BU RDS SOP 009 V1

Title: NHS Site Set-up and Amendment Procedures	
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1. Scope

1.1 The purpose of this Standard Operating Procedure (SOP) is to outline the steps an NHS R&D/R&I department will take in undertaking a study. From assessing feasibility through to archiving, this SOP will explain the procedures carried out at an NHS site at each stage of a research project.

1.2 According to Good Clinical Practice (GCP) guidelines, a site must carry out the necessary feasibility assessment prior to agreeing to commence a research project, in order to safeguard participants, in turn ensuring high quality research data.

1.3 The set-up of studies in the NHS coincides with the Health Research Authority (HRA)[1] 'steps': *Assess, Arrange* and *Confirm*. Each step and the procedures that fall within each are detailed later in this SOP.

2. Responsibilities

The *Sponsor,* usually delegates the *Chief Investigator (CI)* the responsibility of setting up a study by gaining the necessary approvals, prior to inviting sites to undertake the research project. In the case of Postgraduate Researcher (PGR) projects, the PGR will be responsible for these tasks, with the support of the Clinical Governance Advisor.

Trust R&D is responsible for assessing the study for feasibility and suitability alongside *Research Management, Research Nurses, Data Managers and/or Clinical Trial Assistants.* Some duties and roles may differ at each organisation. Trust R&D is responsible for confirming their **capacity and capability** to undertake the study at their particular site – this should then be filed within the TMF.

The *Clinical Governance Advisor (CGA)* is responsible for liaising with the CI/Researcher in identifying contacts at suitable sites to undertake the research study. They are also responsible for advising as to which approval bodies need to be contacted and how to gain the necessary approvals from each party. The CGA may also advise on the next point, regarding NIHR portfolio adoption.

The *National Institute for Health Clinical Research Network (NIHR CRN)* is responsible for offering study support via the designated mailbox, and for offering support regarding study

[1] Please note, as of June 2018, HRA approval is now HRA and Health and Care Research Wales (HCRW) approval

adoption on the NIHR research portfolio. Applicants may apply for inclusion via the IRAS application form and are encouraged to do so.

3. Procedure

There are a number of ways in which NHS sites may be notified of/invited to a research study. If the study is successful in obtaining NIHR portfolio status, then the Clinical Research Network will circulate the study throughout the region to NHS Trust R&D departments. Similarly, R&D may find the study on the NIHR study app, Clinical Trials Gateway website, or will simply be contacted by the Sponsor or Researcher, with details of the project, in obtaining their initial agreement to set-up the study at site.

Assess Stage

3.1 Once a research study has gained the required approvals (including BU Ethics approval) and Bournemouth University (BU) Sponsorship, it can then be sent to potential NHS sites for their feasibility review, as part of the *Assess* stage. It may be that the applicant has already agreed with site(s) that they will participate and will have been added the site and investigator name to the IRAS form, in 'Part C'.

3.2 The site assesses whether or not it has the **capacity and capability** to participate in the study. For multisite projects, it would be advisable to create and send out a feasibility questionnaire/checklist to facilitate site selection. Any sites not identified on 'Part C' of the IRAS form will then need to be added under an amendment – the type of amendment to be submitted, depends on the nature of the study.

Arrange Stage

3.3 Once the site has been 'selected', a set list of documents then needs to be sent to the R&D contact, Research Nurse and any data management staff so that they can initiate local study set-up. The pack is made up of the following documents (HRA, 2018):

- Copy of IRAS Form as submitted for HRA Approval
- Protocol and amendments
- Participant information and consent documents (without local logos/ headers)
- Relevant model agreement
- *Commercial studies only – NIHR Costing template (validated) and delegation log (including known research team names but not signatures)*
- Non-commercial studies only – Organisation Information Document and Schedule Of Event templates (including known information)
- Any other documents that the sponsor wishes to provide to the site to support the set up and delivery of the study
- Copy of HRA initial assessment letter (if one is issued) and (when issued) HRA Approval letter and final documents.

This stage of the process is where sites put in place practical arrangements to provide the **capacity and capability** to deliver the study. Receipt of this document pack initiates two metrics that the site then has to meet:

- **40** days from site selection to confirming capacity and capability to deliver the study;
- If the study is on the NIHR portfolio, the site is expected to recruit their first participant within **30** days from opening the study.

Meeting these metrics is the responsibility of the individual site, and they are expected to report these to the NIHR on a quarterly basis.

3.4 The Sponsor may decide to provide the participating site(s) with an Investigator Site File (ISF) and any equipment or supplies, such as consumables that the site may need to carry out the study adequately.

