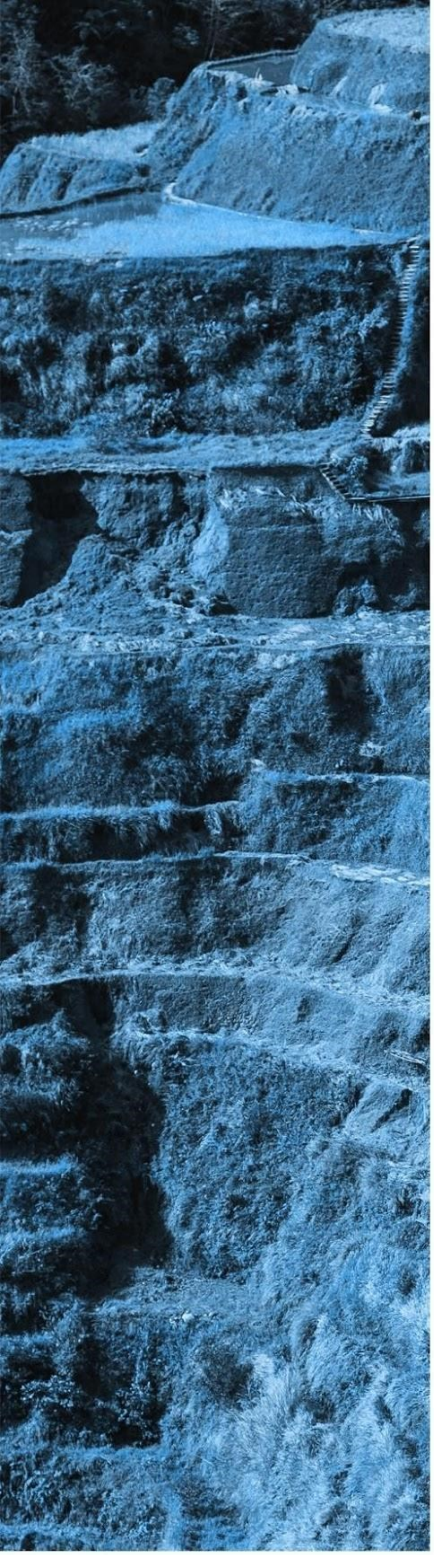

NATIONAL ETHICS COMMITTEE
Philippine National Health Research System
c/o Philippine Council for Health Research and Development
Department of Science and Technology

standard operating procedures

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Fifth Edition. Revised September 2024.

This Standard Operating Procedure and its annexes are available at nec.pchrd.dost.gov.ph.

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INTRODUCTION

In 1984, the National Ethics Committee (NEC) was organized by the Philippine Council for Health Research and Development (PCHRD) through Special Order No. 84-053 issued by then PCHRD Executive Director, Dr. Alberto G. Romualdez, Jr. The NEC was created "to ensure that all health research and development proposals conformed with ethical standards and to promote the establishment of Ethics Review Committees (ERCs) in various localities and institutions". The first chair of the committee was Dr. Generoso Basa from the University of Santo Tomas Faculty of Medicine and Surgery.

The first set of guidelines for the conduct of biomedical research in the country was published by the NEC in 1985. This underwent revisions in 1996 and 2000 to address various developments in health research like global clinical trials, genetic research, and organ transplantation research.

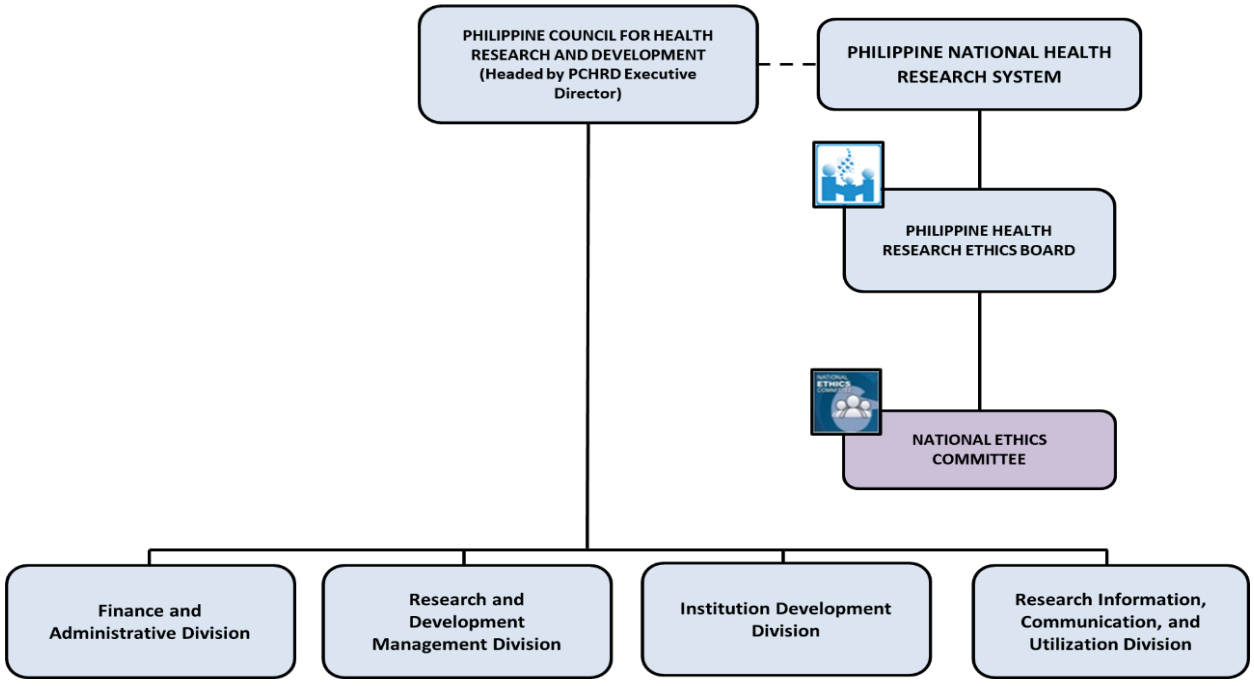
In 2003, the Philippine Health Research Ethics Board (PHREB) was constituted as one of the working committees in the Philippine National Health Research System (PNHRS) and was identified as the national policy making body in health research ethics. With this new development, the role of the National Ethics Committee remained as a reviewing committee at the national level.

To enable the NEC to better discharge its functions as a review committee, the NEC Secretariat, Ms. Imelda B. Mutuc and Ms. Charisma G. Cruz under the supervision of the NEC Chair, Dr. Marita V.T. Reyes, developed and compiled a set of operating procedures (SOPs) in May-July 2008. This was subsequently approved by the NEC during its meeting on August 21, 2008.

In 2010, with more than a 100 ERCs registered at the PHREB database, a gradual phase-out of the NEC was decided even while it continued to do post-approval procedures for previously approved protocols. In July 2010, the NEC no longer accepted new applications for review. It was estimated that the ongoing studies would have ended by December 2012. This, however, did not materialize as the Principal Investigators requested extensions of ethical approval until December 2013.

In the meantime, PCHRD referred 30 project proposals from the DOH-Health Systems Research Management Program for review as an important step in processing the proposals for funding. This referral led to a revisit of the decision on the NEC phase-out and to a realization that there was indeed a need for a review committee at the national level, specifically in the review of research proposals that are not within the scope of existing Institutional Ethics Review Committees or where there are none. Through PCHRD Special Order No. 146 series of 2013, dated December 09, 2013, the NEC was reactivated.

Thus, the present NEC is envisioned to be an essential component of the Philippine National Health Research System (PNHRS) as depicted in the organogram below:



The primary responsibility of the NEC is to safeguard the rights, dignity, and welfare of human participants in research proposals referred to it by PCHRD, PHREB, or other national government agencies.

To be consistent with its advocacy for academic institutions to establish their own research ethics committees, the National Ethics Committee shall not accept applications for review from undergraduate and graduate students. In the case of graduate students, the NEC can make an exception for research that is national in scope in terms of study participants.

However, the NEC shall respond to requests for assistance by institutional research ethics committees in the resolution of difficult ethical issues. It shall advise the PCHRD and other government agencies, including the Philippine Food and Drug Administration (FDA), regarding identified ethical issues on relevant research activities. It shall provide appropriate information to the PHREB in the formulation of policies and guidelines on health research. As part of its activities, the NEC shall network with other national ethics bodies (i.e., Single Joint Research Ethics Board (SJREB), Philippine Genome Center-Ethical, Legal, Social Issues Program) in contributing to the development of an ethical research environment in the Philippines.

The PCHRD shall support the operations of the National Ethics Committee. The committee shall have at least 9 regular members including the chair and vice-chair, and 3 alternate members, appointed by the PCHRD Executive Director. The responsibilities of an NEC member are as follows:

1. Attend NEC meetings consistently.
2. Participate in the ethical review of research proposals and other related reports. The non-scientific member shall give special attention to the Informed Consent Form and process to ensure that these are comprehensible by laypersons and are considerate of community values.
3. Participate in the after-review activities, e.g., monitoring, continuing review, site visits, etc.
4. Declare any conflict of interest (COI) in the review of research proposals.
5. Maintain confidentiality of the documents and deliberations of the NEC meetings.
6. Attend continuing ethics education and other related activities.

The responsibilities of the Chair are as follows:

1. Sets the meeting agenda and presides in regular and special NEC meetings.
2. Conducts a preliminary review of all proposals and decides on the type of review.
3. Assigns primary reviewers for specific research proposals for full review.
4. Assigns reviewers for expedited reviews.
5. Ensures an appropriate and timely decision/action on a proposal.
6. Invites and appoints independent consultants for the review of proposals requiring a particular expertise.
7. Ensures that all NEC members undergo appropriate orientation and continuing training in research ethics, concepts, and guidelines.
8. Submits annual reports to PHREB.

In the absence of the Chair, the Vice-Chair assumes the responsibilities stated above.

All NEC members are mandated to disclose any COI that may affect their decision-making. Each member is required to sign a COI disclosure agreement prior to an appointment. The NEC members must abide by a confidentiality agreement that shall limit their access to, and sharing of, any information that is deemed proprietary. This policy shall also apply to all resource persons, external reviewers and other individuals who will be involved in the ethics review process.

The Office of the Executive Director of PCHRD shall designate a Secretariat that will be responsible in the management of the daily operations of the NEC. The Secretariat shall consist of at least two (2) individuals, one of whom must have supervisory qualifications. The NEC Secretariat shall:

1. Manage submissions of applications for ethics review from study proponents received through the PHREP.
2. Assign an NEC code to every protocol received by the NEC for review.
3. Organize NEC meetings.

4. Prepare NEC meeting agenda and minutes in consultation with the NEC Chair.
5. Prepare the materials for the meeting.
6. Record and summarize deliberations and decisions of the NEC in consultation with the NEC Chair.
7. Prepare communications to proponents for approval and signature of the NEC Chair.
8. Inform the Chair of any incoming communication pertinent to NEC activities and responsibilities.
9. Liaise with the PCHRD administration regarding NEC activities and requirements.
10. Organize the preparation, review, revision, and distribution of SOPs to the NEC members.
11. Maintain and archive NEC documents and files, i.e., research protocols and related documents, NEC minutes of the meetings, NEC membership files, etc.
12. Assist in the preparation of the Annual Report.

On 09 January 2023, the PCHRD issued Special Order no. 23-006, series of 2023, titled Amendment of Functions and Reconstitution of the Membership of the National Ethics Committee (NEC), as follows:

> "1. Ethics review of research protocols that are government-endorsed and are:
> a. Received through the Philippine Health Research Ethics Portal (PHREP);
> b. National in scope in terms of study participants; and
> c. other researches as NEC may deem appropriate for its review.
> 2. Assist institutional research ethics committees in the resolution of difficult ethical issues;
> 3. Provide input to PCHRD and other government agencies including the Food and Drug Administration of the Philippines regarding identified ethical issues in relevant research activities;
> 4. Provide appropriate information to the Philippine Health Research Ethics Board (PHREB) in the formulation of policies and guidelines in health research; and
> 5. Network with other national ethics bodies (e.g., SJREB, PGC-ELSI Program) in contributing to the development of an ethical research environment."

This set of Standard Operating Procedures is a revision of the 2022 SOPs. The NEC is guided by the Declaration of Helsinki (2013), Philippine National Ethical Guidelines for Research Involving Human Participants (2022), CIOMS International Ethical Guidelines for Health-related Research Involving Humans (2016), ICC/ESOMAR International Code (2016), ESOMAR/GBRN Guidelines (2021), the Guideline on Good Clinical Practice (GCP) of the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) (2016), Standards and Operational Guidance for ethics review of health-related research with human participants of the WHO (2011), and the Republic Act No. 10173 or Data Privacy Act of 2012.

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	PREPARATION AND REVISION OF STANDARD OPERATING PROCEDURES	SOP No.	NEC SOP 01
		Version No.	4
		Version Date	27 September 2024
		Effectivity	01 October 2024

1. POLICIES

A set of Standard Operating Procedures (SOPs) shall guide all the major activities of the National Ethics Committee (NEC). Any member of the NEC may propose a specific SOP which the committee shall approve before implementation. The Committee shall review the SOPs annually for 1) internal and external consistency, 2) efficiency, and 3) applicability.

2. PURPOSE OF THE ACTIVITY

The purpose of preparing SOPs is to ensure consistency and transparency of all major activities of the National Ethics Committee, thereby promoting quality assurance in the review process.

3. SCOPE

This SOP is limited to the preparation and revision of the NEC SOPs and Forms. It begins with the identification of a new SOP or an SOP for revision and ends with the coding and inclusion of the new SOP in the SOP manual.

4. WORKFLOW

PROCEDURE	PERSON RESPONSIBLE	PROCESSING TIME
4.1. Identification of new SOP or SOP for revision	NEC Chair / Member(s) / Secretariat	2 weeks
4.2. Formulation of SOP	Assigned member(s)	
4.3. Deliberation	NEC Members	4-8 weeks
4.4. Approval of SOP	NEC Members	
4.5. Coding and Integration of the revised or new SOP in the SOP Manual	Secretariat	
		Total: 6-10 weeks

5. DESCRIPTION OF PROCEDURES

5.1. Identification of new SOP or SOP for revision

A member of the NEC/Secretariat proposes the formulation of a new SOP or an amendment to an existing SOP as an item in the agenda of a regular meeting of the NEC.

5.2. Formulation of SOP

5.2.1. The Chair assigns the responsible person/s to draft the proposed new SOP or the amendment to an existing SOP.

5.2.2. The Secretariat includes the new or amended SOP in the agenda of the following NEC meeting.

5.3. Deliberation

The Chair presides over the deliberations on the new or amended SOP, while the members participate actively during the discussion on the justification and workflow.

5.4. Approval of SOP

5.4.1. The members act on the new or amended SOP by consensus in a regular meeting.

5.4.2. The Chair signs the approved version of the SOP which shall take effect immediately or on a different effectivity date with justification.

5.5. Coding and Integration of the revised or new SOP in the SOP Manual

5.5.1. The Secretariat assigns an NEC SOP number to the new or amended SOP upon its approval.

5.5.2. The Secretariat incorporates the new or amended SOP with the signature of the Chair in the SOP file, signifying the approval and date of the meeting when it was approved.

DOCUMENT HISTORY

NEC SOP version 4			
Nature of Revisions	1. Rephrased the description of procures to be in active voice. 2. Converted the workflow diagram into a workflow table to include the processing time.		
Prepared by	Dr. Marita T. Reyes and NEC Secretariat	**Pages**	6-7
Reviewed and approved by	NEC Committee	**Date**	27 September 2024
Signed for effectivity by	Ricardo M. Manalastas, Jr. NEC Chair	**Date**	01 October 2024

NEC SOP version 3			
Nature of Revisions	1. Addition of Vice -chair alongside the responsibilities of the Chair 2. Removal of the Roles and Responsibilities section 3. Revision of the titles of the procedures		
Prepared by	NEC Secretariat	**Pages**	6-7
Reviewed and approved by	NEC Committee	**Date**	11 February 2022
Signed for effectivity by	Filipinas F. Natividad NEC Chair	**Date**	18 March 2022

NEC SOP version 2			
Prepared by	NEC Secretariat	**Pages**	4-5
Reviewed and approved by	NEC Committee	**Date**	15 July 2014
Signed for effectivity by	Marita V.T. Reyes NEC Chair	**Date**	15 July 2014

NEC SOP version 1			
SOP Authors	Ms. Imelda B. Mutuc and Ms. Charisma G. Cruz	**Page**	2
Reviewed by	Dr. Marita V.T. Reyes	**Date**	7 August 2008
Approved by	NEC Committee	**Date**	21 September 2008

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	CONSTITUTING THE NATIONAL ETHICS COMMITTEE	SOP No.	NEC SOP 2A
		Version No.	4
		Version Date	27 September 2024
		Effectivity	01 October 2024

1. **POLICY**

1.1. The National Ethics Committee (NEC) shall be constituted in accordance with international and national guidelines. It shall have adequate representation of relevant disciplines (i.e., medical and non-medical, scientists and nonscientists), gender, and generational representation, with at least 9 regular members including the chair and vice-chair, and 3 alternate members.

1.2. The NEC members shall be selected through a nominations process based on their (1) disciplinal and demographic representation, (2) interest in research ethics and (3) willingness to commit time and effort for NEC activities. The nominations may come from the current committee members and other sources deemed pertinent by the Chair, PCHRD, and DOST. The following documents shall support the nomination:

a. Nomination letter that includes a justification and acceptance (NEC Form 19)
b. Updated Curriculum Vitae (NEC Form 20)

1.3. Alternate members shall include at least one (1) non-scientist and two (2) scientists who shall be called to substitute for members who cannot attend a meeting in order to comply with quorum requirements. As such, they shall function like regular members.

1.4. The Chair and Vice-Chair shall be nominated by the NEC members.

1.5. All NEC members (regular and alternate) and officers shall be appointed by the Executive Director of PCHRD for a specified term, with possible renewals.

2. **PURPOSE OF THE ACTIVITY**

Prompt constitution of the Committee prevents quorum problems and facilitates decision-making. The activity also ensures that the membership of the Committee adheres to international and national guidelines.

3. **SCOPE**

This SOP applies to the selection of members and designation of officials of the NEC. This SOP begins with the report of vacant positions and ends with the filing of appointment documents.

4. **WORKFLOW**

PROCEDURE	PERSON RESPONSIBLE	PROCESSING TIME
4.1. Identification of vacant positions and call for nominations	NEC Chair	1 week
4.2. Receipt of nominations	Secretariat	2 weeks
4.3. Collation of nominations	Secretariat	1 week
4.4. Evaluation and selection of nominees to be invited	NEC Chair	1 week
4.5. Invitation of new member	Secretariat	1 week
4.6. Receipt of conformé and agreements	Secretariat	2 weeks
4.7. Appointment of new NEC members	NEC Chair and Secretariat	2 weeks
4.8. Filing of appointment documents	Secretariat	2 days
	Total: 10 weeks and 2 days	

5. **DESCRIPTION OF PROCEDURES**

5.1. **Identification of vacant positions and call for nominations**

The Chair identifies the vacant positions, notes the disciplinal / demographic requirements, The Chair then requests for nominations from the NEC members, PCHRD personnel, and other consultants.

