness of the nominations, e.g. CVs of the nominees, Ethics training record, endorsement of the unit/department, etc."

1.5.3. Shortlisting of nominees

The Chair prepares a shortlist of the nominees for regular members based on requirements and qualifications.

1.5.4. Endorsement of Short-listed nominees to the Medical Center Chief

The Chair submits the names of short-listed nominees to the Medical Center Chief for approval and subsequent appointment.

1.5.5. Receipt of Hospital Order of new members

The Staff receives the Hospital Order from the Medical Center Chief and informs the Chair accordingly. He/She then prepares the appointment papers for the new members. The appointment papers shall specify the conditions of the appointment including the roles and responsibilities. (Form 1.1).

1.5.6. Forwarding of Appointment papers to the new members:

The Medical Center Chief sign the appointment papers as noted and dated then the Chair instructs the staff to forward the documents to the concerned new member.

1.5.7. Signing the conforme, and the conflict of interest disclosure and confidentiality agreement

The new member/s signs the confidentiality and conflict of interest disclosure agreements (Form 1.3).

1.5.8. Filing of appointment documents and CVs and signed Agreements in the membership file: See SOP 27 on Management of Active Files.

Requirement for Membership

1. The National Center for Mental Health-REC shall be composed of at least nine (9) members.
2. Membership shall be multi-disciplinary and multi-sectoral to ensure diverse background and experience.
3. The REC Members should have diverse background and experience to foster a comprehensive and efficient review of research activities commonly conducted by the NCMH-REC and Non-NCMH researchers.

4. The membership shall include persons whose primary concerns are in Medical and/or Public Health, with at least one (1) Member who is in a Non-Medical / Non-Scientific area, and at least one (1) Member who is not affiliated with the National Center for Mental Health.
5. Relevant expertise may include Medicine and Research, Social or Behavioural Science, Law, Philosophy, Environmental Science and Public Health. It is recommended that the REC should include a person who will represent the interest and concerns of the community.
6. The REC shall aim for gender balance in its membership with adequate representation of men and women members in order to promote gender sensitivity in its review procedures.
7. The REC shall have representatives from both the older and younger generations
8. The REC shall invite Independent, when necessary, to provide expert opinion related to protocols under review.
9. The REC shall adhere to quorum requirements as defined in International and National guidelines for RECs that review health research (50% plus one). When reviewing clinical trials involving children or pediatric patients, a Pediatrician or Child Development Specialist shall be present during its Board meeting.

The appointed member will be given an appointment letter and confidentiality and conflict of interest agreements for signing. S/he will submit the signed documents and updated CV to the Staff for filing on membership documents.

The Membership Files shall contain the following:

1. Appointment letter signed and dated by the appointee
2. Updated Curriculum Vitae that is signed and dated by the Member (CV is updated every time the appointment is renewed)
3. Training record and photocopy of training certificates of relevant trainings
4. Confidentiality and Disclosure of Conflict of Interest Agreement signed and dated by the Member
5. The REC Secretariat creates one (1) membership file for each Member, and files the following documents in each member's file:
   a) Letter of Appointment
   b) Curriculum Vitae
   c) Training Records
   d) Confidentiality and Disclosure of Conflict of Interest Agreement

Resignation, Disqualification, and Replacement of Members

1. Members may resign their positions by submitting a letter of resignation to the Chairperson and endorsed to the Medical Center Chief.

2. Members may be separated from the REC by disqualification for valid reasons as determined by majority vote of the Committee Members.

3. Members who have resigned or have been disqualified may be replaced by following the nomination and appointment procedures previously stated.

4. The terms of replacement shall be limited to the remaining term of the member that s/he has replaced.

1.6. Forms

1.6.1. Form 1.6 Nomination and Acceptance of Nomination Form
1.6.2. Form 1.2 CV Form
1.6.3. Form 1.1.4 Appointment Letter - Non-Scientist/Non-Medical
1.6.4. Form 1.1.5 Appointment Letter - Non-affiliated
1.6.5. Form 1.3 Confidentiality and Conflict of Interest Agreement
1.6.6. Form 1.4 REC Trainings

1.7. History

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres Ms. Leticia Dizon	Adopted the 2017 DOH SOP
2	February 15, 2021	SOP Team	Composition: Independent and Alternate Consultants, added Described how the non-affiliated member is appointed and rationale for appointing non-affiliated member Described how alternate members are appointed as well

			as duties and responsibilities Responsibilities of Independent Consultant, added
3	April 27, 2021	Dr. Christopher Christian Chu	Added a procedure on nomination and appointment of officers Composition: (b), added Nomination: (f) added Responsibilities of REC Member, Non-Medical Member
5	November 15, 2021	SOP Team	Revised Appointment of Alternate Members (d) Added Duties of Alternate member (i) Purpose: Added second paragraph, selection of REC members Scope: added second paragraph, selection process 1.5.1 - 1.5.6 changed title/procedure to be consistent with the 1.4 Process Flow/Steps 1.5.3 revised procedure, to be consistent with title 1.5.4.5 – 1.5.4.6 Appointment of Members/Alternate Members, revised
6	October 19-20, 2022	Dr. Hyacinth C. Manood	Real-time revision during SOP Workshop:

			Added Policy Statement Responsibility deleted Added Forms Timeline added in Process Flow
7	March 21, 2023	SOP Team	Deleted Alternate member in Policy Statement and in Detailed Instruction 1.5.3. Separated Appointment letters of Members (Recommended by PHREB-CSA) *Form 1.1 Scientist/Medical* *Form 1.1.4 Non-Scientist/Non-Medical* *Form 1.1.5 Non-affiliated*

2.1. Policy Statement

The NCMH-REC shall have a Chair - who shall be appointed by the Medical Center Chief with at least three (3) years of experience as member of level 3 PHREB-Accredited REC. He/She need not be affiliated with the institution. The NCMH-REC shall also have a Vice-Chair and Committee Secretary, who shall be selected among the members who are full-time employees of the institution and have been with the committee for at least three (3) years. The election will be conducted in a special meeting presided by the REC Chair. They should have training on Basic Research Ethics, Good Clinical Practice in Research and advanced courses in Research Ethics for the past three (3) years.

2.2. Purpose

Designation of REC officers aims to ensure that the REC officers are qualified and are selected in a transparent manner in conformity with institutional policy and practice.

2.3. Scope

This SOP begins with the call for a special meeting to elect the concerned officers and ends with the filing of appointment documents of the officers.

2.4. Process Flow

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Call for a special meeting (SOP 21 on Preparing for a Meeting)	Chair	1 day
2	Nomination of specific official	Members	1 day
3	Election of specific official	Members	
4	Endorsement	Chair	1 day
5	Receipt of Appointment of new officers	Staff	1 day
6	Signing of Conforme	New Officers	1 day
7	Filing of appointment documents (SOP 27 on Managing Active Files)	Staff	1 day

2.5. Detailed Instructions

2.5.1. Call for a Special Meeting

The Staff, upon instruction of the Chair, sends a Notice of Meeting (Meeting Agenda Template Form 4.1) to all members of the REC stating the purpose of the meeting to be the election of (an) officer/s. (See SOP 21 on Preparing for a Meeting)

2.5.2. Nominations

The Chair presides over the nomination process for the Vice-Chair and Member Secretary.

2.5.3. Election of specific official

Election of officers shall be by secret ballot and is based on the majority rule. A tie shall be settled by another round of secret ballot.

2.5.4. Endorsement

The list of elected officers is submitted to the Medical Center Chief.

2.5.5. Receipt of appointment of new officers

The REC officer receives the appointment papers of the elected officers that contain the role and responsibilities of the specific officers and the corresponding term of office. (Form **1.1.1** Appointment Letter for Chair, **Form 1.1.2** Appointment Letter for Vice Chair and Form **1.1.3** Appointment Letter for Member Secretary)

2.5.6. Signing of Conforme

The Staff notifies the officers of their appointments and the need to sign the conforme. The concerned officers forthwith report to the REC office to sign the conforme documents.

2.5.7. Filing of appointment documents

The Staff files the appointment papers accordingly
(See SOP 27 on Management of Active Files)

2.6. Forms

2.6.1. Form 4.1 Meeting Agenda Template Form
2.6.2. Form 1.1.1 Appointment Letter for Chair
2.6.3. Form 1.1.2 Appointment Letter for Vice Chair
2.6.4. Form 1.1.3 Appointment Letter for Member Secretary

2.7. History

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres Ms. Leticia Dizon	Adopted the 2017 DOH SOP

3	April 27, 2021	Dr. Christopher Christian Chu	Designated in the SOP who takes over the functions of the Chair in his/her absence Include in the duties and responsibilities of the Member-Secretary: classify the type of review and appointment of the primary reviewers Include in the function of the Chair the responsibility to update the REC on relevant and current issues in research ethics Added Responsibilities of Vice-Chairperson, Medical Members, Non-Medical Members, Non-Affiliated
5	November 15, 2021	SOP Team	Added Purpose, Scope, Responsibility, Process Flow/Steps Responsibility of the Chairperson, added #4
6	October 19-20, 2022	Dr. Hyacinth C. Manood	Real-time revision during SOP Workshop: Election of Chair deleted since Chair is appointed by Medical Center Chief Added Policy Statement Responsibility deleted Added Forms Timeline added in Process Flow

7	March 21, 2023	SOP Team	Revised Policy Statement, **from** *The Chair is the full-time employee with institution* **to** *The Chair need not be affiliated with institution.* Separated Appointment letters of Officers (Recommended by PHREB-CSA) *Form 1.1.1 Chair* *Form 1.1.2 Vice Chair* *Form 1.1.3 Member Secretary*

3.1. Policy Statement

The NCMH-REC shall invite an independent consultant whose expertise is not represented in the current membership but is needed in a study under review. He/She need not be affiliated with the institution.

3.2. Purpose

This activity ensures that the appointment of independent consultants conforms with the institutional practice and complements the pool of expertise in the REC.

3.3. Scope

This SOP begins with the identification of the study that requires an independent consultant and ends with the inclusion of the name of the Independent Consultant in the pool of consultants.

3.4. Process Flow

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Identification of the study that requires an independent consultant	Chair and Member-Secretary	1 day
2	Identification of the independent consultant	Chair and Member-Secretary	1 day
3	Invitation of the independent consultant	Chair	1 day
4	Appointment of independent consultant	Staff	1 day
5	Filing of appointment documents (SOP 26 on Managing Active Files SOP)	Staff	1 day
6	Inclusion in the pool of independent consultants	Staff	1 day

3.5. Detailed Instructions

3.5.1. Identification of the study that requires an independent consultant.

Either the Member-Secretary or the Chair identifies the study that requires an expertise necessary in the review of a research proposal and that may not be provided by the current members of the REC.

3.5.2. Identification of the independent consultant:

The Chair refers to the roster of specialists in the institution or in other institutions for the necessary expertise and selects an appropriate expert. He/She instructs the Staff to prepare letter of invitation.

3.5.3. Invitation to the independent consultant

The Staff prepares a letter of invitation (Form 1.5) containing the Terms of Reference for signature of the Chair and sends this to the identified expert. The letter of invitation contains a section for acceptance of the invitation.

3.5.4. Appointment of Independent Consultant

Upon receipt of the acceptance of the invitation, the Staff prepares a letter of appointment (Form 1.1.6) for signature of the Medical Center Chief and sends the appointment to the independent consultant together with the Confidentiality and Conflict of Interest Agreement (Form 1.3).

3.5.5. Filing of appointment documents

The Staff files the appointment papers accordingly (see SOP 27 on Management of Active Files) The Independent Consultant Files shall contain the following:

1. REC letter of invitation signed and dated by the REC Chairperson
2. Updated Curriculum Vitae that is signed and dated by the Independent Consultant (CV is updated every time the appointment is renewed)
3. Training record and photocopy of training certificates of relevant trainings
4. Confidentiality and Disclosure of Conflict of Interest Agreement signed and dated by the Independent Consultant

3.5.6 Inclusion in the pool of independent consultants

The Staff enters the name of the new independent consultants in the appropriate database containing name, expertise, institution and date of appointment.

3.6. Forms

3.6.1. Form 1.5 Letter of Invitation Form
3.6.2. Form 1.1.6 Appointment Letter for Independent Consultant
3.6.3. Form 1.3 Confidentiality and Conflict of Interest Agreement

3.7. History

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres Ms. Leticia Dizon	Adopted the 2017 DOH SOP
2	February 15, 2021	SOP Team	Added specific review responsibilities of the Independent Consultant

5	November 15, 2021	SOP Team	Rephrased Detailed Instruction Added #4, Specific review responsibility of the Independent Consultant
6	October 19-20, 2022	Dr. Hyacinth C. Manood	Real-time revision during SOP Workshop; Added Policy Statement Responsibility deleted Added Forms Steps in Process flow and Detailed Instructions revised; Timeline added in Workflow
7	March 21, 2023	SOP Team	*Separated Appointment letters of Independent Consultant (Recommended by PHREB-CSA)* *Form 1.1.6* *Independent Consultant* *Added in Form 1.5, that the independent consultant does not have voting privilege during the* *REC meeting*

4.1. Policy Statement

Study protocols may be exempted from ethical review based on the criteria listed in the 2017 National Ethical Guidelines for Health and Health-related Research (NEGHHR 2017) The Research Ethics Review Process Guideline 3.1. The decision to exempt from review rests on the REC Chair for efficiency and in the interest of time.

Study protocols that may be exempted are (1) Research about public behavior (voting trends, opinion surveys, etc.), (2) Evaluation of public programs and Quality control studies by the agency itself, (3) Standard educational tests and curriculum development, (4) Surveillance functions of DOH and Historical and cultural events, (5) Research involving large statistical data without identifiers, Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols) shall be exempted from ethical review. Any alteration in exempted protocols shall invalidate the approval of the protocol. A final report shall be submitted to REC at end of the exempted study.

4.2. Purpose

This SOP aims to classify research protocols that will not require ethical review.

4.3. Scope

This SOP applies to a study protocol submitted that qualifies the criteria for exemption from ethics review. This SOP begins when the Chair decides that the protocol is exempted from review and ends with the Filing of documents in the protocol file folder and update the protocol database.

4.4. Process Flow

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Approve protocol that exempt from review based on Exemption Criteria	Chair	1 day
2	Preparation of Certificate of Exemption	Staff	1 day
3	Grant the Certificate of Exemption to the Principal Investigator	Staff/Chair	1 day
4	Filing of documents in the protocol file folder and update the protocol database	Staff	1 day
5	Inclusion of the exempt from review in the Agenda of the next REC regular meeting	Staff	1 day

4.5 Detailed instructions

4.5.1 Approve protocol that exempt from review based on Exemption Criteria

4.5.1.1. The Chair will approve the study protocol that qualifies the following exemption criteria:

1. Research about public behavior (voting trends, opinion surveys, etc.)
2. Evaluation of public programs by the agency itself
3. Quality control studies by the agency itself
4. Standard educational tests and curriculum development
5. Surveillance functions of DOH
6. Historical and cultural events
7. Research involving large statistical data without identifiers
8. Research not involving humans or human data
9. Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols) shall be exempted from ethical review)
10. Provided that the following do not involve more than minimal risks or harms, these protocols may be considered by the REC for exemption from review.

    a. Protocols for institutional quality assurance purposes, evaluation of public service programs, public health surveillance, educational evaluation activities, and consumer acceptability tests;

    b. Research that only includes interactions involving survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if the following criteria are met:

    - There will be no disclosure of the human participants' responses outside the research that could reasonably place the participants at risk of criminal or civil liability or be damaging to their financial standing, employability, or reputation; and

- The information obtained is recorded by the investigator in such a manner that the identity of the human participant cannot readily be ascertained, directly or through identifiers lined to the participant.

11. Protocols that involve the use of publicly available data or information.

4.5.1.2. If the Chair decides that the protocol is exempted from review, s/he directs the staff to prepare a Certificate of Exemption.

4.5.2 Preparation of Certificate of Exemption

The Staff prepare a Certificate of Exemption from Review (Form 2.8) and forwards to the Chair for signature.

4.5.3 Grant the Certificate of Exemption to the Principal Investigator

Once signed, the Staff will release the Certificate of Exemption from Review (Form 2.8) to the Principal Investigator.

IMPORTANT REMINDER:

- The REC must be notified for any amendment on exempted protocols are not allowed and shall invalidate the approval of the protocol in which case it may be submitted as new protocol for initial review.

- Submission of final report at the end of exempted study.

4.5.4. Filing of documents in the protocol file folder and update the protocol database

The complete protocol folder, including all protocol-related documents, is filed for safekeeping in the storage cabinet and update protocol database for exemption from review.

4.5.5. Inclusion of the exempt from review in the Agenda of the next REC regular Meeting

See SOP 22 on Preparation for the Meeting Agenda

4.6. Forms

4.6.1. Form 2.8 Certificate of Exemption from Review

4.7. History

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres Ms. Leticia Dizon	Adopted the 2017 DOH SOP
3	April 27, 2021	SOP Team	Edited, Person Responsible #1, #4 Revised Detailed Instruction #3, report exempted protocol during the board meeting which include: name of PI, protocol code, sponsor, title, reason for exemption
4	July 07, 2021	SOP Team	Added, types of documents/researches exempted
5	November 15, 2021	SOP Team	Clarified who reviews exemption. Edited Process Flow / Steps and Detailed Instruction #2 Added 4.5.2 #2
6	October 19-20, 2022	Dr. Maria M. Daz	Real-time revision during SOP Workshop: • Added Policy Statement • Responsibility deleted • Added Forms
7	March 21, 2023 June 15, 2023	SOP Team SOP Team	Separated SOP for exemption as *(Recommended by PHREB-CSA)* Added "Any alteration in exempted protocols shall invalidate the approval of the protocol. A final report shall be submitted to REC at end of the exempted study." as *(Recommended by PHREB-CSA)*

5.1. Policy Statement

An expedited review shall be conducted for study protocols that **(1)** do not entail more than minimal risk to the study participants, and **(2)** do not have study participants belonging to a vulnerable group, and **(3)** the study procedures do not generate vulnerability. The results of the initial review shall be released to the principal investigator within twenty one **(21)** days after the submission of all the required documents. The study protocol that underwent expedited review and approved shall be reported in the subsequent regular committee meeting.

5.2. Purpose

Expedited Review aims to demonstrate due diligence and high standards in the system of protection of human participants.

5.3. Scope

This SOP begins with the determination of qualified protocols for expedited review and ends with the inclusion of the review in the agenda of the next meeting.

5.4. Process Flow

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Assignment of primary reviewers	Chair	2 days
2	Notification and Provision of documents and evaluation forms (Form 2.3 and 2.4) to reviewers	Staff	3 days
3	Review the documents with the use of the assessment forms	Primary Reviewers	7 days
4	Accomplishment and Submission of evaluation forms	Primary Reviewers	4 days
5	Consolidation and Finalization of the review results	Chair and Staff	3 days
6	Communication of review results to the primary investigator	Staff	2 days
7	Filing of documents in the protocol file folder and updating the protocol database	Staff	1 day
8	Inclusion of the Review in the Agenda of the next REC regular meeting	Member-Secretary	1 day

5.5 Detailed instructions

5.5.1 Assignment of primary reviewers

5.5.1.1. The Chair will conduct Preliminary review to go over the submitted protocol to decide on the type of review to be applied.

1. An expedited review can be done at the level of the primary reviewers or the Chair, for proposals that do not need a full review, such as the following:
    - Chart review
    - Survey of non-sensitive nature
    - Use of anonymous or anonymized laboratory/pathology samples or stored tissues or data

2. Protocols referred by the Single Joint Research Ethics Board (SJREB) classified for Expedited Review by the REC Chair. (See SOP 6 on SJREB Protocol Review)

3. Any protocol for resubmission shall be subject to Expedited Review if the study satisfies any of the following criteria: (See SOP 9 on Management of Resubmissions)

    - Administrative revisions, such as correction of typing error
    - Addition or deletion of non-procedural items, such as the addition of study personnel names, laboratories, etc.
    - Minor protocol modifications that do not change the risk/benefit assessment

5.5.1.2. Once decided that the study satisfied any of the criteria to be classified for Expedited Review, the Chair shall assign at least two (2) NCMH-REC members to be the Primary Reviewer for expedited review. Preferably be composed of a Medical member (affiliated or nonaffiliated) with related expertise to review the protocol.

5.5.1.3. The Chair shall assign Non-Medical member (affiliated or nonaffiliated) to review the informed consent.

5.5.1.4. If there are no REC members with field of expertise to adequately review the scientific aspect of the study protocol, an Independent Consultant may be invited to join the protocol review. (See SOP 3 on Appointment of Independent Consultants)

5.5.1.5. For Post Approval Review of amendments, progress report, final report and other protocol related documents that qualify for expedited review will be conducted by members who have reviewed the original protocol.

5.5.1.6. The Chair then shall return the protocol with decision to Staff to facilitate distribution for primary review

5.5.2. Notification and provision of documents and evaluation forms (Form 2.3 and 2.4) to reviewers

5.5.2.1. The REC Staff gathers the pertinent documents; *for initial submissions:* the complete protocol and related documents; *for post approval submissions:* the pertinent information from the retrieved protocol and the report itself. The REC Staff prepares copies of the protocol and/or protocol-related documents and assessment forms for delivery, either through manual delivery or through electronic mail, to the primary reviewers and/or independent consultants, if any.

5.5.2.2. The Staff notifies the designated Primary Reviewers and given three (3) days after notification to respond. This provides the primary reviewers opportunity to assess any conflict of interest, availability and suitability to make the necessary review. If they can review the protocol documents within the seven (7) days deadline. If not, other primary reviewers are identified.

5.5.3. Review the documents with the use of the assessment forms

5.5.3.1 The Primary Medical Reviewer (affiliated or nonaffiliated) accomplishes both the Protocol Evaluation Form (Form 2.3) and Informed Consent Evaluation Form (Form 2.4)

5.5.3.2. The primary Non-Medical reviewer (affiliated or nonaffiliated) evaluates Informed Consent documents by using the Informed Consent Evaluation Form (Form 2.4)

5.5.3.3. The Primary Reviewers sign and date the assessment form/s.

5.5.4. Submission of evaluation forms

5.5.4.1. The Primary Reviewers submit the Assessment forms within (7) seven days from the receipt of the protocol review documents and may be submitted in hard copies, duly signed and dated. Electronic copy of the assessment forms may likewise be submitted provided bearing the e-signature of the Primary Reviewers. Electronic copy will be printed by the REC Staff.

5.5.4.2. REC Staff shall check for completeness in entries in the form.

5.5.5. Consolidation and Finalization of the review results.

5.5.5.1 The Chair will consolidate and finalize the review results. In case of differing opinions, Chair may mediate to reach an agreement, and may have the final say. In case of considerable difference and voting cannot be reached, the Chair may refer the protocol to the REC board for full review. (Refer to SOP on Full Review).

5.5.5.2. The comments and decision are consolidated by the staff and given to the Chair for approval prior sending of notification letter (Form 3.10) to the Principal Investigator.

The Primary Reviewers decide whether the protocol can be approved, modified or disapproved.

- The reviewers recommend approval if there are no issues. Approval Letter (Form 2.7) and Certificate of Approval (Form 2.6) are issued to the Principal Investigator.

- If there are findings, reviewers shall recommend revisions. Notification letter (Form 3.10) is issued to the Principal Investigator.

  Resubmission of a protocol that requires either minor or major modification/s, The Principal Investigator will comply 15 days after receipt of the Notification letter (Form 3.10).

  Review of resubmission will be conducted by the original primary reviewers. Minor modifications undergo expedited review, while major changes undergo full board review.
  (Refer to SOP 10 Management of Resubmissions)

- Disapproved protocols are automatically forwarded to Full Board for discussion and decision. Disapproval cannot be done at the Expedited level.

5.5.5.3. Recommended revisions may be classified as follows:

- *Minor modification* – a recommended revision applying to protocols found to have particular aspect/s on its study or related document that

do not impact on potential risks/harms to participants and on the integrity of the research (e.g. incomplete documentation, informed consent elements, unsatisfactory informed consent format). To wit:

1. Administrative corrections like typographical errors or grammar
2. Minor changes on items not directly related on procedure to be done
3. Revisions will not impact risk-benefit example: additional related literature requested

- *Major modification* – a recommended revision applying to protocols found to have significant aspect/s of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data, statistical analysis, mitigation of risk, protection of vulnerability, etc.) that impact on potential risks/harms to participants and on the integrity of the research . To wit :

1. If there will be major revisions on either the protocol or informed consent form; such as inclusion/exclusion criteria, safety issues, methodology, that may impact on the scientific validity of the protocol
2. Revision will have impact on the risk-benefit ratio

5.5.6 Communication of review results to the Principal Investigator

5.5.6.1. As soon as the decision of Primary Reviewers is reached, the decision is communicated to the principal investigators within seven (7) days after receipt of Expedited review results. (See SOP 24 on Communicating REC Decisions)

5.5.7. Filing of documents in the protocol file folder and updating the protocol database.
See SOP 26 on Managing Active Files

5.5.8. Inclusion of the Review in the Agenda of the next REC regular meeting
See SOP 21 on Preparation for the Meeting Agenda

5.6. Forms

5.6.1. Form 2.3 Protocol Evaluation
5.6.2. Form 2.4 Informed Consent Evaluation
5.6.3. Form 3.10 Notification Letter

5.7. History

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres Ms. Leticia Dizon	Adopted the 2017 DOH SOP
3	April 27, 2021	SOP Team	Added Process Flow/Detailed Instruction #7, indicated the notification/approval letter will be approved and signed by the Chair
4	July 07, 2021	SOP Team	Edited Detailed Instruction #5, consolidation of approval prior communication to PI
5	November 15, 2021	SOP Team	Edited Detailed Instruction #2, who assign reviewers; #8, communication to PI thru Notification form
6	October 19-20, 2022	Dr. Maria M. Daz	Real-time revision during SOP Workshop: Added Policy Statement Responsibility deleted Added Forms
7	March 21, 2023	SOP Team	Revised Timeline from 14 days to 21 days Added how the review of post-approval reports that qualify for expedited and State clearly the decision points

			Deletion of phrase "protocol documents are returned to the researchers" from 4.5.3.3 (Recommended by PHREB-CSA)

6.1. Policy Statement

A full review shall be conducted when a proposed study entails more than minimal risk to study participants or when study participants belong to vulnerable groups or when a study generates vulnerability to participants. Only protocols submitted for, at least, fourteen (14) days before a scheduled meeting shall be included in the agenda for full review. Full review shall be conducted through a primary reviewer system. If necessary, independent consultants and/or the Principal Investigator shall be invited during the meeting to clarify certain issues. The decision shall be communicated to the Principal Investigator within forty-two (42) days after submission of required documents.

6.2. Purpose

A full review aims to ensure compliance with technical and ethical standards in the conduct of researches involving human participants and identifiable human data and materials

6.3. Scope

This SOP begins with the assignment of primary reviewers or independent consultant/s and ends with the filing of protocol-related documents.

6.4. Process Flow

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Assignment of primary reviewers or Independent Consultant/s	Chair	1 day
2	Notification and Provision of documents and evaluation forms (Form 2.3 and 2.4) to reviewers	Staff	3 days
3	Review the documents with the use of the assessment forms	Primary Reviewers	21 days
4	Provision of protocol and protocol-related documents to the rest of the committee members	Staff	
5	Presentation of review findings and recommendations during a Committee meeting (SOP 22 on Conduct of Meeting)	Primary Reviewers	1 day
6	Discussion of technical and ethical issues	Members	

7	Summary of issues and resolutions	Chair	
8	Committee action	Chair and Members	
9	Documentation of Committee deliberation and action (SOP 23 on Preparing the Meeting Minutes)	Staff	1 day
10	Communication of Committee Action (SOP 24 Communicating REC Decisions)	Chair and Staff	1 day
11	Filing of protocol-related documents and Updating of the Protocol Database	Staff	1 day

6.5. Detailed Instructions

6.5.1. Assignment of primary reviewers or Independent Consultant/s:

6.5.1.1. The Chair will conduct Preliminary review to go over the submitted protocol to decide on the type of review to be applied.

Criteria for protocols to be classified as subject to Full board Review are as follows:

1. Human Health Research involving medium to high risk to human participants.
2. Intervention studies involving experimental treatments like clinical trials
3. May involve vulnerable populations who should be protected
4. Involves private information that may cause stigma
5. Protocols referred by the Single Joint Research Ethics Board (SJREB) classified for Full board Review by the REC Chair. (See SOP 6 on SJREB Protocol Review)

6.5.1.2. Once decided that the study satisfied any of the criteria to be classified for Full-board Review, the Chair shall assign at least two (2) NCMH-REC members to be the Primary Reviewer. Preferably be composed of a Medical member (affiliated or nonaffiliated) with related expertise to review the protocol.

6.5.1.3. The Chair will assign Non-Medical member (affiliated or nonaffiliated) to review the informed consent.

6.5.1.4. If there are no REC members with field of expertise to adequately review the scientific aspect of the study protocol, an Independent Consultant may be invited to join the protocol review. (See SOP 3 on Appointment of Independent Consultants)

6.5.1.5. For Post Approval Review of amendments, progress report, final report and other protocol related documents that qualify for full board review will be conducted by members who have reviewed the original protocol.

6.5.1.6. The Chair then will return the protocol with decision to Staff to facilitate distribution for primary review

6.5.2. Notification and Provision of documents and evaluation forms to primary reviewers

6.5.2.1. The REC Staff gathers the pertinent documents; *for initial submissions:* the complete protocol and related documents; *for post approval submissions:* the pertinent information from the retrieved protocol and the report itself. The REC Staff prepares copies of the protocol and/or protocol-related documents and assessment forms for delivery, either through manual delivery or through electronic mail, to the primary reviewers and/or independent consultants, if any.

6.5.2.2. The Staff notifies the designated Primary Reviewers and given three (3) days after notification to respond. This provides the primary reviewers opportunity to assess any conflict of interest, availability and suitability to make the necessary review. If they can review the protocol documents within the seven (7) days deadline. If not, other primary reviewers are identified.

6.5.3. Review the documents with the use of the assessment forms

6.5.3.1 The Primary Medical Reviewer (affiliated or nonaffiliated) accomplishes both the Protocol Evaluation Form (Form 2.3) and Informed Consent Evaluation Form (Form 2.4)

6.5.3.2. The primary Non-Medical reviewer (affiliated or nonaffiliated) evaluates Informed Consent documents by using the Informed Consent Evaluation Form (Form 2.4)

6.5.3.3. The Primary Reviewers sign and date the assessment form/s.

6.5.4. Submission of evaluation forms

6.5.4.1. The Primary Reviewers submit the Assessment forms within (7) seven days from the receipt of the protocol review documents and may be submitted in hard copies, duly signed and dated. Electronic copy of the assessment forms may likewise be submitted provided bearing the e-signature of the Primary Reviewers. Electronic copy will be printed by the REC Staff.

6.5.4.2. REC Staff shall check for completeness in entries in the form.

6.5.5. Provision of protocol and protocol-related documents to the rest of the committee members

The staff provides the rest of the members of the REC with an executive summary of the study proposal (included among the submitted documents in the Application, (Form 2.1 and Form 2.2) three (3) days before the committee meeting, at the latest.

6.5.6. Presentation of review findings and recommendations during a committee meeting:

The Staff provides the submitted findings and recommendations by primary reviewers (Form 2.3 Protocol evaluation and Form 2.4 ICF evaluation) to the Chair 3 days before the meeting and presents these during the actual meeting. If a primary reviewer cannot attend the meeting, the Chair exercises his/her prerogative to take over the role of the primary reviewer so that the meeting can proceed.

6.5.7. Discussion of technical, ethical and Informed consent issues:

The Chair leads the discussion of the technical and ethical issues using the protocol evaluation form (Form 2.3) and the Informed Consent evaluation form (Form 2.4) for an orderly exchange of ideas.

6.5.8. Summary of issues and resolutions

The Primary reviewers summarizes the technical and ethical issues that were identified, the issues that were resolved /not resolved, including the recommendations for the issues that were not resolved.

6.5.9. Committee action

The Chair emphasizes the points discussed by all members in a summary and recommends action for compliance and proposes the action. Committee decides on action which may be either of the following:

- Approved
- Minor Modifications
- Major Modifications
- Disapproved

Decision of the REC is arrived at by voting and the majority decision is arrived at and is adopted. If there is a strong objection, the deliberation continues until the strong objector is convinced. A clarificatory interview with the Principal Investigator may be requested.

6.5.10. Documentation of committee deliberation and action

See SOP 24 on Preparation of Meeting Minutes.

6.5.11. Communication of Committee Action

6.5.11.1. As soon as committee decision is reached, the decision is communicated to the principal investigators within seven (7) days from scheduled REC protocol review meeting. (See SOP 25 on Communicating REC Decisions)

- The REC recommend approval if there are no issues. Approval Letter (Form 2.7) and Certificate of Approval (Form 2.6) are issued to the Principal Investigator.

