NHS
Gloucestershire Hospitals
NHS Foundation Trust

Trial Delivery 02 - Training

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

All staff should regularly check the Research & Development Webpage for information relating to the implementation of new or revised versions. Staff must ensure that they are adequately trained in the new procedure and must make sure that all copies of superseded version are promptly withdrawn from use unless notified otherwise by the SOP Controller.

The definitive version of all Gloucestershire Hospitals NHS Foundation Trust SOPs appear online. If you are reading this in printed form, check that the version number and date below is the most recent one as shown on the R&D website:

http://www.gloshospitals.nhs.uk/en/About-Us/Research--Development/

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Author:	Janet Forkes	signature
Reviewed by Associate Director of R&D	Julie Hapeshi 27/03/2018	signature
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The Gloucestershire Hospitals NHS Foundation Trust wishes to acknowledge York Hospitals NHS Foundation Trust and University Hospitals Bristol NHS Foundation Trust who gave permission to use their templates in the development of these SOPs.

Version History Log

This area will be updated with details of all changes made to the SOP whether due for full review or not.

Version	Details of Change	Date Implemented
1.0	Original SOP	23/03/2015
2.0	Review and update on NIHR training	03/02/2017
3.0	Rebranding to GHNHSFT and updating of contacts details	31/03/2018

This SOP will be reviewed every two years unless changes to any relevant legislation require otherwise

Contents

1. Introduction, Background and Purpose

All research hosted and sponsored by the Trust must be conducted to the highest quality and standards possible. To do this all staff must be trained in all aspects of research relevant and commensurate with their role and level of involvement within a trial.

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. Therefore all staff will receive GCP training alongside their Trust and specific professional training to maintain their professional registration.

2. Who should use this SOP?

Any member of staff, honorary member of staff or external researcher under a Letter of Access should refer to this SOP to ensure they are up to date with appropriate training and education requirements for undertaking research.

3. When should this SOP be used?

This SOP should be referred to in the trial set-up phase and should be regularly referred to during the course of any trial delivery to ensure all staff are aware of all training required and that it is provided and documented.

4. Access to Training

When new members of staff start or a new trial is taken on, training needs assessments will be made by the senior managers in the various research teams.

Training will then be provided prior to staff starting work on a trial. The form of training may be by:

- Trial specific investigator days provided by the Sponsor
- Trial specific webex/ teleconference provided by the Sponsor
- Trial specific e-learning packages provided by the Sponsor
- Trial specific manuals and guidance documents(how to complete CRF; how to conduct RECIST [Response Evaluation Criteria in Solid Tumours] and so on)
- Research team training sessions facilitated by the PI of the trial
- Working alongside peers
- Access NIHR national programmes via the NIHR LEARN system
- Inter-organisational peer support groups
- Trust research team meetings and inter-departmental meetings

5. What training is required to take part in Research?

Each individual involved in conducting a trial must be qualified by education, training and experience to undertake trial tasks. Listed below is training to be considered, this is not an exhaustive list and must be looked at in conjunction with Trust mandatory training requirements and any professional bodies staff belong to.

5.1 Good Clinical Practice Training

GCP is a legal requirement for all CTIMPs and a Trust requirement for all research undertaken in the Trust. Training received can be tailored to the roles and responsibilities being undertaken by the individual (See Appendix 4). Training can be face to face or on-line from accredited providers such as the NIHR, please check with the Trust research managers if your GCP training is from another provider. Staff will need to complete an 'Introduction to GCP' before they can start work on any trial if they have not already done so. A 'GCP refresher' session must be completed every 3 years or sooner if there are any major changes to the legislation.

The NIHR Delegation and Training Decision Aid should be referred to and research leads in supporting departments within the Trust run GCP Awareness sessions where full NIHR GCP training is not required by the Sponsor.

5.1.1 CTIMPs

GCP training is a legal requirement for researchers recruiting to and conducting trial related activities for a CTIMP.

Trust Approval will not be given for any CTIMP where the relevant CI/PI and Research Staff do not have the required GCP training. Any pharmacy personnel working on CTIMPs, will undertake a level of GCP training depending upon the level of their involvement in managing IMPs. It will be expected that the Lead Pharmacists will gain pharmacy–specific GCP training. (See RGQMS overview Training Matrix and Pharmacy Department's Research SOP)

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

If the existing training 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.

