STANDARD OPERATING PROCEDURE

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT FIRST CHECKING IT IS THE LATEST VERSION

The definitive versions of all UHPNT RD&I Dept SOPs appear online, not in printed form, to ensure that up to date versions are used. 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 Trust's website: https://www.plymouthhospitals.nhs.uk/research-sops

Approach and Identification of Participants for Research

SOP No: T2

Version No: 2.3

Effective Date: Sep 2019

Supersedes: Version 2.2, Apr 2019

Last Review Date: Sep 2019 Next review date: Oct 2022

	APPROVED BY
Name:	Chris Rollinson
Job Title:	Research Governance Manager
Signature:	
Date:	

1 Purpose and Scope

As a teaching hospital, University Hospitals Plymouth NHS Trust (UHPNT) actively promotes research in order to lead to improvements in the treatments and services offered to patients. All patients attending out-patient appointments at UHPNT should receive a UHPNT out-patient welcome leaflet which makes a statement along the following lines:

"*As a trust we support a range of research activities and you may be asked to take part, you can agree or disagree as you wish*".

Inpatients will also receive a welcome leaflet which makes a statement along the following lines:

"*The hospital carries out research so that we can improve our medical knowledge and therefore help our patients more. As a result we may ask you to take part in research or to have details of your treatment used in our research or clinical trials; you can agree or disagree as you wish*".

The new government white paper "Equity and excellence: Liberating the NHS" (2010) makes over 17 references to research in the NHS including a promise that:

"*The government will: Give patients more information on research studies that are relevant to them, and more scope to join in if they wish*".

The DoH document "The Expert Patient…." (Aug 2001) stated that:

"*Participants in research studies regularly report improved communication with physicians and other health care providers*".

The ability to recruit patients is paramount to the success of any research study. Recruitment to research studies within the NHS is usually a three-step process which involves:

I. initial identification of potential participants using inclusion and exclusion criteria (screening),
II. approach either in person or by post about the study in question, prior to
III. consent.

These processes are under the supervision of Chief and Principal Investigators, and may be guided by members of the clinical team. However, screening and approach are usually performed by the local clinical research team who have access to patients and their medical notes.

This document outlines the procedures to be followed in order to ensure that confidentiality is maintained.

In scope: research hosted by, and/or sponsored by UHPNT. This SOP should be used when potential research participants are being identified and approached, following an e-mail confirming UHPNT RD&I capacity and capability allowing the research to commence.

Definitions

CI	Chief Investigator
Clinical Research Practitioner	An individual responsible for the care of patients taking part in clinical research and having a Trust Substantive, Trust Fix term or Honorary contract and is therefore already bound by the confidentiality terms of their contract. The Caldicott Guardian, the Information Governance team and Research, Development & Innovation Department at University Hospitals Plymouth NHS Trust view the role of the Clinical Research Practitioner (Nurses, Midwives, Physiotherapists, Operating Department Practitioner, Dieticians, Health Care Assistants and other clinical health related professions) as part of the clinical team, in that the Clinical Research Practitioner is offering hospital patients access to enhanced care and the option to choose whether they would like to participate in a research study[3,4].
DoH	Department of Health
HCA	Health Care Assistant
HRA	Health Research Authority
MDT	Multi-Disciplinary Team
UHPNT	University Hospitals Plymouth NHS Trust
PI	Principal Investigators
RD&I	Research, Development & Innovation
REC	Research Ethics Committee
SOP	Standard Operating Procedure

2 Who should read this document?

I. Chief or Principal Investigators wishing to recruit participants to research studies;

II. Consultants with responsibility for the clinical care of patients within the Trust;

III. Clinical Research Practitioners who:

- Have current registration (where applicable);
- Have up to date Research Governance training;
- Are employed under a substantive or honorary contract by the Trust to work as specialist Clinical Research Practitioners, whether attached to specific clinical specialties or in generic research teams or units.

The term "Clinical Research Practitioner" is used to mean a registered practitioner who fulfils the above criteria. This is further defined in the preceding definitions section.

IV. Health Care Assistants, Research Managers and Administrators.

3 Procedure to Follow

Before recruitment for a research study can commence the study must have prior approval by the Health Research Authority (HRA) and a Research Ethics Committee (REC) and UHPNT RD&I capacity and capability confirmation.

The Chief / Principal Investigator AND the Clinical Research Practitioner should first check that the proposed methods to be used for identifying and approaching potential participants are consistent with the study protocol and the terms of the favourable ethical opinion given for the study; if a change is required in how potential participants are identified or approached, then for a study sponsored by the Trust, a protocol amendment should be made and approved before proceeding further. For hosted studies the Sponsor should be approached for further discussion about the recruitment process.

Clinical Research Practitioners who are to identify and approach potential participants as described below should be authorised:

- The Chief / Principal Investigator should delegate to the Clinical Research Practitioner in the usual way, recording this on the study delegation log.

