Supersedes:	Previous NCH-IRB SOPs
Prepared by:	2017 NCH-IRB SOP Committee
Reviewed by:	**NATIONAL CHILDREN'S HOSPITAL INSTITUTIONAL REVIEW BOARD (NCH-IRB)**
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Approval Date:	

4. MEETING CONDUCT, DOCUMENTATION AND ARCHIVING

4.1. Preparation of Meeting Agenda
4.2. Conduct of a Full Board Meeting
4.3. Preparation of Meeting Minutes
4.4. Communicating NCH-IRB Decision to PI
4.5. Management of Active Study Files
4.6. Archiving of Inactive Study Files
4.7. Maintenance of Confidentiality of Study Files and NCH-IRB Documents

See Appendix D
Form 4.1 Meeting Agenda Template
Form 4.2 Meeting Minutes Template
Form 4.3 Request to Access NCH-IRB Files

4.1. PREPARING THE NCH-IRB MEETING AGENDA

4.1.1 Purpose

To describe the procedures involved in agenda preparation before the conduct of the full board meeting of the NCH-IRB.

4.1.2 Scope

This SOP provides instructions related to the preparation of meeting agenda before a full board meeting.

4.1.3 Responsibility

It is the responsibility of NCH-IRB Secretariat, composed of the NCH-IRB Staff under the supervision of the Member-Secretary to prepare the meeting agenda before an NCH-IRB full board meeting.

4.1.4 Process Flow/Steps

NO.	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Prepare the Meeting Agenda	Staff	7 days
2	Finalize the Provisional Meeting Agenda	Member-Secretary and Chair	
3	Make arrangements for the meeting	Secretariat	
4	Distribute Notice of Meeting (*with Provisional Meeting Agenda Inform PI concerned of the scheduled full board meeting*)	Staff	1 day
5	Finalize Meeting Agenda *(from Provisional to Final)*	Member-Secretary	
6	File a copy of the Final Meeting Agenda	Staff	

4.1.5. Detailed Instructions

4.1.5.1. Prepare and Finalize the Meeting Agenda

- One week before the scheduled meeting date, the NCH-IRB Staff checks the submissions since the last full board meeting and prepares a list of items for review using the Meeting Agenda template for the next full board meeting.
- The NCH-IRB Staff forwards the draft meeting agenda to the NCH-IRB Member-Secretary to review and finalize.

4.1.5.2. Finalize the Meeting Agenda

- The NCH-IRB-Member Secretary reviews the draft meeting agenda and makes changes, if needed, then it will be presented to the NCH-IRB Chair for approval and comments and it becomes the provisional meeting agenda.

4.1.5.3. Make arrangements for the meeting

- NCH-IRB Staff contacts NCH-IRB members to check who will be available to attend the meeting to ensure quorum.
- The NCH-IRB Staff makes the necessary arrangements:
  - for reservation of meeting room on the scheduled meeting date and time
  - for snacks of meeting attendees

- Prepares relevant documents to be distributed to NCH-IRB Members who confirmed to attend the meeting.

4.1.5.4. Distribute Notice of Meeting

NCH-IRB Staff distributes the Notice of Meeting *(with the provisional meeting agenda)* together with the relevant documents for review during the meeting to NCH-IRB Members within 7 days prior to meeting date.

4.1.5.5. Finalize Meeting Agenda

The NCH-IRB-Member Secretary finalize the meeting agenda and then presented to the NCH-IRB Chair for approval.

4.1.5.6. File the meeting agenda

- NCH-IRB Secretariat takes note of changes in the provisional meeting agenda after this is presented for approval to the NCH-IRB. If there are no changes, the provisional meeting agenda becomes the final meeting agenda.
- NCH-IRB Staff files a copy of the final meeting agenda in a folder of Meeting Agenda for the year.

4.2. CONDUCT OF A FULL BOARD MEETING

4.2.1. Purpose

To describe the procedures of NCH-IRB when it conducts a full board meeting to review protocol submissions**.**

4.2.2. Scope

This SOP describes the various steps the NCH-IRB follows to review various types of protocol submissions, the types of decision and action taken as well as necessary documentation to record its proceedings.

4.2.3. Responsibility

It is the responsibility of the NCH-IRB Chair to preside over the meeting and exercise leadership to enable the NCH-IRB members and NCH-IRB Staff to fulfill their designated roles in the review of protocol related documents submitted to the NCH-IRB in an efficient and effective manner. It is the responsibility of the Member Secretary to ensure that quorum will be met, that the required documents needed are available, to supervise the staff taking real time minutes of the proceedings and to report the results of expedited review.