5.2. **Receipt of nominations**

The Secretariat receives the nominations from NEC members, PCHRD personnel and/or other consultants, who submits the accomplished NEC Form 19 (Nomination Form for NEC Membership) to the Secretariat, indicating a justification why the nominee is suitable as medical/non-medical, scientist/non-scientist member of the NEC. This shall include an acceptance of the nomination by the prospective member and a copy of their updated curriculum vitae (NEC Form 20: Curriculum Vitae). A deadline shall be set for the submission of nominations.

5.3. **Collation of nominations**

The Secretariat collates the nominations received, prepares a final list, and forwards it to the NEC Chair with the supporting documents.

5.4. **Evaluation and selection of nominees to be invited**

The NEC Chair evaluates the qualifications of the nominees, selects the most appropriate nominee, and directs the Secretariat to draft an invitation letter for the selected nominee.

5.5. **Invitation for NEC membership**

5.5.1. The Secretariat prepares the invitation letter using NEC Form 21 (Invitation Letter Template) to the selected nominee and the Chair finalizes and approves the letter for sending.

5.5.2. The Secretariat attaches NEC Form 01 (Confidentiality Agreement) and NEC Form 2 (Disclosure of Conflict-of-Interest Agreement) to the invitation letter and sends them to the nominee for signature. A deadline shall be set for the submission of the signed documents.

5.6. Receipt of conformé and agreements

5.6.1. The Secretariat receives the signed conformé and NEC Forms 01 and 02 from the invited nominees and informs the Chair that the documents have been received.

5.7. Appointment of new members

5.7.1. The Chair directs the Secretariat to prepare the appointment documents of the new member/s for submission to the appointing authority, which is the PCHRD Executive Director.

5.7.2. The Secretariat submits the complete set of appointment documents to the PCHRD Executive Director, for issuance of a Special Order regarding the appointment.

5.8. **Filing of appointment documents**

The Secretariat collects all documents relevant to the appointment of members and officers (i.e., signed appointment documents, PCHRD Special Order, and signed Confidentiality and Disclosure of Conflict-of-Interest Agreements).

ANNEXES

Form 01: Confidentiality Agreement
Form 02: Disclosure of Conflict-of-Interest Agreement
Form 19: Nomination Form for NEC Membership
Form 20: Curriculum Vitae
Form 21: Template Invitation Letter

DOCUMENT HISTORY

NEC SOP version 4	
Nature of Revisions	1. Updated the policy and process of constituting the NEC membership. 2. Rephrased the description of procures to be in active voice. 3. Converted the workflow diagram into a workflow table to include the processing time.

	4. Added NEC Forms 19, 20, and 21.		
Prepared by	Dr. Marita T. Reyes and NEC Secretariat	**Pages**	8-10
Reviewed and approved by	NEC Committee	**Date**	27 September 2024
Signed for effectivity by	Ricardo M. Manalastas, Jr. NEC Chair	**Date**	01 October 2024

NEC SOP version 3			
Nature of Revisions	1. Updated SOP Number 2. Removal of the Roles and Responsibilities section		
Prepared by	NEC Secretariat	**Pages**	8-10
Reviewed and approved by	NEC Committee	**Date**	11 February 2022
Signed for effectivity by	Filipinas F. Natividad NEC Chair	**Date**	18 March 2022

NEC SOP version 2			
Prepared by	NEC Secretariat	**Page**	6-8
Reviewed and approved by	NEC Committee	**Date**	15 July 2014
Signed for effectivity by	Marita V.T. Reyes NEC Chair	**Date**	15 July 2014

NEC SOP version 1			
SOP Authors	Ms. Imelda B. Muktuk and Ms. Charisma G. Cruz	**Page**	4
Reviewed by	Dr. Marita V.T. Reyes	**Date**	7 August 2008
Approved by	NEC Committee	**Date**	21 August 2008

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	APPOINTMENT OF INDEPENDENT CONSULTANTS	SOP No.	NEC SOP 2B
		Version No.	2
		Version Date	27 September 2024
		Effectivity	01 October 2024

1. **POLICY**
The National Ethics Committee (NEC) shall invite independent consultant/s, as needed, to help in the review of a study that requires expertise not represented in the current membership of the NEC.

2. **OBJECTIVE OF THE ACTIVITY**
This activity aims to ensure that the appointment of independent consultants conforms with institutional practice and complements the pool of expertise in the NEC.

3. **SCOPE**
This SOP specifically pertains to the selection and designation of independent consultants in the review of research protocols of the NEC. 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.

4. **WORKFLOW**

PROCEDURE	PERSON RESPONSIBLE	PROCESSING TIME
4.1. Identification of the study that requires an independent consultant	NEC Chair and Primary Reviewers	4 weeks
4.2. Identification of the independent consultant	NEC Chair / Members	
4.3. Invitation of the independent consultant	NEC Chair and Secretariat	1 week
4.4. Receipt of conformé and agreements	Secretariat	2 weeks
4.5. Appointment of new NEC members	Secretariat	2 weeks
4.6. Filing of appointment documents	Secretariat	2 days
4.7. Inclusion in the pool of independent consultants	Secretariat	
	Total: 9 weeks and 2 days	

5. DESCRIPTION OF PROCEDURES

5.1. **Identification of the study that requires an independent consultant**
The Primary Reviewers and/or the Chair identify a research proposal, the review of which requires expertise that is not within the areas of specialization of the current members of the NEC.

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 the appropriate expert. Other members of the NEC may also suggest appropriate experts. The Chair instructs the Secretariat to prepare the letter of invitation to the identified independent consultant.

5.3. **Invitation of the independent consultant**

5.3.1. The Secretariat prepares the invitation letter using NEC Form 21 (Invitation Letter Template) to the selected consultant and the Chair finalizes and approves the letter for sending.

5.3.2. The Secretariat attaches NEC Form 01 (Confidentiality Agreement) and NEC Form 2 (Disclosure of Conflict-of-Interest Agreement) to the invitation letter and sends them to the consultant for signature. A deadline shall be set for the submission of the signed documents.

5.4. Receipt of conformé and agreements

5.4.1. The Secretariat receives the signed conformé and NEC Forms 01 and 02 from the invited consultant/s and informs the Chair that the documents have been received.

5.5. Appointment of independent consultant/s

5.5.1. The Chair directs the Secretariat to prepare the appointment documents of the consultant/s for submission to the appointing authority, which is the PCHRD Executive Director.

5.5.2. The Secretariat submits the complete set of appointment documents to the PCHRD Executive Director, for issuance of a Special Order regarding the appointment.

5.6. **Filing of appointment documents**

The Secretariat collects all documents relevant to the appointment of members and officers (i.e., signed appointment documents, PCHRD Special Order, and signed Confidentiality and Conflict-of-Interest Disclosure Agreements).

5.7. **Inclusion in the pool of independent consultants**

The Secretariat enters the name of a new independent consultant in the appropriate database containing name, expertise, institution (if applicable), and date of appointment.

ANNEXES

FORM 01: CONFIDENTIALITY AGREEMENT
FORM 02: DISCLOSURE OF CONFLICT-OF-INTEREST AGREEMENT
FORM 20: CURRICULUM VITAE
FORM 21: TEMPLATE INVITATION LETTER

DOCUMENT HISTORY

NEC SOP version 2			
Nature of Revisions	1. Updated the policy and process of constituting the NEC membership. 2. Rephrased the description of procures to be in active voice. 3. Converted the workflow diagram into a workflow table to include the processing time. 4. Added NEC Forms 20, and 21.		
Prepared by	NEC Secretariat	**Pages**	11-12
Reviewed and approved by	NEC Committee	**Date**	27 September 2024
Signed for effectivity by	Ricardo M. Manalastas, Jr. NEC Chair	**Date**	01 October 2024

NEC SOP version 1			
Prepared by	NEC Secretariat	**Pages**	11-12
Reviewed and approved by	NEC Committee	**Date**	11 February 2022
Signed for effectivity by	Filipinas F. Natividad NEC Chair	**Date**	18 March 2022

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	DISQUALIFICATION OF A MEMBER	SOP No.	NEC SOP 03
		Version No.	3
		Version Date	27 September 2024
		Effectivity	01 October 2024

1. POLICY

Disqualification of a member shall be considered on the following grounds: 1. failure to attend three (3) consecutive regular meetings without a justifiable reason (e.g., illness, conflict with official duties); 2. deliberate nondisclosure of a Conflict of Interest; or 3. exhibit conduct unbecoming of a member of the NEC (e.g., accepting a bribe to approve/disapprove a proposal).

2. PURPOSE OF THE ACTIVITY

Establishment of the process for disqualification of a member is important to sustain an active and efficient Committee. The process ensures that the proceedings will be fair and transparent.

3. SCOPE

This SOP applies to incumbent members of the NEC. It begins with the notification of the concerned member and ends with the communication of the decision of the committee.

4. WORKFLOW

PROCEDURE	PERSON RESPONSIBLE	PROCESSING TIME
4.1. Notification of the concerned member	NEC Chair	1 day
4.2. Response of the Member	Concerned Member	1 week
4.3. Deliberation and Decision	NEC Members	1 day
4.4. Communication of the Committee's decision	NEC Chair / Secretariat	1 week
4.5. Filing of the Decision Letter in the Membership files	Secretariat	1 day
	Total: 2 weeks and 3 days	

5. DESCRIPTION OF PROCEDURES

5.1. Notification of the concerned member

The Chair notifies the member who incurs three (3) consecutive absences, who deliberately fails to disclose a Conflict of Interest, or who is found to exhibit conduct unbecoming of an NEC member, and their possible disqualification.

5.2. Response of the Member

The concerned member submits a written explanation to issues raised in the notification letter for deliberation in the next regular meeting. If the concerned member does not respond within two (2) weeks, it shall be taken as an admission of the cause for disqualification.

5.3. Deliberation and Decision

5.3.1. The Committee includes the issue in the agenda of the next regular meeting, wherein the concerned member shall be requested to make themself available in case there are issues to be clarified. The member shall be excused after the clarificatory interview.

5.3.2. The Committee deliberates on the matter in a judicious manner and ensures that the interest of the concerned member is balanced with that of the NEC.

5.4. Communication of the Committee's decision

The Secretariat drafts the decision letter for approval and signature of the Chair and sends this to the concerned member within one (1) week after the meeting.

5.5. Filing of the Decision Letter in the Membership files

The Secretariat files the decision letter in the Membership file folder of the concerned member.

DOCUMENT HISTORY

NEC SOP version 3			
Nature of Revisions	1. Rephrased the description of procures to be in active voice. 2. Converted the workflow diagram into a workflow table to include the processing time.		
Prepared by	NEC Secretariat	**Pages**	13-14
Reviewed and approved by	NEC Committee	**Date**	27 September 2024
Signed for effectivity by	Ricardo M. Manalastas, Jr. NEC Chair	**Date**	01 October 2024

NEC SOP version 2			
Nature of Revisions	1. Change of title 2. Removal of the Roles and Responsibilities section 3. Addition of procedures 5.2 and 5.5		
Prepared by	NEC Secretariat	**Pages**	13-14
Reviewed and approved by	NEC Committee	**Date**	11 February 2022
Signed for effectivity by	Filipinas F. Natividad NEC Chair	**Date**	18 March 2022

NEC SOP version 1			
Prepared by	NEC Secretariat	**Pages**	11-12
Reviewed and approved by	NEC Committee	**Date**	17 April 2015
Signed for effectivity by	Marita V.T. Reyes NEC Chair	**Date**	17 April 2015

NATIONAL ETHICS COMMITTEE	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	MANAGEMENT OF RESEARCH DOCUMENTS FOR INITIAL REVIEW	SOP No.	NEC SOP 4A
		Version No.	7
		Version Date	27 September 2024
		Effectivity	01 October 2024

1. POLICY

1.1. The NEC shall review protocols directed to it by government agencies including the Philippine Health Research Ethics Board (PHREB), Philippine Council for Health Research and Development (PCHRD), Department of Health (DOH), and UP Manila Research Ethics Board (UPMREB). It shall not accept applications for review from undergraduate and graduate students. In the case of graduate students, the NEC can make an exception for research that is national in scope in terms of study participants.

1.2. All submissions shall be submitted through the Philippine Health Research Ethics Portal (PHREP).

1.3. All submitted protocols shall be assigned its NEC code and logged accordingly.

1.4. The proponent shall pay a processing fee and review fee (if applicable) to the PCHRD Cashier through official means.

1.5. The following documents shall be required for submission:

1.5.1. Accomplished NEC Form 3: Application Form for Ethics Review
1.5.2. Study Protocol that includes section on Ethical Considerations and Dissemination Plan
1.5.3. Informed Consent and Assent Forms (whichever is applicable)
1.5.4. Study Forms (Survey Questionnaire, Interview/FGD Guide Questions, Case Report Form)
1.5.5. Certificate of Approval from a Technical Review Panel that indicates scientific soundness based on reasonableness of the research question, SMART objectives, appropriateness of the study design, exclusion and inclusion criteria, collection data and statistical analysis. Include the summary of technical review recommendations from the Technical Review Panel.
1.5.6. Curriculum vitae of proponent and research staff
1.5.7. Endorsement from a government agency
1.5.8. Copy of the official receipt of the processing fee paid to the PCHRD Cashier

Additional Requirements for researchers from foreign institutions:

1.5.9. Ethical Review Clearance from the Institution of the Foreign Researcher
1.5.10. Justification for choosing the Philippines as a research site
1.5.11. Identification of a qualified and appropriate local researcher or adviser who can be responsible for the project based on Philippine regulations

2. PURPOSE OF THE ACTIVITY

Management of research documents for initial review ensures that all documents are properly identified, codified, logged, and acted upon appropriately.

3. SCOPE

This SOP refers to new protocols submitted for review. It starts with the receipt of research documents until the type of review is determined.

4. WORKFLOW

PROCEDURE	PERSON RESPONSIBLE	PROCESSING TIME
4.1. Receipt of Protocol documents for Initial Review	Secretariat	1 day
4.2. Screening for completeness of submissions	Secretariat	
4.3. Assignment of NEC Code	Secretariat	
4.4. Determination of action or type of review	Chair	2 weeks
4.5. Preparation of individual protocol folders (SOP 12)	Secretariat	1 day

	Total: 2 weeks and 2 days

5. **DESCRIPTION OF PROCEDURES**

5.1. **Receipt of Protocol documents for Initial Review**

The NEC secretariat receives the protocol documents through PHREP and the PHREP manager shall automatically assign an auto-generated code specific to the submission, which is the reference code until the NEC code is assigned.

5.2. **Screening for completeness of submissions**

5.2.1. For the submission process to proceed, the following should be submitted:

5.2.1.1. Accomplished NEC Form 3: Application Form for Ethics Review
5.2.1.2. Study Protocol that includes section on Ethical Considerations and Dissemination Plan
5.2.1.3. Informed Consent and Assent Forms (whichever is applicable)
5.2.1.4. Study Forms (Survey Questionnaire, Interview/FGD Guide Questions, Case Report Form)
5.2.1.5. Certificate of Approval from a Technical Review Panel that indicates scientific soundness based on reasonableness of the research question, SMART objectives, appropriateness of the study design, exclusion and inclusion criteria, collection data and statistical analysis. Include the summary of technical review recommendations from the Technical Review Panel
5.2.1.6. Curriculum vitae of proponent and research staff
5.2.1.7. Endorsement from a government agency
5.2.1.8. Copy of the official receipt of the processing fee paid to the PCHRD Cashier

Additional Requirements for researchers from foreign institutions:

5.2.1.9. Ethical Review Clearance from the Institution of the Foreign Researcher
5.2.1.10. Justification for choosing the Philippines as a research site
5.2.1.11. Identification of a qualified and appropriate local researcher or adviser who can be responsible for the project based on Philippine regulations.

5.2.2. If protocol documents are incomplete, the Secretariat notifies the researcher of the documents that are lacking. Submission process shall proceed once the Secretariat receives the indicated documents.

5.2.3. If protocol documents are complete and satisfactory, the Secretariat files and log the submission into the database.

5.3. **Assignment of NEC Code**

The Secretariat assigns NEC code to the submitted protocol indicating:

- Year of submission
- Series number for the year
- Proponent's Surname
- Short Title/Topic

as follows:

YEAR	-	SERIES NO.	-	PROPONENT SURNAME	-	SHORT TITLE / TOPIC

For example, proponent Juan dela Cruz submitted a protocol on HIV in 2014 and was the 5th proposal received in that year, the protocol shall be coded as:

NEC Code: 2014-005-dela Cruz-HIV

5.4. **Determination of action or type of review**

The NEC Chair decides on the category of the protocol documents and instructs the Secretariat to proceed accordingly.

If the protocol is categorized under expedited or full committee review, the Secretariat asks the researcher to pay the review fee to the Philippine Council for Health Research and Development (PCHRD) Cashier, and present a copy of the receipt to the secretariat for verification.

5.4.1. **Full/Expedited Review (SOP 5 and 6 respectively)**

The Secretariat prepares for either full or expedited review by referring to SOP 05 or SOP 06.

5.4.2. **Exemption from Review**

The Committee issues a Certificate of Exemption from Review (NEC Form 6C), signed by the Chair within two (2) weeks upon receipt of complete documentary requirements, when the research protocol meets the following criteria:

5.4.2.1. does not involve human participants nor identifiable human tissue, biological samples, and data (e.g., meta-analysis protocols); or

5.4.2.2. does not involve more than minimal risks or harms such as:

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

5.4.2.2.2. 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:

5.4.2.2.2.1.1. There shall 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

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

5.4.2.3. involves the use of publicly available data or information.