- If there are findings, reviewers shall recommend revisions. Notification letter (Form 3.10) is issued to the Principal Investigator.

  Resubmission of a protocol that requires either minor or major modification/s, The Principal Investigator will comply 15 days after receipt of the Notification letter (Form 3.10).

Review of resubmission will be conducted by the original primary reviewers. Minor modifications undergo expedited review, while major changes undergo full board review.
(Refer to SOP 9 Management of Resubmissions)

- In the case of disapproval the principal investigator may appeal the decision if deemed necessary. Principal Investigator will receive the Notice of REC Decision (Form 3.10). (Refer to SOP 19 Management of Appeals)

6.5.11.2. Recommended revisions may be classified as follows:

- *Minor modification* – a recommended revision applying to protocols found to have particular aspect/s on its study or related document that do not impact on potential risks/harms to participants and on the integrity of the research (e.g. incomplete documentation, informed consent elements, unsatisfactory informed consent format). To wit:

    1. Administrative corrections like typographical errors or grammar
    2. Minor changes on items not directly related on procedure to be done
    3. Revisions will not impact risk-benefit example: additional related literature requested

- *Major modification* – a recommended revision applying to protocols found to have significant aspect/s of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data, statistical analysis, mitigation of risk, protection of vulnerability, etc.) that impact on potential risks/harms to participants and on the integrity of the research . To wit :

    1. If there will be major revisions on either the protocol or informed consent form; such as inclusion/exclusion criteria, safety issues, methodology, that may impact on the scientific validity of the protocol
    2. Revision will have impact on the risk-benefit ratio

(See SOP 25 on Communicating REC Decisions to the Researcher/Principal Investigator)

6.5.12. Filing of protocol-related documents and Updating of the Protocol Database:

(See SOP 27 on Managing Active Files)

6.6. Forms

6.6.1. Form 2.3 Protocol Evaluation
6.6.2. Form 2.4 Informed Consent Evaluation
6.6.3. Form 3.10 Notification Letter

6.7. History

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres Ms. Leticia Dizon	Adopted the 2017 DOH SOP
2	February 15, 2021	SOP Team	Added on Detailed Instruction #7, responsibilities of Chairperson prior approval
3	April 27, 2021	Dr. Christopher Christian Chu	Added, Instructions on Initial Review, Resubmission and Post Approval Review Indicated criteria for minor and major modification
4	July 07, 2021	SOP Team	Edited Detailed Instruction #6, approval of protocol related documents
5	November 15, 2021	SOP Team	Edited Detailed Instruction #6 to, frequency of Progress Report
6	October 19-20, 2022	Dr. Maria Meliza M. Daz	Real-time revision during SOP Workshop:

			Added Policy Statement Responsibility deleted Added Forms
7	March 21, 2023 June 15, 2023	SOP Team SOP Team	Added how the review of post-approval reports that qualify for Full board review and State clearly the decision points Revised 6.5.6 to Discussion of technical, ethical and Informed consent issues Revised 6.5.8 Categorized For Modification to: Minor Modifications Major Modifications (*recommended by PHREB-CSA)*

7.1. Policy Statement

Single Joint Ethics Review Board (SJREB) is a joint review mechanism among PHREB duly accredited Research Ethics Committees (RECs) of DOH hospitals. It is a cooperative mechanism, rather than a stand-alone REC, that draws its review authority from RECs duly accredited by the Philippine Health Research Ethics Board. SJREB conducts joint review of study protocols to be implemented in at least three (3) sites in the Philippines. Sponsors and researchers who choose to do their studies in 3 or more sites may submit their protocols to SJREB. It accepts multi-site protocols that are funded by DOH, PCHRD, DOST, PHIC, PHREB, CHED and other local organizations, including industry organizations and other foreign entities. Sponsors or PI or its representative may submit their protocol to NCMH-REC in parallel to their submission to the SJREB. The REC shall agree and abide with the procedures that SJREB follows. It shall provide the necessary environment to ensure the safe and ethical conduct of research.

7.2. Purpose

The objective of activities described is to ensure that study documents are complete, properly recorded, and properly evaluated to determine appropriate action or type of review to be applied for protocols on initial submission on protocol for SJREB of which NCMH is one of the sites of the research proposal.

7.3. Scope

This SOP begins with the Receipt of invitation to join SJREB review and ends with forward the evaluation to SJREB Secretariat.

7.4. Process Flow

NO.	ACTIVITY	PERSON/S RESPONSIBLE	Timeline
1	Receipt of invitation to join SJREB review	Staff	1 day
2	Submission of membership roster/letter of intent*	Staff	1 day
3	Participation in SJREB meeting	Chair/Members	1 day
4	Receive the initial protocol related documents	Primary Reviewer	3 days

5	Inclusion of SJREB approved protocol in REC meeting	Chair/Staff	1 day
6	Forward the Assessment forms to SJREB Secretariat	Staff	1 day
7	Receive progress report related documents	Staff	1 day
8	Forward the evaluation to SJREB Secretariat	Staff	1 day

7.5. Detailed Instructions

7.5.1 Receipt of invitation to join SJREB review

When invited by SJREB to participate on joint review of study protocol, NCMH-REC will have to submit a Letter of Intent, membership roster with corresponding expertise to participate in the joint review.

7.5.2 Submission of membership roster with corresponding expertise (Accredited REC) or Letter of Intent to participate in joint review

The NCMH-REC Staff should submit the membership list with their CVs and they should identify representatives qualified to do scientific and ethical review for various types of protocols commonly submitted for review.

7.5.3 Participation in SJREB meeting

If attending as level 2 accredited REC, NCMH-REC representative can vote during the review of public health protocols and clinical research not intended for FDA registration. If as level 3 accredited representative, REC can vote for the same and during full board review of clinical trial protocols intended for FDA registration. However, pending accreditation, NCMH-REC retains the option to accept or reject SJREB decision.

7.5.4 Receive the initial protocol package

The Primary Reviewer will receive the transmittal letter, initial protocol package, SJREB Protocol Assessment Form and Informed Consent Form from SJREB Secretariat. The package includes:

- Review Application Form
- Protocol Summary Sheet
- Sites where the protocol will be implemented
- CVs of the coordinating PI and site PIs
- Research Protocol
- Versions of informed consent forms (including those translated in the local language)
- Recruitment and advertisement materials
- Investigator brochure
- Other protocol-related documents

7.5.5 Inclusion of SJREB approved protocol in REC meeting

SJREB approved protocol should be included in the REC meeting/discussion. It should be noted that:

SJREB requires the site RECs to agree and abide with the procedures that SJREB follows. All research sites should agree to provide the necessary environment to ensure the safe and ethical conduct of research, including oversight and stewardship functions as necessary, to monitor the conduct of the study. Also, site RECs are duty bound to accept the results of SJREB review where qualified DOH Hospital RECs participated in the deliberations and decision making.

All RECs participating in joint review agree to share their review responsibilities with SJREB as follows:

- Authority is shared by a duly accredited site REC with SJREB to conduct joint review with representatives from site RECs of multi-site researches. Joint review by SJREB is done only for initial review and renewal of approval. SJREB conducts full board review of clinical trials for investigational medicinal products intended for FDA registration. All participating sites are invited to send a representative to join the deliberations and arrive at a joint decision. Low risk protocols may be exempted from review or may go through expedited review procedures.
- There should be parallel submission of protocol documents to SJREB and all site REC's. Site RECs are expected to conduct a preliminary review of the protocol documents in preparation for the SJREB meeting.
- DOH Hospital RECs accept the results of joint review while non DOH Site RECs are expected to do expedited review and accept the decision of SJREB except when there are strong ethical issues that need to be addressed. All site RECs

will issue a Certificate of Approval together with Notice of REC Decision from SJREB.

- The site REC retains its review functions related to protocol amendments, SAE reports, protocol deviation and violation reports and final reports, all of which involve events at specific sites.
- The site REC maintains active collaboration and communication with SJREB for joint review to achieve its stated objectives and for mutual benefit of improving the research environment in the Philippines.

7.5.6 Forward the Assessment forms to SJREB Secretariat

The Primary Reviewers will review and use the SJREB assessment forms. It will be forwarded thereafter to the SJREB secretariat.

7.5.7 Receive progress report related documents

Primary reviewers refer to the IB and progress report document to check if the protocol and the ICF contain updated information related to patient safety. Review comments should consider the following:

1. Risk Assessment: the risks to the subjects are minimized; the risks to the subjects are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may be expected to be gained from the study.

2. Local Issues: Changes in the investigator's situation or qualifications (e.g., suspension of hospital privileges, medical license; involvement in numerous clinical trials); Evaluation, investigation and resolution of complaints related to the research, if any; Changes in the acceptability of the proposed research in terms of institutional commitments (e.g., personnel and financial resources, adequacy of facilities) and regulations, applicable national law, or standards of professional conduct of practice.); Report from third party observation of the research (including the informed consent process) carried out; Investigator concerns about trial conduct at the local site (e.g., study coordinator ineffectiveness, inability of subjects to understand sections of the informed consent document required by institutional policies), if any.

3. Trial Progress: Start date of the study and expected duration; Total subject enrolment (expected enrolment, actual enrolment, enrolment issues), subject withdrawal (number of subjects who withdrew, lost to follow-up, summary of reasons for withdrawal at local site)

7.5.8 Forward the evaluation to SJREB Secretariat

The NCMH-REC Staff forward evaluation to SJREB Secretariat.

7.6. Forms

7.6.1. SJREB Form 1 Application for SJREB Initial Review
7.6.2. SJREB Form 2 Protocol Evaluation Form
7.6.3. SJREB Form 3 Informed Consent Evaluation Form
7.6.4. SJREB Form 4 SJREB Notice for Protocol Modification
7.6.5. SJREB Form 5 Notice of Approval

7.7. History

Version No.	Date	Authors	Main Change
3	April 27, 2021	Dr. Christopher Christian Chu	Added (new) chapter on SJREB Protocol Review
4	July 07, 2021	SOP Team	Simplified/edited the whole SOP
5	November 15, 2021	Dr. Marc Joseph Oliver V. Buensalido	Edited Responsibility, Process Flow / Steps and Detailed Instruction
6	October 19-20, 2022	Dr. Maria M. Daz	Real-time revision during SOP Workshop: Added Policy Statement Responsibility deleted Added Forms

8.1. Policy Statement

Medical Device Protocols are reviewed through the same expedited (SOP 5) or full board (SOP 6) procedures depending on the level of risks involved in the study. An investigational new device is given a Significant Risk (SR) or Non-Significant Risk (NSR) classification by the regulators in the sponsor country. This information should be provided by the sponsor to the REC. The NCMH-REC should have provision to minimize the risks to human participants during review of the protocol and related documents. This activity is in preparation for the capacitation of REC to achieve its purpose.

8.2. Purpose

To capacitate NCMH-REC with basic technical knowledge and practice on how to review the uses and application of protocols related to safety and performance of medical devices as applied to human participants and to describe procedures in the review of medical device protocol submitted to NCMH-REC.

8.3. Scope

This SOP provides instructions for review and approval of medical device protocols intended for human participants submitted to NCMH-REC.

8.4. Process Flow

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receipt of protocol and protocol related documents for review and determination of the completeness of submission.	Staff	1 day
2	Entry into the Database Incoming & Outgoing Protocols	Staff	
3	Coding	Staff	
4	Determination of the Type of Review • Expedited Review (SOP 5) • Full Review (SOP 6) depending on Significant Risk (SR) or Non-Significant Risk (NSR)	Chair	3 days
5	Assignment of primary reviewers or Independent Consultant/s (SOP 3 on Appointment of Independent Consultants)	Chair	7 days
6	Conduct the review using the assessment forms and submit the decision to the Staff. (See SOP 4 for	Primary Reviewers	7 days

	expedited review and SOP 5 for Full Review).		
7	Preparation of a protocol folder	Staff	1 day
8	Entry into the database, and filing to Active Study File	Staff	1 day

8.5. Detailed Instructions

8.5.1. Receipt of protocol and protocol related documents for review and determination of the completeness of submission

The Staff checks the information/communication from the principal investigator relate to the Significant Risk (SR) or Non-Significant Risk (NSR) determination by regulators (FDA) from the sponsor country. The same procedures are followed when the protocol is submitted for initial review. (See SOP 9 on Management of Initial Submission).

8.5.2. Entry into the Database Incoming & Outgoing Protocols

(See SOP 9 on Management of Initial Submission).

8.5.3. Coding

(See SOP 9 on Management of Initial Submission).

8.5.4. Determination of the Type of Review

The protocol is assigned to an expedited SOP 5 or full board SOP 6 review by the Chair depending on the risk assessment.

Under 21 CFR 812.3(m), a **Significant Risk (SR)** device means an investigational device that:

- Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
- Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

A **Non-Significant Risk (NSR)** device study is one that does not meet the definition for an SR device study.

8.5.5. Assignment of primary reviewers or Independent Consultant/s (See SOP 3 on Appointment of Independent Consultants)

Primary reviewers or Independent Consultant with appropriate expertise are assigned to review the protocol and related documents by the Chair. It is advisable that the bio-engineer with appropriate experience related to the medical device together with a medical doctor with related clinical experience are assigned to review the protocol while a non-medical/non-scientific member reviews the consent from.

8.5.1. When reviewing a medical device protocol, the reviewer should consider the following:

- Proposed investigational plan
- Informed Consent Form
- Description of the device/Product Information
- Description of study participant selection criteria
- Safety monitoring procedures
- Reports of prior investigations conducted with the device
- Principal Investigator's Curriculum Vitae
- Risk Assessment determination for new investigational device
- Statistical Plan and analysis
- Copies of all labeling for investigational use
- FDA approval of the medical device, if applicable

8.5.6. Conduct the review using the assessment forms and submit the decision to the Staff.

The same REC Assessment forms are used for review. The Primary reviewers and Chair decide in expedited review or make a recommendation for discussion during the next full board meeting. (See SOP 5 for expedited review and SOP 6 for Full Review).

8.5.7. Preparation of a protocol folder

The Staff files the protocol documents in a protocol folder and labels it accordingly. (SOP 27 on Management of Active Files)

8.5.8. Entry into the database, and filing to Active Study File

The relevant documents are kept in the protocol file and the REC entry about the protocol is updated in the REC database.

8.6. Forms

8.6.1. Form 2.1 Application for Initial Review
8.6.2. Form 2.2 Protocol Summary Sheet
8.6.3. Form 2.3 Protocol Evaluation Form
8.6.4. Form 2.4 Informed Consent Evaluation Form
8.6.5. Database

8.7. History

Version No.	Date	Authors	Main Change
5	November 15, 2021	Dr. Romell Mendoza	Added SOP (new)
6	October 19-20, 2022	SOP Team	Real-time revision during SOP Workshop: Added Policy Statement Responsibility deleted Added Forms
7	March 21, 2023	SOP Team	Revised the whole SOP 7 adopted NKTI SOP on Review of medical devices

9.1. Policy Statement

The REC shall require the submission of pertinent documents (one (1) hard copy with red folder and soft copy) for an application for ethical review to be accepted. A preliminary evaluation shall determine whether a research proposal is exempted from or needs to undergo ethical review based on the NEGHHR 2017 the Research Ethics Review Process Guideline 3.1.

9.2. Purpose

Management of Initial Submissions ensures that study records are complete, appropriately recorded, and assessed to determine the appropriate action or type of review.

9.3. Scope

This SOP begins with the receipt of study documents for initial review and ends with entry of protocol information in the database.

9.4. Process Flow

STEP	ACTIVITY	PERSON RESPONSIBLE	TIMELINE
1	Receipt of protocol and protocol related documents for initial review and determination of the completeness of submission.	Staff	1 day
2	Entry into the Database Incoming & Outgoing Protocols	Staff	
3	Coding	Staff	
4	Determination of the type of Action/ Type of Review a. Exemption from Review (SOP 4) b. Expedited Review (SOP 5) c. Full Review (SOP 6)	Chair	3 days
5	Preparation of a protocol folder	Staff	1 day
6	Entry into the database, and filing to Active Study File	Staff	1 day

9.5. Detailed Instruction

9.5.1. Receipt of study documents for initial review and determination of the completeness of submission.

9.5.1.1. The REC office is open from 8:00 AM to 5:00 PM, Monday to Friday, during which the Staff accepts study documents and checks the

completeness of the documents based on the ***checklist included in the Application for Initial Review Form (Form 2.1)***. The Staff informs the Researcher of the missing documents and returns to the researcher the set of documents if the documents are incomplete.

Important Reminder:

- All study protocols need technical approval prior to ethical review. For National Center for Mental Health initiated protocols, the Technical Review Committee should have addressed the technical issues apparent to the study protocol. A letter of endorsement signed by the Department Technical Review Committee Chair, or Co-chair in the absence of the chair, to signify that the protocol has been approved should be included in the protocol package for submission to REC. For non-NCMH initiated protocols, a document stating that the research protocol has undergone and passed technical review should be attached to the study protocol submitted for ethical review.

- Upon submission of the initial protocol for REC review, the principal investigator or his/her representative should ensure that the protocol follows the standard protocol format and contains the following REC forms :

  Form 2.1 – Application for Initial Review
  Form 2.2 – Protocol Summary Sheet

9.5.1.2. The staff accepts the study document if submitted three (1) hard copies with red folder and soft copy via the official NCMH-REC email account. For larger files, upload to Google Drive may be recommended. The staff notifies the Researcher by email or phone when the protocol is received both hard and soft copy, whether the protocol and other protocol related documents is complete, and how long the review may take.

9.5.1.3. Study protocols qualified for SJREB review are given instructions to submit to SJREB and endorsed to the SJREB Secretariat through e-mail.

9.5.1.4. A protocol package has to include the following:

- **Basic Documents must be submitted:**

☐ Application for Initial Review (Form 2.1)
☐ Protocol Summary Sheet (Form 2.2)
☐ Study Protocol
☐ Diagrammatic work flow
☐ Gantt chart for Schedule of activities
☐ Supplementary Documents (if applicable)
☐ Questionnaire
☐ Data Collection Forms
☐ Product Brochure
☐ Investigator's Brochure (for clinical trials phase I, II, III) or Basic Product Information Document for Phase IV clinical trials (if applicable)
☐ Philippine FDA Marketing Authorization or Import License (if applicable)
☐ Permit/s for Special Population (please specify) _____ (if applicable)

☐ Informed Consent Form
☐English ☐ Tagalog ☐ Others
☐ Assent Form (if applicable)
☐ English ☐ Tagalog ☐Others
☐ Technical Review Committee/Department Approval
☐ Good Clinical Practice (GCP) Training Certificate of PI, Co-I and the rest of the study team: updated at least within THREE (3) years (for clinical trials)
☐ Curriculum Vitae for all members of the Study Team

- **Study Specific Documents**
  (Submit as needed particularly for externally originated studies and sponsored studies)

☐ Recruitment advertisements (as needed by the study protocol)
☐ Other information or documents for participants (such as diaries, etc.)
☐ Memorandum of Agreement (for collaborative studies)
☐ Non-NCMH researcher or with sponsor

☐ NCMH researcher is funded by a sponsor

☐ Previous ethical review approvals/clearances (for students/personnel of foreign universities researching in the Philippines or those with prior ethical review)

☐ Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, as applicable

☐ Contracts and/or Approval of relevant offices / regulatory authorities (Written review agreement / Authorization and Acknowledgement of review)

9.5.2. Entry into the Database Incoming & Outgoing Protocols.

Once the study protocol has been verified, it will be recorded in the REC Database Incoming & Outgoing Protocols. The specific fields as follows:

- Protocol Code
- Protocol Title
- Principal Investigator
- Date of submission
- Details or Subject
- Status/Remarks

9.5.3. Coding

The staff will assign a code to the protocol submitted, including the year of submission and series number. A unique identifier is assigned to each protocol submitted which is referred to as the Protocol Code Number. This code number is given as follows: NCMH-REC-yyyy (year) –number (chronological number based on the order of receipt).

9.5.4. Determination of the type of Action/ Type of Review

9.5.4.1. The Staff submits all received complete protocol package to the Chair. The Chair conducts a preliminary review of the protocol to determine whether it is **Exempted** from Review or for review as **Expedited** or **Full**, and assignment of Primary Reviewers.

- If the Chair decides that the protocol is **exempted from review**, s/he directs the staff to follow the procedure of Exempt from review.

(SOP 4 Exempt from Review).

- If the Chair determines that the protocol should undergo either **Full** or **Expedited review**, then the REC Staff proceeds to follow either (SOP 5 on Expedited Review or SOP 6 on Full Review).

9.5.4.2. The NCMH REC adheres to the following guidelines in classifying protocols as to the level of review required:

1. **Exempted from Review -** The study protocols that (1) Research about public behavior (voting trends, opinion surveys, etc.), (2) Evaluation of public programs and Quality control studies by the agency itself, (3) Standard educational tests and curriculum development, (4) Surveillance functions of DOH and Historical and cultural events, (5) Research involving large statistical data without identifiers, Protocols that neither involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols) shall be exempted from ethical review.

(See SOP 4 Exempt from Review)

2. **Expedited Review -** An expedited review shall be conducted for study protocols that:

- do not entail more than minimal risk to the study participants,
- do not have study participants belonging to a vulnerable group, and
- the study procedures do not generate vulnerability.
- the study does not involve the collection of stigmatizing information
- the study uses anonymized or archived samples

3. **Full Review -** A full review shall be conducted when:

- a proposed study entails more than minimal risk to study participants,
- when study participants belong to vulnerable groups, or
- when a study generates vulnerability to participants

9.5.5. Preparation of a protocol folder

The Staff files the protocol documents in a protocol folder and labels it accordingly (SOP 27 on Management of Active Files). The Staff sends through email the complete set of protocol documents to the Primary Reviewers and

(Member Reviewers in case of Full Board Review). The Staff also prepares sufficient copies for distribution to those who prefer hard copies.

9.5.6. Entry into the database, and filing to Active Study File

The staff writes the NCMH-REC Protocol Code Number of the protocol on the side of the protocol folder. The protocol file index serving as a Table of Contents for each protocol file. Details of the protocol will be updated to the database. Once adequately labeled, it will be placed on the appropriate shelf of the storage cabinet for Active study Files in Chronological order. On the front cover of the protocol folder, the following will be written:

9.5.7.1. REC Protocol Code Number

9.5.7.2. Full title of the research

9.5.7.3. Name of the Principal Investigator

9.6. Forms

9.6.1. Form 2.1 Application for Initial Review

9.6.2. Form 2.2 Protocol Summary Sheet

9.6.3. Form 2.3 Protocol Evaluation Form

9.6.4. Database

9.7. History

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres Ms. Leticia Dizon	Adopted the 2017 DOH SOP
2	February 15, 2021	SOP Team	Added more details on research exempted from review
3	April 27, 2021	SOP Team	Added Process Flow / Step #7, distribute protocol package to reviewers

4	July 07, 2021	SOP Team	Added Detailed Instruction #5 (c) distribution of protocol package to reviewers
5	November 15, 2021	SOP Team	Added additional information on Detailed Instruction #1, #3, #4
6	October 19-20, 2022	Dr. Donabel E. Jose-Carantes	Real-time Revision during SOP Workshop Added Policy Statement and Forms
7	March 21, 2023	SOP Team	Revised Initial Requirements Checklist in 9.5.1.4 Edited 9.5.1.2 stated the number of copies will be submitted Edited 9.5.1.1 that staff will return to the researcher the set of documents if incomplete Edited 9.5.2 List field of the Database Incoming & Outgoing Protocols.
	June 15, 2023	SOP Team	Deleted “Subsequent amendments to a protocol that was exempted from review shall be submitted for a preliminary evaluation to determine whether the revised protocol can still

			be "exempted from review" from Policy Statement (Recommended by PHREB-CSA)
8	November 20, 2023	SOP Team	Change the number of hard copy from three (3) copy to one (1) copy.

10. 1. Policy Statement

The REC shall require resubmission of a protocol that requires either minor or major modification/s 15 days after receipt of the Decision Letter. Minor modifications shall undergo expedited review, while major changes shall undergo full review.

10. 2. Purpose

Management of resubmission ensures that the researcher addresses the required modifications before approval of the protocol.

10. 3. Scope

This SOP begins with the receipt of the revised protocol documents. It ends with the filing of the documents in the protocol file and the entry of the submission in the protocol database.

10.4. Process Flow

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Receipt, record and manage coding of resubmitted protocol into Database Incoming & Outgoing Protocols	Staff	1 day
2	Sending of documents to the Primary Reviewer	Staff	
3	Review of Resubmission (SOP 4 on Expedited Review; SOP 5 on Full Board Review)	Primary Reviewer	7 days
4	Communication of Decision	Staff	1 day
5	Filing of Documents and Update the Database	Staff	

10.5 Detailed Instructions

10.5.1 Receipt, record and manage coding of resubmitted protocol into Database Incoming & Outgoing Protocols

The Staff receives the resubmitted protocol documents with the Protocol Resubmission Form (Form 2.5) checks the date, version number for the revised Protocol/Informed Consent Form, and completeness of the documents and ensures entry into the Database Incoming & Outgoing Protocols

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10.5.2 Sending of Documents to the Primary Reviewer

The Staff forwards the protocol to the primary reviewer/s.

10.5.3 Review of Resubmission (SOP 5 on Expedited Review; SOP 6 on Full Board Review)

The primary reviewers examine the resubmitted protocol by referring to the resubmission form, noting the recommendations the REC gave, and determining whether these were satisfactorily handled in the resubmitted protocol. The report is submitted to the Chair for inclusion in the next regular meeting by the reviewers.

10.5.4 Communication of Decision

The Staff prepares the Certificate of Approval (Form 2.6) with the Approval Letter (Form 2.7) for accepted resubmitted protocols, which the Chairperson then signs. The Principal Investigator is notified of the NCMH-REC decision. If the protocol still needs to be modified, the Principal Investigator will be notified.

10.5.5 Filing of Documents and Update the Database.

The Staff gathers all the pertinent documents related to the resubmission (revised protocol, assessment forms, excerpts of minutes, approval letter) and enters the relevant information on resubmission in the appropriate protocol database.

10.6. Forms

10.6.1.	Form 2.5	Protocol Resubmission Form
10.6.2.	Form 2.6	Certificate of Approval
10.6.3.	Form 2.7	Approval Letter

10.7. History

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres	Adopted the 2017 DOH SOP

		Ms. Leticia Dizon	
2	February 15, 2021	SOP Team	Clarified who will review resubmissions with minor modifications (Detailed Instruction #3)
3	April 27, 2021	SOP Team	Clarified on Detailed Instruction #3: Chairperson will be the one to review minor modifications
5	November 15, 2021	SOP Team	Edited Responsibility: clarified the role of Secretariat Edited Detailed Instruction #1 to #4, for improvement and clarity
6	October 19-20, 2022	Dr. Donabel E. Jose-Carantes	Real-time Revision during SOP Workshop Added Policy Statement and Forms
7	March 21, 2023	SOP Team	Added procedures on expedited/full board review of re-submitted protocols and post-approval protocols Revised 10.5.1 step for checking the version number of resubmitted revised protocol/ICF (Recommended by PHREB-CSA)

11.1. Policy Statement

The REC shall require the submission of proposed amendments for review and approval before their implementation based on the level of risk of the study. This requirement shall be explicitly stated in the Approval Letter.

11.2. Purpose

This activity aims to ensure that the conduct of the study is in compliance with the approved protocol such that any change such as amendments does not impact safety and welfare of study participants.

11.3. Scope

This SOP begins with the receipt and entry of the submission of amendment to Database of incoming documents and the protocol database and ends with filing of the amendments and committee decision in the protocol file.

11.4. Process Flow

STEP	ACTIVITY	PERSON/S RESPONSIBLE
1	Receipt and entry into Database Incoming & Outgoing Protocols of the submission of amendments.	Staff
2	Retrieval of pertinent protocol file	Staff
3	Notification of chair and primary reviewers	Staff
4	Determination of type of review: expedited (SOP 5) or full review (SOP 6)	Chair and primary reviewer
5	Communication of committee action	Chair
6	Filing of Amendments and decision letter and update of the protocol database	Staff

11.5 Detailed Instructions

11.5.1. Receipt and entry into Database Incoming & Outgoing Protocols of amendments

The Staff receives the Protocol Amendment Application Form 3.1 and enters the date and pertinent information in the Database Incoming & Outgoing Protocols of incoming documents.

11.5.2. Retrieval of pertinent protocol file

The Staff retrieves the corresponding protocol file for reference and guidance of the chair and reviewers.

11.5.3. Notification of Chair and Primary Reviewers

Within three (3) days after the receipt of the Protocol Amendment Application the Staff notifies and sends the pertinent protocol file to the Chair and the previously assigned Primary Reviewers via email.

11.5.4. Determination of type of review

The Primary Reviewer recommends the type of review to the Chair and the Chair will determine the final type of review. The amendments will be classified as Major or Minor with the following criteria:

- *Minor amendments* – recommended amendments applying to protocols found to have particular aspect/s on its study or related document that do not impact on potential risks/benefits to participants and on the integrity of the research (e.g. incomplete documentation, incomplete IC elements, unsatisfactory IC format)

    - Minor amendments would require an expedited review by the previous Primary Reviewers

- *Major amendments* – recommended amendments applying to protocols found to have significant aspect/s of the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data, statistical analysis, mitigation of risk, protection of vulnerability, etc.) that impact on potential risks/harms to participants and on the integrity of the research.

- Major amendments require a full board review.

11.5.5. Communication of committee decision

The REC communicates the committee action (SOP 25). The committee action maybe "approved" or " additional information required " or " specific action/s required from the researcher ". The staff will prepare a draft based on the committee decision on either an expedited review report or minutes of a meeting. Chair will sign the decision letter whether: approval, request for additional information or specific action/s.

11.5.6. Filing of Amendment and committee decision and update of the database. Staff will file the amendment and a copy of the committee decision in the designated protocol folder. The staff will update the pertinent database.

11.6 Forms

11.6.1. Form 3.1 Protocol Amendment Application
11.6.2. Form 3.10 Notification letter
11.6.3. Database

11.7 History

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres Ms. Leticia Dizon	Adopted the 2017 DOH SOP
2	February 15, 2021	SOP Team	Clarified who will classify amendments to Full Board or Expedited Clarified who reviews minor amendments (Detailed Instruction #3)

3	April 27, 2021	SOP Team	Added on Scope: Major protocol amendments are reviewed by Full Board while minor amendments by Expedited review Arranged Detailed Instruction #3 in sequential manner and state who determines the type of amendment review.
5	November 15, 2021	SOP Team	Added on Detail Instruction #1, (4) retrieval of file; #2 (1) Major amendments are reviewed by Full Board while minor amendments are reviewed by Expedited review by the Chairperson
6	October 19-20, 2022	Dr. Maurice L. Sañosa	Real-time Revision during SOP Workshop Added Policy Statement and Forms
7	March 21, 2023	SOP Team	Revised Policy statement and Detailed Instructions, intended for Amendment report not progress report Revised 11.5.4 decision points in the SOP and described minor and major amendments (Recommended by PHREB-CSA)

12.1. Policy Statement

The REC shall require the submission of progress reports at a frequency based on the level of risk of the study. NCMH-REC requires that for minimal risk protocols, annual progress report is submitted while more than minimal risk, progress report shall be submitted twice a year and no more than 6 weeks before expiration of ethical approval. This requirement shall be explicitly stated in the Approval Letter. Previously expedited reviewed protocols will undergo Expedited Review; while previously reviewed full board, its progress report shall be reviewed a full board.

12.2. Purpose

This activity aims to ensure that the conduct of the study is in compliance with the approved protocol and that the safety and welfare of study participants are promoted.

12.3. Scope

This SOP begins with the receipt and entry to Database of incoming documents and ends with filing of progress report and committee decision in the protocol file.

12.4. Process Flow

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Receipt and entry into Database Incoming & Outgoing Protocols of the progress report	Staff	1 day
2	Retrieval of pertinent protocol file	Staff	
3	Notification of Chair and Primary Reviewers	Staff	1 day
4	Communication of committee action	Chair	1 day
5	Filing of Progress report and decision letter and update of the protocol database	Staff	

12.5. Detailed Instructions

12.5.1 Receipt and entry to Database Incoming & Outgoing Protocols

The Staff receives the progress report written in the Progress Report Form and enters the date and pertinent information in the database of incoming documents.

12.5.2 Retrieval of pertinent protocol file

The Staff retrieves the corresponding protocol file for reference and guidance of the Chair and previously assigned Primary Reviewers.

12.5.3 Notification of Chair and Primary Reviewers

Within two days after receipt of the progress report, the Staff notifies and sends the pertinent protocol file to the Chair and the previously assigned Primary Reviewers. As a general rule, progress reports of Expedited Protocols will undergo Expedited Review while progress reports reviewed at Full Board should go through Full Board Review as well.

12.5.4 Communication of Committee decision

The REC communicates the committee action (SOP 25). The committee action maybe “approved” or “additional information required “or “specific action/s required from the researcher “. The staff will prepare a draft based on the committee decision on either an expedited review report or minutes of a meeting. Chair will sign the decision letter whether: approval, request for additional information or specific action/s.

