1. **Policy Statement**

*All communications shall be recorded accurately and appropriately in a physical log book and electronic database. Protocol-related communications are separated from non-protocol-related like administrative communications.  Incoming communications shall be acted upon promptly*

***2. Objective of the Activity***

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

**3. Scope**

*This SOP covers IREB actions related to organizing incoming and outgoing documents and ensuring an appropriate IREB response. This SOP begins with the sorting of incoming/outgoing communications and ends with the storing or filing of incoming/outgoing communications. The policy of document management shall be “First in, first out“ policy.*

**4. Workflow**

The following are the different steps involved in managing IREB incoming and outgoing communications with the corresponding persons responsible in each of these steps:

|  |  |
| --- | --- |
| ***ACTIVITY*** | ***RESPONSIBILITY*** |
| *4.1.  Sorting of incoming/outgoing communications* | *IREB Staff* |
| *4.2. Recording of incoming/outgoing communications* | *IREB Staff* |
| *4.3. Acting on incoming communications* | *Chair or Member Secretary* |
| *4.4. Filing of incoming/outgoing communications and updating of respective Databases* | *IREB Staff* |

***5. Description of Procedures***

*This review process shall be within one (1) month after the submission of the research proposal.*

**Step 5.1 - Sorting of incoming/outgoing communications**:

All communications received by the IREB shall be classified accordingly, e.g., letters, official memoranda, emails, among others. Likewise, the IREB shall separate communications from researchers, sponsors and regulators. Protocol-related and process-related communications shall be segregated and arranged according to the date and time they are received by the IREB Office. Communications whether protocol-related or process-related shall be evaluated as to the urgency of the communication. The one in charge of this step and overseeing the process shall be the secretariat and the Secretary of the IREB.

**Step 5.2 - Recording of incoming/outgoing communications**:

The IREB shall record the incoming/outgoing communications. They shall be recorded in a logbook that documents the date received, sources (i.e. person who sent the communications, and the agency/office. The logbook shall contain, the following: the person who sent the communication, the subject, the person who received the communication, and action taken with details of who received it from the IREB. The Administrative Clerk is the person responsible for this process.

**Step 5.3 - Acting on communications**: The Secretary is responsible for initiating the response on incoming communications. The Secretary finalizes these responses with the approval of the Chair of the IREB. The Chair of the IREB shall be the usual signatory for all outgoing communications.

**Step 5.4 - Storing or filing of incoming/outgoing communication**:

**The IREB office shall provide steel cabinets for the storage of the incoming and outgoing communications**. The IREB shall practice filing of communications (e.g. protocol-related communications and non-protocol related) based on the description of the documents, i.e., the study protocol file and the non-protocol-related documents should be filed in separate and appropriate administrative files in the steel cabinet. The IREB shall use an indexing system for file of communications. Index cards shall be used as control reference files. The Administrative Clerk shall be responsible for this process.

***6. Glossary***

The terms/abbreviations used in this SOP:

***Incoming Communications*** *– are documents which are directed to and received at the IREB office.*

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

***Administrative Documents*** *- documents that pertain to the operations of the*

*IREB and are not directly related to a study or protocol. Examples include the SOPs, Membership files, Agenda and minutes files, and administrative issuances.*

***Protocol-related File/Documents*** *- consist of all other documents aside from*

*the proposal/protocol itself that are required to be submitted for review, e.g., Informed Consent Form, Survey Questionnaire, CV of proponent, advertisements, In-depth Interview Guide Questions Indexing System.*

***7. Forms***

*The following forms/templates/tools are used in the implementation of this SOP:*

Logbook for Incoming Communications

Logbook for Outgoing Communications

Group H SOP 22 Protocol File Index

***8. History of SOP***

|  |  |  |  |
| --- | --- | --- | --- |
| ***Version No.*** | ***Date*** | ***Authors*** | ***Main Change*** |
| *0* |  | *Generaldo D. Maylem, MD* | *First Draft* |

***9. References***

*1. WHO Standards and Operational Guide for Ethics Review of Health-Related Research with Human Participants 2011*

*2.  CIOMS International Ethical Guidelines for Biomedical Research Involving Human Subjects 2016*

*3. Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*4. Philippine National Ethical Guidelines for Research Involving Human Participants 2022*

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| --- | --- |
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