NHS
Gloucestershire Hospitals
NHS Foundation Trust

Management of Research 02 - Confirmation of Capacity and Capability

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 Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.

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

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Reviewed by Assistant Director of Research and Development	Julie Hapeshi 23/03/2018	signature
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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 13	
2.0	Reviewed and updated to show HRA processes, along with reorganisation into the Gloucestershire R&D Consortium suite of SOPs	01/02/2017
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

This SOP sets out to provide clarity about the process to be followed before Confirmation of Capacity and Capability is given to deliver a research study in the Trust for studies receiving HRA Approval. Obtaining Confirmation is an essential precondition to the conduct and delivery of any portfolio or non-portfolio study.

HRA Approval is the new process for the NHS in England that comprises a review by a NHS Research Ethics Committee (REC) (where required) as well as an assessment of regulatory compliance and related matters undertaken by dedicated HRA Staff. In England, it replaces the need for local checks of legal compliance and related matters previously known as local governance review.

This allows NHS organisations to focus their resources on assessing, arranging and confirming their capacity and capability to deliver the study.

HRA Approval applies only to the NHS in England. The HRA has compatibility arrangements in place with the national NHS Permission coordinating function in Northern Ireland, Scotland and Wales that mean that the HRA will share information with those national coordinating functions to benefit study set up in participating NHS/HSC organisation across the UK where applicable. Further information about this can be found at
http://www.hra.nhs.uk/about-the-hra/ourplans-and-projects/assessment-approval/

2. Who Should Use This SOP

This SOP should be used by:

- Members of Gloucestershire Research Support Service (Trust R&D Team)
- Members of the Gloucestershire Research Consortium

3. When this SOP Should be Used

This SOP should be used when anyone applies for Confirmation of Capacity and Capability to undertake a research study in the Trust. This includes studies sponsored or co-sponsored by the Trust as well as studies that are externally sponsored and hosted within the Trust. It includes applications for non-Portfolio studies made direct to the GRSS.

4. Procedure(s)

The HRA has defined the different stages that sponsors and participating organisations (the Trust) go through on the way to mutually agreeing that the study can open at that organisation (the Trust). These stages can be used to identify time points which the Trust may wish to measure in order to examine where barriers to study set up and delivery occur.

a. **Assessing:** Assessing whether or not the Trust has the capacity and capability to participate in the study.

NB this stage will not be required, or will be minimal, for some types of studies where it is automatically expected that the Trust will participate unless there is a significant reason why not. These study types include emergency public health research, studies involving minimal local activity such as distributing questionnaires, on line surveys or supplying previously collected clinical data where consent is already in place, and studies where the clinical pathway has meant that a patient has been transferred for on-going clinical care but the responsibility for the research remains with the original Principal Investigator.

b. **Arranging:** Putting any practical arrangements in place to provide the capacity and capability to deliver the study

c. **Confirming:** Confirming that the Trust has the capacity and capability in place to deliver the study and will deliver the study. This confirmation is given through the mutual confirmation of the contents of the statement of activities for non-commercial studies or sign-off on an agreement.

5 Confirmation of Capacity and Capability

5.1 Assess:

- The sponsor/CI/study co-ordinator invites the Trust to assess their local capacity & capability to participate in a study. This invitation will come via the Research Governance mailbox or directly from the PI/ research team and will consist of :
  Commercial trial – protocol, industry costing template and agreement, Non-commercial – protocol, Statement of Activities(SoA) /trial agreement and Schedule of Events (SoE).
  If any of these documents are missing request from the sponsor.
- A Research Manager (RM) from Gloucestershire Research Support Service (GRSS) will cascade the documentation to the relevant research team and supporting department research contacts for them to assess, with the support of the RM, whether the study is feasible. If the research team consider the study feasible to deliver the RM will confirm with the Sponsor and request the Local Information Pack (see appendix 1).
  NB This invitation must only happen after an application for HRA Approval has been made but can also occur after HRA Approval is in place.
- If the research team or supporting departments do not have capacity or capability to deliver the study the RM will email the sponsor to notify them.
- If the research team agree to deliver the study the RDF will process the study using the Confirmation of Capacity and Capability Checklist and will add the study to EDGE (see R&D SOP MR 03).
- Consider with the research team when the first patient first visit (FPFV) will take place.