12.5.5. Filing of Progress Report and committee decision and update of the database

The Staff files the progress report and a copy of the committee decision in the appropriate protocol folder. She/he proceeds to update the pertinent protocol database.

12.6. Forms

12.6.1. Form 3.2 Progress Report Form

12.6.2. Form 3.10 Notification Letter 12.6.3. Database

12.7. History

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres Ms. Leticia Dizon	Adopted the 2017 DOH SOP
3	April 27, 2021	SOP Team	Added on Scope, type of review for progress report
4	July 07, 2021	SOP Team	Revised the whole chapter. Transferred steps pertaining to SOP on Continuing Review to said SOP
5	November 15, 2021	SOP Team	Edited Scope to include items to be reviewed Edited Responsibility, to include frequency of submission and when to submit Edited Detailed Instruction #4, to include the how to classify the type of review on progress report
6	October 19-20, 2022	Dr. Maurice L. Sañosa	Real-time Revision during SOP Workshop Added Policy Statement and Forms
7	March 21, 2023	SOP Team	Revised Policy Statement, Indicated specifically that for minimal risk protocols, annual progress report is submitted while more than minimal risk,

	June 15, 2023	SOP Team	progress report shall be submitted twice a year and shall be submitted no more than 6 weeks before expiration of ethical approval Edited 12.5.4 Previously expedited reviewed protocols, its progress report shall be reviewed as expedited; and for previously reviewed full board, its progress report shall be reviewed a full board. Added "Previously expedited reviewed protocols will undergo Expedited Review; while previously reviewed full board, its progress report shall be reviewed a full board." in Policy Statement. Deleted "Classification of the type of review" Step 4 in Process Flow and 12.5.4 in Detailed Instruction (Recommended by PHREB-CSA)

13.1. Policy Statement

Principal Investigator shall report protocol deviations and violations in the conduct of approved researches within a week from the detection of the protocol violation/deviation. Major protocol violations undergo full review.

13.2. Purpose

Review of protocol deviations and violations aims to ensure that the safety and welfare of human participants in the study are safeguarded and that the credibility and integrity of data are maintained.

13.3. Scope

This begins with the receipt and documentation of the report of protocol violations and deviations in the Database Incoming Protocols and ends with the filing of all related documents and update of the database.

13.4. Process Flow

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Receipt and documentation of report of protocol violations and deviations in the Database Incoming & Outgoing Protocols	Staff	1 day
2	Retrieval of Pertinent protocol file	Staff	
3	Notification of Chair and primary reviewers	Staff	2 days
4	Determination of type of review: expedited review (SOP 5) or Full Review (SOP 6)	Chair	5 days
5	Inclusion of report in the agenda of the next REC regular meeting	Staff and Chair	1 day
6	Communicate decision to Principal Investigator	Staff, Chair	2 days
7	File documents in protocol file folder and update protocol database	Staff	1 day

13.5 Detailed instructions

13.5.1. Receipt and documentation of report of protocol violations and deviations in the Database Incoming & Outgoing Protocols

The Staff receives the report on protocol deviation or violation in the appropriate report form (Form 3.5) and records this in the database for incoming documents.

13.5.2. Retrieval of the pertinent protocol file

The Staff retrieves the approved protocol and checks the identity of the primary reviewers for reference and guidance of the Chair in the selection/designation of reviewers.

13.5.3. Notification of Chair and primary reviewers

The Staff notifies and sends the protocol deviation or violation report and together with the retrieved pertinent documents to the Chair and primary reviewers.

13.5.4. Determination of type of review: expedited or full review

The Chair and primary reviewers determine the type of review such that major protocol violations undergo full review. Otherwise, the protocol deviation undergoes expedited review. The protocol deviations/violations will be classified as Major or Minor with the following criteria:

- *Minor deviations* – applying to protocols found to have no effects on its study or related document and that do not increase potential risks/harms to participants and on the integrity of the research (e.g. incomplete documentation, incomplete IC elements, unsatisfactory IC format)
    - Minor deviations would require an expedited review by the previous Primary Reviewers (See SOP 5 Expedited Review)

- *Major deviations/violations* – applying to protocols found to have significant impact and changes on the study (e.g., study objectives, recruitment of participants, exclusion/inclusion criteria, collection of data, statistical analysis, mitigation of risk, protection of vulnerability, etc.) that may increase potential risks/harms to participants and on the integrity of the research.

- Major violations require a full board review. (See SOP 6 Full Review)

13.5.5. Inclusion of report in the agenda of the next REC regular meeting (SOP 22)

The Chair includes the report on protocol deviation and violations in the Agenda of the next meeting if it is for full review or the decision report if Expedited review.

13.5.6. Communication of Decision to the Principal Investigator

The Staff prepares the draft decision based on the report of the expedited review or the minutes of the meeting in the full review. Possible decisions include one or several of the following:

1. Submission of additional information
2. Submission of corrective action
3. Invitation to a clarificatory interview
4. Requirement for an amendment
5. Site visit
6. Suspension of recruitment
7. Withdrawal of ethical clearance

13.5.7. Filing of all related documents and update of the protocol database

The Staff collates and files the retrieved protocol documents, the report on protocol deviation and violation and the decision letter in the appropriated protocol file and updates the protocol database with the relevant information.

13.6. Forms

13.6.1. Form 3.5 Protocol Deviation/Violation Report Form
13.6.2. Form 3.10 Notification Letter
13.6.3. Database

13.7. History

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres Ms. Leticia Dizon	Adopted the 2017 DOH SOP

3	April 27, 2021	SOP Team	Edited Responsibility, to clarify that it is the Chairperson who take action Added on Process Flow / Steps the classification of review and assignment of PI
4	July 07, 2021	SOP Team	Added of Detailed Instruction #2, the definition of major, minor and protocol violation
5	November 15, 2021	SOP Team	Edited Detailed Instruction #2, to clarify which falls on Expedited (minor deviation) and Full Board (major deviation)
6	October 19-20, 2022	Dr. Maurice L. Sañosa	Real-time Revision during SOP Workshop Added Policy Statement and Forms
7	March 21, 2023	SOP Team	Revised 13.5.4 the criteria for minor and major protocol deviations Indicated that minor protocol deviations are reviewed as expedited while major deviations and non-compliance are reviewed as full board (Recommended by PHREB-CSA)

14.1. Policy Statement

The NCMH-REC shall require the submission of reports of SAEs and SUSARs by Sponsor/Principal Investigator within 72 hours after knowledge of Principal Investigator of its occurrence, and a complete report is submitted within 14 days. Onsite SAE/SUSARs shall be reviewed in the full board review while trending of offsite SAEs/SUSARs shall be reported every 6 months.

14.2. Purpose

Review of SAE and SUSAR reports aims to ensure that the safety and welfare of human participants in the study site are safeguarded and that information on SAEs and SUSARs are properly documented and evaluated.

14.3. Scope

This SOP applies to the review of reports of Serious Adverse Event (SAE) in various studies and Suspected, Unexpected Serious Adverse Reaction (SUSAR) in clinical trials submitted by Principal Investigator, sponsors, participants and concerned parties to the NCMH REC in accordance with ICH GCP. This SOP begins with the receipt and documentation of submission of report of SAEs and SUSARs in the Database Incoming & Outgoing Protocols and ends with the filing of all related documents and update of the protocol database.

14.4. Process Flow

Step	Activity	Responsibility	TIMELINE
1	Report SAE and SUSAR	PI/Sponsors	72 hours
2	Receipt and documentation of submission of report of SAEs and SUSARs in the Database Incoming & Outgoing Protocols	Staff	1 day
3	Retrieval of protocol file	Staff	
4	Notification of Chair	Staff	
5	Submission of report	Chair	14 days
6	Inclusion of report in the agenda of the next regular REC meeting	Staff	1 day
7	Communication of REC action to the Principal Investigator (SOP 25 - Communication of REC decisions)	Staff	2 days
8	Filing of all related documents (SOP 27 - Management of active files) and update of the protocol database	Staff	1 day

14.5. Detailed Instruction

14.5.1. Report SAE and SUSAR

SAEs and SUSARs must be reported to NCMH-REC by the Principal Investigator.

14.5.1.1. ICH- GCP E6 defines a Serious Adverse Event (SAE) or Serious Adverse Drug Reaction (Serious ADR) Any untoward medical occurrence that at any dose:

- results in death,
- is life-threatening,
- requires inpatient hospitalization or prolongation of existing hospitalization,
- results in persistent or significant disability/incapacity, or
- is a congenital anomaly/birth defect

14.5.1.2. A suspected unexpected serious adverse reaction (SUSAR) is a serious event the nature and severity of which is not consistent with the applicable product information. In the case of an unapproved investigational product, the event is not consistent with the Investigator's Brochure (IB). In the case of a licensed product, the event is not consistent with the approved package insert or summary of product characteristics.

14.5.1.3. The Principal Investigator must report suspected, unexpected, serious adverse reaction(s) (SUSAR)/s and other documents deemed relevant by the investigator to clarify information indicated in the report. This comprises the study protocol SUSAR report package.

14.5.1.4. Death or life-threatening events Onsite SUSARs/SAEs must be reported by the PI to the REC 72 hours after knowledge of PI of its occurrence, and a complete report is submitted within 14 days.

14.5.2. Receipt and documentation of submission of report of SAEs and SUSARs in the Database Incoming & Outgoing Protocols

The Staff receives the accomplished form and enters the submission into the Database Incoming & Outgoing Protocols and gives the receiving copy to the PI or

his/her representative. The staff notes whether the submission is within the required timeline.

14.5.2.1. ONSITE: Serious Adverse Event/s (SAE) and Suspected, Unexpected, Serious Adverse Reaction (SUSAR) Reports

The Staff informs the Chair of the submission. The Staff forwards the SAE/SUSAR comprised of the following documents to the Chair and to the primary reviewers within 48 hours of receipt:

- SAE/SUSARs report forms (Form 3.4)
- Standard CIOMS form
- Latest Investigator's Brochure
- Protocol Summary
- Other supporting documents, if any

14.5.2.2. OFFSITE: Serious Adverse Event/s (SAE) and Suspected, Unexpected, Serious Adverse Reactions (SUSARs) Reports

The PI must submit the offsite SAE and SUSAR report every three (6) months. The Staff forwards the SAE Report Package to the primary reviewers and the chair which comprises of the following documents at least Fifteen (15) days before the NCMH-REC meeting

- SAE/SUSARs report forms (Form 3.4)
- Standard CIOMS form
- Latest Investigator's Brochure
- Protocol Summary
- Other supporting documents, if any

14.5.3. Retrieval of protocol file

14.5.3.1. ONSITE: Serious Adverse Event/s (SAE) and Suspected, Unexpected, Serious Adverse Reaction (SUSAR) Reports

The staff retrieves the identity of the primary reviewers and a tabulation of earlier SAEs and SUSAR reports. If the primary reviewers assess that the report needs immediate action, he/she will forward the report and his/her recommendation to the Chair for further assessment. The Chair will assess

the recommendations for an immediate action either suspension of the study or recruitment.

14.5.3.2. OFFSITE: Serious Adverse Event/s (SAE) and Suspected, Unexpected, Serious Adverse Reactions (SUSARs) Reports

The primary reviewers assigned to the particular study review and return the signed SAE/SUSARs report (Form 3.4) to the Staff together with the SAE report package.

14.5.4. Notification of Chair

14.5.4.1. ONSITE: Serious Adverse Event/s (SAE) and Suspected, Unexpected, Serious Adverse Reaction (SUSAR) Reports

The staff notifies and sends the report and the retrieved documents to the Chair. The Staff includes the SAE report/s on the agenda of the next meeting, provided that cut-off period for REC meeting inclusion is fourteen (14) days prior, in which the primary reviewer is required to attend.

14.5.4.2. OFFSITE: Serious Adverse Event/s (SAE) and Suspected, Unexpected, Serious Adverse Reactions (SUSARs) Reports

The Chair and primary reviewers may recommend any of the following actions:

- notation with no further action required,
- further information or action required or
- suspension of recruitment or suspension of the entire study

14.5.5. Submission of report

14.5.5.1. ONSITE: Serious Adverse Event/s (SAE) and Suspected, Unexpected, Serious Adverse Reaction (SUSAR) Reports

The Chair forwards the report and pertinent documents to the primary reviewers (medical member) for action which should not be later than 14 days prior to the next committee meeting.

Copies of the SAE/SUSARs report (Form 3.4) are distributed to each REC member together with the agenda.

14.5.5.2. OFFSITE: Serious Adverse Event/s (SAE) and Suspected, Unexpected, Serious Adverse Reactions (SUSARs) Reports

The Chair submits the recommendations to the Staff for inclusion in the agenda of the next meeting.

14.5.6. Inclusion of report in the agenda of the next regular REC meeting

14.5.6.1. ONSITE: Serious Adverse Event/s (SAE) and Suspected, Unexpected, Serious Adverse Reaction (SUSAR) Reports

The Staff includes the suggested action/decision of the primary reviewer in the agenda of the next meeting (SOP 21 Preparing the Meeting Agenda) for ratification or discussion and final decision. During the meeting, the Chair calls for a decision on the SAE report/s with respect to the recommendation/s of Chair or reviewer assigned to the concerned study as presented by the REC Chair/Primary Reviewer. The committee may require any of the following actions:

Decision Points:

1. No further action; documents for filing
2. Modification of participant inclusion or exclusion criteria to mitigate the newly identified risks or informed consent documents to include a description of newly recognized risks;
3. Recommend implementation of additional procedures for protecting/ safeguarding participants;
4. Suspension of enrollment of new participants or research procedures among participants who are currently enrolled (check consistency)
5. Request information
6. Recommend suspension of the entire study

14.5.6.2. OFFSITE: Serious Adverse Event/s (SAE) and Suspected, Unexpected, Serious Adverse Reactions (SUSARs) Reports

During the meeting, the Chair calls for a decision on the SAE report with respect to the recommendations of the Chair and the primary reviewers. The REC can recommend any of the following actions:

- No action required, study to continue;
- Modification of participant inclusion or exclusion criteria to mitigate the newly identified risks or informed consent documents to include a description of newly recognized risks;
- Recommend implementation of additional procedures for protecting/ safeguarding participants;
- Suspension of enrollment of new participants or research procedures among participants who are currently enrolled (check consistency)

14.5.7. Communication of REC action to the Principal Investigator/researcher

See SOP 25 Communication of REC decisions

14.5.7.1. Timeline Requirements

The PI must report to the NCMH-REC all SAEs according to the following timelines:

- Death or life-threatening events Onsite SUSARs/SAEs must be reported by the PI to the REC 72 hours after knowledge of PI of its occurrence, and a complete report is submitted within 14 days.
- If the suspected unexpected serious adverse reaction occurred onsite, it must be reported to the NCMH-REC promptly, within no more than 7 days of recognition/notification of the event.
- If a suspected unexpected serious adverse reaction occurred offsite as part of a multi-site research project, it must be reported to the NCMH-REC within 15 days of recognition/notification of the event.

14.5.8. Filing of all related documents and update of the protocol database

See SOP 27 Management of active files

14.6. Forms

13.6.1. Form 3.4 SAE/SUSAR Report
13.6.2. Form 3.10 REC Notification Letter
13.6.4. Form 4.1 Meeting Agenda
13.6.5. Database

14.7. History

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres Ms. Leticia Dizon	Adopted the 2017 DOH SOP
2	February 15, 2021	SOP Team	Clarified who will review SAE/SUSAR from local sites Stated that primary reviewer who is the medical member shall review the SAE/SUSAR Designated the review of RNEs in behavioural research to the medical member or clinical psychologist Indicated that on-site SAE/SUSAR shall be reported within 7 days from the time of knowledge of the on-site SAE/SUSAR and a more complete report shall be submitted within 15 days and that RNEs can be reported within 7 days from knowledge of its occurrence
3	April 27, 2021	SOP Team	Revised the statements that all onsite SAE/SUSAR/RNE whether related or not to the intervention (regardless of who reviewed) shall be discussed during full board meeting
4	July 07, 2021	SOP Team	Added on Scope, elements of onsite SAE/SUSAR review
5	November 15, 2021	Dr. Hyacinth Manood	Added on Purpose: submission of SAE/SUSAR

			Revised Process Flow/Steps and corresponding Detailed Instruction
6	October 19-20, 2022	Dr. Mary Ann B. Lin	Real-time Revision during SOP Workshop Added Policy Statement and Forms
7	March 21, 2023 May 11, 2023	SOP Team SOP Team	Added in 14.5.1.1 Described SAEs and SUSARs in the SOP Added in 14.5.5.1 is the medical member who reviews the SAES (Recommended by PHREB-CSA) Added major review points Revised Policy Statement and 14.5.1.4 as recommended by accreditors must be reported within 72 hours after knowledge of PI of its occurrence, and a complete report is submitted within 14 days. Revised numbering from 13.5.7.1 to 14.5.7.1

15.1. Policy Statement

The REC shall require the submission of RNE reports by Sponsor/Principal Investigator within 72 hours after knowledge of its occurrence, and a complete report is submitted within 14 days. A special meeting shall be considered depending on the level of risk involved. Reportable Negative events are occurrences during the implementation of a research that impact safety, dignity and well-being of participants and/or the study team and the integrity of data. These events need to be reported by Principal Investigator or Safety (DSMB) personnel to the NCMH REC as essential to the continuing concern for a favorable balance of risks and benefits from the study.

15.2. Purpose

The REC activity aims to ensure that the safety and welfare of human participants and the research team are safeguarded and that information on RNEs are properly documented and evaluated.

15.3. Scope

The SOP begins with the receipt and documentation of submission of RNE report in the Database Incoming & Outgoing Protocols and ends with the filing of all related documents and update of the protocol database. RNEs are experiences of researchers that involve personal safety issues (related to both research and research participant in the conduct of research, such as sexual harassment, physical threats, stalking and other hostile reactions. Development of anxiety, depression, and suicidal ideations as a result of the research are other samples of RNE.

15.4. Process Flow

STEP	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Receipt and documentation of submission of RNE in the Database Incoming & Outgoing Protocols	Staff	1 day
2	Retrieval of protocol file	Staff	
3	Notification of Chair	Staff	
4	Call for Special Meeting	Chair	1 day
5	Deliberation on the RNE	REC members	1 day

6	Communication of REC action to the Principal Investigator (see SOP 25 Communication of REC decisions) and the Institutional authority	Chair	1 day
7	Filing of all related documents (SOP 27 Management of active files) and update of the protocol database	Staff	1 day

15.5. Detailed Instruction

15.5.1 Receipt and documentation of submission of RNE report in the Database Incoming & Outgoing Protocols

The staff receives the accomplished RNE report forms (Form 3.9) and enters the submission into the Database Incoming & Outgoing Protocols. The staff notes whether the submission is within the required timeline.

15.5.2. Retrieval of protocol file

The staff retrieves the approved protocol file and checks the identity of the primary reviewers.

15.5.3. Notification of Chair

The staff notifies and sends the report and the retrieved documents to the Chair who may decide to call for a special meeting.

Review of Reportable Negative Event (RNE) in behavioural research is designated to the Medical member or the clinical psychologist.

15.5.4. Call for Special Meeting

The Staff prepares for a special meeting (SOP 21). The researcher and other member of the study team may be invited for a clarificatory meeting.

15.5.5. Conduct of the Special Meeting

The Chair leads the discussion of the special meeting, summarizes the RNE report and informs the REC members regarding the presence of the research team for clarificatory meeting. The safety issues are evaluated i.e. identification of risks to the participants/research team, nature and effectivity of preliminary interventions with or without the help of community constituent/authority, impact on integrity of data

and completion of the research. The research team is excused and the members deliberate on possible options as follows:

15.5.5.1. Recommend suspension of the study until risk is resolved
15.5.5.2. Withdrawal of ethical clearance
15.5.5.3. Submission of a plan to mitigate risk/harm
15.5.5.4. Require an amendment to the protocol
15.5.5.5. Uphold original ethical clearance

15.5.6. Communication of REC action to the Principal Investigator/researcher
See SOP 25 Communication of REC decisions.

15.5.6.1. Timeline Requirements
The PI must report to the NCMH-REC all RNEs according to the following timelines:

- RNE or Unanticipated problems must be reported to the NCMH REC within 72 hours after knowledge of its occurrence to the attention of the Principal Investigator and a complete report is submitted within 14 days
- If the RNE or Unanticipated problems occurred onsite, it must be reported to the NCMH-REC promptly, within no more than 7 days of notification of the event.
- If the RNE or Unanticipated problems occurred offsite as part of a multi-site research project, it must be reported to the NCMH-REC within 15 days of notification of the event.

15.5.7. Filing of all related documents and update of the protocol database
See SOP 27 Management of active files.

15.6. Forms

15.6.1. Form 3.9 RNE report
15.6.2. Form 4.1 Meeting Agenda Template
15.6.3. Form 3.10 Notification Letter

15.7. History

Version No.	Date	Authors	Main Change
4	July 07, 2021	SOP Team	Added on Scope, sample of RNEs
5	November 15, 2021	Dr. Hyacinth Manood	Added in Purpose: submission of RNEs Added other samples of RNE
6	October 19-20, 2022	Dr. Mary Ann B. Lin	Real-time Revision during SOP Workshop Added Policy Statement and Forms
7	March 21, 2023	SOP Team	Edited 15.1 Described RNEs in the policy Added 15.5.6.1 Timelines for submission of RNEs Major review points in 15.5.5 (Recommended by PHREB-CSA)

16.1. Policy Statement

The REC shall require the submission of an application for Continuing Review at least (6) six weeks or equivalent days before the expiration of the ethical clearance of a protocol. Protocols that underwent Full review in its initial submission shall undergo Full review in its application for Continuing review while protocols that underwent Expedited review shall undergo Expedited review in its application for continuing review.

16.2. Purpose

The REC activity aims to ensure that the conduct of the study is in compliance with the approved protocol and that the safety and welfare of study participants are promoted and the integrity of data protected beyond the period of initial ethical clearance and up to the end of the study.

16.3. Scope

The SOP begins with the receipt of an application for continuing review and ends with the entry to Database Incoming & Outgoing Protocols.

16.4. Process Flow

It is the responsibility of the National Center for Mental Health REC Staff to remind the PI to submit the continuing review application not more than 6 weeks before expiry of ethical approval.

STEP	ACTIVITY	RESPONSIBILITY	TIMELINE
1	Receipt of the application for Continuing Review and entry to Database Incoming & Outgoing Protocols (see SOP 27 Management of Active Files)	Staff	1 day
2	Retrieval of protocol file	Staff	
3	Notification of Chair and Primary Reviewer	Staff	1 day
4	Determination of the type of review: expedited (SOP 5 Expedited Review) or full review (see SOP 6 Full Review)	Chair and Primary Reviewer	3 days
5	Communication of Committee action (see SOP 25 Communication of REC decisions)	Chair	2 days
6	Filing of documents in the appropriate protocol folder and update of the protocol database	Staff	1 day

16.5. Detailed Instruction

16.5.1. Receipt of the application for Continuing Review and entry to Database Incoming & Outgoing Protocols

The staff receives logs and enters in the protocol database the information included in the application for continuing review (Form 2.9 Application for Continuing Review).

16.5.2. Retrieval of protocol file

The staff retrieves the approved protocol and prepares a summary of the progress reports, protocol deviation/violation reports, SAE/SUSAR reports, report of negative events (RNEs) and corresponding decisions including the type of initial review during the period of effectivity of initial ethical clearance.

16.5.3. Notification of Chair and Primary Reviewer

The staff notifies the Chair and the Primary Reviewers regarding the submission and the summary of the reports submitted and decisions made during the period of effectivity of initial ethical clearance.

16.5.4. Determination of the type of review: expedited or full review

The Chair shall determine the type of review based on the policy that protocols that underwent Full review in its initial submission shall undergo Full review in its application for Continuing review while protocols that underwent Expedited review shall undergo Expedited review in its application for continuing review.

16.5.5. Communication of Committee action

The Staff prepares the draft decision based on the report of the expedited review or the minutes of the meeting in the full review. The Chair finalizes and signs the decision letter (Form 3.10). Possible decisions include: Approval, Additional information required, submission of an explanation for failure to submit required reports or disapproval.

16.5.6. Filing of documents in the appropriate protocol folder and update of the protocol database

The Staff files the application for Continuing review, the recommendation of the reviewers and decision letter in the appropriate protocol folder.

16.6. Forms

16.6.1. Form 2.9 Continuing Review Application Form
16.6.2. Form 3.10 Notification Letter
16.6.3. Database

16.7. History

Version No.	Date	Authors	Main Change
3	April 27, 2021	SOP Team	Added SOP (new)
4	July 07, 2021	SOP Team	Revised chapter: steps pertaining to Review of Progress Report was transferred to said SOP
5	November 15, 2021	Dr. Hyacinth Manood	Added in Purpose: the submission date and type of review to be used
6	October 19-20, 2022	Dr. Mary Ann B. Lin	Real-time Revision during SOP Workshop Added Policy Statement and Forms
7	March 21, 2023 May 11, 2023	SOP Team SOP Team	Added in 16.4 that the staff secretary reminds the PI to submit the continuing review application not more than 6 weeks before expiry of ethical approval Revised Form 2.9 Add safety issues and amendments in the report Revised Policy Statement from 4 weeks to (4) to six (6) weeks or equivalent days (Recommended by PHREB-CSA)

17.1 Policy Statement

When a decision of early termination of the research has been made, the well-being and safety of study participants that have already been recruited shall be a primary consideration and the plan for termination shall reflect this concern. Early termination shall undergo full review.

17.1 Purpose

Review of the early termination reports aims to ensure that the decision takes into consideration the safety and welfare of study participants that have been already recruited and that there is adherence to the principle of fairness for all concerned.

17.2 Scope

This SOP applies to the review of early termination reports. It begins with the receipt and entry to Database Incoming & Outgoing Protocols of the early termination reports and ends with the communication of committee action to the researcher/investigator and updating of protocol database.

17.4 Process Flow

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Receipt of the early termination report and entry into the Database Incoming & Outgoing Protocols (SOP 27 on Management of Active Files)	Staff	1 day
2	Retrieval of pertinent protocol file	Staff	
3	Notification of Chair and Primary Reviewers	Staff	
4	Full Board Review (SOP 6 on Full Board Review)	Members	12 days
5	Communication of committee action (see SOP 25 on Communicating REC Decisions) and update of the protocol database (SOP 27 Management of Active Files)	Chair / Staff	

17.5 Detailed Instructions

17.5.1 Receipt of the early termination report and entry into the Database Incoming & Outgoing Protocols

The Staff receives the early termination report and enters the appropriate information into the Database Incoming & Outgoing Protocols (see SOP 27 on Management of Active Files)

17.5.2 Retrieval of pertinent protocol file

The Staff retrieves the protocol folder and summarizes the documents that have been submitted

17.5.3 Notification of Chair and Primary Reviewers

The Staff informs the Chair and the Primary reviewers by email or SMS about the report and the summary of documents that have been submitted. The Staff waits for further instructions.

17.5.4 Full Board Review

The Chair instructs the staff to include the report in the agenda of the next meeting and to ensure that the primary reviewers are given the necessary documents so that they can prepare the presentation during the next meeting.

The primary reviewers conduct a full review the contents of the early termination protocol package, and make recommendations on how study termination will be carried out of primary importance are the safety data for participants that have already been recruited, as well as a plan that includes steps and procedures on how the safety and well-being of these participants can be ensured moving forward.

17.5.5 Communication of committee action and update of the protocol database

After taking into consideration all comments and recommendations from all members present in the meeting, ***the committee may require any of the following actions:***

Decision Points:

1. Accept decision for termination
2. Request for additional information
3. Require further action in termination plan

The Staff prepares a draft of the committee decision based on the minutes of the meeting. After the board makes a decision on the early termination of the protocol and officially signed by the Chair, the Staff informs the PI of this decision.

The Staff updates the protocol database accordingly.

17.6 Forms

17.6.1. Form 3.8 Early Study Termination Application
17.6.2. Form 3.10 Notification Letter
17.6.4. Database

17.7 History

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres Ms. Leticia Dizon	Adopted the 2017 DOH SOP
5	November 15, 2021	Dr. Irfa Barcellano-Ducusin	Edited Purpose and Scope for clarification Revised Process Flow / Steps and corresponding Detailed Instruction
6	October 19-20, 2022	Ms. Vanessa Credo	Real-time Revision during SOP Workshop. Added Policy Statement and Forms
7	March 21, 2023 May 11, 2023	SOP Team SOP Team	Revised Form 3.8 Add: Support mechanisms or interventions for enrolled participants and Post-termination actions Added Decision Points in Detailed Instruction 17.5.5 (Recommended by PHREB-CSA)

18.1 Policy Statement

The NCMH-REC shall require the submission of the final report to not more than sixty (60) days from end or close out of the study. Final reports shall follow the initial type of review. Submission and review of final reports signal the completion of the study and its acceptance by the research ethics committee.

18.2. Purpose

This activity aims to ensure that the conduct of the study was in compliance with the approved protocol and that the safety and welfare of the study participants were promoted and the integrity of data protected until the end of the study.

18.3. Scope

This policy applies to the management and review of final reports submitted by the investigators at the end of the study. This SOP begins with the receipt and entry of the final report into the Database Incoming & Outgoing Protocols and ends with an update of the protocol database.

18.4. Process Flow

It is the responsibility of the NCMH-REC Staff to remind investigators to submit the final report to not more than 60 days from completion of study protocol

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Receipt of the final report and entry into the Database Incoming & Outgoing Protocols	Staff	1 day
2	Retrieval of pertinent protocol file	Staff	
3	Notification of Chair and Primary Reviewer	Staff	1 day
4	Expedited Review (SOP 5) or Full Board (SOP 6)	Chair/Primary Reviewers	21 days or 42 days
5	Communication of committee action	Staff/ Chair	2 days
6	Filing of the Final Report and related documents and update of protocol files	Staff	1 day

18.5. Detailed Instructions

18.5.1. Receipt and entry of final report into Database Incoming & Outgoing Protocols

The Staff receives and enters the date of receipt of the final report into the Database Incoming & Outgoing Protocols. Final Report will only be accepted when submitted together with the certification of approval and clearance from the Department's Research and Technical Review Committee.

18.5.2. Retrieval of Pertinent protocol file

The Staff retrieves the corresponding protocol file as reference in the review of the Final Report.

18.5.3. Notification of REC Chair and Primary Reviewer

The Staff notifies the Chair and the Primary reviewers of the receipt of the Final Report and awaits further instructions.

18.5.4. Expedited Review or Full board Review

(See SOP 5 Expedited Review or SOP 6 Full board Review)

The Chair instructs the staff to include the report in the agenda of the next meeting and to ensure that the primary reviewer is given the necessary documents so that s/he can prepare the presentation during the next meeting.

18.5.5. Communication of Committee Action

It is suggested that the REC consider the following decisions in the review of a final report: Acceptance of the Final Report or to require resubmission with correction. (See SOP 25 Communicating REC Decisions).

18.5.6. Filing of the Final Report and related documents and update of the protocol database.

The Staff files the Final Report and related documents in the appropriate folder and updates the protocol database.

18.6. Forms

18.6.1. Form 3.3 Closure/Final Report
18.6.2. Form 3.10 Notification Letter
18.6.3. database

18.5.7 History

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres Ms. Leticia Dizon	Adopted the 2017 DOH SOP
3	April 27, 2021	SOP Team	Added on Scope, submission of Final Report should be within 30 days after completion of study and that it will be reviewed by Full Review
4	July 07, 2021	SOP Team	Edited Detailed Instruction #1, to make it clear
5	November 15, 2021	Dr. Irfa Barcellano-Ducusin	Simplified Purpose and Scope Revised Process Flow / Steps and corresponding Detailed Instruction
6	October 19-20, 2022	Ms. Vanessa Credo	Real-time Revision during SOP Workshop Added Policy Statement and Forms
7	May 11, 2023 June 15, 2023	SOP Team SOP Team	Policy Statement, Process flow and Detailed Instruction - Revised the type of review to expedited review Revised type of review Complied with standard rule - The review of final report shall follow the initial type of review *(Recommended by PHREB-CSA)*

19.1 Policy Statement

The NCMH-REC shall consider the perspective of the researcher regarding the feasibility and acceptability of REC recommendations including its disapproval, Appeals of researchers shall undergo full review and shall be resolved within thirty (30) working days upon receipt of the fully documented appeal.

19.1 Purpose

Management of appeals ensures fairness, transparency and comprehensiveness of ethics review that takes into consideration the perspective of the researcher.

19.2 Scope

The SOP on Management of Appeals covers procedures that begin with the receipt of the appeal and ends with communicating the committee's action to the researcher until the updating of the protocol.

