Research Staff Training

Division: *Strategy & Transformation*

Specific staff groups to whom this policy directly applies	Likely frequency of use	Other staff who may need to be familiar with policy
Staff employed by North Bristol Trust who directly or indirectly work on Clinical Research within the Trust	Role dependant	Staff not employed by North Bristol NHS Trust who are working on Research studies sponsored or hosted by NBT

Main Author(s):	Angelo Micciche – Research Infrastructure Manager
Consultation:	Research & Development Senior Team
Approval Authority (Committee/ Group/ Lead Clinician):	Research and Development Senior Team
Executive Lead (Trust-Wide only):	Tim Whittlestone
Date of Approval:	30th July 2025
Next Review Due:	30th July 2028
Version:	RD/QMS/SOP/005.Version 3.1
KEYWORDS:	Research, Training, Hosted, Sponsored, CTIMPs
Summary of changes since the previous version	Update to Department reference from R&I to R&D Change from Managed Learning Environment (MLE to LEARN Updated network reference to RRDN Updated wording taken from UK policy framework for health & social care research. Clarified location of storage of research relevant training certificates Further Clarity on PI / CI responsibilities for delegated tasks. Clarity on new RRDN Research Competencies and supportive online packages accessible through LEARN

1. Purpose	The purpose of this SOP is to set out the requirements for the qualifications, training and competency of staff involved in research studies at NBT. NBT owes a duty of care to its patients, service users and their carers and relatives, irrespective of the sponsor. This requires NBT to ensure that the rights, safety, dignity and wellbeing of research participants are always safeguarded. The UK Policy Framework for Health and Social Care Research states (Ref section 9.2 d) that: Chief Investigators should satisfy themselves (For multi-site projects, this may be delegated to the principal investigator at each research site) that everyone involved in the conduct of the research is qualified by education, training (Training should be appropriate and proportionate to the type of research undertaken, and should cover the responsibilities of researchers set out in relevant legislation and standards – HRA Researcher Suitability and Training page) that everyone involved in the conduct of the research is qualified by education, training and experience, or otherwise competent, to discharge their roles in the project; In the case of CTIMPs, the UK Clinical Trials Regulations (SI 2004/1031, as amended) stipulate that: "*Each individual involved in conducting a trial shall be qualified by education, training and experience to perform his tasks*" (Schedule 1, Part 2, 2). It is the responsibility of the Chief Investigator (CI) or Principal Investigator (PI), as appropriate, to define the roles and ensure that those managed by them are suitable for carrying out their allocated responsibilities as recorded in the Delegation of Responsibilities Log in the site file (see SOP on Applying for NBT Sponsorship (RI/QMS/SOP/007). The Health Research authority also states researchers should be appropriately trained and qualified for their activities for all studies. Staff in training may undertake tasks that are appropriately delegated to them, provided these tasks fall within the scope of their training and are carried out under supervision.
2. Key Messages	**ABBREVIATIONS / DEFINITIONS** CI = Chief Investigator CTIMP = Clinical Trial of an Investigational Medicinal Product

	CV = Curriculum Vitae EDGE Database = Clinical Research Management System used by NHS trusts to manage and monitor clinical research activities ICH GCP = International Conference on Harmonisation Guidelines for Good Clinical Practice LEARN = North Bristol Trust's Online Learning & Training Database LINK = North Bristol Trust's intranet MHRA = Medicines and Healthcare Products Regulatory Agency NBT = North Bristol NHS Trust NIHR CRN Portfolio = National Institute for Health Research Clinical Research Network Portfolio PI = Principal Investigator R&D = NBT Research & Development Office RRDN = Regional Research Delivery Network SOP = Standard Operating Procedure Sponsor = The individual, company, institution, or organisation which takes on ultimate responsibility for the initiation, management (or arranging the initiation and management) of and/or financing (or arranging the financing) for that research.
3. Relevant Policies & Guidance	• Health Research Authority *UK Policy Framework for Health and Social Care Research* www.hra.nhs.uk • The Medicines for Human Use (Clinical Trials Regulations 2004 https://www.legislation.gov.uk/uksi/2004/1031/contents • ICH Secretariat *Guidelines for Good Clinical Practice (E6 R2, Step 4, 2016)* www.ich.org
4. Operational Areas Included	All environments undertaking research.
5. Operational Areas Excluded	None

6. Who should read this	This SOP applies to anyone undertaking research (as defined by UK policy framework).
7. Roles responsible for carrying out this procedure	All staff involved in conducting research at North Bristol Trust.

8. Procedure

8.1 Research Staff Training Record

Staff working on research studies must ensure that they are familiar with relevant UK clinical trials regulations but not limited to The medicines for Human use (clinical Trials) Regulations 2004, ISO 14155, ICH- GCP. Additionally, they are responsible for maintaining their own training records to demonstrate that all members of the research team are "qualified by education, training and experience to perform his or her respective task(s)' (ICH GCP 2.8).

