Sheffield Teaching Hospitals NHS Foundation Trust

Conditions of Confirmation of Capacity and Capability

Please note the following requirements that must be adhered to by the investigator when embarking on a research project at Sheffield Teaching Hospitals NHS Foundation Trust (STH). **This project has been reviewed by the Research Department. Confirmation of capacity and capability for the research to commence has been granted on the basis described in the HRA Approval letter and supporting documentation** on the understanding that the study is conducted in accordance with the Research Governance Framework, GCP and Sheffield Teaching Hospitals policies and procedures.

The investigator must update the Research Department of the following:

1. Safety reporting

Investigators should ensure that they elicit information regarding adverse events from participants at each study visit. If a Serious Adverse Event (SAE) is discovered the Investigator must alert the Sponsor immediately (within 24 hours) and must comply with sponsor requests for further information to ensure that events are reported to ethics and regulatory bodies within the timelines laid down in the Medicines for Human Use (Clinical Trials) Regulations 2004. Investigators should refer to the STH Research Department SOPs available by request or on the Department website http://www.sheffieldclinicalresearch.org for further guidance.

2. Recruitment reporting in EDGE

MANDATORY REPORTING OF RECRUITMENT

The Research Department is obliged to report study set up and recruitment performance for the Trust to NIHR and to report research activity for all studies to Trust Board. In order to meet these reporting requirements please be advised that it is now a ***mandatory*** condition of STH confirmation of capacity and capability that recruitment to ***all*** research studies* at STH is reported into EDGE (the Accrual Collation and Reporting Database). It is essential that recruitment is entered into EDGE ***real-time*** to enable directorates to accurately monitor performance.

Please be informed that failure to report recruitment to EDGE may result in loss or delay in funding to the Trust and to the Directorate.

***EDGE Exempt Studies**

Not all studies are required to use the EDGE Database.

Studies conducted in a STH Clinical Research Facility (CRF) - These studies will be under the management of the CRF where accrual will be captured in the CRF Manager database and are therefore EDGE exempt.

Recruitment for CRF Link studies (where the CRF provides the research environment for the PI and their team) will require reporting into EDGE as data for these studies are not captured in CRF Manager.

Definition of Recruited Participant: Eligible participant recruited onto the trial.

Note: Screen failures do not count as a recruited participant.

Once you have been issued with a login for EDGE, please refer to the training materials at this link to use the system: http://www.sheffieldclinicalresearch.org/for-researchers/conducting-research/step-4/

For further information regarding the use of EDGE or training provision please contact your local STH EDGE Administrator – Alessia Dunn (alessia.dunn@sth.nhs.uk).

3. Amendments

Investigators should alert the Research Department if there is an amendment (substantial or non-substantial).

Where studies are sponsored by STH, the CI should submit the amendment to their Research Coordinator for review & classification as substantial or non-substantial, prior to submission to relevant bodies.

Where studies are not sponsored by STH, the Sponsor should submit an amendment package (including the required HRA correspondence, the revised documentation and the REC Favourable Opinion letter, if applicable) to the study team and the Research Department in order for a review to be undertaken where required.

4. Training

In accordance with the principles of Good Clinical Practice, investigators should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial related duties and functions. The investigator is responsible for ensuring that the research team have the requisite study-specific/GCP training. If anyone joins the team after confirmation of capacity and capability has been granted, their GCP status should be checked by the Principal Investigator. The Research Department can direct them to GCP training if required.

5. Study status

Under the Research Governance Framework, STH has a responsibility to maintain an accurate record of all research undertaken within the organisation or involving participants, organ, tissue or data obtained through the organisation. A requirement of STH confirmation of capacity and capability is that the Investigator provides ongoing information on study progress. The investigator should inform their Research Coordinator on an ongoing basis of the dates where major milestones are reached as defined below. Equally an investigator should inform their Research Coordinator of any revisions to timelines for example, if the study fails to recruit as originally forecast.

Milestone	Definition
Open to recruitment	Sponsor green light confirmed (as applicable). Research team are actively identifying/screening/recruiting participants and/or collecting data
First patient First visit (FPFV)	Date of first visit at which data (e.g. medical history) is collected from the first study subject confirmed eligible to participate in a given clinical study.
Abandoned	Withdrawn after STH confirmation of capacity and capability. Study closed prematurely prior to recruitment.
On hold	Study temporarily suspended/put on hold.
Closed to recruitment – in follow up	No more participants/patients will be recruited but follow up activities continue at site.
Last patient Last visit (LPLV)	For IMP studies, if not otherwise defined in protocol, this is the end of trial and MHRA can be informed of end of study at this point as per clinical trials toolkit advice http://www.ct-toolkit.ac.uk/ For STH sponsored studies we expect safety data to be collected for a minimum of 30 days post last patient last dose.
Closed to recruitment – follow up complete	All participant/patient activities complete at site, only data entry/queries/sample analysis remaining.
Database Lock	All data collected and cleaned. No further changes of data expected/allowed.
Ended	All study activities finished at site, close-out visit has occurred.
Published	Research project results have been published (may occur after archiving).
Archived	Study documentation archived.

6. Standard Operating Procedures (SOPs)

Investigators should familiarise themselves with any STH SOPs which are relevant to the study they are undertaking. Evidence of training in these SOPs should be recorded in your individual SOP training log, a template log can be found at http://www.sheffieldclinicalresearch.org/clinical-research-office/useful-documents. Investigators may also wish to develop study specific SOPs, if appropriate. Copies should be kept in the Investigator Site File. Investigators should ensure that they use the most current SOPs or file note why this is not the case. A full list of STH Research Department SOPs can be found on the departmental website http://www.sheffieldclinicalresearch.org

7. Progress reports

A copy of all interim, annual or final reports sent to the Research Ethics Committee, Regulatory Authority or Sponsor must be sent to your Research Coordinator in the Research Department. This may include annual progress, end of study, expedited SUSAR or safety reports.

8. Archiving of Essential Documentation at the End of a Study

The STH lead investigator is responsible, according to the principles of GCP, for arranging for the archiving of their research data for all studies. The UK Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 cover the maintenance of a trial master file and the archiving of essential documentation. Investigators must adhere to these Regulations and ensure that facilities used to archive essential documents are compliant with the requirements of the Regulations. The Sponsor of a study will advise the investigator as to when documents may be destroyed.

9. Audit & Inspection

It is a requirement of STH Healthcare Governance that an investigator alerts their Research Coordinator within the Research Department as soon as they receive notification that an external body will be entering STH premises to carry out an audit or inspection of any aspect of their research.

10. The Use of Human Tissue Samples in Research

Investigators should familiarise themselves with the provisions of the Human Tissue Act 2004, a framework for regulating the storage and use of human organs and tissue from the living, and the removal, storage and use of tissue and organs from the deceased for specified purposes. All investigators intending to collect/use human tissue samples in the course of their study must advise the Research Department of this intention upon registering the study. Similarly, the intention to create and maintain a tissue bank must be registered with the Research Department as the storage of tissue for unspecified research purposes is licensable under the HT Act.