19.4 Process Flow

STEP	Activity	Responsibility	TIMELINE
1	Receipt of an appeal	Staff	1 day
2	Retrieval of pertinent protocol file	Staff	
3	Notification of Chair and Primary Reviewer/s	Staff	3 days
4	Inclusion in Agenda of the next regular meeting	Chair and Primary Reviewer	1 day
5	Discussion of and deliberation on the appeal	Chair and Members	1 day
6	Communication of committee action (See SOP 25 on Communicating REC Decisions)	Chair	2 days
7	Filing of documents and updating of the protocol database	Staff	1 day

19.5 Detailed Instructions

19.5.1 Receipt of an Appeal

The Staff receives the letter of appeal and enters the pertinent information into the Database Incoming & Outgoing Protocols.

19.5.2 Retrieval of pertinent protocol file

The Staff retrieves the pertinent file for reference in the review. The file includes the initially submitted protocol, Informed Consent Form research tools and other related documents

19.5.3 Notification of Chairperson and Primary Reviewers

The Staff notifies the Chair and the Primary reviewers about the letter of appeal and awaits further instructions.

19.5.4 Inclusion in the Agenda of the for next regular meeting

The Chair and members instructs the Staff to include the appeal in the agenda of the next meeting, to ensure that the retrieved protocol and related documents are available during the meeting and to inform the researcher to be available on the scheduled meeting in case there is a need for further clarification.

19.5.5 Discussion of and Deliberation on the Appeal

19.5.5.1 The Primary Reviewer summarizes the protocol and the previous discussion of the issues in the protocol as background to the appeal.

19.5.5.2 The Chair presents the contents of the appeal and leads discussion.

19.5.5.3 The researcher may be called in for further clarification of issues. The researcher is asked to step out after the committee has taken up the issues for clarification.

19.5.5.3 The committee then decides (by voting) whether to accept any or all of the points raised in the appeal.

19.5.6 Communication of Committee Action

Based on the careful and objective deliberations, the Chair summarizes the decision points and instructs the staff to prepare the draft decision letter (Form 3.10 Notification Letter) for his/her finalization and forwarding to the researcher (SOP 25 Communicating REC Decisions).

19.5.7 Filing of Documents and Update of Protocol Database

The Staff files all the documents into the appropriate folder and updates the protocol database accordingly.

19.6. Forms

19.6.1. Form 3.10 Notification Letter

19.6.2. Data Base

19.7 History

Version No.	Date	Authors	Main Change
3	April 27, 2021	SOP Team	Added SOP (new)
5	November 15, 2021	Ms. Ely Espinosa	Rephrased Purpose to make it clear Edited Detailed #4 to #6 to make it clearer.
6	October 19-20, 2022	Ms. Vanessa Credo	Real-time Revision during SOP Workshop Added Policy Statement and Forms
7	May 11, 2023	SOP Team	Shorten the timeline from 42 to 30 working days in policy statement Revised 19.5.5.3 from consensus to voting

20.1. Policy Statement

The REC shall conduct visits of selected sites of approved protocols that fall within the following established criteria for such visits: Site visits are part of NCMH REC oversight functions in the following conditions: (a) high risk studies, (b) receipt of significant number of protocol violations, (c) receipt of complaints from participants and families, (d) non-receipt of required after-approval reports from the and (e) multiple studies conducted by a researcher.

20.2. Purpose

Site visits are mechanisms with which the Research Ethics Committee monitors compliance with approved protocols, IFC, process and continuing protection and promotion of participant's dignity, rights and well-being.

20.3. Scope

This SOP includes the steps in conducting visits to study sites for reasons set by the Research Ethics Committee. It begins with the selection of the site to be visited and ends with filing of Site-Visit Reports in the protocol folder and updating of the protocol database.

20.4. Process Flow

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Selection of Site to visit	Members	1 day
2	Notification of researcher	Staff	1 day
3	Creation of Site Visit Team	Chair	3 days
4	Conduct of site visit	Site Visit Team (members)	1 day
5	Draft of report and presentation of report during meeting and discussions and recommendations	Site Visit Team (members)	7 days
6	Transmittal of Final Reports and Recommendations to the Researcher/Investigator	Chair and Staff	1 day
7	Filing of Site Visit Reports in the protocol folder and Update the Protocol Database	Staff	1 day

20.5. Detailed Instructions

20.5.1 Selection of site to visit

The Members may recommend visiting Study Sites for any of the following reasons:

20.5.1.1. high risk studies

20.5.1.2. consistent non-submission or failure to submit after-approval submission requirements

20.5.1.3. reports of major protocol noncompliance

20.5.1.4. significant number of serious adverse events

20.5.1.5. reports of complaints from study participants

Site visits are likewise selected to ensure that the conduct of approved and appropriate procedures, primarily of risky protocols is done accordingly. It may be conducted based on recommendation of Primary Reviewers.

20.5.2 Notification of researcher

The Staff prepares the letter informing the Principal Investigator of the planned study site visit two weeks before the scheduled visit with the approval of the Chair. Attached to the letter are the study Site Visit plan and the study Site report form.

20.5.2.1. The Site Visit Team members are formally informed of their assignment.

20.5.2.2. The Staff prepares the study Site Visit package consisting of the latest version of the approved protocol and informed consent documents, and other relevant documents,(like protocol deviation reports, on-site SAEs / SUSARs - initial and follow-up reports) and a copy of the Study Site Visit Report Form.

20.5.3 Creation of Site Visit Team

20.5.3.1. The Chair selects members of the study Site Visit team and designates the Team Leader. Composed of at least three (3) people: one (1) the Primary Reviewers of the Protocol, one (1) Medical Member who reviews SAEs/SUSARs, and one (1) REC member.

20.5.3.2. The Site Visit Team members are formally informed of their assignment.

20.5.3.3. The staff prepares the study Site visit package consisting of the latest version of the approved protocol and informed consent documents , and other relevant documents, (like protocol deviation reports, on-site SAEs /SUSARs - initial and follow-up reports) anda copy of the Study Site Visit Report Form.

20.5.3.4. The staff and Study Visit Team prepare the study Site Visit plan that includes the following:

20.5.3.4.1. Date and time of planned visit
20.5.3.4.2. Members of the study Site Visit Plan
20.5.3.4.3. Objectives of the visit
20.5.3.4.4. Documents to be reviewed
20.5.3.4.5. Persons to be interviewed

20.5.4. Conduct of Site Visit Team

20.5.4.1. Some important points to consider during the site visit include:

20.5.4.1.1. Study protocol version
20.5.4.1.2. Informed consent documents: verify if the site is using the most recently approved version.
20.5.4.1.3. Post-approval documents: verify if these have been submitted to and approved by the REC.
20.5.4.1.4. Security, privacy, and confidentiality of the documents at the study site.
20.5.4.1.5. Facilities of the study site.
20.5.4.1.6. Determination of the protection of the rights , safety, and welfare of human participants in the study.

20.5.4.2. The study Site Visit team conducts the site visit as per the Study Site Visit Plan. Additional guide in the conduct of the visit is the Study Site Visit Report Form.

20.5.4.3. At the end of the visit, the Study Site Visit Team presents the findings to the Study Team and solicits feedback.

20.5.4.4. The Study Site Visit Team completes the study Site Visit Report Form.

20.5.4.5. Conflicting findings should be resolved in voting.

20.5.4.6. The report is submitted to the Staff within seven (7 days from the date of the visit.

20.5.4.7. The Staff logs the submission in the log of incoming documents.

20.5.4.8. The Staff includes the presentation of the Study Site Visit report in the meeting agenda.

20.5.5 Draft of reports and presentation of report during meeting and discussion for recommendations.

20.5.5.1 The study Site Visit Team collates the draft of reports and presents the report during the Full committee meeting.

20.5.5.2 The REC makes a determination whether the rights, safety, and welfare of research participants are compromised and appropriate recommendations to the Principal Investigator, if there are any.

20.5.5.3 The study Site Visit Team is given 14 days to complete the report findings. The Site Visit Team Leader will be responsible for the presentation of the result during the REC meeting.

20.5.6 Transmittal of Final Report and Recommendations to the Research Investigator.

The Staff prepares a summary of findings and recommendations of the REC based on the deliberations during the meeting. The Chair finalizes the draft for transmittal to the Researcher/Investigator; see SOP 24 Communicating REC Decisions.

The NCMH-REC decision will be sent to the Principal Investigator within fifteen (15) calendar days after the REC board meeting.

The Principal Investigator may be requested to provide additional information, submit additional documents, or implement corrective action.

The Staff follows-up the action taken by the Principal Investigator.

20.5.7 Filing of the Site Visit documents and updates the Protocol Database.

The Staff files the Site Visit Report and the recommendations in the appropriate folder and updates the protocol database accordingly see SOP 26 on Management of Active Files.

20.6. Forms

20.6.1. Form 3.7 Study Site Visit Report Form

20.6.2. Database

20.7. History

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres Ms. Leticia Dizon	Adopted the 2017 DOH SOP
2	February 15, 2021	SOP Team	Edited Detailed Instruction #2, indicated the number of REC members who will constitute the site visit team, to include the primary reviewer who initially reviewed the protocol
3	April 27, 2021	SOP Team	Added on Detailed Instruction #1, criteria for site visit
5	November 15, 2021	Ms. Ely Espinosa	Rephrased Purpose and Scope to make it clear Added on Detailed Instruction #1 the last paragraph, on reason for site visit.
6	October 19-20, 2022	Ms. Vanessa Credo	Real-time Revision during SOP Workshop Added Policy Statement and Forms
7	May 11, 2023	SOP Team	Added decision points in 20.5.6 (Recommended by PHREB-CSA)

21.1. Policy Statement

The REC shall have a regular schedule of meetings every first Tuesday of the month. All meetings shall be held within the premises of the institution. Online or hybrid meetings can be held if face to face meetings are not possible. Special meetings shall be held to resolve issues that require immediate attention, e.g. safety of participants, protocol violation that impact research integrity.

21.2. Purpose

Preparing for a meeting aims to contribute to a smooth, orderly, and efficient conduct of meetings.

21.3. Scope

This SOP begins with the preparation of the agenda and ends with the notification of REC Members and confirmation of attendance.

21.4. Process Flow

STEP	Activity	Person/s Responsible	TIMELINE
1	Preparation of the agenda	Staff	1 day
2	Confirmation of the venue/for online meetings preparation of zoom link	Staff	
3	Assembly of materials and documents/for online meetings, materials and documents are sent to members thru email at least seven days earlier	Staff	1 day
4	Preparation of presentation and recording equipment, food arrangements for the meeting	Staff	1 day
5	Notification of members and confirmation of attendance	Staff	1 day

21.5. Detailed Instructions

21.5.1. Preparation of the agenda.

Please see SOP 22 for the detailed description of preparation of agenda

21.5.2. Confirmation of the venue.

The Staff notifies the building administrator regarding the upcoming meeting of the REC (date, time, appropriate conference room) one week before the schedule. For online meetings, the zoom link must be secured at least three days before the meeting.

21.5.3. Assembly of materials and documents needed for the meeting.

The Staff gathers the documents and materials for the meeting based on the provisional agenda, e.g. copies of the provisional agenda, provisional minutes of the previous meeting, protocols and related documents submitted, at least 7 days before the meeting, post-approval reports, expedited review reports, administrative memos, etc. For online meetings, these materials shall be sent to members through email at least seven days before the meeting.

21.5.4. Preparation of presentation and recording equipment, food arrangements for the meeting.

The Staff ensures that the following are prepared and available for the meeting: laptop (2), projector, and screen, microphones, adequate food and drinks/water depending on the expected duration of the meeting, respective honoraria of committee members, if any.

21.5.5. Notification of REC Members and confirmation of attendance.

The member secretary supervises the staff in the preparation of the Notice of Meeting that includes the provisional agenda. The Staff sends the notice of meeting to the members of the committee, at least, one week before the schedule and follows-up the confirmation of attendance to ensure quorum. In case, quorum cannot be met, the Staff informs the Chair and the member secretary so that they re-scheduled the meeting.

21.6. Forms

21.6.1. Form 4.1 Meeting Agenda Template

21.7. History

Version No.	Date	Authors	Main Change
3	April 27, 2021	SOP Team	Added SOP (new)
5	November 15, 2021	Mr. Alfredo Torres	Used the format for SOP
6	November 10, 2022	Mr. Alfredo Torres	Added Policy Statement and Forms

22.1. Policy Statement

The meeting agenda shall be based on the submissions received at the latest, fourteen (14) days before the scheduled regular meeting. It shall follow an established template for meeting agenda. The provisional agenda shall be included in the Notice of Meeting.

22.2. Purpose

The preparation of the meeting agenda aims to ensure a smooth, orderly, inclusive, and efficient conduct of meetings.

22.3. Scope

This SOP begins with the preparation of a draft meeting agenda and ends with filing of the final meeting agenda.

22.4. Process Flow

STEP	ACTIVITY	PERSON/S RESPONSIBLE
1	Preparation of draft meeting agenda	Staff and Member Secretary
2	Preparation of provisional meeting agenda	Chair
3	Distribution of provisional meeting agenda	Staff
4	Approval of provisional meeting agenda	Members
5	Filing of the final meeting agenda	Staff

22.5 Detailed Instructions

22.5.1. Preparation of the draft meeting agenda.

The Staff under the supervision of the Member Secretary prepares the draft agenda fourteen (14) days before the scheduled meeting, using the Meeting Agenda Template (Form 4.2). The agenda shall include the following:

1. Call to Order
2. Declaration of Quorum
3. Approval of the Provisional Agenda
4. Disclosure of Conflict of Interest
5. Review and Approval of the Minutes of the Previous Meeting
6. Business Arising from the Minutes

7. New Business:

    7.1. Full Review

        7.1.1. Initial Review
        7.1.2. Resubmissions
        7.1.3. Post-approval Reports

    7.2. Report of Expedited Review protocols
    7.3. Report of exempted protocols

8. Other Matters

22.5.2. Preparation of the provisional meeting agenda.
The Chair reviews the draft agenda (within 2 days) as the basis of preparing the provisional agenda for inclusion in the Notice of Meeting.

22.5.3. Distribution of the provisional meeting agenda.
The provisional agenda is included in the Notice of Meeting.

22.5.4. Approval of the provisional meeting agenda.
The REC members approve the provisional agenda during the meeting. (SOP 23 Conduct of Meeting).

22.5.5. Filing of the final meeting agenda.
The Staff files the final (approved) meeting agenda in a special folder that contains all meeting agenda in a chronological order. (See SOP 27 on Management of Active Files)

22.6 Forms

22.6.1. Form 4.2 Meeting Agenda Template

22.7 History

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres	Adopted the 2017 DOH SOP

		Ms. Leticia Dizon	
2	February 15, 2021	SOP Team	Included a step that informs the PI to be available on the date of protocol's discussion on board meeting; and how s/he will be informed. Added on Detailed Instruction #3, PI to receive notice of the meeting
4	July 07, 2021	SOP Team	Revised the Process Flow / Steps and Detailed Instruction
5	November 15, 2021	Mr. Alfredo Torres	Revised the whole SOP Changed sequence on Detailed Instruction #1
6	November 10, 2022	Mr. Alfredo Torres	Added Policy Statement and Forms
7	May 11, 2023	SOP Team	Added Report on Exempted Protocols (Recommended by PHREB-CSA)

23.1. Policy Statement

Meetings shall be presided by the chair or designated substitute, shall proceed only when quorum is declared, and shall be guided by the approved agenda. The presence of a conflict of interest among the members shall be disclosed prior to the discussion of protocols for review. Regular monthly meetings shall be conducted every first Tuesday of the month and special meetings shall be convened as needed.

23.2. Purpose

Meetings are conducted to provide an opportunity for the REC to arrive at collegial decisions regarding study protocols and REC operations and to be informed of pertinent administrative matters.

23.3. Scope

This SOP starts with distribution of meeting materials and ends with the Collection, storage and disposal of meeting materials.

23.4. Process Flow

STEP	ACTIVITY	PERSON/S RESPONSIBLE
1	Distribution of meeting materials	Staff
2	Call the meeting to order	Chair
3	Determination of quorum	Member-Secretary
4	Approval or modification of the provisional agenda	Members
5	Declaration of conflict of interest	Members
6	Approval of the minutes of the previous Meeting	Members
7	Discussion of business arising from the minutes of the previous meeting	Members

8	Review of protocols and protocol-related submissions	Primary Reviewers/Members
9	Reporting of approved expedited review	Chair
10	Reporting for exempted from review	Chair
11	Discussion of operations-related matters	Chair and members
12	Adjournment	Chair
13	Collection, storage and disposal of meeting materials	Staff

23.5. Detailed Instructions

23.5.1. Distribution of meeting materials

23.5.1.1. Face-to-face - The Staff distributes REC forms, research protocols and other related documents for discussion or to be used during the meeting. These meeting will be used by the NCMH REC when all members will attend in their physical presence, meet in person and at the same meeting location.

23.5.1.2. Online -The Staff sent through email the REC forms, research protocols and other related documents for discussion or to be used during the meeting as well as the zoom link one week before the meeting. These meeting will be used by the NCMH REC when all members will attend through online and participate in meetings from remote locations.

23.5.1.3. Hybrid - The Staff distributes hard copy of REC forms, research protocols and other related documents for those who will attend through face-to-face. And for members joining online, The Staff sends through email the REC forms, research protocols and other related documents for discussion or to be used during the meeting as well as the zoom link one week before the meeting. This meeting will be used when the NCMH REC has scheduled the meeting for face-to-face but some members will attend online, especially non-affiliated members and some members cannot physically attend due to inclement weather, national disaster or calamities and other similar events preventing physical presence in the office.

23.5.2. Call the Meeting to order

The Chair declares the formal opening of the Meeting at the appointed time and place once majority of the members are present.

23.5.3. Determination of Quorum

The Member-Secretary checks and reports if the quorum requirements are met to enable the meeting to start. REC quorum requirements should comply with National and International requirements and as defined in these SOPs. Quorum should be maintained throughout the duration of the meeting when members are required to vote to arrive at a decision. The following should be met to constitute quorum in a meeting of REC:

1. 50%+ 1 of members but not less than 5
2. Presence of Medical / Scientific and Non-Medical / Non-Scientific Members
3. Presence of Non-Affiliated member

23.5.4 Approval or Modification of the provisional Agenda

23.5.4.1. The Chair asks the Members to examine and approve the items in the Meeting Agenda.

23.5.4.2. Members may suggest additional items for discussion and the meeting agenda may be modified to include them.

23.5.5. Declaration of conflict of interest

23.5.5.1. The Chair asks the Members to declare their Conflict of Interest related to any protocols to be discussed.

23.5.5.2. The Members check the agenda and declare their COI related to any protocol to be reviewed. They shall be asked to leave the room during the discussion of such protocols, unless they are asked to reply to questions for clarification. Quorum should be maintained when conflicted members leave the room. They return to the room after the discussion and decision making process of the REC.

23.5.6. Approval of the Minutes of the previous Meeting.

The Minutes of the previous meeting should have been sent to all members before the meeting for review and comments. The Chair asks the Members to voice out their comments/corrections, if any, and thereafter asks them to approve the minutes of the last meeting.

23.5.7. Discussion of business arising from the minutes of the previous meeting.
The Chair also asks the members to comment about issues arising from the Minutes and the discussions are recorded in the current Minutes by the staff.

23.5.8. Review of protocols and protocol-related submissions
The list of protocols for full board review is discussed according to the following procedures:

23.5.8.1. The Primary Medical Reviewer summarizes the protocol to enable the members to understand it.

23.5.8.2. He/she uses the assessment form to comment on the technical and ethical issues in the protocol and makes recommendations about clarification, modification or approval. He/she also comments on the qualifications of the researchers and the sites.

23.5.8.3. The Non-Medical / Non-Scientific Reviewer presents his / her assessment of the Patient Information Sheet and Informed Consent Form making use of the Informed Consent Assessment Form. The comments should note the discrepancies between the protocol and the information sheet, the correct consent or assent is enclosed, and provisions for proper signatures in the form.

23.5.8.4. The Independent Consultant as technical resource person if invited shall present his/her review or comments on the protocols.

23.5.8.5. The Chair opens the protocol for discussion of Members taking note of additional and contradictory comments.

23.5.8.6. The Principal Investigator, if needed, is called to enter the room to answer questions and clarify certain protocol related matters, after which, s/he is asked to leave the room.

23.5.8.7. The Chair summarizes the points raised and recommendations made by the Members.

23.5.8.8. The Chair asks the members to vote based on the decision points in the SOPs:

a. Approval (no further revision of the documents is required)
b. Minor Modification
c. Major Modification
d. Disapproval

23.5.8.9. The Member-Secretary takes note of voting results, records them and includes them in the Minutes of the meeting.

23.5.8.10. Once the protocol documents are approved, the REC Members should agree on the frequency of continuing review.

23.5.9. Review of Post approval reports

23.5.9.1 Amendments
23.5.9.2 Progress Reports
23.5.9.3 Protocol deviation/violations
23.5.9.4 Early Study Termination Reports
23.5.9.5 Queries, Notifications, and Complaints
23.5.9.6 SAE, SUSAR Reports/RNE Reports
23.5.9.6 Site Visit Reports

23.5.10 Reporting of approved expedited review protocols

The Chair reports the approved expedited review protocols.

23.5.11 Reporting of exempted from review protocols

The chair reports all protocols that were exempted from review.

23.5.12 Discussion of operations-related matters

The Chair / Member-Secretary or any Member may suggest items or other matters for the information or discussion by the Full Board.

23.5.13. Adjournment

The Chair formally closes the meeting after determination that all the Meeting Agenda items have been discussed. A group photo shall be done for online meetings.

23.5.14. Collection, storage and disposal of meeting materials

The Staff collects the materials and returns to the filing cabinet and extra copies disposed using shredder in accordance with the Disposal policy of National Archives of the Philippines.

23.6. Forms

23.6.1. Form 4.2 Meeting Agenda template
23.6.2. Form 2.3 Protocol Assessment Form
23.6.3. Form 2.4 Informed Consent Assessment Form
23.6.4. Form 4.3 Minutes of the meeting template
23.6.5. Form 3.1 Decision Form

23.7. History of SOP

Version No.	Date	Authors	Main Change
4	July 07, 2021	Dr. Christopher Christian Chu	Added SOP (new)
5	November 15, 2021	Mr. Alfredo Torres	Used the SOP format Added taking of screenshot of attendees
6	November 10, 2022	Mr. Alfredo Torres Ms. Charlene Joyce Magsisi	Added Policy Statement and Forms
7	March 21, 2023	SOP Team	Revised 23.5.1 when these forms of meeting shall be used by the REC

24.1. Policy Statement

The meeting minutes shall be based on the approved agenda and shall be the basis of the decision letter on protocols.

24.2. Purpose

The preparation of the minutes of the meeting ensures the proper documentation of the procedures and decisions in an REC meeting.

24.3. Scope

This SOP begins with the entry of preliminary information on the minutes template and ends with the filing of the approved minutes.

24.4. Process Flow

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Entry of preliminary information on the minutes template	Staff	1 day
2	Preparation of the draft minutes	Staff	
3	Notation of the draft minutes	Chair	7 days
4	Approval of the minutes in the next REC meeting	Chair and Members	1 day
5	Filing of the approved minutes (SOP 27 on Managing Active Files)	Staff	

24.5. Detailed Instructions

24.5.1. Entry of preliminary information on the minutes template

24.5.1.1. The Staff fills up the basic information about each protocol submission for review of the REC Meeting Minutes template with identifying information (Protocol number, title, Principal Investigator, sponsor, etc.) before the meeting date.

24.5.1.2. The Staff uses this prepared template to document the proceedings during the meeting.

24.5.2. Preparation of the draft minutes

24.5.2.1. As the meeting proceeds, the Staff takes down notes, projects the template on screen and does real-time note-taking to enable the Members to closely follow the proceedings, and to facilitate the recapitulation of discussion points by the Chair.

24.5.2.2. The REC comments and recommendations on the scientific issues, ethical issues, and informed consent form issues. No attribution to specific members is stated in the minutes.

24.5.2.3. Within the day, the Member Secretary checks the prepared draft of the minutes.

24.5.3 Notation of the draft minutes

The Meeting Minutes should include the following items:

24.5.3.1. Date and venue of the meeting

24.5.3.2. Member attendance (members present and absent) to determine quorum

24.5.3.3. Guests and observer attendance

24.5.3.4. Presiding Officer

24.5.3.5. Time when the meeting was called to order

24.5.3.6. Status of quorum at the start of the meeting and before every decision making

24.5.3.7. Conflict of interest declaration by members

24.5.3.8. Members who declared COI and the protocol concerned

24.5.3.9. Discussion of items based on the order in meeting agenda

24.5.3.10. Summary of technical and ethical discussion points and recommendations

24.5.3.11. REC decision and voting results according to decision categories, abstention and votes for disapproval with reasons given.

24.5.3.11.1. If the review decision (for initial and continuing reviews) is “approved”, the frequency of submission of progress report is determined.

24.5.3.11.2. If the review decision is disapproved, the reasons for the disapproval are stated.

24.5.3.11.3. If the review decision (for initial and continuing reviews) is "for modification", the items to be revised are identified and the type of review for the resubmission is defined.

24.5.3.12. Attach the list of submissions approved through Exempted and Expedited review for the information of members.

24.5.3.13. Name and signature of the person who prepared the Minutes

24.5.3.14. Name and signature of the Member-Secretary to indicate the contents have been verified and corrected

24.5.3.15. Name and signature of the Chair who approved the Minutes with the date of approval

The Staff who prepared the draft of the Meeting Minutes submits it to the Chair for correction and finalization within three (3) days from the date of the meeting.

The Staff distribute/send the copy of the provisional meeting minutes to the Members for their review and comments within seven (7) days from the meeting date. The Members are expected to submit their corrections to the group.

The Staff finalizes minutes of the meeting incorporating corrections from the Members.

The Staff distributes the final version of the minutes of the meeting together with the Notice of Meeting for the next REC meeting.

24.5.4. Approval of the minutes in the next REC meeting

Approval of the minutes is done through a formal motion from any member of the committee and seconded accordingly.

24.5.5. Filing of the approved minutes

24.5.5.1. The Staff files approved Meeting Minutes in the folder for Minutes of Meetings.

24.5.5.2. Excerpts of Meeting Minutes may be extracted and filed in a specific protocol file folder, and the protocol file index is updated.

24.6. Forms

24.6.1. Form 4.3 Minutes of the meeting

24.7. History

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres Ms. Leticia Dizon	Adopted the 2017 DOH SOP
3	February 15, 2021	SOP Team	Added on Detailed Instruction #2, attendance of Non-Scientist or Lay person, Non-Institutional Member
4	July 07, 2021	SOP Team	Added on Detailed Instruction #2, inclusion of report of exempted protocols
5	November 15, 2021	Dr. Maurice Sañosa	Rephrased Detailed Instruction #2, meeting minutes inclusion
6	November 10, 2022	Mr. Alfredo Torres Ms. Charlene Joyce Magsisi	Added Policy Statement and Forms
7	March 21, 2023	SOP Team	Rephrased 24.5.2.3 to “Within the day, the Member Secretary checks the prepared draft of the minutes.” (Recommended by PHREB-CSA)

25.1. Policy Statement

The REC shall communicate its decisions to the researcher within seven (7) days after the meeting date for Full Board or seven (7) days after receipt of Expedited review results. The communication document shall include clear instructions/recommendations for guidance of the researcher, must be written on an official stationery of the REC and signed by the Chair.

25.2. Purpose

The management of communicating REC decisions ensures that all stakeholders are appropriately, accurately and promptly informed of the results of deliberations of the REC.

25.3. Scope

This SOP begins with the finalization of recommendations of the committee or the reviewers and ends with the filing of the decision document in the protocol file and updating of the protocol database.

25.4. Process Flow

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Finalization of recommendations of the committee (in case of full review SOP 6) or reviewers (in case of expedited review SOP 5)	Chair	1 day
2	Transfer of information from meeting minutes or reports to REC decision forms or templates (Form 3.10)	Staff	1 day
3	Approval of the REC decision document	Chair	1 day
4	Transmittal of REC decision to researcher	Staff	1 day
5	Filing of the decision document in the protocol file (SOP 27 Managing Active Files) and Update of Protocol database	Staff	1 day

25.5. Detailed Instructions

25.5.1. Finalization of recommendations of the committee (in case of full review SOP 6) or reviewers (in case of expedited review SOP 5).

25.5.2. Transfer of information from meeting minutes or reports to REC decision forms or templates (Form 3.10)

25.5.2.1. The Staff prepares the Notification or Approval letter upon approval of the draft minutes, or finalization of the reviewers' recommendations.

25.5.2.2. The Staff transfer the information from meeting minutes or reports to REC Notification letter or Approval letter to communicate them to the Principal Investigator.

25.5.2.3. The Member Secretary checks the prepared draft of the minutes within three (3) days after the meeting date for Full Board or three (3) days after receipt of Expedited review results

25.5.3. Approval of the REC decision document

25.5.3.1. The Chair signs and dates the Notification or Approval letter.

25.5.3.2. All Notification or Approval letters should be ready within seven (7) days after the meeting date for Full Board or seven (7) days after receipt of Expedited review results.

25.5.4. Transmittal of REC decision to researcher

25.5.4.1. The Staff informs the Principal Investigator / Research Assistant that the original copy of the Notification or Certificate of Approval is ready for pick-up.

25.5.4.2. The Staff gives the Notification or Approval letter to the Investigator/Research Assistant.

25.5.4.3. The Staff logs the Notification or Approval letter in the log of outgoing documents when the original copies are released.

25.5.5. Filing of the decision document in the protocol file (SOP 27 Management of Active Files) and Update of Protocol database.

The Staff files a duplicate copy of the Notification or Approval letter in the protocol file folder and updates the Protocol database

25.6. Forms

25.6.1. Form 4.3 Minutes of the meeting template
25.6.2. Form 3.10 Notification Letter

25.7. History

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres Ms. Leticia Dizon	Adopted the 2017 DOH SOP
5	November 15, 2021	SOP Team	Indicated notification letter form number
6	November 10, 2022	Mr. Alfredo Torres Ms. Charlene Joyce Magsisi	Added Policy Statement and Forms
7	March 21, 2023	SOP Team	Rephrased 25.5.2.3 to "the Member Secretary checks the prepared draft of the minutes." (Recommended by PHREB-CSA)

26.1. Policy Statement

All communications shall be recorded accurately and appropriately in a Database Incoming & Outgoing Protocols. Protocol-related communications are separated from administrative communications. Incoming communications shall be acted upon promptly.

26.2. Purpose

The management of REC incoming and outgoing documents/communications aims to establish accountability and an efficient and effective tracking system.

26.3. Scope

This SOP begins with the sorting of incoming/outgoing communications and ends with the storing or filing of incoming/outgoing communications.

26.4. Process Flow

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Sorting of incoming/outgoing communications	Staff	1 day
2	Recording of incoming/outgoing communications	Staff	1 day
3	Acting on incoming communications	Staff and Chair	1 day
4	Filing of incoming/outgoing communications and Updating of respective Databases	Staff	1 day

26.5. Detailed Instructions

26.5.1. Sorting of incoming/outgoing communications

Separating protocol-related from administrative communication.

26.5.2. Recording of incoming/outgoing communications

The Staff logs every protocol-related document received in the Database Incoming & Outgoing Protocols. This log should contain at least the following items:

1. Protocol Code
2. Protocol Title
3. Principal Investigator

4. Date of submission
5. Details or Subject
6. Status/Remarks
7. Type of Submission (e.g. Protocol for Initial Review, Resubmitted Protocol, Application for Protocol Amendment, Protocol Violation/Deviation Report, SAE Report, etc.)

The Staff also logs protocol and protocol-related documents when they are forwarded to members for review in the Database Incoming & Outgoing Protocols. This log should contain the following items:

1. Date
2. Name of Reviewers
3. Type of Submission
4. Formulated processing days to ensure compliance with the review timeline

26.5.3. Acting on incoming communications

The Staff response on incoming communications and Chair finalize the response by signing the protocol-related document for outgoing communications.

26.5.4. Filing of incoming/outgoing communications and Updating of respective Databases

The Staff file Protocol-related communications in the study protocol file while non-protocol-related documents are filed in the appropriate administrative file on the day that they are submitted.

26.6. Forms

26.6.1. Database Incoming & Outgoing Protocols
26.6.3. Protocol File Index

26.7. History

Version No.	Date	Authors	Main Change
1	September 04,	Dr. Hyacinth Manood	Adopted the 2017 DOH SOP

	2017	Ms. Epifania Crespo Mr. Alfredo Torres Ms. Leticia Dizon	
2	April 27, 2021	SOP Team	Renamed chapter
3	July 07, 2021	SOP Team	Revised to be consistent with format
4	November 10, 2022	Mr. Alfredo Torres Ms. Charlene Joyce Magsisi	Added policy Statement and Forms

27.1. Policy Statement

Active files shall be kept in a secured cabinet, arranged in an orderly manner that shall allow easy identification and retrieval. Access to the active files shall be governed by SOP 26 on Managing Access to Confidential Files.

