Responsibilities of Investigators Conducting Research

The Chief Investigator (CI): An individual who is responsible for the conduct of the whole project in the UK. The named CI should be a researcher who is professionally based in the UK, as they will be:

- Able to supervise the research effectively
- Have sufficient time to support all necessary research activities
- Readily available to communicate with the Research Ethics Committee (REC) and other review bodies during the application process and where necessary during the conduct of the research.

The Principle Investigator (PI): An individual responsible for the conduct of the research at a research site. There should be one PI for each research site. In the case of a single-site study, the chief investigator and the PI will normally be the same person.

On occasions it may be necessary to have two (2) nominated PIs at NuTH. In such cases permission should be requested from the R&D team prior to agreement with external sponsors. Two nominated PIs should only be considered for studies involving both paediatric and adult patients (or cross-over trials) if clinical pathways are vastly different and require specialist interventions.

HRA: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/

A CI working on a Clinical Trial of Investigational Medicinal Product (CTIMP), Advanced Therapy Investigational Medicinal Products (ATIMPS) or a Clinical Investigation of a medical device must be registered with the General Medical Council (GMC) and fully licensed to practise.

More information is available in ICH GCP E6(R2) section 4 “investigator”:

http://www.ich.org/products/guidelines/efficacy/efficacy-single/article/integrated-addendum-good-clinical-practice.html

Both CIs and PIs must:

- Ensure qualifications of study team
- Ensure appropriate delegation
- Provide sufficient and documented oversight of trial activities
- Ensure adequate resources
- Provide medical care for trial subjects
- Maintain communication with Sponsor and regulatory authorities

- Ensure protocol compliance
- Ensure safety of Investigational products where applicable
- Ensure safety reporting activities are conducted within legal timeframes
- Ensure randomisation, unblinding and pharmacovigilance
- Ensure informed consent is correctly conducted and recorded
- Ensure records and reports are accurate and correct
- Ensure applicable progress reports are submitted
- Ensure final reports and publications are completed within applicable timeframes

Investigator Responsibilities

Investigator Responsibilities when Conducting Research in the Trust
The Investigator is responsible for the daily management of their research at their site. They must provide adequate oversight and leadership for a study and all related activities. Investigator oversight must be documented, for example within meeting minutes and medical records.
It is the Investigator's responsibly to ensure Trust-wide Policies and Standard Operating Procedures (SOPs) and/or study-specific SOPs are followed.
The Investigator must ensure that the necessary approvals for their research are in place prior to the research commencing including but not limited to: • A favourable opinion from a Research Ethics Committee • NHS Capacity and Capability from Trust Research & Development (R&D) (NJRO) • Approvals from relevant regulatory bodies (e.g. MHRA, NIGB, ARSAC)
For Clinical Trials of Investigational Medicinal Products (CTIMPs) and trials of Advanced Therapy Medical Products (ATMP) the Investigator must ensure that the study is performed in accordance with: • The Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 1031) & Amendment Regulations 2006 (SI 1928)) • The principles of GCP based on Article 2 to 5 of the GCP Directive[1].
For Investigations of Medical Devices the Investigator must ensure that the study is performed to all applicable legislation.
The Investigator must ensure all essential documents are maintained for their research in the form on an Investigator Site File (ISF)/ Project file.

[1] See statutory instrument 1928 http://www.opsi.gov.uk/si/si2006/uksi_20061928_en.pdf and statutory instrument 1031 http://www.uk-legislation.hmso.gov.uk/si/si2004/20041031.htm

The Investigator must ensure research is conducted in accordance with the approved protocol (unless an Urgent Safety Measure (USM) is required) and that appropriate systems are in place to guarantee version control of documentation e.g. Protocol/abstract, to ensure researchers are working to the correct and most recent version. Waivers to a protocol are not permitted in any circumstance.
The Investigator must ensure that each member of their research team is qualified by education, training and experience for their role in the study. Investigators must ensure that delegated duties are appropriate and a delegation log is maintained and up-to-date.
Research conducted in the Trust (with the exception of those studies involving staff only), the research team should be trained in the principles of GCP. This training must be updated at least **every 3 years** but should be pragmatic to the study. The Trust agrees to follow the MHRA/HRA joint statement for GCP training. https://www.hra.nhs.uk/about-us/news-updates/updated-guidance-good-clinical-practice-gcp-training/ CVs must be updated every three years in-line with GCP or after significant changes, such as a change in job title.
The Investigator must ensure that, as applicable, arrangements (including staff training and competence) are in place for obtaining informed consent from research participants before research activity is undertaken. Investigators are expected to complete the online bitesize consent training within the learning zone “Research Consent”
The Investigator must ensure that amendments to the protocol or other study documentation are submitted to Trust R&D for review to confirm that there are no changes to Confirmation and Capacity status of the research. Amendments must also be submitted to the REC and Regulatory Authorities for approval as applicable. Researchers working under a Biobanks REC approval should inform the Biobank Managers of these changes. Support departments should be contacted for their acknowledgement of amendments when applicable.
The Investigator must protect the integrity and confidentiality of research data. The Investigator must abide by all appropriate legislation in relation to patient data, including, but not limited to: • Data Protection Act 2018 • Mental Capacity Act 2005

