Gloucestershire Hospitals NHS Foundation Trust

SOP 10: Hosting CTIMPs and other Clinical Studies

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IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the Research, Innovation & Genomics Webpage for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive version of all Gloucestershire Hospitals NHS Foundation Trust SOPs appear online. If you are reading this in printed form, check that the version number and date below is the most recent one as shown on the RIG website:

https://www.gloshospitals.nhs.uk/about-us/research-our-hospitals/

The Gloucestershire Hospitals NHS Foundation Trust wishes to acknowledge York Hospitals NHS Foundation Trust, Weston NHS Foundation Trust and University Hospitals Bristol NHS Foundation Trust who gave permission to use their templates in the development of these SOPs.

Version History Log

This area will be updated with details of all changes made to the SOP whether due for full review or not.

Version	Details of Change	Date Implemented
1.0	Original SOP	R&D SOP 06
2.0	Reviewed and updated along with reorganisation into the Gloucestershire R&D Consortium suite of SOPs	13/01/2017
3.0	Rebranding to GHNHSFT and updating of contact details and reference documents	31/03/2018
4.0	Updated references, updated team names, updated terms and clarification of processes, Removal of SOP categories and change of reference codes	30/10/2023
5.0	Update of department name from R&D to RIG. Renewal period set at three years. Glossary updated. Update to feasibility process. Minor amendments throughout	12/02/2026

This SOP will be reviewed every three years unless changes to any relevant legislation require otherwise

Related Documents:

SOPs
SOP 02 - Research documentation and file management
SOP 03 - Training
SOP 04 - Informed consent in research
SOP 05 - End of trial procedures
SOP 06 - Trial archiving
SOP 12 - Trial management system EDGE
SOP 13 - Monitoring and Oversight of Hosted Studies
SOP 20 - Adverse events and reaction safety reporting
SOP 21 - Research misconduct and fraud
SOP 22 - Non-Compliance and Serious Breaches
SOP 37 - Process for submitting Expression of Interest for Research Studies

Glossary

C&C	Capacity & Capability
CRO	Clinical Research Organisation
CTIMPs	Clinical Trials of Investigational Medical Products
EOI	Expression of Interest
GCP	Good Clinical Practice
GHNHSFT	Gloucestershire Hospitals NHS Foundation Trust
HRA	Health Research Authority
ICH	International Conference on Harmonisation
ISF	Investigator Site File
MHRA	Medicines and Healthcare products Regulatory Agency
NIHR	National Institute for Health and Care Research
OID	Organisation Information Document
PI	Principal Investigator
PS	Professional Services team
QA	Quality Assurance
REC	Research Ethics Committee
RIG	Research, Innovation and Genomics
RPM	Research Portfolio Manager
RRDN	Regional Research Delivery Network
SAE	Serious Adverse Event
SUSAR	Suspected Unexpected Serious Adverse Reaction
TMF	Trial Management File

Contents

1. Introduction, Background and Purpose

To ensure that Clinical Trials of Investigational Medical Products (CTIMPs) adhere to the guidance set out for researchers in The Medicines for Human Use (Clinical Trials) Regulations 2004, ICH/GCP, Medicines and Healthcare Products Regulatory Agency (MHRA), the Health Research Authority (HRA) and the UK wide National Research Ethics Service advice, there are certain aspects of trial preparation, design and set-up that need to be followed.

This SOP provides guidance on hosting CTIMPS and other Clinical Studies that are externally sponsored, including Commercially Sponsored Studies. It is intended, in many cases, to be read alongside specific SOPs that deal with particular aspects of Trial Management in more detail.

2. Who Should use this SOP

The Research, Innovation and Genomics (RIG) Team, and anyone who is thinking of applying to the Trust to host a CTIMP or other Clinical Study, should refer to this SOP as early as possible in the process to ensure that they are familiar with the requirements of such an undertaking.

3. When should this SOP be used?

This SOP should be followed when planning to take part in an externally sponsored CTIMP or other Clinical Study alongside any Sponsor created, Trial Related SOPs.