5.5. Preparation of individual protocol folders (NEC SOP 12: Management of NEC files)

ANNEXES

Form 03: Application Form for Ethics Review of Research Protocols
Form 6C: Checklist for Exemption of Review
Form 15C: Certificate of Exemption Template

DOCUMENT HISTORY

NEC SOP version 4			
Nature of Revisions	1. Updated the policy and requirements for submission. 2. Rephrased the description of procures to be in active voice. 3. Converted the workflow diagram into a workflow table to include the processing time.		
Prepared by	Dr. Marita T. Reyes and NEC Secretariat	**Pages**	15-18
Reviewed and approved by	NEC Committee	**Date**	27 September 2024
Signed for effectivity by	Ricardo M. Manalastas, Jr. NEC Chair	**Date**	01 October 2024

NEC SOP version 6			
Nature of Revisions	1. Inserted additional requirements for researchers from foreign institutions		
Prepared by	NEC Secretariat	**Pages**	15
Reviewed and approved by	NEC Committee	**Date**	07 July 2023
Signed for effectivity by	Ricardo M. Manalastas, Jr. NEC Chair	**Date**	07 July 2023

NEC SOP version 5	
Nature of Revisions	1. Updated the SOP Number. 2. Inclusion of the required documents in the Policy statement emphasizing the submission of a certificate of technical review

	detailing the items considered and an ethical review from the foreign institution, in case of foreign researchers 3. Revised the method of submission 4. Revised the criteria of exemption from review to align with the criteria in the National Ethical Guidelines 5. Developed a Checklist for Exemption from Review (Form 3A) 6. Removal of the Roles and Responsibilities section		
Prepared by	NEC Secretariat	**Pages**	15-18
Reviewed and approved by	NEC Committee	**Date**	11 February 2022
Signed for effectivity by	Filipinas F. Natividad NEC Chair	**Date**	18 March 2022

NEC SOP version 4			
Nature of Revisions	1. Inclusion of "The NEC will not proceed with the ethical review for unresolved technical issues and will inform the referring agency." 2. All submissions will be through PHREP 3. Revised the criteria for exemption of ethical review		
Prepared by	NEC Secretariat	**Pages**	11-14
Reviewed and approved by	NEC Committee	**Date**	06 August 2019
Signed for effectivity by	Filipinas F. Natividad NEC Chair	**Date**	06 August 2019

NEC SOP version 3			
Nature of Revisions	1. Processing and review fee were included 2. Determination of the category of review 3. Inclusion of the criteria for exemption from review 4. Inclusion of the corresponding Form 15c: Certificate of Exemption from Review		
Prepared by	NEC Secretariat	**Pages**	11-14
Reviewed and approved by	NEC Committee	**Date**	19 October 2017
Signed for effectivity by	Filipinas F. Natividad NEC Chair	**Date**	19 October 2017

NEC SOP version 2			
Prepared by	NEC Secretariat	**Pages**	11-13
Reviewed and approved by	NEC Committee	**Date**	15 July 2014
Signed for effectivity by	Marita V.T. Reyes NEC Chair	**Date**	15 July 2014

NEC SOP version 1			
Prepared by	Ms. Imelda B. Mutuc and Ms. Charisma G. Cruz	**Page**	2
Reviewed by	Dr. Marita V.T. Reyes	**Date**	7 August 2008
Approved by	NEC Committee	**Date**	21 September 2008

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	REVIEW OF RESUBMISSIONS	SOP No.	NEC SOP 4B
		Version No.	2
		Version Date	27 September 2024
		Effectivity	01 October 2024

1. POLICY

The NEC shall require the resubmission of a protocol undergoing review, when the protocol requires either minor or major modification/s, not later than four (4) weeks after the Proponent receives the Decision Letter. Minor modifications shall undergo expedited review while major modifications shall undergo full review.

Resubmission documents shall consist of the following:

- Cover Letter containing a matrix of the NEC's recommendations, the proponents' actions, and the document name and page containing the revision
- Revised protocol documents (e.g., Main Proposal, Informed Consent Forms, etc.)
- Additional documents required by the NEC, if any

2. OBJECTIVE OF THE ACTIVITY

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

3. SCOPE

This SOP pertains to the resubmission of revised or modified protocols that have been previously reviewed by the NEC. The procedure begins with the receipt of the revised protocol documents and ends with the filing of the documents in the protocol file and the entry of the submission in the protocol database.

4. WORKFLOW

PROCEDURE	PERSON RESPONSIBLE	PROCESSING TIME
4.1. Receipt and Tagging in PHREP	Secretariat	1 day
4.2. Notification of the Primary Reviewers	Secretariat	
4.3. Review of the Resubmission	NEC Members	2 weeks
4.4. Communication of Decision	Chair / Secretariat	1 day
4.5. Filing of Documents in the Study Folder and Updating of the Database	Secretariat	
	Total: 2 weeks and 2 days	

5. DESCRIPTION OF PROCEDURES

5.1. **Receipt and Tagging in PHREP**

The Secretariat receives the study documents, checks the documents for compliance and tags the submission as complete for logging in the PHREP.

5.2. **Notification of the Primary Reviewers**

The Secretariat logs the previous study recommendations from prior Decision Letters (Form 15a) pertaining to the original protocol and informs the primary reviewers about the resubmission and the nature of the modifications required.

5.3. **Review of the Resubmission**

The assigned reviewers conduct the review of the resubmitted protocol by referring to the Cover Letter and the protocol documents, and by noting the previous recommendations made by the NEC. The reviewers then evaluate whether these were satisfactorily addressed in the resubmitted protocol.

5.4. **Communication of Decision**
The Secretariat collates the evaluations of the primary reviewers and drafts the decision letter. The Chair reviews, approves, and signs the final decision letter to be sent to the proponent (SOP 11A: Management of Communications).

5.5. **Filing of Documents in the Study Folder and Updating of the Database**
The Secretariat gathers all the pertinent documents related to the resubmission (revised protocol, assessment forms, excerpts of minutes, approval letter,) and updates the log for research submissions (Form 09: Log of Research Submissions).

ANNEXES
Form 09: Log of Research Submissions
Form 15A: Decision Letter Template

DOCUMENT HISTORY

NEC SOP version 2			
Nature of Revisions	1. Updated the policy 2. Rephrased the description of procures to be in active voice. 3. Converted the workflow diagram into a workflow table to include the processing time.		
Prepared by	NEC Secretariat	**Pages**	19-20
Reviewed and approved by	NEC Committee	**Date**	27 September 2024
Signed for effectivity by	Ricardo M. Manalastas, Jr. NEC Chair	**Date**	01 October 2024

NEC SOP version 1			
Prepared by	NEC Secretariat	**Pages**	19-20
Reviewed and approved by	NEC Committee	**Date**	11 February 2022
Signed for effectivity by	Filipinas F. Natividad NEC Chair	**Date**	18 March 2022

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	FULL REVIEW	SOP No.	NEC SOP 05
		Version No.	8
		Version Date	27 September 2024
		Effectivity	01 October 2024

1. POLICY

1.1. Proposals that: 1. involve vulnerable participants; 2. entail more than minimal risk; and 3. use stem cell technology and other emerging technologies shall undergo the full review process. Proposals shall be evaluated for scientific and social value, scientific validity and ethical soundness using international and national ethical guidelines. All final reports shall undergo Full Review regardless of the above criteria.

1.2. The process of Full Review makes use of the primary reviewer system where one member with scientific/medical interests and one with non-scientific/non-medical interest shall be assigned as primary reviewers who will make a comprehensive ethical review report for presentation during a committee meeting. The NEC may seek the help of independent consultants in the review. However, only the members of the Committee participate in the final decision.

1.3. The reviewers of the proposals for full review must be present during the meeting; however, in the absence of the primary reviewer/s, it shall be the prerogative of the Chair to include the protocol in the agenda and assume the role of the primary reviewer. Decisions shall be made by consensus.

1.4. The results of the initial review process shall be communicated within 7 weeks from categorization for review. Only proposals submitted with complete documentation at least 2 weeks prior to the scheduled regular meeting shall be included in the ongoing review cycle.

1.5. The proponent may appeal any decision of the NEC by submitting a letter containing the justification for the appeal addressed to the Chair. All appeals shall be discussed in a regular committee meeting.

2. PURPOSE OF THE ACTIVITY

Full review of pertinent research documents ensures that all members of the Committee are able to participate in the assessment of, and deliberation on, a study that is of more than minimal risk and/or that involves vulnerable participants.

3. SCOPE

This SOP applies to the ethical evaluation of all research proposals that require a full review. It starts with the assignment of the primary reviewers and ends with the filing of the decision letter and excerpts of minutes.

4. WORKFLOW

PROCEDURE	PERSON RESPONSIBLE	PROCESSING TIME
4.1. Assignment of Primary Reviewers (PRs)	NEC Chair	1 day
4.2. Forwarding of Documents for Review and Evaluation Forms to PRs	Secretariat	
4.3. Forwarding of Documents to Committee Members	Secretariat	
4.4. Inclusion of the Protocol in the agenda of the next NEC Meeting	NEC Chair / Members	2 to 6 weeks and 3 days
4.5. Conduct of Meeting (SOP 08)	Secretariat	1 day
4.6. Presentation of Reports	Primary Reviewers	
4.7. Discussion	NEC Members	
4.8. Deliberation and Formulation of Decision	NEC Members	

4.9. Communicating the NEC Decision and Post-approval Requirements	Secretariat	1 day
4.10. Filing of Decision Letter and Excerpts of Minutes	Secretariat	1 day
	Total: 3-7 weeks	

5. DESCRIPTION OF PROCEDURES

5.1. **Assignment of Primary Reviewers (PRs)**

5.1.1. The Chair assigns the Primary Reviewers, selecting them based on their expertise in the light of the type of research to be reviewed.

5.1.2. Independent consultants may be identified to act as resource in the review.

5.2. **Forwarding of Documents for Review and Evaluation Forms to PRs**

5.2.1. The Secretariat informs the PRs about their selection. The PRs notify the Secretariat if they are able to do review. In case a PR is not available, the Chair shall appoint another PR.

5.2.2. The Secretariat forwards the proposal and supplementary documents to the PRs including the review forms (NEC Form 04 and 05 or NEC Form 6A and 6B) to be used in the review.

5.2.3. The review includes:

5.2.3.1. technical/scientific assessment, especially on the methodology, appropriateness of study site, inclusion/exclusion criteria, relevant policies, study tools, questionnaires, etc.

5.2.3.2. ethical assessment especially on vulnerability of participants, risks involved, balancing of risks and benefits, protection of privacy, management of conflict of interest, protection of patients' rights, etc.

5.2.3.3. assessment of the informed consent/assent form and process including appropriateness of translation to local language/dialect

5.2.3.4. appropriateness of qualifications of researchers and co-researchers

5.3. **Forwarding of Documents to Committee Members**

The Secretariat forwards the submission documents to the committee members in preparation for discussion during the meeting. The Secretariat shall exert best effort to do this at least one (1) week before the meeting.

5.4. **Inclusion of the Protocol in the agenda of the next NEC Meeting**

5.4.1. In consultation with the Chair, the Secretariat includes the research proposal in the next meeting agenda (SOP 07, Section 6.2).

5.4.2. The Secretariat notifies the Primary Reviewers of the date of the meeting when the proposal will be discussed.

5.5. **Conduct of Meeting (SOP 08)**

The meeting proceeds following the approved meeting agenda.

5.6. **Presentation of Reports**

On the appropriate agenda item, the PRs present their review report that includes a summary of the protocol and their comments and recommendations.

5.7. **Discussion**

5.7.1. The Chair acknowledges the report and invites the other committee members to contribute their own findings to generate a comprehensive review for decision making.

5.7.2. The Chair moderates the discussion in an orderly manner following the sequence of topics in the evaluation form, ensuring that important ethical concerns are addressed.

5.8. **Deliberation and Formulation of Decision**

5.8.1. The Chair summarizes the issues and their resolution in preparation for decision making.

5.8.2. The Committee decides by consensus. The decision of the committee shall be any of the following for specific submissions.

5.8.2.1. **Initial submissions**

a. **Approved -** The proposal is approved and shall be granted an ethical clearance as written.

b. **Disapproved -**The proposal is not granted an ethical clearance because of major ethical and scientific problems. The reasons for the disapproval shall be clearly identified and included in the NEC evaluation letter to the researcher.
c. **Minor Revisions Required -** The proposal is not granted an ethical clearance until the minor revisions to the proposal are received and approved. These minor revisions shall include a change in the title, improvements in the language of the Informed Consent Form or other alterations that do not alter the favorable benefit-risk assessment. Subsequent submissions shall undergo expedited review through SOP 4B and SOP 06.
d. **Major Revisions Required -** The proposal is not granted an ethical clearance until major revisions to the proposal are received and approved. Major revisions shall include change in the research objectives, change in the research design, or any change that will alter the favorable benefit-risk assessment. Subsequent submissions shall undergo full review through SOP 4B and SOP 05.

5.8.2.2. **Progress reports**

a. **Accepted** - The report is accepted and found satisfactory e.g., report submitted on time, information on recruitment status, adverse events, protocol deviation, amendments, other challenges and issues, courses of action.
b. **Need for additional Information -** The report needs additional information regarding issues identified by the Committee.
c. **Action required -** The Committee decides that the researcher needs to act on certain issues identified by the Committee in order to protect participants.

5.8.2.3. **Final reports** - All final reports undergo full review.

a. **Accepted -** The report is accepted and found satisfactory e.g., report submitted on time, title and objectives of the study consistent with the original proposal unless with prior approved amendment/s, reported adverse events resolved appropriately with summary of results.
b. **Need for additional Information -** The report needs additional information regarding issues identified by the Committee.
c. **Action required -** The Committee decides that the researcher needs to act on certain issues identified by the Committee in order to protect participants.
d. **Not accepted - T**he Committee finds certain aspects of the report that have implications on veracity and consistency. The Committee requires resubmission of the corrected report.

5.8.2.4. **Amendment**

a. **Approved** - The Amendment is approved and can be implemented as written.
b. **Need for additional information** - The Committee finds that the amendment requires justification.
c. **Revision of the Consent form and/or reconsent of participants** - The Committee finds that the amendment is major so that the consent form has to be revised accordingly. Reconsent may also be required.

5.8.2.5. **Early Termination Report**

a. **Acknowledgment** - The Committee finds that the early termination of the study by either the sponsor/funder or the researcher is justified and that the participants' welfare has been looked into properly.
b. **Need for additional information** - The Committee finds the justification for early termination unclear and needs further explanation.
c. **Action needed** - The report does not describe an acceptable management of the welfare of the participants.

5.8.2.6. **Reportable Negative Events (RNEs)**

a. **Acknowledgment** - The RNEs are deemed not related to the study or have been managed satisfactorily.
b. **Need for additional information** - The details of the report are inadequate or there is a need for justification for a late report.

c. **Action needed** - The report does not describe an acceptable management of the welfare of the participants.

5.8.2.7. **Protocol deviations/violations** - The source/cause of the deviation (whether it is from the participant, researcher, or others) is determined from the protocol deviation report in order to recommend appropriate corrective action.

a. **Notation -** Protocol deviations/violations are minor and there is no negative impact on the risk-benefit ratio and integrity of data.
b. **Need for additional information** - The details of the deviation/violation are inadequate or there is a need for an explanation of why and how the deviation/violation happened.
c. **Need for Corrective Action** - The Committee requires the Researcher to implement corrective action so that the deviation/violation will not be repeated, well-being of the participants is promoted, and integrity of data is protected.

5.8.2.8. Application for Continuing Review

a. **Approval of Extension of Ethical Clearance -** Justification is satisfactory and accepted.
b. **Need for Additional Information -** Non-submission of required post-approval documents must be explained and justified.
c. **Disapproval of Extension of Ethical Clearance -** Justification for extension is not acceptable.

5.9. **Communicating the NEC Decision and Post-approval Requirements**

The decision of the NEC shall be communicated to the Researcher following SOP 11A: Management of Communications.

The requirement for and frequency of submission of reports (i.e., progress and final reports, RNEs, protocol deviations/violations, and early termination report) are stated in the approval letter that is sent to the proponent after the initial review of the study. The frequency of submissions for continuing review is determined based on the level of risk and duration of the study. The Secretariat prepares a draft and the Chair approves and signs the letter to be sent to the Researcher.

5.10. **Filing of Decision Letter and Excerpts of Minutes**

The Secretariat updates the protocol files and database accordingly (SOP 12), using the NEC Form 09: Log of Research Submissions.

ANNEXES

Form 04: Reviewer's Worksheet
Form 05: Review Checklist for Informed Consent Form and Process
Form 6A: Reviewer's Worksheet for Stem Cell Research
Form 6B: Informed Consent Checklist for Stem Cell Research
Form 09: Log of Research Submissions
Form 10: Log of Post-Approval Submissions
Form 11: Application for Extension of Ethical Clearance (Continuing Review)
Form 12A: Application Form for Ethics Review of Progress Reports
Form 12B: Application Form for Ethics Review of Protocol Deviation / Violation
Form 12C: Application Form for Ethics Review of Reportable Negative Event Report
Form 12D: Early Termination Report
Form 13: Application Form for Ethics Review of Amendments
Form 14: Application Form for Ethics Review of Final Report

DOCUMENT HISTORY

NEC SOP version 4	
Nature of Revisions	1. Updated the policy and process 2. Rephrased the description of procures to be in active voice. 3. Converted the workflow diagram into a workflow table to include the processing time.

Prepared by	Dr. Marita T. Reyes and NEC Secretariat	**Pages**	21-26
Reviewed and approved by	NEC Committee	**Date**	27 September 2024
Signed for effectivity by	Ricardo M. Manalastas, Jr. NEC Chair	**Date**	01 October 2024

NEC SOP version 7			
Nature of Revisions	1. Revised the initial review period.		
Prepared by	NEC Secretariat	**Pages**	21
Reviewed and approved by	NEC Committee	**Date**	07 July 2023
Signed for effectivity by	Ricardo M. Manalastas, Jr. NEC Chair	**Date**	07 July 2023

NEC SOP version 6			
Nature of Revisions	1. Replaced of SAEs/SUSARs into Reportable Negative Effects; removed clinical trial-related terms 2. Removal of Roles and Responsibilities section 3. Inclusion of Final Reports in Full Review 4. Inclusion of new Forms 5. Removal of Alert for Continuing Review and replacement with Application for Continuing Review		
Prepared by	NEC Secretariat	**Pages**	21-26
Reviewed and approved by	NEC Committee	**Date**	11 February 2022
Signed for effectivity by	Filipinas F. Natividad NEC Chair	**Date**	18 March 2022

NEC SOP version 5			
Nature of Revision	1. In the absence of the primary reviewer/s it will be the prerogative of the Chair to include the protocol in the agenda and assume the role of the primary reviewer.		
Prepared by	NEC Secretariat	**Pages**	15-21
Reviewed and approved by	NEC Committee	**Date**	08 November 2018
Signed for effectivity by	Filipinas F. Natividad NEC Chair	**Date**	08 November 2018

NEC SOP version 4			
Nature of Revision	1.Change of title from Full Review of Research Proposals to Full Review		
Prepared by	NEC Secretariat	**Pages**	15-21
Reviewed and approved by	NEC Committee	**Date**	19 October 2017
Signed for effectivity by	Filipinas F. Natividad NEC Chair	**Date**	19 October 2017

NEC SOP version 3			
Nature of Revision	1. Addition of mechanism for appeals in the policy statement 2. Criteria for decision points on Progress and Final reports 3. Management of Protocol deviations/violations		
Prepared by	NEC Secretariat	**Pages**	14-20
Reviewed and approved by	NEC Committee	**Date**	21 February 2017
Signed for effectivity by	Filipinas F. Natividad	**Date**	21 February 2017

	NEC Chair		

NEC SOP version 2			
Prepared by	NEC Secretariat	**Pages**	14-20
Reviewed and approved by	NEC Committee	**Date**	15 July 2014
Signed for effectivity by	Marita V.T. Reyes NEC Chair	**Date**	15 July 2014

NEC SOP version 1			
SOP Authors	Ms. Imelda B. Mutuc and Ms. Charisma G. Cruz	**Page**	2
Reviewed by	Dr. Marita V.T. Reyes	**Date**	7 August 2008
Approved by	NEC Committee	**Date**	21 September 2008

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	EXPEDITED REVIEW	SOP No.	NEC SOP 06
		Version No.	8
		Version Date	27 September 2024
		Effectivity	01 October 2024

1. POLICY

1.1. Protocol documents/reports that do not involve vulnerable populations or have no vulnerability issues and/or do not entail more than minimal risk shall undergo Expedited Review. Protocol documents shall be evaluated for scientific and social value, scientific validity and ethical soundness using international and national ethical guidelines.

