Sheffield Teaching Hospitals NHS
NHS Foundation Trust

Clinical Research & Innovation Office

STANDARD OPERATING PROCEDURE

STH Researcher

Research alerts and recording of research information in patient case notes

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Date effective	19 Mar 2024	**Author**	Erica Wallis
Related SOPs	A106 Informed consent A124 Maintaining the Case Report Form (CRF) for externally sponsored studies A127 Archiving of Essential Documents Generated During Clinical Research C128 Case Report Forms C120 The Use of Human Tissue in Research		
Approved by (name & role)	Dr Dipak Patel, Associate Director R&I	**Date**	05 Feb 2024
Signature:			

Standard Operating Procedure: Clinical Research & Innovation Office

Research alerts and 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 UK Policy Framework for Health and Social Care Research.

This SOP will outline the procedure for the placing research alerts in medical records and for the recording and retention of research information in patient case notes.

Background and Definitions

It is vital that the procedure for identification of patients that are actively involved in clinical trials, is clear and consistent. Identification is necessary to ensure that all clinical staff are aware that the patient is part of a clinical trial involving medicine and/or other treatment that might impact on their care. This identification is particularly important in the case of emergency admission to hospital where rapid access to information about clinical trial involvement may be pertinent to a participant's emergency care. In addition, procedures need to be consistently available by which clinical staff treating a trial patient can notify trial staff and trial investigators that their participant has received additional care outside of the trial, so that investigators can assess if these events influence their trial participation, or require any onward reporting. This SOP applies to all research studies which involve STH patient information systems, such as patient notes, electronic records and Patient Administration System (PAS) as part of clinical trial or research study activity.

The legal framework for research documentation is clearly defined under ICH GCP and in Clinical Trials Regulations 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 can be applied to all research involving patients, patient data or tissue.

Increasingly medical records are being created and/or held electronically rather than in hard copy. The MHRA has provided a position statement on the requirements for electronic medical records as a suitable conduit for the recording and retention of source data within clinical trials.

Retention of, and access to source data is key in the verification of the integrity of study data. As such the sponsor must be provided with access to source data within the terms of the participant consent for the purposes of such study data verification.

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 scanned certified copy. This form of storage is accessible indefinitely and addresses issues of archiving in accordance with standards set by the MHRA.

The purpose of this Standard Operating Procedure (SOP) is to describe a system for identifying research participants (both in the patient case notes and in core electronic records systems) and for recording, retaining and making available further information on and clinical data generated by the research.

Scope

All aspects of this SOP will apply to the medical records for participants on all research studies which are classed as clinical trials.

Clinical trials are those studies which measure the efficacy and/or safety of an intervention. They will be classed in the IRAS form project filter as:

- Clinical trial of an investigational medicinal product
- Clinical investigation or other study of a medical device
- Combined trial of an investigational medicinal product and an investigational medical device
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

In addition to all processes being followed for all clinical trials, the following aspects of this SOP will apply in the following cases:

- The processes for including a research alert and informed consent records in medical records should also be used for any other study where there is a need to place a research alert in the medical records for any specific reason. This would be for any study where involvement in the study is of direct clinical relevance to the clinical care of the patient

- The processes for filing informed consent must also be followed for participants in all research studies which involve the storage of samples which are relevant to the Human Tissue Act

- The processes for recording of source data in medical records must be followed in the case of any research study which collects clinical data which will be of relevance to the participants' ongoing clinical care

Procedure

1. Documentation of informed consent in medical records – This section applies to:

- all clinical trials
- all studies which involve the storage of samples which are relevant to the Human Tissue Act
- any other study where consent takes place alongside usual care and documentation of informed consent in medical records is desirable for any reason

1.1. The process of informed consent is described in full in STH CRIO SOPA106 "Informed Consent". The procedure must be fully documented in the medical records. The written record of informed consent should include:

1.1.1. the date the participant was sent or received the information sheet. The time should also be included for studies where consent is obtained on the same day that the PIS is provided.

1.1.2. the date they discussed the project for the purposes of consent and with whom

1.1.3. the extent of the discussion around informed consent including any specific questions answered

1.1.4. the date of consent. The time should also be included for urgent care studies and studies where consent is obtained on the same day that the PIS is provided.

