

	University of the Philippines Manila RESEARCH ETHICS BOARD	UPMREB SOP 004/04-0-2012 Effective Date: 06 April 2022
	IV. DOCUMENTATION & ARCHIVING	

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1. Objectives

This SOP describes how the UPMREB manages documentation and communication of review, such as how the minutes of the meetings are to be prepared, used, distributed, and filed; how to ensure proper completion, distribution, and filing of written study protocol- or review-process-related communication, how administrative records and UPMREB administrative documents (exclusive of study protocol files) are processed, stored, or disposed of; how active and inactive or archived study protocol files are maintained, including their amendments and/or modifications; and how to handle original documents and copies of documents in order to protect confidentiality of documents.

2. Scope

This SOP is applicable to regular review panels, to minutes of the meeting, all communication records related to study protocols with UPMREB approval or undergoing UPMREB review; to administrative documents, active study protocol files, and inactive study protocol files that are retained or archived for at least three (3) years after completion of the research so that the records are accessible for auditors and inspectors. This SOP applies to all kinds of handling, distribution, and storage of submitted study protocols, UPMREB documents, and correspondences.

3. Responsibilities

The Technical Secretariat Staff, under the supervision of the Panel Secretary, has the primary responsibility for study protocol and administrative documentation and archiving in respective panels. The Panel Chair is responsible for final approval of documents.

4. Minutes of the Meeting Workflow

ACTIVITY	RESPONSIBILITY
Prepare the template of the Minutes of the Meeting ↓	Review Panel Staff
Prepare draft of Minutes ↓	Review Panel Staff
Approve the draft Minutes ↓	Review Panel Staff
Approve the Minutes of the previous meeting ↓	Panel Members
Store the approved final Minutes of the Meeting	Review Panel Staff

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DETAILED INSTRUCTIONS

4.1. Preparation of the template of the Minutes of the Meeting

- 4.1.1. The Panel Secretary and Review Panel Staff uses the **FORMAT OF THE MINUTES OF THE MEETING [UPMREB FORM 4(A)2012]** to organize a template of the minutes ahead of the meeting date.
- 4.1.2. In case of a special review panel meeting, the **FORMAT OF THE MINUTES OF THE MEETING [UPMREB FORM 4(A)2012]** will be adjusted to actual content requirements of the meeting of this type of panel.
- 4.1.3. All the relevant identifying information should be filled out such as standard text in the regular sections and relevant study protocol information.
- 4.1.4. The draft of the minutes of the meeting is generated as the meeting progresses. The Review Panel Staff in charge of documentation notes all board opinions and actions in all specific sections of the agenda, as the agenda is developed and discussed, with respective reasons in the case of study protocol-related actions.
- 4.1.5. The development of the minutes during the meeting is displayed in a multimedia screen to allow members to make immediate corrections.

4.2. Preparation of the draft of the Minutes

- 4.2.1. Opinions and actions included in the minutes are understood to be collective and need not be attributed to specific members, unless in the case of administrative or operational queries from members who require follow-up information or action.
- 4.2.2. The Review Panel Staff in charge of documentation submits a complete draft of the minutes to the Panel Secretary within **seven (7) days** after the meeting for form and content corrections and finalization. The finalized draft is sent to the Panel Chair immediately for approval.
- 4.2.3. The following information must be indicated in the minutes:
 - Date and venue of meeting
 - Members attendance (members present and absent)
 - Guests and observers attendance



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- Time when the meeting was called to order
- Presiding officer
- Items discussed per Meeting Agenda
- Number of votes per full board action
- Confirmation and reconfirmation of quorum
- Name and signature of person who prepared the Minutes
- Date of completion
- Name and signature of the Panel Secretary to indicate that the contents have been verified and corrected
- Name and signature of the Panel Chair to indicate approval
- Date of approval by the Panel Chair

4.3. Approval of the draft Minutes

- 4.3.1. The Panel Chair approves the draft of the minutes by affixing his/her signature and the date he/she signs the minutes.
- 4.3.2. Upon approval of the draft of the minutes, the Review Panel Staff drafts the decision documents and transfers contents of the *Conclusions and Recommendations* section (per study protocol discussed) into the applicable forms.

