Principal Investigator Responsibilities

It is the responsibility of the principal Investigator to ensure that the study is conducted in accordance with the *UK Policy Framework for Health and Social Care 2017*, ICH GCP (if applicable), the terms of the Health Research Authority approval and Leeds Teaching Hospitals NHS Trust policies and procedures including the requirements for research governance and clinical trials performance management listed below. If you are not able to comply with these requirements, the study may be suspended at this organisation.

Research Governance:

Comprehensive feasibility assessment must be undertaken and managerial approval within the Clinical Support Unit must be obtained before starting the study.

Healthcare staff should be suitably informed about the research their patients are taking part in and information specifically relevant to their care arising from the study should be communicated promptly.

Agreements must be in place with appropriate support departments.

Arrangements must be in place for the management of financial and other resources provided for the study, including intellectual property arising from the research.

All data and documentation associated with the study must be available for audit/monitoring by authorised Trust or external agencies.

All members of the research team, where applicable, have appropriate employment contracts or letters of access to carry out their work in the Trust.

Each member of the research team must be qualified by education, training and experience to discharge his/her role in the study. Students and new researchers must have adequate supervision, support and training.

The research must follow the protocol approved by the relevant research ethics committee. Any proposed amendments to or deviations from the protocol must be submitted for review (as necessary) by the Research Ethics Committee, the Research Sponsor, regulatory authority and any other appropriate body. Where the amendment has resource implications within the CSU, the CSU research lead/clinical director/general manager and R&I should be notified.

Adverse Events in clinical trials of investigational medicinal products must be reported in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004.

Procedures should be in place to ensure collection of high quality, accurate data and the integrity and confidentiality of data during processing and storage in line with Trust Information Governance Policies and arrangements must be made for the appropriate archiving of data when the research has finished.

In compliance with the Health Research Authority (HRA) regulations, clinical trials (and other studies falling within the HRA definition) must be registered on a publically accessible database (such as https://clinicaltrials.gov/) prior to commencement.

Findings from the study should be exposed to critical review through accepted scientific and professional channels.

All members of the research team involved in seeking informed consent must adhere to GCP standards. Investigators are directed to the R&I website for further information about GCP training for clinical trials.

Studies involving the use of human tissue must be performed in compliance with the code of practice of the Human Tissue Authority.

The Research Delivery Standard Operation Procedures (SOPs) should be followed where applicable. http://lthweb.leedsth.nhs.uk/sites/research-and-innovation/research-and-development-homepage/resources

Research Performance:

Approval for this project to be carried out in the Trust is granted on the understanding that you:

Enter all participants recruited to your research study to our local performance management system, EDGE. Guidance on how to do this can be found here.

Work with R&I to resolve blocks and delays on trials to ensure that LTHT meets the NIHR metrics regarding our performance in initiation and delivery of research.

NIHR metrics for Performance in Initiating & Delivering Clinical Research

The National Institute for Health Research requires providers of NHS services in receipt of NIHR funding to measure and publish their performance in initiating and delivering clinical research.
LTHT clinical trial performance is measured against these 2 national metrics to improve the initiation and delivery of clinical trials approved by the Trust.

Initiation – Performance in the initiation of research (for clinical trials) is measured using the NIHR minimum data set. This data set includes the date that the Sponsor sends the local information pack to R&I/Research team (known as "Date Site Selected") and the date that the first participant is recruited (known as "First Participant Recruited Date") together with other dates that occur across the study lifecycle, at both a site and study level. Further information on this can be found here.

Delivery – for all commercial clinical trials hosted by the Trust the agreed number of patients must be recruited within the agreed recruitment period.

The Trust submits quarterly performance reports to the Department of Health setting out our performance.

New requirement
Please note: If your study will involve the testing or use of an **interventional procedure which is new to LTHT** you must obtain the approval of the New Interventional Procedures Group (NIPG). Details and application form are available from Jason Dunne, secretary to NIPG, telephone 0113 - 206 6951 or email jason.dunne@nhs.net
If your study will involve an interventional procedure which is new to you as an individual (but not to LTHT) you must ensure you have agreement from your clinical director, clinical lead and general manager