1.2. Expedited Review is also applicable to minor revisions or amendments to an approved protocol e.g., decrease in the amount of blood to be extracted, change in site, change of contact person, addition of Principal Investigator/s or sub-investigator/s, change in contact numbers and similar actions that have minimal impact on patient safety and risks.

1.3. The review shall be conducted by at least two reviewers, one scientific and one non-scientific. The summary and status of Expedited Reviews shall be presented during the next NEC Meeting. The result of the expedited review may be revised during a meeting if feasible and necessary.

1.4. The results of the initial review process shall be communicated within 6 weeks from categorization for review.

1.5. The proponent may appeal any decision of the NEC by submitting a letter containing the justification for the appeal addressed to the Chair. All appeals shall be discussed in a regular committee meeting.

2. PURPOSE OF THE ACTIVITY

Expedited Review aims to make the work of the Committee efficient by assigning the comprehensive review of pertinent research that entail minimal risk and which do not involve vulnerable participants to a few experts and thus relieving the agenda of the Committee meeting.

3. SCOPE

This SOP applies to the ethical evaluation of proposals (e.g., new protocols, resubmissions, amendments) which are deemed subject to Expedited Review. It starts with the assignment of reviewers and ends with the inclusion of the review report in the agenda of the next regular meeting.

4. WORKFLOW

PROCEDURE	PERSON RESPONSIBLE	PROCESSING TIME
4.1. Assignment of Primary Reviewers (PRs)	NEC Chair	1 day
4.2. Forwarding of the Protocol/Report to the Primary Reviewers	Secretariat	
4.3. Review of Protocol and Supplementary Document	NEC Members	2 to 5 weeks and 2 days
4.4. Submission of Evaluation Results to Secretariat	NEC Members	
4.5. Forwarding of Summary of Evaluations to Chair	Secretariat	3 days
4.6. Communicating the NEC Decision and Post-approval Requirements		
4.7. Filing of Decision Letter and Excerpts of Minutes		1 day
4.8. Inclusion of the Expedited Review Report in the Next Meeting Agenda		
		Total: 3 to 6 weeks

5. DESCRIPTION OF PROCEDURES

5.1. **Assignment of Primary Reviewers (PRs)**

5.1.1. The Chair assigns the Reviewers, selecting them based on their expertise in the light of the type of research to be reviewed.

5.1.2. Independent consultants may be identified to act as resource in the review.

5.2. **Forwarding of the Protocol/Report to the Primary Reviewers**

5.2.1. The Secretariat notifies the assigned reviewers, who notifies the Secretariat if they are unable to do the review so that other members can be assigned if necessary.

5.2.2. The Secretariat sends the reviewers copies of the research submissions together with the review forms (Forms 06 and 05 or 6A and 6B).

5.3. **Review of Protocol and Supplementary Documents**

5.3.1. The reviewers accomplish the review forms and shall write their comments and recommendations.

5.3.2. The review includes:

5.3.2.1. technical/scientific assessment, especially on the methodology, appropriateness of study site, inclusion/exclusion criteria, relevant policies, study tools, questionnaires, etc.

5.3.2.2. ethical assessment especially on vulnerability of participants, risks involved, balancing of risks and benefits, protection of privacy, management of conflict of interest, protection of patients' rights, etc.

5.3.2.3. assessment of the informed consent/assent form and process including appropriateness of translation to local language/dialect

5.3.2.4. appropriateness of qualifications of researchers and co-researchers

5.4. **Submission of Evaluation Results to Secretariat**

5.4.1. The reviewers submit their evaluation results to the Secretariat with their recommendations. The recommendation of the NEC reviewer shall be any of the following for specific submissions as follows:

5.4.1.1. **Initial submission**

a. **Approved** - The protocol is approved and shall be granted an ethical clearance as written.
b. **Disapproved** - The proposal is not granted an ethical clearance because of major ethical and scientific problems. The reasons for the disapproval shall be clearly identified and included in the NEC evaluation letter to researcher.
c. **Minor Revisions Required** - The proposal is not granted an ethical clearance until the minor revisions to the protocol are received and approved. These minor revisions may include a change in the title, improvements in the language of the Informed Consent Form or other alterations that do not alter the favorable benefit-risk assessment. Subsequent submissions shall undergo Expedited Review through SOP 4B and SOP 06)
d. **Major Revisions Required** - The proposal is not granted an ethical clearance until major revisions to the protocol are received and approved. Major revisions may include change in the research objectives, change in the research design, or any change that will alter the favorable benefit-risk assessment. Subsequent submissions shall undergo Full Review through SOP 4B and SOP 05.

5.4.1.2. **Progress reports**

a. **Accepted -** The report is accepted and found satisfactory.
b. **Need for additional Information -** The report needs additional information regarding issues identified by the Committee.
c. **Action required -** The researcher needs to act on certain issues identified by the Committee in order to protect participants.

5.4.1.3. **Amendment**

a. **Approved -** The Amendment is approved and can be implemented as written.
b. **Need for additional information -** The Committee finds that the amendment requires justification.

c. **Revision of the Consent Form and/or reconsent of participants -** The Committee finds that the amendment is major so that the Consent Form has to be revised accordingly. Reconsent may also be required.

5.4.1.4. **Early Termination Report**

a. **Acknowledgment -** The Committee finds that the early termination of the study by either the sponsor/funder or the researcher is justified and that the participants' welfare has been considered properly.
b. **Need for additional information -** The Committee finds the justification for early termination unclear and needs further explanation.
c. **Action needed -** The report does not describe an acceptable management of the welfare of the participants

5.4.1.5. **Reportable Negative Event (RNE)**

a. **Acknowledgment of the Report -** The RNE/s are deemed not related to the study or have been managed satisfactorily. No further action is required.
b. **Need for additional information -** The details of the report are inadequate or there is a need for justification for a late report.
c. **Action needed -** The report does not describe an acceptable management of the welfare of the participants

5.4.1.6. **Protocol deviations/violations** - The source/cause of the deviation (whether it is the responsibility of the participant, researcher, or others) is determined from the protocol deviation report in order to recommend appropriate corrective action.

a. **Notation -** Protocol deviations/violations are minor and there is no negative impact on the risk-benefit ratio and integrity of data. No further action is required.
b. **Need for additional information -** The details of the deviation/violation are inadequate or there is a need for an explanation of why and how the deviation/violation happened.
c. **Need for Corrective Action -** The Committee requires the researcher to implement corrective action so that the deviation/violation will not be repeated.

5.4.1.7. **Application for Continuing Review**

a. **Approval of Extension of Ethical Clearance -** Justification is satisfactory and accepted.
b. **Need for additional Information** - Non-submission of required post-approval documents has to be explained and justified.
c. Disapproval of Extension of Ethical Clearance - Justification for extension is not acceptable

5.5. **Forwarding of Summary of Evaluations to Chair**

5.5.1. The Secretariat collates the review results and forwards the summary to the Chair.
5.5.2. The Chair evaluates the review reports for compatibility and consistency. He/she makes the final decision taking into consideration the reviewers' recommendations and his/her own findings and assessment.

5.6. **Communicating the NEC Decision and Post-approval Requirements**

The decision of the NEC shall be communicated to the researcher following SOP 11A: Management of Communications.

The requirement for and frequency of submission of reports (i.e., progress and final reports, RNEs, protocol deviations/violations, and early termination report) is stated in the approval letter that is sent to the proponent after the initial review of the study. The frequency of submissions for continuing review is determined based on the level of risk and duration of the study. The Secretariat prepares a draft and the Chair approves and sign the letter to be sent to the Researcher.

5.7. **Filing of Decision Letter and Excerpts of Minutes**

The Secretariat updates the protocol files and database accordingly (SOP 12). The research shall be logged using the NEC Form 10: Log of Research Submissions.

5.8. **Inclusion of the Expedited Review Report in the Next Meeting Agenda**

5.8.1. The Secretariat prepares the report on Expedited Reviews of research proposals for initial review using the Form 09: Log of Research Submissions, and includes the report in the next meeting agenda (SOP 07).

5.8.2. The Chair and Secretariat present the report during the next NEC meeting.

ANNEXES

Form 04: Reviewer's Worksheet
Form 05: Review Checklist for Informed Consent Form and Process
Form 6A: Reviewer's Worksheet for Stem Cell Research
Form 6B: Informed Consent Checklist for Stem Cell Research
Form 09: Log of Research Submissions

DOCUMENT HISTORY

NEC SOP version 8			
Nature of Revisions	1. Rephrased the description of procures to be in active voice. 2. Converted the workflow diagram into a workflow table to include the processing time.		
Prepared by	Dr. Marita T. Reyes and NEC Secretariat	**Pages**	27-31
Reviewed and approved by	NEC Committee	**Date**	27 September 2024
Signed for effectivity by	Ricardo M. Manalastas, Jr. NEC Chair	**Date**	01 October 2024

NEC SOP version 7			
Nature of Revisions	1. Revised the initial review period.		
Prepared by	NEC Secretariat	**Pages**	27
Reviewed and approved by	NEC Committee	**Date**	07 July 2023
Signed for effectivity by	Ricardo M. Manalastas, Jr. NEC Chair	**Date**	07 July 2023

NEC SOP version 6			
Nature of Revisions	1. Replaced of SAEs/SUSARs into Reportable Negative Effects; removed clinical trial-related terms 2. Removal of Roles and Responsibilities section 3. Removal of item on Preparation of evaluation letter 4. Inclusion of new Forms 5. Removal of Alert for Continuing Review and replacement with Application for Continuing Review		
Prepared by	NEC Secretariat	**Pages**	27-32
Reviewed and approved by	NEC Committee	**Date**	11 February 2022
Signed for effectivity by	Filipinas F. Natividad NEC Chair	**Date**	

NEC SOP version 5	
Nature of Revision	1. Amendment to the Policy Statement regarding "The result of the expedited review may be revised during a meeting if feasible and necessary."

Prepared by	NEC Secretariat	**Pages**	22-28
Reviewed and approved by	NEC Committee	**Date**	06 February 2019
Signed for effectivity by	Filipinas F. Natividad NEC Chair	**Date**	06 February 2019

NEC SOP version 4			
Nature of Revision	1. Expansion of the criteria for expedited review to include proposals that have "vulnerability issues". 2. Clarification of the Scope of the SOP as starting "with the assignment of reviewers" and ending "with the inclusion of the review report in the agenda of the next regular meeting". 3. Clarification of an Acknowledgment decision. "The SAEs that are not related to the study while the SUSARs have been managed satisfactorily. No further action is required. 4. Clarification of the notation decision for minor deviations 5. Minor edits. 5.1 Change of title from Expedited review of Proposals to Expedited Review 5.2 Protocol submissions to Proposals/Reports		
Prepared by	NEC Secretariat	**Pages**	22-28
Reviewed and approved by	NEC Committee	**Date**	19 October 2017
Signed for effectivity by	Filipinas F. Natividad NEC Chair	**Date**	19 October 2017

NEC SOP version 3			
Nature of Revision	1. Addition of mechanism for appeals in the policy statement 2. Criteria for decision points on Progress and Final reports 3. Management of Protocol deviations/violations		
Prepared by	NEC Secretariat	**Pages**	20-27
Reviewed and approved by	NEC Committee	**Date**	21 February 2017
Signed for effectivity by	Filipinas F. Natividad NEC Chair	**Date**	21 February 2017

NEC SOP version 2			
Prepared by	NEC Secretariat	**Pages**	20-26
Reviewed and approved by	NEC Committee	**Date**	15 July 2014
Signed for effectivity by	Marita V.T. Reyes NEC Chair	**Date**	15 July 2014

NEC SOP version 1			
SOP Authors	Ms. Imelda B. Mutuc and Ms. Charisma G. Cruz	**Page**	2
Reviewed by	Dr. Marita V.T. Reyes	**Date**	7 August 2008
Approved by	NEC Committee	**Date**	21 September 2008

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	PREPARATION FOR A MEETING	SOP No.	NEC SOP 07
		Version No.	5
		Version Date	27 September 2024
		Effectivity	01 October 2024

1. POLICY

1.1. The NEC shall have regular bi-monthly meetings, preferably on the 2nd Friday of the months of February, April, June, August, October, and December. A schedule of meeting may be moved depending on the availability of the members. Special meetings may also be scheduled in between regular meetings if there are urgent matters, when time considerations may impact negatively on research conduct, and when there are ethical concerns that need the Committee's immediate decision.

1.2. All meetings shall have a quorum of at least five (5) members, including the non-scientist, or 50% plus 1 member, whichever is higher. If quorum is not achieved during the meeting, the meeting may proceed as a caucus that shall be appropriately documented. The Secretariat shall obtain confirmation of attendance prior to the meeting to determine possibility of quorum.

1.3. The meeting agenda shall be prepared to ensure that all proposals, reports, and other concerns are discussed in the meeting. For an orderly conduct of the meeting, a standardized template of the agenda shall serve as a guide to the presiding officer and all the meeting attendees.

1.4. The meeting shall take place in a closed physical or virtual venue to maintain confidentiality especially in the review of research proposals. The Secretariat shall manage preparations for the meeting.

2. PURPOSE

This SOP aims to describe the processes required in scheduling NEC meetings and ensuring that the preparations before the meeting are properly done.

3. SCOPE

This SOP applies to and describes all processes to be followed in scheduling and preparing for NEC meetings.

4. WORKFLOW

PROCEDURE	PERSON RESPONSIBLE	PROCESSING TIME
4.1. Setting the Date of an NEC Meeting	NEC Chair / Member(s) / Secretariat	1-2 days
4.2. Preparation of the Provisional Meeting Agenda	NEC Chair / Secretariat	2 days
4.3. Notification of the Members and Invited Guests	Secretariat	1 day
4.4. Confirmation of Attendance	NEC Members	1 week
4.5. Ascertainment of Quorum	Secretariat	
4.6. Physical / Virtual Arrangements and Preparation of Meeting Materials	Secretariat	1 week
	Total: 2 weeks and 4-5 days	

5. DESCRIPTION OF PROCEDURES

5.1. **Setting the Date of an NEC Meeting**

5.1.1. Regular meetings of the NEC are held on the 2nd Friday of the months of February, April, June, August, October, and December. However, depending on the availability of the Chair and Members, the meeting may be set on another date.

5.1.2. The Chair calls for a special meeting for the following reasons:

5.1.2.1. At the request of at least two (2) members who identified specific concerns that have implications on the integrity of data of an ongoing research or the increased risk of current participants
5.1.2.2. For full review of new submissions that may be unduly delayed because of the long wait for the next regular meeting.
5.1.2.3. For full review of accumulated new submissions that may overload the agenda of the next regular meeting.
5.1.2.4. For other reasons that the Chair recognizes as urgent.

5.2. **Preparation of the Provisional Meeting Agenda**
The Secretariat drafts a provisional agenda of the meeting in consultation with the Chair using NEC Form 7: Provisional Agenda Template

5.3. **Notification of the Members and Invited Guests**
5.3.1. The Secretariat notifies the NEC members of the meeting date and venue through phone call, text message or email.
5.3.2. Upon instructions of the Chair, the Secretariat invites guests to the meeting with a clear explanation of their role in the meeting.

5.4. **Confirmation of Attendance**
5.4.1. Members confirm their attendance prior to the meeting date. If quorum cannot be achieved, the meeting shall be moved to another date when majority of members can attend.
5.4.2. Members who cannot attend the meeting duly informs the Secretariat of the reason of their non-attendance.

5.5. **Ascertainment of Quorum**
5.5.1. The Secretariat takes note of the members who confirmed their attendance to check for quorum.
5.5.2. The Secretariat informs the Chair of the presence or absence of a quorum, giving the names of members who will attend the meeting.

5.6. **Physical / Virtual Arrangements and Preparation of Meeting Materials**
The Secretariat makes arrangements for the meeting and shall prepare the materials needed.

ANNEX
NEC Form 07: Provisional Agenda Template

DOCUMENT HISTORY

NEC SOP version 5			
Nature of Revisions	1. Updated the policy 2. Rephrased the description of procures to be in active voice. 3. Converted the workflow diagram into a workflow table to include the processing time.		
Prepared by	NEC Secretariat	**Pages**	32-34
Reviewed and approved by	NEC Committee	**Date**	27 September 2024
Signed for effectivity by	Ricardo M. Manalastas, Jr. NEC Chair	**Date**	01 October 2024

NEC SOP version 4			
Nature of Revisions	1. Revised the schedule of NEC regular meetings from quarterly to bi-monthly.		
Prepared by	NEC Secretariat	**Pages**	33
Reviewed and approved by	NEC Committee	**Date**	07 July 2023
Signed for effectivity by	Ricardo M. Manalastas, Jr. NEC Chair	**Date**	07 July 2023

NEC SOP version 3			
Nature of Revisions	1. Removal of Roles and Responsibilities section 2. Replaced details regarding quorum of members 3. Updated Setting the Date of an NEC Meeting 4. Updated meeting venue to include virtual venues		
Prepared by	NEC Secretariat	**Pages**	33-35
Reviewed and approved by	NEC Committee	**Date**	11 February 2022
Signed for effectivity by	Filipinas F. Natividad NEC Chair	**Date**	18 March 2022

NEC SOP version 2			
Prepared by	Dr. Marita V.T. Reyes, Dr. Filipinas Natividad, and NEC Secretariat	**Pages**	28-30
Reviewed and approved by	NEC Committee	**Date**	13 June 2016
Signed for effectivity by	Marita V.T. Reyes NEC Chair	**Date**	13 June 2016

NEC SOP version 1			
SOP Authors	Ms. Imelda B. Mutuc and Ms. Charisma G. Cruz		Page 2
Reviewed by	Dr. Marita V.T. Reyes	Review Date	7 August 2008
Approved by	NEC Committee	Approval Date	21 September 2008

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	CONDUCT OF MEETING	SOP No.	NEC SOP 08
		Version No.	4
		Version Date	27 September 2024
		Effectivity	01 October 2024

1. POLICY

1.1. The meeting shall be presided by the Chair and shall start when the Chair calls the meeting to order.

1.2. The Provisional Agenda of the meeting shall be approved by the Committee at the start of the meeting. Any member can propose items in the agenda that are deemed important for deliberation or discussion. The meeting shall be conducted in accordance with the approved agenda.

1.3. A quorum is declared when five (5) members including one (1) whose interest is non-scientific are present.

1.4. All issues should have been properly discussed and decisions properly documented at the end of the meeting. The meeting shall end upon adjournment by the Chair.

1.5. Meetings conducted physically (face-to-face) or virtually (online) shall observe the same policy on quorum and conduct of meeting.

2. PURPOSE OF THE ACTIVITY

Regular NEC meetings are held to be able to discuss, deliberate and be updated on important matters involving NEC, and to conduct full review, as well as continuing review of research. Proper conduct of a meeting shall ensure that topics in the agenda are thoroughly discussed; conflict of interest issues are managed; recommendations, ideas and suggestions of the members are heard; and decisions and deliberations are documented.

