York and Scarborough Teaching Hospitals NHS Foundation Trust R&D Unit
Standard Operating Procedure
R&D/S24

Identifying Research Participants in the Medical Records and on CPD

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the R&D Unit's website and/or Q-Pulse for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive versions of all R&D Unit SOPs appear online. If you are reading this in printed form check that the version number and date below is the most recent one as shown on the R&D Unit website: https://www.research.yorkhospitals.nhs.uk/sops-and-guidance-/ and/or Q-Pulse

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This SOP will normally be reviewed every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Reviewers	Details of significant changes
1.0	17th December 2012		
2.0	4th January 2016		More details were added to section 4.3 and two new sections were included (4.4 'Wallet cards', and 4.5 'Advise trials patients'). Sections 4.3-4.5 apply to studies where Serious Adverse Events reporting is a requirement. Section 4.4 'Active Protocols on the Intranet' was removed. Trial protocols are no longer stored on the Intranet. Section 4.6 outlines a new procedure for accessing CTIMP trial protocols and IBs/SmPCs. Section 4.6 applies to CTIPMs only.
3.0	21st August 2017		General updates
4.0	9th March 2022		Change of link to R&D Unit website. Change to Trust name. Section 4.1 updated to clarify if and when a research label is required. Section 4.2 updated to advise that research data needs to be uploaded electronically to CPD. Section 4.3 updated with new WARDLIST procedure Section 5.0 added 'R&D/T18 How to add and change the status on alerts'
5.0	27th February 2023	Jonathan Hawker Monica Haritakis Sarah Appleby	General formatting changes Added section regarding the new risk-based approach Changes made to reflect the inclusion of a risk-based approach to research, Change of author
6.0	3rd January 2024	Jonathan Hawker	Some minor formatting updates, new QA email added and information

			regarding WARDLIST updated to.

Contents

1 Introduction, Background and Purpose

When undertaking a research study it is important that:

- other health professionals are aware of a patient's involvement in a research study via the case notes or CPD;
- other health professionals have access to study information that might be relevant to a patient's medical care;
- research teams are notified of hospital admissions or adverse events in study patients if required by the trial protocol;
- the case notes for research participants are retained for a specified period following the end of the study.
- a risk-based approach to research is followed.

The purpose of this Standard Operating Procedure (SOP) is to describe a system for identifying (either in the patient case notes and/or on Core Patient Database (known as a CPD Flagging or Alert system), and /or via use of research wallet cards) that a patient participated in a research study.

Information regarding access to clinical trial protocols and Reference Safety Information (RSI) is covered in R&D/S30.

2 Who Should Use This SOP

This SOP is aimed at investigator teams and all health professionals who come into contact with research participants within the Trust.

3 When this SOP Should be Used

This SOP applies when a patient has consented and enrolled to take part in a research study (Section 4);

4 Procedure(s)

The following procedures should be followed:

4.1 A risk based approach to conducting research studies

There is an emphasis on risk-based approaches to research delivery by the regulatory bodies. ICH GCP states that methods that are used to assure and control the quality of the trial should be proportionate to the risks and trials should avoid unnecessary complexity, procedure, and data collection.

To comply with these recommendations a risk-based approach to the way clinical trials are conducted has been adopted. Not every project will require documentation in medical records and flagging on CPD or paper notes. Guided by risk and tolerance levels this will reduce time and resources on low risk studies which can be utilised in areas of high risk and complexity, such as

complex CTIMPs and interventional studies. The purpose of identifying Research Participants in the Medical Notes and on CPD is to ensure that:

- other health professionals are aware of a patient's involvement in a

research study via the case notes or CPD;

- other health professionals have access to study information that

might be relevant to a patient's medical care;

- research teams are notified of hospital admissions or adverse events

in study patients if required by the trial protocol;

- the case notes for research participants are retained for a specified

period following the end of the study.

By assessing studies against these principles a decision can be made as to whether a risk-based approach can be applied to a particular research study. The research delivery teams should inform the Research QA Team if they identify a study that may be suitable for an exemption to flagging and documentation in medical records. The research delivery teams should send the following information to yhs-tr.research.qa@nhs.net:

- Type of study (observational, interventional, IMP, device)
- Consenting procedures
- Clinical and other risks to the patients
- Patient safety reporting requirements
- Any issues of co-enrolment to other projects
- Impact on participants' Standard of Care (SoC)
- Communication with the SoC clinical team
- Source data records (paper and CPD) and document retention period

The research QA team will complete a risk assessment. This will involve defining risk mitigation/acceptance levels and documenting a risk management plan & quality tolerance limit. By utilising a studies protocol and cross referencing it with the criteria above this will allow the QA and Delivery Teams to make an informed decision as to whether a risk-based approach can be applied. If the study is found to be suitable for this approach a File Note will be issued detailing the assessment and outcome. This approach would not be suitable for a CTIMP study.

Throughout the study duration amendments should be reviewed to determine if changes to protocol and procedure require ongoing risk assessment. If the original File Note is no longer fit for purpose it should be amended.

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4.2 Flagging Research Participants in the hospital casenotes

Once a patient has consented to take part in a research study, if any source data has been obtained from the paper notes, or any research information relevant to the participant is located in the paper notes **a research label** should be attached to their hospital case notes to indicate their involvement unless an exemption has been agreed. Individual Trusts may have their own policy as to where a label should be placed. This may be on the inside of patient case notes or on the front. Advice should be sought from the local Information Governance Department if in doubt.