Actions

- Create a new EDGE record for the study as well as a new study folder on the RDSU drive.
- Obtain the Local Information Pack from the sponsor ensuring it is complete (see appendix 1) which may include requesting the pharmacy and/or lab manual as appropriate to the study and will be considered the 'date site selected' for the purposes of EDGE workflows.
- Undertake an assessment of the study agreement/statement of activities and industry costing template/schedule of events
- Review NHS cost and resource implications , contact Commissioners/ Specialist Commissioners to confirm Excess Treatment Costs will be covered by them
- If happy with the study agreement, localise and return to sponsor requesting hard copies signed by the sponsor
- If happy with statement of activities complete relevant section and hold until issue of Confirmation of Capacity and Capability email.
- Request authorisation from the relevant support departments, emails or meeting notes may be used as confirmation.
- An ARSAC certificate is required for every administration of radioactive material (for medical purposes). If the procedure is required by the project but is not part of normal care, a research ARSAC certificate will be needed.
- A check of IRMER status/requirements
- Identify (check the Schedule of Events) honorary employment contract / letter of access requirements and ensure that all relevant research passports/honorary contract (or letter of access) application forms and/or copies of NHS substantive contracts are available (or are obtained). (See R&D SOP IE 02)
- Consider who will be responsible for uploading accruals to EDGE. If the study is being undertaken by one of the Trust's research teams it will be their responsibility to do this. If the study is being undertaken by an external organisation and the Trust's research team are not involved then it will be the Research Manager responsibility to negotiate how many accruals the Trust will receive, ensure they are notified of accruals and upload them to EDGE.

5.2 Arrange:

Actions

- Clarify with the sponsor and team if there is study specific training required
- Confirm SIV date
- Confirm IMP delivery date
- Any other arrangements e.g. Service Level Agreements, freezer, drug cabinet etc

5.3 Confirm:

Actions

- Ensure HRA Approval has been received and upload latest versions of documents to the study folder onto the RDSU Drive.
- Ensure study agreement is fully executed or SoA is completed

- Pharmacy confirmation of readiness has been received (IMP studies)
- Laboratory confirmation of readiness has been received (if relevant)
- All required honorary contracts/letter of access ready to issue
- Confirmation of Site Initiation received
- If the above are confirmed agree a start date/drug delivery date with the sponsor (if available) and issue relevant Confirmation of Capacity and Capability email to sponsor and, email Trust approval letter to PI following Confirmation of Capacity and Capability. If using the SoA as the agreement (non-commercial studies) attach this to the email.
- Where possible confirm with the research team when the FPFV (first patient first visit) date will be ensuring that it falls within the NIHR data point metrics NIHR High Level Objective 4 and High Level Objective 5 (Trust approval within 40 day target of date site selected and first participant recruited within 30 days of date site confirmed).
- Lastly, ensure the route for uploading of accruals has been agreed (see last point in **Assess**).

6 Related SOPs and Documents

HRA
http://www.hra.nhs.uk/about-the-hra/ourplans-and-projects/assessment-approval/

R&D SOP MR 01 Hosting CTIMPS and other clinical studies

Appendix 1

Local Information Package

The sponsor should provide the following information to the site:

- Copy of the HRA Initial Assessment letter
- Copy of IRAS application form (R&D form if pre HRA Approval study (April 2016))
- Protocol
- Any amendments
- Participant Information and consent documents
- Relevant model agreement (where applicable)
- NIHR Costing template (validated by the Clinical Research Networks – check front page) – commercial studies
- Schedule of Events – non-commercial studies
- Statement of Activities – non-commercial studies
- To be provided once available:
  HRA Approval letter and final document versions