Research Staff Training

Research & Development

Standard Operating Procedure for Research Staff Training at West Hertfordshire Hospitals NHS Trust Including Good Clinical Practice, SOP, Staff Induction Training and Maintenance of the Training File

SOP Number: SOP-07-06	**Effective Date:** October 2021
Version Number: v06	**Review Date:** 2 - 3 years

1.0 BACKGROUND

This document sets out the procedures to be followed by all West Hertfordshire Hospitals Trust (WHHT) staff who are involved in research.

It provides guidance on the steps involved in recording, maintenance and storage of the training records of research staff to ensure compliance with the Trust's policies.

2.0 PURPOSE

- To ensure all WHHT staff participating in clinical research are appropriately qualified and trained to meet research governance, regulatory and Trust requirements and are able to produce evidence of such training
- To ensure new research staff members are appropriately inducted and are able to produce evidence of such training
- To outline the responsibilities of all research staff in the maintenance of their own individual training files
- To outline the requirements for all research staff to attend Good Clinical Practice (GCP) training provided by the WHHT R&D Department

3.0 APPLICABLE TO

Any Trust employee involved with clinical research including, but not limited to, Unit Heads, Chief Investigators (CI), Principal Investigators (PI), Co-Investigators, Consultants, Clinicians, Clinical Trial Pharmacists, Research Managers, Statisticians, Research Nurses, Allied Health Professionals, Trial Coordinators, Data Managers and members of the Research & Development Department.

4.0 RESPONSIBILITIES

4.1 Responsibilities of the Trust

WHHT are responsible for providing appropriate individual learning and competence for all research staff. Staff must ensure they have completed all mandatory training required by the employer(s) in order to fulfil this responsibility and must adhere to relevant policies and procedures.

4.2 Responsibilities of the Sponsor

The Sponsor shall ensure appropriate management and documentation of research (clinical trials) to meet ethical and regulatory requirements. The Sponsor should ensure that:

- Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s) (ICH GCP)

- Employers of staff undertaking health and social care research have a responsibility for developing and promoting a quality research culture in their organisations and for ensuring that their staff are supported in, and held to account for, the professional conduct of research. This will involve 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

4.3 Responsibilities of the Chief Investigator/ Principal Investigator

The Sponsor is responsible for ensuring all staff members participating in clinical research are appropriately qualified and trained.

If WHHT is the Sponsor, this duty has been delegated to the CI/PI responsible for the trial.

The CI/PI is responsible for ensuring all research staff working on their research study have received appropriate protocol specific training and are competent to perform the roles delegated to them.

In addition CI/ PI's are responsible for ensuring all staff members participating in each clinical trial have attended GCP training within the last 2-3 years (as described in section 5). The CI/PI must ensure that research staff without GCP training are not involved in obtaining consent for clinical trials related research activities in compliance with SOP-04, unless stated in individual studies that this is not required.

4.4 Responsibilities of Research Staff

All research staff members that are working on research projects must ensure that they have demonstrated their competency in the areas that their role requires. All research staff members are responsible for maintaining their own training files (Appendix 2 and 4) and provide evidence of such training when requested by the Trust, the Sponsor or the regulatory authorities.

5.0 PROCEDURE

5.1 Induction Research Training

It is the responsibility of each individual's line manager to implement formal training plans that have been tailored to the individual needs of the clinical trial personnel and their role. It is recommended the formal training plans cover key training requirements, that are reviewed regularly by the individual and their line manager, to ensure training needs are being met (Appendix 5).

5.2 GCP Training

Mandatory for: All employees/any other staff (or staff likely to provide cover) involved in performing trial-related procedures in Clinical Trial of an Investigational Medicinal Product (CTIMP) sponsored or hosted by WHHT. This also includes all staff in support departments within the Trust who are performing research specific investigations (outside of their usual role) for CTIMPs.

Recommended for: All employees/any other staff involved in performing trial-related procedures in **non-CTIMPs** sponsored or hosted by WHHT.