4.4. Approval of the Minutes of the Previous Meeting

- 4.4.1. The approved draft of the minutes will be verified in the PRMC meeting which is held **three** (3) working days before the actual meeting.
- 4.4.2. The minutes will be sent to the panel members together with the approved agenda and protocol synopses immediately after the PRMC meeting.
- 4.4.3. During the panel meeting, the Panel Chair presents the minutes of the previous meeting for panel approval.
- 4.4.4. The Review Panel Staff finalizes the minutes of the meeting.
- 4.4.5. The Panel Chair approves the final minutes by affixing his/her signature and the date he/she signs the minutes.



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4.5. Storage and Distribution of the Minutes

- 4.5.1. The Review Panel Staff files the signed copy of the approved final minutes in the Minutes Folder.

5. Study Protocol Communication Records Workflow

ACTIVITY	RESPONSIBILITY
Sort all communications received and issued by the UPMREB ↓	Screening and Database Management Staff
Record the details of the communication ↓	Screening and Database Management Staff and Administrative Secretariat Staff
Store communication files	Screening and Database Management Staff and Administrative Secretariat Staff

DETAILED INSTRUCTIONS

5.1. Sorting of all communications received and issued by the UPMREB

- 5.1.1. Communications can come in the form of letters, official memoranda, or emails.
- 5.1.2. The Screening and Database Management Staff sorts all communications received and prepares them for recording.
- 5.1.3. The Review Panel Staff, under the supervision of the Panel Secretary, drafts the letter indicating panel action and incorporates the recommendations into the following forms as applicable:
- **CERTIFICATION OF APPROVAL [UPMREB FORM 4(B)2019]** for study protocols for initial review, resubmissions, continuing review applications, and study protocol amendments, that have been granted approval; or
 - **NOTICE OF PANEL ACTION TO STUDY PROTOCOL SUBMISSIONS [UPMREB FORM 4(C)2019], LETTER FOR CLARIFICATORY INTERVIEW [UPMREB FORM 4(D)2012], NOTICE OF PANEL ACTION TO STUDY PROTOCOL AMENDMENT/CONTINUING REVIEW APPLICATION/FINAL REPORT/DEVIATION/EARLY STUDY TERMINATION**



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REPORT/QUERIES, NOTIFICATIONS AND COMPLAINTS/SAE
REPORT/SITE VISIT REPORT [UPMREB FORM 4(F)2019],
ARCHIVING NOTIFICATION [UPMREB FORM 4(G)2012],

- REQUEST FOR UPMREB CERTIFICATION OF EXEMPTION FROM ETHICAL REVIEW [UPMREB FORM 4(Q)2019], or
- LETTER OF EXEMPTION FROM ETHICAL REVIEW FOR CASE REPORTS [UPMREB FORM 4(U)2021], or
- CHANGES IN EXEMPTED PROTOCOLS [UPMREB FORM 4(V)2021] as the case may be.

5.1.4. The Review Panel Staff forwards the decision documents to the Panel Chair for approval.

5.1.5. The Panel Chair approves the decision documents by affixing his/her signature.

5.1.6. The Review Panel Staff files the decision documents in the respective file folders.

5.1.7. Unclaimed PI's copy of notice of panel action, after three months of notice, will be filed in the respective protocol folders.

5.2. Recording of the details of the communication

5.2.1. Study protocol-related communications received by the UPMREB are recorded in the **SUBMISSIONS AND ISSUANCES LOG [UPMREB FORM 4(M)2012]**. This form is updated as each submission is received. The record should contain, but is not limited to, the following:

- Type of Submission
- Date Received
- UPMREB Code
- Title
- Name of Principal Investigator
- Description of Submission
- Type of Review
- Review Panel
- Meeting Date



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- Remarks
- Date of Decision
- Date of Issuance

5.2.2. Inquiries relating to UPMREB procedures, study protocols, and/or others are received via email and are logged using the UPMREB FORM 4(X)2022 Email Communication Log. This form is updated as each inquiry is received and acted upon. The record should contain, but is not limited to, the following:

- Date Received (Incoming)
- Received by (Incoming)
- Source/ Contact Address
- Description/ Nature of Communication
- Date & Action Taken
- Date Received (Outgoing)
- Received by (Outgoing)
- Remarks/ Status

5.3. Storage of communication records

5.3.1. Upon completion of the **SUBMISSIONS AND ISSUANCES LOG [UPMREB FORM 4(M)2012]**, the Review Panel Staff files a copy of the communication in the study file.