The Investigator must ensure all the necessary employment contracts, honorary research contracts or other access arrangements are in place for all research staff before the study commences.
The Investigator must ensure that an appropriate CI/PI is named on the study at all time. In cases where an Investigator will be absence from employment (sick leave/maternity) or leaves their position and interim or new CI/PI must be nominated and approved by R&D.
The Investigator must ensure that all employment contracts remain active throughout the study. Where an employee is working under the research passport scheme, continuous access must be maintained and renewal applications should be received by R&D three (3) months in advance of expiry.
Where clinical duties are undertaken by an Investigator and/or delegated to others within the research team, the Investigator must ensure that all Trust mandatory clinical training is undertaken and a record is maintained within the site file.
The Investigator must ensure that all clinical staff have the applicable registrations and licences to practice for the duration of the study, including any revalidation requirements.
The Investigator must ensure that students and inexperienced researchers involved in the study have adequate supervision. Supervision should be documented.
The Investigator must ensure where appropriate that relevant healthcare professionals (e.g. GPs) are informed of their patients' participation in research.
The Investigator must take responsibility for the monitoring, recording and reporting of Adverse Events (AEs) Serious Adverse Events (SAEs) and Suspected Unexpected Serious Adverse (Drug) Reactions (SUSARs) which occur during the conduct of a CTIMP or an ATMP. For SUSARs there is a requirement for expedited reporting of the event within 7 days if the event was fatal or life-threatening and 15 days if the event is non-fatal or non-life threatening. It is the Sponsor's responsibility to report SUSARs to the Regulatory Authorities and therefore it is the Investigators responsibility to inform the Sponsor immediately (within 24 hours) of becoming aware of a SUSAR. Applicable timelines should be followed for Investigations of Medical Devices when reporting Adverse Device Effect (ADE) and (unanticipated) Serious Device Effects (u)SADEs
Investigators must provide access to all study documents, devices and equipment as required for monitoring, auditing and inspection purposes.
Investigators should discuss with their employing organisation any arrangements that need to be put in place to ensure effective exploitation of intellectual property (IP).

Investigators must ensure appropriate archiving of their investigator site file/project file at the end of a study.
Investigators must notify Trust R&D, REC and Regulatory Authorities as appropriate of changing timelines on a study and of the end of a study.

Responsibilities of All Staff where the Trust is a PIC (Participant Identification Centre) for a Study A PIC is a site(s) that is not involved in direct research activity and whose only involvement is to provide requested data to another site/sponsor who will invite, consent and execute the research specific activity. The research Sponsor will be responsible for the care of the patient that falls within the remit of the research project; however the PIC site remains responsible for the patient's routine care. In such cases the Trust expects:
The local contact for the research must ensure that the additional work involved in patient identification is costed correctly and will not infringe on clinical duties.
The local contact for the research will obtain Capacity and Capability from the R&D Department, and ensure that local Caldicott approval is in place.
The local contact for the research must maintain an ISF with the relevant authorisations, protocols and patient information. This documentation will be provided by the sponsor.
The local contact for the research must ensure that they have knowledge of the sponsor's expectations and standard operations procedure for the study and agree to the terms and conditions.
The local contact for the research must ensure that all members of staff whom are to be expected to work on this study are fully trained to the sponsor's specifications, and also work to local policy and guidance.

Responsibilities of Trust Staff Acting as a Local Contact for a Study Trust staff may be approached to act as a local contact for an external researcher wishing to conduct research within the Trust. The local contact is expected to:
Ensure the external researcher has the appropriate contract in place (e.g. Letter of Access or Honorary Research Contract) to gain access to the Trust.
Ensure that all guest staff has the appropriate mandatory training (In particular for clinical duties) and this is documented.
Act as a supervisor and ensure the external researcher is aware of and trained in relevant internal procedures and guidelines.
Be available to the external researchers as they conduct their research in the Trust
Ensure that the correct local authorisations are in place for the study and that Capacity and Capability has been granted for the study to commence.

