University Hospitals Bristol NHS
NHS Foundation Trust

Guidance Notes:

ARCHIVING OF RESEARCH DOCUMENTATION

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1. PURPOSE & SCOPE

1.1. The purpose of this document is to describe the procedure for archiving project documentation for all research projects at University Hospitals Bristol NHS Foundation Trust (UH Bristol).

1.2. Retention of project documentation is a regulatory requirement for clinical trials of Investigational Medicinal Products (CTIMPs).

1.3. The procedure for archiving 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.

2. REASONS FOR ARCHIVING DOCUMENTATION

2.1. Project documentation must retained so that data are accessible after a project has completed to enable, for example:

- Further analysis of project data;
- MHRA or other inspection/monitoring to Good Clinical Practice.

3. STANDARDS OF RETENTION

3.1. All documentation must be complete, legible and recorded so that it is traceable at all times and readily accessible to the authorities upon request.

3.2. Documents must be retained for the minimum length of time stipulated in regulations and guidance (see paragraphs 5 and 6 below), whilst at the same time taking full account of the principles enshrined in the Data Protection Act that personal data should be held for no longer than is absolutely necessary.

3.3. For projects which do not complete and depending on the stage at which a project is terminated, some documentation may still need to be archived. The Principal Investigator (PI) should seek guidance from the sponsor and/or follow any advice as set out in the protocol and/or the study agreement between the sponsor and UH Bristol.

3.4. Documents should be removed from ring binders or lever arch files to keep storage space to a minimum.

3.5. Documents may be held together by plastic archiving clips but plastic wallets and all paper clips, staples or metallic means of combining sheets should be removed to prevent rusting or other chemical deterioration.

3.6. The Trust's third party storage facility, Restore, requires that packed archiving boxes weigh no more than 15 kilos. For health and safety reasons, it is recommended that wherever archiving boxes are stored, they do not exceed this upper limit. Archiving boxes which are to be stored at an off-site facility should be sized between 1.00 and 1.3 cubic feet.

3.7. CTIMP studies which are not going into a third party storage facility should be labelled using the template labels on the R&I website. All storage boxes going into a third party storage facility should be labelled with a unique code comprising the R&D project number, the box number and the total number of boxes, for example CH/2008/2315 Box 2/5, in addition to any assignment number provided by the third-party archiving organisation. Boxes to be stored at an off-site storage facility must be labelled with a marker pen on the short end of the box. It is also recommended that a list setting out the contents of the box is placed inside the box or attached to the inside lid of the box.

3.8. For non-CTIMP studies where source data or patient identifiable data has been collected and needs to be retained at this site, archiving arrangements should be as set out in this guidance. For all other types of non-CTIMP studies, the PI should check with the Sponsor what archiving arrangements are required. In some cases, there may be no need to archive material at this site.

3.9. It is important that research data are stored in a physical location that is weatherproof, secure at all times and environmentally controlled. Access to the research data should be restricted to authorised personnel, and should therefore be kept in a locked cabinet or in an area with swipe card access. For projects being stored at a third party storage facility, archiving should be managed by a reputable provider in premises that satisfy these criteria.

4. RESPONSIBILITIES

4.1. The Sponsor has overall responsibility for the archiving of essential documents.

4.2. For commercial studies, the Sponsor may put in place arrangements for third party archiving. However, it is the responsibility of the participating site to archive their documents. Increasingly, it is common practice for the Sponsor to request the participating site to arrange third party archiving and to remunerate accordingly.

4.3. The Principal Investigator (PI), for both commercial and non-commercial studies, is responsible for archiving data generated as a participating site and for maintaining a record of the archived material.

4.4. In the case of a multi-centre trial sponsored by UH Bristol, the study agreement delegates responsibility for archiving to the participating sites. The lead investigator at

each site has a responsibility to allow UH Bristol or the regulatory authorities to access to archived data upon request.

4.5. If the documentation is to be stored at third party storage facility contracted by UH Bristol, the PI should liaise with the Research Management Office or the relevant trial unit manager, as appropriate, about initial set up of arrangements with the third party provider. The PI is responsible for packing the documentation into archiving boxes and ensuring that the boxes are collected for storage. The Research Management Office, or the relevant trial unit, is responsible for invoicing and authorising payments.

4.6. The PI is responsible for maintaining a record of material archived and for returning a completed Project Archiving Record to the Research Management Office. A template is available on the R&I web pages.

4.7. If the PI leaves the Trust during the archival period, arrangements should be made to ensure the safekeeping and security of information. There should be a clearly documented handover of responsibility.

5. ARCHIVING – CLINICAL TRIALS OF INVESTIGATIONAL MEDICINAL PRODUCTS (CTIMPS)

5.1. The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 makes the archiving of clinical trial documentation a legal requirement. The ICH GCP (Good Clinical Practice) Guidelines define and list all of the documents that are essential for the conduct of a clinical trial.

