
	University of the Philippines Diliman COLLEGE OF HOME ECONOMICS RESEARCH ETHICS COMMITTEE	UPCHE REC SOP 23/03 Approval Date: 07-Oct-2024 Effective Date: 04-Nov-2024
	SOP 23. Management of Active Files	

Supersedes:	02
Version:	03
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	(Adapted from UPMREB SOP and 2020 PHREB SOP Workbook)
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23.1. Policy Statement

The UPCHE REC shall keep active files in a secured cabinet, arranged in an orderly manner that facilitates easy identification and retrieval. Access to the active files shall be governed by SOP on Management of Access to Confidential Files (SOP 25).

23.2. Objective

This SOP aims to ensure accessibility, easy retrieval of current files, and protection of active files that require confidentiality through proper management.

23.3. Scope

This SOP covers implemented procedures for protocols that are accepted for review, undergoing review, or approved by the REC. This SOP begins with the classification and coding of active files and ends with the periodic updating of the files.

23.4. Workflow for Management of Active Files (3 working days)


	ACTIVITY	PERSON RESPONSIBLE	TIMELINE*
1	Classifying and coding active files	Secretariat (Administrative and Member Secretary)	1
2	Preparation of protocol folder	Administrative Secretary	1
3	Updating the protocol file and database	Administrative Secretary	1

*working days

23.5. Description of Procedure

23.5.1. Classifying and coding active files:

- a. Active files are study protocols that have been received by the Administrative Secretary and are either undergoing review (full or expedited) or approved by the REC.
- b. The Administrative Secretary under the supervision of the Member Secretary classifies active files as follows:
 - Initial Submission
 - Resubmission
 - Progress Reports
 - Amendments
 - Protocol Deviation/ Violation Reports
 - SAE, SUSAR and RNE Reports
 - Early Termination Report
 - Application for Continuing Review


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- Final Report
- c. The Administrative Secretary assigns a code to the Initial Submission and indicates the same for the rest of the submissions related to the initial submission. Active study files are coded as **YYYY-NNNN**, where YYYY represents the year and NNNN represents sequential study protocol number (as received by the Administrative Secretary).
 - d. Study files are encoded into the Study Protocol Database. The elements included in the databases are summarized:

Database	Elements/Content
Study Protocol Database	UPCHE REC Code, Date Received, Study Title, Principal Investigator, Investigator Category, Study Category Type of Study, Endorsing College/Institution, Use of Special Populations or Vulnerable Groups, Funding Agency, Type of Review, Primary Reviewers, Dates of Meeting, Date of Approval, Resubmission, Due Date of Progress Report, Dates of Onsite SAE/SUSAR Reports, Final report status, Date of Inactivation, Status
Sub-database:	
Principal Investigators database	Name, Sex, Birthday, Institution, College/Unit, Department, Telephone, Mobile, Fax No., Email Address, Highest Educational Attainment, School, Specialization, Sponsors, Declaration of Conflict of Interest of PI
Reviewers database	Reviewer No., Name, Home Address, Mailing Address, Contact Number, Institution, Birthday, Date of Appointment, Classification, Area of Expertise, Ethics or GCP Trainings Attended
Onsite Serious Adverse Events/SUSAR/RNE Database	Report No., Event No., UPCHE REC Code, Date of Submission of AEU, Date of AE, Type of Report, Reporter's Name, Patient Initials, Country, Date of Birth, Age, Sex, Narrative of the AE, Suspected drug, Dose of drug, Route of administration of drug, Concomitant Drugs, Dose of Concomitant Drugs, Comorbidities, Causality, Nature of SAE Action, Outcome
Offsite Serious Adverse Events/SUSAR Database	Date of Report, Date Received, SAE, SAE count, Nature of each SAE
Institution and Study Site Database	Name, Classification, Address, Telephone Number, Fax, Email Address, Website, Administrator

23.5.2. Preparation of protocol folder:

- a. For submissions with hard copies of the protocol, the Administrative Secretary files all documents pertaining to a study in a vertical folder that is labeled on the front cover and along the spine with: Protocol Code- Study Title - Proponent's Family Name - Sponsor or Funding Agency.

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- b. The Administrative Secretary attaches a protocol index on the inside front cover that indicates the contents of the folder.