Training should be updated when legislation is changed, and when new policies or practice have been implemented.

All research staff should hold their own research training record (electronic), secondary paper records are permitted where this is required by the sponsor. This training record repository (electronic) should include a copy of their current CV updated to include their current post.

An electronic copy of the research team member's CV and latest ICH GCP certificate must be stored in the individual's record on the EDGE Database (www.edge.nhs.uk).
It is the responsibility of individual members of staff to maintain their own training record on an ongoing basis. This training record must be available for inspection by the Sponsor, the Trust regulatory authorities and other relevant authorities.

When a member of staff leaves their post, they may want to take their training record file with them. In such cases, a copy of the training record file must be made and archived with the site file, with the individuals date of leaving added to their CV. The Team leader or other delegated research team member is responsible for ensuring this process is completed. The copies should be kept with the essential documentation, as defined by the sponsor, and retained, in the event of an audit or inspection until they are no longer required in accordance with the study's documented destruction date or in line with the Trusts data storage policies, if stored electronically (e.g., on MS Teams)

8.2 Standard Operations Procedures (SOPs)

(a) NBT Staff

All NBT staff working on research studies sponsored or hosted by NBT are required to be fully aware and compliant with the Trust's research SOPs, policies and guidance issued by R&D.

These research SOPs should be accessed and read via the Trust's LEARN system (The Trust's Learning & Development electronic platform) which can be accessed through a web browser. The LEARN system provides both the staff member and the Trust with an electronic record of training. It also services as a repository of various e-learning courses and offers a facility to book face to face courses, where relevant.

By accessing each SOP via the LEARN platform, the individual is deemed to have read, understood, and agreed to conduct their research in accordance with the standards outlined in the SOP. The LEARN platform automatically records the name of the individual and the date the SOP was accessed, providing an auditable record
It is the responsibility of the individual to raise any concerns with their line manager or Research & Development where compliance with the relevant SOPs is not possible, or where additional support or training is needed

It is the responsibility of the individual's line manager or the person delegating the task to ensure that the individual is sufficiently competent, and appropriately trained in the relevant SOP, to carry out the task effectively.

(b) Non-NBT Staff

All non-NBT staff working on research studies sponsored or hosted by NBT are required to be fully aware of, and compliant with, the Trust's research SOPs issued by R&D. It is acknowledged, however, that staff as part of a trials unit or someone delivering a NBT-sponsored study on behalf of the trust, may also need to comply with additional SOPs relevant to their organisation or role.

These research SOPs should be accessed via the relevant Trust's Research team and this training should be documented in the site file.

By reading each SOP on the website, it is deemed that the individual has read, understood and will conduct their research in accordance with the standards detailed in the SOPs. It is the responsibility of the individual delegating the task to ensure that the individual conducting the task is suitably competent to carry it out.

8.3 Training in the International Conference on Harmonisation Guidelines for Good Clinical Practice (ICH-GCP, Including UK Statutory Instruments)

Staff can access ICH GCP (including UK statutory instruments) training through the following methods:

- If the individual is due to take part in a NIHR RRDN Portfolio-adopted project, they will be eligible to complete a free online course. Details of these courses are available online via the NIHR website (https://www.nihr.ac.uk/health-and-care-professionals/training/good-clinical-practice.htm)
- Face-to-face training sessions arranged by the Research & Development department or external providers. These sessions take place based on demand and are free to attend.
- Training courses provided by trial sponsors or collaborative research organisations, where applicable.
- Self-directed reading etc. (for non-CTIMPs).

(a) Requirements for CTIMPs and MHRA Registered Device Trials

The Medicines for Human Use (Clinical Trial) Regulations 2004 apply to CTIMPs and make it a statutory requirement to observe the principles set out in ICH GCP (Including UK Statutory Instruments)

While ICH-GCP (including UK Statutory instruments) may not be a requirement for all studies as it is considered best practice there is a presumption that all staff and investigators would complete ICH-GCP training (including UK Statutory Instruments).

It is NBT policy that all CIs, PIs and other research personnel who have a direct bearing on patient care involved in the conduct of MHRA registered device trials & CTIMPs; that are sponsored by or hosted by NBT must complete an ICH GCP (including UK statutory instruments) training course every three years, unless there is a need to repeat sooner due to competence or change in regulation. CI's & PI's must also adhere to The Medicines for Human Use (Clinical Trials) Regulations 2004

In the case of a CTIMP, where any elements of the study are not compliant with ICH-GCP, there is an expectation that these exceptions must be explicitly approved by both the MHRA and HRA.