3. SCOPE

This SOP applies to the process involved in the conduct of the NEC meeting. It starts when the Chair calls the meeting to order and ends at adjournment.

4. WORKFLOW

PROCEDURE	PERSON RESPONSIBLE
4.1. Call to Order	NEC Chair
4.2. Approval of the Meeting Agenda	NEC Members
4.3. Declaration of Conflict of Interest (COI)	NEC Members
4.4. Declaration of a Quorum	NEC Chair / Secretariat
4.5. Approval of the Minutes of the Previous Meeting	NEC Members
4.5.Discussion/deliberation on the Topics in the Approved Agenda	NEC Members
4.6.Summary of Decisions	NEC Chair
4.7.Adjournment	NEC Chair

5. DESCRIPTION OF PROCEDURES

5.5.**Call to Order**

The meeting starts when the Chair calls it to order, taking note that all, if not majority, of the members are already present.

5.6.**Approval of the Meeting Agenda**

The present members revise and/or approve the Provisional Meeting Agenda prepared by the Secretariat and Chair

5.7. **Declaration of Conflict of Interest (COI)**

The members declare if there is COI prior to a full review of research. Those with COI shall be exempted from giving their decision in the review of the research.

5.8. **Declaration of a Quorum**

5.8.1. The Secretariat determines if there is quorum at the start of the meeting and reports the reasons for non-attendance of the members who cannot make it to the meeting. If quorum is not achieved, the meeting continues as a caucus and the Secretariat documents it accordingly in the minutes of the meeting

5.8.2. The Secretariat takes note that quorum is maintained throughout the meeting, especially when a member/s declares a COI for a certain research scheduled for review in the meeting.

5.9. **Approval of the Minutes of the Previous Meeting**

The Chair and Members review and approve the minutes of the previous meeting. Businesses arising from the minutes shall be included in the discussion.

5.10. **Discussion/deliberation on the Topics in the Approved Agenda**

5.10.1. The meeting shall progress according to the approved agenda.

5.10.2. The Secretariat documents the deliberations of each topic/issue and shall include these in the minutes of the meeting.

5.10.3. During review of proposals, the primary reviewers present their findings and recommendations to the group. They members deliberate on the research to come up with a decision (refer to SOP 5 Section 6.8).

5.11. **Summary of Decisions**

The Chair summarizes the decisions, actions, and resolutions that the group came up with for each topic in the agenda.

5.12. **Adjournment**

The Chair adjourns the meeting after all topics in the agenda have been discussed.

DOCUMENT HISTORY

NEC SOP version 4			
Nature of Revisions	1. Updated the policy and process 2. Rephrased the description of procures to be in active voice. 3. Converted the workflow diagram into a workflow table to include the processing time.		
Prepared by	NEC Secretariat	**Pages**	35-37
Reviewed and approved by	NEC Committee	**Date**	27 September 2024
Signed for effectivity by	Ricardo M. Manalastas, Jr. NEC Chair	**Date**	01 October 2024

NEC SOP version 3			
Nature of Revisions	1. Removal of Roles and Responsibilities section 2. Inclusion of meetings conduced virtually observing the same policy for conduct of meeting.		
Prepared by	NEC Secretariat	**Pages**	36-38
Reviewed and approved by	NEC Committee	**Date**	11 February 2022
Signed for effectivity by	Filipinas F. Natividad NEC Chair	**Date**	18 March 2022

NEC SOP version 2			
Prepared by	NEC Secretariat	**Pages**	31-33
Reviewed and approved by	NEC Committee	**Date**	19 June 2015
Signed for effectivity by	Marita V.T. Reyes NEC Chair	**Date**	19 June 2015

NEC SOP version 1			
SOP Authors	Ms. Imelda B. Mutuc and Ms. Charisma G. Cruz		Page 2
Reviewed by	Dr. Marita V.T. Reyes	Review Date	7 August 2008
Approved by	NEC Committee	Approval Date	21 September 2008

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	PREPARATION OF MINUTES OF THE MEETING	SOP No.	NEC SOP 09
		Version No.	4
		Version Date	27 September 2024
		Effectivity	01 October 2024

1. POLICY

The Minutes of the Meeting shall be based on the approved agenda. It shall reflect the nature of the issues raised, how these were resolved, and the corresponding decisions made during the meeting. It shall also contain the names of the members present who participated in the deliberations of certain research, and those who did not participate in the review of research due to conflict of interest.

The draft minutes of the meeting shall be prepared on real time during the meeting. The provisional minutes shall be ready two weeks before the next Committee meeting and approval shall be made in that meeting.

2. PURPOSE OF THE ACTIVITY

The minutes of the meeting are carefully prepared to ensure that all decisions made are accurately recorded for reference.

3. SCOPE

This SOP covers the processes in the preparation of minutes of the meeting, the persons responsible for drafting and approval of the document, and the information included in the minutes.

4. WORKFLOW

PROCEDURE	PERSON RESPONSIBLE	PROCESSING TIME
4.1. Preparation of the Draft Minutes of the Meeting	Secretariat	At most, 8 weeks in consideration of the schedule of the next meeting
4.2. Review of the Draft Minutes of the Meeting	NEC Chair and Members	
4.3. Approval of the minutes of the meeting	NEC Chair and Members	

5. DESCRIPTION OF PROCEDURES

5.1. **Preparation of the Draft Minutes of the Meeting**

5.1.1. The Secretariat prepares the draft of the minutes using Form 08: Minutes of the Meeting on real time.

5.1.2. The Secretariat ensures that the minutes contain the attendance and presence of quorum, the identity of the presiding officer, the agenda, the management of conflict of interest, the issues discussed, the proposed management/resolutions and the final recommendation/s. The minutes shall include a summary of the actions on specific issues and the persons responsible at the end of the document.

5.1.3. The Secretariat sends the draft of the minutes to the Chair for revision/correction two weeks before the next Committee meeting.

5.2. **Review of the Draft Minutes of the Meeting**

5.2.1. During the subsequent NEC meeting, the Committee reviews the draft minutes and gives comments, clarifications, and suggestions.

5.2.2. The Secretariat incorporates the suggestions and revisions in the minutes.

5.3. **Approval of the minutes of the meeting**

The Committee finalizes and formally approves the minutes as presented or revised during the regular meeting.

ANNEX:

NEC Form 08: Minutes of the Meeting Template

DOCUMENT HISTORY

NEC SOP version 4			
Nature of Revisions	1. Updated the policy and process 2. Rephrased the description of procures to be in active voice. 3. Converted the workflow diagram into a workflow table to include the processing time.		
Prepared by	NEC Secretariat	**Pages**	38-39
Reviewed and approved by	NEC Committee	**Date**	27 September 2024
Signed for effectivity by	Ricardo M. Manalastas, Jr. NEC Chair	**Date**	01 October 2024

NEC SOP version 3			
Nature of Revision	4. Removal of Roles and Responsibilities section 5. Typographical revisions		
Prepared by	NEC Secretariat	**Pages**	39-40
Reviewed and approved by	NEC Committee	**Date**	11 February 2022
Signed for effectivity by	Filipinas F. Natividad NEC Chair	**Date**	18 March 2022

NEC SOP version 2			
Prepared by	NEC Secretariat	**Pages**	34-35
Reviewed and approved by	NEC Committee	**Date**	19 June 2015
Signed for effectivity by	Marita V.T. Reyes NEC Chair	**Date**	19 June 2015

NEC SOP version 1			
SOP Authors	Ms. Imelda B. Mutuc and Ms. Charisma G. Cruz		Page 2
Reviewed by	Dr. Marita V.T. Reyes	Review Date	7 August 2008
Approved by	NEC Committee	Approval Date	21 September 2008

1. POLICY

1.1. Monitoring involves the review of post-approval reports submitted during the effectivity of the ethical clearance. These reports include interim or progress reports (quarterly, semi-annually, or annually, as determined by the National Ethics Committee or NEC), Reportable Negative Events (RNEs), protocol deviations/violations, amendments to the protocol, and early termination decision. Final reports shall be submitted two months after the completion of the study.

1.2. Application for continuing review refers to the request for extension and renewal of ethical clearance. The requirement for continuing review shall be stated in the NEC approval letter.

1.3. The NEC shall give the researcher sanctions for non-compliance with monitoring and continuing review requirements. After thorough deliberation on the impact on participant safety and rights, the NEC shall decide on any of the following actions:

- Closer monitoring of study implementation
- Suspension of protocol-related procedures
- Withdrawal of ethical clearance for the study

1.4. The researcher has 30 days to appeal the NEC decision.

2. PURPOSE OF THE ACTIVITY

Monitoring of the conduct of the study ensures that the study procedures are done according to the approved protocol and that the safety and well-being of the study participants are addressed consistently. Continuing Review ensures that protection of human participants and integrity of data are maintained after the original ethical clearance has lapsed until the actual completion of the study.

3. SCOPE

Monitoring and/or continuing review are conducted for reports submitted and for a request for extension of ethical clearance. It starts upon submission of the required reports or request for extension of ethical clearance and ends with communicating with the researcher regarding acceptance of the reports without any required further action or approval of the application for extension of ethical clearance.

4. WORKFLOW

PROCEDURE	PERSON RESPONSIBLE	PROCESSING TIME
4.1. Receipt of Request for Monitoring or Continuing Review	Secretariat	1 day
4.2. Logging of Submitted Document	Secretariat	
4.3. Retrieval of Pertinent Related Documents	Secretariat	
4.4. Review of the Post-Approval Submissions including application for Continuing Review	Primary Reviewers / NEC Members	2 weeks
4.5. Collation of Assessments	Secretariat	3 days
4.6. Communication to the Researcher	Chair and Secretariat	
	Total: 2 weeks and 3 days	

5. DESCRIPTION OF PROCEDURES

5.1. **Receipt of Request for Monitoring or Continuing Review**

The Secretariat receives the request, checks the timeliness of the report and/or application, and notes the information accordingly. The appropriate application forms to accomplish for review are as follows:

- Form 11: Application for Extension of Ethical Clearance (Continuing Review)
- Form 12A: Application Form for Ethics Review of Progress Reports
- Form 12B: Application Form for Ethics Review of Protocol Deviation / Violation
- Form 12C: Application Form for Ethics Review of Reportable Negative Event Report
- Form 12D: Early Termination Report
- Form 13: Application Form for Ethics Review of Amendments
- Form 14: Application Form for Ethics Review of Final Report

5.2. **Logging of Submitted Document**
The Secretariat enters the study information in the NEC Form 11: Log of Post-Approval Submissions.

5.3. **Retrieval of Pertinent Related Documents**
The Secretariat facilitates retrieval of study records, e.g., approved protocol and ICF or latest versions of the protocol and ICF, earlier progress reports, etc., whichever is relevant to the present submission, through the PHREP.

5.4. **Review of the Post-Approval Submissions including application for Continuing Review**
The PHREP automatically notifies the Primary Reviewers of the need for review of the submitted documents. The Primary Reviewers consequently accomplishes the assessment forms (Form 04: Reviewer's Worksheet and/or Form 05: Review Checklist for Informed Consent Form and Process) and submit these through the PHREP.

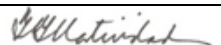
5.5. **Collation of Assessments**
The Secretariat collates the assessments of the reviewers and drafts the decision letter for approval and signature of the Chair.

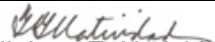
5.6. **Communication to the Researcher**
The Secretariat communicates the result of the evaluation to the Researcher according to SOP 11A (communicating with the researcher).

ANNEX:
Form 04: Reviewer's Worksheet
Form 05: Review Checklist for Informed Consent Form and Process
Form 10: Log of Post-Approval Submissions
Form 11: Application for Extension of Ethical Clearance (Continuing Review)
Form 12A: Application Form for Ethics Review of Progress Reports
Form 12B: Application Form for Ethics Review of Protocol Deviation / Violation
Form 12C: Application Form for Ethics Review of Reportable Negative Event Report
Form 12D: Early Termination Report
Form 13: Application Form for Ethics Review of Amendments
Form 14: Application Form for Ethics Review of Final Report

DOCUMENT HISTORY

NEC SOP version 6			
Nature of Revisions	1. Rephrased the description of procures to be in active voice. 2. Converted the workflow diagram into a workflow table to include the processing time.		
Prepared by	NEC Secretariat	**Pages**	40-42
Reviewed and approved by	NEC Committee	**Date**	27 September 2024
Signed for effectivity by	Ricardo M. Manalastas, Jr. NEC Chair	**Date**	01 October 2024

NEC SOP version 5			
Nature of Revision	1. Removed policies related to clinical trials 2. Updated the NEC Form numbers to be used 3. Removal of Roles and Responsibilities section		
Prepared by	NEC Secretariat	**Pages**	41-44
Reviewed and approved by	NEC Committee	**Date**	11 February 2022
Signed for effectivity by	 Filipinas F. Natividad NEC Chair	**Date**	18 March 2022

NEC SOP version 4			
Prepared by	NEC Secretariat	**Pages**	36-39
Reviewed and approved by	NEC Committee	**Date**	21 February 2017
Signed for effectivity by	 Filipinas F. Natividad NEC Chair	**Date**	21 February 2017

NEC SOP version 3			
Prepared by	Dr. Sonny Matias E. Habacon and Dr. Marita V.T. Reyes	**Pages**	35-37
Reviewed and approved by	NEC Committee	**Date**	24 April 2016
Signed for effectivity by	 Marita V.T. Reyes NEC Chair	**Date**	24 April 2016

NEC SOP version 2			
SOP Authors	NEC Secretariat and Chair		
Reviewed by	Dr. Marita V.T. Reyes	Review Date	19 June 2015
Approved by	NEC Committee	Approval Date	19 June 2015

NEC SOP version 1			
SOP Authors	Ms. Marie Jeanne Berroya and Ms. Anthea Maliz Cortes		
Reviewed by	Dr. Marita V.T. Reyes	Review Date	02 April 2013
Approved by	NEC Committee	Approval Date	02 April 2013

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	MANAGEMENT OF COMMUNICATION	SOP No.	NEC SOP 11A
		Version No.	3
		Version Date	27 September 2024
		Effectivity	01 October 2024

1. POLICY

1.1. NEC Communication is classified as incoming and outgoing communication.

1.2. Incoming communication include applications for initial review, post-approval reports, and requests for extension of ethical clearance. Initial review and post-approval reports are covered by SOPs 4A and 10, respectively. Outgoing communication include decisions on initial review, monitoring review, and responses to requests for extension of ethical clearance.

1.3. The Committee shall communicate its initial review decisions within 7 weeks after categorization of protocol for full review and within 6 weeks for expedited review. All responses to requests and inquiries shall be sent within 2 weeks from date of receipt.

1.4. Decisions on requests for formal extension of ethical clearance shall be based on the NEC record of submission of progress and other reports pertinent to continuing review.

1.5. The Chair shall sign all official outgoing communication. The Secretariat shall save and document all communication sent through email for future reference. All study-related communications shall be treated with confidentiality.

2. PURPOSE OF THE ACTIVITY

Management of Communication aims to make the process efficient and responsive to the needs of the NEC stakeholders.

3. SCOPE

This SOP covers the steps required in the management of incoming (i.e., requests for extension of ethical clearances, other post-approval requests) and outgoing communication.

4. WORKFLOW

4.1. **Incoming Communications**

PROCEDURE	PERSON RESPONSIBLE	PROCESSING TIME
4.1.1. Entry to Logbook	Secretariat	1 day
4.1.2. Preparation of NEC Response	NEC Chair and Secretariat	1-2 days
4.1.3. Release of the NEC Response	NEC Chair and Secretariat	1 day
	Total: 3-4 days	

4.2. **Outgoing Communications**

PROCEDURE	PERSON RESPONSIBLE	PROCESSING TIME
4.2.1. Preparation of Draft	Secretariat	1-2 days
4.2.2. Review and Finalization of Communication	NEC Chair	1 day
4.2.3. Release of the NEC Response	NEC Chair and Secretariat	1 day
	Total: 3-4 days	

5. DESCRIPTION OF PROCEDURES

5.1. **Incoming Communication**

5.1.1. **Entry to Logbook**

The Secretariat logs the date, name of sender and nature of communication.

5.1.2. **Preparation of NEC Response**

The Secretariat refers requests for extension of ethical clearance to the Chair with information on post-approval reports. The Chair asks the Secretariat to draft either a positive or a negative response.

5.1.3. **Release of the NEC Response**

The Chair signs the formal response and the Secretariat communicates the response through the PHREP or through email.

5.2. **Outgoing Communication**

5.2.1. **Preparation of Draft**

The Secretariat prepares the draft of the decision letter on initial and post-approval reviews based on review reports and minutes of the meeting, using NEC Form 15a: Decision Letter Template and NEC Form 15b: Ethical Clearance Template.

5.2.2. **Review and Finalization of Communication**

The Chair reviews, finalizes and signs the letter prepared by the Secretariat.

5.2.3. **Release of the NEC Response**

The Chair signs the formal NEC response. The Secretariat communicates the response through the PHREP or through email.

ANNEX:

Form 15A: Decision Letter Template
Form 15B: Ethical Clearance Template

DOCUMENT HISTORY

NEC SOP version 3			
Nature of Revisions	1. Updated the policy and process. 2. Rephrased the description of procures to be in active voice. 3. Converted the workflow diagram into a workflow table to include the processing time.		
Prepared by	NEC Secretariat	**Pages**	43-44
Reviewed and approved by	NEC Committee	**Date**	27 September 2024
Signed for effectivity by	Ricardo M. Manalastas, Jr. NEC Chair	**Date**	01 October 2024

NEC SOP version 2			
Nature of Revisions	1. Updated SOP Number 2. Revised the process for Release of NEC Response 3. Simplified the wording of the step Review and Finalization of Communication.		
Prepared by	NEC Secretariat	**Pages**	44-46
Reviewed and approved by	NEC Committee	**Date**	10 December 2021
Signed for effectivity by	Filipinas F. Natividad NEC Chair	**Date**	18 March 2022

NEC SOP version 1			
Prepared by	NEC Secretariat	**Pages**	40-42
Reviewed and approved by	NEC Committee	**Date**	19 June 2015
Signed for effectivity by	Marita V.T. Reyes NEC Chair	**Date**	19 June 2015

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	MANAGEMENT OF QUERIES AND COMPLAINTS	SOP No.	NEC SOP 11B
		Version No.	2
		Version Date	27 September 2024
		Effectivity	01 October 2024

1. POLICY

The NEC shall attend to queries and complaints from proponents, research participants or other stakeholders promptly and appropriately while exercising due diligence. The nature of queries or complaints shall determine whether they can be answered by the NEC secretariat (e.g., process-related), Chair (e.g., review-related), or primary reviewers (e.g., topic/decision-related) of the specific protocol. Queries and complaints and responses to these shall be included in the agenda of the coming meeting.