It is the responsibility of NCH-IRB Members to prepare and participate in NCH-IRB full board meetings to enable the NCH-IRB to conduct good review and take appropriate action related to documents submitted to the NCH-IRB.

It is the responsibility of the NCH-IRB Staff to prepare and make available all documents needed during the meeting and to take down minutes of the proceedings.

4.2.4. Process Flow/Steps

NO.	ACTIVITY	PERSON/S RESPONSIBLE
1	Call the Meeting to order	Chair
2	Determine Quorum	Member Secretary
3	Assign presiding member in the absence of Chair	
4	Declare Conflict of Interest	Members, Chair
5	Approve the Minutes of the previous Full Board Meeting and discuss business arising from the Minutes	Members

6	Approve or modify the agenda	
7	Discuss and decide on protocols for initial review (*conduct clarificatory interview when necessary*)	Primary Reviewers and Members
8	Decide on protocol document resubmission	
9	Discuss and decide on major Protocol Amendments	
10	Discuss and decide on Progress Reports for full board review	
11	Approve Final Reports	
12	Discuss Protocol Deviation/ Violation Reports for appropriate action	
13	Report Onsite SAEs for appropriate action	Designated Member
14	Report Expedited Review results	Member-Secretary
15	Report/ Discuss other matters for full board action/ information	Chair/ Member-Secretary and Members
16	Formally close the Full Board Meeting	Chair

4.2.5. Detailed Instructions

4.2.5.1. Call the Meeting to order.

The Chair declares the formal opening of the Meeting at the appointed time and place once majority of the members are present.

4.2.5.2. Determine Quorum

The Member Secretary checks and reports if the quorum requirements are met to enable the meeting to start. NCH-IRB Quorum requirements should comply with national and international requirements and as defined in these SOPs. Quorum should be maintained throughout the duration of the meeting when members are required to vote to arrive at a decision. The following should be met to constitute quorum in a full board meeting of NCH-IRB:

- 50%+ 1 of panel membership but not less than 5
- presence of 1) medical/scientific 2) non-medical/scientific and 3) Non-medical/non-scientific members or lay member
- presence of non-affiliated member
- presence of at least one male and at least one female member

4.2.5.3. Assignment of Presiding Officer in the absence of the Chair or in the presence of Conflict of Interest

The Chair assigns the member secretary or primary reviewer of protocol in question to preside over the discussion

4.2.5.4. Declare Conflict of Interest

- The Chair asks the NCH-IRB members to declare their conflict of interest related to any protocols to be discussed.
- The NCH-IRB chair/members check the agenda and declare their COI related to any protocol to be reviewed. They should be asked to leave the room during the discussion of such protocols, unless they are asked to reply to questions for clarification. Quorum should be maintained when conflicted members leave the room. They return to the room after discussion of their protocol.

4.2.5.5. Approve the Minutes of the previous Full Board Meeting and discuss business arising from the Minutes

- The Minutes of the previous meeting should have been sent to all members before the meeting for comments. The Chair asks the members to approve the Minutes of the last meeting and asks the members to voice out their comments, if any.
- The Chair also asks the members to comment about issues arising from the Minutes and the discussions are recorded in the current Minutes by the Secretariat.

4.2.5.6. Approve or modify the agenda

- The Chair asks the Members to examine and approve the items in the Meeting Agenda.
- NCH-IRB members may suggest additional items for discussion and the meeting agenda may be modified to include additional items for discussion.

4.2.5.7. Discuss and decide on protocols for initial review

The list of protocols for initial review is discussed according to the following procedures:

- The primary medical reviewer summarizes the protocol to enable the members to understand it.
- He/she uses the assessment form to comment on the technical and ethical issues in the protocol and makes recommendations about clarification, modification or approval. He/she also comments on the qualifications of the researchers and the sites.
- The Chair opens the protocol for discussion of NCH-IRB members taking note of additional and contradictory comments.