27.2. Purpose

The management of active files ensures accessibility, easy retrieval of current files, and protection of those that require confidentiality.

27.3. Scope

This SOP begins with the classification and coding of active files and ends with the periodic updating of the file.

27.4. Process Flow

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Classification and coding of Active Files	Staff	1 day
2	Preparation of the Protocol Folder	Staff	1 day
3	Periodic updating of the Protocol File	Staff	2 days

27.5. Detailed Instructions

27.5.1. Classification and coding of Active Files

The Staff under the supervision of the member secretary classifies active files as follows:

1. Initial Submission
2. Resubmission
3. Progress Report
4. Amendment
5. Protocol Deviation
6. Protocol Violation
7. SAE Serious Adverse Event (SAE
8. SUSAR – Suspected Unexpected Serious Adverse Reaction –
9. Early Termination

10. Continuing Review
11. Final Report/ Close Out Report

The staff assigns a code to the Initial Submission and indicates the same for the rest of the submissions related to the initial submission. The code consists of the year and the serial number that indicate the sequence order of receipt. (NCMH-REC-YYYY-SN)

27.5.2. Preparation of the Protocol Folder

The Staff files all documents pertaining to a study in a vertical folder that is labelled on the front cover and along the spine with: Protocol Code - Study Title - Name of Principal Investigator. The staff attaches a protocol index on the inside front cover that indicates the contents of the folder.

27.5.3. Periodic updating of the Protocol File

The Staff ensures that the documents are filed in chronological order such that the most recent documents are topmost. These documents include the following:

1. Protocol (Original and Revised) versions
2. Informed consent (Original and Revised) versions
3. Reports: Progress, Protocol Deviation/Violation, SAE/SUSAR, Final, Amendment,
4. Early Termination, Site Visit Reports
5. Assessment Forms for each of the submitted and reviewed reports which should be signed and dated
6. Excerpts of Minutes of Meetings when the protocol and reports were included in the agenda
7. Decision and Approval Letters
8. Communications

The Staff updates the protocol index each time a new document is added to the file. The protocol folder is periodically checked for orderliness and completeness.

27.6. Forms

26.6.1. Protocol file Index

27.7. History of SOP

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres Ms. Leticia Dizon	Adopted the 2017 DOH SOP
2	February 15, 2021	SOP Team	Added on Detailed Instruction #3 the format for protocol code, color coding of folders Added on Detailed Instruction #4 the protocol amendment and deviation in the database
5	November 15, 2021	Dr. Maurice Sañosa	Added in Detailed Instruction, the color coding of protocol documents Added on Detailed Instruction #4, due date of application for continuing review to be included on database
6	November 10, 2022	Mr. Alfredo Torres Ms. Charlene Joyce Magsisi	Added Policy Statement and Forms

28.1. Policy Statement

Files of studies which have been terminated or completed or declared inactive shall be kept in a separate storage for 3 years. Studies of Researchers who have not resubmitted their proposals within 3 months after receiving the Notification Letter (Form 3.10) shall be considered inactive.

28.2. Purpose

Archiving inactive, terminated, or completed protocols ensures efficient retrieval of information from the files for reference and compliance with national and international guidelines.

28.3. Scope

This SOP begins with the acceptance of final or early termination reports and identification of a protocol as inactive and ends with the inclusion of the files in the archives and update of the protocol database.

28.4. Process Flow

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Acceptance of Final or Early Termination Reports (SOP 18 on Review of Final Reports, SOP 17 Review of Early Termination Reports) and Identification of a Protocol as Inactive.	Member Secretary and Staff	1 day
2	Updating of corresponding protocol folder	Staff	1 day
3	Transfer of the protocol folder in the archives and Update of the Protocol Database	Staff	1 day

28.5. Detailed Instructions

28.5.1. Acceptance of Final or Early Termination Reports and Identification of an Inactive File

The Committee members approve or accept the final report or early termination report during a meeting (SOP 18 Review of Final Report; SOP 17 Review of an Early Termination Report). In the identification of an Inactive File, The Staff informs the

Member Secretary of the failure of a concerned researcher/ proponent/ investigator to respond to the recommendations of the REC in the last 3 months during which time the researcher/proponent/investigator has been appropriately reminded of the requirement. This is included in the agenda of the next meeting where the protocol is declared inactive.

28.5.2. Updating of the corresponding active file

The Staff files the Final or Early termination report in the corresponding protocol folder, including the excerpts of the minutes that approved the report or declared the protocol as inactive.

28.5.3. Transfer of the Protocol Folder in the Archives and Update of the Protocol Database

The Staff checks whether the documents listed in the protocol file index are complete and remove extraneous documents. Then, the Staff transfers the folder to the archive section and updates the protocol database.

An archive number is assigned to the protocol by adding the / (year of archiving) as a suffix to the original protocol code. For example if the Final Report of Protocol NCMH-REC-2022-001 is approved in 2023, the archiving code is NCMH-REC 2022-001/2023.

28.6. Forms

28.6.1. Database

28.7. History

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres Ms. Leticia Dizon	Adopted the 2017 DOH SOP
2	February 15, 2021	Dr. Irfa Barcellano-Ducusin	Added on Process Flow / Steps and Detailed Instruction the assignment of new code for archived files

4	July 07, 2021	SOP Team	Added on Detailed Instruction #1 file classified as inactive protocol
6	November 10, 2022	Mr. Alfredo Torres Ms. Charlene Joyce Magsisi	Added Policy Statement and Forms
7	March 21, 2023	SOP Team	Added archive number assigned to the protocol by adding the / (year of archiving) as a suffix to the original protocol code

29.1. Policy Statement

Access to the REC confidential files shall be regulated and limited to REC members and staff. Other persons with legitimate interest in these files (e.g. institutional authorities, regulatory agencies, sponsors) shall be allowed to access specific files with proper justification. Researchers/Investigators shall be allowed access only to their own protocol files upon request.

29.2. Purpose

Management of access to confidential files helps protect the intellectual property rights of researchers and enhances the credibility and integrity of the REC

29.3. Scope

This SOP begins with the receipt of the request to access and ends with the return of the documents to the protocol folder.

29.4. Process Flow

Step	Activity	Person/s Responsible	TIMELINE
1	Receipt and log of request for access to confidential files	Staff	1 day
2	Approval of requests for access and retrieval of documents	Chair	1 day
3	Supervision of use of retrieved document	Staff	1 day
4	Return of document to the files	Staff	

29.5. Detailed Instructions

29.5.1. Receipt and log of request for access to confidential files

The staff receives the request to access specific files and refer this to the Chair.

29.5.2. Approval of requests for access and retrieval of documents

29.5.2.1. The requirements for approval of requests for access to confidential files:

29.5.2.1.1. Authority of the requesting individual
29.5.2.1.2. Reason for the request
29.5.2.1.3. Signing of confidentiality agreement

29.5.2.2. The Chair considers the indicated reason for the request and when found satisfactory approves it.

29.5.2.3. The staff asks the individual requesting to sign the confidentiality agreement and proceeds to retrieve the pertinent document.

29.5.3. Supervision of use of retrieved document

29.5.3.1. Access to NCMH-REC documents is generally for room use only, but requests to make copies can be accommodated on a case to case basis.

29.5.3.2. The Staff makes only the exact number of copies requested.

29.5.3.3. The recipient signs the REC log upon receipt of the copies.

29.5.4. Return of document to the files

The Staff is responsible for returning the documents in the protocol file folder, making sure that all documents are complete as per Protocol File Index.

29.6. Forms

29.6.1. Request Letter
29.6.2. Database

29.7. History

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres Ms. Leticia Dizon	Adopted the 2017 DOH SOP

2	February 15, 2021	SOP Team	Clarified on Detailed Instruction #2, Chairperson will be the one to approve access to confidential files
3	April 27, 2021	SOP Team	Added on Responsibility, Chairperson approves access to confidential files Added on Detailed Instruction #2, reason why non-member would want to access confidential files
6	November 10, 2022	Mr. Alfredo Torres Ms. Charlene Joyce Magsisi	Added Policy Statement and Forms

30.1. Policy Statement

Queries and complaints from clients, patients, or research participants shall be attended to promptly and appropriately while exercising due diligence. The nature of queries shall determine whether they can be answered by the REC staff or referred to the primary reviewers of the specific protocol. All complaints shall be referred to the Chair who shall determine the level of risk involved. Complaints of minimal risk shall be referred to the primary reviewers for resolution. Complaints of more than minimal risk shall be taken up in a special meeting within 48 hours for deliberation by the committee en banc with the primary reviewers leading the discussion.

30.2. Purpose

Managing queries and complaints aims to promote public trust and confidence in the institution, especially in the REC and to ensure that the rights and well-being of participants are attended to.

30.3. Scope

This SOP begins with the receipt, logging, and acknowledgement of queries and complaints and ends with the logging of the response and inclusion in the agenda of the REC meeting.

30.4. Process Flow

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Receipt, log, and acknowledgement of queries and complaints (SOP 25 on Managing REC Incoming and Outgoing Communications)	Staff	1 day
2	Referral of query or complaint to appropriate authority. 2.1 Referral of protocol-related query to primary reviewers. 2.2. Referral of all complaints to the Chair	Staff	2 days

3	Formulation of response 3.1. Protocol-related queries 3.2. Minimal-risk complaints 3.3. More than minimal risk complaints : en-banc committee	Primary Reviewers Chair and members	5 days
4	Communication of response (SOP on 24 Communicating REC Decisions)	Staff	1 day
5	Logging of the response (SOP 25 on Managing REC Incoming and Outgoing Communications) and inclusion in the agenda of the REC meeting (SOP 21 on Preparing the Meeting Agenda)	Staff	1 day

30.5. Detailed Instructions

30.5.1. Receipt, logging, and acknowledgement of queries and complaints (SOP 26 on Managing REC Incoming and Outgoing Communications)

The Staff receive and log the queries and complaints to the Database Incoming & Outgoing Protocols with the information below.

1. Date and time
2. Name of concerned party
3. Specific study
4. Nature of query or complaint

30.5.2. Referral of query or complaint to competent authority.

The Staff refers queries related to specific protocols approved by the REC to the primary reviewers.

On the other hand, the Staff refers all complaints to the chair who determines the level of risk affected by the issue.

30.5.2.1. Minimal risk complaints are referred to the primary reviewers of the concerned protocol.

30.5.2.2. Complaints that involve more than minimal risk are referred to the Committee through a special meeting that shall be called within 48 hours. The Staff notifies the concerned primary reviewers that they will lead the discussion such that pertinent materials are provided to them as reference.

30.5.3. Formulation of response

30.5.3.1. For queries, the primary reviewers accomplish the Form 3.6 Query Reply.

30.5.3.2. For minimal risk complaints, the primary reviewers accomplish Form 3.6 Complaints Resolution.

30.5.3.3. For more than minimal risk, the committee may choose any of the following options:

30.5.3.3.1. Constitute a site visiting team to gather more information, verification and clarification regarding the source and cause/s of the complaint for its early resolution.

30.5.3.3.2. Designate the primary reviewers to meet with the complainants and the researcher (preferably separately) for clarification of issues and obtain suggestions for resolution.

30.5.3.3.3. Formulate recommendation if satisfied with the adequacy of information –

- request for explanation/justification from researcher
- accept request/demand of participant
- suspension of further recruitment
- amendment of protocol and re-consent of participants
- others

30.5.4. Communication of response

The Staff prepare responses to the inquiry complaint and sign by the Chair.

30.5.5. Logging of the response and inclusion in the agenda of the REC meeting

The Staff Logs the response, See SOP 26 Managing REC Incoming/Outgoing Communications and include in the agenda of the next meeting, See SOP 22 Preparing the Meeting Agenda

30.6. Forms

30.6.1. Form 3.6 Query/Complaint Form

30.7. History

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres Ms. Leticia Dizon	Adopted the 2017 DOH SOP
6	November 10, 2022	Mr. Alfredo Torres Ms. Charlene Joyce Magsisi	Added Policy Statement and Forms

31.1. Policy Statement

The REC shall designate a team to annually review its set of SOPs to determine its continuing relevance and effectiveness to its operations.

31.2. Purpose

Writing and revising SOPs ensures continuing quality assurance of REC functions.

31.3. Scope

This SOP begins with the proposal and approval for revision or writing of a new SOP and ends with the distribution of approved SOPs and keeping of copies in the REC files.

31.4. Process Flow

STEP	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Proposal and approval for revision or writing of a new SOP	Members and Staff	7 days
2	Designation of the SOP Team	Chair	1 day
3	Identification of reference template with corresponding layout	SOP Team	1 day
4	Drafting of new SOPs and submission to the REC Chair	SOP Team	60 days
5	Review and finalization of new SOPs in an REC meeting and submission to the Medical Center Chief	Members/Chair	7 days
6	Approval and signing of new SOP	Medical Center Chief II	1 day
7	Distribution of approved SOPs and keeping of copies in the REC files	Staff	1 day

31.5. Detailed Instructions

31.5.1. Proposal and approval for revision or writing of a new SOP

The REC members and Staff can propose for a revision of an SOP or a new SOP.

31.5.2. Designation of a SOP Team

31.5.2.1. The Chair assigns members to be part of the SOP Team, and invites resource persons as needed.
31.5.2.2. The SOP Team receives an orientation from the Chair regarding its duties and responsibilities.
31.5.2.3 The Chair may organize SOP Team workshops to facilitate the drafting of SOPs.

31.5.3. Identification of reference templates with corresponding layout

31.5.3.1 Identify reference templates with corresponding layout from SOPs of other RECs to guide the SOP team in drafting new SOPs

31.5.3.2. A REC SOP shall have the following format:

(a) SOP Number
(b) Title
(c) Policy Statement
(d) Purpose of the SOP
(e) Scope which defines the extent of coverage of the SOP and its limitations
(f) Process Flow/Steps
(g) Detailed Instructions which elaborates the steps outlined in the process flow
(h) Standard forms and checklists to be used
(i) Each SOP should be given a number and a title that is self-explanatory and is easily understood
(j) The SOP Document History describes the different versions of the document by version number, version date, and description of main changes. This is attached with the SOP master file

31.5.3.3. The typical SOP uses a header with the following elements:

(a) Institutional seal or logo
(b) Name of Institution
(c) SOP identifier
(d) SOP title
(e) Effectivity date
(f) Page number

31.5.4. Drafting of new SOPs and submission to the REC Chair

The REC SOPs should contain details under the following main topics:

1. Introduction – contains a statement of ethical principles that will guide the REC
2. Structure and Composition – describes the composition of REC membership with specific review functions
3. Initial Review Procedures – describe types of review and initial review procedures
4. Post Approval Review Procedures – describe how the REC monitor implementation of approved protocols
5. Documentation and Archiving – describe administrative procedures that support the review functions; how to draft and revise SOPs

The SOP Team submits the completed SOP draft to the REC Chair.

31.5.5. Review and finalization of new SOPs in an REC meeting and submission to the Medical Center Chief

31.5.5.1. The Chair presents the draft SOPs during the REC meeting for the members to discuss and finalize.
31.5.5.2. The REC Chair submits the approved draft to the Medical Center Chief for approval.

31.5.6. Approval and signing of new SOPs

31.5.6.1. The Medical Center Chief reviews and approves the SOPs by signing in the designated section.
31.5.6.2. The approved SOPs will be implemented after approval by the Medical Center Chief.

31.5.7 Distribution of approved SOPs and keeping of copies in the REC files.

31.5.7.1. The Staff distributes the new REC SOPs to all Members and files the original copy in the REC storage cabinet.

31.5.7.2. The SOP Manual with downloadable forms is uploaded on the Hospital website for the use of and guidance of researchers.

31.6. History

Version No.	Date	Authors	Main Change
1	September 04, 2017	Dr. Hyacinth Manood Ms. Epifania Crespo Mr. Alfredo Torres Ms. Leticia Dizon	Adopted the 2017 DOH SOP
3	April 27, 2021	SOP Team	Added on Detailed Instruction #3 the following main topics on SOP: Post Approval Review and Documentation and Archiving
6	November 10, 2022	Mr. Alfredo Torres Ms. Charlene Joyce Magsisi	Added Policy Statement

Active Study File	A compilation of protocol related documents of an on-going study that has been approved by ERC
Adverse Drug Reaction (ADR)	All noxious or unintended responses to a new medical product or an already marketed product which shows that there is a relationship between the product and the adverse event
Adverse Event (AE)	Any unintended unfavorable sign or experience associated with the use of the investigational product whether or not related to the product.
Agenda	A list of items to be taken up at a meeting
Amendments	Change(s) from a previously approved protocol requested by the Principal Investigator
Amendments Package	A group of protocol related documents that have been modified and submitted to the ERC for approval
Archives	A designated place/section used for the storage for completed protocols, inactive files or terminated studies
Assent forms	A form used to explain the study related procedures to minors or research volunteers who lack the capacity to give consent in order to get their agreement to join the study. It is a supplementary form to the informed consent given by the guardian or the legally acceptable representative.
Audit	A systematic and independent examination of approval activities and documents related to a research study or clinical trial to determine whether the review and approval activities were conducted and data were recorded and accurately reported according to the SOPs, GCP, Declaration of Helsinki and applicable regulatory requirements.
Beneficence	The ethical obligation to maximize benefits and to minimize harms. (CIOMS, International Ethical Guidelines for Biomedical Research Involving Human Subjects, 2002). It entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.

(IRB Guidebook, US Department of Health and Human Services, retrieved from http://www.hhs.gov/ohrp/irb/irb_glossary.htm).

Benefits Any direct or indirect good effect or something of positive value to health or welfare from the research study to the participants; something that promotes or enhances well-being.

Bioequivalence The absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the similar of drug action when administered at the same molar dose under similar conditions in an appropriately designed study. Where there is an intentional difference in rate (e.g., in certain extended release dosage forms) certain pharmaceutical equivalents or alternatives may be considered bioequivalent if there is no significant difference in the extent to which the active ingredient or moiety from each product becomes available at the site of drug action. This applies only if the difference in the rate at which the active ingredient or moiety becomes available at the site of drug action is intentional and is reflected in the proposed labelling, is not essential to the attainment of effective body concentrations on chronic use, and is considered medically insignificant for the drug (Food and Drug Administration, US Department (2009). Code of Federal Regulations, Food and Drugs, 21(5), Subchapter D. Part 320. USA: FDA

Blinding Also known as masking, is a procedure in which one or more parties of the trial are kept unaware of the treatment assignment(s). Single blinding usually refers to the subjects being unaware which treatment he/she is receiving, while double-blinding usually refers to the subjects, investigator(s), monitor(s), and, in some cases, data analyst(s) being unaware of the treatment assignment(s) (ICH Harmonized Tripartite Guideline, Guideline for Good Clinical Practice (E6,R1). See also double blinding.

Bureau of Food and Drugs

The national regulatory agency under the Department of Health that mandated to guarantee the safety and effectiveness of all pharmaceutical products, biologics, vaccines, and medical devices used in the diagnosis, treatment, and prevention of diseases. It is now called the Philippine Food and Drugs Authority by virtue of Republic Act 9711 of 2009.

Case Record Form the **or Case Report Form (CRF)**	A printed, optical or electronic document designed to record all of protocol required information to be reported to the sponsor on each trial participant.
Clarificatory Meeting/Interview	A face- to-face meeting or consultation of the REC with the researcher for the purpose of obtaining explanations or clarity regarding some research issues identified by the REC.
Clinical Trial/Study	Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of an investigational product(s), and/or to identify and adverse reactions to an investigational products(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The term clinical trial and clinical study are synonymous.
Cognitively	Having either a psychiatric disorder (e.g., psychosis, neurosis, personality
Impaired	or behaviour disorders, or dementia) or a development disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgement and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be comprised in their ability to make decisions in their best interest (IRB Guidebook, US Department of Health and Human Services, retrieved from http://www.hhs.gov/ohrp/irb/irb_glossary.htm).
Comparator	An investigational or marketed product (i.e., active control), or placebo used as a references in a clinical trial
Compensation	Payment and/or medical care received or provided to subjects injured in research. Payment received by the research participants may include reimbursement for lost earnings, travel costs and other expenses incurred as a study participant, as recompense for inconvenience and time spent. It does not include remuneration for participating in the study.

Competence	Technically, a legal term, used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequence of acting (or not acting) on that information, and to make a choice (IRB Guidebook, US Department of Health and Human Services, retrieved from http://www.hhs.gov/ohrp/irb/irb_glossary.htm).
Compliance	Adherence to all the trial-related requirements, Good Clinical Practice (GCP) requirements and the applicable regulatory requirements.
Conditional approval	Approval of the protocol by the Ethics Committee to proceed after certain conditions or modifications set by the ERC are met.
Confidentiality	Prevention of disclosure to non-authorized individuals, of protocol related proprietary information or of a subject's identity
Conflict of Interest (COI)	A situation where the objective exercise of one's official duties as a member of the ERC, as a key investigator, or as an independent consultant are affected by one's private interest
Contract Research	A person or an organization (commercial, academic, or other) contracted
Organization	by the sponsor to perform one or more of a sponsor's trial-related duties **(CRO)** and functions.
Declaration of Helsinki	A code of ethics for clinical research approved by the World Medical Association in 1964 and widely adopted by medical associations in various countries. This is World Medical Association's (WMA) response to the Nuremberg Code. The declaration of Helsinki was adopted by the WMA in 1964 and has been amended five times, at regular intervals. A note of clarification about placebo-controlled trials was added in 2002 (Retrieved fromhttp://www.wma.net/e/policy/b3.htm).
Deviation/ by **Non-Compliance/**	Any event that is not in accordance with regulations or approval given the ERC **Violation**
Discontinuation	The deed of terminating participation in a clinical trial by a research subject earlier than the completion of all protocol-required terms. In

	some case, the discontinuation may be initiated by the investigator for a cause or inability to locate or follow up subject or by the sponsor.
Documentation	All records, in any form (including, but not limited to, written, electronic, magnetic, and optical records, and scans, x-rays, and the electrocardiograms) that describe or record the methods, conduct, and/or results of a trail, the factors affecting a trial, and the actions taken and includes all actions or decisions given by the ERC
Double Blinding	One in which neither the subject nor any of the investigator or sponsor staff who are involved in the treatment or clinical evaluation of the subjects are aware of the treatment received [ICH Harmonized Tripartite Guideline, Statistical Principles for Clinical Trials (E9)].
Drug	A substance used as medication or used in the diagnosis, cure, mitigation, treatment or prevention of diseases.
Effectiveness	The degree to which a diagnostic test or treatment produces a desired result in patients in the daily practice of medicine (Retrieved from https://www.ecri.org/patient/references).
Efficacy	An indication that the therapeutic effect of a clinical trial intervention is acceptable; that is, at least as good as the control intervention or standard of care to which it is compared. It is the ability of a treatment modality to produce an effect to alleviate a disease. This is the "degree to which a diagnostic test or treatment produces a desired result in patients under the idealized circumstances of a clinical trial." (Retrieved from https://www.ecri.org/patient/references).
Emergency Meeting	An ERC meeting that is scheduled outside of the regular meeting.
Epidemiology	Usually involves population-based investigations that lead to improved
Research Ethical Principles	understanding of risk factors for disease or for progression of diseases "Refers to those general judgements that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions" (National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research. (1979). The

	Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research. US, NIH, Office of Human Research Subjects). Three basic principles, among those generally accepted, that are particularly relevant to the ethics of research involving human subjects are the principles of respect of persons, beneficence and justice.
Ethics Review Committee (ERC)	An independent body constitute 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 others 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.
Exclusion Criteria	Factors utilized to determine whether an individual is ineligible for a clinical trial or research study.
Expedited Review	A review and approval process by two or more designated ERC members done for minimal risk protocols during initial review and approval of minor changes during resubmission ands amendment process
Feasibility	Possibility or likelihood to be accomplished or implemented.
Food and Drug Administration(FDA)	The new name and the reorganized and strengthened Bureau of Food and Drug by virtue of the "Food and Drug Administration (FDA) Act of 2009" or Republic Act No. 9711 of August 18, 2009, "An act strengthening and rationalizing the regulatory capacity of the Bureau of Food and Drugs (BFAD) by establishing adequate testing laboratories and field offices, upgrading its equipment, augmenting its human resources complement, giving authority to retain its income, renaming it the Food and Drug Administration, amending certain sections of republic Act No. 3720, as amended, and appropriating funds thereof." The FDA (Section 5) shall have the following Centers and offices: (a) The Centers shall be established per major product category that is regulated, namely: (1) Center for Drug Regulation and Research (to include veterinary medicine, vaccines and biological); (2) Center for Food Regulation and Research; (3) Center for Cosmetics

	Regulation and Research (to include household hazardous/urban substances); and (4) Center for Device Regulation, Radiation Health, and Research. These Centers shall regulate the manufacture, importation, exportation, distribution, sale, offer for sale, transfer, promotion, advertisement, sponsorship of, and/or, where appropriate, the use and testing of health products. The Centers shall likewise conduct research on the safety, efficacy, and quality of health products, and to institute standards for the same."
Full Board Review	Review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concern are in non-scientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting (IRB Guidebook, US Department of health and Human Services. retrieved from http://www.hhs.gov/ohrp/irb/irb_glossary.htm).
Gender	Socially defined feminine or masculine roles, attitudes, and values.
Gender Sensitivity	The ability to perceive existing gender differences, issues, and inequality and to incorporate these into strategies and actions.
Good Clinical Practice (GCP) participation **Guidelines**	An international ethical and scientific quality standards for designing, conducting, recording and reporting trials that involve the of human subjects. Compliance with these standards provide public assurance that the rights, safety, and well-being of trial subjects are protected, consistent with the principles that have their origin in the International Declaration of Helsinki, and that the clinical trial data are credible (CPMP/ICH/135/95). These are standards and procedures for clinical trials that encompass the design, protocol approval, monitoring, termination, audit, analyses, reporting, and documentation of human studies. It defines the responsibilities and activities of the sponsor, principal investigators and monitor involved in the clinical trials. The GCP ensures that the studies are scientifically and ethically sound, and all the clinical properties of the product under investigation are property documented. For complete information, reference is made to the published WHO and International Conference on Harmonization Code of Good Clinical Practice (IRB Guidebook, US Department of Health and Human Services, retrieved from

	http://www.hhs.gov/ohrp/irb/irb_glossary.htm). It is standard for clinical studies which encompasses the design, conduct, monitoring, termination, audit, analyses, reporting and documentation of the studies and which ensures that the studies are scientifically and ethically sound and that the clinical properties of the pharmaceutical products (diagnostic, therapeutic or prophylactic) under investigation are properly documented (WHO, Guidelines for Good Clinical Practice for Trials of Pharmaceutical Products).
Guardian	One who is legally responsible for the care and management of the person or property of an incompetent person or a minor or someone who can make important personal decisions in behalf of another person.
Guideline	A written suggestion, rule, etc., intended as a guide for specific practice or action.
Helsinki Declaration	Guidelines adopted in 1964 by the 18th World Medical Assembly (WMA) held in Helsinki, Finland, and revised in 2000 by the 52nd WMA General Assembly, for Physicians conducting biomedical research. This declaration outlines clinical trial procedures required to ensure patient safety, consent and ethics committee reviews in human subjects.
Hypothesis	A tentative explanations for an observation, phenomenon, or scientific problem that can be tested by further investigation.
Incapacity	A person's mental status and means, inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Often used as a synonym for incompetence (IRB Guidebook, US Department of Health and Human Services, retrieved from http:/www.hhs.gov/ohrp/irb/irb_glossary.htm).
Inclusion Criteria	The factors used to judge a participant's eligibility to be part in trial or research. These factors are justified by the purpose of the researcher in conducting the research.
Incompetence	Technically, a legal term meaning inability to manage ones own affairs. Often used as a synonym for incapacity (IRB Guidebook US

Department of Health and Human Services htttp://www.hhs.gov/ohrp/irb/irb_glossary.htm).

Independent Consultant — An expert who is not a member of the ERC who is invited to provide expert opinion about a specific protocol being reviewed by the ERC. An independent consultant does not have the right to vote to determine ERC decision.

Informed Consent Form (ICF) — A written, signed, and dated form confirming a competent participant's willingness to voluntary participate in a particular trial or research, after having been informed of all aspects that are relevant to the participant's decision to participate and given time to reflect on the decision.

Initial Review — The review of a protocol for the first time to assess its scientific soundness and compliance with ethical principles

Inspection — The act by regulatory authorities of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authorities to be related to the clinical trial and that may be located at the site of the trial, at the sponsor's and/or Contract Research Organization's (CRO) facilities, Office of Ethics Committee, or at the other establishment deemed appropriate by the regulatory authorities.

Intervention/Treatment - A process or action that is the focus of a clinical study. Interventions include drugs, medical devices, procedures, vaccines, and other products that are either investigational or already available. Interventions can also include noninvasive approaches, such as education or modifying diet and exercise.

Intervention Study (Clinical Trial) - A type of clinical study in which participants are assigned to groups that receive one or more intervention/treatment (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study's protocol. Participants may receive diagnostic, therapeutic, or other types of interventions.

Investigational Product — A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled

	(formulated or package) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use
Investigator	A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator (PI).
Investigator's Brochure	A compilation of the clinical and non-clinical data on the investigational product(s) which is relevant to the study of the investigational product(s) in human participants.
Legally Authorized law	An individual or juridical or other body authorized under applicable
Representative	to consent, on behalf of a prospective subject, to the subject's participation in the clinical trial.
Legally Competent Person	Qualified or fit to perform an act, in accordance with law, free from addiction or mental defects that renders one incapable of taking care or oneself or one's property (Merriam Webster's Dictionary of Law (c), 1996).
Majority Vote	A vote by one-half plus one ERC members attending a formal meeting that meets the quorum requirements
Medical Device	A diagnostic or therapeutic article that does not achieve any of its principal intended purpose through chemical action within or on the body. Such devices include diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopaedic pins or other orthopaedic equipment. (IRB Guidebook, US Department of Health and Human Services, Retrieved from http://www.hhs.gov/ohrp/irb_glossary.htm).
Minimal Risk	A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or test.

More than Minimal Risk Occurs when the participants in the course of the research would be exposed to more than a remote possibility of a "substantial or prolonged pain, discomfort, distress" or "clinically significant deterioration of a medical condition"

Moderate Risk Risks are recognized as being greater than minimal, but are not considered high. There is a medium to high probability of a moderate-severity event occurring as a result of study participation (e.g., reversible worsening of a non-fatal disease such as seasonal allergy while receiving placebo or pneumonia from a bronchoscopy), but there is adequate surveillance and protections to identify adverse events promptly and to minimize their effects. Requires Moderate Intensity Monitoring.

Monitoring A process of checking or scrutinizing research participants' health status during a clinical trial, and/or to oversee the progress of a trial or researcher's compliance with the protocol and regulatory requirements within which the protocol is given ethical approval.

Multicenter Trial/ Study A clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator.

Nuremberg Code A "code of research ethics developed during the trials of Nazi war criminals following World War II and widely adopted as a standard during the 1950s and 1960s for protecting human subjects" (IRB Guidebook, US Department of Health and Human Services, retrieved from http://www.hhs.gov/ohrp/irb/irb_glossary.htm). It is a series of 10 principles for permissible medical experiments involving human subjects, articulated in 1947 as part of the judgment in Nuremberg against some of the physicians who led the experiments on inmates of the Nazi concentration camps (Retrieved from http://ohsr.od.nih.gov/guidelines/nuremberg.html).

Observational Study - The general design of the strategy for identifying and following up with participants during an observational study. Types of observational study models include cohort, case-control, case-only, case-cross-over, ecologic or community studies, family-based, and other.

Other Adverse Event - An adverse event that is not a serious adverse event, meaning that it does not result in death, is not life-threatening, does not require inpatient hospitalization or extend a current hospital stay, does not result in an ongoing or significant incapacity or interfere substantially with normal life functions, and does not cause a congenital anomaly or birth defect; it also does not put the participant in danger and does not require medical or surgical intervention to prevent one of the results listed above.

Phase I Study Initial introduction of an Investigational New Drug (IND) into humans, studies designed to determine the metabolism and pharmacological actions of drugs in humans, and studies designed to assess the side effects associated with increasing doses.

Phase II Study A study of drug metabolism, structure-activity relationship, and mechanism of action in humans, as well as studies in which investigational drugs are used as research tools to explore biological phenomena or disease processes.

Phase III Study A study expanded to controlled and uncontrolled trials performed after preliminary evidence suggesting efficacy of the drug has been obtained. They are intended to gather the additional information about efficacy and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to provide an adequate basis for physician labelling.

Phase IV Study A study of a medical product conducted after marketing authorization approval to provide continuing safety evidence of the product when it is available for use of the general population

Philippine Health Research Ethics Board
Created on 1 March 2006 through DOST Special Order No. 091 Series of 2006 as a policy-making body for research ethics in the Philippines.

Philippine National Formally organized in 2004, it was conceptualized in support of a vibrant,

Health Research System dynamic, and responsible health research community working on a unified health research agenda with enhanced cooperation between the Department of Health, the Department of Science and

Technology, and the Commission on Higher Education. The Philippine Health Research Ethics Board is one of the six groups working under its Governing Council.