For certain studies, the requirement for staff to have completed GCP training may be removed where the following conditions apply:

- The study has been assessed by the RDSG as low risk and where there is no change to patient care
- The PI for the study agrees that this is appropriate and is willing to be contacted with any queries
- A departmental clinician with GCP training and listed on the study delegation log is able to provide oversight and guidance in the clinical area and take responsibility for these staff members
- Staff are substantive WHHT members of staff with all training relevant to this role
- Staff are aware of the study and clear written guidance is available on the process for them to follow

GCP training is available for all staff and we recommend that this is completed when possible.

5.3 Procedure

If a member of clinical staff can also be identified from the Trial Master File (TMF) or Investigator Site File, for example through a signature on an essential document, then that member of staff should have attended a GCP course or completed the online course in the last 2-3 years, and also be listed on the trial delegation log. (see SOP-06) A delegation log should be used for all trials and in the event a template is not provided by the Sponsor our WHHT generic template should be used (see SOP-08).

Accredited GCP training courses are available, please contact the R&D office.

Targeted GCP training courses (Clinical Trial Awareness Sessions) are also organised by the R&D Department on request.

Introduction to Good Clinical Practice (GCP) eLearning

For staff without formal GCP training, staff should enroll and work through the Introduction to Good Clinical Practice (GCP) eLearning modules, available online through the NIHR Learn.

Good Clinical Practice (GCP) Refresher eLearning

For staff who have attended GCP training within the last 2-3 years and require an update, they should complete the Refresher eLearing course.

Attached is a list of the topics covered in the online GCP training course (Appendix 3).

5.4 Research Staff

All research staff are required to update their GCP training every 2-3 years by completing the online GCP course.

Evidence of such training should be kept in each individual's training records (Appendix 4).

5.5 Audit of GCP training

Original copies of GCP certificates should be maintained securely in the individual's training file or centrally within units and a copy held in the TMF. If this is not practical, a file note should be written documenting the central location where all certificates are held. This applies to all certificates as they are updated. Out of date certificates should be kept and not destroyed. Access to individual training files may be requested by the R&D Department, the Trust, the Sponsor or the regulatory authorities as part of an audit or routine GCP inspection.

5.6 SOP Training (Training in written procedures)

Prior to roll out of new SOPs, the R&D Department will organise targeted SOP training sessions for all relevant research staff. Targeted training sessions may form part of research team meetings or will be organised as separate sessions. An attendance log will also be produced by the R&D Department after each delivered SOP training session.

In addition to the SOP training sessions, all staff must read and complete the SOP Signature Sheet (Appendix 7). This signature page will be used to confirm each staff member has read and understood the contents and requirements of SOPs. It will also confirm acceptance to follow the procedures outlined in the SOP once implemented. Dependent on the individual's role, SOPs must be read and acknowledged within 3 months of Trust start date (new starters) or SOP roll out date (current staff).

All original copies of the signed agreement signature page should be filed in the staff member's training file. It is recommended these are reviewed during yearly appraisals. It will be the responsibility of each staff member to maintain a record of this training; the R&D Department will not keep copies.

Prior to each yearly appraisal research staff will also be encouraged to review their competencies, first completed as part of their induction to the department. (Appendix 5). During the appraisal this document can be used to discuss/highlight any training needs required by the staff member. Should a staff member not feel competent in a particular area mandatory to their research role, additional training and support can be provided by the R&D Department or DI.

Once all SOPs are implemented, refresher training sessions will be delivered to research staff where required by the R&D Department on an ongoing basis.

The impact of new or updated SOPs on current studies will be documented by the SOP Working Group (SOPWG).

5.7 SOP/Policy non-compliance

Where a significant and/or persistent deviation from research SOPs/Policy is identified the Escalation Plan (Appendix 8) and, as necessary, the Trust competency/disciplinary process will be followed.

5.8 Trial specific training

The Sponsor is responsible for ensuring all staff members participating in clinical research are appropriately qualified and trained.

If WHHT are the Sponsor, this duty has been delegated to the CI/PI responsible for the trial.

The CI/PI is responsible for ensuring all research staff working on their research study have received appropriate protocol specific training and are competent to perform the roles delegated to them.