- The PI is called to enter the room to answer questions and clarify certain protocol related matters, after which, he/she is asked to leave the room.
- The Chair summarizes the points raised and notes different views among members that should be resolved. The Chair asks the members to vote based on the decision points in the SOPs
  - Approval *(no further revision of the documents is required)*
  - Minor Modification
  - Major Modification,
  - Disapproval

- The Non-Medical/Non Scientific Reviewer presents his/her assessment of the Patient Information Sheet and Informed Consent Form making use of the ICF Assessment Form. The comments should note the discrepancies between the protocol and the information sheet, the correct consent or assent is enclosed, and provisions for proper signatures in the form.
- The Member Secretary takes note of voting results, records them and includes them in the Minutes of the meeting.
- Once the protocol documents are approved, the NCH-IRB should agree on the frequency of continuing review.

4.2.5.8. Decide on protocol document resubmission

- The Secretariat includes in the Meeting Agenda resubmissions required for Major Modification for full board discussion.
- The Primary Reviewers check if the researchers complied with the NCH-IRB requirements and recommends appropriate decision. The NCH-IRB members vote to approve the resubmission.

4.2.5.9. Discuss and decide on Major Protocol Amendments

- The Member Secretary screens amendments to determine Major Protocol Amendments that require full board review and to ensure inclusion in the Meeting Agenda.
- The Primary Reviewers review the amendment and present their assessment to full board.
- The NCH-IRB members vote **APPROVAL, MINOR MODIFICATION** to the proposed amendment, citing reasons for action, subject to expedited review at the level of the Chair, **MAJOR MODIFICATION** to the proposed amendment, stating reasons for action, subject to full board review, **DISAPPROVAL**.

4.2.5.10. Discuss and decide on Progress Reports for full board review

- The NCH-IRB Staff/Member Secretary screens Progress Reports that require full board review to ensure inclusion in the Meeting Agenda.
- The Primary Reviewers review Progress Reports and present their assessment to full board.
- The NCH-IRB members vote to **UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION, REQUEST INFORMATION or RECOMMEND FURTHER ACTION** the Progress Reports.

4.2.5.11. Approve Final Reports

- The NCH-IRB Staff submits a list of Final Reports to full board review and includes them in the Meeting Agenda.
- The Primary Reviewers review Final Reports and present their assessment to full board.
- The NCH-IRB members vote **APPROVAL or RECOMMEND FURTHER ACTION.**

4.2.5.12. Discuss Protocol Deviation/Violation Reports for appropriate action

- The NCH-IRB Staff includes all Protocol Deviation/Violation Reports in the Meeting Agenda.
- The Primary Reviewers review the Reports and present their assessment and recommendation for appropriate action to full board.
- The NCH-IRB members vote to take corresponding action on the Protocol Deviation/Violation Reports.

4.2.5.13. Report Onsite SAEs for appropriate action

- The NCH-IRB Staff prepares a list of Onsite SAEs/SUSARs and submits them to full board for appropriate action.
- The Designated NCH-IRB Reviewer reviews the Onsite SAE/SUSAR Reports and present their assessment and recommendation for appropriate action to full board.
- The NCH-IRB members vote to **UPHOLD ORIGINAL APPROVAL WITH NO FURTHER ACTION, REQUEST INFORMATION or RECOMMEND FURTHER ACTION**.

4.2.5.14. Report Expedited Review results

- The NCH-IRB Staff prepares a list of all Expedited Review results approved by the Member Secretary and submits them to full board to inform the NCH-IRB members.
- NCH-IRB Members may comment on the Report

4.2.5.15. Report/Discuss other matters for full board action/information

- The NCH-IRB Chair/Member-Secretary or any NCH-IRB Members may suggest items or other matters for the information or discussion by full board.
- The NCH-IRB Chair/Member-Secretary or any NCH-IRB Members may report queries and complaints that may need board discussion for appropriate action.

4.2.5.16. Formally close the Full Board Meeting

The Chair formally closes the full board meeting after determination that all the Meeting Agenda items have been discussed.

4.3. PREPARATION OF MEETING MINUTES

4.3.1 Purpose

To describe procedures for the preparation and approval of the minutes of the NCH-IRB full board meeting

4.3.2 Scope

This SOP provides instructions related to the preparation of the NCH-IRB full board meeting minutes and its approval by the NCH-IRB members.

4.3.3 Responsibility

It is the responsibility of the Secretariat, composed of the NCH-IRB Staff under the supervision of the Member-Secretary, to document the conduct of the full board meeting, including the issues discussed, the decisions and recommendations made in accordance with the items in the NCH-IRB meeting agenda.

