1. **POLICY STATEMENT**

The ISU-IREB 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 NEGRIHP 2022 The Research Ethics Review Process Guideline 46. 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.”

1. **OBJECTIVES**

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

1. **SCOPE**

This procedure applies to all protocols submitted to the ISU-IREB for ethical review.

         The ISU-IREB accepts the following protocols for review: 1) DOST -funded

        research 2) DOH-funded research 3) Research of HEIs and/or 4) other private and public agencies conducting research provided the main or principal investigator or researcher is from Region 2. Acceptance of research proposals from other regions shall be subject to the discretion of ISU-IREB whether to accept the research proposal or not. The other research sites also agree to provide the necessary environment to ensure the safe and ethical conduct of the research, including oversight and stewardship functions as necessary as they agree to monitor procedures that the ISU-IREB may deem necessary. These conditions should be written in a document signed by other hospitals/ institutions accepting ISU-IREB review.

1. **WORKFLOW**

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| --- | --- | --- |
| **No** | **ACTIVITY** | **RESPONSIBILITY** |
| 1 | Receipt of study documents for initial review and determination of the completeness of submission | ISU-IREB Staff |
| 2 | Entry into the logbook | ISU-IREB Staff |
| 3 | Coding | ISU-IREB Secretariat |
| 4 | Determination of Type of Review  a.   Exemption from Review  b.  Expedited Review  c.   Full Review | ISU-IREB Chair |
| 5 | Preparation of a protocol folder | ISU-IREB Staff |
| 6 | Entry into the database | ISU-IREB Staff |

1. **DESCRIPTION OF PROCEDURES**
2. **Receipt of study documents for initial review and determination of the completeness of submission**

The IREB office is open from 8 am to 5 pm during Monday to Friday except holidays which theISU- IREB Staff accepts study documents. The ISU-IREB Staff checks the completeness of the documents based on the **FORM 6A REVIEW CHECKLIST**. If incomplete, the IISU-REB Staff informs the proponents of the missing documents.

The ISU-IREB Staff ensures that the **FORM 6B REVIEW APPLICATION FORM** with its Protocol Summary Sheet is completely filled-up, signed, and dated by the researcher.

The research proposal requires submission of Technical Clearance from the institution /agency where the research proposal originated and this should be attached to the study protocol submitted for ethical review.

Upon submission of the initial protocol for ISU-IREB review, the researcher/s or his/her representatives should ensure that the protocol follows the standard protocol format and contains a Protocol Summary / Synopsis in the **FORM 6B REVIEW APPLICATION FORM**.

**5.2 Entry into the logbook**

The ISU-IREB logbook is an official document of having received particular documents on a specific date and time. It includes information on (1) the title of the study, (2) the name of the researcher/s (3) the date of submission, (4) the name of the receiver, and (5) Action. It is also good to include the name and signature of the individual who actually submitted the documents in case s/he is not the proponent.

1. **Coding**

For efficient file management, it is necessary to use a unique identifier to refer to this file, The Protocol Code Number. This code number is given as follows: IREB YYYY (year)-number (00X) (chronological number based on the order of receipt).

Instruct the person submitting the package to inform the researcher to use the Protocol Code Number to identify the protocol in all submissions and in all his/her communications to the ISU-IREB.

1. **Determination of Type of Review**
2. **Exemption from Review**

The ISU-IREB Chair conducts a preliminary review of the protocol to determine whether it is Exempted from Review or for review as Expedited or Full.

If the ISU-IREB Chair decides that the protocol is exempted from review, s/he directs the ISU-IREB Staff to follow SOP 21 on Communicating ISU-IREB Decision to Researchers.

If the ISU-IREB Chair determines that the protocol should undergo either Full or Expedited review, then the ISU-IREB Staff proceeds to follow SOP 4. On Expedited Review or SOP 5. On Full Review.

