York Foundation Trust R&D Unit
Standard Operating Procedure
R&D/S77

Identification of Potential Research Participants

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded versions are promptly withdrawn from use unless notified otherwise by the SOP Controller.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: www.northyorksresearch.nhs.uk/sops.html and/or Q-Pulse

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	Date:	24th July 2017
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	Signature:	Signed copy held by R&D Unit
	Date:	24th July 2017

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	Details of significant changes
1.0	30th April 2012	
2.0	7th June 2013	
3.0	6th March 2014	Removal of reference to GP records, clarification of text, correction of typographical errors
4.0	20th June 2016	Changes to sequence, minor revisions of terms and punctuation. Some re-writing for clarity and to remove contradiction.
5.0	24th August 2017	Change of Author to Hilary Campbell Addition of staff with letter of access/ honorary Contract

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1 Introduction, Background and Purpose

It is in the interests of patients that they should be made aware of opportunities to consider participating in suitable research.

For compliance with Data Protection legislation and the NHS Confidentiality Code potential participants in research studies should be identified by members of their clinical team. These patients have not yet been informed about the research and have not consented to research use of their data.

The Caldicott Guardian for the Trust has determined that it is appropriate for staff employed by YTHFT as specialist research nurses, midwives or administrators belonging to a trial team to be regarded as part of the wider clinical team for the purpose described in this SOP, and to be involved in identifying and approaching potential participants using this procedure. This also includes staff who have been issued with a letter of access or an honorary contract by the R&D Department.

2 Who Should Use This SOP

- Chief or Principal Investigators wishing to recruit participants to research studies;
- Research nurses, midwives, research administrators and other staff working on research studies.

3 When this SOP Should be Used

This SOP should be used when potential research participants are being identified and approached, following issue of NHS Permission.

4 Authorising the Identification of patients

The Chief / Principal Investigator and the Trial team should first check that the proposed methods to be used for identifying and approaching potential participants are consistent with the protocol and the terms of the favourable ethical opinion. The identification of candidate trial participants may commonly include the following:-

- attending multi-disciplinary team (MDT) meetings or clinics
- encouraging patients' interest using the Sponsor's ethically approved advertising material
- inviting members of the wider clinical team to suggest suitable patients in meetings or correspondence
- searching patient records and reports to identify candidate participants
- following up leads to exclude unsuitable patients and to include those with a reasonable chance of being interested and eligible
- approaching candidate trial patients at their clinic visits to introduce the trial

- giving or sending the Sponsor's ethically approved recruitment information to candidate participants, to introduce and explain the research
- noting in patients' medical records that trial information has been provided to patients, and the outcome of any conversation or correspondence

The Chief/Principal Investigator is responsible for consulting and informing his / her colleagues about the research protocol and gaining their agreement. Trial team members who are to identify candidates for screening should be named on the delegation log. Delegated trial team members should be properly briefed by the Investigator on any conditions or limits placed on this recruitment activity. R&D/T29 may be used as a template file note to document any conditions.

5 Pre screening actions

Following authorisation as above, the Research nurse, midwife or administrator is regarded as a member of that clinical team S/he may then carry out identification activities such as those listed above.

A candidate trial participant has not yet agreed to participate in the study at this stage. Two important principles have to be balanced: to minimise approaches made to candidates with no prospect of eventual enrolment, and to limit the access of extraneous personal data while exploring candidates' prospects.

6 Data handling

It must be remembered that during this process the patient has not agreed to participate in the study. This activity is, meant to lead to the point where the patient can be consented and enrolled according to the Protocol. No study data collection or other study procedures should take place until full informed consent has been given. Any notes or lists produced at this stage should be limited to immediate working purposes. If pre-screening information is retained it must be destroyed once recruitment is closed.

A record of approaches to potential participants should be retained in the Investigator Site File, noting the dates of approach and outcomes, but this should not include identifiable data about unconsented patients. If there is a requirement for a screening log with patient identifiable information allowing the research team to track patients over a period of time, care should be taken not to generate lists, notes or other data that are uncontrolled and give rise to data security risks. Any lists with patient identifiable information should be kept in a separate file/ X-drive with access restricted to the individual research teams only and should be disposed of as soon as is possible.

- The patient's medical record should be treated as the secure depository of clinical data, compiled to support patient care
- The patient's trial data should be recorded only with informed consent and according to Protocol, to support reliable science

7 Related SOPs and Documents

R&D/T29	File Note Identification of Research Participants