Placebo — A substance that is not biologically active, does not interact with other substances nor is it expected to affect the health status of an individual. It is an inactive pill, liquid, or powder that has no treatment value. In clinical trial, experimental treatments are often compared with placebo to assess the experimental treatment's effectiveness. In some studies, the participants in the control group will receive a placebo instead of an active drug or experimental treatment (Retrieved from http://www.clinicaltrials.gov/ct/info/whatis).

Placebo-Controlled Trials — Clinical trials that assign the administration of a placebo to the control group while the test drug is given to the experimental group.

Pre-Clinical Trials or Study — Investigation of the pharmacologic properties of a drug or preparation done in animals prior to human studies. Pre-clinical studies shall include pharmacodynamics, pharmacokinetics, and toxicity studies (BFAD, Guidelines for Registration of Pharmaceutical Products, 1997).

Principal Investigator — The chief or person primarily responsible for the implementation of a research project.

Protocol — A document that describes the objective(s), design, methodology, statistical considerations, and organization of a trial/research

Protocol Amendment — A written description of a change(s) to, or formal clarification of a protocol (WHO, Operational Guidelines for Ethics Committees that Review Biomedical Research, 2000, TDR/PRD/ETHICS/2000, p.22).

Protocol Approval by Sponsor

The affirmative action of the sponsor on the protocol development when the technical and ethical reviewers have finally approved all the changes of the protocol. This usually act as the signal for the submission of the protocol and the other required documents to an IRB, national regulatory authorities and research sites as applicable.

Quorum — The minimum number (i.e., majority of the members) and type of members of the REC that is required to be present in any meeting for

	the proceedings to be considered valid. International and national guidelines require the presence of at least five (5) regular members including the non-affiliated and the non-scientist members.
Randomization	The process of assigning trial subjects to treatment or control groups using an element of chance to determine the assignments in order to reduce bias (ICH Harmonized Tripartite Guideline, Guideline for Good Clinical Practice). Random, random assignment, randomization, is the assignment of subjects to different treatments, interventions, or conditions according to chance rather than systematically. Random assignment of subjects to conditions is an essential element of experimental research because it makes more likely the probability that differences observed between subject groups are the result of the experimental intervention (IRB Guidebook, US Department of Health and Human Services, retrieved from http://www.hhs.gov/ohrp/irb/irb_glossary.htm).
Remuneration	Payment for participation in research
Reportable Negative Event	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. Examples are brewing hostilities in the research community, natural calamities, unleashed dogs, threats of harassment, etc.
Rescue Medication	Quick relief or fast-acting medications or procedure used to immediately manage or relieve symptoms when they occur
Research	Organized set of activities intended to generate data that are generalizable into new knowledge, principle, or technology. Investigative work undertaken on a systematic and rigorous basis using quantitative and qualitative methods to generate new knowledge.
Research Ethics Committee	An independent body (a review board or a committee, institutional, regional, national, or supranational), constituted of medical professionals and non-medical members, whose responsibility is to ensure the protection of the rights, safety and well-being of human subjects involved in a trial and to provide public assurance of that protection, by, among other things, reviewing and

approving/providing favourable opinion on the trial protocol, the suitability of the investigator/s, facilities, and the materials to be used in obtaining and documenting informed consent of the trial subjects (ICH-Guideline for Good Clinical Practice (E6, R1), art. 1.27).

Research Protocol A document that provides the background rationale and objective(s) of a biomedical research project and describes its design methodology and organization, including ethical and statistical considerations. Some of these considerations may be provided in other documents referred to in the protocol.

Respondent The person or group of persons answering or replying to research questions or providing the data that are collected during the research. They are also referred as subject or participant in a research and further as a unit, unit of analysis, experimental unit, during sampling or data analysis.

Retrospective Study A research that looks backwards and examines exposures to suspected risk or protection factors in relation to an outcome that is established at the start of the study. Many valuable case-control studies, such as Lane and Claypon's 1926 investigation of risk factors for breast cancer, were retrospective investigations. Most sources of error due to confounding and bias are more common in retrospective studies than in prospective studies. For this reason, retrospective investigations are often criticized. If the outcome of interest is uncommon, however, the size of prospective investigation required to estimate relative risk is often too large to be feasible. In retrospective studies the odds ratio provides an estimate of relative risk. Special care should be taken to avoid sources of bias and confounding in retrospective studies (Retrieved from http://www.stasdirect.com/help/basics/prospective.htm).

Risk The probability of discomfort or harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Risk to research participants must be justified by the anticipated benefits to the subjects or to society. The investigators(s) and IRB must assess the risk and benefits of proposed research.

Risk Factors Variables or Conditions that increase the risk or chances of disease or infection; determinants of disease development.

Scientists	Professionals with advanced training and expertise in the medical or non-medical areas of science.
Social Scientists	Professional who uses the scientific method to study human society and individual relationships.
Serious Adverse Event (SAE)	Any untoward medical occurrence that at any dose: results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect
Side Effect	Any sign or symptom that a research participant may experience after having been administered an investigational or control drug or substance, where such sign and symptom can be expected, and which does not necessarily results in an adverse event.
Site Visit	An action taken by ERC members or representatives which involves going to study site to assess how the investigators are conducting a trial or research and maintaining proper documentation for an ERC approved protocol.
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 reaction.
Sponsor	An individual, company, institution, or organization which takes responsibility for the initiation, management, and/or financing of a clinical trial.
Sponsor-Investigator	An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a subject. The term does not include any person other than an individual (e.g. it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.
Standard Operating Procedure (SOP)	Detailed, written instruction, in certain format, describing all activities and actions undertaken by an organization to achieve uniformity of the performance of a specific function

Study Site An institutional, hospital, clinic or any community where participants for study are recruited and where the actual study is conducted.

Terminated Study A study approved by Ethics Committee that is being recommended for termination before its scheduled completion

Unexpected ADR An adverse reaction, the nature or severity of which is not consistent with the informed consent/information sheets or the applicable product information (e.g., investigator's brochure for the unapproved investigational product or package insert/summary of product characteristics for an approved product)

Vulnerable subject/ Participant

Individuals whose willingness to volunteer in a clinical trial may be unduly influenced by the expectation, whether justified or not, of benefits associated with the participation, or of a retaliatory response from the senior members of a hierarchy in case of refusal to participate. Examples are members of a group with a hierarchical structure, such as medical, pharmacy, dental and nursing students, subordinate hospital and laboratory personnel, employees of the pharmaceutical industry, members of the armed forces, and persons kept in detention. Other vulnerable subjects include patients with incurable diseases, person in nursing homes, unemployed or impoverished person in emergency situations, ethnic minority groups, homeless persons, nomads, refugees, minors, and those incapable of giving consent.

Waiver of Informed Consent

The act of intentionally or knowingly relinquishing or abandoning the right to consent to medical treatment by a patient or to participate in a medical experiment by a subject after achieving an understanding of what is involved, especially the risk (Merriam-Webster's Dictionary of Law (c), 1996). It is also refers to the permission given by an Ethics Review Committee for research to be conducted without the informed consent of subjects, under exceptional circumstances, such as when research has to be undertaken in an emergency situation.

Hybrid meetings are meetings or events that feature at least one group of in-person/face-to-face attendees connecting virtually with other meeting attendees

Structure and Composition

Appendix A

Form 1.1 Appointment Letter for Medical or Scientist Member
Form 1.1.1 Appointment Letter for Chair
Form 1.1.2 Appointment Letter for Vice Chair
Form 1.1.3 Appointment Letter for Member Secretary
Form 1.1.4 Appointment Letter for non -scientist or non-medical Member
Form 1.1.5 Appointment Letter for Non Affiliated Member
Form 1.1.6 Appointment Letter for Independent Consultant
FORM 1.5 Invitation of Independent Consultant
Form 1.2 Curriculum Vitae of REC Members
Form 1.3 Confidentiality and Conflict of Interest Agreement
Form 1.4 Training Record of REC Member
Form 1.6 Nomination Form

Form 1.1
APPOINTMENT LETTER OF REC MEMBER

(Date)
Dear (Name of Member),

As an appointed **Scientist/Medical** member of the NCMH-REC, you will have the following roles and responsibilities:

1. Serve as Primary Reviewer for research protocol documents within area of expertise, and as General Reviewer for all researches discussed at convened meetings of the REC.

2. Conduct Expedited or Full Board review of protocols assigned by the REC Chair.

3. Submit within seven (7) days to the Staff the completed Protocol Assessment form when designated as Primary Reviewer.

4. Perform Post-Approval review procedures of protocol-related documents within seven (7) calendar days.

5. Conform at all times with the legal and ethical principles accepted by the REC.

6. Attend all regularly scheduled REC meetings (i.e. monthly meeting every 1st Tuesday of the month) as well as basic and continuing education on Research Ethics at least once a year.

7. Update Curriculum Vitae and Training Record every time appointment is renewed.

8. Perform other tasks requested by the REC Chair.

Membership shall be for three (3) years, from <date>____ to <date>____ with possible renewal for up to three (3) consecutive terms. If you agree with the terms of this appointment, please sign on the space below and return one (1) copy to the National Center for Mental Health – Research Ethics Committee Staff accompanied with signed Confidentiality and Conflict of Interest Agreement, Curriculum Vitae and GCP Certificate.

Very truly yours,

(Medical Center Chief)
Conforme:

(Signature over printed name) (Date)

Form 1.1.1
APPOINTMENT LETTER OF CHAIR

(Date)
Dear (Name of Member),

As an appointed **Chair** of the NCMH-REC, you will have the following roles and responsibilities:

1. Ensures that all REC Members receive orientation and undergo basic Research Ethics training immediately after their appointment and continuing education thereafter.
2. Chair shall enjoin NCMH-REC members and staff to attend trainings/seminars/workshops as needed, and ensure that adequate resources are provided for continuing professional development. Therefore NCMH is responsible for allocating an annual budget for specific trainings and other educational activities for NCMH-REC member and staff.
3. Obtains administrative and logistics support for the sustained operations of the REC.
4. Approves the agenda and presides over REC review meetings (If Chair has Conflict of Interest relative to the protocol for deliberation s/he designates the Member-Secretary or any designated Member to preside over the meeting
5. Classifies type of review of a particular research protocol as to Expedited or Full Board review or Exempt from Review.
6. Selects suitable (somebody with related expertise) Member / Independent Consultant to be the Primary Reviewer of a protocol whether by Full board or Expedited review, and ensures that aforementioned member does not have conflict of interest.
7. Manages complaints from study participants, authorities or the general public.
8. Designates a Member or group of members to investigate in cases of complaints or report of major non-compliance. Ensures that the REC is perceived as fair and impartial, and complies with Institutional, National and International standards.
9. Provides updates on relevant and contemporary issues related to ethics in health research, as well as relevant literature to the REC members.
10. Represents the REC in various Local, National and International meetings and conferences.
11. Prepares the Annual Work Financial Plan (WFP) and the Project Procurement Management Plan (PPMP) and approved by the Medical Center Chief.
12. Ensure adherence to quality standards to maintain the accreditation status.

Membership shall be for three (3) years, from <date>____ to <date with possible renewal for up to three (3) consecutive terms. If you agree with the terms of this appointment, please sign on the space below and return one (1) copy to the National Center for Mental Health – Research Ethics Committee Staff accompanied with signed Confidentiality and Conflict of Interest Agreement, Curriculum Vitae and GCP Certificate.

Very truly yours,

(Medical Center Chief)

Conforme:
(Signature over printed name) (Date)

Form 1.1.2
APPOINTMENT LETTER OF VICE CHAIR

(Date)
Dear (Name of Member),

As an appointed **Vice Chair** of the NCMH-REC, you will have the following roles and responsibilities:

1. Presides over meetings in the absence of the Chair.
2. Performs other duties as designated by the Chair.
3. Serve as Primary Reviewer for research protocol documents within area of expertise, and as General Reviewer for all researches discussed at convened meetings of the REC.
4. Conduct Expedited / Full Board review of protocols assigned by the REC Chair.
5. Submit within seven (7) days to the Staff the completed Protocol Assessment form when designated as Primary Reviewer
6. Perform Post-Approval review procedures of protocol-related documents within seven (7) days.
7. Conform at all times with the legal and ethical principles accepted by the REC.
8. Attend all regularly scheduled REC meetings (i.e. monthly meeting every 1st Tuesday of the month) as well as basic and continuing education on Research Ethics at least once a year.
9. Update Curriculum Vitae and Training Record every time appointment is renewed.

Membership shall be for three (3) years, from <date>____ to <date with possible renewal for up to three (3) consecutive terms. If you agree with the terms of this appointment, please sign on the space below and return one (1) copy to the National Center for Mental Health – Research Ethics Committee Staff accompanied with signed Confidentiality and Conflict of Interest Agreement, Curriculum Vitae and GCP Certificate.

Very truly yours,

(Medical Center Chief)

Conforme:

(Signature over printed name) (Date)

Form 1.1.3

APPOINTMENT LETTER OF MEMBER SECRETARY

(Date)

Dear (Name of Member),

As an appointed **Member Secretary** of the NCMH-REC, you will have the following roles and responsibilities:

1. Supervises the REC Staff related to good REC office management.
2. Prepares and finalizes the meeting agenda of Full board meeting after consultation with the Chairperson.
3. Collects and reviews the assessment forms submitted by the Primary Reviewers before the meeting.
4. Classifies type of review of a particular research protocol as to Expedited or Full Board review or Exempt from Review upon approval of REC Chairperson.
5. Appoints or designates the primary reviewer for such particular review upon approval of REC Chairperson.
6. Serve as Primary Reviewer for research protocol documents within area of expertise when assigned by the REC Chair.
7. Conduct Expedited / Full Board review of protocols when assigned by the REC Chair.
8. Submit within seven (7) days to the Staff the completed Protocol Assessment form when designated as Primary Reviewer
9. Perform Post-Approval review procedures of protocol-related documents within seven (7) days.
10. Ensures that the Members completely fill out necessary forms used for the review of protocol or protocol related submissions.
11. Supervises the REC Staff in the preparation of the meeting agenda and minutes.
12. Supervises the REC Staff in the preparation of the annual report of the REC to be submitted to the Medical Center Chief, DOH, PHREB and other bodies.
13. Ensures good REC documentation and archiving.
14. Ensures overall REC compliance with Good Clinical Practice.
15. Ensures good financial management of REC resources.

Membership shall be for three (3) years, from <date>____ to <date with possible renewal for up to three (3) consecutive terms. If you agree with the terms of this appointment, please sign on the space below and return one (1) copy to the National Center for Mental Health – Research Ethics Committee Staff accompanied with signed Confidentiality and Conflict of Interest Agreement, Curriculum Vitae and GCP Certificate.

Very truly yours,

(Medical Center Chief)

Conforme:

(Signature over printed name) (Date)

Form 1.1.4
APPOINTMENT LETTER OF REC MEMBER

(Date)
Dear (Name of Member),

As an appointed **Non-Scientist/Non-Medical** member of the NCMH-REC, you will have the following roles and responsibilities:

1. Non-Scientific or Non-Medical / Layperson will be responsible for the review of Informed consent form and shall focus on the human subject / participant concerns to ensure adequate and proper application of International and National principles and guidelines.

2. Conduct Expedited or Full Board review of protocols assigned by the REC Chair.

3. Submit within seven (7) calendar days to the Staff the completed Protocol Assessment form when designated as Primary Reviewer.

4. Perform Post-Approval review procedures of protocol-related documents within seven (7) calendar days.

5. Conform at all times with the legal and ethical principles accepted by the REC.

6. Attend all regularly scheduled REC meetings (i.e. monthly meeting every 1st Tuesday of the month) as well as basic and continuing education on Research Ethics at least once a year.

7. Update Curriculum Vitae and Training Record every time appointment is renewed.

8. Perform other tasks requested by the REC Chair.

Membership shall be for three (3) years, from <date>____ to <date with possible renewal for up to three (3) consecutive terms. If you agree with the terms of this appointment, please sign on the space below and return one (1) copy to the National Center for Mental Health – Research Ethics Committee Staff accompanied with signed Confidentiality and Conflict of Interest Agreement, Curriculum Vitae and GCP Certificate.

Very truly yours,

(Medical Center Chief)

Conforme:

(Signature over printed name) (Date)

Form 1.1.5
APPOINTMENT LETTER OF REC MEMBER

(Date)
Dear (Name of Member),

As an appointed **Non-Affiliated, (Medical/Non-Medical/Social Scientist)** member of the NCMH-REC, you will have the following roles and responsibilities:

1. Serve as Primary Reviewer for research protocol documents within area of expertise, and as General Reviewer for all researches discussed at convened meetings of the REC.

2. For Non-Scientific or Non-Medical / Layperson will be responsible for the review of Informed consent form and shall focus on the human subject / participant concerns to ensure adequate and proper application of International and National principles and guidelines.

3. Conduct Expedited or Full Board review of protocols assigned by the REC Chair.

4. Submit within seven (7) calendar days to the Staff the completed Protocol Assessment form when designated as Primary Reviewer.

5. Perform Post-Approval review procedures of protocol-related documents within seven (7) calendar days.

6. Conform at all times with the legal and ethical principles accepted by the REC.

7. Ensure the independence of the REC in its work and decision-making.

8. Attend all regularly scheduled REC meetings (i.e. monthly meeting every 1st Tuesday of the month) as well as basic and continuing education on Research Ethics at least once a year.

9. Update Curriculum Vitae and Training Record every time appointment is renewed.

10. Perform other tasks requested by the REC Chair.

Membership shall be for three (3) years, from <date>____ to <date with possible renewal for up to three (3) consecutive terms. If you agree with the terms of this appointment, please sign on the space below and return one (1) copy to the National Center for Mental Health – Research Ethics Committee Staff accompanied with signed Confidentiality and Conflict of Interest Agreement, Curriculum Vitae and GCP Certificate.

Very truly yours,

(Medical Center Chief)
Conforme:
(Signature over printed name) (Date)

Form 1.1.6
APPOINTMENT LETTER OF INDEPENDENT CONSULTANT

(Date)

Dear (Name of Independent Consultant),

As an appointed **Independent Consultant** of the NCMH-Research Ethics Committee. Your responsibility includes the following:

1. Serve as primary reviewer in protocols for which there is no expertise in REC.

   Review must focus on:

   - Procedures and research method
   - Risk/benefit assessment
   - Risk mitigation
   - Vulnerability issues
   - Providing updates about the research topic
2. You must complete the assessment form to be reviewed by the REC at the time the study is reviewed.
3. You may attend the NCMH-REC meeting, present your assessment and participate in the discussion. However, you have no voting privilege during the REC meeting and will not be part of quorum requirements but your report(s) will become permanent part of the study file.

Membership shall be for three (3) years, from <date>____ to <date>____ with possible renewal for up to three (3) consecutive terms. If you agree with the terms of this appointment, please sign on the space below and return one (1) copy to the National Center for Mental Health – Research Ethics Committee Staff accompanied with signed Confidentiality and Conflict of Interest Agreement, Curriculum Vitae and GCP Certificate.

Very truly yours,

(Medical Center Chief)
Conforme:
(Signature over printed name) (Date)

FORM 1.5
INVITATION TO INDEPENDENT CONSULTANTS

Date

(Name of Independent Consultant)
(Institution)

Dear _____

We hereby invite you to serve as Independent Consultant for the following protocol: (Title of Protocol), (Protocol Number), (Name of Principal Investigator), (Sponsor)

Your responsibility includes the following:

4. Serve as primary reviewer in protocols for which there is no expertise in REC. Review must focus on:
   - Procedures and research method
   - Risk/benefit assessment
   - Risk mitigation
   - Vulnerability issues
   - Providing updates about the research topic
5. You must complete the assessment form to be reviewed by the REC at the time the study is reviewed.
6. You may attend the NCMH-REC meeting, present your assessment and participate in the discussion. However, you have no voting privilege during the REC meeting and will not be part of quorum requirements but your report(s) will become permanent part of the study file.

Membership shall be for three (3) years, from <date>____ to <date>____ with possible renewal for up to three (3) consecutive terms. If you agree with the terms of this appointment, please sign on the space below and return one (1) copy to the National Center for Mental Health – Research Ethics Committee Staff accompanied with signed Confidentiality and Conflict of Interest Agreement, Curriculum Vitae and GCP Certificate.

Thank you for your support and cooperation.

Very truly yours,

(Signature above name of REC Chairperson)
Conforme:
(Printed name and signature) (Date)

Form 1.2
CURRICULUM VITAE OF REC MEMBER

Name		Date of Birth	
Position in the REC		Address	
Term of Appointment		Contact Number	
Education			
Research Ethics Training/s			

WORK EXPERIENCE

A. Occupation	
B. Previous work experience	
C. Present work experience	
Research-related experience	

_____ _____
Signature over Printed Name Date

Form 1.3

CONFIDENTIALITY AND CONFLICT OF INTEREST AGREEMENT

Know all Men by these Presents:

In view of the appointment of (Name), as a member of the National Center for Mental Health – Research Ethics Committee (NCMH-REC), and hereinafter referred to as the **Undersigned**, and

Whereas:
the **Undersigned** has been asked to assess research studies and protocols involving human subjects in order to ensure that the same are conducted in a humane and ethical manner, with the highest standards of care according to the applied national and local laws and regulations, institutional policies and guidelines;

the appointment of the **Undersigned** as a member of the NCMH-REC is based on individual merits and not as an advocate or representative of a home province/ territory/ community nor as delegate of any organization or private interest;

the fundamental duty of an NCMH-REC member is to independently review both scientific and ethical aspects of research protocols involving human subjects and make a determination and the best possible objective recommendations, based on the merits thereof under review; and

the NCMH-REC must meet the highest ethical standards in order to merit the trust and confidence of the communities in the protection of the rights and well-being of human subjects;

The following terms and conditions covering **Confidentiality and Conflict of Interest** arising in the discharge of said appointed NCMH-REC Members' functions are hereby stipulated in this Agreement for purposes of ensuring the same high standards of ethical behavior necessary for the NCMH-REC to carry out its mandate.

Confidentiality

This Agreement thus encompasses any information deemed Confidential, Privileged, or Proprietary provided to and/or otherwise received by the **Undersigned** in conjunction with and / or in the course of the performance of his / her duties as a Member / Independent Consultant of the NCMH-REC.

Any written information provided to the **Undersigned** that is of a Confidential, Privileged, or Proprietary in nature shall be identified accordingly. Written Confidential information provided for review shall not be copied or retained. All Confidential information (and any copies and notes thereof) shall remain the sole property of the REC.

As such, the **Undersigned** agrees to hold in trust and in confidence all Confidential, Privileged or Proprietary information, including trade secrets and other intellectual property rights (hereinafter collectively referred to as the "information"). Moreover, the **Undersigned** agrees that the information shall be used only for contemplated purposes and none other. Neither shall the said information be disclosed to any third party.

The **Undersigned** further agrees not to disclose or utilize, directly or indirectly, any information belonging to a third party, in fulfilling this agreement. Furthermore, the **Undersigned** confirms that her performance of this agreement is consistent with National Center for Mental Health policies and any contractual obligations owed to third parties.

Conflict of Interest

It is recognized that the potential for conflict of interest will always exist; however, there is concomitant faith in the ability of the NCMH-REC to manage these conflict issues, if any, in such a way that the ultimate outcome of the protection of human subjects remains.

It is the policy of the NCMH-REC that no Member / Consultant may participate in the review, comment or approval of any activity in which he/she has a conflict of interest except to provide information as requested by the NCMH-REC.

The **Undersigned** will immediately disclose to the Chairperson of the NCMH-REC any actual or potential conflict of interest that s/he may have in relation to any particular proposal submitted for review by the NCMH-REC, and to abstain from any participation in discussions or recommendations in respect of such proposals.

If an applicant submitting a protocol believes that an NCMH-REC member has a potential conflict, the investigator may request that the Member be excluded from the review of the protocol.

The request must be in writing and addressed to the Chairperson. The request must contain evidence that substantiates the claim that a conflict exists with the NCMH-REC member(s) in question. The NCMH-REC may elect to investigate the applicant's claim of the potential conflict.

When a Member / Consultant have a conflict of interest, the Member should notify the Chairperson and may not participate in the NCMH-REC review or approval except to provide information requested by the Board.

Examples of conflict of interest cases may include but is not limited to any of the following:

- ☐ A Member / Consultant is involved in a potentially competing research program.
- ☐ Access to funding or intellectual information may provide an unfair competitive advantage.
- ☐ A Member's / Consultant's personal biases may interfere with his / her impartial judgment.

Agreement on Confidentiality and Conflict of Interest

[To the Undersigned: Please sign and date this Agreement, if you agree with the terms and conditions set forth above. The original (signed and dated Agreement) will be kept on file in the custody of the NCMH-REC. A copy will be given to you for your records.]

In the course of my activities as a Member of the National Center for Mental Health - Research Ethics Committee, I will be provided with confidential information and documentation (which we will refer to as the "Confidential Information"). I agree to take reasonable measures to protect the Confidential Information, subject to applicable legislation, not to disclose the Confidential Information to any person; not to use the Confidential Information for any purpose outside the Board's mandate, and in particular, in a manner which would result in a benefit to myself or any third party; and to return all Confidential Information (including any minutes or notes I have made as part of my Board duties) to the Chairperson upon termination of my functions as an NCMH-REC member.

Whenever I have a conflict of interest, I shall immediately inform the Chairperson not to count me toward a quorum for voting.

I have read and accept the aforementioned terms and conditions as explained in this Agreement.

Name and Signature of Appointee	Date
Noted by:	
Signature above name of REC Chairperson	Date

FORM 1.4
TRAINING RECORD OF NCMH-REC MEMBER

Last name		First name	

BASIC COURSES	ORGANIZER	VENUE	DATE	FUNDING SOURCE
1. GCP Training				
2. Research Ethics				
3. REC Standard Operating Procedures (SOP)				

CONTINUING ETHICS EDUCATION: Research Ethics Workshops, Conferences, Meetings, Lectures	ORGANIZER	VENUE	DATE	FUNDING SOURCE
1.				
2.				
3.				
4.				
5.				

Nomination Form 1.6

1. General Information			
Name of Nominee:			
Affiliation:	Name of Department:	Name of Institution:	Position:
Highest Educational Attainment :	Name of Institution:	Year/s attended:	Course/Degree:
Research Related Trainings including Research Ethics:	Name of Course: 1.	Offered by:	Year:

Acceptance of Nomination: Signature of Nominee: _____ Date:_____
Name and signature of Nominator: Date:_____ Position: Institution:

Received by: _____ **Date:** _____
Signature over Printed name

Initial Review Procedures

Appendix B

Form 2.1 Application for Initial Review
Form 2.2 Protocol Summary Sheet
Form 2.3 Protocol Evaluation Form
Form 2.4 Informed Consent Evaluation Form
Form 2.5 Protocol Resubmission Form
(for Initial and Continuing Review)
Form 2.6 Certificate of Approval
Form 2.7 Letter of Approval
Form 2.8 Certificate of Exemption from Ethics Review
Form. 2.9 Application for Continuing Review

SJREB Form 1 Application for SJREB Initial Review
SJREB Form 2 Protocol Evaluation Form
SJREB Form 2 Informed Consent Evaluation Form
SJREB Form 4 SJREB Notice for Protocol Modification
SJREB Form 5 Notice of Approval

FORM 2.1
APPLICATION FOR INITIAL REVIEW

		REC Protocol No.	<to be filled up by REC Staff>
Sponsor Protocol No.	<to be filled up by REC Staff>	Submission Date	<to be filled up by REC Staff>
Protocol Title			
Type of Research	☐ Biomedical studies ☐ Clinical Trials ☐ Public Health Research ☐ Social Research ☐ Health Operations Research ☐ Others(specify): _____		
Principal Investigator			
Study Duration			
Sponsor			
Telephone No.		Fax No.	
E-mail Address		Preferred means of contact	☐ Phone ☐ Email
Institution			

Are you an employee of the sponsor?	☐ Yes	☐ No
Did you do consultancy or part time work for the sponsor?	☐ Yes	☐ No
In the past year, did you receive ₱250,000 or more from the sponsor?	☐ Yes	☐ No
Other ties with the sponsor:		

Ethical Responsibility and Conflict of Interest (COI) Statement

I hereby pledge to address all forms of COI that I may have and perform my tasks objectively, protect the scientific integrity of the study, protect all human participants and comply with my ethical responsibilities as Investigator.

Principal Investigator Signature	

- **Basic Documents must be submitted: (check the documents applicable to your proposal for submission)**

☐ Application for Initial Review (Form 2.1)
☐ Protocol Summary Sheet (Form 2.2)
☐ Study Protocol
☐ Diagrammatic work flow
☐ Gantt chart for Schedule of activities
☐ Supplementary Documents (if applicable)
☐ Questionnaire
☐ Data Collection Forms
☐ Product Brochure
☐ Investigator's Brochure (for clinical trials phase I, II, III) or Basic Product Information Document for Phase IV clinical trials (if applicable)
☐ Philippine FDA Marketing Authorization or Import License (if applicable)
☐ Permit/s for Special Population (please specify)
_____ (if applicable)

☐ Informed Consent Form
☐ English ☐ Tagalog ☐ Others
☐ Assent Form (if applicable)
☐ English ☐ Tagalog ☐ Others
☐ Technical Review Committee/Department Approval
☐ **Good Clinical Practice (GCP)** Training Certificate of PI, Co-I and the rest of the study team: updated at least within THREE (3) years (for clinical trials), **GRP, BRET, RCR** or any **Ethics Training** for Non-Clinical Trials
☐ Curriculum Vitae for all members of the Study Team

- **Study Specific Documents**
(Submit as needed particularly for externally originated studies and sponsored studies)

☐ Recruitment advertisements (as needed by the study protocol)
☐ Other information or documents for participants (such as diaries, etc.)
☐ Memorandum of Agreement (for collaborative studies)
☐ Non-NCMH researcher or with sponsor
☐ NCMH researcher is funded by a sponsor
☐ Previous ethical review approvals/clearances (for students/personnel of foreign universities researching in the Philippines or those with prior ethical review)
☐ Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, as applicable
☐ Contracts and/or Approval of relevant offices / regulatory authorities (Written review agreement / Authorization and Acknowledgement of review)

Received by:_____ _____
REC Staff Date

FORM 2.2
PROTOCOL SUMMARY SHEET

REC Protocol Number	**Title**
<to be filled up REC Staff>	<to be filled up by Principal Investigator>
Sponsor	**Principal Investigator**
<to be filled up by Principal Investigator>	<to be filled up by Principal Investigator>

Rationale	<to be filled up by Principal Investigator>
Objectives	<to be filled up by Principal Investigator>
Study Design / Methodology	<to be filled up by Principal Investigator>
Inclusion Criteria	<to be filled up by Principal Investigator>
Exclusion Criteria	<to be filled up by Principal Investigator>
Data Analysis Plan	<to be filled up by Principal Investigator>
Study Outcomes	<to be filled up by Principal Investigator>

Ethical Considerations
<to be filled up by Principal Investigator>

NCMH-REC FORM 2.3
PROTOCOL EVALUATION FORM
To be filled up by the primary reviewer

Protocol Number

Instruction: Please do literatures search to update your knowledge about this protocol

Protocol Title:	Date (m/d/y):
Principal Investigator	Contact Number/Email:
Co – Principal Investigator / Members of the Research Team:	Contact Number/Email:
Institution:	Duration of the Study:
Total No. of Participants:	No. of Study Sites:
Expected No. from Philippine sites:	No. of Study Sites:
Sponsor:	Contact No./Email:
Reviewers:	

☐ Intervention ☐ Epidemiology ☐ Observational study
☐ Document review ☐ Case study ☐ Genetic
☐ Social survey ☐ others, specify _____

	NATIONAL CENTER FOR MENTAL HEALTH RESEARCH ETHICS COMMITTEE
	Chapter 6
Version no. 7 **Date of Approval:** June 16, 2023 **Date of Effectivity:** June 19, 2023	**FORMS**

Review Type: ☐ Full Board ☐ Expedited ☐ Exempt

Description of the Study in brief: Mark whatever applies to the study.

☐ Randomized	☐ Drug	☐ Use of genetic materials
☐ Double-blind	☐ Medical Device	☐ Multicenter study
☐ Single-blind	☐ Vaccine	☐ Global protocol
☐ Open-label	☐ Diagnostics	☐ Sponsor-initiated
☐ Observational	☐ Questionnaire	☐ Investigator-initiated

A. Protocol Document Review	
1. Social and Scientific Value ☐ Clear ☐ Not Clear	Comments/What should be improved?
2. Objectives of the Study ☐ Clear ☐ Not Clear	Comments/What should be improved?
3. Need for Human Participants ☐ Yes ☐ No	Comments/What should be improved?
4. Background Information ☐ Sufficient ☐ Not Sufficient	Comments/What should be improved?
5. Methodology ☐ Clear ☐ Not Clear	Comments/What should be improved?
6. Sufficient Number of Participants ☐ Yes ☐ No	Comments/What should be improved?
7. Control Arms (placebo, if any) ☐ Yes ☐ No	Comments/What should be improved?
8. Data Analysis Plan ☐ Appropriate ☐ Not Appropriate	Comments/What should be improved?
9. Study Outcomes ☐ Defined ☐ Incomplete ☐ Not Defined	Comments/What should be improved?
10. Level of Risk ☐ Negligible ☐ Low Risk ☐ Minimal Risk ☐ More than minimal ☐ Moderate ☐ High Risk	Comments/What should be improved?
11. Risk Assessment	Comments/What should be improved?