5.3.2. For SAE Files, the Review Panel Staff stores the signed serious adverse event/s report in the study protocol file folder.

5.3.3. The Review Panel Staff then writes in the protocol folder contents index as each communication is filed.

6. Administrative Records Workflow

ACTIVITY	RESPONSIBILITY
Compile administrative documents and/or records ↓	Administrative Secretariat Staff/Members/Chair
Sort and store documents ↓	Administrative Secretariat Staff
Dispose unnecessary copies	Administrative Secretariat Staff

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DETAILED INSTRUCTIONS

6.1. Compilation of administrative records

6.1.1. The Administrative Secretariat Staff maintains administrative documents not related to specific study protocols, but used in daily operations of the UPMREB such as:

- Reference materials and guidelines
- Standard Operating Procedures
- Communications issued to and received from persons other than principal investigators, on matters that are not related to any study protocols
- UPMREB members and staff files (CVs, Appointment letters, Signed **CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE [UPMREB FORM 1(C)2012]**, **TRAINING RECORDS [UPMREB FORM 1(D)2012]**, Certificates of training
- Log of copies of documents requested by non-members [**UPMREB FORM 4(H)2012: BORROWERS LOG**]
- Forms
- Agenda [**UPMREB FORM 4(S)2019: ADMINISTRATIVE MEETING AGENDA TEMPLATE**] and Minutes of General Assembly and Executive Committee Meeting [**UPMREB FORM 4(T)2019: ADMINISTRATIVE MEETING MINUTES TEMPLATE**]
- Audit Reports

6.1.2. These documents are maintained separately from study protocol-related documents.

6.2. Sorting and storage of documents

6.2.1. The Administrative Secretariat Staff labels and files administrative documents sequentially.

6.2.2. Guidelines are filed numerically by subject and alphabetically.

6.2.3. SOP Manuals are filed chronologically.



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- 6.2.4. Important communications are filed in the communications folder and recorded chronologically in the **SUBMISSIONS AND ISSUANCES LOG [UPMREB FORM 4(M)2012]**.
- 6.2.5. Members' and staff files are filed alphabetically by last name.
- 6.2.6. Only the most recently updated **CURRICULA VITAE [UPMREB FORM 1(B) 2012]** are filed in the individual member's folder.
- 6.2.7. Signed **CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURES [UPMREB FORM 1(C) 2012]** and training certificates are filed chronologically under every member's or staff's file.
- 6.2.8. **TRAINING RECORDS [UPMREB FORM 1(D) 2012]** must be updated as each training certificate is submitted by the member or staff for filing.
- 6.2.9. Active UPMREB blank forms are kept in individually labeled folders or envelopes. The folders or envelopes are filed numerically with a list or index of forms written as:
 - Form number
 - Subject of form

6.3. Disposal of unnecessary copies

- 6.3.1. Guidelines and references that have been superseded or outdated for three (3) years are removed from the files and disposed of properly.
- 6.3.2. Removed document files are shredded and permanently deleted from electronic and physical files.

