RDSOP04 Procedure for identification of potential participants in research studies and delegation of clinician responsibility to Research Delivery Team staff

Greater Manchester Mental Health NHS Foundation Trust
**Title of Standard Operating Procedure:**
RDSOP04 Procedure for identification of potential participants in research studies and delegation of clinician responsibility to Research Delivery Team staff

**Document Summary:**
Procedure for identification of potential participants in research studies and delegation of clinician responsibility to Research Delivery Team staff

**Document Author:**
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**Target Audience:**
R & I staff, Clinical staff

**Consultation:**
R & I Operations Group, R & I Committee members

**Approval Committee:**
R & I Committee

**Cross Reference Document(s):**
Research Conduct Policy
All Trust R & I SOP's

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<th>Minimum Monitoring Requirement</th>
<th>Frequency</th>
<th>Process for monitoring</th>
<th>Evidence</th>
<th>Responsible Individual(s)</th>
<th>Response Committee(s)</th>
</tr>
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<tbody>
<tr>
<td>Review of SOP content</td>
<td>Every 3 years</td>
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<td>Minutes of R &amp; I Committee</td>
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1. Introduction

The importance of research and innovation in the NHS is identified in much guidance and the NHS Constitution outlines rights of patients with regards research.

Under GDPR and the Data Protection Act 2018, commercial companies and charitable research organisations will continue to use ‘legitimate interests’ as their legal basis for processing personal data. However, public authorities (as defined in Freedom of Information legislation), when carrying out public tasks, such as research in NHS organisations, will use ‘task in the public interest’ as their legal basis.

Consent is an important part of the research process and is frequently sought for participation in research studies. It is important to note that consent to participation in research is not the same as consent as the legal basis for processing under data protection legislation. An example is that a person is asked to consent to participate in research but is told that, if they agree to participate, data about them will be processed for a task in the public interest. (see https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-detailed-guidance/legal-basis-processing-data/)

Greater Manchester Mental Health NHS Foundation Trust (GMMH) is a research active Trust and as such is required to meet the recruitment targets set by the National Institute for Health Research (NIHR) Clinical Research Networks (CRNs) for Portfolio studies. Research Delivery Team (RDT) staff (i.e. Clinical Studies Officers (CSOs) and Research Nurses (RNs)) assist the Trust directly to meet our obligation to inform Service Users of studies which they are potentially eligible to participate in. In order to do this satisfactorily and efficiently they should be seen as healthcare professionals supporting the clinical teams. Their time should be used appropriately and within data protection guidelines in order to reduce the burden on Trust clinicians and increase recruitment to research studies.

Research Delivery Team staff are GMMH employees and as such will complete their mandatory IG training annually. On occasion, the Lead CSO may seek support from Clinical Research Network staff employed by another NHS Trust. In this instance, the R&I Office will be responsible for ensuring that they hold a Letter of Access with the Trust and that they have read the Information Governance and Confidentiality Handbook (IG01).

2. Purpose

To allow clinical staff to delegate their responsibility to inform identified Service Users about opportunities to participate in, or find out more about, specific potentially relevant research studies to Research Delivery Team staff.

To allow clinical staff to delegate their responsibility to screen their caseloads for potential participants for a research study to Research Delivery Team staff.
To allow admin R&I staff support any duties carried out by RDT in line with this SOP procedures.

By having this procedure in place, it will ensure that GMMH complies with the NHS Constitution to let Service Users know about relevant research opportunities, and reduce the time burden and bureaucratic demands on staff and minimise potential barriers to knowledge about and offers to participate in research, whilst ensuring that the screening or first approach is undertaken by healthcare professionals on behalf of the clinical team having regard for national guidance and legislation.

### 3. Definitions

<table>
<thead>
<tr>
<th>Portfolio</th>
<th>A research study adopted onto the NIHR (National Institute for Health Research) Portfolio, which would then receive support from the Clinical Research Networks.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinician</td>
<td>Consultant, Care Co-ordinator or senior member of the care team who has responsibility for a caseload of patients.</td>
</tr>
<tr>
<td>Research Delivery Team staff</td>
<td>Clinical Studies Offices (CSOs) and Research Nurses (RNs) employed either by GMMH or host NHS Trusts for NIHR Clinical Research Networks</td>
</tr>
<tr>
<td>PARIS</td>
<td>The electronic patient record database of GMMH service users.</td>
</tr>
<tr>
<td>BI</td>
<td>Business Intelligence, responsible for collecting and providing anonymised patient data from the electronic patient records as requested within agreed processes.</td>
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### 4. Roles and Responsibilities

#### 4.1 Duties within the Organisation

It is the personal responsibility of all staff whether substantive or honorary or NHS staff holding letters of access to follow Trust procedural documents.