• The following are some types of documents/research that may be exempt from the review:

1. Research about public behavior (voting trends, opinion surveys, etc.)
2. Evaluation of public programs by the agency itself

iii.  Quality control studies by the agency itself

iv.  Standard educational tests and curriculum development

v.   Surveillance function of DOH

vi.  Historical and cultural events

vii. Research involving large statistical data without identifiers

viii.  Research not involving humans or human data

ix.  Other studies deemed by ISU-IREB as exempt

• The following are some types of documents/research that may be expedited from the review:

1. Minimal/low-risk health research that requires personal information
2. About a topic that should not result in causing social stigma

iii.    Does not involve vulnerable populations

iv.    Retrospective studies using anonymized data from medical records

v.     Studies using simple questionnaires without identifiers

vi.    Laboratory research that uses anonymized human tissue/specimen

   A full-board review where the reviewers meet in quorum to deliberate on the protocol and make a decision may be about the following:

1. human health research involving medium to high risks to human participants
2. intervention studies involving experimental treatments like clinical trials
3. may involve vulnerable populations who should be protected
4. involves private information that may cause stigma

The Chair/Member-Secretary designates at least one ISU-IREB member to be the primary reviewer of the protocol regardless of whether the type of review is expedited or full board. Primary reviewers are selected on the basis of expertise related to the protocol.

The medical/scientific member analyzes the scientific and ethical aspects of the protocol using the FORM 6C PROTOCOL ASSESSMENT FORM while the non-medical member focuses on the FORM 6D ICF ASSESSMENT FORM

If the ISU-IREB membership does have the needed expertise, the Chair/Member Secretary chooses from the roster of IC. If none is available a consultant with the needed expertise is recruited as per SOP 3 on Appointment of Independent Consultants (IC).

1. **Preparation of a Protocol Folder**

        The timeline from receipt of a complete package to distribution to primary reviewers is within 7

        calendar days.

         The initial protocol review package consists of all the documents in the initial protocol package plus blank copies of the FORM 6C PROTOCOL ASSESSMENT FORM and FORM 6D ICF ASSESSMENT FORM, with the transmittal letter to the primary reviewers.

1. **Entry into the database**

After ensuring the completeness of the initial protocol package, log the pertinent data in the Log of Incoming Documents and in the digital protocol database – date and time of submission, ISU-IREB protocol code number, the full title of the study, and the full name of PI, type of document – initial protocol package, action – e.g. referred to Chair/Member-Secretary for determination of the type of review and designation of primary reviewers.

As soon as subsequent data is available, complete the required protocol details in the protocol database. For both the Log of Incoming Documents and the protocol database – add data on the type of review, the full name of reviewers, and the date and time the protocol review package was distributed to the primary reviewers. For the protocol database, add the date of the full panel meeting when the protocol is scheduled for deliberation.

Attach the FORM 6E INDEX PROTOCOL FILEand fill up with the name and version no. and date of the documents contained in the initial protocol package – protocol, ICF-English, ICF-local dialect (specify), case report form/data collection form, advertisement/IREB recruitment materials, budget, schedule of research activities, and curriculum vitae (CV) of PI and Co-I (if any) with their Certificate of GCP Training (if required), and date of submission.

File the properly labeled protocol file folder in the appropriate shelf of the storage cabinet for active study files taking note of the sequence of protocol code numbers on the file binders.

1. **GLOSSARY**

**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

**Database** – a collection of information that is structured and organized so that this can be easily assessed, 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 ISU-IREB Chair or a designated member of the committee regarding a submitted study proposal based on criteria in SOP 6 5.4A.

**Expedited Review** – is the ethical evaluation of a research proposal and other protocol-related documents, a resubmission, and after-approval submissions, conducted by only 1-2 members of the ISU-IREB without the involvement of the ISU-IREB.

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

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

**Initial Submission** – a set of documents consisting of the full proposal and other study-related documents that need to be submitted so that a 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 ISU-IREB for review.

**Technical Review** – the process of examining, assessing, or evaluating a research protocol by technical experts, seasoned researchers, statisticians, and other relevant specialists or authorities to ensure the scientific soundness and appropriateness of the objectives and design of the study and the qualifications of the researcher/s.

1. **FORMS**

FORM 6A REVIEW CHECKLIST

FORM 6B REVIEW APPLICATION FORM

     FORM 6C PROTOCOL ASSESSMENT FORM

     FORM 6D ICF ASSESSMENT FORM

     FORM 6E INDEX PROTOCOL FILE

**HISTORY OF SOP**

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| --- | --- | --- | --- |
| **Issue No.** | **Date** | **Authors** | **Main Change** |
| 0 |  | ISU-IREB SOP Team | - |
|  |  |  |  |

1. **REFERENCES**

2020 PHREB Workbook for Developing Standard Operating Procedures

2017 Department of Health Guidelines for Research Ethics Committee Standard Operating Procedure

2016 CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects

2011 WHO Standards and Operational Guidance for Ethics Review of Health-related

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| Prepared by: |  |
| Recommending Approval: |  |
| Approved by: |  |
| Approval Date: |  |