7. Active Files Workflow

ACTIVITY	RESPONSIBILITY
Create a coding system for active files ↓	UPMREB
Organize the contents of the active study files ↓	Technical Secretariat Staff
Maintain the active study files	Technical Secretariat Staff

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7.1. Creation of coding system for active study files

- 7.1.1. Active files are study protocols that have been received by the UPMREB Secretariat and are either undergoing review (full board or expedited) or approved by the respective UPMREB Panel.
- 7.1.2. Active study files are coded as **UPMREB YYYY-NNNN- 00**, where **YYYY** represents the year, **NNNN** represents sequential study protocol number (as received by the UPMREB Secretariat), and **00** numerically represents the number of sites such that if it is a single site study or the first site reviewed in a multi-center study, the suffix 01 is added, if second the suffix 0002 is added and so on.
- 7.1.3. Study protocol files of undergraduate students are coded similarly, but the suffix **00** is replaced by **UND** written as **UPMREB YYYY-NNNN-UND**.
- 7.1.4. Study protocol files that are also processed by SJREB are coded similarly, but another suffix **SJREB** is placed after the suffix indicating the site, written as **UPMREB YYYY-NNNN-00-SJREB**.
- 7.1.5. Protocols exempted from ethical review are coded similarly, but the suffix **000** is replaced by **EX** and written as **UPMREB-YYYY-NNNN-EX**.
- 7.1.6. The study file code should appear prominently on the study protocol folder.

7.2. Organization of contents of active study files

- 7.2.1. Study files are encoded into the **STUDY PROTOCOL DATABASE [UPMREB FORM 4(R)2017]**, which contains the following information:
 - Reference No. (RGAO)
 - UPMREB Code
 - Date Received
 - Study Title
 - Principal Investigator
 - Paper/Investigator Category
 - Study Category
 - Type of Study
 - Purpose of Study
 - Study Site



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- Endorsing College/Institution
- Use of Special Populations or Vulnerable Groups
- Total Budget
- Funding Agency
- Technical Review
- Source and Date of Technical Review
- Previous Ethics Approval or Clearance Issued by Other Sites
- Type of Review
- Date of UPMREB Panel Review
- Assigned UPMREB Review Panel
- Primary Reviewers
- Meeting Date
- Date of Approval
- Due Date of Progress Report
- Date of Inactivation
- Status

7.2.2. The elements included in the Study Protocol Database are linked to the following sub-databases, with respective contents:

7.2.2.1. Principal Investigators Database

- Investigator No.
- Name
- Sex
- Birthday
- Institution
- College/Unit
- Department
- Telephone
- Mobile
- Facsimile
- Email Address
- Educational Attainment
- School
- Specialization
- Sponsors
- Declaration of Conflict of Interest of PI

7.2.2.2. Reviewers Database



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- Reviewer No.
- Name
- Home Address
- Mailing Address
- Contact Number
- Institution
- Birthday
- Date of Appointment
- Review Panel
- Classification
- Area of Expertise
- Ethics or GCP Trainings Attended

7.2.2.3. Meeting Database

- Meeting No.
- Date of Meeting
- Place
- Time
- Panel
- Presided by
- Attendees
- Agenda

7.2.2.4. Serious Adverse Events Database

- Report No.
- Event No.
- UPMREB Code
- Date of Submission of AE
- Date of AE
- Type of Report
- Reporter's Name
- Patient Initials
- Country
- Date of Birth
- Age
- Sex
- Narrative of the AE
- Suspected drug



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- Dose of drug
- Route of administration of drug
- Concomitant Drugs
- Dose of Concomitant Drugs
- Comorbidities
- Foreseeability
- Causality
- Classification
- Action
- Outcome

7.2.2.5. Institution and Study Site Database

- No.
- Name
- Classification
- Address
- Telephone Number
- Fax
- Email Address
- Website
- Administrator

7.2.3. The Technical Secretariat Staff puts study protocol files in electronic file folders upon processing of the submission of the study protocol, ensuring that one folder contains documents for one study protocol and labeled with the code of the study protocol.

7.2.4. A study file folder contains the following documents, as applicable:

- All versions of study protocol
- Related documents that came with the study protocol
- Principal investigator and co-investigators' CVs and other similar documents
- Reviewers' assessment forms
- Panel action in the form of excerpts from minutes
- Amendment reports
- Continuing review applications
- Final report
- Serious Adverse Event Reports or Safety Notifications



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- Non-compliance (Deviation or Violation) reports
- Participant Queries
- Site Visit Reports
- Certificate of Approval
- Notice of Panel Action/Notification of UPMREB Decision
- Miscellaneous communication

7.3. Maintenance of active study protocol files

- 7.3.1. The Technical Secretariat Staff files all the aforementioned documents in the electronic study folder as they come.
- 7.3.2. The UPMREB Coordinator conducts weekly monitoring of operations implemented by the Technical Secretariat staff to supervise proper documentation, filing, and archiving of protocol-related documents.