4.3.4 Process Flow/Steps

NO.	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Prepare template of Minutes of Meeting	Secretariat	3 days
2	Preparation/Correction/Finalization of minutes of the meeting		
3	Approve minutes of the meeting	Members	
4	File minutes of the meeting	Staff	1 day

4.3.5 Detailed Instructions

4.3.5.1. Prepare template of Minutes of Meeting

- The NCH-IRB Staff fills up the basic information about each protocol submission for review of the NCH-IRB Meeting Minutes template with identifying information *(Protocol number, title, PI, sponsor, etc.)* before the meeting date.
- NCH-IRB Secretariat uses this prepared template to document the proceedings during the full board meeting.

4.3.5.2. Preparation/Correction/Finalization of minutes of the meeting

- As the NCH-IRB meeting proceeds, the NCH-IRB Secretariat takes minutes of the meeting on real time according to the prescribed format and projects this on the multimedia screen to enable the NCH-IRB Members to closely follow the proceedings, and to facilitate the recapitulation of discussion points by the NCH-IRB Chair/Member Secretary/Appointed Member.
- The NCH-IRB decisions and recommendations are collective in nature. No attribution to specific NCH-IRB member is stated in the minutes.
- The meeting minutes should include the following items
  - Date and venue of the meeting
  - Member attendance
  - Attendance of Researchers/PI, Independent Consultant and guest or observer, if any
  - NCH-IRB Chair
  - Time when the meeting was called to order
  - Status of quorum at the start of the meeting and before every decision making
  - Members who declared COI and the protocol concerned
  - Discussion of items based on the order in meeting agenda
  - Summary of technical and ethical discussion points and recommendations
  - NCH-IRB decision and voting results according to decision categories, abstention and votes for disapproval with reasons given.
    - If the review decision *(for initial and continuing reviews)* is "approved", the frequency of submission of progress report is determined.
    - If the review decision is disapproved, the reasons for the disapproval are stated.
    - If the review decision *(for initial and continuing reviews)* is "for modification", the items to be revised are identified and the type of review for the resubmission is defined.

  - Attach the list of approved protocols through expedited review for the information of NCH-IRB members.
  - Name and signature of the person who prepared the minutes
  - Name and signature of the Member-Secretary to indicate the contents have been verified and corrected

- Name and signature of the Chair who approved the minutes with the date of approval

- The NCH-IRB Staff who prepared the draft of the Meeting Minutes submits it to the Member-Secretary for correction and finalization within 3 days from the date of the meeting.
- The NCH-IRB Staff group-e-mails the copy of the provisional meeting minutes to the NCH-IRB Members for their review and comments within 3 days from the meeting date. The NCH-IRB Members are expected to e-mail their corrections to the group.
- The NCH-IRB Secretariat finalizes minutes of the meeting incorporating corrections from the NCH-IRB Members.
- The NCH-IRB Staff distributes the final version of the minutes of the meeting together with the Notice of Meeting for the next NCH-IRB meeting.

4.3.5.3. Approve minutes of the meeting

- The Chair asks the members to approve the Minutes within 3 days from the full board meeting.
- The NCH-IRB members may suggest further corrections.
- The NCH-IRB members approve the Minutes.
- The Chair signs approval after the meeting.

4.3.5.4. File minutes of the meeting

- The NCH-IRB Staff files approved meeting minutes in the folder for Meeting Minutes.
- Excerpts of meeting minutes may be extracted and filed in specific protocol file folder, and the protocol file index is updated.

4.4. COMMUNICATING NCH-IRB DECISION TO THE PRIMARY INVESTIGATOR

4.4.1. Purpose

To describe the procedure for communicating the NCH-IRB decision to the PI.

4.4.2. Scope

This SOP provides instructions related to the preparation of NCH-IRB communication to the PI and the management of such documents.

4.4.3. Responsibility

It is the responsibility of the NCH-IRB Secretariat to prepare the Approval or Notification Letter to the PI to be signed by the NCH-IRB Chair.

4.4.4. Process Flow/Steps

NO.	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Prepare Notification/ Approval Letter to PI	Secretariat, Chair	within 2 days after the full board meeting
2	Send Notification/ Approval Letter to PI	Staff	
3	File Notification/ Approval Letter to PI		
4	Update protocol database		

4.4.5. Detailed Instructions

4.4.5.1. Prepare Notification/Certificate of Approval to PI

- Based on the final version of the Meeting Minutes, the NCH-IRB Staff prepares the NCH-IRB communication to the PI in duplicate copies using the standard SOP template.
- For the Notification Letter, the NCH-IRB Staff copies the list of recommendations from the meeting minutes to communicate them to the PI.
- The NCH-IRB Chair signs and dates the Notification/Certificate of Approval.

