TITLE	MANAGEMENT OF ACCESS TO CONFIDENTIAL FILES
POLICY STATEMENT	Access to confidential files maintained by the Research Ethics Board (REB) shall be strictly regulated to ensure the protection of sensitive information and to uphold ethical and institutional standards. Only authorized individuals shall have access to these files. REB members and designated REC Secretariat staff shall be granted full access to confidential documents strictly for the performance of their official duties. These individuals are required to observe the highest level of confidentiality and must comply with institutional confidentiality agreements and policies. Researchers or principal investigators shall be permitted access only to their own protocol files upon written request. This access is limited to documents relevant to their own submissions, including decision letters, correspondence, and reviewer comments when applicable. External parties, such as institutional authorities, regulatory agencies, and sponsors, may be granted access to specific files only upon submission of a formal request that includes a valid justification for the access. Such requests must be reviewed and approved by the REB Chair or an authorized designate, and may be subject to additional confidentiality agreements. Temporary access, such as for auditors or consultants, must be time-limited, task-specific, and supervised by REB staff, with confidentiality agreements signed as appropriate. All confidential files shall be securely stored, whether in physical or electronic formats, with access limited to authorized users only. Any unauthorized access or breach of confidentiality must be reported immediately to the REB Chair and will be subject to investigation and appropriate corrective action. The REB shall maintain an access log documenting all instances of external or exceptional access to confidential files, including the identity of the requester, purpose and duration of access, and the staff member overseeing the process. This policy ensures that all access to confidential information is managed responsibly and transparently, in alignment with ethical obligations and institutional requirements.
OBJECTIVE OF THE ACTIVITY	To ensure the secure, ethical, and transparent management of access to confidential files maintained by the Research Ethics Board (REB). It aims to protect sensitive information, uphold the intellectual property rights of researchers, and maintain the integrity and credibility of the REB. This SOP establishes clear procedures for granting access only to authorized individuals with legitimate reasons, in compliance with institutional and legal standards. It also promotes accountability by requiring proper documentation and supervision of all access requests. Overall, this SOP

	supports responsible information handling while enabling efficient and consistent REB operations.
SCOPE	This covers all procedures and activities related to the management and control of access to confidential files maintained by the Research Ethics Board (REB). It applies to REB members, REB Secretariat staff, researchers, institutional authorities, regulatory bodies, sponsors, and any other individuals or entities who may request access to such files. The SOP outlines the steps involved from the moment a formal request for access is received, through the evaluation and approval process, up to the supervised review or release of documents, and finally the secure return and reintegration of the files into the appropriate protocol folder. It includes detailed procedures for document handling, distribution, access authorization, supervision, and documentation of access. This SOP also covers both physical and electronic records, ensuring secure storage, restricted access, and proper logging of all activities related to confidential files. It is intended to ensure that all access is justified, traceable, and conducted in accordance with ethical, legal, and institutional requirements.

Workflow

STEP	ACTIVITIES	RESPONSIBILITY	INTERFACE
1	Receipt and logging of request for access to confidential files	STAFF SECRETARY	
	↓		
2	Approval of requests for access and retrieval of documents	MEMBER SECRETARY OR CHAIR	
	↓		
3	Supervision of use of retrieved documents	STAFF SECRETARY	
	↓		
4	Return of document to the files	STAFF SECRETARY	

Description of Procedures

Step 1 - Receipt and logging of request for access to confidential files: All requests for access to confidential files must be submitted in writing using the designated Confidential File Access Request Form. Upon receipt, the staff secretary verifies the completeness of the form and forwards it to the appropriate authority, such as the Chair or Member Secretary, for review. The request is then logged in the Confidential File Access Log, capturing essential details including the requestor's name, requested information, date received, and current status. An acknowledgment of receipt is sent to the requestor. The approving authority evaluates the

request based on the purpose, level of access required, and data sensitivity. All records of requests and decisions are securely stored and retained in accordance with the organization's records management policy.

Step 2 - Approval of requests for access and retrieval of documents: Upon receiving a properly completed request form for access to confidential files, the staff forwards it to the Chair or Member Secretary for evaluation. The approval process considers key requirements, including the authority or role of the requesting individual, the stated reason for the request, and the relevance of the requested information. The Chair or Member Secretary reviews the justification provided and, if found satisfactory and aligned with confidentiality protocols, grants approval. Following this, the staff contacts the requester and requires them to sign a Confidentiality Agreement to formally acknowledge their responsibility in handling sensitive information. Once the agreement is signed, the staff proceeds with retrieving the pertinent confidential documents as specified in the approved request. The access granted is strictly limited to the information indicated in the request, and the retrieval process is carried out in a secure and controlled manner to maintain confidentiality. All actions, including the approval, signing of the confidentiality agreement, and retrieval of documents, are recorded in the Confidential File Access Log to ensure accountability and compliance with data protection standards.

Step 3 - Supervision of use of retrieved documents: Once access to confidential files has been approved and the documents are retrieved, the Research Ethics Board (REB) ensures proper supervision of their use to maintain the integrity and confidentiality of the information. Before accessing the documents, the user is required to sign the Confidential File Access Logbook to formally acknowledge receipt and responsibility for the use of the material. The REB staff Secretary strictly enforces a room-use policy, meaning that the documents must be reviewed within a designated secure area and are not allowed to be taken outside this space. To further protect the confidentiality of the files, photocopying is not permitted except in cases where it is deemed necessary for ongoing research, and only authorized individuals such as the principal investigator or concerned researchers may be allowed to request copies. These requests are subject to additional review and must be justified in line with the approved purpose of access. Throughout the process, the REB staff secretary monitors the user's handling of the documents, ensuring compliance with the confidentiality agreement and preventing unauthorized use or disclosure of information.

Step 4 - Return of document to the files: Who is responsible in ensuring that the document is returned to the proper file? The staff secretary returns the retrieved files to the protocol file.

Glossary

What terms/abbreviations used in this SOP need to be defined for effective implementation? Examples:

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 REB 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 REB 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.

Forms

Request Letter
H01-01 Logbook of Outgoing Communications
H02-01 Logbook of Protocol Submission
H03-01 Protocol Folder Index

History of SOP

Version No.	*Date*	*Authors*	*Main Change*
1	*2025 Mav 15*	*MVJapitana*	*First draft*

References

Republic Act No. 9470 (RA 9470)

2. *Implementing Rules and Regulations (IRR) of RA 9470*

3. *General Records Disposition Schedule (GRDS) issued by NAP*

4. *BOR Approved Administrative and Finance Manual incorporating the Records Management Manual*

5. *OP Memorandum No. 30, s. 2024 Inclusion of Records Inventory Report and Records Management Table Submission in the Office, Division and Individual Performance Commitment and Review Form*

6. *SD-DRC-01 University Records Disposition Schedule*

7. *PR-DRC-02 Control of External References Procedures*

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