Trial specific training must be undertaken prior to commencement of any trial specific activities, or complex trial assessments.

All staff are required to receive an appropriate level of training to allow them to perform their trial related duties, taking into consideration training needs for staff who join a trial team after the trial has started.

All records of trial specific training must be maintained as trial supporting documents (either with the individual trial site or centrally) for as long as they may be needed to support historical reconstruction of the trial.

6.0 RELATED DOCUMENTS

- Standard Operating Procedures Working Group Terms of Reference
- Membership of Standard Operating Procedures Working Group
- SOP-01: Sop on SOPs
- SOP-02: SAEs (Sponsored)
- SOP-04: Informed Consent
- SOP-05: SAEs (Hosted)
- SOP-06: Trial Master File
- SOP-08: Role of CI, Pharmacy, Nuclear Medicine and R&D
- Local Trust policies on training
- Medical Devices Training Policy (Intranet)
- Trust local induction checklist (intranet)

7.0 APPENDIX

Appendix 1- Definitions
Appendix 2-Guidance note on staff training files
Appendix 3-Topics covered in full day GCP training
Appendix 4-Staff Training Log
Appendix 5-Induction Framework for Clinical Research Staff
Appendix 6-Training Attendance Log
Appendix 7- SOP Signature Sheet
Appendix 8- Escalation Plan

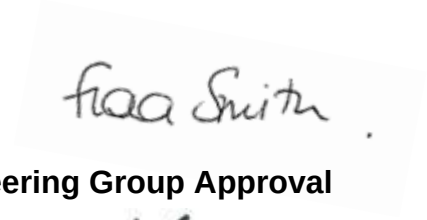
8.0 VERSION HISTORY

Revision Chronology:		
Version Number	**Effective Date**	**Reason for Change**
SOP-07-06	**Oct 2021**	Amendments following review including: 1. Change from general Standard Operating Procedures (gSOP) to SOP 2. Change from GCP training days to online training courses 3. Update to the circumstances where GCP if not required 4. Complete update of Appendix 5 including the name of the document from ‘Training Needs Analysis’ to ‘Induction Framework for Clinical Research Staff’

		5. Addition of a new appendix for 'SOP signature sheet' (Appendix 7) 6. Addition of a new appendix for 'Escalation Plan' (Appendix 8) 7. Other minor amendments including clarification of terms 8. Removal of the '10.0 Agreement' section -all agreement signatures will be collated on a new 'SOP Signature Sheet Document'
gSOP-07-05	**Oct 2017**	Minor amendments following minor amendments
gSOP-07-04	**01/10/2015**	Minor amendments following dissolution of consortium
gSOP-07-03	**07/05/2014**	Minor amendments following review
gSOP-07-02		SOP modified for implementation at WHHT
gSOP-07-01 (MVCC)		SOP written for implementation at MVCC

9.0 AUTHORSHIP & APPROVAL

Author

Signature  **Date** 28/10/2021

R & D Steering Group Approval

Signature  **Date** 28/10/2021

Appendix 1: Definitions

Chief Investigator (CI)
The investigator with overall responsibility for the research. In a multi-site study, the CI has co-ordinating responsibility for research at all sites. All applications for ethical review should be submitted by the CI.

Clinical Trial
A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the study protocol. Participants may receive diagnostic, therapeutic, or other types of interventions. A Study Type.

Good Clinical Practice (GCP)
Good Clinical Practice is a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects.

International Conference on Harmonisation (ICH)
International Conference for Harmonisation, a collaboration between regulators and the pharmaceutical industry in Europe, the United States and Japan to establish common standards for clinical trials. ICH GCP is a widely recognised standard for Good Clinical Practice in clinical trials.

Investigational Medicinal Products (IMP)
A pharmaceutical form of an active substance or placebo being tested, or to be tested, or used, or to be used, as a reference in a Clinical Trial, and includes a medicinal product which has a marketing authorisation but is, for the purposes of the trial - a) used or assembled (formulated or packaged) in a way different from the form of the product authorised under the authorisation, b) used for an indication not included in the summary of product characteristics under the authorisation for that product, or c) used to gain further information about the form of that product as authorised under the authorisation.

