

	Centro Escolar University INSTITUTIONAL ETHICS REVIEW BOARD	SOP No: 6
		Version No: 02
	VI. MANAGEMENT OF INITIAL SUBMISSIONS	Approval Date: MM/DD/2020
		Effective Date: MM/DD/2020

1. Policy Statement

The CEU IERB shall require the submission of a set of pertinent documents for an application for ethical review to be accepted. A preliminary evaluation shall determine whether a research proposal is exempted from or needs to undergo ethical review based on the NEGHHR 2017 The Research Ethics Review Process Guideline 3.1. Subsequent amendments to a protocol that was exempted from review shall be submitted for a preliminary evaluation to determine whether the revised protocol can still be “exempted from review”.

2. Objective

Management of Initial Submissions ensures that study documents are complete, properly recorded, and properly evaluated to determine appropriate action or type of review.

3. Scope

The CEU IERB shall accept for initial review only study protocol submitted by the faculty, staff, and students of the institution. This SOP begins with the receipt of study documents for initial review and ends with entry of protocol information in the database.

4. Workflow

ACTIVITY	RESPONSIBILITY
Screen for completeness and receive soft copy and hard copy of study protocol submissions ↓	Secretariat Staff
Classify study protocol submissions (Exempted, Expedited, Full Board) ↓	Overall Secretary
Assign appropriate reviewers	Overall Secretary

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5. Detailed Description of Procedures

5.1. Screening of study protocol submission

The principal investigator submits protocol-related documents through the official email of the CEU IERB which will then be screened by the Secretariat for completeness enumerated on the *CEU IERB Form 11.0 (2020) Review Checklist*:

Basic Documents (must submit)

- ☐ *CEU IERB Form 11.0 (2020) Review Checklist*
- ☐ *CEU IERB Form 12.0 (2020) Registration and Application Form*
- ☐ *CEU IERB Form 13.0 (2020) Study Protocol Assessment Form*
- ☐ Study protocol
- ☐ Data collection forms (including CRFs)
- ☐ Diagrammatic workflow
- ☐ Curriculum Vitae of Principal Investigator (PI), co-investigators (co-I) and other study team members
- ☐ Proof of payment of ethics review fee (as applicable)

Study-specific Documents (submit as needed)

- ☐ *CEU IERB Form 14.0 (2020) Informed Consent Assessment Form*
- ☐ Informed consent form in English
- ☐ Informed consent form in local language
- ☐ Assent form in English (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
- ☐ Assent form in local language (for studies involving minors and relevant populations deemed incompetent to sign an informed consent form)
- ☐ Ethics Training Certificate of PI, Co-I and the rest of the study team
- ☐ Recruitment advertisements (as needed by the study protocol)
- ☐ Material Transfer Agreement (for any research involving transfer of biological specimens)
- ☐ Memorandum of Agreement (for collaborative studies)
- ☐ Previous ethical review approvals/clearances (for students/personnel of foreign universities researching in the Philippines or those with prior ethical review)

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- National Commission for Indigenous People (NCIP) Clearance (for studies with indigenous populations; can be processed while CEU IERB review is on-going)
- Clearance or permit from respective regulatory authorities (such as FDA approval for clinical trials and DENR local transport permit, as applicable)

5.1.2. The Secretariat Staff accepts complete protocol submissions only and returns incomplete or incorrect submissions.

5.1.3. The Secretariat Staff notifies the principal investigator through e-mail regarding results of screening process:

5.1.3.1. Incomplete protocol submissions are returned to principal investigators, indicating the reasons, along with study protocol-specific instructions on how these will be addressed (i.e. uploading applicable documents, revising specific sections into a correct version, etc.).

5.1.3.2. Principal investigators with complete protocol package are notified through email to submit the hard copies.

5.1.4. The Principal Investigators are given **seven (7) working days** to comply with screening requirements, or submit the required number of hard copies of the approved protocol submissions, after which, the submission will be deleted in the CEU IERB database to maintain only active applications

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5.2.Receipt of study protocol submissions

5.2.1. The Secretariat Staff screens the printed copies for consistency with the documents uploaded in the online submission.

5.2.2. The Secretariat Staff accepts the electronic protocol submission, and assigns a code to the package. The printed copies are also stamped “Received”, the date received, and code.

5.2.3. Upon submission, the Secretariat Staff forwards the protocol submissions to the Overall Secretary for review classification.

5.2.4. The Secretariat Staff acknowledges receipt of study protocol and communicates to the PI the assigned code, review classification, and date of full board meeting in which the study protocol will be reviewed using *CEU IERB Form 19.0 (2020) Acknowledgement Letter*.

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5.2.5. The Secretariat Staff registers the received study protocol submissions for initial review in the *CEU IERB Form 49.0 (2020) Study Protocol Database*. Other submissions are logged into the *CEU IERB Form 41.0 (2020) Submissions Log*.

5.2.6. Access to the IERB data base and documents (print or digital) will be limited to the Executive Committee officers and the secretariat. Access of other Executive members for such documents is allowed upon approval by the Overall Chair.

5.3. Classification of submission

5.3.1 The CEU IERB Overall Secretary classifies the study protocol review pathway as either **Expedited Review**, **Full Board Review** or **Exempt from Ethical Review** filtered through the following criteria for Expedited Review:

- The research poses low risk.
- The study does not involve vulnerable populations.
- The study does not involve the collection of stigmatizing information.
- The study uses anonymized or archived samples.
- Continuing review of clinical trials that do not involve further recruitment of participants
- Continuing review of studies previously classified under expedited review
- Study protocol amendments that are administrative in nature and do not affect the study protocol.
- Study protocol amendments that do not change the overall risk profile of the study.