- All Notification/Certificate of Approval should be ready within 2 calendar days from the meeting date for full board or within 2 calendar days from receipt of expedited review results.

4.4.5.2. Send Notification/Certificate of Approval to PI

- The NCH-IRB Staff informs the PI/Research Assistant that the original copy of the Notification or Certificate of Approval is ready for pick-up.
- The NCH-IRB Staff emails a scanned copy of the Notification/Certificate of Approval to the PI.
- NCH-IRB Staff logs the Notification/ Approval in the Log of Outgoing Document when the original copies are released.

4.4.5.3. File Notification/Approval Letter to PI

The NCH-IRB Staff files a duplicate copy of the Notification/Approval Certificate in the protocol file folder and updates the Protocol File Index.

4.4.5.4. Update protocol data base

The NCH-IRB Staff updates the protocol data base

4.5. MANAGEMENT OF ACTIVE STUDY FILES

4.5.1. Purpose

To describe the NCH-IRB procedures related to the management of active study files.

4.5.2. Scope

This SOP provides instructions related to the management of active study files that include protocol submissions, all documents that reflect all actions taken by the NCH-IRB before completion of the study. It also provides instructions for the maintenance and storage of other NCH-IRB documents that include SOPs, NCH-IRB membership files, agenda and meeting minutes, relevant international and national regulations and guidelines, etc.

4.5.3. Responsibility

It is the responsibility of NCH-IRB Secretariat to manage all protocol submissions and documents that reflect all NCH-IRB actions and organize them in an orderly manner. The NCH-IRB Secretariat also manages the maintenance and storage of all NCH-IRB documents and records.

4.5.4. Process Flow/Steps

NO.	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	File protocol and other protocol related documents in an organized manner	Secretariat, Staff	7 days
2	Update protocol file folder regularly as documents come or are produced		
3	Store properly labeled protocol file folder in the appropriately labeled file storage cabinet		
4	Create an electronic protocol database and update it regularly with PI submissions and NCH-IRB decisions/actions		

5	Keep other NCH-IRB files in storage cabinets		

4.5.5. Detailed Instructions

4.5.5.1. File protocol and other protocol related documents in an organized manner

- Protocol files are considered active from the moment the protocols are received for initial review until such time they are inactivated either by its completion or termination or its withdrawal from the review process. Active protocol files are either those undergoing NCH-IRB review process or NCH-IRB - approved ongoing studies. It is necessary to use a unique identifier or code to refer to protocol file for efficient file management and retrieval.
- Study Protocols are identified using a unique identification number known as Protocol Code No. given by the NCH-IRB as described in SOP 2.1 on Management of Initial Submission.
- The protocol file folder contains the following documents arranged chronologically in an organized manner according to the Protocol File Index per type of submission *(eg. initial submission, protocol amendment, progress report, SAE Reports, Protocol Violation/Deviation, etc.)*:
  - All versions of study protocol
  - Protocol related documents *(ICF, CRF, recruitment materials, patient diary, IB, etc.)*
  - Principal investigator and co-investigators' CVs and valid GCP Training Certificate, if required
  - Reviewers' assessment forms
  - Decision letters *(notification letters or approval letter/s – initial and renewal)*
  - Post-Approval submissions *(protocol amendment, progress report, SAE report, protocol deviation/violation report, early termination report)* and corresponding reviewers' assessment and NCH-IRB decision letters
  - Participant queries/complaints, if any
  - Site Visit Reports, if any
  - Miscellaneous communication related to the protocol
  - Final report

- File in a durable binder all protocol-related documents in chronological sequence with the most recent file/document at

the top, Update the Protocol File Index whenever a new document is filed.
- Stick a protocol file label *(Protocol code no., title of the protocol, name of PI, sponsor on the front cover of the file binder)*.
- Stick a label with the Protocol No. on the side of the file binder.