5.2. EC Directive 2003/63/EC requires that essential documents be retained for at least fifteen years after completion or discontinuation of the trial or for at least two years after the last approval of a marketing application in the region.

5.3. The Medicines for Human Use (Clinical Trials) Regulations require that the medical files of trial subjects are retained for at least 5 years after completion of the trial.

5.4. For practical purposes, commercial trial documents are usually archived for a period of 15 years. The cost of archiving commercial studies should be recovered by UH Bristol and the archiving fees specified in the agreement between UH Bristol and the Sponsor.

5.5. Where UH Bristol is the Sponsor, clinical trial documentation will be retained for a period of 15 years following completion of the trial.

6. ARCHIVING – PROJECTS OTHER THAN CLINICAL TRIALS OF CTIMPs (NON-CTIMPs)

6.1. There is no legal requirement to archive documentation for non-CTIMPs. The Medical Devices Regulations 2002 do not include any express legal requirement to archive trial data gathered from clinical investigations of Medical Devices (ciMDs).

6.2. However the ICH GCP Guidelines state that the same principles for CTIMPs *"may also be applied to other clinical investigations that may have an impact on the safety and*

well-being of human subjects." The Guidelines state that *"the Sponsor or owners of the data should retain all of the Sponsor-specific essential documents pertaining to the trial."* Joint guidance issued by the Department of Health and the MRC (Medical Research Council) recommends 5 years.

6.3. In view of the above, it is therefore good practice to archive research documentation for all non-CTIMP studies.

6.4. Where UH Bristol is the Sponsor of a non-CTIMP project, documentation must be retained for a minimum a period of 5 years. Depending on the type of study (e.g. clinical genetic studies) or the patient group (e.g. children) a longer period may be required. If the study involves children under 18 years old, essential documents should be archived until three years after the youngest subject reaches 18 years old, or 5 years after the conclusion of the research, whichever is longer.

7. ARCHIVING PROCEDURE

7.1 The following procedure should be followed by the PI in order to archive research documentation:

STEP 1) Upon completion (or termination) of a project, notify the appropriate authorities (e.g. ethics and MHRA) and complete other obligations.

STEP 2) Ensure that the Site File or Trial Master File is tidy and complete and documents are stored in a logical order.

STEP 3) Collate and order CRFs (Case Report Forms) and other patient-related medical documentation.

STEP 4) Contact the Research Management Office or your trials unit manager if documentation is to be stored at a third party storage facility.

STEP 5) Complete the UH Bristol Project Archiving Record Form.

The Research Management Office will record the date of receipt of the Project Archiving Record Form and due date for destruction.

8. RETRIEVING ARCHIVED DOCUMENTS

8.1 Retrievals from archive are restricted to a limited number of circumstances and should be kept to an absolute minimum.

8.2 The retrieval of any documents held at third party storage facility will require authorisation by the Research Management Office or the trials unit manager. The costs for doing so must be recovered from the Sponsor (if it is not UH Bristol). The retrieval should be controlled and documented.

8.3 The Research Management Office maintains a log of commercial projects where UH Bristol has a contractual arrangement with an off-site storage facility and non-commercial CTIMP studies archived since 2004.

9. DESTRUCTION OF DOCUMENTS

9.1 The Research Management Office will contact the PI at least one month before the due date for destruction to confirm arrangements for destruction.

9.2 The actual date of destruction will be recorded by the Research Management Office.

10. REFERENCES & RELATED GUIDANCE

Department of Health (DoH)
Research Governance Framework for Health & Social Care, 2nd Edition, April 2005
http://www.dh.gov.uk/en/publicationsandstatistics/publications/publicationspolicyandguidance/dh_4108962

Department of Health (DoH)
Research involving the NHS: Retention of Records
http://www.dh.gov.uk/prod_consum_dh/idcplg?IdcService=GET_FILE&dID=137285&Rendition=Web

Department of Health (DoH) & Medical Research Council (MRC)
Clinical Trials Toolkit: Joint Project Notes on the Archiving, Storage & Destruction of Documents
http://www.ct-toolkit.ac.uk/_db/_documents/Archiving.pdf

ICH Secretariat
Guidelines for Good Clinical Practice (GCP) (E6 R1 Step 4, 1996)
http://www.ema.europa.eu/pdfs/human/ich/013595en.pdf

Institute of Clinical Research (ICR Publishing)
Archiving Clinical Trial Documents (2nd Ed.)

UK Government
Medicines for Human Use (Clinical Trials) Regulations 2004 SI 2004/1031
http://www.nres.npsa.nhs.uk/applications/after-ethical-review/endof/

UK Government
Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2006 SI 2006/1928
http://www.nres.npsa.nhs.uk/applications/after-ethical-review/endof/

UK Government
Data Protection Act 1998
http://www.legislation.gov.uk/ukpga/1998/29/contents