Please ensure that you establish if there are multiple volumes of notes for the patient. This is sometimes stated on the paper notes but not always, therefore please check CPD via the Casenote Location to see if there are multiple volumes of notes. If so, please request the additional volumes and affix the research label.

The protocol or research contract will provide guidance on the proposed retention period of a research participant's case notes; advice should be sought from the Sponsor in any instances of uncertainty.

If a sponsor provides labels these may be used in preference, or in addition to the R&D template of research labels. Please check that if a sponsor has provided labels they **do not indicate diagnosis**, and **at the minimum** they specify: **the study short title, study ID number, CI/PI or Research Nurse contact details and retention period.**

Template sheets of labels (Template Labels 1- 'safety reporting required' and Template Labels 2- 'observational/safety reporting not required') are available to download (refer to Section 5) and can be edited and printed for use. All blank areas on the label should be completed as applicable.

If applicable, at each study visit where possible a check should be made to ensure a research label is still clearly attached to the case notes. Ensure that if a patient's case notes consist of more than 1 volume, each volume has a research label attached. Replace any missing labels.

All case notes should be checked for correct retention dates prior to study archiving. It may be necessary to change the date on the label to reflect actual end date of the study. It is the responsibility of the PI to ensure that all case notes are appropriately labelled (although this may be delegated to a suitably qualified member of the research team).

4.3 Research Documentation in the Case Notes

All relevant research related documentation should be uploaded to CPD under the research referral unless an exemption has been agreed. This at the very least will consist of a copy of the completed consent form, patient information sheet and copy of the sent GP letter (where applicable).

Written records of key study events (including each study visit) should be recorded electronically on CPD, unless the protocol states otherwise.

Example of key events to be recorded in the research participants' notes include:

-Provision of the information sheet/invitation to consider study;

-Obtaining informed consent;

-Eligibility decision and any required supportingInformation not available elsewhere within the notes;

-Randomisation or trial entry;

-Trial visits or follow-up phone calls required by the protocol;

-Treatment and dosing decisions, including changes to

concomitant medications;

-Any trial-related decisions relating to the clinical care of the participant;

-Adverse Events (including seriousness, causality, severity);

-Withdrawal, termination or end of trial involvement

(source: GCP Guide, MHRA).

4.4 Flagging Research Participants on CPD for research studies where safety reporting is a requirement (CTIMPs & non-CTIMPs)

Once a patient has consented and enrolled to take part in a research study that requires safety reporting their participation should be registered on CPD as soon as possible. The **CPD Alert Flag** is to be used for any study that requires Serious Adverse Reporting (CTIMPs & non-CTIMPs) to give the hospital wards notification about admission of clinical trial patients.

Participants are registered on CPD via the Medical Review Lists. A delegated member of each research team should be appropriately trained to use the CPD alert system. A study template should be set up with appropriate message for the ward stating what the study is and who to contact (including out of hours contact details).

The system is not required to be used for studies where safety reporting is not required (observational studies).

Once the intervention phase for a study participant has finished and Serious Adverse Events reporting is no longer required, the participant's status **must be** changed so that an alert is no longer visible (the flag must be changed to complete).

The designated Clinical Trials Assistant is responsible for filtering CPD every day (WARDLIST), morning and afternoon, to look for any hospital admissions involving trial participants. As weekend admissions cannot be checked, teams must ensure the Friday afternoon and Monday morning checks are performed.

The routine practice for WARDLIST checks is that the assigned Clinical Trials Assistant will complete the check and email all Research Teams and the York Pharmacy Research Team to make them aware of the current and previous admissions. Ensure you keep documentary evidence of the daily WARDLIST checks (paper/electronic logs, email correspondence, diaries/calendars). The Research Nurses will then investigate the alerts raised and take the appropriate action as required by the study protocol. If a Research Nurse in that particular Care Group is not available to flag a WARDLIST alert to then it must be sent to the Senior Research Nurses or the PI for review. The Clinical Trials Assistant

completing the WARDLIST checks must ensure that acknowledgement of receipt is received for each of the alerts sent.

The R&D Administrator: Delivery Team, collates all responses and communications in relation to WARDLIST alerts. QA will check these communications on a monthly basis and archive them accordingly.

Note: CPD Alert system should not be used in isolation. It is to be used alongside the alerts in medical notes.

4.5 Wallet cards

Use of patient wallet cards is recommended, particularly for CTIMP studies. Wallet card is a wallet-sized card containing information about the clinical trial a patient participated in, including who to contact out-of-hours. Some sponsors provide trial specific wallet cards, R&D template is available to download (refer to Section 6) and can be edited and printed for use.

4.6 Advise trial patients (if appropriate)

Once a patient has consented to take part in a research study that requires safety reporting, he/she should be advised to contact the Research Team if admitted to the hospital (or ask the hospital ward staff to contact the relevant Research Team).

5 Related SOPs and Documents

R&D/S05 Research Related Adverse Event Reporting Procedure for CTIMP Studies

R&D/S19 Research Related Adverse Event Reporting for non-CTIMPS

R&D/S30 Access to Protocols and RSI

R&D/T26 Template Case Note Labels 1-'safety reporting required'

R&D/T47 Template Case Note Labels 2- 'observational/safety reporting NOT required'

R&D/T48 Wallet Cards Template

R&D/T18 How to add and change the status on alerts