BU RDS SOP 010 V1

Title: Recruitment (NHS Patients)	
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1. Scope

1.1 The purpose of this Standard Operating Procedure (SOP) is to outline Good Clinical Practice (GCP) requirements for recording participant activity and events relating to participants in research projects, when the project is recruiting NHS patients.

1.2 When applying via the Integrated Research Application System (IRAS) form, the applicant should ascertain whether informing the participant's GP regarding the research is required. If so, then a GP letter will need to be submitted for approval.

1.3 Similarly, poster materials that are patient facing require NHS REC approval prior to use.

2. Responsibilities

The *Chief Investigator (CI)/Researcher* is responsible for providing the participating site(s) with the most up to date approved versions of documents, required to allow the participant to make a fully informed decision before giving their informed consent. These documents should be filed in the Sponsor Trial Master File (TMF). In the case of student research, in accordance with the UK Policy Framework for Health and Social Care Research, the CI is a member of the supervisory team, with the student acting as the 'Researcher'. In certain cases, the student may act as the Principal Investigator, depending on the nature of the study.
The Postgraduate Researcher (PGR) may act as the CI if they hold a clinical post/contract that ensures they have the appropriate expertise and experience to undertake this role. Exemption is also made if the researcher is undertaking doctoral-level study in receipt of a fellowship. Furthermore, it is advisable and acceptable to appoint a clinical supervisor within the NHS Trust, especially if the researcher and supervisor do not have appropriate clinical experience.

The *participating site staff* (in particular, the *Research Nurse*) are responsible for ensuring that they are allowing the participant the REC approved time to consider participation in the study. They should also allow them the opportunity to ask questions about the project prior to agreeing to give their informed consent, ensuring they evidence in the medical record/maternity records (if applicable) all study visits, conversations and GCP –compliant checks with the participant.
In circumstances where the PGR holds an honorary contract or letter of access, with the NHS Trust(s) in which they are recruiting, they will need to ensure the above documentation is maintained, and in accordance with Good Clinical Practice (GCP) as the standard to which

the research is conducted. Those researchers on Clinical Academic Doctoral programmes are likewise responsible for ensuring that documentation and adherence to GCP is upheld.

The *participating site staff* are also responsible for recording study recruitment via screening and enrolment logs, and providing updates to the Sponsor when requested. In the case of PGR student in possession of an honorary contract or letter of access, they will be required to contribute to the maintenance of these logs.

The *Clinical Governance Advisor (CGA)* is responsible for reporting monthly, the recruitment of studies adopted onto the National Institute for Health (NIHR) portfolio via the Central Portfolio Management System (CPMS). The CGA in this situation will act as the *Research Activity Coordinator,* whilst the researcher shall be identified as the *Study Coordinator* – as per accepted terminology.
The CGA is also responsible for assisting the *CI/Researcher* with applying for approval via amendments to participant documents. Whilst the CI is ultimately responsible for study amendments, and has the final sign-off, they may delegate this duty to the Researcher.

3. Procedure

3.1 When recruiting an NHS participant (they may not be patients, rather staff members or volunteers) to a study and in accordance with GCP guidelines, the person delegated and appropriately trained to receive this consent should confirm with the PI that the patient is indeed eligible to participate. Once this has occurred, then for patient participants, the medical notes/maternity records should contain a statement verifying that the participant met **all** the inclusion criteria and **none** of the exclusion.

When a PGR is undertaking the role of the PI, they should work closely with their clinical supervisor in confirming the eligibility of participants, where medically relevant and where patient safety is a consideration. As PI the PGR may delegate this duty to participating site staff if they wish, however they will remain ultimately responsible for the site activity (as per GCP guidelines). When a PGR is carrying out the duty of obtaining informed consent, then they should either undertake the BU Informed Consent training, or the course offered by the NIHR Clinical Research Network (CRN).

There may be times when eligibility criteria are not clear. If this is the case, then the Sponsor should be contacted for further clarification.

3.2 The CI/Researcher should provide the participating site staff with a screening log and an enrolment log, or ensure that they have their own templates, so that all participants invited and recruited and all participants who have declined or become ineligible, are recorded. If the PGR or Clinical Academic Doctoral is recruiting, then they should have an active role in maintaining this record.

3.3 The original informed consent form will be kept in the participating site's Investigator Site File (ISF), with a copy going to the participant, and one in the medical record. Where the PGR is receiving obtained consent, and in the case of single site studies, they may keep the original informed consent forms within the Sponsor's TMF, that they should maintain throughout the course of their study. This record must be held in a secure location and is subject to monitoring by the Sponsor, or the site's R&D team.

The CI/Researcher should ensure that the TMF contains the most recent version of the Participant Information Sheet (PIS), Informed Consent Form (ICF), and any other documents used in recruiting participants, alongside those that have been superseded.

3.4 If the project has been adopted onto the NIHR portfolio, then there is the requirement to report each site's recruitment to the Central Portfolio Management System (CPMS), which is managed and overseen by the NIHR. A template spreadsheet is available on the website on which to record site recruitment.

3.5 Depending on the nature of the project, questionnaires or Case Report Forms (CRFs) may also need to be submitted for approvals. CRFs are the Sponsor's tool through which they can collect additional clinical information, with the participant's consent. Amendments to CRFs do not need approval, however often they will be amended due to a change in a protocol, which does require approvals.

4. Abbreviations and definitions

CGA	Clinical Governance Advisor
CI	Chief Investigator
CPMS	Central Portfolio Management System
CRF	Case Report Form
CRN	Clinical Research Network
GCP	Good Clinical Practice
GP	General Practitioner
IRAS	Integrated Research Application System
ISF	Investigator Site File
NIHR	National Institute for Health Research
PGR	Postgraduate Researcher
PI	Principal Investigator
R&D	Research and Development (NHS Research Governance)
REC	Research Ethics Committee
TMF	Trial Master File

5. Related documentation and references

Central Portfolio Management System - https://www.nihr.ac.uk/research-and-impact/documents/NIHR-CRN-Portfolio/CPMS-support/How%20to%20log%20on%20to%20CPMS.pdf

Central Portfolio Management System, How to Guide. (2017). [online] Available at: https://www.nihr.ac.uk/research-and-impact/documents/NIHR-CRN-Portfolio/CPMS-support/CPMS%20AddingSites%20web.pdf [Accessed 3 Sep. 2018].