4. Process for Study Initiation

4.1 Identification of Trials to Host

All departments within the Trust are encouraged to consider participating in research projects. Information on National Institute for Health and Care

Research (NIHR) portfolio adopted trials and studies in development and ready to set up locally, come to the Trust through a number of routes. If a team is interested in taking part in research but are not aware of any multicentre trials that might be suitable, then the team can request support in identifying a trial from the RIG Professional Services (PS) Team

4.2 Setting up a Trial or Study – Feasibility

Before a hosted study is accepted for set-up, and prior to the Trust being accepted as a site, it is usual that an expression of interest (EOI) will be requested from the Sponsor or a delegated representative such as clinical research organisation (CRO). This request may come via the South West Central Regional Research Delivery Network (RRDN) or through a direct approach. The process for approval to submit an EOI is described in SOP 37 - Process for submitting Expression of Interest for Research Studies, and Guideline 03 EOI process.

A prospective PI (or delegate) must present the proposed study and the rationale behind why the EOI should be submitted to and receive agreement from the EOI panel made up of members of the RIG team, before an EOI is submitted.

4.3 Health Regulatory Authority (HRA) approval

HRA Approval is the process for the NHS in England, that brings together the assessment of governance and legal compliance, undertaken by dedicated HRA staff, with the independent Research Ethics Committee (REC) opinion provided through the UK Research Ethics service. It replaces the need for local checks of legal compliance and related matters by each participating organisation in England.

The Sponsor of a multi-centre study will provide the Local Information Pack for the Trust to confirm local capacity and capability (SOP 11) to deliver the study at site..

4.4 Trust approval

Following discussion and agreement with the Sponsor (as described in SOP 11), the RIG PS team, on behalf of the Trust, confirms the arrangements for the study by either exchanging signed agreements or, in some instances for non-commercially sponsored studies, agreeing the Organisation Information Document (OID) (this stage happens after HRA Approval is in place). The GHNHSFT Confirmation of Capacity and Capability email sent from PS, with attached PI responsibility letter will include all appropriate conditions for the approval.

Prior to confirmation of capacity and capability, where a study is to be delivered without the direct involvement of the RIG Delivery Team, there will be a risk assessment by the Quality Assurance (QA) Manager from RIG. Details are described in SOP 13: Monitoring and Oversight of Hosted Research Studies.

The Sponsor confirms the date on which the study can start recruitment (green light) for the Trust. (See more at: http://www.hra.nhs.uk/research-community/hra-approval-the-new-process-for-the-nhs-in-england/#sthash.pEhoDTJC.dpuf). This will be once the following have occured:

- arrival of Investigator site file at site (see SOP 02)
- arrival of Pharmacy site file at site (see SOP 02)
- arrival of Drug supply and required equipment to be supplied by the Sponsor or their representative, if applicable
- Completion of Trial specific training including GCP (see SOP 03 and SOP 04)
- The return to Sponsor of a copy of the completed delegation log fully signed off by PI
- Completion of Site initiation Meeting or Site Initiation Teleconference

4.5 NIHR Portfolio

The NIHR RDN Portfolio consists of high-quality research studies that apply, and are eligible for, NIHR RDN support. Decision to apply for a portfolio adoption is that of the study Sponsor.

Non-portfolio studies are not eligible for support from NIHR funded staff (such as the delivery team) and will require full funding if there are financial implications for the Trust. Significant, unfunded financial implications may prevent confirmation of capacity and capability being given.

5. Standard Operating Procedures (SOPs)

5.1. GHNHSFT RIG SOPs

The Trust RIG SOPs will apply to all locally Hosted CTIMPs and other Clinical Studies and must be followed by all Principal Investigators (PIs) and research teams.

Adherence to the Trust RIG SOPs will be assessed at trial set-up, initiation and monitoring. Any deviations from the local SOPs must be justified.

Where protocols refer to specific trial related SOPs, these will take precedence over the local SOPs unless there are any legal reasons why they should not be. If this is the case, the QA Manager and the RIG Portfolio Manager (RPM) responsible for the set-up of the study will review and seek clarification from the Sponsor.