Study file folder contains the following documents, as applicable:

1. Index
 2. Initial Submission:
 - a. Original study protocol
 - b. Related documents that came with the study protocol
 - c. Principal investigator and co-investigators' CVs and other similar documents
 - d. Reviewers' assessment forms (Protocol and ICF)
 - e. Action in the form of excerpts from minutes
 - f. Approval letters
 - g. Action Letter/Notification of UPCHE REC Decision
 3. Resubmission
 - Resubmitted study protocol
 - Reviewers' assessment forms (Protocol and ICF)
 - Action in the form of excerpts from minutes
 - Approval letters
 - Action Letter/Notification of UPCHE REC Decision
 4. Post-approval Reports
 - Amendment reports
 - Continuing review applications
 - Serious Adverse Event Reports or Safety Notifications etc.
 - Final report
 - Action in the form of excerpts from minutes (for post-approval reports)
 - Notification of PI
- c. For online or submissions via email, the Administrative Secretary files all documents pertaining to a study in a folder that is labeled with: Protocol Code-Study Title - Proponent's Family Name. Contents of the folder are the same for hard copy and soft copy of protocols.

23.5.3. Updating the protocol file and database:

- a. The Administrative Secretary secures the documents and ensures that these are filed in reverse chronological order such that the most recent versions are topmost. The protocol index is updated every time a new document is added to the file. For electronic files, the filing is in chronological order. The following documents are included:
 - i. Protocol (Original and Revised) versions
 - ii. Informed consent (Original and Revised) versions
 - iii. Reports: Progress, Protocol Deviation/Violation, SAE/SUSAR, Final, Amendment, Early Termination, Site Visit Reports
 - iv. Assessment Forms for each of the submitted and reviewed reports which should be signed and dated
 - v. Excerpts of Minutes of Meetings when the protocol and reports were included in the agenda

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- vi. Decision and Approval Letters
- vii. Communications


- b. The Administrative Secretary maintains individual Active Files cabinets under the supervision of the Member Secretary.
- c. With approval from the Chair, the Administrative Secretary maintains a back-up file of the electronic database. It is stored in an external hard drive and kept in a fixed and secure place. Only the Chair and the Administrative Secretary may have access to the back-up file.
- d. The Administrative Secretary periodically updates the database as new files are added to the protocol folder.

23.6. Forms

For this SOP, all UPCHED REC forms will be utilized especially in updating information in the various databases.

23.7. Document History

Version No.	Date	Authors	Main Change(s)
01		Maria Patricia V. Azanza, Ph.D. Joanne R. Bantang, Ph.D. Cecile Leah T. Bayaga, Ph.D. Kristyn T. Caragay Charla Rochella S. Saamong Mary Anne Ramos-Tumanan, Ph.D. Casiana Blanca J. Villarino, Ph.D. Fredelyn S. Gascon	First draft
02	04 December 2020	Maria Patricia V. Azanza, Ph.D. Joanne R. Bantang, Ph.D. Cecile Leah T. Bayaga, Ph.D. Kristyn T. Caragay Charla Rochella S. Saamong Mary Anne Ramos-Tumanan, Ph.D. Casiana Blanca J. Villarino, Ph.D. Fredelyn S. Gascon	References: Removed the list of references from this SOP and collated all references used for the entire SOP into one section.
02	18 November 2022	Maria Patricia V. Azanza, Ph.D. Joanne R. Bantang, Ph.D. Cecile Leah T. Bayaga, Ph.D. Kristyn T. Caragay Marian Michelle D. Navales Mary Anne Ramos-Tumanan, Ph.D. Casiana Blanca J. Villarino, Ph.D. Fredelyn G. Tolete	Revised the SOP right header box to include a simplified SOP code and added date of approval Updated 6.2 pertaining to the contents of a study file and its filing.
02	04 August 2023	Maria Patricia V. Azanza, Ph.D. Joanne R. Bantang, Ph.D. Cecile Leah T. Bayaga, Ph.D. Kristyn T. Caragay	Added timeline (in working days) for each step in the Workflow

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		Ma. Leonora dL Francisco, Ph.D. Adelaida V. Mayo, Ph.D. Edgar G. Belda Jr. Mary Anne Ramos-Tumanan, Ph.D. Casiana Blanca J. Villarino, Ph.D. Fredelyn G. Tolete	Reformatted numbering of the sections to follow the SOP number (e.g., 3.1. Policy Statement) Changed from SOP 22 to SOP 23 after SOP on Review of Progress Report was added to the SOPs for post approval.
03	13 March 2024	Prof. Emeritus Maria Patricia V. Azanza Mary Anne Ramos-Tumanan, Ph.D. Joanne R. Bantang, Ph.D. Cecile Leah T. Bayaga, Ph.D. Kristyn T. Caragay Ma. Leonora dL Francisco, Ph.D. Adelaida V. Mayo, Ph.D. Edgar G. Belda Jr. Casiana Blanca J. Villarino, Ph.D. Fredelyn G. Tolete	The order and content of the study protocol database was revised. It was indicated clearly that the filing of hard copies of protocol files is in reverse chronological order while electronic files are filed in chronological order.
03	08 July 2024	See updated list of authors	Updated the list of authors to include all regular members following the change in membership of the UPCHE REC.