Swansea Bay University Health Board
Research and Development Department

SOP on Archiving for SBU HB Hosted and Sponsored Studies v2.1, 5.10.20

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1. Purpose

The purpose of this document is to describe the principles and procedures for archiving essential documents of studies Sponsored and hosted by Swansea Bay University Health Board (SBU HB). This SOP is to be followed by all SBU HB staff involved in conducting research within the Health Board.

The named archivist within the R&D Department is responsible for archiving studies sponsored by SBU HB and for hosted studies where Sponsor has given the responsibility of archiving to SBU HB.

It is recognised that both the Cancer and Delivery Teams supporting studies have Working Instructions in place to archive study documents for hosted studies.

This SOP excludes studies which are co-sponsored between SBU HB and Swansea Trials Unit (STU). Swansea Trials Unit SOP on Preparation and Management of Archived Clinical Research Data (STU-SOP-TC-001) will be used for these studies, contact stu@swansea.ac.uk for further advice.

2. Background

This SOP details the procedure to be followed by all SBU HB staff involved in archiving of research documentation generated during studies sponsored by or hosted at SBU HB.

Archiving study documents is the responsibility of the Sponsor but may be delegated to the NHS Organisation in accordance with the site agreement or contract for the study. If the Sponsor has delegated archiving to SBU HB the off- site storage at Transmedia Technology Ltd is used. (Details can be found on Appendix 1).

SBU HB R&D study documents will also be held at Transmedia Technology Ltd, off site storage facility.

The Named Archivist within the SBU HB R&D Department is responsible for archiving SBU HB Sponsored and unsupported hosted studies, including any R&D study documents in accordance with this SOP. Unsupported studies in this context refers to studies which are not supported by one of the research delivery teams. If your study is unsupported, please contact SBU.RandD@wales.nhs.uk for advice and guidance.

Cancer and Delivery Teams supporting studies are responsible for archiving hosted study documentation, as long as agreed by Sponsor at study set up.

3. Roles and Responsibilities

The Sponsor representative, Principal Investigator (PI) or Local study team conducting the study will notify SBU HB R&D when the study documentation is ready for archiving. SBU HB R&D Department will review archiving responsibilities during the study set up and R&D approval process

SBU HB Named Archivist will liaise with Transmedia Technology Ltd for collection of SBU HB Sponsored or unsupported hosted study documents.

Cancer and Delivery Teams supporting studies will liaise with Transmedia Technology Ltd directly for collection of their documents

4. Procedure

The following procedure is to be used by all staff with the responsibility for preparing documents for archiving, following receipt of notification that the study essential documents should be archived.

Part A – notification

Notification that a study has ended may be received in various ways by the R&D Department. This could be:-

- End of Study Notification form
- Email from Health and Care Research Wales, Permissions Service
- Via confirmation from Sponsor/CI direct (old studies pre-Reda)
- Via notification from REC (with REC acknowledgement letter)
- Via R&D Monitoring visit
- Email from local research teams

Part B - preparation to archive documents from:-

Pre-Reda studies

- Remove Pre-Reda R&D study documents from the storage area in readiness for archiving. (R&D Department only)
- Review all documents and ensure the relevant acknowledgements are in place.
    - Investigator Site File (ISF) review usually carried out by delegated study team member, research nurse/manager/coordinator

- Pharmacy File review to be carried out by delegated pharmacy staff
- Commercial Sponsored studies ISF are usually reviewed at the close out visit.

R&D Department

- R&D Department to arrange archiving in accordance with site agreement/contract.
- All essential documents are archived together, eg R&D study documents/site file/pharmacy file

Cancer and Delivery Teams

- to arrange archiving in accordance with site agreement/contract.

Reda studies (Pre-LPMS)- R&D Department only

- Remove Reda record from the 'Active' storage area, in the R&D Office and move in Reda Studies Completed file.
- All essential documents are archived together, eg R&D study documents/site file/pharmacy file.
  - Investigator Site File (ISF) review usually carried out by delegated study team member, research nurse/manager/coordinator
  - Pharmacy File review to be carried out by delegated pharmacy staff
  - Commercial Sponsored studies ISF are usually reviewed at the close out visit.

5. Retrieval of Archived documentation

Any documents which are required from Transmedia Technology Ltd storage must be requested from:-
The Named Archivist or the R&D Department – (For Sponsored or Unsupported Hosted Studies requests should be received from the CI/PI/local study team/Sponsor/or the Regulatory Bodies. Please contact SBU.RandD@wales.nhs.uk for further advice.

Any documents requested from Transmedia Technology Ltd storage will need to be viewed in the R&D Department at SBU HB. Stored trial data will not be permitted to be removed from the R&D Department.

Documents archived by the Cancer or Delivery Teams – request should be made directly with the delegated person responsible for archiving.

6. Length of Archive and Destruction of Documentation

Length of Archive

The length of time documents are archived is the decision of the Sponsor. It is recommended that documents are kept for at least five years from the study end date.

Recommended storage times for study types can be seen below:

- Non – Clinical Trial of an Investigative Medicinal Product (Non-CTIMP) – 5 years
- Clinical Trial of an Investigative Medicinal Product (CTIMP)
- Documents to be retained for a minimum of:
- **5 years** after the conclusion of the trial if not part of a marketing authorisation application
- Regulation 31A(7) of SI 2004/1031 (as amended)
- **15 years** after the conclusion of the trial if part of a marketing authorisation application
- Section 5.2.c of Annex I of 2001/83/EC (as amended)

- Studies involving children – part 2 (2nd Edition) 2009 states that records should be retained "until that patient's 25th birthday or 26th if young person was 17 at conclusion of treatment, or 8 years after death. If the illness could have potential relevance to adult conditions or have genetic implications, the advice of clinicians should be sought as to whether to retain the records for a longer period."

Destruction of Documentation

<u>R&D Department/Named Archivist</u>
The destruction of study documentation after the expiry date should be carried out by the appropriate person. The Sponsor must confirm when trial records can be destroyed (by letter or email).
The Named Archivist within the SBU HB R&D Department is responsible for the destruction of SBU HB Sponsored and unsupported hosted studies.

A record of the documents destroyed will be kept in the Archive folder within the R&D Department for five years after destruction.

<u>Cancer and Delivery Teams</u>
The destruction of study documentation should be carried out by a responsible person delegated to this duty. It is recommended a record of studies destroyed is kept within the Cancer Team or Delivery Team Archive Folder within their department for five years.

7. Related Documents

- Swansea Trials Unit SOP on Preparation and Management of Archived Clinical Research Data (STU-SOP-TC-001)

Appendix 1

Transmedia Technology Limited
Contact Details
V1, July 16

Main Office Address:
Transmedia Technology Limited,
Kingsway,
Swansea West Business Park,
Fforestfach,
Swansea,
SA5 4DL

Email:
info@tmt.co.uk

Telephone Local Rate
0330 445 0110

Main Office Directions
Exit M4 at Junction 47
At the roundabout, exit onto A483
(2nd exit West bound, 4th exit East bound)
At the roundabout, take the first exit and keep right.
At the traffic lights, turn right onto Ffordd Cynore/B4620
Continue through two sets of traffic lights, entering
Fforestfach Industrial Estate
Turn left onto Kingsway then immediately on your left is
Transmedia Technology