4.5.5.2. Update protocol file folder regularly as documents come or are produced

- The NCH-IRB Staff logs every protocol-related document received. This log should contain at least the following items:
  - Date/Time received
  - Protocol Code No.
  - Study Title
  - Principal Investigator
  - Initials of Person who received the document
  - Type of Submission *(eg. Protocol for Initial Review, Resubmitted Protocol, Application for Protocol Amendment, Protocol Violation/Deviation Report, SAE Report, etc.)*
  - NCH-IRB Action Required.

- The NCH-IRB Staff also logs protocol and protocol-related documents when they are forwarded to NCH-IRB members for review. This log should contain the following items:
  - Date/Time Sent
  - Sending Person
  - Mode *(eg. e-mail, courier, etc.)*
  - Receiving Person
  - Content of Document
  - Remarks

- Protocol-related paper files/documents are added to the protocol file folder on the day that they are submitted or accomplished *(assessment forms, NCH-IRB decision letters)*.
- The binders are kept in locked cabinets.

4.5.5.3. Store properly labeled protocol file folder in the appropriately labeled file storage cabinet

- Place the protocol file binders in the shelf in vertical position and sequentially arrange according to their Protocol Code No.
- Label the storage cabinet with the year when the protocols were submitted.

- Keep all active study files in a secure filing cabinet, with access limited only to NCH-IRB Chair and Secretariat. The NCH-IRB Staff keeps the keys of file storage cabinets.
- Active files can be accessed outside of regular protocol review in accordance with the SOP 4.6 on Maintaining Confidentiality of Study Files and NCH-IRB Documents.

4.5.5.4. Create an electronic protocol database and update it regularly with PI submissions and NCH-IRB decisions/actions

- Create an electronic database to contain a list of all protocols received by the NCH-IRB with sufficient columns to contain all protocol-related information, PI submissions and action taken by the NCH-IRB from initial review to final report approval.
- The Study Protocol or related document is first entered into the NCH-IRB protocol database using its protocol code number, title, names of PI and sponsor, etc.
- Create a secure protocol database to facilitate protocol monitoring including due dates of reports and determining active protocol status. The database should use an electronic format and should be password-protected. It should have at least the following fields:
  - Protocol Code
  - Protocol title
  - Department/
  - PI and details
  - Submission date
  - Full board or Expedited Review
  - Primary Reviewers
  - Review decision
  - Full Committee review meeting date
  - Date of resubmission and Review decision
  - Full Committee review meeting date
  - Approval date and expiration date
  - Due date for progress report and Review decision
  - Date of approval
  - Date of SAEs/SUSARs and Review decision
  - Date of Study Site Visit and Review decision
  - Date of Early Protocol Termination and Review decision
  - Date for continuing review and Review decision
  - Date of final report and Review decision

- The NCH-IRB Staff should also maintain a back-up copy of the protocol database in an external drive that is updated every 1st

day of the month, or the following day if the day falls on a non-working day.

4.5.5.5. Keep other NCH-IRB files in storage cabinets

- Keep other NCH-IRB files that include the SOPs, Membership Files, international and national guidelines and regulations, etc. in the office cabinets and regularly update them for reference of the NCH-IRB members

4.4. ARCHIVING OF INACTIVE STUDY FILES

4.4.1. Purpose

To describe NCH-IRB procedures related to archiving of terminated, inactive and completed studies

4.4.2. Scope

This SOP provides instructions to the Secretariat related to requirements for archiving inactive files.

4.4.3. Responsibility

It is the responsibility of NCH-IRB Staff, under the supervision of the Member-Secretary, to archive in an orderly manner all protocol files that have been terminated, completed or inactive. They are kept together in a designated place in the hospital where confidentiality and security of the documents can be maintained.

4.4.4. Process Flow/Steps

NO.	ACTIVITY	PERSON/S RESPONSIBLE	TIMELINE
1	Identify inactive, terminated, completed files	Secretariat	7 days
2	Affix appropriate label to files for archiving and record in Database of Archived Documents	Staff	
3	Transfer files to the archiving room/cabinet		
4	Update protocol database		

4.4.5. Detailed Instructions

4.4.5.1. Identify files for archiving

- Studies are considered to be completed when the closure/final report of the study has been reviewed and approved by the NCH-IRB.
- Studies are also classified as inactive when no further communication has been received by the NCH-IRB after **90 days**.
- Studies that underwent early termination are subsequently categorized as terminated upon receipt of relevant information about termination.
- The NCH-IRB Staff removes the protocol file folders from the storage file cabinet for active studies, checks its contents and updates the protocol file index.
- NCH-IRB Staff shreds extra copies that are not needed.