1.2. A copy of the fully signed informed consent form and the associated participant information sheet must filed in the medical records. This should be filed behind a Research divider (available from the Clinical Research & Innovation Office by contacting sth.researchadministration@nhs.net quoting the study STH number and the number of dividers required).

1.2.1. Where the study in question is an urgent public health study or is carried out in response to a pandemic or involves the recruitment of large numbers of participants and other arrangements can be put in place to allow clinicians to be aware of the study or to access the participant information sheet via other means, unless the study sponsor requires otherwise, it is permissible for only the completed pages of the consent form itself to be filed, without the associated participant information sheet.

1.2.2. In the case of healthy volunteer studies and other studies where participants may be recruited who do not have already have STH notes, where it has been agreed that

participants will not have hospital medical records created for the purposes of the trial, refer to section 4 of this SOP.

1.3. In the case of the need for reconsent to take place the above processes should be repeated

2. Research Alerts – This section applies to

- all clinical trials except low risk trials eg healthy volunteer vaccine trials and similar by prior agreement with the Clinical Research & Innovation Office and study sponsor.
- any other study where there is a need to place a research alert in the medical records for any specific reason

2.1. The PI (or delegated member of the research team) ensures they have sufficient research alert stickers (appendix 3) and Research section dividers available for the estimated patient recruitment. The PI or delegated member of the research team requests supplies by contacting sth.researchadministration@nhs.net quoting the study STH number and specifying the number of research alert stickers required. Research dividers can be ordered via standard trust print routes.

2.2. The PI (or delegated member of the research team) selects the appropriate research alert page:

2.2.1. The PI or delegate chooses the IMP research alert page (PD5382) if the study is a clinical trial of an IMP or medical device, and the research study alert page (PD5381) for other studies requiring an alert page.

2.3. The PI or delegate may pre-populate the research alert page with the trial details. These include STH number, study title, study drug/device, code break procedures and contact numbers, location of protocol and contact details for key members of the study team. It is the PI or delegated person's responsibility to update the research alert page in line with any changes to the study or study conduct.

2.4. When a participant is enrolled in the trial, the PI or delegate completes a research sticker and participant specific details on the research alert page.

2.5. The completed sticker is stuck on the inside front cover of the participants medical records. The completed alert page is filed behind an Alert divider placed at the front of the notes. 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

2.6. The PI or delegate logs into Lorenzo and navigates to the participant's electronic medical record. The PI or delegate creates an alert in Lorenzo by adding the participant to the Research Alert register. This will result in a pop-up alert showing when the patient is selected which reads "***This patient is taking part in an interventional research study. Please check the Research Alert Page in the patient notes for further details."***

2.7. When the participant's participation in the trial is complete the PI or delegate logs into Lorenzo to remove the research alert from the participant's electronic record. The PI or delegate also completes the relevant dates in the research alert page to close the alert, which should then be moved from the Alert section of the notes to behind the Research divider

3. Recording of source data in medical records – This section applies to

- All clinical trials except low risk trials eg healthy volunteer vaccine trials and similar where source data files will be used instead of the creation of medical records by prior agreement with the Clinical Research & Innovation Office and study sponsor (see section 4).
- any research study which collects clinical data which will be of relevance to the participants' ongoing clinical care

3.1. 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 (noting exceptions above).

3.2. 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 contemporaneously in the standard clinical care continuation sheets of the treating speciality/ consultant.

3.3. All source data records should be clearly identified by a date (and a time where relevant). Where data is collected specifically for the research then the identity of the person collecting the data should also be clear.

3.4. Source data may be collected electronically where systems for electronic health records are in place. It is important that electronic health records are completed contemporaneously during the visit and by the person collecting the source data so that they can be considered as source data. If it is not possible for electronic medical records to be completed in real time then the original record of the source data as recorded during the visit must be retained in the medical records or other source data file and must be considered as source.

3.5. Source data relating to investigations and investigation reports must be filed in medical records either electronically or in hard copy as appropriate where the investigations are of clinical relevance. Where the investigation is of clinical relevance or otherwise requires clinical interpretation, the filed record should also carry a record of who has reviewed the investigation and/or report, when this review took place and an assessment of the clinical significance of any findings.