☐ Appropriate ☐ Not Appropriate	
12. Benefits Assessment ☐ Appropriate ☐ Not Appropriate	Comments/What should be improved?
13. Inclusion Criteria ☐ Appropriate ☐ Not Appropriate	Comments/What should be improved?
14. Exclusion Criteria ☐ Appropriate ☐ Not Appropriate	Comments/What should be improved?
15. Withdrawal Criteria ☐ Appropriate ☐ Not Appropriate	Comments/What should be improved?
16. Involvement of Vulnerable Participants ☐ Yes ☐ No	Comments/What should be improved?
17. Protection of Vulnerable Participants ☐ Appropriate ☐ Not appropriate	Comments/What should be improved?
18. Voluntary, non-coercive recruitment of participants ☐ Yes ☐ No	Comments/What should be improved?
19. Are the qualifications and experience of the participating investigators, research team appropriate ☐ Yes ☐ No	Comments/What should be improved?
20. Disclosure of potential Conflicts of Interest ☐ Yes ☐ No	Comments/What should be improved?
21. Facilities and infrastructure of participating sites ☐ Yes ☐ No	Comments/What should be improved?
22. Community consultation ☐ Yes ☐ No ☐ NA	Comments/What should be improved?
23. Involvement of local researchers and communities in the protocol preparation and implementation ☐ Yes ☐ No ☐ NA	Comments/What should be improved?
24. Contribution to local capacity building ☐ Yes ☐ No ☐ NA	Comments/What should be improved?

25. Benefit to local communities ☐ Yes ☐ No ☐ NA	Comments/What should be improved?
26. Sharing of study results ☐ Yes ☐ No ☐ NA	Comments/What should be improved?
27. Are blood/tissues sample sent abroad ☐ Yes ☐ No ☐ NA	Comments/What should be improved?

B. Recommendation

Decision: ☐ Approval ☐ Minor Modification
☐ Major Modification /Resubmission ☐ Disapproval

Reviewer's Name :		
	Signature above printed name	**Date** (M/D/Y)

NCMH-REC FORM 2.4

INFORMED CONSENT EVALUATION FORM

To be filled up by the primary reviewer

Protocol Number

Protocol Title:	Date (m/d/y):
Principal Investigator	

A. Informed Consent Document Review	
1. Does the Informed Consent document state that the procedures are primarily intended for research? ☐ Yes ☐ No	**Comments / What should be improved?**
2. Are procedures for obtaining Informed Consent appropriate? ☐ Yes ☐ No	**Comments / What should be improved?**
3. Does the Informed Consent document contain comprehensive and relevant information? ☐ Yes ☐ No	**Comments / What should be improved?**
A. Objective of the Study	
B. Reason for inviting the respondents	
C. Procedures involve (e.g. accomplishment of a survey form, how many pages, how long will it take to finish)	
4. Is the information provided in the protocol Consistent with those in the consent form? ☐ Consistent ☐ Inconsistent	**Comments / What should be improved?**
5. Are study related risks mentioned in the consent form? ☐ Yes ☐ No	**Comments / What should be improved?**
6. Is the language in the Informed Consent document understandable? ☐ Yes ☐ No	**Comments / What should be improved?**

7. Is the Informed Consent translated into the local language/dialect? ☐ Yes ☐ No	**Comments / What should be improved?**
8. Are there vulnerable participants? ☐ Yes ☐ No	**Comments / What should be improved?**
9. Are the different types of consent forms (assent, patient representative) appropriate for the types of study participants? ☐Appropriate ☐Inappropriate ☐N/A	**Comments / What should be improved?**
10. Are names and contact numbers from the Research team & the REC in the Informed Consent? ☐ Yes ☐ No	**Comments / What should be improved?**
11. Does the ICF provide privacy and confidentiality protection? ☐ Yes ☐ No	**Comments / What should be improved?**
12. Is there any undue inducement for participation? ☐ Yes ☐ No	**Comments / What should be improved?**
13. Is there provision for medical/psychosocial support? ☐ Ye ☐ No ☐ Not Applicable	**Comments / What should be improved?**
14. Is there provision for treatment of study-related Injuries? ☐ Yes ☐ No ☐ Not Applicable	**Comments / What should be improved?**
15. Is the amount paid to participants stated? ☐ Ye ☐ No ☐ Not Applicable	**Comments / What should be improved?**
16. Is there an option/right to withdrawal at any time without consequences by the participants? ☐ Yes ☐ No	**Comments / What should be improved?**

B. Recommendation

Decision: ☐ Approval ☐ Minor Modification
☐ Major Modification/Resubmission ☐ Disapproval

Reviewer's Name :		
	Signature above printed name	**Date** (M/D/Y)

FORM 2.5

PROTOCOL RESUBMISSION FORM

(For Initial and Continuing Review)

Submission Date: _____

To (Name of Principal Investigator) _____
Contact Number _____
Protocol Title _____
REC Protocol No. _____
Sponsor Protocol No. _____
Protocol Version No. / Date _____
ICF Version No. / Date _____

Document to be revised

☐ Protocol ☐ Informed Consent
☐ Advertisement ☐ Composition of Research

☐ Other documents received for review (e.g. advertisements recruitment, survey tools, questionnaires, etc.): _____

This is to inform you of the NCMH-REC decision related to the documents you have submitted:

REC Recommendations	Principal Investigator's Revisions	Page No.	Reviewer's Comment
Protocol			
Informed Consent			
Others			

Indicate the changes made – highlight/underline – (include the page numbers) in the revised document

Please submit the revised documents within fifteen days (15) from receipt of this notice.

Type of Review

☐ Full Board
☐ Exempt

REC Decision

☐ Expedited ☐ Approved
☐ Minor modifications required
☐ Major modifications required
☐ More information required
☐ Others

Signature above printed name of Primary Reviewer	Date
Signature above printed name of NCMH-REC Chairperson	Date

FORM 2.6
Certificate of Approval

Date _____

This is to certify that the following protocol and related documents have been granted approval by the National Center for Mental Health-REC for implementation:

REC Protocol No.		Sponsor Protocol No.	
Principal Investigator/s		Sponsor	
Title			
Protocol Version No.		Version Date	
ICF Version No.		Version Date	
Other documents			
Members of research team			
Study sites			

Type of review	☐ Expedited ☐ Full board Meeting date:	Duration of Approval From (date) To	Frequency of Progress Report Submission

REC Chairperson	Signature	Date

Investigator Responsibilities after Approval:

- Submit document amendments for NCMH-REC approval before implementing them
- Submit continuing review application for renewal of ethical clearance if the study is not completed at least (6) six weeks or equivalent days before the expiration of the ethical clearance. Submit on or before <date of submission>
- Submit onsite SAE/SUSAR to within 72 hours from knowledge of SAE/SUSAR and a complete report in 14 days
- Submit progress report at a frequency indicated on your certificate of approval
- Submit final report to not more than 60 days from completion of study protocol
- Report protocol deviation/ violation
- Comply with all relevant international and national guidelines and regulations
- Abide by the principles of good clinical practice and ethical research
- Submit Reportable Negative Event to within 72 hours from knowledge RNE and a complete report in 14 days
- Submission of early protocol termination
- The possibility of a site visit by the REC
- Use the assigned protocol code number in all communications to the REC

Received by:

Signature _____

Name _____ Date _____

Form 2.7
APPROVAL LETTER

Date

NAME
Principal Investigator

Dear Dr. PI,

We would like to inform you that your Research Protocol entitled "**TITLE**" with Code: **NCMH-REC-YYYY-SS** has been approved to proceed by the National Center for Mental Health – Research Ethics Committee (NCMH-REC). This approval is based on the protocol and relevant materials you submitted last **DATE SUBMISSION**. Kindly use the assigned protocol code number in all your communication with NCMH-REC.

Final approval of this protocol was processed through Expedited Review. Expiry date of approval is one (1) year from now, **<date of expiration>,**.

The following are the standard guidelines for you to follow:

1. The NCMH Research Ethics Committee approval is good for a period of 12 months. If the study cannot be completed by <**date of expiration>**, you are required to submit an application for continuing review (Form 2.9) at least (6) six weeks or equivalent days before the expiration of the ethical clearance. Submit on or before <date of submission>

2. Once the study has been completed or terminated at an earlier time, you are required to submit a Study Completion/Termination form so that the Committee can officially close the protocol.

3. You are required to submit a Protocol Amendment Form (Form 3.1) to be approved by the Committee if there are changes to be made in the approved protocol and materials utilized in the study.

4. In such instance that there is a protocol deviation, you are required to accomplish a Deviation/Non-compliance/Violation Report form within 7 working days after the occurrence in order to document the event.

5. Annual Progress Report form must be accomplished for minimal risk protocols while more than minimal risk, progress report shall be submitted twice a year and no more than 6 weeks before expiration of ethical approval, Submit on or before **<date of submission>**.

6. NCMH-REC should be provided with a copy of the result/outcome of the study to not more than 60 days from completion of study protocol.

7. Failure to comply with the standard guidelines can lead to termination of the research protocol.

For your information and guidance.

Very truly yours,

(Name) (Date)
Signature above printed name of Chairperson
National Center for Mental Health – Research Ethics Committee

Received by:

Signature _____

Name _____ Date _____

Form 2.8
Certification of Exemption Form Ethics Review

This is to certify that the following protocol and related documents have been reviewed and granted exemption from review by the National Center for Mental Health - REC for implementation. Any amendment on exempted protocols are not allowed and shall invalidate the approval of the protocol. A final report shall be submitted to REC at end of the exempted study.

REC Protocol No.		Sponsor Protocol No.	
Principal Investigator/s		Sponsor	
Title			
Protocol Version No.		Version Date	
ICF Version No.		Version Date	
Other documents			
Period of Approval		Approval Date and Expiry	

REC Chairperson	Signature	Date

Received by: Name and Signature Date _____

Form 2.9
Application for Continuing Review

General Information				
Title of Study				
APPROVAL DATE: <dd/mm/yyyy>		EXPIRY OF ETHICAL CLEARANCE: <dd/mm/yyyy>		
REC Code (to be provided by REC)		Study Site		
Name of Researcher		Contact Information	Tel. No.: Mobile No.:	
Co-Researcher (if any)			Fax No.: Email:	
Sponsor			Sponsor Contact No.:	
Institution				
Address of Institution				
1. START DATE: 1.1. Date of research site initialization: <dd/mm/yyyy> 1.2. Explanation, if not yet initialized as of date of this application: <reason/s>				
2. ACTION REQUESTED: 2.1. Renewal: New participant accrual to continue 2.2. Renewal: Enrolled participant follow up only 2.3. Renewal: Data analysis only 2.4. Other (specify):				
3. HAVE THERE BEEN ANY AMENDMENTS SINCE THE LAST REVIEW/APPROVAL? 3.1. No 3.2. Yes (Describe briefly and indicate date/s of Study Protocol Amendment Submission/s)				
4. HAVE THERE BEEN ANY DEVIATION/NONCOMPLIANCE REPORTS SINCE THE LAST REVIEW/APPROVAL? 4.1. No 4.2. Yes (Describe briefly and indicate date/s of Study Protocol Deviation Submission/s)				

5. SUMMARY OF STUDY PROTOCOL PARTICIPANTS:	
<number>	5.1. Accrual ceiling set by the Panel
<number>	5.2. New participants accrued since last review/approval
<number>	5.3. Total participants accrued since study protocol began

6. ACCRUAL EXCLUSIONS

6.1. None

6.2. Male

6.3. Female

6.4. Other (specify):

7. IMPAIRED PARTICIPANTS

7.1. None

7.2. Physically

7.3. Cognitively

7.4. Both

8. HAVE THERE BEEN ANY CHANGES IN THE PARTICIPANT POPULATION, RECRUITMENT OR SELECTIONCRITERIA SINCE THE LAST REVIEW/APPROVAL?

8.1. No

8.2. Yes (Explain changes and indicate date/s of Study Protocol Amendment Submission/s)

9. HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW/ APPROVAL? Attach latest version of participant information sheet and informed consent form/document

9.1. No

9.2. Yes (Explain changes and indicate date/s of Study Protocol Amendment Submission/s)

10. HAS ANY INFORMATION APPEARED IN THE LITERATURE, OR EVOLVED FROM THIS OR SIMILAR RESEARCH THAT MIGHT AFFECT THE PANEL'S EVALUATION OF THE RISK/BENEFIT ASSESSMENT OF HUMAN PARTICIPANTS INVOLVED IN THIS STUDY PROTOCOL?

10.1. No

10.2. Yes (Describe briefly and provide copy of literature cited, including the Investigator's Brochure if applicable)

11. HAVE THERE BEEN ANY UPDATES OR MEASURES IN THE PROTOCOL TO GUARANTEE PROTECTION OF PRIVACY AND CONFIDENTIALITY OF PARTICIPANT INFORMATION IN COMPLIANCE WITH LOCAL REGULATIONS (e.g. DATA PRIVACY ACT OF 2012)?

11.1. No

11.2. Yes (Describe briefly these provisions)

12. IS A BIOBANK BEING MAINTAINED FOR THIS STUDY?

12.1. No

12.2. Yes (Describe governance and custodianship, access to data and transfer of materials, and measures protecting privacy and confidentiality)

13. HAVE ANY UNEXPECTED DISCOMFORTS, COMPLICATIONS, OR SIDE EFFECTS BEEN NOTED SINCE LAST REVIEW/ APPROVAL?

13.1. No

13.2. Yes (Summarize and indicate date/s of SUSAR report submission/s)

14. HAVE ANY PARTICIPANTS WITHDRAWN FROM THIS STUDY SINCE THE LAST REVIEW/APPROVAL?

14.1. No

14.2. Yes (Explain context surrounding withdrawal and documenting due diligence exerted by the study team in managing these withdrawals)

15. HAVE THERE BEEN NEW/ADDITIONAL INVESTIGATIONAL NEW DRUG/DEVICE REGISTRATIONS ASSOCIATED WITH THIS STUDY SINCE THE LAST REVIEW/APPROVAL? (Indicate registration information)

15.1 None	FDA Registration No.
15.2 IND	Product Name:
15.3 IDE	Sponsor:
	Holder:

16. HAVE THERE BEEN ANY NEW INTERVENTION(S) OR METHODS IN THE CONDUCT OF STUDY THAT IS/ARE NOT IN THE APPROVED PROTOCOL

16.1. No

16.2. Yes (Describe use and indicate date/s of Study Protocol Deviation/Non Compliance/Violation Report Submission/s)

17. HAVE ANY INVESTIGATORS BEEN ADDED OR DELETED SINCE LAST REVIEW/ APPROVAL?

17.1. No

17.2. Yes (Enumerate personnel and indicate date/s of Study Protocol Amendment Submission/s. Append CV if not yet submitted)

18. HAVE ANY NEW COLLABORATING SITES (INSTITUTIONS) BEEN ADDED OR DELETED SINCE THE LAST REVIEW/ APPROVAL?

18.1. No

18.2. Yes (Enumerate sites and indicate date/s of Study Protocol Amendment Submission/s)

19. HAVE ANY INVESTIGATORS DEVELOPED EQUITY OR CONSULTATIVE RELATIONSHIP WITH A PARTY RELATED TO THIS STUDY PROTOCOL WHICH MIGHT BE CONSIDERED A CONFLICT OF INTEREST SINCE THE LAST REVIEW/ APPROVAL?

19.1. No

19.2. Yes (Append a statement of disclosure)
20. HAVE THERE BEEN CHANGES IN STUDY PERSONNEL SINCE THE LAST REVIEW/ APPROVAL? 20.1. NONE 20.2. DELETED (Enumerate and indicate date/s of Study Protocol Amendment Submission/s) 20.3. ADDED (Enumerate and indicate date/s of Study Protocol Amendment Submission/s)
21. HAVE THERE BEEN OTHER CHANGES NOT MENTIONED ABOVE SINCE THE LAST REVIEW/APPROVAL? Attach protocol synopsis. 21.1. No 21.2. Yes (Describe changes and indicate date/s of Study Protocol Amendment Submission/s)
22. HAS THE STUDY SITE BEEN VISITED BY NCMH REC OR ANOTHER ETHICS COMMITTEE, AUDITED BY SPONSOR, OR INSPECTED BY ANY REGULATORY AGENCY? 22.1. No 22.2. Yes (Provide details regarding the visit/audit/inspection (when, where, etc), findings and recommendations, and corrective action of the site, if any)
23. PROGRESS STATUS (List the different components or activities in approved study protocol, provide a short description and indicate completion status, e.g., 50% complete, 75% complete) 23.1. <Component 1> <Provide description as needed> 23.2. <Add components as necessary>
SIGNATURE OF PRINCIPAL INVESTIGATOR:
DATE SIGNED: <dd/mm/yyyy>

RECOMMENDATIONS (for NCMH-REC use only)

Comments of Primary Reviewer
RECOMMENDED ACTION: □ APPROVE □ REQUEST INFORMATION: (INDICATE INFORMATION) □ RECOMMEND FURTHER ACTION: (INDICATE ACTION)

□ PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE

PRIMARY REVIEWER 1. 2. 3.	Signature	DATE
NCMH-REC CHAIR		

SJREB FORM 1
APPLICATION FOR SJREB INTIAL REVIEW
To be filled up by the Coordinating Investigator

Protocol Number:

Sponsor Protocol Number: Submission Date:

Protocol Title:

Type of Research:

☐ Clinical Research ☐ Clinical Trial ☐ Laboratory Research

☐ Genetic Research ☐ Socio-behavioral ☐ Public Health

Others:
_____

Study Duration:

Sponsor:

Coordinating Investigator:

Telephone Number: Fax:

Email:

Institution

Declaration of Conflict of Interest (COI)

Are you an employee of the sponsor/s?	☐ Yes	☐ No
Did you do consultancy or part time work for the sponsor/s	☐ Yes	☐ No
In the past year, did you receive P500,000 or more from the sponsor/s?	☐ Yes	☐ No

Other ties with the sponsor:

Ethical Responsibility and COI Statement

I hereby pledge to address all forms of COI that I may have and perform my tasks objectively, protect the scientific integrity of the study, protect all human participants and comply with my ethical responsibilities as Coordinating Investigator (CI).

CI Signature:

Documents Submitted:

- ☐ Protocol Summary
- ☐ Patient Information Sheet
- ☐ Informed Consent Form
- ☐ Advertisement
- ☐ CVs
- ☐ GCP Certificate
- ☐ Study Budget
- ☐ Revised Protocol

Received by SJREB Secretariat:

Date:

SJREB FORM 2

PROTOCOL EVALUATION FORM

To be filled up by the primary reviewer

Protocol Number

Instruction: Please do literatures search to update your knowledge about this protocol

Protocol Title:	Date (m/d/y):
Institution:	Contact Number/Email:
Co – Principal Investigator / Members of the Research Team:	Contact Number/Email:
Total No. of Participants:	No. of Study Sites:
Expected No. from Philippine sites:	No. of Study Sites:
Sponsor:	Contact No./Email:
Duration of the Study:	
Reviewers:	

☐	Intervention	☐	Epidemiology	☐	Observational study
☐	Document review	☐	Case study	☐	Genetic
☐	Social survey	☐	others, specify _____		

Review Type: ☐ Full Board ☐ Expedited ☐ Exempt

Description of the Study in brief: Mark whatever applies to the study.

☐	Randomized	☐	Drug	☐	Use of genetic materials
☐	Double-blind	☐	Medical Device	☐	Multicenter study
☐	Single-blind	☐	Vaccine	☐	Global protocol
☐	Open-label	☐	Diagnostics	☐	Sponsor-initiated
☐	Observational	☐	Questionnaire	☐	Investigator-initiated

A. Protocol Document Review	
1. Objectives of the Study ☐ Clear ☐ Not Clear	Comments/What should be improved?
2. Need for Human Participants ☐ Yes ☐ No	Comments/What should be improved?
3. Background Information ☐ Sufficient ☐ Not Sufficient	Comments/What should be improved?
4. Methodology ☐ Clear ☐ Not Clear	Comments/What should be improved?
5. Sufficient Number of Participants ☐ Yes ☐ No	Comments/What should be improved?
6. Control Arms (placebo, if any) ☐ Yes ☐ No	Comments/What should be improved?
7. Data Analysis Plan ☐ Appropriate ☐ Not Appropriate	Comments/What should be improved?
8. Study Outcomes ☐ Defined ☐ Incomplete ☐ Not Defined	Comments/What should be improved?
9. Level of Risk ☐ Negligible ☐ medium ☐ High	Comments/What should be improved?
10. Risk Assessment ☐ Appropriate ☐ Not Appropriate	Comments/What should be improved?

11. Benefits Assessment ☐ Appropriate ☐ Not Appropriate	Comments/What should be improved?
12. Inclusion Criteria ☐ Appropriate ☐ Not Appropriate	Comments/What should be improved?
13. Exclusion Criteria ☐ Appropriate ☐ Not Appropriate	Comments/What should be improved?
14. Withdrawal Criteria ☐ Appropriate ☐ Not Appropriate	Comments/What should be improved?
15. Involvement of Vulnerable Participants ☐ Yes ☐ No	Comments/What should be improved?
16. Protection of Vulnerable Participants ☐ Appropriate ☐ Not appropriate	Comments/What should be improved?
17. Voluntary, non-coercive recruitment of participants ☐ Yes ☐ No	Comments/What should be improved?
18. Are the qualifications and experience of the participating investigators, research team appropriate ☐ Yes ☐ No	Comments/What should be improved?
19. Disclosure of potential Conflicts of Interest ☐ Yes ☐ No	Comments/What should be improved?
20. Facilities and infrastructure of participating sites ☐ Yes ☐ No	Comments/What should be improved?
21. Community consultation ☐ Yes ☐ No ☐ NA	Comments/What should be improved?
22. Involvement of local researchers and communities in the protocol preparation and implementation ☐ Yes ☐ No ☐ NA	Comments/What should be improved?
23. Contribution to local capacity building ☐ Yes ☐ No ☐ NA	Comments/What should be improved?

24. Benefit to local communities ☐ Yes ☐ No ☐ NA	Comments/What should be improved?
25. Sharing of study results ☐ Yes ☐ No ☐ NA	Comments/What should be improved?
26. Are blood/tissues sample sent abroad ☐ Yes ☐ No ☐ NA	Comments/What should be improved?

B. Recommendation

Decision: ☐ Approval ☐ Minor Modification
☐ Major Modification /Resubmission ☐ Disapproval

Summary of Contents:

Reviewer's Name :		
	Signature above printed name	**Date** (M/D/Y)

SJREB FORM 3

INFORMED CONSENT EVALUATION FORM

To be filled up by the primary reviewer

Protocol Number

Protocol Title:	Date (m/d/y):
Principal Investigator	

A. Informed Consent Document Review	
1. Does the Informed Consent document state that the procedures are primarily intended for research? ☐ Yes ☐ No	**Comments / What should be improved?**
2. Are procedures for obtaining Informed Consent appropriate? ☐ Yes ☐ No	**Comments / What should be improved?**
3. Does the Informed Consent document contain comprehensive and relevant information? ☐ Yes ☐ No	**Comments / What should be improved?**
4. Is the information provided in the protocol Consistent with those in the consent form? ☐ Consistent ☐ Inconsistent	**Comments / What should be improved?**
5. Are study related risks mentioned in the consent form? ☐ Yes ☐ No	**Comments / What should be improved?**
6. Is the language in the Informed Consent document understandable? ☐ Yes ☐ No	**Comments / What should be improved?**
7. Is the Informed Consent translated into the local language/dialect? ☐ Yes ☐ No	**Comments / What should be improved?**
8. Are there vulnerable participants? ☐ Yes ☐ No	**Comments / What should be improved?**
9. Are the different types of consent forms (assent, patient representative) appropriate for the types of study participants?	**Comments / What should be improved?**

☐Appropriate ☐Inappropriate ☐N/A	
10. Are names and contact numbers from the Research team & the REC in the Informed Consent? ☐ Yes ☐ No	**Comments / What should be improved?**
11. Does the ICF provide privacy and confidentiality protection? ☐ Yes ☐ No	**Comments / What should be improved?**
12. Is there any undue inducement for participation? ☐ Yes ☐ No	**Comments / What should be improved?**
13. Is there provision for medical/psychosocial support? ☐ Ye ☐ No ☐ Not Applicable	**Comments / What should be improved?**
14. Is there provision for treatment of study-related Injuries? ☐ Yes ☐ No ☐ Not Applicable	**Comments / What should be improved?**
15. Is the amount paid to participants stated? ☐ Ye ☐ No ☐ Not Applicable	**Comments / What should be improved?**
16. Is there an option/right to withdrawal at any time without consequences by the participants? ☐ Yes ☐ No	**Comments / What should be improved?**

B. Recommendation

Decision: ☐ Approval ☐ Minor Modification ☐ Major Modification /Resubmission ☐ Disapproval

Summary of Contents:

Reviewer's Name :		
	Signature above printed name	**Date** (M/D/Y)

SJREB FORM 4
SJREB NOTICE FOR PROTOCOL MODIFICATION
(for initial and continuing review)

To: (Name of CI)

_____

Contact No.:

_____

Protocol Title:

_____

Protocol No./Version Date:

_____

ICF Version No./Version Date:

_____

Sponsor Protocol No.:

_____

Type of Submission:

☐ Initial Review ☐ Final Report ☐ Progress Report

☐ Amendment ☐ Resubmission ☐ Others

This is to inform you of the decision related to the documents you have submitted:

Items for Review	Revisions Required from the Principal Investigator
Protocol:	
Informed Consent:	
Others:	

Please submit the revised documents within 15 days from receipt of this notice.

Type of Review:

- ☐ Expedited
- ☐ Full Board
- ☐ Exempt

SJREB Decision:

- ☐ Approved
- ☐ Minor Modification Required
- ☐ Major Modification Required
- ☐ More Information Required
- ☐ Others

Meeting Date: _____

SJREB Chairperson	Name	Signature	Date

SJREB FORM 5
NOTICE OF APPROVAL
This is to certify that the following protocol and related documents Have been granted approval by the SJREB for implementation

Protocol Number:

Sponsor Protocol No.: Date (D/M/Y):

Coordinating Investigator: Sponsor:

Title:

Protocol Version No.: Version Date:

ICF Version No: Version Date:

Other Documents: Version Date:

Members of Research Team:

Study Sites:

	Duration of Approval From (date) To	Frequency of continuing review
Expedited Full Board		

Meeting Date: _____

SJREB Chairperson	Name	Signature	Date

Investigator Responsibilities after Approval:

- Submit document amendments to the site REC approval before implementing them;
- Submit annual report for renewal of approval to SJREB;
- Submit SAE and SUSAR reports to the site REC within seven (7) calendar days;
- Submit progress report every ____ months;
- Submit final report after completion of protocol procedures at the study site;
- Report protocol deviation/violation to the REC study sites;
- Comply with all relevant international and national guidelines and regulation; and
- Abide by the principles of good clinical practice and ethical research

Reviewed by:

Name:

Signature: Date:

Post Approval Review Procedures

Appendix C

Form 3.1 Protocol Amendment Application Form
Form 3.2 Progress Report
Form 3.3 Closure/Final Report
Form 3.4 Onsite Serious Adverse Event Report
Form 3.5 Protocol Violation/Deviation Report
Form 3.6 Query/Complaint Record
Form 3.7 Study Visit Site Report
Form 3.8 Early Study Termination Application
Form 3.9 Reportable Negative Event Report
Form 3.10 Notification Letter

FORM 3.1
PROTOCOL AMENDMENT APPLICATION FORM

Date of submission	REC Protocol Number	Sponsor Protocol Number
Principal Investigator	**Email / Mobile Number**	**Sponsor**

Title of Study	

Study Site		Date of Initial Approval	

Items to be Amended	List of Amendments*	Reasons	Reviewer's Comments

*Indicate pages in the document where the amendment is found. Underline or highlight the amendments done in the documents

Name & Signature of Principal Investigator		Date:	

Received by:

REC Staff		Signature		Date	

FOR NCMH-REC USE

Assessment by Primary Reviewers	**Type of amendments:** **Minor** ☐ **Major** ☐ **Does the amendment increase the risks to participants?** **Yes** ☐ **No** ☐ **Does the amendment increase the benefits to participants?** **Yes** ☐ **No** ☐ **Is there favourable benefit/ risk ratio?** **Yes** ☐ **No** ☐	**Comments**	**Recommendation**

Primary reviewer:

Name of Reviewer:		Signature		Date	

Received by:

REC Staff		Signature		Date	

REC Final Decision	☐ Approve ☐ Request further information / modification ☐ Others: _____

NCMH-REC Chairperson	Signature:	Date

FORM 3.2

PROGRESS REPORT

To be filled up by the Principal Investigator

REC Protocol No		Initial Approval Date	
Protocol Title			
Investigator		Sponsor	

Any amendment since the last review? (Describe briefly) ☐ No ☐ Yes

Any change in participant population, recruitment or selection criteria since the last review? (Explain the changes) ☐ No ☐ Yes

Any change in the Informed Consent process or documentation since the last review? (Please explain) ☐ No ☐ Yes

Is there any new information in recent literature or similar research that may change the risk/ benefit ratio for participants in this study? (Summarize) ☐ No ☐ Yes

Any unexpected complication or side effect noted since the last review? (Summarize) ☐ No ☐ Yes

Were there protocol deviation/ violation reports? ☐ No ☐ Yes (Summarize) What corrective actions were taken?
Any new investigator that has been added to or removed from the research team since the last review? (Please identify them and submit the CVs of new investigators.) ☐ No ☐ Yes
Are there any new collaborating sites that have been added or deleted since the last review? Please identify the sites and note the addition or deletion. ☐ No ☐ Yes

Summary of recruitment:

<number>	Accrual ceiling set by REC
<number>	New participants accrued since last review
<number>	Total participants accrued since protocol began
<number>	No. of participants who are lost to follow up
<number>	No. of participants withdrawn from the study
<number>	No. of participants who experienced SAEs/ SUSARs

Received by: <REC Staff>	Date Received:

FOR NCMH-REC USE ONLY

ASSESSMENT BY THE PRIMARY REVIEWER	COMMENTS	RECOMMENDATION
Do the risks to the study participants remain reasonable in relation to anticipated benefits? ☐ Yes ☐ No		
Are there new findings in the IB or literature (e.g., important toxicity or adverse event information) that need to be included in the informed consent? ☐ Yes ☐ No		
Is there need to revise the ICF? ☐ Yes ☐ No		
Is there need to reconsent subjects enrolled in the study? ☐ Yes ☐ No		
Are there concerns about conduct of the research team (e.g., suspension of medical license, frequent protocol violation, patient or third party complaints, etc.) or institutional commitment that may affect patient safety? ☐ Yes ☐ No		
Are there concerns about patient safety, inability to comply with the protocol, high dropout rate that affect study implementation? ☐ Yes ☐ No		

Check the protocol file to ensure consistency of the progress report with actual reports (SAE, protocol deviation/ violation, etc.) submitted by the Principal Investigator

Recommended Action:

- ☐ Approve
- ☐ Request further information, specify
- ☐ Recommend further action, specify
- ☐ (e.g. Require protocol / ICF amendment, re-consent) to address concerns about patient safety)
- ☐ Others

Primary Reviewer:	Signature:	Date:

NCMH-REC Chair	Signature:	Date:

FORM 3.3
CLOSURE/FINAL REPORT

REC PROTOCOL CODE NO.:		
PROTOCOL TITLE:		
PRINCIPAL INVESTIGATOR:		
PROTOCOL (INITIAL) APPROVAL DATE: <dd/mm/yyyy>		
Email:	**Telephone:**	**Mobile:**
STUDY SITE: <Name and address>		
SPONSOR:		
SPONSOR CONTACT PERSON:		
Email:	**Telephone:**	**Mobile:**

1. Study Arms:

Summary of recruitment:

- ☐ Accrual ceiling set by REC
- ☐ New participants accrued since last review
- ☐ Total number of participants accrued since protocol began
- ☐ No. of participants who are lost to follow up
- ☐ No. of participants withdrawn from the study
- ☐ No. of participants who experienced SAEs/ SUSARs

2. Number of participants who completed the study: _____
3. Amendments to the original protocol (including dates of approval):
4. Summary of onsite SAEs reported:
5. Summary of participants' complaints or grievances documented regarding conduct of study:
6. Summary of benefits to participants:
7. Summary of indemnifications of study related injury (If Applicable):
8. If terminated early, specify reason for termination:
9. Progress reports submitted (with dates of approval):

10. Duration of the study (months):

11. Informed consent form used (with version no./date) and attach most recent version:

DATE OF LAST REVIEW:

SIGNATURE OF PRINCIPAL INVESTIGATOR:

DATE:

RECEIVED BY: (Name of NCMH-REC Staff)

REPORT SUBMISSION DATE: (to be filled out by the NCMH-REC)

12. Study objectives and summary of results:

NCMH-REC USE

COMMENTS OF PRIMARY REVIEWER (i.e. compliance with the terms of the approved protocol including post-approval review requirements, and overall assessment of risks against benefits in the conduct of study)

RECOMMENDED ACTION:

- ☐ APPROVE
- ☐ REQUEST INFORMATION: (specify)
- ☐ RECOMMEND FURTHER ACTION: (specify)
- ☐ PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE

PRIMARY REVIEWER Signature _____

Date: Name <Title, Name, Surname>

FORM 3.4

ONSITE SERIOUS ADVERSE EVENT REPORT

Whenever there is any SAE event in any research approved by the National Center for Mental Health – Research Ethics Committee (NCMH-REC), it has to be reported by the Principal Investigator (PI) to the NCMH-REC.

