Great Western Hospitals NHS
NHS Foundation Trust

Standard Operating Procedure:

Training for Research active staff.

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BACKGROUND

All research conducted at the Great Western Hospitals NHS Foundation Trust ("the Trust") must be done so to the highest quality and standards possible to ensure patient safety and integrity of the trial.

To do this, all staff participating in research must be trained to the standard required by their role and level of involvement in each trial.

Training forms one component of a system for ensuring high quality research. Training should be commensurate with, and relevant to, the role that staff will play in research. This means that the training must be relevant to the type(s) of research being undertaken.

The Medicines for Human Use (Clinical Trials) Regulations 2004 states that no person shall conduct a clinical trial unless done so under the expectations of Good Clinical Practice (GCP). Therefore all

staff involved in a clinical trial will receive GCP training alongside mandatory Trust training and the training requirements of their professional registration.

PURPOSE

The Research Governance Framework sets out the responsibilities of employers:

"Employers of staff undertaking health and social care research have responsibility for developing and promoting a high quality research culture in their organisation and for ensuring that their staff are supported in, and held to account for, the professional conduct of research. This involves careful attention to training, career planning and development, and the use of clear codes of practice and systems for monitoring compliance, dealing with non-compliance or misconduct, and learning from errors and complaints. These responsibilities apply to both private and public sector employers."

The purpose of this SOP is to ensure that all staff involved in a trial are aware of the training requirements, that access to the training has been provided, and that completion of the training has been documented.

PROCEDURE

1. **WHO?**
   Any member of staff, honorary member of staff or external researcher should refer to this SOP to ensure they are up to date with appropriate training requirements for undertaking research within the Trust

2. **WHEN?**
   This SOP should be referred to in the set-up phase of all trials and should be regularly referred to during the course of trial delivery.

3. **HOW?**
   When a new member of staff joins a trial site team, a training needs assessment should be carried out. This is the responsibility of the Principle Investigator in conjunction with the Research & Innovation team.
   Training will then be provided before the staff member starts working on the trial. This training may delivered in various ways:
   - Trial specific investigator days provided by the Sponsor
   - Trial specific web/teleconference provided by the Sponsor
   - Trial specific e-learning packages provided by the Sponsor
   - Trial specific manuals and guidance documents
   - Research team training sessions facilitated by the PI of the trial
   - Working alongside peers
   - Access to NIHR national programmes via the NIHR website
   - Inter-organisational peer support groups
   - Trust research team meetings and inter-departmental meetings

4. **What?**
   Each individual involved in conducting a trial must be qualified by education, training and experience to undertake the trial tasks assigned to them.

   Below is a list of training to be considered by all staff involved with trials at the Trust. This is not an exhaustive list and must be looked at in conjunction with the Trust's mandatory training requirements and those of any professional bodies that the staff belong to.

4.1 GCP [Good Clinical Practice Training]

GCP training is a legal requirement for all Clinical Trials of Investigational Medicinal Products and is a requirement of the Research and Innovation department for all staff undertaking research within the Trust.

GCP Training can be tailored to the requirements of individuals and the role they will be fulfilling in a trial. Training can be face to face or on-line from accredited providers such as the NIHR [National Institute of Health Research].

Please check with Research & Innovation if you're unsure if a provider is accredited.

Staff must complete "Introduction to GCP" training before they start work on any trial. "GCP Refresher" sessions must then be completed every 3 years or sooner if there are any major changes to the legislation or a trial sponsor demands it.

Updates to any GCP related content will be delivered from the R and I team via a monthly newsletter which is disseminated throughout the Trust and to individual PI's.

Any Urgent Safety Measures will follow Sponsor directed Trial procedures i.e. Pi signing of an acknowledgment form.

See Appendix 2 for the MHRA statement regarding GCP training.