Mandatory
Training which must be completed by all employees and any other staff involved in clinical trials and is therefore compulsory.

Principal Investigator (PI)
The investigator responsible for the 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.

The Medicines & Healthcare products Regulatory Agency (MHRA)
The MHRA is the competent authority for the UK in relation to the Directive 2001/20/EC and the Clinical Trials Regulations, and for Medical Devices, the competent authority in relation to the Medical Devices Regulations 2002.

The Regulations
Medicines for Human Use (Clinical Trial) Regulations 2004 transposed the EU Clinical Trials Directive into UK legislation, as Statutory Instrument 2004 no 1031. This became effective on the 1st May 2004. An amendment to implement Directive 2005/28/EC was made to the Regulations as Statutory Instrument 2006 no 1928.

Appendix 2: Guidance note on staff training files

PURPOSE

In order to comply with the EU Directive, principles of GCP and WHHT Policy, staff participating in clinical research trials shall provide evidence of qualification and training. Each member of research staff should have a training file – either individually or held centrally within units.

It is recognised that Chief Investigators, Principal Investigators, Co-Investigators have access to appropriate clinical research training such as Good Clinical Practice. However, whilst appropriate training will be provided, these professional groups will be responsible for their own management of training needs and maintenance of training records and associated documentation.

All research staff must ensure that they are appropriately qualified and trained to carry out the tasks delegated to them. Staff are responsible for setting up and maintaining their own training files.

The CI/PI or delegated individual shall ensure:

- All research staff participating in research follows all applicable WHHT R&D SOPs and/or unit level guidance documents.
- Staff are appropriately trained and informed of current R&D SOPs and guidance documents.

Each individual's line manager shall ensure an assessment of individual need should be performed on appointment to establish a baseline framework of skills and competencies. Where possible this should run in parallel with local appraisal processes.

Within units, a central and/or individual training record shall be maintained for research staff. This should be referenced in the TMF/Site File.

- To ensure all training activities of research staff are documented in the form of a training log and reviewed regularly to ensure all training needs are up-to-date.
- To ensure a training file and/or related documentations are readily available for regulatory and/or other audit and monitoring activities.

Members of staff new to clinical research requiring guidance with setting up and maintaining a Trial Master File and/or guidance on Good Clinical Practice, other regulatory and ethics requirements can contact the R&D team for guidance/training.

The following items are suggested <u>minimum</u> contents for training files:

Curriculum Vitae (CV) – provide evidence of education, training, qualifications and experience to date. Some evidence of the level of experience in clinical trials should be indicated e.g. numbers, phases and therapy areas of trials and dates of GCP training should be listed. It is recommended that CVs should be updated regularly, preferably in line with the organisational appraisal system (yearly). In addition CVs should be personally signed and dated to confirm the date of the document and ownership by the named individual.

Confirmation that GCP training has taken place (including clear reference to the framework used in the training, such as UK Statutory Instruments and EU Directives).

Job Description – current job description and any previous job descriptions relevant to clinical research. This job description should be dated and signed by the post holder and their manager to demonstrate the date on which current roles and responsibilities were agreed.

Training Records Logs (Role specific training records) – current and previous training record logs detailing all internal and external training received whilst in post. They should list all training

undertaken which enables the individual to competently perform their job and the duties delegated to them in a clinical trial. As a minimum, the training record log should document the following: all GCP training, mandatory training and other training received through courses. A sample copy of the training record log to be used is found in Appendix 4.

Standard Operating Procedures (SOP) (Written procedures training records) – keep evidence of having read the SOPs. All staff participating in clinical research shall work to applicable WHHT policies and WHHT SOPs issued by the Standard Operating Procedures Working Group (SOPWG). It is mandatory to read, understand and work to all SOPs. Training sessions on SOPs will be provided by the Research & Development Office.

Publication Details – maintain details of all publications and abstracts.