2. OBJECTIVE OF THE ACTIVITY

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

3. SCOPE

This SOP is limited to queries and complaints from proponents, research participants, or other stakeholders in studies that have been issued an ethical approval. This SOP begins with the receipt, logging, and acknowledgment of queries and complaints and ends with the logging of the response and inclusion in the agenda of the NEC Quarterly or Special meeting.

4. WORKFLOW

PROCEDURE	PERSON RESPONSIBLE	PROCESSING TIME
4.1. Receipt, Logging, and Acknowledgment of Queries and Complaints	Secretariat	1-5 days
4.2. Quick Response or Referral of Query or Complaint to the Chair	NEC Chair / Secretariat	1-10 days
4.3. Communication of Response	Secretariat	1 day
4.4. Logging of the Response and Inclusion in the Agenda of the NEC Meeting	Secretariat	
		Total: 3-16 days

5. DESCRIPTION OF PROCEDURES

5.1. **Receipt, Logging, and Acknowledgment of Queries and Complaints**

The NEC Secretariat receives queries and complaints through the email and acknowledges them no later than five (5) days upon receipt. The Secretariat logs all queries and complaints including the date, proponent/concerned individual, NEC Code (if applicable), and the nature of query or complaint, in Form 18 (Log of Queries and Complaints).

5.2. **Quick Response or Referral of Query or Complaint to the Chair**

5.2.1. The Secretariat answers general queries on NEC procedures and policies within five (5) days.

5.2.2. The Chair prepares a response and/or consults the primary reviewers or NEC members for protocol-specific queries or complaints within ten (10) days.

5.2.3. For queries that require guidance of the Committee, the Chair responds no later than five (5) days after the regular or special meeting.

5.3. **Communication of Response**

The Secretariat prepares a draft response to be finalized by the Chair and sent by email to the concerned individual.

5.4. **Logging of the Response and Inclusion in the Agenda of the NEC Meeting**

The Secretariat logs all queries or complaints via electronic folder for filing in the appropriate protocol file, including the date, time, proponent/concerned individual, NEC Code (if applicable), and the nature of query or complaint.

ANNEX:
Form 18: Log of Queries and Complaints

DOCUMENT HISTORY

NEC SOP version 2			
Nature of Revisions	1. Rephrased the description of procures to be in active voice. 2. Converted the workflow diagram into a workflow table to include the processing time.		
Prepared by	NEC Secretariat	**Pages**	45-46
Reviewed and approved by	NEC Committee	**Date**	27 September 2024
Signed for effectivity by	Ricardo M. Manalastas, Jr. NEC Chair	**Date**	01 October 2024

NEC SOP version 1			
Prepared by	NEC Secretariat	**Pages**	47-48
Reviewed and approved by	NEC Committee	**Date**	11 February 2022
Signed for effectivity by	Filipinas F. Natividad NEC Chair	**Date**	18 March 2022

1. POLICY

1.1. The NEC files shall be kept properly as study files or administrative files. All study files shall be identified through codification and kept in the database. Access to files shall be regulated and limited. The NEC shall endeavor to maintain a paperless filing and archival system.

1.2. Files are classified as active or inactive. Active files are documents pertaining to protocols which are currently being reviewed or which may have been approved, including those involving ongoing studies, and current administrative files. Inactive files pertain to completed, terminated, and withdrawn and "lost" studies. Lost studies refer to studies where no communication has been received for at least three (3) months.

1.3. Electronic copies of active and inactive study files are maintained in secure databases with encryptions (i.e., PHREP and Secretariat hard drives) and password protected laptops indefinitely.

1.4. Hard copies of membership files, staff files, and minutes of meetings are kept for a period of ten (10) years. After this period, they are discarded by shredding provided the soft copies of minutes of meetings and database are maintained indefinitely.

1.5. Only the Secretariat and members of the NEC can access study files and only in relation to the review process. Those who have access to the files are bound by the confidentiality agreement to ensure the security and confidentiality of these copies.

2. PURPOSE OF THE ACTIVITY

The files of the Committee shall be properly managed so that identification, security, confidentiality, easy retrieval and efficient review and reporting are ensured.

3. SCOPE

This SOP covers the management of active and inactive files and the process by which they will be filed, organized, and archived.

4. WORKFLOW

PROCEDURE	PERSON RESPONSIBLE	PROCESSING TIME
4.1. Identification of the Type of File and Filing of Documents	Secretariat	1 day
4.2. Logging of Study Documents		1 day
4.3. Periodic Updating of NEC Files		
		Total: 2 days

5. DESCRIPTION OF PROCEDURES

5.1. **Identification of the Type of File and Filing of Documents**

5.1.1. The Secretariat classifies files as study or administrative, active or inactive. Study files, which include protocols, are kept in separate folders which are labelled with their initial codes. Administrative files include the following folders: agenda, minutes of meetings, meeting documents, membership files, SOPs, National and International Guidelines, secretariat files, etc.

The filing system shall be classified as follows:

Membership and Secretariat Files

a. Updated (and signed) curriculum vitae of members

b. Appointment letters and terms of reference
c. Record of trainings in ethics review
d. Confidentiality agreement
e. Conflict of interest agreement

Study Files
a. Protocol versions
b. Reports
c. Communications and responses
d. Researchers' CV
e. Reviewers' evaluations

Minutes of Meetings
a. Minutes of meetings
b. Annexes of documents used in the meeting
c. Attendance during meeting

Administrative Files
a. NEC Standard Operating Procedures
b. DOST Administrative Orders, PCHRD Special Orders, Memorandum of Agreement and Circulars

Regulatory References
a. National Ethical Guidelines
b. PNHRS Law and Implementing Rules and Regulations
c. International Guidelines (WHO, ICH, CIOMS, Helsinki Declaration, etc.)

5.1.2. The Secretariat downloads all study files received through the PHREP or through email into the appropriate study folder and logged into the appropriate Form.

5.2. **Logging of Study Documents**
Each study shall contain a log record in a Google Sheet that includes the following information:
a. submission date
b. NEC Code
c. title of the study
d. name of the proponent
e. contact details of proponent
f. implementing agency/institution
g. funding agency/sponsor
h. review date
i. name/s of reviewer/s
j. type of review
k. documents submitted (e.g., original and revised protocol, original and revised ICF)
l. date of the initial decision letter
m. date of the initial approval letter
n. completion date

5.3. **Periodic Updating of NEC Files**
The Secretariat periodically checks the completeness and orderliness of the NEC files. Inactive files and study folders are labelled as "Archived" after one (1) year of inactivity and study completion, respectively.

ANNEXES:
Form 09: Log of Research Submissions
Form 10: Log of Post-Approval Submissions

DOCUMENT HISTORY

NEC SOP version 4	
Nature of Revisions	1. Rephrased the description of procures to be in active voice.

	2. Converted the workflow diagram into a workflow table to include the processing time.		
Prepared by	NEC Secretariat	**Pages**	47-49
Reviewed and approved by	NEC Committee	**Date**	27 September 2024
Signed for effectivity by	Ricardo M. Manalastas, Jr. NEC Chair	**Date**	01 October 2024

NEC SOP version 3			
Nature of Revisions	1. Updated the SOP title specified for active files and archiving 2. Addition of databases to be used in the Policy statement 3. Addition of Procedure Step no. 5.3. Periodic Updating of NEC files 4. Removal of Roles and Responsibilities section		
Prepared by	NEC Secretariat	**Pages**	49-51
Reviewed and approved by	NEC Committee	**Date**	11 February 2022
Signed for effectivity by	Filipinas F. Natividad NEC Chair	**Date**	18 March 2022

NEC SOP version 2			
Prepared by	NEC Secretariat	**Pages**	43-45
Reviewed and approved by	NEC Committee	**Date**	19 June 2015
Signed for effectivity by	Marita V.T. Reyes NEC Chair	**Date**	19 June 2015

NEC SOP version 1			
SOP Authors	Ms. Imelda B. Mutuc and Charisma G. Cruz		Page 42-44
Reviewed by	Dr. Marita V.T. Reyes	Review Date	7 August 2008
Approved by	NEC Committee	Approval Date	21 August 2008

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	MANAGEMENT OF ACCESS TO CONFIDENTIAL FILES	SOP No.	NEC SOP 13
		Version No.	2
		Version Date	27 September 2024
		Effectivity	01 October 2024

1. POLICY

Access to all NEC files shall be regulated and limited to the Secretariat and members of the NEC, and only in relation to the review process. They are bound by the confidentiality agreement to ensure the security and confidentiality of these study and administrative files. PHREB Accreditors may be given access to NEC files if necessary. Researchers who submitted their protocols through the PHREP have their own account and log in credentials and can thus access their own protocols and related documents on their own. Persons other than the aforementioned may apply for access to confidential files following the process below.

2. PURPOSE OF THE ACTIVITY

All files of the Committee are considered confidential and shall be securely stored and managed so that the protection of the researchers' intellectual property and the Committee's integrity can be maintained.

3. SCOPE

This SOP covers the management of confidential files and the process by which they are filed, organized, and accessed.

4. WORKFLOW

PROCEDURE	PERSON RESPONSIBLE	PROCESSING TIME
4.1. Receipt and Logging of Request for Access to Confidential Files	Secretariat	1 day
4.2. Approval of Requests for Access to Confidential Files	NEC Chair	3 days
4.3. Removal of Identifying Information and Release of Document/s to Requesting Party	Secretariat	1-2 days
	Total: 5-6 days	

5. DESCRIPTION OF PROCEDURES

5.1. Receipt and Logging of Request for Access to Confidential Files

The Secretariat shall receive the accomplished and signed Form 16 (Application Form for Access to Confidential Files) and shall refer this to the Chair/Co-chair.

5.2. Approval of Requests for Access to Confidential Files

The Chair or Co-Chair shall consider the indicated reason for the request and if found satisfactory, approve the request. The Secretariat shall log the request and approval into Form 17 (Log of Access to Confidential Files).

5.3. Removal of Identifying Information and Release of Document/s to Requesting Party

Depending on the indicated reason for the request of the confidential files, the Secretariat shall redact identifying information in the requested files. The Secretariat shall reiterate and verify the Confidentiality Agreement signed in Form 16 before releasing the pertinent document/s to the requesting party.

ANNEXES:

Form 16: Application Form for Access to Confidential Files
Form 17: Log of Access to Confidential Files

DOCUMENT HISTORY

NEC SOP version 2			
Nature of Revisions	1. Rephrased the description of procures to be in active voice. 2. Converted the workflow diagram into a workflow table to include the processing time.		
Prepared by	NEC Secretariat	**Pages**	50-51
Reviewed and approved by	NEC Committee	**Date**	27 September 2024
Signed for effectivity by	Ricardo M. Manalastas, Jr. NEC Chair	**Date**	01 October 2024

NEC SOP version 1			
Prepared by	NEC Secretariat	**Pages**	51-52
Reviewed and approved by	NEC Committee	**Date**	11 February 2022
Signed for effectivity by	Filipinas F. Natividad NEC Chair	**Date**	18 March 2022

I sign this document as _____ of the National Ethics Committee and voluntarily agree not to disclose or reproduce any confidential information and/or research protocols under consideration during the course of my activities with the Committee, or anytime afterwards.

Confidentiality covers information or materials prepared by the investigators, and/or sponsors for the ethics committee review either in written or verbal forms. This information includes technical and scientific data, financial and personal information concerning wages, remunerations, salaries, and benefits. I agree to return the related data or document to the office of NEC after the completion of the activity.

In case I have to disclose the confidential information by court order, I will so inform the committee within two days after notification.

Signature _____

Name _____

Institutional Affiliation (if applicable) _____

Address _____

_____

Noted:

_____
NEC CHAIR

_____
DATE

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	DISCLOSURE OF CONFLICT-OF-INTEREST AGREEMENT (For Members and Consultants of the National Ethics Committee)	NEC Form No.	02
		Version No.	03
		Version Date	27 September 2024

In general, *Conflict of Interest* occurs when there is conflict (actual, potential, or perceived) between an individual's duties and his/her personal or private interest. *Conflict of Interest* impairs one's abilities to exercise objectivity in the performance of official duties.

The Members (including the Chair) of the National Ethics Committee and its consultants shall sign this agreement to disclose any *Conflict of Interest* that they may have in the review of research protocols and other related documents.

The following can be used as a guide to determine whether an individual has *Conflict of Interest*.

INSTRUCTIONS TO NEC MEMBERS OR CONSULTANTS
Before affixing your signature below, please consider each of the following statements in relation to: 1) all your past and current official positions; and 2) all your immediate family members, especially spouse and children. Then, check (√) your answer in the 'yes' or the 'no' column.

	STATEMENTS	**YES**	**NO**
1.	I/My family have owned stocks and shares in the proponent organization(s).		
2.	I/My family have received a salary, an honorarium, compensation, concessions, and gifts from the proponent organization(s).		
3.	I/My family have served as an officer, director, advisor, trustee, consultant, or an active participant in the activities of the proponent organization(s).		
4.	I/My family/my other organizations have had research work experience with the principal investigator(s).		
5.	I/My family/my other organizations have a long-standing issue against the principal investigator(s), the proponent organization(s), or the funding agency.		
6.	I/My family have regular social activities, such as parties, home visits and sports events, with the principal investigator(s).		
7.	I/my family/my other organizations have an interest in or an ownership issue against the proposed topic.		

As a member/consultant of the National Ethics Committee I shall disclose any conflict of interest that I may have in connection with the review of specific research protocols and related documents.

I shall do this before or during any deliberations so that I may not participate in the decision regarding the said protocol.

SIGNATURE OVER PRINTED NAME DATE

INSTITUTIONAL AFFILIATION (if applicable)

ADDRESS

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	APPLICATION FORM FOR ETHICS REVIEW OF A RESEARCH PROPOSAL	NEC Form No.	03
		Version No.	05
		Version Date	27 September 2024

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		*Study Site/s	
*Name of Proponent		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher (if any)			Fax No:
			*Email:
*Institution			
*Address of Institution			
*Type of Study	☐ Clinical Trial (Sponsored) ☐ Clinical Trials (Researcher-initiated) ☐ Health Operations Research (Health Programs and Policies) ☐ Social / Behavioral Research ☐ Public Health / Epidemiologic Research		☐ Biomedical research (Retrospective, Prospective and diagnostic studies) ☐ Stem Cell Research ☐ Genetic Research ☐ Others _____
*Study Site	☐ Multicenter (International)	☐ Multicenter (National)	☐ Single Site
*Source of Funding	☐ Self-funded ☐ Scholarship/Research Grant ☐ Government-Funded Specify: _____ ☐ Others _____		☐ Sponsored by a Pharmaceutical Company Specify: _____ ☐ Institution-Funded Specify: _____
*Duration of the study	Proposed Start date: Proposed End date:	Proposed No. of study participants:	
*Has the Research undergone Technical Review?		☐ Yes (please attach technical review results)	☐ No
*Were the following sections technically reviewed and approved?	☐ **Title** ☐ **Introduction** ☐ **Background** ☐ **Statement of the Problem** ☐ **Significance of the study** ☐ **Objectives**		

	☐ **Literature Review** ☐ **Conceptual Framework** ☐ **Methodology:** ☐ Study Design ☐ Study Population ☐ Recruitment Process ☐ Study variables ☐ Sampling: ☐ Sampling Method ☐ Sample Size ☐ Data Collection and Analysis ☐ Instruments and data collection methods ☐ Bias ☐ Data Analysis ☐ **Ethical Consideration** ☐ **Other attachments**

*Has the Research been submitted to another ERC?	☐ Yes	☐ No

Brief Description of the study

Checklist of Documents

Basic requirements:	**Supplementary Documents:**
☐ Letter request for review ☐ Endorsement/Referral Letter ☐ Foreign Institutional Ethics Review Approval (if applicable) ☐ Full proposal / study protocol ☐ Technical Review Approval with Summary of Technical Review Recommendations and how they were addressed. ☐ Curriculum Vitae of Researcher/s ☐ Informed Consent Form ☐ English version ☐ Filipino version ☐ Others _____ ☐ Assent Form (if applicable) ☐ English version ☐ Filipino version ☐ Others: _____	☐ Questionnaire (if applicable) ☐ Data Collection Forms (if applicable) ☐ Product Brochure (if applicable) ☐ Philippine FDA Marketing Authorization or Import License (if applicable) ☐ Permit/s for special populations (please specify) _____ ☐ Others (please specify) _____

Accomplished by:

_____ **Name and Signature**	_____ **Date**

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	REVIEWER'S WORKSHEET	NEC Form No.	04
		Version No.	04
		Version Date	27 September 2024

Title of Study					
NEC Code		Type of Review			
Proponent		Institution			
Name of Reviewer		Date Received	Primary reviewer?	☐ Yes	☐No
Guide questions for reviewing the proposal / protocol					
Does the study have social value?			☐ Unable to Assess	☐ Yes	☐ No
Comment:					
Is the study background adequate?			☐ Unable to Assess	☐ Yes	☐ No
Comment:					
Are the research questions supported by the Review of Literature?			☐ Unable to Assess	☐ Yes	☐ No
Comment:					
Are the study objectives Specific, Measurable, Attainable, Realistic, Time-bound?			☐ Unable to Assess	☐ Yes	☐ No
Comment:					
Is the research design appropriate?					
● Is the population identified and defined?			☐ Unable to Assess	☐ Yes	☐ No
Comment:					
● Is the selection of study participants described?			☐ Unable to Assess	☐ Yes	☐ No
Comment:					
● Is the sample size justified?			☐ Unable to Assess	☐ Yes	☐ No
Comment:					
● Is the plan for data analysis described?			☐ Unable to Assess	☐ Yes	☐ No
Comment:					
● Are there dummy tables?			☐ Unable to Assess	☐ Yes	☐ No
Comment:					
Does the research need to be carried out with human participants?			☐ Unable to Assess	☐ Yes	☐ No
Comment:					
Does the study have a vulnerability issue?			☐ Unable to Assess	☐ Yes	☐ No
Comment:					

Are appropriate mechanisms/interventions in place to address the vulnerability issue/s?	☐ Unable to Assess	☐ Yes	☐ No
Comment:			
Are there risks/ probable harms to the human participants in the study?	☐ Unable to Assess	☐ Yes	☐ No
Comment:			
Are there measures to mitigate the risks?	☐ Unable to Assess	☐ Yes	☐ No
Comment:			
Is there a favorable balance of benefits and risks?	☐ Unable to Assess	☐ Yes	☐ No
Comment:			
Is/are the investigator/s adequately trained and do they have sufficient experience to undertake the study?	☐ Unable to Assess	☐ Yes	☐ No
Comment:			
Is the informed consent procedure / form adequate and culturally appropriate?	☐ Unable to Assess	☐ Yes	☐ No
Comment:			
Is there a disclosure of conflict of interest?	☐ Unable to Assess	☐ Yes	☐ No
Comment:			
Are the research facilities adequate?	☐ Unable to Assess	☐ Yes	☐ No
Comment:			
Are there any other concerns in the study?			

