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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.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

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

This SOP will be reviewed every two 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 research studies
SOP 20 - Adverse event and reaction reporting
SOP 21 - Research misconduct and fraud
SOP 22 - Non-Compliance and Serious Breaches

Glossary

AcoRD	Attributing costs of health and social research and development
C&C	Capacity & Capability
EOI	Expression of Interest
CRN	Clinical Research Network
GCP	Good Clinical Practice
GHNHSFT	Gloucestershire Hospitals NHS Foundation Trust
HRA	
ICH	International Conference on Harmonisation
ICD-10	International Classification of Diseases 10th Revision Code
ISF	Investigator Site File
MHRA	Medicines and Healthcare products Regulatory Agency
NIHR	National Institute for Health Research
OID	Organisation Information Document
PI	Principal Investigator
REC	Research Ethics Committee
SAE	Serious Adverse Event
SUSAR	Suspected Unexpected Serious Adverse Reaction

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), 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 R&D 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. 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 are not aware

of any multicentre trials that might be suitable, then the team can get support in identifying a trial from, the R&D Department 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 meeting/communication with all the departments/ teams involved and this can be facilitated by the Research Portfolio Managers.

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. Is there a suitable Principal Investigator (PI) for the study?

ii. Does the patient population identified in the eligibility criteria for the trial, treated at the Trust for that part of their patient pathway?

iii. The number of eligible patients attending/referred to the Trust in a year, preferably over the last 3 years. On average should be taken.. This can be found via a number of Trust systems; a few examples are given below:

   a. Contact the Business Intelligence team or Clinical Coding Team and ask for a report on specific ICD-10 codes. The generic email address for the Business Intelligence Team is bi-unit.informationanalysts@nhs.net/, and the generic email address for the Clinical Coding Team is ghn-tr.cdcstaff-grh@nhs.net .

   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.

iv. What is the standard treatment pathway?

v. How does the trial protocol pathway vary from the standard pathway? 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?

vi. How long is the recruitment period? How long is the follow up period?

vii. Is there a minimum number of recruits the site has to find to be considered as a viable site by the Sponsor?

viii. What is provided by the Sponsor?

   a. Free or subsidised drugs
   b. Per patient payment
   c. Free or additional funding for research specific tests or procedures
   d. Equipment
   e. Lab supplies or other disposables?

ix. Have Excess Treatment Costs been identified? (See NHS England » Excess treatment costs: Guidance on the national management model for England/) and Attributing costs of health and social research and development (AcoRD) -Department of Health (October 2012)

x. Are suitably trained staff available?

xi. Where are the clinics and are the standard clinic slots sufficient? Will extra rooms be needed?

xii. Does the team have sufficient time to complete the data collection in a timely fashion and meet expectations for monitoring?

The outcome of the meeting will be fed back to the Sponsor. It is a requirement for the Research Governance Team to be involved in completing the initial paperwork such as Expressions of Interest (EOI), site feasibility forms and site selection forms. This will ensure the correct processes are followed and will shorten the length of time set-up will take.

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 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 capacity and capability (SOP 11).

Following discussion and agreement with the Sponsor, the R&D Governance team on behalf of 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 Organisation Information Document (OID) (this stage happens after HRA Approval is in place). GHNHSFT Confirmation of capacity and capability email will include all appropriate conditions for the approval.

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 confirmation of:

- the arrival of Investigator site file (see SOP 02)
- the arrival of Pharmacy site file (see SOP 02)
- the arrival of Drug supply, if applicable
- Trial specific training including GCP (see SOP 03 and SOP 04)
- 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 Research Governance Team 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 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.

7 Standard Operating Procedures (SOPs)

7.1 GHNHSFT R&D SOPs

The Trust R&D 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 R&D 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 Research Portfolio Managers (RPMs) 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 procedures.

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 procedures.

8. Recruitment

8.1 Informed Consent

The PI will be responsible for overseeing all recruitment. The PI can delegate the informed consent process to adequately trained research staff. Studies that will not be supported by the R&D delivery teams, staff to support the studies will need to be identified before C&C is given. With the agreement of the Sponsor members of the research 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.

8.2 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).

8.3 Recruitment to time and target

The PI and the research team should monitor recruitment to time and target. The screening plan 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.

9. Running a CTIMP trial

- 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 - MHRA 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, SAEs and SUSARs under the Clinical Trial Regulations (see also SOP 20, SOP 21, SOP 22 and SOP) 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 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.

10. Monitoring

Responsibility for monitoring Hosted studies lies with the study sponsor. However, the Research Governance Team will undertake monitoring. Details of trials requiring monitoring can be found in SOP 13.

11. Trial Closedown

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

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 (SOP 06)

13. 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)