Standard Operating Procedure

Archiving/Pre-Archiving

Document Control Sheet

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BACKGROUND

All Research & Development projects should be archived in accordance with ICH GCP guidelines, EU directive on Clinical Trials (2004) and UK Policy Framework for Health and Social Care Research 2017.

It is essential that project documentation can be accessed after the project is complete. Based upon the information archived it must be possible to reconstruct the project and demonstrate that all project activity was compliant with the protocol and followed relevant SOPs.

ICH GCP Guidelines (5.5.11, 5.5.12) state that essential documents be retained 'until at least 2 years after the last approval of a marketing application in an ICH region'.

Archiving is not expected to be the sole responsibility of the Investigator. The Sponsor is responsible for informing the Investigator/Institution as to when documents no longer need to be retained.

PURPOSE

To describe the procedure for archiving site files and study documents when a project has reached completion.

SCOPE

This procedure affects all completed Research & Development Projects.

RESPONSIBLE PERSONNEL

Head of R&D
Senior Research Advisor
Lead Clinical Trials Nurse
Generic Research Nurses
Paediatric Research Nurse
Cancer Trials Nurses
R&D Lead Facilitator
R&D Co-ordinator
R&D Support Officer

ABBREVIATIONS
ICH GCP – International Conference On Harmonisation Good Clinical Practice
GCP – Good Clinical Practice
R&D – Research and Development
PI – Principal Investigator

PROCEDURE
WHO?
The R&D Co-ordinator is responsible for co-ordinating the archiving process.

WHEN?
Research Nurses/PI/delegate of PI will inform R&D Coordinator when a study is ready for:

Archiving – The study is completed and the Sponsor has closed down the study, issued the relevant close down paperwork (if appropriate) and informed the study team that the study can be archived.
or
Pre-archiving – The study has been completed locally but is as yet to be closed down by the Sponsor. To save space these studies are boxed up and stored at Ailsa until a time when the sponsor confirms that it can be closed down and archived (only for studies we have Research Nurses attached to).

HOW? (Archiving)
1 R&D Co-ordinator
- receives communication from Research Nurse / Sponsor (could also come from PI/delegate of PI) to inform that study is ready to be archived
  (Please Note: It is the responsibility of Research Nurse/PI/delegate of PI to collect all study documentation ready for being moved to archiving boxes)
- updates the Archiving Inventory for 'pending studies to be boxed up' (folder location: Governance – Archiving) by adding the project to the list with a note of what stage it is at i.e. study closure docs awaited or ready to be boxed up and that it is for Archiving
- instructs R&D Support Officer to box up study, use labels for each box (see appendix 1) and seal the box
  (Please Note: On the label there is no date required for the 'Date Records Created' box, in this space just record the number of boxes used i.e. Box 1 of 2, Box 2 of 2 etc)
- emails Head Porter when boxes are ready to be collected and taken to Ailsa
- updates the 'pending studies to be boxed up' on the Archiving Inventory with date boxes will be collected

2 Once receipt of boxes has been confirmed at Ailsa (normally by Senior Research Advisor) the study can be updated on the following locations:

- moved to ‘Archived Studies – Ailsa’ on the Archiving Inventory (folder location: Governance – Archiving)
- add to the ‘Corporate Records Retention & Disposal Register - Medical - v00.1 2018-06-19’ of which only R&D Co-ordinator has access to (this drive is a shared drive for Corporate Records Management).

HOW? (Pre-archiving)

1. R&D Co-ordinator
    - receives communication from Research Nurse to inform that study is ready to be pre-archived.
      (Please Note: It is the responsibility of the Research Nurse to collect all study documentation ready for being moved to pre-archiving box)
    - updates Archiving Inventory for ‘pending studies to be boxed up’ (folder location: Governance – Archiving) by adding the project to the list with a note of what stage it is at i.e. ready to be boxed up and that it is for Pre-Archiving
    - instructs R&D Support Officer to box up study, use labels for each box (see appendix 2) and seal the box
    - on the label the ‘Date Due for Destruction’ should read PRE-ARCHIVING
    - on the label there is no date required for the ‘Date Records Created’ box, in this space just record the number of boxes used i.e. Box 1 of 2, Box 2 of 2 etc
    - emails Head Porter when boxes are ready to be collected and taken to Ailsa
    - updates the tracker ‘pending studies to be boxed up’ on Archiving Inventory with date boxes will be collected

2. Once receipt of boxes has been confirmed at Ailsa (normally by Senior Research Advisor) the study can be moved to ‘Pre-archiving’ on the Archiving Inventory (folder location: Governance – Archiving).

ACCESS TO ARCHIVING / PRE-ARCHIVING STORAGE

1. If a Research Nurse requires access to archiving held at Glenrosa Ward, Ailsa Hospital they must request this from the R&D Co-ordinator.
2. The R&D Co-ordinator will contact Information Governance Manager (Corporate Records) to inform them that the Lead Clinical Trials Nurse will be accompanying a member of staff to access Glenrosa Ward.
3. The Information Governance Manager (Corporate Records) will check they are on the authorised access list (R&D Co-ordinator, Senior Research Advisor and Lead Clinical Trials Nurse are on the access list) and ask the staff member to complete the access register and then provide the set of keys and pass code.
4. If the Archiving/Pre-Archiving box is removed from Glenrosa Ward the R&D Co-ordinator will be informed and a record will be made of projects that are removed from storage and their location until returned

to storage (folder location: Governance – Archiving – Archiving Inventory)

5. To return to storage steps 1,2 and 3 above will be followed and the Archiving Inventory updated to reflect that the box has been returned to storage

OTHER RELATED PROCEDURES
N/A

REFERENCES
N/A

APPENDICES
Appendix 1 - Label for Archiving
Appendix 2 - Label for Pre-archiving

Appendix 1
Label for Archiving

Corporate Records Storage

Directorate	Medical
Department	R&D

Box Reference Number		
Description of Records		
Date Records Created	**From**	Box ..... of .....
Date Due for Destruction		
Retain PERMANENTLY	**Yes** ☐	**No** ☒

Date appraised		**Signed**	

Appendix 2
Label for Pre-archiving

Corporate Records Storage

Directorate	Medical
Department	R&D

Box Reference Number			
Description of Records			
Date Records Created	**From**	Box ..... of	
Date Due for Destruction	PRE-ARCHIVING		
Retain PERMANENTLY	**Yes** ☐		**No** ☒

Date appraised		**Signed**	