7.4. Maintenance of electronic study protocol files

- 7.4.1. The Technical Secretariat Staff maintains electronic copies of study protocol files submitted to UPMREB (e.g. study protocol package, review assessment forms) and the communication records issued by UPMREB related to the study protocol, as applicable (e.g. notice of review, notice of panel action, etc.).
- 7.4.2. Study protocol folders are labeled with the UPMREB codes and the last name of the investigator (YYYY-NNNN-00_Panel #_<Last name of Investigator>), and contain folders which will be labeled according to submission i.e. initial, resubmission, continuing review, amendment, deviation, early termination, SAE, and/or final report.
- 7.4.3. Communication records issued by the UPMREB will be labeled as follows:
- 7.4.3.1. Notice of panel action is labeled as <Date (dd-mm-yyyy)_Decision#_Last name of PI_UPMREB Code>
- 7.4.3.2. Agenda is labeled as <Date (dd-mm-yyyy)_Agenda_Review Panel_#th meeting>
- 7.4.3.3. Minutes of the meeting are labeled as <Date (dd-mm-yyyy)_Minutes_Review Panel_#th meeting_version (draft/final)>

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7.4.3.4. Other documents are labeled as <Date (dd-mm-yyyy)_Type of document_Last name, as applicable>

7.4.4. The notice of action are included in the corresponding study protocol folders which are organized according to submission package.

7.4.5. The agenda and minutes of the meeting are stored under a separate folder labeled <Year_Agenda and Minutes of the meeting> which contains folders of the agenda and minutes of the meeting organized according to panel, month, and type of meeting (i.e. regular or special meeting).

7.4.6. Electronic files are organized per year and stored in the UPMREB google drive. Files are also backed up in the UPMREB external hard drive. Archived files will be stored for at least three (3) years after approval of the final report or expiration of the last approval, if no final report was submitted.

8. Archived (Inactive/Completed/Terminated) Files Workflow

ACTIVITY	RESPONSIBILITY
Manage completed/inactive/terminated study files ↓	Technical Secretariat Staff
Sort administrative documents to be archived ↓	Administrative Secretariat Staff
Establish archived documents retrieval process	Technical Secretariat Staff

DETAILED INSTRUCTIONS

8.1. Management of Archived (inactive/completed/terminated) study files

8.1.1. Archived (Inactive/Completed/Terminated) study files are either:

- Study protocols with approved (by the UPMREB) final reports, or
- Approved study protocols are reclassified as *Inactive* if no communication is received from study team six months after expiration of ethical clearance
- Study protocols for initial review with resubmissions or communication beyond 90 days from date of notice of panel action

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- 8.1.2. The Screening and Database Management Staff generates a list of inactive protocols using the description in **SOP IV-8.1.1** to be included in the agenda of the meeting. This will be reported during the panel meeting.
- 8.1.3. Archiving notifications will be communicated to the principal investigators within **seven (7) days** after the full board meeting.
- 8.1.4. Upon receipt of **UPMREB FORM 3(C) 2012: FINAL REPORT FORM**, the UPMREB panel reviews it in accordance with **SOP III-4.3: FINAL REPORTS**.
- 8.1.5. Upon panel approval of the **UPMREB FORM 3(C) 2012: FINAL REPORT FORM**, the Screening and Database Management Staff removes the contents of the entire file from the active study filing area and verifies that all documents are present in an organized manner.
- 8.1.6. The archived protocols are placed in an envelope labeled with the protocol's UPMREB Code, Surname of the Principal Investigator, and the date of inactivation.
- 8.1.7. Correspondingly, the data about the study and the year when archived should be entered on the Study Protocol Database.

