North Bristol NHS Trust

Standard Operating Procedure

Research Staff Training

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Document Version History

VERSION NUMBER	EFFECTIVE DATE	REASON FOR CHANGE
1.0	27-08-10	SOP renamed, updated in line with new template and recoded from ISOP-C02
2.0	08-02-16	Addition of research competencies and requirements for CI/ NBT-PI responsibilities training

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT CHECKING IT IS THE LATEST VERSION

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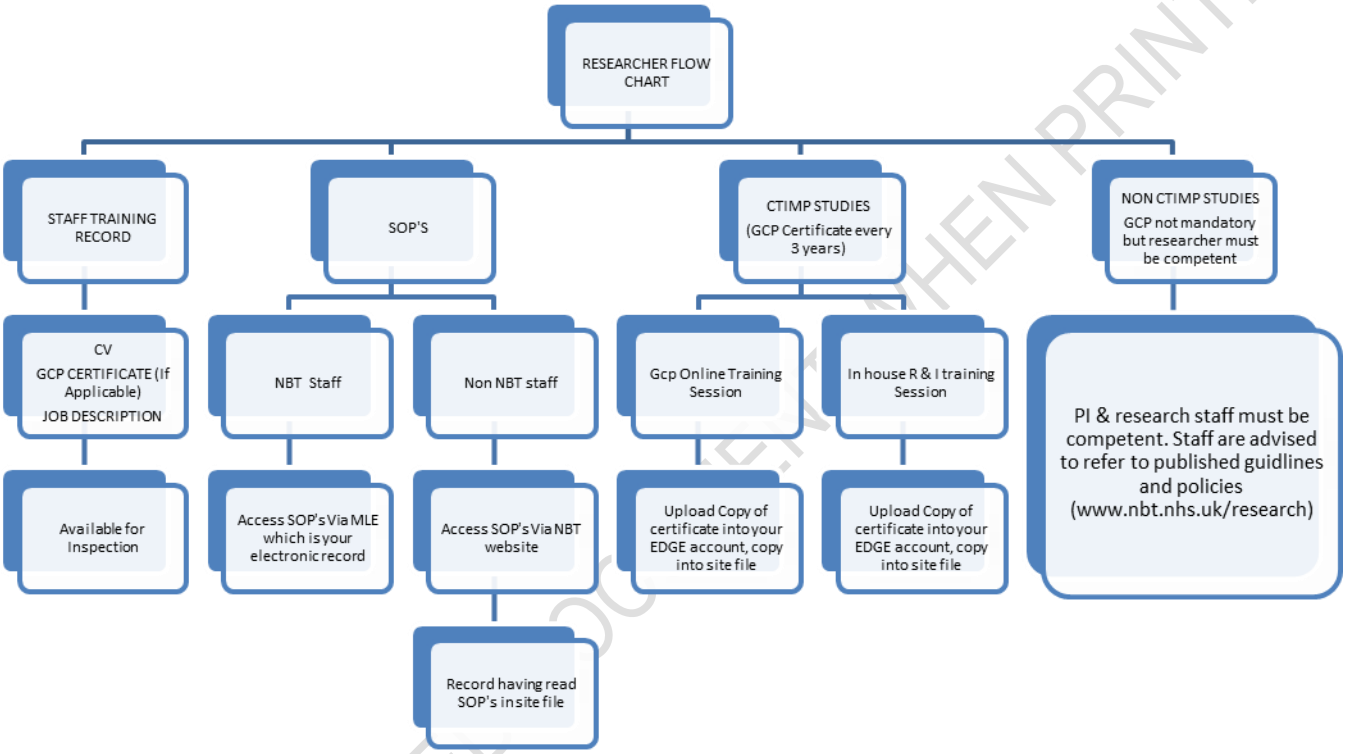
i. SOP Flowchart



1. PURPOSE AND SCOPE

The purpose of this SOP is to set out the requirements for the qualifications and training 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 identity of the sponsor. This requires NBT to ensure that the rights, safety, dignity and wellbeing of research participants are safeguarded at all times.

