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SOP 345 Identifying Trial Participants at the time of their Hospital Admission

For Use in:	Research
By:	All staff
For:	All staff involved in the conduct of research
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This Standard Operating Procedure (SOP) is available on the Research & Development pages on the NNUH website

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2. Definitions of Terms Used / Glossary

PAS	Patient Administration System
Patient	A person receiving or registered to receive medical treatment
Participant	A person who takes part in a research trial
R&D	Research and Development
SOP	Standard Operating Procedure

3. Objectives

To describe the mechanism for identifying trial participants at the time of their hospital admission

4. Scope

This SOP describes the procedures to be followed to ensure there is sufficient information within NNUH patient information systems (patient notes and electronic records) to allow identification of patients who are active clinical trial participants, but who are not remaining in hospital for the duration of the trial **should** they ever be admitted to hospital.

5. Purpose

It is vital that the procedure for identification of patients that are actively involved in clinical trials, but who are not hospitalised for the duration of the trial, is clear and consistent, should they ever be admitted to hospital.

Identification is necessary to ensure that staff are aware that the patient is part of a clinical trial involving medicine and/or treatment that might impact on their care.

It allows trial investigators to be aware that their participant has received additional care outside of the trial, and to assess if these events influence their trial participation, and to complete the necessary paperwork.

This SOP applies to all research studies which involve NNUH patient information systems, such as patient notes, electronic records and the Patient Administration System (PAS) as part of the clinical trial or research study activity.

6. Responsibility

It is the responsibility of the local Investigator, or delegate, to:

- Ensure that information about trial activity is recorded and kept up-to-date in the relevant patient information systems, and that where activity relates to a clinical trial it is clearly stated which trial this relates to
- Ensure the Research & Development (R&D) Office issue unique registration numbers for all research approved by the Trust. This number should be used as part of the identification process; therefore it is important that patient records have the registration number recorded
- Ensure that participants have information about who to contact in relation to their trial involvement, such as the local investigator or research nurse.
- Ensure that contact numbers for the research team should be included in the Participant Information Sheet, and, where appropriate, participants should be issued with a Participant's Contact Card (See **SOP 510 Medical Cover**, Section 6)

7. Procedure NNUH

Alerts in PAS

- Alerts should be placed on the PAS system to identify that a patient is participating in a clinical trial (Alert is "patient has a medical condition" with an image of a doctor's bag with a red cross)
- In the alert section of PAS free text can be entered, which should include the patient's trial reference number and a contact email or phone number for the trial team member that should be informed of the patient's admission.
- This information is available to the receptionist when a patient is admitted and can be passed on to the admission team.
- An email alert can also be placed. The details of the recipient of the alert email should be determined by the local investigator in consultation with the NNUH IT Department.
- A new alert can be added by staff who have access to this part of the PAS system.

Ophthalmology & Obstetrics maintain separate patient notes; therefore it is **vital** that an alert is set up on PAS to notify departments who hold individual health records that the patient is research active.

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Attaching Labels to Patient Notes

- Research Labels (yellow label) must be fixed to the **inside front** cover of the case notes where physical notes are still available.
- Information on the label is important for health records to determine how long the records require retention
- An ALERT label should also be placed on the **outside front** of the notes to draw attention to the information sticker inside the cover

Copy of Participant Consent Form

Patient participation in a clinical trial must be recorded in the patient notes detailing the following:

- Version of the Participant Information Sheet which the patient has seen, read and understood.
- The version of the Consent Form signed
- The name of the clinician/ researcher to whom written consent has been given and confirming that the trial Inclusion/Exclusion criteria have been met and the patient has been given opportunity to ask any questions
- A photocopy of the Participant Consent Form should be placed in the patient notes in accordance with the case-note architecture / case-notes filing policy Trust Docs Reference Number 1029
- A copy of the Participant Information sheet should also be placed in the notes alongside this to inform other hospital staff of the basic information regarding the research trial in which the patient is involved

Subsequent visits

- Ongoing verbal consent from study participants that they wish to continue in the clinical trial needs to be provided and documented in medical notes
- ALL approaches made to potential clinical trial participants should be detailed in patient notes so that researchers are aware of previous discussions the patient has had, and whether the patient has a preference about whether they would like to be approached further or not.

Important information:

- Add PAS alert to all patient's involved in a clinical trial
- Add Alert sticker to patient notes where applicable
- Add copy of consent form to patient notes
- Add Participant Information Sheet to patient notes

8. References and Related Documents

References	
ICH GCP E6 / SI 2004/1041	
SOP No.	**SOP Title**
SOP 510	Medical Cover for Clinical Research Trials
Trust Docs 1029	Health Records Architecture

9. Approval

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10. Training Implication

Training Implication	**Yes**
Actions required	• Additional training may be required