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|  | University of the Philippines Diliman COLLEGE OF HOME ECONOMICS RESEARCH ETHICS COMMITTEE | UPCHE REC SOP 25/03 |
| | SOP 25. Management of Access to Confidential Files | Approval Date: 07-Oct-2024 Effective Date: 04-Nov-2024 |

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|----------------|---|
| Supersedes: | 02 |
| Version: | 03 |
| Authored by: | <div> Mary Anne R. Tumanan, Ph.D. Cecile Klaudine C. Cabigas, RND Joanne R. Bantang, Ph.D. Merilyn Barrameda B. Berdin Kristyn T. Caragay Ma. Leonora dL Francisco, PFT, Ph.D. Maria Asuncion M. Hije John Limwelle P. Lectura, RPm Loriezel P. Lectura Adelaida V. Mayo, Ph.D. Charla Rochella S. Saamong Sofia Belen A. Sarte Ronilyn M. Tamayo, RND Casiana Blanca J. Villarino, PFT, Ph.D. </div> <div> Maria Fema S. Aquino, Ph.D. Airisae Rae P. Basinang, PFT Consuelo T. Chua, Ph.D. Miriam I. Ugaddan Josephine Louise F. Jamero Maria Josephine T. Lumawig Michael A. Magcamit Darwin M. Malabanan Jin Mark D.G. Pagulayan, PFT Joseph G. Taluban Jr. Maria Carmela C. Taob, RND Lorena W. Tengco, RND Fredelyn G. Tolete </div> <div> <i>Previous REC Members:</i> Maria Patricia V. Azanza, Ph.D. Cecile Leah T. Bayaga, Ph.D. Lilibeth J. Baylosis Edgar G. Belda Jr. Kathleen Keisha R. Constantino Bless Lorraine T. Desabelle </div> <div> Johanna Victoria A. Faustino Marian Michelle D. Navales Maria Monica E. Rayala Rowena Grace R. Sanchez Rev. Fr. Jose S. Tupino III </div> |
| | (Adapted from UPMREB SOP and 2020 PHREB SOP Workbook) |
| Endorsed by: | Mary Anne R. Tumanan, Ph.D. Chair, UPCHE REC |
| Date: | |
| Approved by: | Shirley V. Guevarra, Ph.D. Dean, College of Home Economics University of the Philippines Diliman |
| Approval Date: | |

UNIVERSITY OF THE PHILIPPINES COLLEGE OF HOME ECONOMICS
RESEARCH ETHICS COMMITTEE
Rm 217, 2nd Floor, College of Home Economics
Ma. Regidor St, UP Diliman, Quezon City 1101
Telephone: +63 2 9818500 local 3407; Email: upcherec.upd@up.edu.ph

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25.1. Policy Statement

Access to REC confidential files shall be regulated and limited to REC members and staff. Individuals or non-members 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.

25.2. Objective

Proper management of confidential files in the REC aims to ensure protection of the intellectual property rights of researchers and simultaneously enhance the integrity of the REC.

25.3. Scope

This SOP includes procedures for accessing confidential files including document handling and distribution. This SOP begins with the receipt of the request to access and ends with the return of the documents to the protocol folder.

25.4. Workflow for Management of Access to Confidential Files (5 working days)


| | ACTIVITY | PERSON RESPONSIBLE | TIMELINE* |
|---|---|---------------------------|-----------|
| 1 | Receipt of request for access to confidential files | Administrative Secretary | 1 |
| 2 | Approval of request for access and retrieval of documents | Member Secretary or Chair | 2 |
| 3 | Supervision of the use of retrieved document | Administrative Secretary | 1 |
| 4 | Return of the document to the files | Administrative Secretary | 1 |

*working days

25.5. Description of Procedure

25.5.1. Receipt of request for access to confidential files:

- The Administrative Secretary receives requests for access to confidential REC files and records all requests in the Log of Request for Copies of Documents (Form 40).
- The UPCHE REC considers the following as confidential:

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- i. Study protocols
- ii. Study protocol-related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)
- iii. Meeting Minutes
- iv. Decisions, action letters/notification of UPCHE REC decision, approval letters
- v. Study protocol-related communications
- vi. Membership files

25.5.2. Approval of request for access and retrieval of documents:

- a. The Chair or Member Secretary assesses the reason for the request and approves it if found legitimate and satisfactory.
- b. The Administrative Secretary asks the individual requesting access to the files to sign the confidentiality agreement and proceeds to retrieve the pertinent document.
- c. Non-members can access specific documents upon formal request and completion/signing of Form 41 [Confidentiality Agreement for Nonmembers]. The form requires the approval of the Chair.
- d. Regulatory authorities have access to UPCHE REC files provided it is within the mandate of the said authority, and upon reasonable notice to make the files available.
- e. All REC members and Administrative Secretary with a signed Form 2 [confidentiality agreement and conflict of interest disclosure] can have access to UPCHE REC confidential documents upon request.

25.5.3. Supervision of the use of retrieved document:


- a. The Administrative Secretary asks the user to sign the logbook and enforces the restriction to room-use of documents. For soft copies, the requested copies will be sent to the REC members via email.
- b. The Administrative Secretary makes only the exact number of copies requested.

25.5.4. Return of the document to the files:

- a. The Administrative Secretary returns the retrieved documents to the proper file. Physical files are kept in cabinets in the REC office with a lock and key.
- b. The Secretariat (Member Secretary and Administrative Secretary) hold the keys to the locks.
- c. On the other hand, electronic files are password-protected and are stored in a computer inside the REC office

25.6. Forms

For this SOP, the following form(s) were utilized:

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- Form 2: Confidentiality Agreement and Conflict of Interest Disclosure
- Form 40: Log of Request for Copies of Documents
- Form 41: Confidentiality Agreement for Non-Members

25.7. 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 |
| 02 | 11 August 2023 | Maria Patricia V. Azanza, 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. Marian Michelle D. Navales Mary Anne Ramos-Tumanan, Ph.D. Casiana Blanca J. Villarino, Ph.D. Fredelyn G. Tolete | Added timeline (in working days) for each step in the Workflow Reformatted numbering of the sections to follow the SOP number (e.g., 3.1. Policy Statement) Changed from SOP 24 to SOP 25 after SOP on Review of Progress Report was added to the SOPs for post approval. |
| 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. |