8.2. Sorting of archived administrative documents

- 8.2.1. The Administrative Secretariat Staff should perform inventories of miscellaneous administrative documents yearly.
- 8.2.2. Administrative documents that are related to any fund released by UPM are required to be archived in a manner that allows easy retrieval for audit purposes. These include documents that specify appointment of personnel, issuance of honorarium, approved annual budget, financial reports, as well as financial/funding policies. One set of such documents are stored in the appropriate storage container/cabinet for archived administrative files.
- 8.2.3. Unnecessary copies are disposed of accordingly (see section 6.3 above).

8.3. Retrieval of documents

- 8.3.1. Only authorized UPMREB Technical Secretariat Staff can retrieve documents either from active study files or from the archives.



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- 8.3.2. Active or inactive study files can be borrowed, upon written request by the PI or the UPMREB personnel, and only for room use.
- 8.3.3. A **BORROWERS LOG [UPMREB FORM 4(H)2012]** is placed in a pocket on the study file folder cover to list down individuals who will take out the actual physical folder from the protocol cabinet:
- Study file code
 - Date when borrowed
 - Borrower's Name
 - Signature of borrower
 - Signature of Technical Secretariat Staff upon return of document to file box.
 - Date Received by the Secretariat



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8.4. Disposal of inactive protocol files

- 8.4.1. The Screening and Database Management Staff generates a list of inactive protocols that are beyond three years past its date of inactivation from the Study Protocol Database at the end of the year.
- 8.4.2. The Screening and Database Management Staff submits the list to the UPMREB Coordinator for review, verification, and approval for disposal.
- 8.4.3. The Screening and Database Management Staff retrieves the inactive protocols and disposes the files accordingly.

9. Confidentiality of study files and UPMREB documents Workflow

ACTIVITY	RESPONSIBILITY
Classify documents as confidential ↓	UPMREB
Request access to UPMREB documents ↓	Members, non-members
Reproduce confidential documents ↓	Screening and Database Management Staff
Maintain log of copies issued	Screening and Database Management Staff

DETAILED INSTRUCTIONS

9.1. Classification of documents as confidential

- 9.1.1. Access to confidential documents is restricted by the UPMREB to members and staff, but limited access can be provided to non-members who have a legitimate purpose to access the documents.
- 9.1.2. The UPMREB considers the following as confidential:
 - Study protocols
 - Study protocol-related documents (case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)
 - Meeting Minutes
 - Decisions, notice of panel action/notification of UPMREB decision, certificate of approval
 - Study protocol-related communications



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9.2. Access to confidential UPMREB documents

- 9.2.1. All UPMREB members and the staff with a signed **CONFIDENTIALITY AGREEMENT AND CONFLICT OF INTEREST DISCLOSURE [UPMREB FORM 1(C) 2012]** can have access to UPMREB confidential documents upon request.
- 9.2.2. Non-members can access specific documents upon formal request and completion/signing of **CONFIDENTIALITY AGREEMENT FOR NON-MEMBERS [UPMREB FORM 4(I) 2012]**. The form requires the approval of the UPMREB Panel Chair and the UPMREB Chair. Regulatory authorities have full access to UPMREB files provided it is within said authorities' mandate, and upon reasonable notice to make the files available.
- 9.2.3. All requests for access are recorded by the Screening and Database Management Staff in the **LOG OF REQUEST FOR COPIES OF DOCUMENTS [UPMREB FORM 4(J) 2012]** before the documents are released.

9.3. Reproduction of confidential documents

- 9.3.1. The Secretariat makes only the exact number of copies requested.
- 9.3.2. The recipient signs for the copies requested in the **LOG OF REQUEST FOR COPIES OF DOCUMENTS [UPMREB FORM 4(J) 2012]** upon receipt of the copies.

9.4. Maintenance of log of copies

- 9.4.1. The Screening and Database Management Staff ensures the diligent recording of all document copies issued in the **LOG OF REQUEST FOR COPIES OF DOCUMENTS [UPMREB FORM 4(J) 2012]**.
- 9.4.2. This log is filed in a separate folder labeled *Log of Copies Issued*.