5.2. Pharmacy SOPs

Pharmacy specific pre-existing SOPs and pharmacy research SOPs must be followed and the PI is responsible for ensuring that the trial adheres to these procedures.

5.3. Laboratory/Radiology/Support Departments

Specific pre-existing SOPs and Guidelines must be followed and the PI is responsible for ensuring that the trial adheres to these procedures.

6. Recruitment

6.1. Informed Consent

The PI will be responsible for overseeing all recruitment. The PI can delegate the informed consent process to adequately trained research staff, with agreement from the Sponsor or Trials Unit. For studies that will not be supported by the RIG delivery teams, staff to support receiving of consent need to be identified before C&C is given. With the agreement of the Sponsor, members of the research delivery team who are not clinicians or registered healthcare professionals may be delegated the responsibility of taking the participant through the consent process and receive informed consent (see SOP 04). This must be clearly documented in writing during the set-up process.

6.2. Recording Recruitment Activity

Recruitment must take place in accordance with the processes outlined in the current approved study protocol.

The PI and staff delegated the role will be responsible for keeping records of participants who are screened, fail screening, are recruited and withdraw from the study using the logs in the ISF and the EDGE Research Management System (see SOP 12).

6.3. Recruitment to Time and Target

During feasibility and study set-up a realistic recruitment target is agreed between site and Sponsor. The PI and the research team should monitor recruitment to time and target throughout the study, in accordance with the current NIHR high level objectives. The plan for screening agreed at site

initiation will be reviewed and updated if recruitment is behind target. Early negotiation with the Sponsor regarding the recruitment target is advisable if target looks unachievable.

7. Running a CTIMP

- Within the Trust CTIMPS cannot be supported outside of the RIG delivery teams.
- All staff at the research site must adhere to the duties delegated to them on the delegation log contained within the ISF (paper or electronic).
- All research staff must adhere to the current approved research protocol and must be aware of study amendments that come from the Sponsor. This will ensure all research staff are working with the most currently approved Trial Documentation. Not adhering to the current approved research protocol may be considered a Serious Breach requiring reporting to the Sponsor, who will decide if HRA and MHRA (if applicable) should be notified. A Research Misconduct Investigation may be initiated by the Sponsor.
- All staff must be aware of the responsibility to report Serious Breaches, Suspected Research Misconduct and Fraud, SAEs and SUSARs under the Clinical Trial Regulations (see also SOP 20, SOP 21, SOP 22 and SOP 23) and to log these on EDGE as well as in the TMF / ISF.
- The TMF / ISF must be maintained to a high standard and in line with the specified guidance from the Sponsor as regarding the template and in accordance with GCP (see SOP 02).
- Regular communication between the Sponsor and research team and between research team members should be maintained and documented throughout the study.
- PI and research staff must abide by GHNHSFT regulations regarding GCP training, currently requiring to be updated every 3 years.

8. Monitoring

Responsibility for monitoring and oversight of hosted studies lie with the study sponsor. However, the RIG PS Team may undertake monitoring if required (as described in SOP 13).

9. Trial Closedown

The PI, local Research delivery Team/research staff and RIG Research Portfolio Managers will liaise as necessary to ensure trial closedown is completed as per the sponsor's instructions. (See SOP 05)

10. Archiving

The PI and local Research Team will ensure that all relevant Trial Material is archived according to advice from the Sponsor and/or the Trust SOP (SOP 06)

11. References

HRA
http://www.hra.nhs.uk

http://www.hra.nhs.uk/research-community/hra-approval-the-new-process-for-the-nhs-in-england/#sthash.pEhoDTJC.dpuf

Excess Treatment Costs
NHS Accelerated Access Collaborative » Excess treatment costs (england.nhs.uk)

NIHR RDN Portfolio:
https://www.nihr.ac.uk/support-and-services/support-for-delivering-research/research-delivery-network/RDN-portfolio