The UK Policy Framework for Health and Social Care Research states that:

> "The chief investigator is the overall lead researcher for a research project. In addition to their responsibilities if they are members of a research team, chief investigators are responsible for the overall conduct of a research project, including….satisfying themselves 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 this standard 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).

2. DEFINITIONS/ABBREVIATIONS

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
CV	Curriculum Vitae
EDGE Database	The research database used by NBT for managing set up and delivery of studies
ICH GCP	International Conference on Harmonisation Guidelines for Good Clinical Practice
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&I	NBT Research & Innovation Office
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. WHO SHOULD USE THIS SOP

This SOP applies to all investigators and research team members involved in research studies sponsored or hosted by NBT.

4. WHEN SHOULD THIS SOP BE USED

This SOP should be referred to during preparation of, and throughout the conduct of a research study sponsored or hosted by NBT.

5. PROCEDURE

5.1. Research Staff Training Record

Staff working on research studies must ensure that they are familiar with the requirements of ICH GCP and that they maintain their own training records to show 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 file including the items listed in **Appendix A** in addition to the statutory and mandatory training passports, details of which are available on the staff intranet. This training record should include a copy of their current CV updated to include the current post.

An electronic copy of the research team member's CV and latest ICH GCP certificate should also be stored in the individual's record in the EDGE Database (www.edge.nhs.uk) and site file.

It is the responsibility of individual members of staff to maintain their own training record file on an ongoing basis. This training record must be available for inspection by the Sponsor, regulatory authorities and other relevant authorities.
Where any member of staff leaves post, they will want to take their training record file with them. A copy of the training record file should be taken and archived by the CI with the date of leaving added to the CV. The copies should be kept until they are no longer required in the event of an audit or inspection.

5.2. Research Staff Training Record – 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 issued by R&I.

These research SOPs should be accessed and read via the Managed Learning Environment (MLE) system on the Trust intranet. The MLE system provides the staff member and the Trust with an electronic record of training.

By accessing each SOP on MLE, it is deemed that the individual has read, understood and will conduct their research in line with the standards detailed in the SOPs.

(b) Non-NBT Staff

All non-NBT staff working on research studies sponsored or hosted by NBT are required to be fully aware and compliant with the Trust's research SOP's issued by R&I.

These research SOPs should be accessed via the Trust website (www.nbt.nhs.uk/research) 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 line with the standards detailed in the SOPs.

5.3. **Training in the International Conference on Harmonisation Guidelines for Good Clinical Practice (ICH-GCP)**

The objectives for the ICH GCP (including UK statutory instruments) training course are set out in **Appendix B**. Staff members can access this training in the following ways:

- By contacting R&I to book a place on a forthcoming in-house training session. These sessions take place based on demand and are free to attend.
- If the individual is due to take part in a NIHR CRN Portfolio-adopted project, they will be eligible to complete a free online course. Details of these courses are available online via the NIHR website (www.nihr.ac.uk)
- Self-directed reading etc. (for non-CTIMPs).

(a) 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.

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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 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.

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 that are sponsored by or hosted by NBT must complete an ICH GCP training course every three years, unless there is a need to repeat sooner due to competence or change in regulation.

A copy of the ICH GCP certificate must be provided to R&I and a copy inserted in the relevant site file and uploaded on to the individual's EDGE account and included in the site file.

It is NBT policy that all CIs and PIs of CTIMPs or MHRA registered device trials are required to undertake CI/ NBT-PI responsibilities training, and this will be completed at Site initiation visits / meetings and offered as separate course[1]. This can be refreshed at any stage due to competence or change in regulation. A copy of this training certificate is to be uploaded on to the individual's EDGE account and included in the site file.

Other staff involved in the conduct of CTIMPs or MHRA registered device trials that do not have a direct bearing on patient care at NBT need to be appropriately trained and competent in their activities. This training should be appropriate and proportionate to the activities undertaken by the staff involved in the clinical trial.

(b) Other 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 CTIMPs hosted and sponsored at NBT. It is therefore recommended that all PIs and CIs attend ICH GCP and CI / PI responsibilities training to attain competence in this area.

Members of the research team in non-CTIMPs are expected to be qualified by education, training, or experience.

