Sheffield Teaching Hospitals NHS
NHS Foundation Trust

STANDARD OPERATING PROCEDURE

STH Researcher

Recording of research information in patient case notes

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	A124 Maintaining the Case Record Form (CRF) for externally sponsored studies
Approved by	*Senior Research Manager*

Standard Operating Procedure: Research Department

Recording of research information in patient case notes

This SOP has been produced in accordance with Medicines for Human Use (Clinical Trials) Regulations 2004, and subsequent amendments, ICH GCP Guidelines and Research Governance Framework 2005. This SOP will outline the procedure for the retention of research information in patient case notes.

Background

The legal framework for research documentation is clearly defined under ICH GCP for studies involving Investigational Medicinal Products (IMP). Clear guidance on what is required for Trial Master Files and Investigator Site Files is found within ICH GCP (section 8). Source data is also defined under GCP as "All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. Source data are contained in source documents." Whilst the legal framework applies only to IMP studies the best practice it describes is applicable to all research involving patients, patient data or tissue. This SOP will advise all researchers interacting with the Trust and Trust patient's case notes to ensure a consistent approach to this important aspect of clinical research and ensure patient safety is maintained.

Definition

Documentation of participation in the patient case notes is required for all patients recruited into all studies being conducted at STH.

Items required in order to document participation are:

- Alert divider
- Research Department divider
- Research Sticker
- Research Reference Tracking Sheet
- Research Alert page (IMP or non-IMP)

For all studies the Research Alert Page must also be completed and included in the patient case notes..
At Sheffield Teaching Hospitals NHS Foundation Trust patient case notes are not destroyed but are transferred to alternative media. At the time of writing this SOP the media is optical disc. This form of storage is accessible indefinitely, and addresses issues of archiving in accordance with standards set by the MHRA.

Procedure

1. The Chief Investigator (CI) or Principal Investigator (PI) (or delegated member of the research team) will consider the information that will be required to be kept in patient case notes, prior to the involvement of any participants in a research study.

2. The CI or PI (or delegated member of the research team) will ensure they have sufficient research alert stickers (appendix 3) available for the estimated patient recruitment. Research alert stickers will be available from the Research Department (please contact your allocated Research coordinator who will send the required number of stickers out via internal post). Some commercially sponsored studies have their own stickers which may be used if approved by the Research Department, as part of the Research Governance checks.

    a. Upon completion of the patient's involvement in the study the sticker will be replaced with a second 'completed' sticker.

3. The CI, PI or delegated person will ensure they have sufficient alert section dividers and research section dividers (one per participant). These will both be available from the Research Department.

4. Upon successful screening for inclusion the CI, PI or delegated person gains informed consent from the participant and records the process fully in the continuation notes. This record should include:
   - the date and time the participant received the information sheet
   - the date and extent they discussed the project and with whom
   - the date of consent and time

   For further detailed guidance see National Research Ethics Service Guidance http://www.nres.nhs.uk/applications/guidance

5. The CI, PI or delegated person places a completed research alert sticker on the inside front cover of the patient case notes and inserts an alert section divider if one is not already present. This alert section divider is situated after the Single Assessment Process initial assessment and contains, besides research alerts, clinically relevant alerts relating to infection control and/or resuscitation status.

6. The CI, PI or delegated person completes the research alert page (Appendix 1) and files it in the alert section. This contains important and relevant trial details and has contacts and sources of further information for all staff interacting with the patient. The research alert page will direct readers to refer to the research section of the notes for further information.

   a. The CI, PI or delegated person will choose the IMP research alert page(PD5382) if the study is a clinical trial of an IMP or medical device, and for all other studies the research study alert page(PD5381) will be used.
   b. It is the CI, PI or delegated person's responsibility to update the research alert page in line with any changes to the study or study conduct.

7. The research section divider is inserted in the case notes at the end of the clinical records and will contain, as a minimum, a copy of the signed informed consent form and associated patient information sheet. Guidance on what is required to be kept in the research section is detailed on the research section divider.

8. All research activity should be recorded contemporaneously on continuation sheets in the research section, unless the activity is directly associated with clinical care, in which case it will be recorded in the standard clinical care continuation sheets of the treating speciality/ consultant.

9. For trials where clinical and research activity are inseparable, a reference/tracking sheet (PD5383)(Appendix 2) should reference the date of research activity recorded in the clinical notes. This is preferable to duplicating complete entries for the purposes of the research section.

10. Where source data is held outside of the patient case notes the reference sheet should describe where the source data is stored.

Recording of research information in participant case notes: Healthy Volunteers

For studies involving volunteers, a participant's case notes are not required and may not exist. In this instance a source data file should be created to ensure any identifiable documents are stored separately from the Case Report Form.

The exact format of the source data file should be determined prior to study commencement, and should contain as a minimum:

- a front sheet that details the participant's details

- brief details of the trial and importantly emergency contact details
- patient Information sheet and Informed consent in line with NRES Guidance
- continuation sheets where all research activity is detailed contemporaneously.

Further guidance on volunteer studies can be gained from the STH Clinical Research Facility.

Associated Documents

	Document	Research Department Network Location	Website	Database	Created by
2	Alert Page (non IMP)	PD5381_Research Alert Page Non IMP	No	No	AL
3	Alert Page (IMP)	PD5382_Research Alert Page IMP	No	No	AL
4	Reference/Tracking Sheet	PD5383	No	No	DW
5	Research Sticker	Available from Research co-ordinator	No	No	AL
6	Research Divider	Available from Research co-ordinator	No	No	DW
7	Alert Divider	Available from supplies	No	No	na