NHS
Gloucestershire Hospitals
NHS Foundation Trust

Managing Research 01 - Hosting CTIMPs and other Clinical Studies

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 & Development 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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.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 R&D website:

http://www.gloshospitals.nhs.uk/en/About-Us/Research--Development/

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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

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

Contents

1. Introduction, Background and Purpose

In order to ensure that 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) and 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 ?

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. Identification of Trials to Host

All departments within the Trust are encouraged to consider participating in research projects. Information on NIHR 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 do not know of any multicentre trials that might be suitable then the team can get support in identifying a trial from their Trust Divisional R&D Lead, Gloucestershire Research Support Service (GRSS) and the West of England CRN Research Delivery Managers and research facilitators. (See reference section for links).

5. Setting up a trial or study- Feasibility

Wherever possible it is preferable to have a preliminary face to face meeting with all the departments/ teams involved and this can be facilitated by the GRSS.

At this meeting due consideration of issues related to the Trust's ability to host a study such as those listed below need to be considered:

i. Does the patient population identified in the eligibility criteria for the trial come to the Trust for that part of their patient pathway?
ii. How many of the patient cohort attended the Trust in a year, preferably over the last 3 years and take the average. This can be found via a number of Trust systems, a few examples are given below:
    a. Contact the Informatics Department and ask for a report on specific ICD 10 codes
    b. Contact Pathology Department for a report on a specific diagnosis
    c. Contact Pharmacy to get a report on how many patients have been prescribed a given drug regime.
iii. What is the standard treatment pathway?
iv. How does the trial protocol pathway vary? What are above standard treatment and investigations, what aspects of the protocol are using less resources than standard? Are the timings the same as standard, extended or reduced?
v. How long is the recruitment period? How long is the follow up period?
vi. Is there a minimum number of recruits the site has to find to be considered as a viable site by the Sponsor?
vii. What is provided by the Sponsor?
    a. Free or reduced priced drugs
    b. Per patient payment
    c. Free or additional funding for research specific tests or procedures
    d. Equipment
viii. Have Excess Treatment Costs been identified? (See https://www.england.nhs.uk/commissioning/research/etc/ and Attributing costs of health and social research and development (AcoRD) -Department of Health (October 2012)
ix. Are suitably trained staff available?
x. Where are the clinics and are the standard clinic slots sufficient?
xi. Does the team have sufficient time to complete the data collection in a timely fashion?

The outcome of the meeting will be fed back to the Sponsor, and GRSS can assist in completion of initial paperwork such as Expressions of Interest (EOI), site feasibility forms, site selection forms.

6. Health Regulatory Authority (HRA) approval

6.1 NIHR portfolio research

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 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 capacity and capability (R&D SOP MR 02).

Following discussion and agreement with the Sponsor, the Trust confirms their capacity and capability to deliver the study by either exchanging signed agreements or, in some instances for non-commercially sponsored studies, agreeing the Statement of Activities (this stage happens after HRA Approval is in place). The Trust Approval letter will include all appropriate conditions for the approval.

The HRA time lines for processing and granting Trust approval will be adhered to wherever possible (see HRA website).

The Sponsor confirms date at which the study can start/ site initiation date at that 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 confirmation of:

- the arrival of Investigator site file (see R&D SOP TD 01)
- the arrival of Pharmacy site file (see R&D SOP TD 01)
- the arrival of Drug supply
- Trial specific training including GCP (see R&D SOP TD 02 and 03)
- 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

6.2 Trust Approval for Non-Portfolio Studies

Where a study is not on the NIHR Portfolio, or there are no plans for it to seek adoption, the GRSS R&D review will still involve feasibility/ capacity & capability review as well as a review of the documentation against the Research Governance Framework requirements.

Non-portfolio studies are not eligible for support from NIHR funded staff/research nurses/CSOs and will require full funding if there are financial implications for the Trust. Significant, unfunded financial implications may prevent Trust Approval being given.

On receiving the 'Green Light' from the Sponsor it is advised that the researcher should make a final check with the GRSS office that the researcher can 'go ahead' locally.

7 Standard Operating Procedures (SOPs)

7.1 Gloucestershire R&D Consortium SOPs

The Consortium SOPs will apply to all locally Hosted CTIMPs and other Clinical Studies and must be followed by all PIs and research teams.

Adherence to the Consortium 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 R&D Managers will review and seek clarification from the Sponsor.

7.2 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 also.

7.3 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 also.

8. Recruitment

8.1 Informed Consent

The PI will be responsible for overseeing all recruitment with the assistance of the local Research Team. With the agreement of the Sponsor members of the research team who are not clinicians may be delegated the responsibility of taking the participant through the consent process and receive informed consent (see R&D SOP TD 03). This must be clearly documented in writing during the set-up process.

8.2 Recording recruitment activity

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

The PI and Local Research Team will be responsible for keeping records of participants who are screened, fail screening, are recruited and drop out of the study using the logs in the ISF.

Record of participants who are screened, fail screening, are recruited and drop out will also be recorded by the research team on the EDGE Research Management System (see R&D SOP MR 03).

8.3 Recruitment to time and target

The PI and the research team should monitor recruitment to time and target, both for the recruitment of the first patient into the trial within 70 days of the receipt of valid research application (VRA) to Trust *(exceptions will be made for trials recruiting ten or fewer recruits annually)*and annually.

9. Running a CTIMP trial

- All staff at the research site must adhere to the duties delegated to the delegation log contained within the ISF.
- All research staff must adhere to the current approved protocol. Any trial related activity/intervention that is not outlined in the current approved protocol may be considered a Serious Breach requiring reporting to the MHRA and a Research Misconduct investigation may be initiated by the Sponsor.
- All staff must be aware of the responsibility to report Serious Breaches, SAEs and SUSARs under the Clinical Trial Regulations (see also R&D SOP PH 02, 03 and 04) and to log these on EDGE as well as the site file.
- The site ISF must be maintained to a high standard and in line with the specified guidance from GCP (see R&D SOP TD 01).
- Regular communication between the Sponsor and research team and between research team members should be maintained and documented.

10. Monitoring

Responsibility for monitoring Hosted studies lies with the study sponsor. However, the R&D Office may choose to undertake audits of Hosted Studies to ensure local activity complies with ICH/GCP, Research Governance and CTIMP regulations (See also R&D SOP MR 05)

11. Trial Closedown

The PI, local Research Team and R&D Managers will liaise as necessary to ensure trial closedown is completed as per the Sponsor's instructions. (See R&D SOP TD04)

12. 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 (R&D SOP TD 05)

13. Related SOPs and documents

R&D SOP TD 01Research documentation and file management
R&D SOP TD 02 Training
R&D SOP TD 03 Informed consent in research
R&D SOP TD 04 End of trial procedures
R&D SOP TD 05 Trial archiving
R&D SOP MR 03 Trial management system EDGE
R&D SOP MR 04 Monitoring research studies
R&D SOP PH 02 Adverse event and reaction reporting
R&D SOP PH 03 Research misconduct and fraud
R&D SOP PH 04 Non-Compliance and Serious Breaches

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
https://www.england.nhs.uk/commissioning/research/etc/