1. **Policy Statement**

It is the responsibility of the IREB to keep particular documents in its custody confidential. This is to protect the intellectual property rights of research proponents and to protect IREB members from unnecessary scrutiny and pressure from non-authorized individuals. Confidential, privileged and proprietary identifiable documents entered into a database system are subject to protections under the Data Privacy Act of 2012, any written information provided to the IREB that is of a confidential, privileged, or proprietary in nature shall be identified accordingly. Written information provided for review shall not be copied or retained. All confidential information (and any copies and notes thereof) shall remain the sole property of the IREB. Further, the IREB agrees not to disclose or utilize, directly or indirectly, any information belonging to a third party, in fulfilling this agreement.

As such, the IREBagrees to hold in trust and in confidence all confidential, privileged or proprietary information, including trade secrets and other intellectual property rights (hereinafter collectively referred to as the “information”). Moreover, they agree that the information shall be used only for contemplated purposes and none other. Neither shall the said information be disclosed to any third party.

Confidential files include study protocol-related documents (e.g. protocols, case report forms, informed consent documents, scientific documents, expert opinions or reviews), meeting minutes, decisions, action letters/notification of committee decision, approval letters, and study protocol-related communications. Generally, institutions have in-house policies or standards to promote confidentiality of institutional files. IREBs must make an effort to be familiar with these policies and procedures so that these can be adopted by the IREB.

For example, access to the IREB confidential files shall be regulated and limited to IREB members and staff.  Other persons with legitimate interest in these files (e.g. institutional authorities, regulatory agencies, sponsors) shall be allowed to access specific files with proper justification. Researchers/Investigators shall be allowed access only to their own protocol files upon request.

1. **Objectives of the Activity**

Management on the access of any information deemed confidential, privileged, or proprietary provided to and/or otherwise received by members of the IREB will help protect the intellectual property rights of researchers and enhances the credibility and integrity of the IREB.

The objective is to institutionalize management of access to confidential files helps protect the intellectual property rights of researchers and enhances the credibility and integrity of the IREB.

1. **Scope**

This SOP provides instructions for accessing including document handling and distribution to maintain confidentiality of all study files and documents. This SOP begins with the receipt of the request to access and ends with the return of the documents to the protocol folder.

**4. Workflow**

Only the Chair and the member secretary can approve requests for access anf retrieval of documents.

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| ***ACTIVITY*** | ***RESPONSIBILITY*** |
| 1: Receipt and logging of request for access to confidential files | ISU-IREB Staff |
| 2: Approval of requests for access and retrieval of documents | Member Secretary or Chair |
| 3: Supervision of use of retrieved document | Staff |
| 4: Return of document to the files | Staff |

1. **Description of Procedures**

Access to confidential files must undergo the following procedure:

**5.1 - Receipt and logging of request for access to confidential files**: The staff receives the request (Form 25A) to access specific files and refers this to the Chair or Member Secretary for approval.

**5.2 - Approval of requests for access and retrieval of documents**: The Chair or Member Secretary considers the indicated reason for the request and when found satisfactory approves it.  The staff asks the individual requesting to sign the confidentiality agreement and proceeds to retrieve the pertinent document.

**Step 3 - Supervision of use of retrieved document**: The staff asks the user to sign the logbook, enforces the restriction to room-use of documents and limits photocopying to concerned researchers/principal investigators. The staff should maintain record copies made of confidential documents

**Step 4 - Return of document to the files**: The staff will evaluate the returned files and when found satisfactory returns the retrieved files to the protocol file.

1. **Glossary**

**Confidentiality** - is the duty to refrain from freely disclosing private/ research information entrusted to an individual or organization.

**Study-related Communications** – documents that refer to an exchange of information or opinions regarding a study, usually between the IREB and the researcher.

**Sponsor**- an individual, company, institution or organization which takes responsibility for the initiation, management, and financing of a clinical trial.

**Intellectual property** –refers to intangible creations of the human mind (such as inventions, literary and artistic works, designs, and symbols, names and images used in commerce, that are considered as owned by the one who thought of it.  Intellectual property includes information and intellectual goods.

**Intellectual property right** – the exclusive right given to persons over the use of the creations of his/her mind for a certain period of time.

**Meeting Minutes** – narration of the proceedings of the assembly of IREB   members.

**Regulatory Authorities** – refer to government agencies or institutions that have oversight or control over the conduct of research, e.g., Department of Health, Food and Drug Administration, Research Institutions.

**Conflict of Interest** -a situation in which aims or concerns of two (primary and secondary) different interests are not compatible such that decisions may adversely affect the official/primary duties.

**Anonymization** – process of removing the link between the research participant and the personally identifiable data, in such a way that the research participant cannot be determined nor traced.

**Room-use Restriction** – the rule that limits the use of a document within the designated premises.

1. **Forms**

Form 25A Request Form

Form 25B Log of Requests

Form 25C Log of Access

1. **History of SOP**

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

1. **References**

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

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

*Philippine Health Research Ethics Board Standard Operating Procedures 2020*

*National Ethical Guidelines for Research Involving Human Participants 2022*

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| Recommending Approval: |  |
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