Summary of Findings:

Recommendation: ☐ **Approved**

☐ **Minor revisions required:**

_____

_____

☐ **Major revisions required**

_____

_____

☐ **Disapproved**

Reasons for disapproval:

_____

_____

_____ _____

Name and Signature of Reviewer **Date**

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	REVIEW CHECKLIST FOR INFORMED CONSENT FORM AND PROCESS	NEC Form No.	05
		Version No.	04
		Version Date	27 September 2024

Title of Study				
NEC Code		Type of Review		
Proponent		Institution		
Name of Reviewer		Primary reviewer?	☐ Yes	☐ No
Guide questions for reviewing the informed consent process and form				
Is it necessary to seek the informed consent of the participants?	☐ Unable to Assess		☐ Yes	☐ No
If NO, please explain.				
If YES, are the participants provided with sufficient information regarding:				
● Purpose of the study?			☐ Yes	☐ No
● Expected duration of participation?			☐ Yes	☐ No
● Procedures to be carried out?			☐ Yes	☐ No
● Discomforts and inconveniences?			☐ Yes	☐ No
● Risks (including possible discrimination)?			☐ Yes	☐ No
● Random assignment to the trial treatments?	☐ Not applicable		☐ Yes	☐ No
● Benefits to the participants?			☐ Yes	☐ No
● Alternative treatments/ procedures?	☐ Not applicable		☐ Yes	☐ No
● Compensation and/or medical treatments in case of injury?			☐ Yes	☐ No
● Who to contact for pertinent questions and / or for assistance in a research- related injury?			☐ Yes	☐ No
● Refusal to participate or discontinuance at any time will not involve penalty or loss of benefits to which the subject is entitled?			☐ Yes	☐ No
● Extent of confidentiality?			☐ Yes	☐ No
Comment on the above list of information:				
Is the informed consent written or presented in a language that participants can understand?			☐ Yes	☐ No
Comment:				
Does the protocol include an adequate process for ensuring that consent is voluntary?			☐ Yes	☐ No
Comment:				
Do you have any other concerns?				

Summary of Findings:

Recommendation: ☐ **Approved**

☐ **Minor revisions required:**

_____

_____

☐ **Major revisions required**

_____

_____

☐ **Disapproved**

Reasons for disapproval:

_____

_____

_____ _____

Name and Signature of Reviewer **Date**

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	REVIEWER'S WORKSHEET FOR STEM CELL RESEARCH	NEC Form No.	6A
		Version No.	03
		Version Date	27 September 2024

Title of the Study				
NEC Code		Type of Review		
Proponent				
Institution		Has an ERC/IRB?	☐ Yes	☐ No
Sponsor				
Funding Agency				
Name of Reviewer		Primary Reviewer?	☐ Yes	☐ No
Guide questions for reviewing the protocol of Stem Cell research				
Is there comprehensive literature review and information that describes the development of the stem cell therapy in this study?			☐ Yes	☐ No
Comment:				
Nature of Stem Cell Use: Therapy	☐ Clinical Trial: ☐ Phase 1 ☐ Phase 2 ☐ Phase 3 ☐ Experimental Therapy ☐ Established Therapy for new indications/formulation			
Source of Stem Cells:	☐Human (adult) ☐autologous ☐allogeneic ☐Human (embryonic) ☐cellular reprogramming ☐animal (pls. identify _____) ☐plant (pls. identify _____) ☐others (pls. describe _____)			

Will the stem cells be directly transplanted to the human recipient? ☐yes ☐no

If YES, where? ☐ outside the Philippines, pls. specify _____
☐ locally, pls. specify _____

If NOT, will the stem cells be

stored?	☐yes	☐no	☐not indicated
processed?	☐yes	☐no	☐not indicated
cultured?	☐yes	☐no	☐not indicated
expanded?	☐yes	☐no	☐not indicated
or genetically modified?	☐yes	☐no	☐not indicated
Is the laboratory GMP/GLP certified?	☐yes	☐no	☐not indicated
Is the hospital/facility accredited by the DOH Bureau of Health?	☐yes	☐no	☐not indicated
Will animal serum/feeder cells be used?	☐yes	☐no	☐not indicated
Are release criteria described/indicated?	☐yes	☐no	☐not indicated

Comment:

Which stem cell markers will be used?

What is the route of administration/transplantation?
☐ intravenous

☐ intrathecal ☐ subdermal ☐ intramuscular direct to the target organ _____			
Are indicators of clinical efficacy described? Are there homing indicators? Are there functional indicators? Are there persistence indicators? Comment:	☐yes ☐yes ☐yes ☐yes	☐no ☐no ☐no ☐no	
Does the study design address the study objectives?	☐yes	☐no	
Comment:			
Is the selection of patients fair and equitable?	☐yes	☐no	
Comment			
Do the participants/ subjects belong to vulnerable groups? Is vulnerability addressed?	☐yes ☐no ☐yes ☐no		
Comment:			
Are the benefits adequately described?	☐yes	☐no	
Comment:			
Will surrogate markers for good outcomes be used?	☐yes	☐no	☐not indicated
What are these?			
Are the risks identified?	☐yes	☐no	
Comment:			
Do the benefits outweigh the risks?	☐yes	☐no	
Comment:			
Is the process for obtaining informed consent described in the protocol?	☐yes	☐no	
Who will obtain the informed consent? ☐ attending physician ☐ project leader ☐ proponent ☐ nurse ☐ others, pls. identify _____			
Will standard health care be provided?	☐yes	☐no	☐not indicated
Comment:			
Are financial arrangements reasonable and fair?	☐yes	☐no	☐not indicate
Comment:			
Is there a potential conflict of interest?	☐yes	☐no	
Comment:			
Is the training and practice of the researcher/proponent adequate and appropriate to ensure safe and competent conduct of the study and care of the participants?	☐yes	☐no	
Comment:			

Is there a commitment to publish study results?	☐yes	☐no	☐not indicated
Comment:			

Summary of Findings:

Recommendation: ☐ **Approved**

☐ **Minor revisions required:**

_____

_____

☐ **Major revisions required**

_____

_____

☐ **Disapproved**

Reasons for disapproval:

_____

_____

_____ _____

Name and Signature of Reviewer **Date**

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	INFORMED CONSENT CHECKLIST FOR STEM CELL RESEARCH	NEC Form No.	6B
		Version No.	03
		Version Date	27 September 2024

Title of the Study				
NEC Code		Type of Review		
Proponent				
Name of Reviewer		Primary Reviewer?	☐ yes	☐ no
GUIDE QUESTIONS				
Is there a separate document for patient information and informed consent? Comment:			☐ yes	☐ no
Is the participant/patient provided with sufficient information with regard to each of the following items?				
1. Purpose of the study			☐ yes	☐ no
2. Unproven and experimental aspects of cell-based intervention			☐ yes	☐ no
3. Clarification of therapeutic misconception			☐ yes	☐ no
4. Expected duration of participation			☐ yes	☐ no
5. Permanency of stem cell therapy			☐ yes	☐ no
6. Discomforts and inconveniences			☐ yes	☐ no
7. Alternative care			☐ yes	☐ no
8. Risks (nature and likelihood)			☐ yes	☐ no
9. Benefits (nature and likelihood)			☐ yes	☐ no
10. Confidentiality / Protection of Privacy			☐ yes	☐ no
11. Voluntary withdrawal			☐ yes	☐ no
12. Financial arrangements			☐ yes	☐ no
13. Compensation			☐ yes	☐ no
14. Provision of standard of care			☐ yes	☐ no
15. Contact information of person/s in-charge			☐ yes	☐ no
Comments:				

Recommendation: ☐ **Approved**

☐ **Minor revisions required:**

_____

_____

☐ **Major revisions required**

_____

_____

☐ **Disapproved**

Reasons for disapproval:

_____

_____

_____ _____

Name and Signature of Reviewer **Date**

NATIONAL ETHICS COMMITTEE	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	CHECKLIST FOR EXEMPTION OF REVIEW	NEC Form No.	6C
		Version No.	01
		Version Date	10 December 2021

Title of the Study		
NEC Code		Type of Review: Preliminary
Proponent		
Institution		
Project Objectives		

GUIDE QUESTIONS	**Yes**	**No**
1. Does the study involve direct interaction with participants?		
2. Do the participants belong to a vulnerable group? Or, are there vulnerability issues generated by the study?		
Describe the vulnerability issue.		
3. Does the study use identifiable human tissue samples and/or data?		
4. Are the risks from the study procedures more that minimal?		
Describe the risk/s:		
5. Are there benefits to be gained by the participants?		
Describe potential benefits.		
6. Are the risks and benefits described in the protocol and is there mention that the benefits outweigh the risks?		
Describe your own assessment of the balance between benefits and risks.		
7. Which of the following can be waived?		
The informed consent process		
The requirement for a signed ICF		
Information in the ICF which are not relevant		
Summary of Findings:		

Recommendation: ☐ **Exempted**
☐ **Expedited Review**
☐ **Full Review**

_____ _____

Name and Signature of Reviewer **Date**

Title:
Venue:
Date: Time:

1. Call to Order
2. Declaration of Quorum
3. Approval of the Agenda
4. Disclosure of Conflict of Interest
5. Review of Minutes of the Previous Meeting
6. Business Arising from the Minutes of the Meeting
7. New Business
8. Full Review of New Proposals (Initial)
   8.1. NEC Code - Title – Researchers – Submission Date - Primary Reviewers
   8.2. NEC Code - Title – Researchers – Submission Date - Primary Reviewers
9. Report on Expedited Review of Proposals
   9.1. NEC Code - Title – Researchers – Submission Date - Primary Reviewers
   9.2. NEC Code - Title – Researchers – Submission Date - Primary Reviewers
10. Report on Full Review of Proposals (Resubmission)
    10.1. NEC Code - Title
    10.2. NEC Code - Title
11. Report on Expedited Review of Proposals (Resubmissions)
    11.1. NEC Code - Title
    11.2. NEC Code - Title
12. Report on Post-Approval Submissions
    12.1. NEC Code - Title
13. Updates on Approved, Ongoing Research (Continuing Review)
    13.1. NEC Code - Title
    13.2. NEC Code - Title
14. Other Matters
    14.1. Newly Accepted Proposals for Review
        14.1.1. NEC Code – Title
    14.2. Administrative/Operations issues
15. Schedule of the Next Meeting
16. Adjournment

Nature of Meeting:
Date:
Time:
Venue:

Attendance
Present:

Name	Chair
Name	Vice-Chair
Name	Member (Identify non-scientist member who is present)

Also Present:

Name	Secretariat
Name	Guest

Absent:

Name	Member
Name	Member

1. **Call to Order**
2. **Declaration of Quorum**
3. **Approval of the Agenda**
4. **Disclosure of Conflict of Interest**
5. **Review of Minutes of the Previous Meeting**
6. **Business Arising from the Minutes of the Meeting**
7. **New Business**
8. **Full Review of New Proposals (Initial)**
   a.

NEC Code:	
Title:	
Researcher/s:	
Initial Submission date	
Primary Reviewers	
Discussion: ● **Social Value:** ● **Scientific Soundness:** ● **Vulnerability issue:** ● **Measures to protect vulnerable population:** ● **Risk/benefit ratio:** ● **Measures to mitigate risks:** ● **Confidentiality and privacy:** ● **Informed Consent process, form and content:**	
Summary of Findings	
Recommendations:	
Decision:	Protocol: Approval, Minor, Major, Disapproval

	Informed Consent: Approval, Minor, Major, Disapproval

9. Report on Expedited Review of Proposals

a.

NEC Code:	
Title:	
Researcher/s:	
Initial Submission date	
Resubmission date	
Primary Reviewers	
Comments:	
Decision:	
Decision letter date	

10. Updates on Full Review of Proposals (Resubmission)

a.

NEC Code:	
Title:	
Researcher/s:	
Initial Submission date	
Resubmission date	
Latest Resubmission date	
Primary Reviewers	
Comments:	
Decision:	
Decision letter date	

11. Updates on Expedited Review of Proposals (Resubmissions)

a.

NEC Code:	
Title:	
Researcher/s:	
Initial Submission date	
Resubmission date	
Latest Resubmission date	
Primary Reviewers	
Comments:	
Decision:	
Decision letter date	

12. Report on Post-Approval Submissions (Request for Amendment and Extension of Clearance)

a.

NEC Code:	
Title:	
Researcher/s:	
Initial Submission date	
Approval letter date	

Request for extension submission date	
Primary Reviewers	
Decision:	
Decision letter date	

b.

NEC Code:	
Title:	
Researcher/s:	
Initial Submission date	
Approval letter date	
Request for amendments submission date	
Primary Reviewers	
Decision:	
Decision letter date	

13. Other Matters
14. Schedule of the Next Meeting
15. Adjournment

Prepared by:

Name
Date:

Noted:

NEC Chair
Date:

NATIONAL ETHICS COMMITTEE	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	LOG OF RESEARCH SUBMISSIONS	NEC Form No.	09
		Version No.	02
		Version Date	11 February 2022

Year:

No	*Submission Date	NEC Code	Title	Proponent/s	Contact Details		Implementing Agency / Institution	Funding Agency / Sponsor	Documents submitted	Review Date/s	Name of Reviewers	Type of Review	NEC Comments/ Recommendations	Date of Initial Decision Letter	Date of Initial Approval Letter	Date of Study Completion
					Email	Telephone										
1.																

Legend:
*Submission date is only logged once a complete set of basic requirements are submitted. Depending on the type of research, this may include Full Proposal, Endorsement/Referral letter, ICF/Assent Forms, Technical Review Results/Explanation, CV of proponent, fully accomplished NEC Form 3: Application for Review, Questionnaires, and Data Collection Forms.

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	LOG OF POST-APPROVAL SUBMISSIONS	NEC Form No.	10
		Version No.	03
		Version Date	27 September 2024

Year: __

No	NEC Code	Title	Document Type	Proponent/s	Received Date	Type of Review	Reviewer/s	Review Date/s	Status	Decision	Remarks
1.											

NATIONAL ETHICS COMMITTEE	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	APPLICATION FOR EXTENSION OF ETHICAL CLEARANCE (CONTINUING REVIEW)	NEC Form No.	11
		Version No.	03
		Version Date	27 September 2024

General Information			
*Title of Study			
*NEC Code (To be provided by NEC)		*Study Site	
*Name of Proponent		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher (if any)			Fax No:
			*Email:
*Institution			
*Address of Institution			
Effectivity Period of Ethical Clearance			

1. Date of start of study			
2. Number of required participants:		3. Number of enrolled participants:	
4. Number of signed Informed Consent forms on file:		5. Number of participants who withdrew	
	Number of reports submitted	Dates of submission	Action of the Committee
6. Progress Reports			
7. Amendment Reports			
8. Reportable Negative Event Reports			
9. Protocol Deviation / violation Reports			
10. Issues/problems encountered.			

Accomplished by:	
Name & Signature	**Date**

To be accomplished by Primary Reviewer	
Summary of Findings:	
Recommendations:	
Name & Signature of Reviewer	**Date**

General Information			
*Title of Study			
*Name of Proponent		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher (if any)			Fax No:
			*Email:
*Institution		*Study Site/s	
*Address of Institution			
Effectivity Period of Ethical Clearance			

Progress Report	
1. Start of study	2. Expected end of study
3. Number of enrolled participants	4. Number of required participants
5. Number of participants who withdrew	
6. Deviations from the approved protocol	
7. New information (literature or in the conduct of the study) that may significantly change the risk-benefit ratio	
8. Issues/problems encountered	

Accomplished by:	
Name & Signature	**Date**

To be accomplished by the Reviewer	
Summary of Findings	
Recommendations	
Name and Signature of Reviewer	Date

NATIONAL ETHICS COMMITTEE	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	APPLICATION FORM FOR ETHICS REVIEW OF PROTOCOL DEVIATION / VIOLATION	NEC Form No.	12B
		Version No.	03
		Version Date	27 September 2024

General Information			
*Title of Study			
Version number/date of the NEC approved protocol			
*Name of Proponent		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher/s (if any)			Fax No:
			*Email:
*Institution of researcher		*Study Site/s	
*Address of Institution			
Effectivity Period of Ethical Clearance	From:	To:	

Protocol or ICF procedure/provisions deviated from / violated (Use additional sheets if necessary)	**Deviations / Violations committed**	**Effect on risks/benefits and data integrity**	**Corrective/Preventive Action to Avoid Similar Deviation / Violation**
Participant Responsibility			
Researcher Responsibility			
Research Staff Responsibility			
Facility Problem			

Accomplished by:	
Name & Signature	**Date**

To be accomplished by the Reviewer	
Summary of Findings	
Recommendations	
Name and Signature of Reviewer	Date

NATIONAL ETHICS COMMITTEE	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	APPLICATION FORM FOR ETHICS REVIEW OF REPORTABLE NEGATIVE EVENT REPORT	NEC Form No.	12C
		Version No.	03
		Version Date	27 September 2024

General Information			
*Title of Study			
*Name of Proponent		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher (if any)			Fax No:
			*Email:
*Institution		*Study Site/s	
*Address of Institution			
Effectivity Period of Ethical Clearance			

Reportable Negative Event 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	

Accomplished by:	
Name & Signature	**Date**

To be accomplished by the Reviewer	
Summary of Findings	
Recommendations	
Name and Signature of Reviewer	Date

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	EARLY TERMINATION REPORT	NEC Form No.	12D
		Version No.	03
		Version Date	27 September 2024

General Information			
*Title of Study			
*Name of Proponent		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher (if any)			Fax No:
			*Email:
*Institution		*Study Site/s	
*Address of Institution			
Effectivity Period of Ethical Clearance			
Recommended by:	☐ Funding Agency ☐ Researcher / Proponent ☐ Others _____		

Protocol Implementation Details:	
1. Start of study	2. Expected end of study
3. Number of enrolled participants	4. Number of required participants
5. Reason/s for termination	
6. Support mechanisms / Interventions for Enrolled Participants	
7. Post-Termination Actions	
Accomplished by:	
Name & Signature	**Date**

To be accomplished by the Reviewer	
Summary of Findings	
Recommendations	
Name and Signature of Reviewer	Date

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	APPLICATION FORM FOR ETHICS REVIEW OF AMENDMENTS	NEC Form No.	13
		Version No.	03
		Version Date	27 September 2024

General Information			
*Title of Study			
Version number/date of the NEC approved protocol			
*Name of Proponent		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher/s (if any)			Fax No:
			*Email:
*Institution of researcher		*Study Site/s	
*Address of Institution			
Effectivity Period of Ethical Clearance	From:	To:	

Protocol or ICF procedure/provisions to be amended (Use additional sheets if necessary)	**Proposed amendments**	**Justification**

Accomplished by:	
Name & Signature	**Date**

To be accomplished by the Reviewer	
Summary of Findings	
Recommendations	
Name and Signature of Reviewer	Date

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	APPLICATION FORM FOR ETHICS REVIEW OF FINAL REPORT	NEC Form No.	14
		Version No.	04
		Version Date	27 September 2024

General Information			
*Title of Study			
Version number/date of the NEC approved protocol			
*Name of Proponent		Contact Information	*Tel No:
			*Mobile No:
*Co-researcher/s (if any)			Fax No:
			*Email:
*Institution of researcher		*Study Site/s	
*Address of Institution			
Effectivity Period of Ethical Clearance	From:	To:	

Summary of Implementation of the Study:	
1. Start of study	2. End of study
3. Number of enrolled participants	4. Number of required participants
5. Number of participants who withdrew	6. Start and end dates of participant recruitment
7. Deviations from the approved protocol	8. Issues/problems encountered
9. Summary of findings:	
10. Conclusions:	
11. Proposed Policy/Program Recommendations	
12. Plan for dissemination of study results:	

Accomplished by:	
Name & Signature	**Date**

To be accomplished by the Reviewer	
Summary of Findings	
Recommendations	
Name and Signature of Reviewer	Date

FORM 15A: DECISION LETTER TEMPLATE
(Date)

(NAME OF PROPONENT)
(Designation)
(Institution)
(Address)

RE: (**Title of project/study)**
NEC code:

Subject: (Nature of action requested, e.g., ethical clearance extension, acceptance of report, etc.)