4.1.1 CTIMPs [Clinical Trials of Investigational Medicinal Products]

GCP training is a legal requirement for researchers recruiting to and conducting trial related activities for a CTIMP. Trust Permission will not be given for any CTIMP where the relevant Principal Investigator and Research Staff do not have the required GCP training.

Any pharmacy personnel working on CTIMPs, will undertake a level of GCP training dependent upon the amount of their involvement in managing the Investigational Medicinal Product. It will be expected that the Lead Pharmacists will gain pharmacy–specific training.

Existing training certificates will be acceptable if dated within the 3 years prior to the trial starting.

If the existing training accreditation will expire during the recruitment phase of the study, the affected person must update appropriate training within 3 months of the expiry date. Failure to update GCP training within 3 months of the renewal date may lead to the trial being suspended temporarily or closed locally.

4.1.2 Non-CTIMPs Interventional and Non-Interventional Trials and Studies that involve contact with service users

GCP training is a Trust requirement for researchers recruiting to and conducting trial related activities for any research involving patients.

4.1.3 Observational/Data/Tissue only studies

For research where patient consent is not required the Lead professional for any such study will have to complete GCP training. Other members of staff working on the study will be made aware of the principles of GCP either by attending a short department training session or by completing the Sponsor's abbreviated GCP training. This will be documented in the site file.

4.1.4 Staff-based Projects

The staff running staff-based projects (i.e. those only recruiting members of NHS Staff) will undertake GCP training.

4.2 Informed Consent Training

The delegation of Informed Consent to an appropriate, suitably qualified member of the research team should be considered on a trial-by-trial basis, taking into account trial requirements and local circumstances.

Staff must show evidence of NIHR training in receiving consent from vulnerable patient group(s) [Adults lacking capacity or children].

4.2.1 Medically Qualified Staff

The PI will assess if the co-investigators on the trial require any additional training including guidance on engaging in the informed consent process with potential trial participants and any protocol specific activities.

4.2.2 Non-Medically Qualified Staff

- Staff must adhere to their professional codes of conduct.
- Staff must complete GCP training as soon as possible after joining a research team.
- Engaging new team members in the informed consent process of Non CTIMPs will be done by shadowing a clinician or experienced research nurse/ trial co-ordinator.
- Non-medical staff may be delegated the duty of receiving informed consent from a participant of a CTIMP as appropriately designated according to their qualification and experience.
- Staff must be fully informed on the disease area being researched as well as being familiar with the verbal and written information being given to the potential trial participant for each specific trial they are intending to work on.

4.3 Trial Specific Training

Other training requirements will be dependent upon the individual trial and the training needs of the research team. These needs will be assessed at trial set up and reviewed during the life of the trial.

This not only covers the immediate research team, but also members of supporting departments within the Trust and collaborating staff in other Trusts.

4.4 Trust Mandatory Training and Maintenance of Professional Registration

All research staff will keep their mandatory Trust training and professional bodies training requirements up to date. Each member of the research team is responsible for arranging this training themselves.

4.5. Recording Training

In order to demonstrate that training has occurred, documentation must be maintained and retained for all staff involved in the conduct of clinical trials and where appropriate, for staff involved in supporting functions. These records must be maintained and then archived as trial supporting documentation for as long as they may be needed to support historical reconstruction of the trial.

The documentation required by a Sponsor and the Research and Innovation department for each staff group will depend on the research undertaken. It may include the following documentation for each member of the research team:

- A Curriculum Vitae (CV) to demonstrate current and previous relevant education and experience, hand signed and dated to confirm the date of the document and ownership by the named individual.
    - CVs are to be reviewed and updated every three years in order to demonstrate compliance with GCP requirements or in the intervening period if there are any significant changes/updates required. [Please Note, A recently signed and dated CV may be requested at the commencement of a study from all Key individuals working on the study in particular the PI, Sub I and Research Staff].
- Confirmation that GCP training has taken place in the form of a dated GCP Certificate which includes the details of the provider prior to any research activity being undertaken. [See section 4.1 for further information]
- Role specific training relevant to the post holder's duties and clinical trial role(s) and responsibilities and therapeutic area training.
- Trial specific training – all staff must receive an appropriate level of training to allow them to perform their trial duties. This includes providing training to staff that join the trials team after the trial has started.