3.6. Where source data collected solely for the purposes of research is not relevant to the clinical care of the participant outside the research study and in certain cases where it is not feasible to file source data contemporaneously in medical notes, the source data may be held separately from medical notes in a source data file which should be stored securely, generally alongside the study Investigator Site File. Where the source data has relevance to clinical care it should be filed in the medical notes when this becomes feasible and in any case at the end of the study. Where such source data is of no relevance to clinical care it may be archived alongside the Investigator Site File.

4. Recording of research information in participant case notes: Healthy Volunteers

4.1. For studies involving volunteers, a participant may not have existing Trust medical records. Where this is the case medical records should be created if the study requires creation of a medical alert (see section 2) or where the participants' involvement in the study will create records of relevance to their medical care outside the research (see section 3). Where the creation of medical records is not necessary a source data file should be created to ensure any identifiable documents are stored separately from the Case Report Form.

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

4.2.1. a front sheet that details the participant's details including routine and emergency contact details and brief details of the study

4.2.2. continuation sheets and/or data collections forms where all research activity is detailed contemporaneously.

4.2.3. A copy of the signed informed consent pages, with or without the corresponding patient information sheet (see section 2) may be filed in the source data file where this is a sponsor requirement and also where it is felt this will be helpful for staff to confirm consent or to track consents for the purposes of reconsenting. The signed ICF must be filed in the source data files in cases where the source data files <u>will not</u> be archived in the same location as the Investigator Site File (which will contain the original signed consent forms and PIS) for any reason. The decision on whether or not to file the ICF

and/or PIS should be made on a study-wide basis before the study commences following consultation with the sponsor.

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

5. Access to source data held in medical records

5.1. The participant information sheet and consent form will generally grant the Sponsor and regulatory authorities access to identifiable medical records for the purposes of audit and monitoring.

5.2. Where this is the case the medical records must be made available for these purposes to agents working on behalf of the Sponsor or regulatory authorities. This will generally be during an onsite monitoring or audit visit and the study team will make the necessary arrangements so that the medical notes for relevant participants will be available to the monitor for the duration of their visit. The monitor will not be permitted to retain copies of any identifiable medical records except where explicit and specific patient consent has been provided within the terms of the ethical approval or where CAG approval for such transfer of identifiable data is in place.

5.3. In the case of electronic records where it is possible for the monitor to be issued with access to the EHR (eg in the case of EDMS), this will be arranged in advance of the monitor's visit by liaison with the STH IT team in accordance with the Guidelines for Obtaining Monitor Access within the NIHR Sheffield Clinical Research Facility.

5.4. Where it is not possible for the monitor to be provided with a personal log-in the monitor may view electronic records accessed by a member of the study team only under the personal supervision of that member of the study team.

5.5. In cases where monitoring of source data needs to take place via a remote monitoring visit medical records may be shared with an authorised monitor via MS Teams only. Paper records may be shared by showing records via a video camera and electronic records may be shared via screen share. The monitor must not record or retain screen shots of medical records viewed in this way. Identifiable documents may not be sent to the monitor electronically via email or via MS Teams or any other means except where explicit and specific patient consent has been provided within the terms of the ethical approval or where CAG approval for such transfer of identifiable data is in place.

Appendix 1 Associated Documents

	Document	Clinical Research & Innovation Office Network Location	Website	RMS	Created by
2	Alert Page (non IMP)	PD5381_Research Alert Page Non IMP	Yes	No	AL
3	Alert Page (IMP)	PD5382_Research Alert Page IMP	Yes	No	AL
5	Research Sticker	Available from sth.researchadministration.nhs.net	No	No	AL
6	Research Divider	Available from sth.researchadministration.nhs.net	No	No	DW
7	Alert Divider	Available from supplies	No	No	N/A
8	Guidelines for Obtaining Monitor Access within the NIHR Sheffield Clinical Research Facility	S:\General\Research Governance\Monitoring Documents\Research Department Monitoring Requirements\	No	No	CRF
9	MHRA Position Statement and Guidance – Electronic Health Records	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/470228/Electronic_Health_Records_MHRA_Position_Statement.pdf	No	No	N/A

Appendix 2 SOP revisions and history

SOP number	Effective date	Reason for change	Author
THIS SOP			
A108 V4	19 Feb 2024	• Revision to restrict requirements for recording of research information in notes to certain studies. • Revision to include electronic health records in the provision of research alerts and the collection of source data • Addition of procedures for sponsor access to source data • Other minor revisions	EW
PREVIOUS SOPs			
A108 3.5	28 Oct 2010		AL