The Research & Innovation Office is responsible for managing Trust R&I SOPs including their approval, dissemination and archiving. All Trust R&I SOPs must be made available via Trust websites.

#### 4.2 Specific to this SOP

The Head of Research & Innovation Office is responsible for ensuring this procedure is carried out within information governance guidelines, with the support of the Information Governance team, R&I Committee and Quality Improvement Committee.
and in line with all legislation allowing healthcare professionals working with clinical teams access to patient records and to contact service users without informed consent for the purposes of informing service users about research that might be relevant to them.

The Head of R&I is responsible for ensuring that easy to follow communications materials are made available in all locations, explaining the Trusts approach to research and that service users can expect to be contacted. This material should also detail how service users can opt out if they do not wish to be contacted in future about research opportunities.

The R&I Committee is responsible for overseeing the use of this operating procedure and to ensure it is regularly monitored by R&I Office staff.

5. Procedures for identification of potential participants in research studies and delegation of clinician responsibilities

Options:

5.1 Via RDT / Clinicians

The preferred and accepted method for identifying potential participants for a specific Portfolio research study is that the RDT discuss inclusion and exclusion criteria with clinicians who will screen their own caseloads and agree who may be suitable for the study. The member of the care team would then either:

A) Pass on information about a research study to the service user who can then contact the researcher directly, or

B) Request the service user’s permission for the care team to pass on their details to the researcher, who will contact the service user themselves (request consent to contact).

This allows the direct care team to determine whether it is appropriate to contact the patient, and engenders the trust of patients, both in the specific activity and in research activity in general.

5.2 Via BI Lists or pseudo-anonymised patient database / Clinicians
In order to enable easier identification of potential participants on a clinician’s caseload, the Lead CSO may request from Business Intelligence a pseudo-anonymised list of those service users who fit basic inclusion /exclusion criteria for a particular study. They would not be given names and addresses of service users, but would have the PARIS ID. Alternatively the Lead CSO can interrogate the full pseudo-anonymised spreadsheet of all Trust patients to limit the number of potentials for further screening (via 5.1 or 5.3) (see DPIA for research screening and first contact 2019). [Both types of list are referred to as ‘The List’]

Using the condensed list a RDT member could then liaise with the Care Co-ordinator, Consultant or member of the care team to ask if the care team member could contact the service user directly and either send out information about the study or ask for consent to contact.

### 5.3 Using Clinical delegation of Screening to RDT staff

Where members of the care team do not have time to screen their own caseloads against inclusion criteria or against ‘the list’ of potential participants they could delegate this to RDT staff. Once potential participants are identified, the clinician should then decide whether it is appropriate to approach them at the present time, and, if so, whether to contact service users themselves or to delegate this first contact to RDT staff (see 5.4).

### 5.4 Using Delegation of First Contact to RDT

Where members of the care team are happy for the RDT staff to contact directly service users identified as potential participants, they can delegate first contact to a RDT staff member. The RDT staff member would need the service user’s name, address and telephone number and could contact them either by phone or write to them about the study.

For each study, the method of identifying, screening and contacting potential participants should be covered in the protocol and in sections A27-1, A27-2 and A29 of the IRAS form and thus have received a favourable opinion from the Research Ethics Committee and Health Research Authority. If changes are implemented, a substantial amendment needs to be submitted via IRAS and approval received prior to commencing the new recruitment process.

