1. **POLICY STATEMENT**

To describe the procedures of ISU-IREB when the protocol resubmissions are received.

This will serve as a guide to the ISU-IREB in the management of resubmissions including the determination of the level of review and the required timeline,

The ISU-IREB shall require resubmission of a protocol that requires either minor or major modification/s not later than 4 weeks after receipt of the Decision Letter. Minor modifications shall undergo expedited review while major modifications shall undergo full review.

1. **OBJECTIVES**

Management of resubmissions ensures that the researchers addressed the required modifications before approval of the protocol.

1. **SCOPE**

This procedure applies to the ISU-IREB review and approval of the study protocols recommended for minor or major modifications during the initial and continuing review.

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

1. **WORKFLOW**

|  |  |  |  |
| --- | --- | --- | --- |
| **No.** | **Activity** | **Person(s)**  **Responsible** | **Timeline** |
| 1 | Receipt and Entry in the Logbook | ISU-IREB Staff | Within       20 working  Days |
| 2 | Coding     of      Resubmitted      Protocol Documents | ISU-IREB Staff |
| 3 | Notification of the Chair and Reviewers | ISU-IREB  Chair and staff |
| 4 | Review of the Resubmission   1. Expedited Review 2. Full Review | ISU-IREB Primary  Reviewers |
| 5 | Communication of Decision | ISU-IREB Staff |
| 6 | Filing of Documents in the protocol file  folder  and  update  of  the protocol database | ISU-IREB Staff |

1. **DESCRIPTION OF PROCEDURES**

**5.1 Receipt and Entry in the Logbook**

The ISU-IREB Staff receives documents, checks the nature of the document, and ensures that the submission is properly logged.

1. **Coding of Resubmitted Protocol Documents**

The ISU-IREB Staff indicates the code assigned to the protocol when it was initially submitted and the date of receipt on all the documents.

1. **Notification of the Chair and Reviewers**

The ISU-IREB Staff retrieves the FORM 5C DECISION LETTER that pertains to the original protocol and informs the Chair about the resubmission and the nature of the modifications required from the researcher. Given the necessary information, the Chair either evaluates the resubmitted protocol at his/her level or directs the ISU-IREB staff to inform the reviewers concerned and forward to them the necessary documents.

1. **Review of the Resubmission**

     The assigned reviewers conduct a review of the resubmitted protocol by referring to the resubmission form noting the different recommendations made by the ISU-IREB and evaluating whether these were satisfactorily addressed in the resubmitted protocol. The reviewers submit the report to the Chair for inclusion in the next regular meeting.

**5.4 Communication of Decision**

For Resubmissions approved at the level of the ISU-IREB Chair, the Chair dictates his/her decision to staff for preparation of the draft letter, finalization, and sending to the researcher. For the resubmissions that underwent Full Review, refer to SOP 21 Communicating ISU-IREB Decision.

**5.5 Filing of Documents in the protocol file folder and update of the protocol database**

The ISU-IREB Staff gathers all the pertinent documents related to the resubmission and enters the relevant information on resubmission in the appropriate protocol database.

1. **GLOSSARY**

**Logbook** – a real-time chronological record of incoming protocols that include the Date/Time 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.

**Protocol Database** – contains significant information about protocols that are organized systematically so that these can be easily accessed, managed, interpreted, analyzed, and updated. It is usually in an electronic platform used for tracking and monitoring the implementation of a study.

**Resubmission** – the revised study proposal that is re-forwarded to the ISU-IREB following     the recommendations from the initial review.

1. **FORMS**

FORM 7A RESUBMISSION FORM

FORM 5C DECISION LETTER

1. **HISTORY OF SOP**

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

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

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