Additionally for each trial an individual is involved with, there must be documentary evidence that they have received relevant trial-specific and where required therapeutic area training. These records must be maintained as trial supporting documents (either with the individual trial site or centrally) for as long as they may be needed to support historical reconstruction of the trial.

Appendix 3: Topics covered during GCP training

Topics covered in Introduction to Good Clinical Practice (GCP) eLearning

- ICH GCP Guideline (E6 Document)
- EU GCP Directives 2001/20 and 2005/28
- The Medicines for Human use (Clinical Trials) Regulations 2004 (SI 1031) and amendments (SI 1928, 2984 of 2006, SI 941 pf 2008, and SI 1164 of 2009)
- Ethics committees and governance
- Sponsor and Investigator activities
- Serious Breaches
- Investigational Medicinal Product
- Informed Consent
- Safety Reporting
- GCP Inspection and Quality Issues

Appendix 4: Staff Training Log

Name: **Training period:**

Job title:

Title of Course/ Study Day	Date(s) from/to	Organised by	Key objectives	Qualification/ certificate achieved

Appendix 5:

Induction Framework for Clinical Research Staff

Version 1.0 - December 2020

Table of Contents

Theme 1: Background to Clinical Research

Introduction

This is a competency framework for all research staff and includes anyone who contributes to the work undertaken by site-based clinical research teams. The purpose of this competency framework is to define the knowledge, skills and attributes of research staff in order to enable research staff to:

- Understand more clearly what is required from them
- Document their knowledge, skills, attributes and experience
- Identify learning needs and interests
- Provide evidence of achievement to promote fair and consistent assessment
- Demonstrate adherence to Good Clinical Practice (GCP)
- Recognise the contribution of every member of the research team
- Identify opportunities for personal development, training and career progression
- Can be used as evidence for nursing revalidation portfolio
- May form the basis for progression through NHS gateways (e.g. Agenda for Change).

What is competency?

A competency is the task or activity which is performed to enable inferences about competence to be made. As an individual's knowledge, skills and confidence in their role increase, they are able to demonstrate increasing independence and higher levels of performance.

How to use this framework?

The Framework consists of four themes within which specific research competencies are defined.

The Themes

1. Background to clinical research
2. Study set-up
3. Study conduct
4. Data management

The Levels

Each competency is presented with examples of the knowledge, skills and behaviours that will be required for competent performance, and examples of how competence may be demonstrated based on a detailed review of research roles and responsibilities. However, these are by no means exhaustive and should be used as a guide rather than a mandate.

The Framework is intended to be sufficiently flexible to be of relevance to all research posts, although not all themes will be applicable to all research posts.

Assessment

In order to assess, review and record competency, this booklet provides an assessment framework to enable the mentee and their mentor/line manager to review and record their current level of performance within each competency and set targets for progression.

Space is provided to record evidence of achievement alongside some, if not all of the following:

- Reflective accounts and discussions
- Testimonies from other colleagues, managers and peers
- Evidence of everyday performance
- Questioning/discussion whilst performing activities/during formal reviews
- Formal assessment
- Role play e.g. before discussing a trial with a patient, a mentee may wish to practice
- Preparing and/or presenting PowerPoint presentations to individuals or groups
- Collection and recording of study data
- Patient feedback

Evidence must be:

- **Valid and Relevant** - the evidence must relate directly and appropriately to the competency
- **Sufficient** - the evidence should not be a one off event but must demonstrate consistent achievement
- **Authentic** - the evidence must be the mentee's own work or demonstrate their significant role in collaborative work
- **Current** - the evidence must be current and should not be solely reliant on work undertaken in the past (but past experience may be cited where relevant)

The mentee should collate evidence on an ongoing basis and notify their mentor/line manager when they feel that they have sufficient evidence to demonstrate competence at the pre-agreed level (and within agreed time frames).

Assessment Schedule

Initial Action Plan Assessment 1 (within the first week) The purpose of the assessment is to identify the mentee's initial learning and development needs. The mentee will be introduced to the competency record which gives an indication of the skills and knowledge that they are expected to achieve in their new role.