The method of recruitment should be identified in the Recruitment Plan, developed at the start of the specified Portfolio study.
The following decisions regarding identifying potential participants should be fully documented in the recruitment plan:

- When clinicians delegate their responsibility for screening of medical records to RDT staff following an extract of potentials
- When clinicians delegate screening of their entire caseload without first extracting a list of potentials
- Where clinicians delegate first contact to RDT staff where potentials have been identified either by screening notes or using extracted lists (as 5.2 above)
- RDT staff must complete a spreadsheet on activities/delegations and save on the RDT drive for quarterly monitoring by R&I.
- RDT staff to have full access to and training on PARIS but may only access patient records:
  o Where a specified member of the clinical team has delegated responsibility for screening their caseload OR
  o To assess risk prior to making face-to-face contact OR
  o To update PARIS with information relating to service user contact both pre and post consent
  o Following participant recruitment where a service user has indicated on the consent form their agreement to access their medical notes for the purposes of the study.
- In all instances, RDT staff must be fully compliant with mandatory IG training before being issued with a Paris account and must ensure annual compliance.
- Named RDT member (Lead CSO) to have access to the full pseudo-anonymised list of all Trust clients on PARIS as per approved Data Protection Impact Assessment.
- The list is to be used to identify potential participants who fit basic inclusion and exclusion criteria in relation to gender, age, primary and secondary diagnosis, date of diagnosis, years in service, name of responsible clinician, Care Co-ordinator, service, and thus limit the number of potential participants prior to more intensive screening or first contact.
- The list may only be held on a secure network drive with restricted access and never removed, transferred to laptops or printed.
- Basic details from the list, Care Co-ordinator name and PARIS ID only to be extracted for use when discussing with clinicians.
- When making first contact with service users, RDT staff must be wary of harassment or provoking distress by multiple ‘reminder’ letters or phone calls. The agreed process must comply with ethical approval (see above).
- During this first contact by RDT staff it must be made clear to the SU that this contact is made on behalf of their clinical team.
- The voluntary nature of research participation and lack of effect on normal clinical care must also be made clear and all ethically approved project
6. Approvals

Delegation of First Contact SOP approved by Research Governance Group 14 October 2015.

Access and analysis of pseudo-anonymised patient database agreed by Privacy Impact Assessment 2015 (Steve Lankshear, Lead CSO)

Delegation of screening to CRN staff agreed Quality Governance Committee January 2018.

Procedure for identification of potential participants in research studies and delegation of clinician responsibilities to CRN staff agreed R&I Operations Group 22 February 2018.


RDSOP04 Procedure for identification of potential participants in research studies and delegation of clinician responsibility to Research Delivery Team staff agreed by R&I Committee October 2019

7. Review

This procedure has taken into account GDPR, and Data Protection Act 2018 and associated Health Research Authority guidance.

8. References


UK Policy Framework for Health & Social Care Research (Nov 2017)

End of Procedure
Appendix 1

Form to record delegation of duties:

The following form is to be completed for each Research Delivery Team member/s (Clinical Studies Officer or Research Nurse) within each clinical team. RDT can request R&I admin support to complete tasks associated with delegated duties.

<table>
<thead>
<tr>
<th>Name of Research Delivery Team member/s</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Team/Service</td>
<td></td>
</tr>
<tr>
<td>Team Manager</td>
<td></td>
</tr>
<tr>
<td>Screening delegation required (YES/NO)</td>
<td></td>
</tr>
<tr>
<td>First contact delegation required (YES/NO)</td>
<td></td>
</tr>
</tbody>
</table>

By signing this form, the team manager/responsible clinician is agreeing that the RDT member can screen and/or (delete as required) contact service users on their case load in order to offer them appropriate research opportunities. The Research Delivery Team member is required to ensure that they have had a discussion with a person within the direct care team with relevant knowledge of the service user’s care prior to contact being made and that the relevant approvals are in place to cover the methods of identification, screening and first contact for any relevant study.

<table>
<thead>
<tr>
<th>Signed by Team Manager/Responsible Clinician</th>
<th>Signed by Research Delivery Team member/s</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name:</td>
<td>Name/s:</td>
</tr>
<tr>
<td>Date:</td>
<td>Date/s:</td>
</tr>
</tbody>
</table>

Signed form will be reviewed 12 months from first signature, re-signed and re-dated by involved individuals.

This Form is to be completed and sent to researchoffice@gmmh.nhs.uk. The Trust Lead CSO will maintain a spreadsheet of delegation/screening which will be accessible to all members of the R&I team and will ensure timely review.