3.5 As the study is sponsored by the University, it will be categorised as a *non-commercial* study, and therefore the HRA document entitled *Organisation Information Document* may be used as the 'contract' between BU and the participating site. The most up to date document may be viewed here along with other key study documentation templates. The *Statement of Activities* contains a delegation log that the Sponsor can request the participating site use. Sites will most often wish to confirm whether the Sponsor wishes them to use the Sponsor's template documents – the CGA may be contacted regarding this.

Confirm Stage

3.6 At the end of *Arrange* stage, the site will then *Confirm* that they have the **capacity and capability** to carry out the study, aiming to do so by the end of the 40 day metric. Some R&D departments choose to do this via a letter which will then require filing in the Trial Master File (TMF). If the *Organisation Information Document* has been used, then the site R&D will send this back with the letter/email, adding the date and name of the person at site authorising the document. Likewise this needs to be filed in the TMF. This date then counts as the *date site confirmed.*

The date the Sponsor has signed the study agreement (if not using the *Organisation Information Document* document) or has given the green light (see 3.12 below), if using the *Organisation Information Document*, is identified as the *date site confirmed by Sponsor*.

3.7 It is important to bear in mind that NHS Trusts may have additional pressures on their resource; therefore site set-up can take longer than anticipated. There may also be additional checks and signatures required per site that the Sponsor should take into consideration when liaising with a site (e.g. sign off by the service manager for the clinical area the study addresses). The requirements and guidelines of GCP should be followed at all times.

3.8 **NIHR Portfolio studies only.** Depending on the nature of the research study, and the activities required in order for the site to meet the protocol requirements, Trust R&D may need to make an application to their local Clinical Research Network (CRN) in order to secure Excess Treatment Costs (ETCs). Sometimes the cost of treatment within the research is more expensive than the cost of standard care, which then most often results in ETCs being identified. ETCs are identified in the HRA Schedule of Events document, for non-commercial studies.

According to AcoRD (Attributing the costs of health and social care Research and Development), costs associated with a research study are categorised as either a *research*

cost, *service support cost* or a *treatment cost.* There is a funding attribution flowchart in the appendix of this SOP. The Study Support team at the local CRN may be contacted for advice and guidance with regard to ETCs, copying the CGA into correspondence.

Site Initiation

3.9 Depending on the nature of the project, the Sponsor may decide to visit the site to carry out a site initiation visit (SIV), or alternatively will carry out an SIV over the telephone.

3.10 Sites should localise documents with their Trust header and local contact details, and send these to the CI/PI for filing in the TMF. The site should also send a scanned copy of the final delegation log for filing in the TMF.

3.11 All correspondence with sites, whether participating or not should be filed in the TMF.

Opening the Study at an NHS Site

3.12 Once the site has been initiated and has sent back the necessary confirmation of **capacity and capability**, they can be opened to recruitment, provided the Sponsor is happy that the delegation log, any specific training and additional arrangements are available and complete.

3.13 The Sponsor may decide to formalise the process and grant the site 'green light' to begin recruitment.

3.14 Copy in the CGA to all correspondence with the site so that the progress of the study can be monitored by Research Development & Support.

Amendments

3.15 Much like when setting up a study, assessing amendments can sometimes impact the site's **capacity and capability** to run the research. If the site is unable to meet the requirements of an amendment, then they are within their rights to reject the amendment, and to carry on with the activities for which they have capacity. All correspondence regarding this must be filed with the TMF. Advice may be sought from the CGA if required.

3.16 Procedures for submitting an amendment and categories of amendment are outlined in BU RDS SOP 002 – correspondence should take place as early as feasible in order to the Trust R&D

4. Abbreviations and definitions

CGA	Clinical Governance Advisor
CI	Chief Investigator
ETC	Excess Treatment Cost
GCP	Good Clinical Practice
HRA	Health Research Authority
IRAS	Integrated Research Application System
ISF	Investigator Site File
NIHR CRN	National Institute for Health Research Clinical Research Network

PGR	Postgraduate Researcher
PI	Principal Investigator
R&D	Research & Development (Trust Research Governance)
R&I	Research & Innovation
SIV	Site Initiation Visit
TMF	Trial Master File

5. Related documentation and references

Assessing, Arranging, and Confirming: clarifications on HRA terminology, (appendix document), Health Research Authority

Attributing the costs of health and social care Research and Development (AcoRD), (2012), Department of Health

Organisation Information Document and other templates/guidance, available here (https://www.hra.nhs.uk/planning-and-improving-research/research-planning/prepare-study-documentation/), Health Research Authority

UK Policy Framework for Health and Social Care Research. (2017). Health Research Authority

Appendix

Attributing the costs of health and social care Research and Development (AcoRD), Department of Health

Figure 1: Funding attribution flowchart