SOP Identification of Potential Research Participants

SOP Identifier		Identification of Potential Research Participants	
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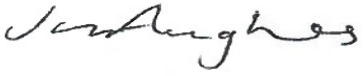
	Signature & Date	 24/07/20	
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1.0	24/07/23	Initial Document		
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1. Purpose

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.

2. Background

The Information Governance Department and R&D department at Swansea Bay UHB have determined that it is appropriate for staff employed within the Health Board and the Joint Clinical Research Facility (JCRF) under Honorary Clinical Contracts as specialist research nurses, midwives or research officers/administrators/assistants 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.

In addition to the Organisation wide General Data Protection Regulation (GDPR) transparency notice alerting the public that Swansea Bay UHB is a research active organisation, the legal basis on which the decision to classify research staff as members of the direct care team is justified as follows:

Access will depend on the type of research and patient contact involved;

A. If the research has potential to impact the treatment of a patient directly and the individuals carrying out the screening exercise will themselves have clinical contact with the patient; then that individual can be classed as part of the direct care team for that patient. **Access Approved.**

B. If the research has potential to impact the treatment of a patient directly but the individuals carrying out the screening exercise will not have clinical contact with the patient; then that individual should be classed as support to the direct care team for that patient. **Access Approved**.

C. If the research does not have the potential to impact the treatment of a patient directly (such as the study is for service review); then that individual should not be classed as part of, or support to, the direct care team of that patient. It is important to note that, even with option C, when a study can still change

treatment planning in general rather than a particular individual and could have an indirect clinical impact, then access to patient records will still be covered by Article 9(2)(h) as the purpose still relates to health care, just in a more general way. **Access Approved.**

D. When there is no direct clinical impact or service review purpose, further Information Governance (IG) and R&D review of access to patient data is required.

3. Roles and Responsibilities

- Chief or Principal Investigators wishing to recruit participants to research studies;
- Research nurses, midwives, research officers/administrators/assistants;
- This can also be extended to other multidisciplinary teams for example Physiotherapists, Speech and Language Therapists etc, who are requiring to conduct research in ABM UHB.

4. Procedure

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

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.

The Chief/Principal Investigator is responsible for consulting and informing his colleagues about the research protocol and gaining their agreement. With the treating Consultant's permission patients may be approached as possibly eligible for a particular study.

4.2 Pre screening actions

Following authorisation as above, all of the staff mentioned in point 2 are regarded as a member of that clinical team S/he 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 where they are held, or book out the medical records of these potential participants and check the patients' apparent suitability in relation to the eligibility criteria;

- If a potential participant is identified in an MDT meeting or via a clinic list, ONLY take note, at that time, of the minimum details, that would allow their records to be identified and checked for potential eligibility. Usually a hospital number will be sufficient.

- Send the ethically approved invitation letter provided by the Sponsor to the potential participant to introduce and explain the research, use reply slip or give contact details to a potential participant so they can confirm their interest and agreement to further contact about the research, if being used.

- Search patient databases to identify potential patients.

- 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 patient's medical record.

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 is 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 Investigator Site File, on the screening log, noting the date of the approach and the outcome.

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 medical record should be treated as the secure depository of clinical data; these 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.

5. References

- SOP Medical records & Databases