SOP-QA-36 V5

Title: Retention of health records of clinical trial patients

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Document History

Version	Description of update	Date Effective
3	New SOP author identified Updated reference regarding GDPR and Data Protection Act (2018) at 1.1 and 5 Reference to TrakCare® at 3.3 Addition of patient record destruction algorithm at appendix 1	1-6-18
4	GDPR changed to UK GDPR and change to scope of studies at 1.2 Research Study identification requirements clarified at 3.4 3.10 removed. Addition of 'Lead Research Nurse' at Appendix 1	21-6-21
5	Scheduled review at three years. New SOP author identified.	21-6-24

1. Scope

1.1 This SOP describes the process to be followed to ensure that paper-based health records of patients participating in clinical trials are managed, stored and archived in accordance with regulatory requirements (including the UK GDPR, the Data Protection Act (2018) and NHS Grampian (NHSG) policy on the retention and disposal of patient records).

1.2 This SOP applies to University of Aberdeen (UoA) and/or NHS Grampian (NHSG) researchers that have recruited patients from NHSG into a Clinical Trial of an Investigational Medicinal Product (CTIMP), Medical Device Clinical Investigation (MDCI), combined trial of an investigational medicinal product and an investigational medicinal device, or other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice, Health Records staff and archiving team staff.

2. Responsibilities

Researchers	Ensure paper health records of participants are identified appropriately.
Health Records	Ensure paper health records identified as participants in a research trial are not destroyed before the specified time.
Archiving team	Ensure paper health records of participants are archived appropriately.

3. Procedure

3.1 Maintaining study files, retention of study documentation and allocation of resources to provide storage should be considered at the planning stage of a clinical trial. Information on the length of storage of documents is provided to the Research Ethics Committee (REC) and Research & Development office (R&D) as part of the submission for approval of the study, and

should be in line with legislative requirements, Sponsor recommendations and national and local policy for the retention and storage of documents.

3.2 In the case of a CTIMP and/or MDCI, retention of essential documents is mandatory for a period of **twenty-five** years, to allow further analysis by the original or other research team, subject to consent, and to support monitoring by regulatory and other authorities. For example, this may be necessary in the event of unexpected side effects after a trial drug has been approved.

Paper health records

3.3 It is essential that the medical records of **all** patients recruited to a CTIMP, or MDCI are marked by activating an alert on TrakCare® and by placing a sticker on the pink sheet of the patient medical record. If there is no pink sheet it may be adhered to the inside cover of the health record (see SOP-QA-36 Appendix 1).

3.4 Minimum requirements on the sticker are:

- Patient Name
- CHI number
- Research Study (Name, IRAS Number)
- Do not destroy until
- Contact
- Signature

3.5 Stickers should be attached at the point consent is taken from a participant.

3.6 If there are study specific stickers provided by the Sponsor these must be adhered alongside the retention sticker.

Archiving of paper notes

3.7 Paper records of patients noted as having participated in clinical trials shall not be destroyed at the end of standard minimum retention periods until authorised by the NHSG R&D team.

3.8 The earliest destruction date recorded (see 3.4) shall prevent any paper record being destroyed until the specified date has been reached.

3.9 Should a clinical trial patient be deceased and their records fall into a category to be scanned (eg death records of cancer patients) then that paper record shall be removed from the normal health records procedure and forwarded to NHSG R&D Team.

4. Abbreviations and definitions

TrakCare®	Patient Management System

5. Related documentation and references

SOP-QA-32	Archiving
-	UK General Data Protection Regulation (GDPR)
-	Data Protection Act (2018)
-	Scottish Government Records Management: NHS Code of Practice (Scotland)

SOP-QA-36 V2 Appendix 1

Recording Patient as Clinical Trial Participant on TrakCare® Patient Management System

By following the steps below an alert will be added to the patient's TrakCare® PMS record to show they are a clinical trial participant. This shall protect their record from destruction at the end of standard retention periods.

Once logged into TrakCare® PMS:

1. Select Patient Demographic.
2. MPI.
3. Click on the 'Alerts' link on the right of the screen.
4. Clinic on 'New'.
5. Type Clinical (or CLINI tab) in the Alert Category field.
6. Using the spyglass icon next to the Alert field, select Clinical Trial Participant.
7. In the Expected Review Date field, enter the date at which the records no longer need to be retained and thereby the alert no longer necessary.

Establishing if Paper Health Records of patients involved in clinical research can be destroyed after scanning