

STANDARD OPERATING PROCEDURE FOR RESEARCH
Identification of potential research participants

SOP REFERENCE NUMBER	CLPG19 SOP 9	
VERSION NUMBER	Version 1	
REPLACES SEPT DOCUMENT		
REPLACES NEP DOCUMENT	STANDARD OPERATING PROCEDURE: Identification of potential research participants v2	
KEY CHANGES FROM PREVIOUS VERSION	Minor changes to reflect HRA process for research approvals. Clarification on scope and specificity of screening.	
AUTHOR	Research & Development Manager	
CONSULTATION GROUPS		
IMPLEMENTATION DATE		
AMENDMENT DATE(S)		
LAST REVIEW DATE		
NEXT REVIEW DATE		
APPROVAL BY CLINICAL GOVERNANCE & QUALITY SUB-COMMITTEE	March 2018	
RATIFICATION BY QUALITY COMMITTEE	April 2018	
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SOP SUMMARY		
This policy sets out the procedure for Research staff involvement in identification of potential participants to take part in Ethically approved clinical research.		
The Trust monitors the implementation of and compliance with this policy in the following ways:		
Monitoring of implementation and compliance with this procedure will be undertaken by the Executive Medical Director, Research manager, Research lead, R&D department staff and R&D group.		
Services	Applicable	Comments
Trustwide	✓	
Essex MH&LD		
CHS		

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**STANDARD OPERATING PROCEDURE:
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1. **BACKGROUND AND PURPOSE**

For compliance with Data Protection legislation and the NHS Confidentiality Code, potential participants in research studies should be identified by members of the clinical team. These patients have not yet been informed about the research and have not consented to research use of their data. It is in the interests of patients that they should be made aware of opportunities to consider participating in suitable research. The Caldicott Guardian for the Trust has determined that it is appropriate for staff employed as Clinical Studies Officers, Research Delivery Coordinators, Research Assistants, Research Administrators or Research Nurses to be regarded as part of the clinical team for the purpose described in this SOP, and to be involved in identifying and approaching potential participants using this procedure. While this procedure is specifically to cover the role of research staff in screening, it should be noted this is not the only way that potential participants are identified for clinical research. For example consultants or members of clinical teams may screen their own case-loads or patients may contact researchers directly following study advertisements, registering on public databases such as Join Dementia Research (JDR) or via searching publically available information such as the UK Clinical Trials Gateway.

2. **WHO**

- Chief, Principal or Sub Investigators wishing to recruit participants to research studies
- Clinical Studies Officers, Research Delivery Coordinators, Research Assistants, Research nurses and research administrators

3. **WHEN**

This SOP should be used when potential research participants are being identified and approached in accordance with an ethically approved study protocol, following issue of HRA approval and Trust Confirmation of Capacity and Capability for the project.

4. **PROCEDURE**

4.1 Authorising the Identification of patients

The Chief / Principal Investigator and the Research 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. Research team members must be named in the site file study delegation log. *(See CLPG19 SOP 18 - Study Files and Filing for Externally Sponsored Clinical Trials)*

The Chief/Principal Investigator is responsible for consulting and informing his or her colleagues about the research protocol and gaining their agreement to identify patients from their case-load. The names of Doctors whose patients' records are to be consulted or patients approached should be listed on a file note which is authored and signed by the Investigator. If a patient does not have a named consultant, the lead consultant for the relevant service should be consulted. If the patient does not have a named consultant and there is no lead consultant for the service, the head of the service should be consulted.

4.2 Pre-screening actions

Following authorisation as above, the Research staff member is regarded as a member of that clinical team. They may then carry out any or all of the following activities as appropriate:

- Attend relevant multi-disciplinary team (MDT) meetings or clinics or ask other members of the clinical team for suggestions
- 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 in situ, or book out the medical records of these potential participants and check the patients' apparent suitability in relation to the eligibility criteria;
- Send ethically approved invitation letter to introduce and explain the research, use reply slip or give contact details to potential participant so they can confirm their interest and agreement to further contact about the research.
- Search patient databases to identify potential patients.

4.3 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. If pre-screening information needs to be retained it must be destroyed once recruitment is closed. A list of names of potential participants who have actually been approached should be retained in the Trial Master File / Investigator Site File / Study File, on the screening log noting the date of the approach and the outcome.

Screening activity should be as specific and targeted as practically possible in accordance with the six Caldicott principles regarding handling of patient-identifiable data:

- justify the purpose(s) of every proposed use or transfer
- don't use it unless it is absolutely necessary, and
- use the minimum necessary
- access to it should be on a strict need-to-know basis
- everyone with access to it should be aware of their responsibilities, and
- understand and comply with the law.

To ensure specificity of screening, where possible requests should be made to the Trust Information team in order to generate pseudo-anonymised shortlists (by Electronic Health Record number) for further screening. Such shortlists can generally take into account broad study inclusion / exclusion criteria such as ICD-10 diagnosis, demographic data or presence or absence of comorbidities. Screening of clinic appointment lists is allowed where there is a high chance that those attending would be eligible for a particular study. The guiding principle is to increase the likelihood that records screened in detail will be for those eligible to take part in the study.

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. The patient's

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medical record should be treated as the secure depository of clinical data; data should not be copied or extracted until, after informed consent, the investigator team has authority to extract data and transcribe it on to approved study documentation.

- If a potential participant appears to be suitable, note ONLY the minimal amount details (usually Paris / Mobius number is sufficient), required to make a decision on whether to approach the patient
- When a patient has been approached or had information sent as above, a note of this, and of the outcome, should be recorded in the screening log for that study, and if the patient does not wish to be contacted for any future studies, a note of this should be entered on their electronic patient record.

5. RELATED SOPS AND DOCUMENTS

CLPG19 SOP 5 - Confirming Capacity and Capability

CLPG19 SOP 18 - Study Files and Filing for Externally Sponsored Clinical Trials