Each member of staff is responsible for keeping a record of all training completed to evidence their own Professional Development / Validation.

Staff should also provide the trust Research & Innovation team with electronic or hard copies of any certificates so that they can be uploaded onto the Trust R&D training drive. This means that if a member of the research team leave before a trial is completed, their key documents evidencing they were undertaking appropriate trial roles will still be accessible.

5. APPENDICES

Appendix 1: HRA statement - Training requirements for researchers – progress update.

The HRA has issued the following statement about researcher training:
For research, 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. There is no set requirement for the frequency of such training. Researchers are expected to maintain awareness of current standards through reference to published guidance and relevant policies. Training should be updated when legislation has changed, new policies or practice have been implemented, different research activities are to be undertaken, or a significant period of time has elapsed since research activities have been conducted.
For research involving CTIMPs, there is a requirement for GCP training. However, the timing of this training is not specified in legislation or guidance but should be appropriate and proportionate. See the MHRA website for further details.

This statement is supported by:
Human Tissue Authority (HTA) Devolved Administrations
National Research Ethics Advisors' Panel (NREAP) National Institute for Health Research (NIHR)
Medicines and Healthcare products Regulatory Agency (MHRA)
NHS R&D Forum

The HRA urges the adoption of a more proportionate approach and consideration of appropriate training requirements.

The HRA is committed to implementing a unified approval process with proportionate standards for compliance and inspection, collaborating with others to improve the environment for research in the UK.

Appendix 2: What is the MHRA's position on Good Clinical Practice (GCP) training?

The UK Clinical Trials Regulations (SI 2004/1031, as amended) state that no person shall conduct a clinical trial otherwise than in accordance with the conditions and principles of GCP (Regulation 28) and 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 therefore follows that each person involved in a clinical trial of an investigational medicinal product (CTIMP) must receive training in GCP commensurate with their roles and responsibilities.

The frequency of GCP training is not defined in the regulations. However, it is recommended that training is given at appropriate intervals to ensure that staff maintain current awareness of the UK Regulations and applicable European guidelines. How often this training is repeated is a business decision for the organisation concerned. A fixed frequency such as every two years may not be appropriate. Systems should also be in place to allow for ad hoc training in between scheduled training events, for example in the event that there are significant regulatory updates, and this should be reflected in the organisation's procedures.

Training needs may range from a detailed knowledge of GCP principles and associated UK Regulations and European guidance to an awareness of particular GCP principles, and training can be tailored accordingly. If an activity is part of a person's normal clinical role and all other protocol activities are undertaken by a member of the research team, then no GCP training may be required; however this should be reviewed as part of the risk assessment for a trial. The MHRA strongly recommends training in relevant aspects of GCP for anyone involved in conducting CTIMPs, even if the activities are part of an individual's routine job (for example, tailored training in aspects such as documenting activities in source notes and recording adverse events). It is recommended that assessments of the scope or level of GCP training required by particular individuals or roles are documented.

GCP training can be provided in a range of formats, including face-to-face, web-based and as self-directed reading. The organisation should assess the suitability of the training method prior to implementation.

On inspection, MHRA GCP inspectors will look for evidence that individuals involved in the conduct of CTIMPs have received adequate training in GCP and appropriate legislative requirements commensurate with their roles and responsibilities. This is not limited to checking for the presence of a training certificate but is likely to involve discussions regarding individuals' roles and responsibilities in the conduct of CTIMPS, the scope and format of the associated training and the rationale for the frequency of training. Inspectors will also review compliance with the organisation's policies or procedures on GCP training and organisations involved in the conduct of CTIMPs are recommended to review their policies and procedures in light of this statement.

Appendix 3 – Example training log