3.1 Clinical Research Practitioner Actions

The Clinical Research Practitioner is regarded as a member of the clinical team responsible for care of those patients with the researched condition. They may carry out any or all of the following activities

- Attend relevant multi-disciplinary team (MDT) meetings or clinics; liaise with other members of the clinical team regarding patients who may potentially be eligible to take part in a clinical research study. For potentially eligible participant's only the minimum amount of personally identifiable data should be recorded, for example the hospital and/or NHS numbers of patients;
- Receive copies of MDT minutes, emails from clinical team members or similar documents securely transmitted within the organisation with minimum details as above of potentially eligible patients;

- View the medical records of these potential participants and check the patients' apparent suitability in relation to the eligibility criteria;
- If a potential participant appears to be suitable, note ONLY their name and their hospital and/or NHS numbers and check clinic lists or make other enquiries as needed to identify the patient's next availability;
- **Must CHECK** with the treating Consultant or healthcare professional responsible for care of the potential participant that s/he has been informed about their diagnosis. With the treating consultants permission they may;
- approach the patient in clinic, introduce themselves and explain:
  - the role of the Clinical Research Practitioner as a member of the clinical team whose job includes looking for patients who might be suitable for research studies being run within the organisation;
  - that they have been identified as possibly eligible for a particular study;
  - that whether or not the patient chooses to take this further is entirely up to the patient; that they will only be included in the suggested research when they have had full details, a chance to consider, and have given their written consent;
  - that if they are at all interested in the research, the Clinical Research Practitioner will arrange a date / time for a more detailed discussion, which will include the Doctor or other investigator responsible for the study, who will have to confirm that the study is indeed suitable for the patient.
  - If the potential participant is contacted *via* post, e-mail or phone call, it must be clear that the patient is being contacted on behalf of their treating consultant or health care professional to see if they are interested in taking part in the research study.
  - Use sponsor provided and ethically approved invitation material to introduce and explain the research, use reply slip or give contact details to potential participants so they can confirm their interest and agreement to further contact about the research.

When the Clinical Research Practitioner has checked a patient's medical record and/or approached the patient as above, they will make a brief note of this, and of the outcome, in the patient's medical record.

3.1.1. Self-referred patients

For self-referred or referred patients, the Trust, with a potential participant's consent contact their GP and or Secondary Care Team to seek confirmation of their eligibility to take part in a study. If after sending the initial request by letter there is no response we will ring to enquire as to the progress. If after this there is no confirmation from

either the GP and or Secondary Care Team after this, the self-referred patient will be deemed ineligible for a study.

3.2 Data handling

It must be remembered that during this process the patient has not agreed to participate in the study. 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 the information given above and should not include any clinical or other personal data. A list of names of potential participants who have been approached should be retained in the Investigator Site File, noting the date (it may in some studies be important to record the time as well) of the approach and the outcome, with the initials of the Clinical Research Practitioner.

In the course of this exercise great care should be taken not to generate lists, notes or other data that are uncontrolled and give rise to data security risks. Clinicians should **not** refer possible study participants to Clinical Research Practitioner by copying GP letters or other clinical information; they may use internal e-mail with minimum information as described in Section 3.1. The patient's medical record should be treated as the secure depository of clinical data; these data should not be copied or extracted for research purposes until after the patient has given their informed consent to take part in a research study. Only then does the research team have the authority to extract data and transcribe it on to approved study documentation.

4 Document Ratification Process

The review period for this document is set as ***default of three*** years from the date it was last ratified, or earlier if developments within or external to the Trust indicate the need for a significant revision to the procedures described.

This document will be approved by the ***RD&I Manager or their Deputy***.

Non-significant amendments to this document may be made, under delegated authority from ***a Senior RD&I manager***, by the nominated author. These must be ratified by ***a Senior RD&I manager***.

Significant reviews and revisions to this document will include a consultation with ***appropriately knowledgeable staff***. For non-significant amendments, informal consultation will be restricted to ***staff*** who are directly affected by the proposed changes.

Dissemination and implementation

4.1. Dissemination of this SOP

4.1.1. New SOPs and new versions of existing SOPs: The Research Governance Manager will be responsible for ensuring authorised SOPs are uploaded on the RD&I intranet site. Internal Trust Staff are expected to use the RD&I intranet site to access latest versions of SOPs and to check the website regularly for updates.

Notice of new or amended procedural documents that have undergone a major amendment will be given *via* the following routes:

• Inclusion in the Trust weekly e-bulletin Vital Signs

• Direct email to Trust Researchers and or teams

4.2. Training in this SOP

4.2.1. All staff whose activities are subject to this SOP should ensure that they read and understand the content of the SOP.

5 Reference material

1. Government white paper, Equity and excellence: Liberating the NHS, 2010, Page 17. DoH
2. The Expert Patient: A New Approach to Chronic Disease Management for the 21st Century, DoH publication, 2001, Page 28. DoH
3. York Foundation Trust RD&I Unit. Standard Operating Procedure RD&I/S77. Research Practitioner Identification of Potential Participants. Version 1, 2012.
4. Sheffield Clinical Research Facility. Standard Operating Procedure CRF.A104. Approach and Identification of Participants for Research Studies – Previously Attended STH Hospitals. Version 1, 2010

The Trust would like to acknowledge both the York Foundation Trust and the Sheffield Research Facility who's SOPs helped form this current SOP.

6 Amendment History

Version Number:	2.2
Date Of Amendment:	Apr 2019
Details Of Amendment:	Updated as a result of a patient complaint to make the process clearer.
Version Number:	2.1
Date Of Amendment:	Jan 2019
Details Of Amendment:	Updated Trust and Dept. name. Reduce signature requirement to single senior RD&I Manager.
Version Number:	2.0
Date Of Amendment:	Aug 2017
Details Of Amendment:	Updated SOP template and numbering system. Reviewed and updated SOP.
Version Number:	2.1

STANDARD OPERATING PROCEDURE

Date Of Amendment:	Jan 1019
Details Of Amendment:	Updated Trust name and logo.
Version Number:	2.2
Date Of Amendment:	Apr 2019
Details Of Amendment:	Updated SOP to make clear the procedure for contacting potential participant's about research opportunities.
Version Number:	2.3
Date Of Amendment:	Sep 2019
Details Of Amendment:	Updated SOP to make clear the procedure for Self-referred & referred patients