SECTION 1

Principal Investigator:	

Study Title:		Protocol No.:	

Name of the study medicine / device:	Report Date: ☐ Initial ☐ Follow-up Onset Date:

Sponsor:	Date of first use:

Title of the Report	Date of the report

Subject's initial / number: _____ Age: _____ ☐ Male ☐ Female

Subject's history:	Laboratory findings:

SAE:	Treatment: Outcome: ☐ Resolved ☐ On-going
Seriousness:	Relation to

☐ Death ☐ Life Threatening ☐ Drug ☐ Device ☐ Study

☐ Hospitalization:

☐ Initial ☐ Prolonged

☐ Disability/Incapacity

☐ Congenital Anomaly

☐ Others

☐ Not related

☐ Possibly

☐ Probably

☐ Definitely related

☐ Unknown

Note: PI should attach standard SAE report form (CIOM) to this NCMH-REC form.

FOR NCMH-REC USE

Received by:

Name (REC Secretariat)	Signature	Date

Reviewer's Comments/ Recommendations

Reviewer's Name:	Signature	Date

Changes to the protocol recommended? ☐ No ☐ Yes

Comments:

Changes to the informed consent form recommended? ☐ No ☐ Yes

Comments:

Recommendation

Name of Reviewer	Signature	Date

REC Final Action:

- ☐ Request an amendment to the protocol or the consent form
- ☐ Request further information
- ☐ Suspend enrolment of new research participants
- ☐ all trial-related procedures
- ☐ Termination of the Study
- ☐ Take note and continue monitoring
- ☐ Conduct Study Site Visit
- ☐ Others:

_____

Type of review:

- ☐ Expedited review
- ☐ Full board review

Date of meeting

_____

FORM 3.5

PROTOCOL VIOLATION/DEVIATION REPORT

REC Protocol No.	Sponsor Protocol No.	Date of Submission

Study Title			
Investigator		Contact No.:	
Sponsor		Contact No.:	
Reported by		Contact No.:	
Description:			

For NCMH-REC
Primary Reviewer Assessment

PI Deviation from the Protocol _____ Major _____ Minor	Participant Non-Compliance	Study Staff

Recommendation :

Noted (no further action needed)
Corrective action required
Site visit needed

Date of Full Board meeting

REC Decision:	
Required corrective action	

FORM 3.6
QUERY/COMPLAINT

INSTRUCTIONS: This form should accomplished by any party communicating queries and complaints for information or action by the NCMH-REC. In case of communication from research subjects or participants, the NCMH-REC personnel can encode the information on their behalf if needed. Information reported in this form is processed either as a study-protocol-related or non-study-protocol-related communication, as the case may be. For protocol-related communication, put the relevant study protocol information below; if not, put N/A. If necessary, a letter may be attached to this form by the sending party, but a summary of the nature of communication should still be encoded in this form to allow proper filing of communication. Obtain an electronic copy of this form and encode all information required in the space provided, and email this form at ncmhrec@gmail.com

NATURE OF COMMUNICATION

☐ Study-protocol-related
☐ Non-study-protocol-related

NCMH-REC PROTOCOL CODE:

STUDY PROTOCOL TITLE:

PRINCIPAL INVESTIGATOR:

INITIAL APPROVAL DATE: <dd/mm/yyyy>

DATE OF LAST CONTINUING REVIEW APPROVAL: <dd/mm/yyyy>

Reason, if no CRA Approval:

☐ Pending SJREB Approval
☐ Less than 10 months since last initial approval
☐ No CRA Submission
☐ Others (specify): _____

Version and date of latest approved protocol:		
Version and date of latest approved ICF:		
Email:	**Telephone:**	**Mobile:**
STUDY SITE: <Name and address>		
STUDY SITE ADDRESS:		
SPONSOR:		
SPONSOR CONTACT PERSON:		
Email:	**Telephone:**	**Mobile:**
DATE RECEIVED: <dd/mm/yyyy>		
1. **RECEIVED BY (NCMH-REC Staff) :** < NAME >		
2. COMMUNICATION DELIVERED/SENT THROUGH: 2.1. ☐ Telephone 2.2. ☐ E-mail dated: <dd/mm/yyyy> 2.3. ☐ Walk-in (indicate date/time) 2.4. ☐ Other, specify:		
3. PERSON SENDING THE COMMUNICATION 3.1. **<TITLE, NAME, SURNAME>** 3.2. **Address:** <Street Number, Street, Barangay, City, Postal Code> 3.3. **Telephone**: <area code, number> 3.4. **Mobile:** <Provider code, number> 3.5. **Email:**		
4. CONNECTION/RELATION OF PERSON TO THE STUDY PROTOCOL 4.1. ☐ **Study participant** 4.2. ☐ **Other: <specify>** 4.3. ☐ **Not applicable**		
5. TYPE OF CONCERN		
5.1. ☐ Query <specify>		
5.2. ☐ Notification <specify>		
5.3. ☐ Complaint <specify>		

5.4. ☐ Others <specify>

6. Signature of Person Accomplishing this form:

RECOMMENDATIONS (for NCMH-REC use only)

REFERRED TO

☐ Full Board Review by Panel
☐ Expedited Review at the level of the Panel Chair
☐ Other: <Specify>

RECOMMENDED ACTION:

☐ NO FURTHER ACTION
☐ REQUEST INFORMATION: <specify>
☐ RECOMMEND FURTHER ACTION: <specify>
☐ PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE

NCMH-REC Chair	Signature	
DATE: <dd/mm/yyyy>	Name	<Title, Name, Surname>

If study-protocol-related, this form should be reviewed and signed by primary reviewer

PRIMARY REVIEWER	Signature	
Date: <dd/mm/yyyy>	Name	<Title, Name, Surname>

FORM 3.7
STUDY SITE VISIT REPORT

Outcome:	

Principal Investigator:		Phone:	

Sponsor		Site	

Reason for Site Visit		Persons Interviewed	

Total number of expected subjects:		Total subjects enrolled:	

	Yes	No	Comments
Are site facilities appropriate?			
Is confidentiality of documents maintained (e.g. cabinets with lock and keys)?			
Are the test articles properly kept and maintained?			
Are Informed Consent Forms complete?			
Are approved ICF versions used?			
Are copies of the approved versions of the protocol documents kept in the site?			
Are files of all communication with the REC found in the site?			
Does the site keep copies of all communication with the REC in the site?			
Are copies of adverse event reports kept?			
Are Investigator functions properly delegated to qualified research personnel?			
Is there appropriate documentation of qualifications of personnel?			
Are all Case Record Forms up to date?			
Are copies of protocol deviation/ violation reports kept in the site?			
Is there evidence of appropriate corrective action taken as recommended by the REC?			

Duration of visit: (hours)		Starting from:		Finish:	

Names of NCMH-REC Member Visitors:	

Report prepared by:		Date:	
Signature			

FORM 3.8
EARLY STUDY TERMINATION APPLICATION

REC Protocol No:		Sponsor Protocol No.	
Protocol Title:			
Principal Investigator:			
Phone :		E-Mail:	
Department:			
Sponsor:			
REC Approval Date:		Date of Last Report:	
Starting Date:		Termination Date:	
No. of Participants:		No. Enrolled:	

Summary of Results:	
Accrual Data:	
Reason for early termination	

Is this a temporary Halt to the study? What is the justification for temporarily halting The study? When do you expect The study to re-start?	
Are there any potential implications for research participants as a result of terminating/halting the study Prematurely? Please describe the steps taken to Address them.	

P.I. Signature:		Date:	

To be filled up by NCMH-REC

Signature: Received by:	 <Printed Name>	Date Received:	<mm/dd/yyyy>

RECOMMENDATIONS (for NCMH-REC use only)

PRIMARY REVIEWER 1. 2. 3.	Signature	DATE
RECOMMENDED ACTION: ☐Accept decision for termination ☐Request for additional information ☐Require further action in termination plan	Type of review: ☐Expedited review ☐Full Board review Date of meeting _____	
NCMH-REC FINAL DECISION:		
Certified by: NCMH-REC CHAIR	Signature:	Date:

Form 3.9
Reportable Negative Event Report

Instructions to the Researcher: Please accomplish this form and ensure that you have included in your submission the documents that you checked in Section 3. Checklist of Documents.

General Information			
*Title of Study			
*REC Code (To be provided by REC		*Study Site	
*Name of Researcher		Contact Information	*Tel. No.:
			*Mobile No.:
*Co-researcher (if any)			Fax No,:
			*Email:
*Institution			
*Address of Institution			
Ethical clearance effectivity period			
RNE Report			
1. Start of study		2. Expected end of study	
3. Number of enrolled participants		4. Number of required participants	
5. Description of Negative (harms, risks) Events a. Involving Participants b. Involving members of the Study Team c. Involving Data safety and integrity		6. Actions taken to prevent future (RNEs, interventions and Outcomes	
7. Recommendations			

Form 3.10
NOTIFICATION LETTER

(Date)

(Name)
Principal Investigator

Dear (Principal Investigator),

We would like to inform you that your research protocol entitled (Title) with Code: (Code) submitted last (date of submission) has been reviewed by the National Center for Mental Health – Research Ethics Committee (NCMH-REC). However, there are major (or minor) modifications required on the following:

(Enumerate the issues to be modified or revised)

Kindly complete the entries in the attached Resubmission Form 2.5 including the version number and date of your revised protocol. Indicate the changes made – highlight/underline and include the page numbers in the revised document. Submit within 15 days from the receipt of this letter.

Should you have any inquiry, you may email us at ncmhrec@gmail.com or contact us at local 265. Kindly use the assigned protocol code number in all your communication with NCMH-REC. Thank you.

Very truly yours,

(Name) (Date)
Signature above printed name of Chairperson
National Center for Mental Health – Research Ethics Committee

Documentation and Archiving

Appendix D

Form 4.1 Meeting Agenda Template
Form 4.2 Meeting Minutes Template
Form 4.3 Requests to Access REC Files

FORM 4.1
NOTICE OF MEETING

National Center for Mental Health – Research Ethics Committee
Address
Telephone Number
Date

NOTICE OF MEETING

To : National Center for Mental Health – Research Ethics Committee Members
(Name of REC Member 1)
(Name of REC Member 2)
(Name of REC Member 3)
(Name of REC Member 4)

Date of Meeting
Time of Meeting
Venue of Meeting
Agenda
PROTOCOL REVIEW
(Note: All protocols for review should include the following information: Protocol No., Title, Principal Investigator, Sponsor, Reviewers)
1. New Protocols
2. Resubmitted Protocols
3. Protocol for Clarification
4. Protocol Amendments
5. Progress Reports
6. Final Reports
7. Protocol Deviation/Violation
8. Early Study Termination
9. Site Visit Reports
10. Onsite SAE Reports
11. Expedited Review Report (includes all protocols reviewed through expedited means)
12. Exempted Reports
13. Queries/Complaints
14. Continuing Review application

Other Matters

Prepared by:

Signature above printed name of REC Member-Secretary
Signature above printed name of Chairperson

FORM 4.2
MINUTES OF THE MEETING TEMPLATE

<ordinal> Regular Meeting)
<mm/dd/yyy> Venue, Time

ATTENDANCE

PRESENT

(Name1, position, expertise, affiliated/non-affiliated, male/female)
(Name2, position, expertise, affiliated/non-affiliated, male/female)
(Name3, position, expertise, affiliated/non-affiliated, male/female)
(Name4, position, expertise, affiliated/non-affiliated, male/female)
(Name5, position, expertise, affiliated/non-affiliated, male/female)
(Name6, position, expertise, affiliated/non-affiliated, male/female)

ABSENT

(Name 7, position, expertise, affiliated/non-affiliated, male/female)
(Name8, position, expertise, affiliated/non-affiliated, male/female)
(Name9, position, expertise, affiliated/non-affiliated, male/female)

Others: Staff or Guest PI

1. **CALL TO ORDER**
2. **DECLARATION OF QUORUM**
3. **APPROVAL OF THE PROVISIONAL AGENDA**
4. **DISCLOSURE OF CONFLICT OF INTEREST**
5. **READING AND APPROVAL OF THE MINUTES OF THE LAST MEETING**
6. **BUSINESS ARISING FROM THE MINUTES OF THE LAST MEETING**
7. **STUDY PROTOCOL REVIEW**

7.1. FULL REVIEW

7.1.1. Study Protocols for Initial Review (NONE or #)

Code	
Study Protocol Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal investigator	
Type of review	
Primary reviewers	
Technical Review	
Funding Agency/CRO	
Study site	
Quorum status	
Conflict of interest	
Assessment of scientific soundness	**1. Social Value** **2. Objectives/Expected output** **3. Literature review** **4. Research design** **5. Sampling design, sample size** **6. Inclusion criteria, exclusion criteria, withdrawal criteria** **7. Data collection and processing plan** **8. Specimen collection and processing** **9. Statistical and data analysis plan** **10. PI qualifications** **11. Suitability and choice of site** **12. Validation of research instruments among Filipino participants** **13. Duration of participant involvement**
Assessment of ethical issues	**1. Conflict of Interest and Transparency:** **2. Privacy and confidentiality including data protection plan** **3. Vulnerability** **4. Risks and safety monitoring plan** **5. Benefits** **6. Compensation** **7. Community Considerations** **8. Dissemination or data sharing plan** **9. Documentation of collaborative study and TOR**
Assessment of informed consent issues	**1. Informed consent process and recruitment:** **2. Informed Consent Form (ICF) (including translation)**

Conclusion and recommendations	
Action taken	**Decision** (Approve <date of continuing review>, Major Modification, which require full board deliberation, Minor Modification, which can be expedited at the level of the Chair, Disapprove, Pending, if major clarifications are required before a decision can be made)
Approval expiration date (if applicable)	
Frequency of continuing review (in case of approval	
Reasons	

7.1.2. **Resubmissions or Study Protocols for Modification (NONE or #)**

Code	
Study Protocol Resubmission Date	<dd/mm/yyyy>
Study Protocol Initial Submission Date	
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Funding Agency/CRO	
Study site	
Quorum status	
Conflict of Interest	
Assessment of PI response to initial review	
Conclusion and recommendations	
Action taken	**Decision** (Approve <date of continuing review>, Major Modification, which require full board deliberation, Minor Modification, which can be expedited at the level of the Panel Chair, Disapprove, Pending, if major clarifications are required before a decision can be made)
Approval expiration date (if applicable)	

Frequency of continuing review (in case of approval	
Reasons	

7.1.3. **Study Protocols for Clarificatory Interview (NONE or #)**

Code	
Study Protocol Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Funding Agency/CRO	
Quorum status	
Conflict of Interest:	
Assessment of PI responses to Panel queries	
Conclusion and recommendations	
Action taken	**Decision** (Decisions are based on the Panel's assessment of the PI's response to their queries.)
Reasons	

7.1.4. **Withdrawal of Study Protocol Applications (NONE or #)**

Code	
Withdrawal Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Funding Agency/CRO	
Quorum status	
Conflict of Interest:	
Assessment of reasons for	

Study Protocol withdrawal	
Conclusion and recommendations	**1. Total of participants enrolled** **2. Status of participants currently enrolled** **3. Effect of withdrawal on safety and well-being of subjects** **4. Effect on overall risk-benefit ratio**
Action taken	**Decision** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made)
Reasons	

7.1.5. **Study Protocol Amendment Applications (NONE or #)**

Code	
Initial Approval Date	<dd/mm/yyyy>
Version and date of latest approved protocol:	<Version #> <dd/mm/yyyy>
Version and date of latest approved ICF:	<Version #> <dd/mm/yyyy>
Amendment Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Funding Agency/CRO	
Quorum status	
Conflict of Interest:	
Assessment of amendment requested	**1. Effect of amendment on feasibility of the study** **2. Effect of amendment on safety and well-being of subjects** **3. Effect of amendment on overall risk-benefit ratio**
Conclusion and recommendations	
Action taken	**Decision** (Approve, Minor modification to the study protocol amendment, citing reasons for action, subject to expedited review at the level of the Panel Chair, Major modification to the study protocol amendment, stating reasons for action, subject to full board review, Disapprove, Pending, if major clarifications are required before a decision can be made)
Reasons	

7.1.6. **Continuing Review Applications (NONE or #)**

Code	
Initial Approval Date	<dd/mm/yyyy>
Version and date of latest approved protocol:	<Version #> <dd/mm/yyyy>
Version and date of latest approved ICF:	<Version #> <dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Funding Agency/CRO	
Quorum status	
Conflict of Interest:	
Assessment of progress reported	**1. Protocol or conduct of the study** **A. Changes in the participant population, recruitment or selection criteria since the last review/approval** **B. Changes in the informed consent process or documentation since the last review/ approval** **C. Any new information that might affect the panel's evaluation of the risk/benefit assessment of human participants involved in this study protocol** **D. New/additional investigational new drug/device registrations associated with this study new intervention(s) or methods in the conduct of study that is/are not in the approved protocol** **E. Changes in the investigators and study personnel** **F. Changes in collaborating sites/institutions** **G. Others** **2. Protection of welfare** **A. Updates or measures in the protocol to guarantee protection of privacy and confidentiality of participant information in compliance with local regulations (e.g. Data privacy act of 2012)** **B. Any unexpected discomforts, complications, or side effects noted or any safety issues** **C. Participants that have withdrawn from this study since**

	the last review/approval **D. Changes in conflict of interest** **E. Management of biobank, as applicable** **F. Site visit conducted for this study** **G. Others** **3. Assessment of progress status on overall risk-benefit assessment ratio**
Conclusion and recommendations	
Action taken	**Decision** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made)
Reasons	

7.1.7. **Final Reports** **(NONE or #)**

Code	
Initial Approval Date	<dd/mm/yyyy>
Version and date of latest approved protocol	<Version #> <dd/mm/yyyy>
Version and date of latest approved ICF	<Version #> <dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Funding Agency/CRO	
Quorum status	
Conflict of Interest:	
Assessment of Final Report:	
Conclusion and recommendations	
Action taken	**Decision** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made)
Reasons	
<add more as needed>	

7.1.8. Study Protocol Non-Compliance (Deviation or Violation) Reports (NONE or #)

Code	
Initial Approval Date	<dd/mm/yyyy>
Version and date of latest approved protocol	<Version #> <dd/mm/yyyy>
Version and date of latest approved ICF	<Version #> <dd/mm/yyyy>
Date of Report	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Funding Agency/CRO	
Quorum status	
Conflict of Interest:	
Assessment of Non-Compliance Report:	**1. Description of reported deviation** **2. Nature of report** **3. Description of investigator preventive action** **4. Description of investigator corrective action** **5. Investigator's assessment on the impact of the deviation on the safety of participant/s** **6. Investigator's assessment on the impact of the deviation on the credibility of data** **7. Description of sponsor corrective action** **8. Over-all assessment, including whether noncompliance have potentially serious consequences that could critically affect data integrity or put patients' safety at risk**
Conclusion and recommendations	
Action taken	**Decision** (No further action required, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made)
Reasons	
<add more as needed>	

7.1.9. Early Study Termination Reports (NONE or #)

Code	

Initial Approval Date	<dd/mm/yyyy>
Version and date of latest approved protocol:	<Version #> <dd/mm/yyyy>
Version and date of latest approved ICF:	<Version #> <dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Funding Agency/CRO	
Quorum status	
Conflict of Interest:	
Assessment of risks from early termination	**1. Current participants being enrolled and might be affected** **2. Summary of results to date** **3. Reason for termination with justifications** **4. Over-all assessment, including implication of the report on the rights, safety, and welfare of the study participants, including adapting specific provisions for continued protection and dissemination of specific information to the study participants**
Conclusion and recommendations	
Action taken	**Decision** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made)
Reasons	

7.1.10. **Queries and Complaints** **(NONE or #)**

Code	
Initial Approval Date	<dd/mm/yyyy>
Version and date of latest approved protocol:	<Version #> <dd/mm/yyyy>
Version and date of latest approved ICF:	<Version #> <dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	

Primary Reviewers	
Technical Review	
Funding Agency/CRO	
Quorum status	
Conflict of Interest:	
Assessment of query:	**1. Type of query** **2. Effect of query on safety and well-being of subjects** **3. Effect on overall risk-benefit ratio**
Conclusion and recommendations	
Action taken	**Decision (**No further action, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made)
Reasons	
Assessment of notification:	**1. Type of notification** **2. Effect of notification on safety and well-being of subjects** **3. Effect on overall risk-benefit ratio**
Conclusion and recommendations	
Action taken	**Decision (**No further action, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made)
Reasons	
Assessment of complaint:	**1. Type of complaint** **2. Effect of complaint on safety and well-being of subjects** **3. Effect on overall risk-benefit ratio**
Conclusion and recommendations	
Action taken	**Decision (**No further action, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made)
Reasons	

7.1.11. **SAE and SUSAR Reports** **(NONE or #)**

Code	
Initial Approval Date	<dd/mm/yyyy>
Version and date of latest approved protocol:	<Version #> <dd/mm/yyyy>
Version and date of latest approved ICF:	<Version #> <dd/mm/yyyy>

Report Date	<dd/mm/yyyy>	
Study Protocol Title		
Principal Investigator		
Type of Review		
SAE Reviewer		
Technical Review		
Funding Agency/CRO		
Quorum status		
Conflict of Interest:		
Assessment of reported SAE::	Suspected Drug	
	Patient no	
	Report Date	
	Date of SAE	
	Date of 1st use	
	Duration of Therapy	
	Age	
	Sex	
	Country	
	Nature of SAE	<Patient died, Involved or prolonged inpatient hospitalization, involved persistence or significant disability or incapacity, life threatening
	Summary description of the SAE	
	Co-morbidities	
	Reaction abated after stopping drug	<Yes/No/NA>
	Reaction appeared after reintroduction	<Yes/No/NA>
	Treatment of SAE	
	Status	
	Country	
	Causality assessment	<Certain, Probable, Possible, Unlikely, Conditional, Unclassifiable>

	Reason/Comment	
	Adequacy of Treatment of SAE	
Conclusion and recommendations		
Action taken	**Decision Points** (No further action required, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made)	
Reasons		
<add more as needed>		

7.1.12. **Site Visit Reports** **(NONE or #)**

Code	
Initial Approval Date	<dd/mm/yyyy>
Version and date of latest approved protocol:	<Version #> <dd/mm/yyyy>
Version and date of latest approved ICF:	<Version #> <dd/mm/yyyy>
Site Visit Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Funding Agency/CRO	
Quorum status	
Conflict of Interest:	
Assessment of Site Visit Report	**1. Details on the site visit conducted (i.e. when, where, team composition, reason for site visit)** 2. **Overall assessment, including the implications of results of the Site Visit on the rights, safety, and welfare of the study participants; and overall determination of protocol compliance in the study site.**
Conclusion and recommendations	
Action taken	**Decision Points (**No further action required, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made)

Reasons	

7.2. REPORT OF PROTOCOL SUBMISSIONS CLASSIFIED AS EXEMPTED FROM ETHICAL REVIEW

7.2.1. Protocols Exempted from Ethical Review (NONE or #)

Code	
Study Protocol Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Funding Agency/CRO	
Date of Action	

7.3. REPORT OF PROTOCOL SUBMISSIONS FOR EXPEDITED REVIEW AND FULL BOARD PROTOCOLS WITH MODIFICATION EXPEDITED AT THE LEVEL OF THE CHAIR

7.3.1. Approved Protocols (NONE or #)

Code	
Study Protocol Initial Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Funding Agency/CRO	
Study Protocol Approval Date	<dd/mm/yyyy>

7.3.2. Study Protocol Amendments (NONE or #)

Code	
Initial Approval Date	<dd/mm/yyyy>
Version and date of latest approved protocol:	<Version #> <dd/mm/yyyy>
Version and date of latest	<Version #> <dd/mm/yyyy>

approved ICF:	
Date of Amendment Submission	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Funding Agency/CRO	
Action taken	**Decision** (Approval, Minor modification to the study protocol amendment, citing reasons for action, subject to expedited review at the level of the Panel Chair, Major modification to the study protocol amendment, stating reasons for action, subject to full board review, Disapprove, Pending, if major clarifications are required before a decision can be made)
Date of Action	

7.3.3. **Continuing Review Applications** **(NONE or #)**

Code	
Initial Approval Date	<dd/mm/yyyy>
Version and date of latest approved protocol:	<Version #> <dd/mm/yyyy>
Version and date of latest approved ICF:	<Version #> <dd/mm/yyyy>
Date of Report	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Funding Agency/CRO	
Action taken	**Decision** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made)
Date of Action	

7.3.4. **Final Reports** **(NONE or #)**

Code	
Initial Approval Date	<dd/mm/yyyy>

Version and date of latest approved protocol:	<Version #> <dd/mm/yyyy>
Version and date of latest approved ICF:	<Version #> <dd/mm/yyyy>
Date of Report	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Funding Agency/CRO	
Action taken	**Decision Points** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made)
Date of Action	

7.3.5. **Study Protocol Non-Compliance (Deviation or Violation) Reports(NONE or #)**

Code	
Initial Approval Date	<dd/mm/yyyy>
Version and date of latest approved protocol:	<Version #> <dd/mm/yyyy>
Version and date of latest approved ICF:	<Version #> <dd/mm/yyyy>
Date of Report	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Funding Agency/CRO	
Action taken	**Decision** (No further action, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made)
Date of Action	

7.3.6. **Early Study Termination Reports** **(NONE or #)**

Code	
Initial Approval Date	<dd/mm/yyyy>

Version and date of latest approved protocol:	<Version #> <dd/mm/yyyy>
Version and date of latest approved ICF:	<Version #> <dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Funding Agency/CRO	
Action taken	**Decision** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made)
Date of Action	

7.3.7. Queries, Notifications, and Complaints (NONE or #)

Code	
Initial Approval Date	<dd/mm/yyyy>
Version and date of latest approved protocol:	<Version #> <dd/mm/yyyy>
Version and date of latest approved ICF:	<Version #> <dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Funding Agency/CRO	
Action taken	**Decision** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made)
Date of Action	

7.4. REPORT OF RESULTS OF PROTOCOL SUBMISSIONS PROCESSED BY SJREB

7.4.1. Approved Protocols (NONE or #)

Code	
SJREB Code	

Study Protocol Initial Submission Date	<dd/mm/yyyy>
Study Protocol Title	
Country Pricipal Investigator	
Site Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Funding Agency/CRO	
Study Protocol Approval Date	<dd/mm/yyyy>

7.4.2. **Study Protocol Amendments** **(NONE or #)**

Code	
SJREB Code	
Initial Approval Date	<dd/mm/yyyy>
Version and date of latest approved protocol:	<Version #> <dd/mm/yyyy>
Version and date of latest approved ICF:	<Version #> <dd/mm/yyyy>
Date of Amendment Submission	<dd/mm/yyyy>
Study Protocol Title	
Country Pricipal Investigator	
Site Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Funding Agency/CRO	
Action taken	**Decision** (Approval, Minor modification to the study protocol amendment, citing reasons for action, subject to expedited review at the level of the Panel Chair, Major modification to the study protocol amendment, stating reasons for action, subject to full board review, Disapprove, Pending, if major clarifications are required before a decision can be made)
Date of Action	

7.4.3. Continuing Review Applications (NONE or #)

Code	
SJREB Code	
Initial Approval Date	<dd/mm/yyyy>
Version and date of latest approved protocol:	<Version #> <dd/mm/yyyy>
Version and date of latest approved ICF:	<Version #> <dd/mm/yyyy>
Date of Report	<dd/mm/yyyy>
Study Protocol Title	
Country Pricipal Investigator	
Site Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Funding Agency/CRO	
Action taken	**Decision** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made)
Date of Action	

7.4.4. Final Reports (NONE or #)

Code	
SJREB Code	
Initial Approval Date	<dd/mm/yyyy>
Version and date of latest approved protocol:	<Version #> <dd/mm/yyyy>
Version and date of latest approved ICF:	<Version #> <dd/mm/yyyy>
Date of Report	<dd/mm/yyyy>
Study Protocol Title	
Country Pricipal Investigator	
Site Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	

Funding Agency/CRO	
Action taken	**Decision Points** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made)
Date of Action	

7.4.5. **Study Protocol Non-Compliance (Deviation or Violation) Reports (NONE or #)**

Code	
SJREB Code	
Initial Approval Date	<dd/mm/yyyy>
Version and date of latest approved protocol:	<Version #> <dd/mm/yyyy>
Version and date of latest approved ICF:	<Version #> <dd/mm/yyyy>
Date of Report	<dd/mm/yyyy>
Study Protocol Title	
Principal Investigator	
Type of Review	
Country Pricipal Investigator	
Site Principal Investigator	
Technical Review	
Funding Agency/CRO	
Action taken	**Decision** (No further action, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made)
Date of Action	

7.4.6. **Early Study Termination Reports (NONE or #)**

Code	
SJREB Code	
Initial Approval Date	<dd/mm/yyyy>
Version and date of latest approved protocol:	<Version #> <dd/mm/yyyy>
Version and date of latest approved ICF:	<Version #> <dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	

Country Pricipal Investigator	
Site Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Funding Agency/CRO	
Action taken	**Decision** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made)
Date of Action	

7.4.7. **Queries and Complaints (NONE or #)**

Code	
SJREB Code	
Initial Approval Date	<dd/mm/yyyy>
Date of Last Continuing Review Approval:	
Version and date of latest approved protocol:	<Version #> <dd/mm/yyyy>
Version and date of latest approved ICF:	<Version #> <dd/mm/yyyy>
Application Date	<dd/mm/yyyy>
Study Protocol Title	
Country Pricipal Investigator	
Site Principal Investigator	
Type of Review	
Primary Reviewers	
Technical Review	
Funding Agency/CRO	
Action taken	**Decision** (Approve, Request information, Recommend further action, Pending, if major clarifications are required before a decision can be made)
Date of Action	

8. OTHER MATTERS

9. ADJOURNMENT

Meeting was adjourned at **<time>.**

Prepared by: DATE: <dd/mm/yyyy>	Signature over <Title, Name, Surname> SECRETARIAT STAFF
Checked by: DATE: <dd/mm/yyyy>	Signature over <Title, Name, Surname> MEMBER SECRETARY
Approved by: DATE: <dd/mm/yyyy>	Signature over <Title, Name, Surname> CHAIR

FORM 4.3

REQUEST TO ACCESS REC FILES

I, (Name, Surname) as a non-member of the National Center for Mental Health Research Ethics Committee, understand that the documents I am given access to by the National Center for Mental Health Research Ethics Committee are confidential. I shall use the information only for the purpose indicated in this form and shall not duplicate, give or distribute these documents to any person(s) without permission from the National Center for Mental Health Research Ethics Committee. Upon signing this form, I agree to take reasonable measures and full responsibility to keep the information as Confidential.

Requested document	
Reason for request	
Number of copies requested	

RECIPIENT	Signature	
Date: <dd/mm/yyyy>	Name	<Title, Name, Surname>

REC MEMBER-SECRETARY	Signature	
Date: <dd/mm/yyyy>	Name	<Title, Name, Surname>

Declaration of Helsinki, 2013

WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011

Philippine National Health Research System (PNHRS) National Ethical Guidelines for Health Research 2011

CH Harmonized Guidelines/Integrated Addendum to ICH E6 (R1): GUIDELINES FOR GOOD CLINICAL PRACTICE E6 (R2) 2016

International Ethical Guidelines for Health-related involving Humans (CIOMS) 2016

National Ethical Guidelines for Health and Health Related research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

NCMH-Research Ethics Committee, Standard Operating Procedure, November 2021

SJREB Standard Operating Procedure, 2021

SOP on Review of Medical Devices 2021
https://nkti.gov.ph/images/CTRU/ResearchForms/Standard_Operating_Procedures_III_Initial_Review_Procedures.pdf

National Ethical Guidelines for Research involving Human Participants, 2022