5.3.2. Research that qualifies for exemption from ethical review will be filtered through the criteria listed in the 2017 National Ethical Guidelines for Health and Health-related Research (NEGHHR 2017).

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5.3.3. Undergraduate researches are classified for expedited review and shall fulfill the following criteria:

- Research that is of minimal risk
- Non-therapeutic or non-interventional
- Research that will compromise the security, safety, and well-being of students shall not be allowed.

5.3.4. Undergraduate research classified to be involving more than minimal risk is submitted to CEU IERB with the Faculty Adviser as the principal investigator. The Faculty Adviser serves as the supervisor of the research and is responsible for the accountability and ethical conduct of the study.

5.3.5. Researches that do not involve human participants nor identifiable human tissue, biological samples, and human data are technically exempt from review, but will be subject to verification and approval at the level of the Chair.

5.3.6. Study protocols that do not meet the criteria for expedited review or exemption are classified under full board review.

5.3.7. In special cases, protocols may be forwarded by the Secretary to the Chair for classification.

5.3.8. The Secretariat Staff forwards the classified protocol submission to the Chair/Secretary for assignment of reviewers.

5.4. Review of protocols for exemption

5.4.1. The Overall Chair or his designee reviews and approve study protocols for exemption.

5.4.2. Exemption from ethical review is issued through a *CEU IERB Form 44.0 (2020) Certificate of Exemption from Ethics Review*.

5.4.3. Protocols that qualify for EXEMPTION are automatically archived and reclassified as INACTIVE, and protocol records will be made available by CEU IERB for three years from date.

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5.4.4. Exempted study protocols can be re-classified as expedited review at the level of the Chair within seven days upon receipt of protocol package.

5.4.5. Study protocols granted for exemption are exempt from further review including continuing review. Modifications that significantly affect previous risk-benefit assessment or qualification for exemption may be submitted as new protocol for initial review.

5.5.Assignment of Primary Reviewers

5.5.1 The Overall Secretary assigns one (1) scientific reviewer and one (1) non-scientific member as primary reviewers of the study protocol, if for Full Board Review. For Expedited Review, The protocol-related documents are forwarded to the Panels Chair. The Panel Chair chooses the primary reviewers. Reviewers are selected on the basis of their expertise. The scientific/medical reviewer is tasked to review technical soundness and related ethical issues while the non-scientific reviewer is tasked to review the informed consent process and forms.

5.5.2. Study protocols may be assigned to an independent consultant if there are no available experts among the regular members. In these cases, the Chair serves as the other scientific reviewer.

5.5.3. The Secretariat Staff notifies the primary reviewers for protocol assignments using *CEU IERB Form 18.0 (2020) Notice of Review*, within three working days from receipt of protocol submission.

5.5.4. The Primary reviewer acknowledges receipt of study protocol package for review and agrees to review within the time frame. Otherwise, the protocol will be re-assigned to another primary reviewer if there is no response within three days.

5.5.5. Study protocol review will be facilitated via e-mail for online review.

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5.5.6. The Secretariat Staff may forward the hard copy of the study protocol to the reviewers upon request.

5.5.7. The Secretariat Staff files one set of the study protocol package along with the CEU IERB letters in a properly coded Study protocol file folder and places it in the Active Study File cabinet.

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6. Glossary

- **Initial Submission** – a set of documents consisting of the full proposal and other study-related documents that need to be submitted so that review can be conducted.
- **Study Documents** – include all materials (protocol, forms, certificates, research tools) pertinent to a research proposal that have to be submitted to the REC for review.
- **Initial Review** – ethical and technical review conducted on the initially-submitted study documents. It may be expedited or full.
- **Amendment** – a change in /revision of the protocol made after its approval.
- **Coding** - a unique number assigned to a protocol indicating the year and series it was received.
- **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 and Signature of the Submitting Entity, Name and Signature of the Receiving Person and Action done.
- **Database** – a collection of information 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.
- **Exemption 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.
- **Full Review** – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval submissions, conducted by the research ethics committee en banc, in the presence of a quorum, using established technical and ethical criteria.
- **Expedited Review** – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission and after-approval

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submissions, conducted by only 2-3 members of the committee without involvement of the whole committee.

7. Forms

- CEU IERB Form 11.0 (2020) Review Checklist
- CEU IERB Form 12.0 (2020) Registration and Application Form
- CEU IERB Form 13.0 (2020) Study Protocol Assessment Form
- CEU IERB Form 14.0 (2020) Informed Consent Assessment Form
- CEU IERB Form 18.0 (2020) Notice of Review
- CEU IERB Form 19.0 (2020) Acknowledgement Letter
- CEU IERB Form 41.0 (2020) Submissions Log
- CEU IERB Form 44.0 (2020) Certificate of Exemption from Ethics Review
- CEU IERB Form 49.0 (2020) Study Protocol Database

8. History

Version No.	Date	Authors	Main Change

9. References

CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016

WHO Standards and Operational Guidance for Ethics Review of Health Related Research with Human Participants 2011

National Ethical Guidelines for Health and Health-related Research 2017

Philippine Health Research Ethics Board Standard Operating Procedures 2020

University of the Philippines Manila Research Ethics Board Standard Operating Procedures