5.4. **Other Training**

Depending on the nature of the research, it may be necessary for staff to undertake other training courses, for example venepuncture, dry ice training, informed consent 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 and retained in the site file.

Staff, delegated activities by the CI/NBT-PI for NBT sponsored CTIMPs will be required to demonstrate and evidence their competence in line with their delegated duties.

Delegated staff receiving informed consent will be required to undertake competency training and assessment. This will form part of the site initiation visit and CI/NBT-PI responsibilities training, alongside being noted at monitoring visits.

[1] PI / CI training on responsibilities to be completed by the end of FY 18/19 as newly introduced

Please refer to NBT website (www.nbt.nhs.uk/research) and the managed learning environment (available through the NBT intranet) for any courses that may be available.

5.5 **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 to a Trial Manager as appropriate.

5.6 **Research Competencies**

R&I maintain a set of core competency documents for researchers to review and complete, known as "Research Competencies". These Research Competencies provide a supportive framework in which to develop and maintain appropriate levels of practice.

The Research Competencies will be updated in line with the research SOPs and SOP amendments.

The Research Competencies will be reviewed regularly (at least annually) by the individual and their line manager. They will also be reviewed when a member of staff is added to the delegation log.

6. DISSEMINATION AND TRAINING

SOPs will be distributed in accordance with the SOP on Preparation of Research SOPs (RI/QMS/SOP/001).

This SOP and any associated templates and forms will be uploaded to the Trust website (www.nbt.nhs.uk/research) and the Managed Learning Environment (MLE) system on the Trust intranet shortly after having been released.

All staff whose activities are subject to this SOP should ensure that they read and understand the content of this SOP.

The training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the content of this SOP.

7. RELATED SOPS AND DOCUMENTS

- Health Research Authority
  UK Policy Framework for Health and Social Care Research
  www.hra.nhs.uk

- ICH Secretariat
  Guidelines for Good Clinical Practice (E6 R2, Step 4, 2016)
  www.ich.org

- The following R&I documents are available on the NBT website: www.nbt.nhs.uk/research

RI/QMS/SOP/001	Preparation of Research SOPs
RI/QMS/SOP/007	Applying for NBT Sponsorship

Appendix A

Suggested Content of Staff Training Record

An individual's training record should contain the following information:

- Current job description and any previous job descriptions which are relevant to the current post. It is important to add the dates of these positions if they are not noted in the Curriculum Vitae (CV).
- Current CV which demonstrates education, training, qualifications and experience to date.
- Training record logs, both current and previous training record logs. These should list all training that the individual has undertaken which shows that they are able to undertake the responsibilities delegated to them in a study.
- Certificates of course attendance and agenda of courses and meetings. These may be photocopies or originals.
- Details of any relevant training conducted prior to appointment, which may not be listed in the current CV.
- Any other non research related training or qualifications attained in relation to your own personal development, can either be manually added to your MLE record (copy certificate, date attended and course title) or you may keep this in a separate file of your choice.

Appendix B

ICH GCP Training Course Objectives

The course objectives are as follows:

(a) Understand the key principles of ICH GCP enshrined in the Medicines for Human Use (Clinical Trials) Regulations 2004 and as amended, the fundamentals of the European Union Clinical Trials Directive 2001/20/EC and how these regulations should be implemented;

(b) Formulate strategies for incorporating the principles of GCP into systems at NBT in order to comply with the UK regulations;

(c) Understand the regulatory requirements for taking informed consent;

(d) Understand the regulatory requirements for safety recording and reporting of;

- Adverse Events (AEs),
- Adverse Reactions (ARs),
- Serious Adverse Events (SAEs),
- Adverse Reactions (SARs),
- Suspected Unexpected Serious Adverse Reactions (SUSARs),
- Urgent Safety Measures, and
- the dissemination of Medicines and Healthcare products Regulatory Agency (MHRA) notified Serious Breaches of GCP and/or the protocol;

(e) Outline the essential documents required for a CTIMP that should be held in the site file;

(f) Understand the principles of an MHRA systems inspection and recognise the requirements of a sponsor's monitoring/audit systems;

(g) Be aware of the best sources of further information and practical guidance for UK regulations;

(h) Keep up-to-date with any changes in UK legislation.