5.1.2 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.

5.1.3 Observational/Data/Tissue only studies

Researchers should refer to the HRA Approval letter for guidance on GCP requirements along with contacting the GRSS office.

5.1.4 Staff-based Projects

For staff running staff-based projects (i.e. those only recruiting members of NHS Staff not patients) GCP training is not required.

5.2 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 account of local circumstances.

Staff working with vulnerable patient group(s) must show evidence of NIHR Informed Consent training.

5.2.1 Medically Qualified Staff

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

5.2.2 Non-Medically Qualified Staff

- Staff must adhere to their professional codes of conduct.
- Staff must attend an NIHR Informed Consent Training Session as soon as possible after joining a research team
- Staff must be fully informed on the disease area being researched as well as being fully informed and familiar with the verbal and written information being given to the potential trial participant for each specific trial they are intending to work on.
- Engaging in the consenting process will be in a staged approach as follows:
    - i) The new member of staff will buddy up with a clinician or experienced research nurse/ trial co-ordinator and with the patient's agreement sit in on trials talks and then shadow/ work alongside the experienced member of the team whilst they complete the process of entering a patient into a trial.

ii) Again buddying up, the new research member of staff will take on a given part of the trial talk to take the potential participant through with the final receiving of consent being done by the experienced member of staff.

iii) When, in the opinion of the experienced member of staff and /or PI the new member of staff is competent and confident in a given trial then they will take on the lead of taking a potential trial participant through a trials talk with the final receiving of consent being done by the experienced member of staff.

iv) The new member of research staff must complete 3 observed trial talks competently before they can be signed off to undertake the whole consenting process independently.

- To mirror the 3 yearly update in GCP research staff involved in the consenting process will undertake 3 yearly Informed Consent Workshops or individual review arranged by the Trust and/or line manager.
- All research staff receiving informed consent will undertake trial specific training for each trial they are delegated to work on.

(See Appendix 3 and 4 for copies of The Competency check list/ sign off sheets)

5.3 Trial Specific Training

Other training requirements will be dependent upon the trial in question and the training needs of the research team will be assessed at trial set up and reviewed during the life of the trial. This covers not only the immediate research team, but the wider health care team in supporting departments within the Trust and collaborating staff in other Trusts.

5.4 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.

6.0 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 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 for each staff group will depend on the research undertaken. It may include the following documentation for each member of the research team:

- A current job description dated and signed by the post holder and their line manager to demonstrate the date on which current roles and responsibilities have been agreed. This will be in the member of staff's personnel file.
- A Curriculum Vitae (CV) to demonstrate current and previous relevant education and experience signed and dated to confirm the date of the document and ownership by the named individual.
- Confirmation that GCP training has taken place in the form of a dated GCP Certificate which includes the details of the provider.
- Role specific training relevant to the post holder's duties and clinical trial role(s) and responsibilities and therapeutic area training.
- Trust SOP training records – see RGQMS training matrix for job specific requirements
- Trial specific training – all staff must receive an appropriate level of training to allow them to perform their trial–related 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. They should also provide the trust Research Governance team electronic or hard copies of any certificates so that the certificates can be uploaded onto the Trust R&D training drive (see Appendix 2 for further details). This means that should 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.

For new staff there are role specific competency workbooks to be worked through dependent upon the staff group and job banding. These are based upon the RCN competencies and will be supervised by the staff member's line manager (.

7 Related SOPs and documents

R&D SOP TD 01 Research Documentation and File Management

www.hra.nhs.uk/resources/research...governance/research-governance-frameworks

Appendix 1 – Research-Related Training Log

Trainee Name	Training Course	Date	Related Studies	Expiry Date	Certificate Received
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Appendix 2 – Trust electronic training certificate depository

(waiting back from IT)

Appendix 3 Informed consent training record

NAME:.....

Trial..... Date.....

Supervised by..... .....
Name Job Title

Informed Consent Measures met?* YES/NO

Improvements to be made.....

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Trial..... Date.....

Supervised by..... .....
Name Job Title

Suggested improvements incorporated YES/NO

Informed Consent Measures met?* YES/NO

Further improvements to be made.....

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Trial..... Date.....