Dear (***Title and Family name of proponent***):

(Acknowledgment of request and submitted documents with version numbers and dates)

1. _
2. _
3. _
4. _
5. _

(Information on type of review and date of meeting if full review)

(List of findings)

(List of recommendations)

(Specific instructions to the proponent, if any, including the date of deadline for response, which is four (4) weeks after receipt of the decision letter)

Very truly yours,

(Signature)
(Name)
Chair

FORM 15B: ETHICAL CLEARACE TEMPLATE
(Date)

(NAME OF PROPONENT)
(Designation)
(Institution)
(Address)

RE: **(Title of project/study)**
NEC code:

Subject: (Nature of action requested, e.g., ethical clearance extension, acceptance of report, etc.)

Dear (***Title and Family name of proponent***):

(Acknowledgment of request and submitted documents with version numbers and dates)

1. _
2. _
3. _
4. _
5. _

(Information on type of review and date of meeting if full review)

(Validity of ethical clearance)

(Provisions for post-approval submissions: frequency of submission of Progress Reports, Protocol Deviation/Violation, Amendments, Early Termination Report, Application for Continuing Review, Final Report)

(Mention that the citation of clearance in a publication is contingent on acceptance of the final report.)

Very truly yours,

(Signature)
(Name)
Chair

FORM 15C: CERTIFICATE OF EXEMPTION TEMPLATE
(Date)

(NAME OF PROPONENT)
(Designation)
(Institution)
(Address)

RE: (**Title of project/study)**
NEC code:

Subject: Certificate of Exemption from Ethical Review

Dear (***Title and Family name of proponent***):

(Acknowledgment of request and submitted documents with version numbers and dates)

1. _
2. _
3. _
4. _
5. _

After a preliminary review of the above documents, the National Ethics Committee deemed it appropriate that the above proposal be EXEMPT FROM REVIEW.

This means that the study may be implemented without undergoing an expedited or full review.

However, the researcher is required to submit any amendment to the approved protocol or informed consent prior to implementation to ensure that the exemption still holds. A Final Report (NEC Form No. 14) shall. also be submitted 30 days after completion of the study.

Very truly yours,

(Signature)
(Name)
Chair

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	APPLICATION FORM FOR ACCESS TO CONFIDENTIAL FILES	NEC Form No.	16
		Version No.	01
		Version Date	10 December 2021

General Information			
*Name			
*Address		Contact Information	*Tel. No:
*Email Address			*Mobile No:
*Institution			
*Address of Institution			
***Purpose of Request**			
***Title of the Requested Document/s**			

Confidentiality Agreement

I voluntarily agree not to disclose or reproduce any content from the confidential documents I am requesting access to. Confidentiality covers all protocol / study files, as well as administrative files that are not published in the NEC, PHREB, or DOST-PCHRD websites. I agree not to use any of the accessed information for purposes other than those stated above.

Accomplished by:

Name and Signature	**Date submitted**

Decision of Chair

☐ Approved ☐ Disapproved

Additional Instructions:

_____

Name and Signature	**Date**

Year:

No	Date of Request	Name	Address	Email Address	Institution	Address of Institution	Purpose of Request	Title of Requested Document	Decision	Date of Release of Confidential File (if approved)	Date of Return of the File
1.											

Year:

No	Date and Time	Name	Email Address	NEC Code (if applicable)	Nature of Query or Complaint	Action
1.						

	NATIONAL ETHICS COMMITTEE STANDARD OPERATING PROCEDURES		
	NOMINATION FORM FOR NEC MEMBERSHIP	NEC Form No.	19
		Version No.	01
		Version Date	27 September 2024

NOMINATOR INFORMATION

Full Name _____

Institution and designation _____

Email and Mobile number _____

I, _____, nominate _____ to be a member of the National Ethics Committee.

_____

SIGNATURE OVER PRINTED NAME DATE

NOMINEE INFORMATION (Please attach accomplished NEC Form 20: Curriculum Vitae)

Full Name _____

Institution _____

Contact Details _____

Email _____

Mobile Number _____

Discipline / Sectoral representation _____

Nomination Justification:

1. Describe the relevant expertise and perspective that the Committee can benefit from the nominee.

2. Describe any research and research ethics background of the nominee.

ACCEPTACE OF NOMINATION

I, _____, accept the nomination to be a member of the National Ethics Committee.

_____

SIGNATURE OVER PRINTED NAME DATE

Please insert picture here

FULL NAME: _____

DATE OF BIRTH: _____

CONTACT INFORMATION

Mailing address	Home	
	Office	
Mobile Number		
Email		

EDUCATIONAL BACKGROUND (add more rows as needed)

	Degree	Years Attended	Year Graduated
College			
Post-graduate			

WORK EXPERIENCE (including administrative positions) (add more rows as needed)

Position	Institution	Inclusive Years of Service

RESEARCH EXPERIENCE (add more rows as needed)

Project Topic	Position in the Project	Year completed

RESEARCH ETHICS TRAINING (add more rows as needed)

Topic	Training Provider	Month and Year of training

SIGNATURE OVER PRINTED NAME	DATE

FORM 21: TEMPLATE INVITATION LETTER
(Date)

(NAME OF NOMINEE
(Designation)
(Institution)
(Address)

Subject: Invitation to be a Member of the National Ethics Committee

Dear **(Title and Family name of invitee)**,

You have been nominated by ____, a (member of the NEC / PCHRD / other affiliation), to be a (regular / alternate) member of the National Ethics Committee, as a (scientist / non-scientist) member from the _____ discipline.

As a (regular / alternate) (scientific / non-scientific) member, you will have the following responsibilities:

-
-
-
-

The term of office shall be for ____ (__) years.

Should you accept our invitation, kindly sign the conformé below and accomplish the attached NEC Form 1: Confidentiality Agreement and NEC Form 2: Disclosure of Conflict-of-Interest Agreement. Please return the signed documents within two (2) weeks, on or before (date).

If you have any further questions, please do not hesitate to email Ms. Daphne Joyce Maza at nec@pchrd.dost.gov.ph or through the NEC Viber number (___).

Thank you very much.

Very truly yours,

(Signature)
(Name)
Chair

Conforme:

(Signature Over Printed Name)
(date)

GLOSSARY

Active Files – are documents pertaining to protocols which are currently being reviewed, have been approved. These include those involving ongoing studies, and current administrative files.

Adjournment – Formal closure of the meeting. Motion for adjournment and record of the time are minuted.

Agenda - the list of topics or items to be taken up in a meeting arranged in a sequential manner. It is an outline of the meeting procedure and starts with a "Call to Order".

Amendment - A written description of a change(s) to, or formal clarification of a protocol and changes on any other supporting documentation made from the originally approved protocol or informed consent form by the research ethics review body after the study has begun.

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

Approval - Favorable or affirmative decision of the Research Ethics Committee following a review of the protocol and other required documents and thus research may already be started and undertaken as set forth by the ethics committee.

Archiving - is the systematic keeping of protocol files in storage after the studies have been completed with final reports accepted, or terminated or declared inactive.

Review Forms – evaluation tools accomplished by the reviewers when appraising the protocol or the informed consent form.

Benefits – summary of probable positive or favorable outcomes ranging from benefit to the community (or society), indirect gains such as education, or direct therapeutic value

Business Arising from the Minutes – are matters generated from the discussions in the previous meeting that need continuing attention and require reporting.

Coding - a unique number assigned to a document. A protocol code indicates the year and order of receipt. The SOP code indicates its serial position among the other SOPs and its version number.

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.

Complaint – the documentation of an expression of discontent or unease about certain events or arrangements in connection with a study.

Confidentiality - It is the prevention of disclosure of the IEC/IRB information, deliberations and documents to non-authorized individuals. It is the duty of healthcare providers and health researchers toward patients and research participants to protect privacy and to refrain from unauthorized disclosure of information pertaining to them.

Conflict of Interest - A situation that arises when a member of the Ethics Committee holds two competing interests with respect to specific applications for review such that one may jeopardize his/her ability to provide free and independent evaluation of the research focused on the protection of the research participants. Conflict of interests may arise when an EC member has financial, material, institutional or social ties to the research project.

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

Consensus - general agreement or concord; harmony. Consensus does not require that all REC members support the decision, but that all members consider the decision at least acceptable and no member considers the decision unacceptable.

Continuing Review – Refers to the extension and renewal of ethical clearance which may be given with appropriate justification.

Database – a structured/organized collection of information so that the data can easily be accessed, managed and updated.

Decision – the result of the deliberations of the REC in the review of a protocol or other submissions.

Disapproval - A negative action of the Ethics Committee on the protocol. The study cannot be implemented if it has been disapproved by the Committee.

Draft Minutes of the Meeting – Proceedings of the meeting prepared by the Secretariat.

Early Termination - refers to the decision of the researcher, principal investigator, the institution, sponsor or ethics committee to end the implementation of a study before its completion.

Ethical Clearance - A certification that a research proposal has complied with ethical requirement, A decision of an ethics review committee after review of a research protocol that signifies approval and permission to proceed with the research. See also approval.

Ethics Review - The evaluation of a research protocol and other related documents by an ethics review committee to promote the safety and protection of the dignity of human participants. This is a systematic process by which this independent committee evaluates a study protocol and related documents to determine if ethical and scientific standards for carrying out biomedical research on human participants are upheld. It ensures that the dignity, rights, safety and well- being of research participants are promoted.

Exclusion Criteria – Conditions that indicate that an individual is ineligible for a clinical trial or research study.

Exempt from Review - a decision made by the REC Chair or designated member of the committee regarding a submitted study proposal based on criteria in the NEGHHR 2017 The Research Ethics Review Process Guideline 3.1. This means that the protocol will not undergo an expedited nor a full review.

Expedited Review – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by a limited number of REC members (i.e., only 2-3 members) and finalized without the need of an en banc review.

Expertise – a proficiency, skill or know-how possessed by experts in a certain academic/scientific or professional field.

Final Report – is a summary of the outputs and outcomes (including documented risks and benefits) of the study upon its completion, as well as the status of all participants. The REC requires the accomplishment of the Final Report form within a reasonable period after the end of the study.

Food and Drug Administration - The new name and the reorganized and strengthened Bureau of Food and Drugs by virtue of the "Food and Drug Administration (FDA) Act of 2009" or Republic Act No. 9711 of August 18, 2009.

Full Review –Review of proposed research at a convened meeting at which a majority of the membership of the REC are present, including at least one member whose primary concerns 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. Also known as Full Board Review.

Good Clinical Practice (GCP) Guidelines – An international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation 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).

Good Laboratory Practices (GLP) – Standards and procedures whereby a laboratory achieves a defined consistent and reliable standard in performing laboratory tests and activities (Department of Health Administrative Order No. 47-A series of 2001, 30 August 2001).

Good Manufacturing Practice (GMP) – National standards and regulations for licensing of laboratories engaged in the manufacture and production of drugs, vaccines and other pharmaceuticals intended for human administration or consumption. It is that part of quality assurance which ensures that products, including vaccines and biologics are consistently produced and controlled to quality standards appropriate for their intended use, including all phases of vaccine clinical trials, and as required by registration and marketing authorization.

Guidelines – A set of rules or recommendations intended to effect a course of action

Helsinki Declaration – A set of ethical principles regarding human experimentation developed for the medical community by the World Medical Association (WMA). It is widely regarded as the cornerstone document on human research ethics.

Inactive Study – a study whose proponent has not communicated with the REC with regard to issues pertaining to the approval or implementation of the study – within a period of time required by the REC.

Inclusion Criteria – The factors used to judge a participant's eligibility to be part in a trial or research. These factors are justified by the purpose of the researcher in conducting the research.

Incoming Communications – are communications which are directed to and received by the secretariat, including applications for initial review, post-approval reports, requests for extension of ethical clearance and inquiries.

Independent Consultant – An expert who gives advice(s), comment(s) and suggestion(s) upon review of the study protocols with no affiliation to the institute(s) or investigator(s) proposing the research proposal.

Informed Consent –It is "a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation." (CIOMS, 2002).

Initial Review – the ethical assessment of the first complete set of study documents submitted to the REC for assessment that can be exempted from review or that undergoes expedited or full review

Initial Submission - a set of documents consisting of the full proposal and other study-related documents that is received by the REC for ethical review prior to implementation of the study

Logbook – a real-time chronological record of incoming protocols that includes the Date /Time of Receipt, Title of the Document, Name of the Proponent, Name Submitting Entity, Name of the Receiving Person and Action done

Major Revisions Required – One of the decision points when reviewing research. Major revisions include change in the research objectives, change in the research design, or any change that will alter the favorable benefit-risk assessment. Subsequent submissions must undergo full review through SOP 4 and SOP 5.

Meeting Agenda - the list of topics or items to be taken up in a meeting arranged in a sequential manner. It is an outline of the meeting procedure and starts with a "Call to Order".

Meeting Minutes - the official narration and record of the proceedings of the assembly of REC Members, based on the agenda.

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 tests.

Minor Revisions - Changes in the protocol or informed consent form that do not alter the benefit/risk balance or affect data integrity. Examples include change in the title, or improvements in the language of the Informed Consent Form. The consequent submissions

may undergo expedited review through SOP 4 and SOP 6).

National Ethical Guidelines (NEG) – A set of policies and actions recommendations developed by the Philippine Health Research Ethics Board as guidance in the conduct of research in the Philippines.

NEC Code – The unique number assigned to studies or related documents to mark, represent and identify them for a systematic arrangement of files. It indicates the year of submission, series number for the year, proponent's surname, short title/topic, and series number of the submitted document (for post-approval submission).

Non-medical members - are individuals without academic degrees in the medical profession nor a master's degree in the nursing profession.

Non-Scientists – are individuals whose primary interest is not in any of the natural, physical and social sciences and whose highest formal education is a bachelor's degree.

Operations-related Matters – are items included in the agenda that are not directly related to any protocol under review.

Outgoing Communications – are documents generated within the REC office intended for individuals or offices related to the operations of the REC.

Philippine Council for Health Research and Development (PCHRD) - is one of the three sectoral councils of the Department of Science and Technology (DOST). It is a forward-looking, partnership-based national body responsible for coordinating and monitoring research activities in the country.

Philippine Health Research Ethics Board (PHREB) – 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 Health Research Ethics Portal (PHREP) – is an integrated online health research ethics management system developed by PCHRD and PHREB to facilitate paperless ethics review of research

Philippine National Health Research System (PNHRS) – Formally organized in 2004, it was conceptualized in support of a vibrant, 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.

PHREP Code – The standard and unique code that is automatically assigned by the PHREP system to research and documents uploaded to it.

Post-approval reports – are reports submitted by the researcher to the REC after the protocol has been approved for implementation for monitoring purposes. These include, progress reports, protocol deviation/violation reports, amendments, early termination report, final report, application for continuing review.

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Primary Reviewer System – The NEC uses this system wherein researches for full review are assigned to two (2) reviewing members called Primary Reviewers (a scientist and a non-scientist) who will conduct a thorough review of the research and present their findings during the meeting for deliberation. The final decision will be agreed upon by the Committee during a meeting.

Primary Reviewers – Reviewers assigned by the Chair in the initial review of researches (including medica/scientific member and non-medical/non-scientific member) to conduct a thorough review of the research, and present their findings and recommendations during the meeting for deliberation.

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

Proponent - a person who puts forward a proposition or proposal. Also refers to a researcher.

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.

Protocol Amendment – A written description of a change(s) to, or formal clarification of a protocol during its implementation.

Protocol database - a collection of information (e.g., regarding protocols) that is structured and organized so that this can easily be accessed, managed, interpreted, analyzed and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

Protocol Deviation - Accidental or unintentional changes to, or non-compliance with the research protocol that does not increase risk or decrease benefit or; does not have a significant effect on the subject's rights, safety or welfare; and/or on the integrity of the data. Deviations may result from the action of the subject, researcher, or research staff. A deviation may be due to the research subject's non-adherence, or an unintentional change to or non-compliance with the research protocol on the part of a researcher. (retrieved from https://mmcri.org/deptPages/hrpp/downloads/defineprotocoldeviation.pdf)

Protocol File/Folder – is an organized physical or electronic compilation of all documents related to a Protocol

Protocol Violation - Accidental or unintentional change to, or non-compliance with the IRB approved protocol without prior sponsor and IRB approval. Violations generally increase risk or decrease benefit, affects the subject's rights, safety, or welfare, or the integrity of the data. (retrieved from https://mmcri.org/deptPages/hrpp/downloads/defineprotocoldeviation.pdf)

Provisional Meeting Agenda – is the order of business that includes the list of topics or items approved for discussion in a meeting by the REC Chair.

Query – the act of asking for information or clarification about a study.

Quorum – presence of the majority of the REC members including the non-affiliated and the non-scientist members.

Regular Meeting - a periodically scheduled assembly of the REC

Reportable Negative Events (RNEs) - 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.

Research Ethics Committee – also called ethics review committee (ERC), institutional ethics review board (IERB), independent ethics committee (IEC), or institutional review board (IRB); a committee constituted to review the ethical aspects of a research proposal and its possible implementation. This is an independent body whose responsibility is to ensure the protection of the rights, safety and well-being of human participants involved in a trial and to provide public assurance of that protection.

Resubmissions - the revised study proposals that are forwarded to the REC in response to the recommendations given during the initial review. It also pertains to relevant post-approval documents for revision.

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

Risks – summary of probable negative or unfavorable outcomes ranging from inconvenience, discomfort, or physical harm based on the protocol

Scientists – are individuals whose formal education is at least a master's degree in a scientific discipline, e.g., biology, physics, social science, etc.

Special Meeting - an assembly of the Committee outside of the regular schedule of meetings for a specific purpose, usually to decide on an urgent matter like selection of officer, approval of a revised or new SOP,

report of critical research problem that requires immediate action

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

Study Documents – include all materials (protocol, forms, certificates, research tools) pertinent to a research proposal that have to be submitted to the REC for a comprehensive review.

Study Site - physical location of where the study is being conducted, e.g., community, institutional facility.

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

Vulnerable participants - Individuals whose willingness to volunteer in a study may be unduly influenced by the expectation, whether justified or not, of benefits associated with participation, or of a retaliatory response from senior members of a hierarchy in case of refusal to participate. Vulnerable persons are those who are relatively (or absolutely) incapable of protecting their own interests.