Great Western Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure:

ARCHIVING for Trust Hosted Research

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Author:

Name: Catherine Lewis-Clarke Position: R&I Manager Signature:

Date: 1 APRIL 2017

Approved by:

Name: S J Pells Position: Director of R&I Signature: Date: 01/04/17

Name: SPEGLER Position: Lead Research practitioner Signature: Date: 01/04/2017

1. BACKGROUND

The procedures for archiving follows study close out and may vary depending on the sponsoring organisation. However, the Trust has a responsibility to ensure that appropriate arrangements are in place for archiving research documentation in accordance with applicable legislation and guidelines.

Trial documentation must be retained for specified periods of time so that data is accessible after a trial has completed to enable, for example:

- Further analysis of trial data;

- MHRA or other inspection

- Monitoring adherence to Good Clinical Practice (GCP)

2. PURPOSE

The purpose of this SOP is to detail the procedure for archiving trial documentation for all trials hosted by the Great Western Hospitals NHS Foundation Trust (the Trust).

Retention of trial documentation is a legal requirement for clinical trials of Investigational Medicinal Products, and clinical trials of medical devices - it is also good practice to treat non-interventional studies in the same manner.

3. APPLICABLE TO

This SOP is for all staff working on research at the Trust. The responsibility for the archiving process applies to Principal Investigators of trials hosted by the Trust and sponsored by an external organisation. This task will be delegated by the PI to the R&I Department who will ensure this process is completed in a timely manner.

4. PROCEDURE

This SOP will be referred to during trial feasibility/set up to ensure that the requirements and cost of archiving have been identified and can be fully met in a timely manner.

Archiving will then take place once the Sponsor has given specific instruction to the participating site to do so and the Trust will comply with arrangements as per site agreement/statement of activity.

On receipt of written instructions from the Sponsor the PI and the local trials team will work with the R&I Department to prepare the trial essential documents for archiving. Where pre agreed arrangements for archiving have been made these will be followed. If the Sponsor is responsible the host site will ensure all essential documents are returned for archiving following the process set out by the Sponsor. If responsibility falls to the Host Site then the data will be archived appropriately and stored in a physical location that is weatherproof and secure at all times.

The Trust Storage facility is currently Crown Records Management, Britannia Trade Park, Swindon.

A record is kept of all trial data is and is held within the R&I Department. All retrievals/ re-archiving will be controlled and documented. Retrievals from archive are restricted to a limited number of circumstances and should be kept to an absolute minimum.

Any requests for retrieval of any documents held at third party storage facility will require authorisation by the R&I Manager.

Access to the research data will be restricted to authorised personnel, and will therefore be kept in a locked cabinet or in an area with swipe card, keypad or locked access.

The duration of archiving retention will vary dependant on the research undertaken and as such will be stored as per the Sponsors instruction and/or Protocol in line with current legislation.

In regards to electronic data, the site must ensure consideration is given to maintaining continued access to data possibly over a number of decades. Updating of IT systems, the hardware and software will be under the guidance of the Trust IT Support Service. New written procedures will be produced if and when required to identify the new systems to be used, outline the transfer and validation of the data.

Essential documents will only be destroyed upon receipt of written instruction to do so from the sponsor/CI or PI.

The R&I team may contact the Sponsor/ CI or PI at least one month before the due date for destruction to confirm arrangements.

Actual destruction methods will be those outlined by the Sponsor or in accordance with the Trust policy.

The actual date of destruction will be recorded by the R&I team.

5. SUPPORTING DOCUMENTS

http://ichgcp.net/8-essential-documents-for-the-conduct-of-a-clinical-trial

GWH Retention of Records Policy - (available on Trust intranet – or copy on request).

GWH Records Management Policy - (available on Trust intranet – or copy on request).

Trust SOP for Study Close Out.