Supervised by..... .....
Name Job Title

Suggested improvements incorporated YES/NO

Informed Consent Measures met?* YES/NO

Further improvements to be made.....

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Measures:

It is assumed that the trainee will perform both the 'Informing the patient about the trial' and 'Taking informed consent' for each of the three assessments on the previous page and that, as a minimum, the following measures should be met.

Description of randomisation

Voluntary nature of consent

All questions raised by the patient answered

Explanation of the study equipoise

Comprehensive understanding (by the trainee) of the study, including trial history, study question/aim, potential toxicities, side effects and trial procedures.

Evidence of the patient understanding the study, including potential toxicities, side effects and trial procedures.

A working knowledge of the Trust Informed Consent SOP and adherence to this SOP during the Informed Consent Process.

Only to be completed after a minimum of three supervised Informed Consents (see previous page) and after the supervisee has attended an ICH GCP training course.

Attended ICH GCP course: .....
Date

Supervisor/Trainer: To the best of my knowledge.....
Insert name

can perform Informed Consents to a high standard, understands the principles of Informed Consent and may be allowed to perform Informed Consents without further supervision.

Signed..... Date.....

Supervisee: I understand that I may perform Informed Consents unsupervised, but will only do so when I feel confident and competent to do so.

Appendix 4

Informed consent competency sheet

Competency	Date	Assessor Signature	Staff Signature
Mental capacity in research			
Demonstrate understanding of mental capacity act and its impact			
Demonstrate ability to define when a person lacks capacity			
Demonstrate ability to assess for mental capacity			
Demonstrate awareness of when and how to gain assent			
Principles of gaining consent/ assent for participation in research			
Demonstrate an awareness of the Declaration of Helsinki and Good Clinical Practice in relation to gaining consent and assent			
Can define valid informed consent and assent and explain the difference			
Undertaking consent/ assent			
Demonstrate an awareness of the ideal physical environment within which to take informed consent/ assent			
Demonstrates detailed understanding and can explain Types of observational and interventional studies			
Demonstrates detailed understanding and can explain The need for inclusion and exclusion criteria			
Demonstrates detailed understanding and can explain Randomisation, equipoise and blinding			
Documentation			
Demonstrates an understanding of the documentation required to underpin a Capacity assessment			
Demonstrates an ability to accurately assess and record eligibility for the study or record why a patient is ineligible within the research and medical documentation			
Can explain why it is important to accurately record the participant's understanding of a study			
Demonstrates an ability to complete a consent / assent form with a participant in accordance with GCP			
Demonstrates an understanding and compliance with the recording and retaining of consent/ assent documentation in accordance with the protocol.			
Reflection			
Able to demonstrate reflective practice with regard to gaining informed consent / assent - Verbally to manager (recorded on IC training sheet) - Written reflection for portfolio			

Appendix 5 Delegation and training decision aid

Delegation and Training Decision Aid

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Individual learning and competence ↓ / Study activity →	Leading delivery of a study at a site *Usually only Principal Investigator*	Leading the delivery of a function or activity	Delivering with freedom to act	Delivering without freedom to act *Limited to working under Standard Operating Procedures and Instructions*	Identifying potential participants *Limited to working under Standard Operating Procedures and Instructions*	Research aware *Not actively delivering the study*
Profession / Role	Professional or role-specific experience requirements					
Research	Full GCP training as a minimum*, may require more for leading functions or activities			Fundamentals training** focused on delivery of standards in limited duties		Awareness raising***
Site policies and processes	Site-wide or departmental SOPs, may also be writing these		Site-wide or departmental SOPs			
Study specific knowledge / instructions	Study procedures, writing study specific instructions		Study procedures and instructions	Study specific instructions		
	Sign delegation of duties log with oversight and agreement of PI			Sign Authorised Persons record with oversight of someone delegated this duty		

Download this document at: https://sites.google.com/a/nihr.ac.uk/dandtta/

* Descriptions of our GCP courses are available at http://www.nihr.ac.uk/our-faculty/clinical-research-staff/learning-and-development/national-directory/good-clinical-practice/

** Our Fundamentals training resources are designed for people working under SOPs without freedom to act, find out more at: https://sites.google.com/a/nihr.ac.uk/dandtta/

*** Awareness raising could be achieved through a short verbal explanation, leaflet, poster or other appropriate method, including but not limited to training.