Responsibilities of All Staff collecting tissue within the Trust
Staff may be approached to act as a local centre for an external/internal Biobank wishing to collect samples within the Trust.
Ensure that the correct local authorisations are in place for the study and that no objection has been granted for the study to commence.
Researchers must ensure that any additional work involved in patient identification, patient consent and sample collection is costed correctly and will not infringe on clinical duties
Researchers must ensure that all members of staff whom are to be expected to work on this study are fully trained to the sponsor's specifications, and also work to local policy and guidance.
Researchers must ensure that each member of their research team is qualified by education, training and experience for their role in the study.
Researchers must ensure that anyone collecting tissue for their studies/projects within the Trust is using the most up to date, REC approved consent & PIS.
Researchers must ensure that they are suitably trained in Trust process and clinical procedures before collecting tissue directly from patients.

Investigator Responsibilities when running a Biobank within the Trust
The local contact is expected to:
Ensure that the correct local authorisations are in place for the study and that NHS "No Objection" has been granted for the Biobank to commence.
An access committee is formed of people with the appropriate experience and that any applications for prospective collections are referred to R&D to obtain its own individual NHS Management permission.
The local contact for the research must ensure that any additional work involved in patient identification, patient consent and sample collection is costed correctly and will not infringe on clinical duties
The local contact for the research must ensure that all members of staff whom are to be expected to work on this study are fully trained to the sponsor's specifications, and also work to local policy and guidance, including mandatory clinical training.
The Investigator must ensure that each member of their research team is qualified by education, training and experience for their role in the study.

PI where the Trust is a PIC (Participant Identification Centre) for a Study A Participant Identification Centre (PIC) is a site(s) that is not involved in direct research activity and whose only involvement is to provide requested data to another site/sponsor who will invite, consent and execute the research specific activity. The research Sponsor will be responsible for the care of the patient that falls within the remit of the research project; however the PIC site remains responsible for the patient's routine care. In such cases the Newcastle upon Tyne Hospitals NHS Foundation Trust expects:
The local contact for the research must ensure that the additional work involved in patient identification is costed correctly and will not infringe on clinical duties.
The local contact for the research will obtain NHS Permission from the Research & Development Department, and ensure that local Caldicott approval is in place.
The local contact for the research must maintain an Investigator Site File with the relevant authorisations, protocols and patient information. This documentation will be provided by the sponsor.
The local contact for the research must ensure that they have knowledge of the sponsor's expectations and standard operating procedure for the study and agree to the terms and conditions.
The local contact for the research must ensure that all members of staff whom are to be expected to work on this study are fully trained to the sponsor's specifications, and also work to local policy and guidance.

Responsibilities of Trust Staff Acting as a Local Contact for a Study Trust staff may be approached to act as a local contact for an external researcher wishing to conduct research within the Trust. The local contact is expected to:
Ensure the external researcher has the appropriate contract in place (e.g. Letter of Access or Honorary Research Contract) to gain access to the Trust.
Act as a supervisor and ensure the external researcher is aware of and trained in relevant internal procedures and guidelines.
Be available to the external researchers as they conduct their research in the Trust
Ensure that the correct local authorisations are in place for the study and that NHS Permission has been granted for the study to commence.

Responsibilities of All Staff collecting tissue within the Trust Staff may be approached to act as a local centre for an external/internal Biobank wishing to collect samples within the Trust.
Ensure that the correct local authorisations are in place for the study and that no objection has been granted for the study to commence.
Researchers must ensure that any additional work involved in patient identification, patient consent and sample collection is costed correctly and will not infringe on clinical duties
Researchers must ensure that all members of staff who are to be expected to work on this study are fully trained to the sponsor's specifications, and also work to local policy and guidance.
Researchers must ensure that each member of their research team is qualified by education, training and experience for their role in the study.
Researchers must ensure that anyone collecting tissue for their studies/projects within the Trust is using the most up to date, REC approved consent & PIS.

Investigator Responsibilities when running a Biobank within the Trust The local contact is expected to:
Ensure that the correct local authorisations are in place for the study and that NHS "No Objection" has been granted for the Biobank to commence.
An access committee is formed of people with the appropriate experience and that any applications for prospective collections are referred to R&D to obtain its own individual NHS Management permission.
The local contact for the research must ensure that any additional work involved in patient identification, patient consent and sample collection is costed correctly and will not infringe on clinical duties
The local contact for the research must ensure that all members of staff whom are to be expected to work on this study are fully trained to the sponsor's specifications, and also work to local policy and guidance.
The Investigator must ensure that each member of their research team is qualified by education, training and experience for their role in the study.