Standard Operating Procedures for Clinical Research Kanti Children's Hospital			
	ARCHIVING STUDY RECORDS		
SOP#:	**Effective Date:20 Sep,2020**	**Version: 1.0**	**Page: Page 1 of 4**

PURPOSE: This document provides procedures for archiving activities to be undertaken by Kanti Children's Hospital. This SOP complements the information contained in the Guide for IRC / research committee for archiving study documents related to clinical research at Kanti Children's Hospital.

SCOPE: These procedures cover the management of all records both in paper and digital format, throughout research activities after completion of data collection and analysis. This SOP applies the institution, Investigator and research personnel who conduct clinical research studies and Clinical Trials at Kanti Children's Hospital**.**

RATIONALE. This SOP is developed to ensure the effective management of paper and digital records from closure of the study to destruction. Following these procedures will enable entities to identify all paper and digital records which need to be destroyed on-site after definite period; records to be retained on-site which are required by sponsor for preservation and future access as archives. Adhering to these procedures will also mitigate the risk of information loss and unauthorized access to the records. Record management and archiving are one of the key pillars of research site closure.

RESPONSIBILITIES: The PI and designated study team member are responsible for archiving research/ trial related documents in coordination with the IRC member secretary or designated staff of IRC.

DEFINITIONS:

Archive: A way of sorting and organizing older documents, whether it be digitally (photographs online, e-mails, etc.) or manually (putting it in folders, photo albums, etc.).

Case Report Form (CRF): A printed, optical, or electronic document designed to record all of the protocol required information to be reported to the sponsor on each trial subject.

Source Documents: Original documents, data, and records (e.g., hospital records, clinical and office charts, laboratory notes, memoranda, subject's diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate and complete, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept at pharmacy, laboratories, and medico-technical departments involved in the clinical trial).

PROCEDURE:

1. The PI will ensure that his/her records are available for review by the IRC within a reasonable period of time upon request.

2. The PI must ensure that all research records (e.g. signed informed consent documents, source documents, case report forms, laboratory results, and regulatory binder documents) are preservedfor a minimum of five (5) yearsafter the study is closed by the IRC.

3. If the sponsor requires records to be maintained for an alternative period of time, the PI and study personnel will ensure that all research records are preserved for the period of time that meets the requirements of all parties but no less than the five years as required by the IRB

4. The PI should review all written agreements with sponsor to ensure that any additional specific contractual obligations associated with record retention and accessibility are met.

5. The PI and/ or research designee is responsible for the following:
   5.1. Ensure that research study documents should be archived in a legible condition and prompt retrieval should be possible when required.
   5.2. Follow the Sponsor's archiving procedures. The study Sponsor should provide the Principal Investigator (PI) with details of exactly what is to be archived from site.

6. The documents to be archived should include:
   - Site Files.
   - Case Report Forms (CRFs).
   - Pharmacy Site File (if applicable).
   - Sponsor File.
   - Any other documents that may be required to show a clear audit trail of a process performed in relation to the clinical trial.
   - Any source data documents that are not part of a participant's medical notes.

7. Preparing Documents for Archiving**:**
   7.1. The Site File(s) should be organized in suitable binders and/or box files which are to be clearly labeled with the following information.
      - Sponsor's name
      - Sponsor's ID number
      - Short study title
      - Name of the PI

- Brief summary of the contents

7.2. All dividers, paper clips, duplicate documents and irrelevant correspondence should be removed. Only correspondence relating to any agreements or significant discussions relating to the study should be included.

7.3. All CRFs should be removed from their binder, if applicable, and filed with individual patient packs.

7.4. Documents relating to study visits should be bound in chronological order, with the earliest visit on top. These can then be filed directly into the Archive box, put into individually labeled envelopes or filed in a box file. One unused copy of the latest version of the CRF should also be retained if possible.

8. For each archived study, the research designee will maintain a list detailing what has been included in the archived study documents known as *Archiving Log.*

9. Prior to archiving, the research designee will label each Archive Box with:
    - The protocol number
    - The box number and how many boxes there are (e.g. 1 of 5)
    - The name and address of the Sponsor(s)
    - The short title(s)
    - The name and contact information of the PI.
    - List of content for that particular Archive Box (e.g. Regulatory File, CRFs for subjects 001-023).
    - Date of archiving.
    - Expected end date of archiving for each study.
    - A copy of the outer label will also be placed within the box in case the outer label fades over time. The outer label should be secured to the box in a waterproof plastic sleeve.

10. Once documents have been archived, the research designee will document a statement detailing document preparation for archiving that includes:
    - Archive box numbers
    - Where the documents have been archived
    - Number of actual archive boxes
    - Date of archiving
    - Length of time of archiving
    - Expected end date of archiving

11. Monitoring of the Archival Room;

11.1 The room will be locked and the key will be with the administrative focal person of IRC.
11.2 There will be a ledger kept in the room Person should enter his/ her name with time of entry and exit clearly.
11.3 The archival room is under surveillance of CCTV and its footage will be examinedby the administrative focal person at least once in every 15 days. The date and time of such examination will be recorded in a record book. Prompt action is taken if warranted by such examination. If no actions are necessary, the footage of examined duration may be deleted from records.
11.4 The report will be presented in every IRC meeting.

12. Destruction of archived documents after storage
    12.1 The research designee should be contacted prior to destruction
    12.2 Once the agreed date of destruction is known, the research designee or IRC will contact the study Sponsor for written authorization for destruction. Destruction must not take place without written authorization from the Sponsor. If there is no longer an identifiable Sponsor the research designee or IRC will authorize destruction on the agreed date.
    12.3 A certificate of destruction must be issued and the reasons for destruction should be documented.
    12.4 A copy of the record of destruction together with any written authorization for destruction will be retained by KCH IRC for an additional 5 years from the date that the study documents were destroyed.

13. Archiving trial data on computers:
    13.1. The PI will inform the research designee as soon as it is known that electronic study data will need to be archived.
    13.2. Electronic study data should be encrypted and copied onto a read-only media device for archiving with the study documents as described above.

The PI will ensure that all study data held on computer servers are permanently deleted as soon as the study has been reported and the participants notified of the results.

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