4.4.5.2. Affix appropriate label to files for archiving and record in Database of Archived Documents

- The NCH-IRB Staff labels protocol file as inactive by attaching a **red sticker** and adding the year the study is declared inactive.
- The NCH-IRB Staff logs the protocol number and other protocol identifiers in the Database of Archived Documents.

4.4.5.3. Transfer files to the archiving room

- The NCH-IRB Staff transfers the file to the designated secure archive room.
- As in active study files, files in the secure storage cabinet for archived studies are arranged sequentially. The storage cabinet is properly labeled with the year in the original protocol code.
- Protocols are archived for 3 years. Archived protocols can be accessed in accordance with the SOP 4.6 on Maintaining Confidentiality of Study Files and NCH-IRB Documents.
- After 3 years in the archive, the files may be transferred to the hospital archive or shredded.

4.4.5.4. Update protocol database

- The archiving data should be entered accordingly in the protocol database.
- NCH-IRB Staff reviews entries in the protocol data base for the protocol for archiving, to check if all fields are completely filled.

4.5. MAINTENANCE OF CONFIDENTIALITY OF STUDY FILES AND OTHER DOCUMENTS

4.5.1. Purpose

To describe NCH-IRB procedures related to maintaining the confidentiality of the study files and other NCH-IRB documents

4.5.2. Scope

This SOP provides instructions to the NCH-IRB Secretariat related to maintaining the confidentiality of all study files and documents.

4.5.3. Responsibility

It is the responsibility of the NCH-IRB Secretariat to ensure that confidentiality is maintained in the management of all study files and records and to follow the confidentiality procedures when requests to access the files are granted.

4.5.4. Process Flow/Steps

NO.	ACTIVITY	PERSON/S RESPONSIBLE
1	Properly manage all active and archived NCH-IRB files	Member-Secretary, Staff
2	Receive request to access confidential files	Staff
3	Approve and log in requests for access and retrieval of documents	Secretariat
4	Supervise the use of retrieved confidential document	

5	Return document to the file folder	Staff

4.5.5. Detailed Instructions

4.5.5.1. Properly manage all active and archived NCH-IRB files.

- Properly handle original documents and copies of these documents during the day-to-day operation of the NCH-IRB to protect the confidentiality of study files and related documents. Proper handling also involves proper control and care in the distribution and storage of confidential documents of the NCH-IRB.
- Study files submitted to the NCH-IRB and related documents are considered confidential, such as:
  - Study protocols and related documents *(case report forms, informed consent documents, diary forms, scientific documents, expert opinions or reviews)*
  - NCH-IRB documents *(Meeting minutes, advice, and decisions)*
  - Correspondence *(with experts, auditors, study participants, etc.)*

4.5.5.2. Receive request to access NCH-IRB confidential files

Access to NCH-IRB confidential documents is subject to the following limitations:

- Non-members can access specific documents by submitting a formal request. The Secretariat will require a *Confidentiality Agreement Form for Non-Members and Request to Access NCH-IRB Files* to be signed by the person making the request, and approved by the NCH-IRB Chair or designated NCH-IRB Member in the absence of the NCH-IRB Chair.
- Regulatory authorities can have full access to NCH-IRB documents provided it is within their mandate *(e.g. FDA)*, and within a reasonable notice to make the files available.
- The Secretariat records all transactions whenever any document of the NCH-IRB is accessed as described above.

4.5.5.3. Approve and log in requests for access and retrieval of documents

- A separate log is kept in the protocol folder to record access as described above. It contains the following information:
  - Study file code
  - Date borrowed
  - Name of borrower
  - Signature of borrower upon retrieval

- Signature of NCH-IRB Secretariat upon return of document to the file folder
- Document copied
- Number of copies made
- Number of copies received

- All requests for access are recorded by the Secretariat Staff in the log before copies of any documents are released.

4.5.5.4. Supervise the use of retrieved confidential document

- Access to NCH-IRB documents is generally for room use only, but requests to make copies can be accommodated on a case to case basis.
- The Secretariat makes only the exact number of copies requested.
- The recipient signs the NCH-IRB log upon receipt of the copies.

4.5.5.5. Return document to the protocol file folder

The NCH-IRB Staff is responsible for returning the documents in the protocol file folder in the storage cabinet after making sure that all documents are complete as per Protocol File Index.