A copy of the ICH GCP certificate must be provided to R&D by uploading it to the individual's EDGE account. If an EDGE account is not available, the certificate should be uploaded to their LEARN account. Staff who are working on a research study, and do not have access to EDGE or the LEARN platform are responsible for maintaining their own records of training certificates and must provide them on request by R & D or other regulatory authorities.

For CIs and PIs involved in CTIMPs or MHRA-registered device studies, it is strongly recommended that they provide evidence of training in PI responsibilities. This may include completion of the NIHR PI Essentials course, prior participation in the Associate PI Scheme, or demonstrable and substantial experience in conducting CTIMP or device studies

A copy of this training certificate should be uploaded on to the individual's EDGE account or LEARN Account, if an EDGE account is not available. Staff who do not have access to either system must maintain their own records and provide a copy on request.

Staff involved in the conduct of CTIMPs or MHRA-registered device trials who do not have a direct role in patient care at NBT must still be appropriately trained and competent in the activities they undertake. The level and type of training should be appropriate and proportionate to their specific responsibilities within the trial.

(b) Requirement for other types of Research Studies

For CIs and PIs involved in other types of research i.e. not CTIMPs, it is not a legal requirement to conduct the research in accordance with the conditions and principles of ICH GCP (Inc. UK Statutory instruments). However, such research should be conducted in a manner that provides public assurance that the rights, safety, and well-being of research participants are protected, and that the research data is reliable.

NBT requires that all research delivery is maintained at the same high standards as those applied to CTIMPs hosted and sponsored at NBT. It is therefore recommended that all PIs and CIs (of non CTIMPs) attend ICH GCP (Including UK Statutory Instruments) and training in CI / PI responsibilities, where available, to ensure competence in this area.
Members of the research team in non-CTIMPs are expected to be qualified by education, training, or experience.

8.4 Other Training

Depending on the nature of the research, staff may be required to complete additional training courses for example venepuncture, dry ice training, informed consent, or other study-specific procedures etc.

The CI/PI, in collaboration with the Sponsor, is encouraged to arrange project-specific training, where such training needs are identified. These should be recorded on the staff member's training record stored within EDGE.

Staff, delegated activities by the CI/NBT-PI for NBT sponsored CTIMPs will be required to demonstrate and provide evidence of their competence in line with their delegated duties.
Individual's must proactively identify any tasks for which they are not competent and line managers or those delegating tasks are equally responsible for ensuring that staff are appropriately trained and a competent to undertake those tasks.

Staff delegated to receive informed consent must complete competency training and assessment. This requirement will form part of the site initiation visit and included in the CI/NBT-PI responsibilities training, where available. Training completion should be documented in the staff members training record within EDGE or LEARN, if no EDGE account is available. Where access to these systems is not possible, individual's must maintain their own training records and provide a copy on request by Sponsor, NBT or other regulatory authority.

Please refer to NBT website (www.nbt.nhs.uk/research), Microsoft Teams Research Department Team and / or LEARN (available through the NBT LINK) for any courses that may be available.

8.5 Delegation Log

It is the PI's responsibility to ensure that the study delegation log is reviewed and updated regularly. This task can be delegated as appropriate.

While the task is delegated, the responsibility is not. The PI should review the delegation log periodically, with a frequency proportionate to changes in staff, study amendments, or updated to delegated responsibilities.

8.6 Research Competencies

R&D use a set of core competency documents known as 'Research Competencies' for researchers to review and complete. These competencies, developed and maintained by the RRDN, provide a supportive framework for developing, maintaining and recording appropriate levels of practice. It is expected all new and existing staff will use these competencies as part of their professional development.

R&D support the progression of R&D staff through the RRDN Research Competency Framework and other related development tools. R & D have prepared supportive online resources to assist with the RRDN competencies, which are accessible via the LEARN platform.
The Framework will be reviewed periodically, and feedback will be provided to the RRDN, as the owners of the competencies, to inform future updates.

9. Dissemination and Training

SOPs will be distributed in accordance with the SOP on Preparation of R&D Research SOPs (RD/QMS/SOP/001).

This SOP and any associated templates and forms will be uploaded to the LEARN system on the Trust LINK shortly after having been released. All staff should access SOPs through the LEARN system.

All staff whose activities fall under the cope of this SOP are responsible for reading and understanding its content.

10. References (if applicable):

Health Research Authority – Research Suitability and training
https://www.hra.nhs.uk/planning-and-improving-research/best-practice/researcher-suitability-and-training/

Health Research authority – Updated guidance on Good Clinical Practice (GCP) Training
https://www.hra.nhs.uk/about-us/news-updates/updated-guidance-good-clinical-practice-gcp-training/Health Research Authority – Good Clinical Practice

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/good-clinical-practice/

The Medicines for Human Use (Clinical Trials Regulations 2004
https://www.legislation.gov.uk/uksi/2004/1031/contents