Intermediate Learning and Development Assessment 2 (at 1 month) At this assessment, the mentee will review progress with their mentor in relation to the competency record. Areas of difficulty or concern will be identified and action plans agreed.

Intermediate Learning and Development Assessment 3 (at 3 months) At this stage, the mentee should be working with a degree of autonomy, be actively involved in research and should be working fairly independently.

Final Induction Assessment (at 6 months) This assessment involves an evaluation of their ability to work as a competent researcher. The mentee's mentor will review their experience as documented in the competency record and the mentee will also have an assessment of the knowledge that they will have gained.

Annual Progress review (Yearly in line with appraisal) This assessment involves an evaluation of their ability to work as a competent researcher and their current training needs.

Action Plans

Initial Action Plan (within first week)

Mentor's Signature: Date Mentee's

Signature: Date

Brief summary of progress and general comments (month 1)

Mentor's Signature: Date Mentee's

Signature: Date

Brief summary of progress and general comments (month 3)

Mentor's Signature: Date Mentee's

Signature: Date

Final summary (month 6)

Mentor's Signature: Date

Mentee's Signature: Date

Yearly review* (Year _____)

Mentor's Signature: Date

Mentee's Signature: Date

*Please print this page out separately to add subsequent years

Theme 1: Background to Clinical Research

Competency 1A: Guidance and Legislation

1A- Demonstrate an understanding of the background and scope of the regulatory frameworks governing clinical research

Knowledge

- Development of research ethics and governance related to clinical research
- Principles of:
    - Declaration of Helsinki
    - Nuremburg Code
    - International Conference of Harmonisation Good Clinical Practice (ICH GCP)
    - UK Policy Framework for Health and Social Care Research (replaced Research Governance Framework)
- Relevant UK legislation:
    - Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031) and Amendment Regulations 2006 (2006/1928)
    - Human Tissue Act
    - Mental Capacity Act
    - Role of MHRA in the regulation of CTIMP and medical devices research ○ Serious breaches in GCP; procedures when breaches of protocol are identified or when fraud/misconduct is suspected

Skills and Behaviours

- Attends and maintains GCP training as per Trust/Network policy
- Applies the principles of GCP to everyday tasks and practices
- Demonstrates an interest in the background of clinical research and identifies the relevance of the regulatory frameworks that govern its conduct

Examples of how competence may be demonstrated

Level 1

- Attends Introduction to GCP course (Certificate of Attendance)
- Discusses how the principles of GCP are implemented using everyday examples of their working practices
- Recognises their own limitations and attends/completes relevant training

Level 2

- Demonstrates a comprehensive understanding of the regulatory and legal frameworks related to the planning, delivery and closure of clinical research studies
- Recognises their own limitations and attends/completes relevant training

Level 3

- Provides comprehensive advice and guidance

- Ensures processes, policies and standard operating procedures are in place to support compliance with regulatory requirements

Competency 1B: Research in the NHS

1B- Demonstrate an awareness of the background, political influence and strategy regarding clinical research in the NHS

Knowledge

- Political and strategic developments in clinical research:
    - NIHR and Department of Health (NHS) Strategy
    - Role of NIHR Clinical Research Networks
    - Divisional structure
- Research in the local NHS trust(s): NIHR portfolio and non-NIHR portfolio research

Skills and Behaviours

- Aware of studies taking place in their own Team/Department/Network
- Aware of the Clinical Research Network in which they work and the Network's role in supporting research in their Trust/Organisation
- Understands the relevance of historical development of clinical research to current research and policy

Examples of how competence may be demonstrated

Level 1

- Aware that research is important to improve patient care
- Aware that research is embedded in the NHS
- Attends Introduction to GCP course (Certificate of Attendance)
- Demonstrates awareness of studies in their own team/department and wider specialty area/network

Level 2

- Aware of the Clinical Research Network in which they work and can explain the Network's role in supporting research in their Trust/Organisation
- Demonstrates an understanding of the historical and political context in which clinical research is being undertaken

Level 3

- championing the role of clinical research in the development of health and social care
- supporting and influencing the embedding of clinical research in local NHS infrastructure/practice

Competency 1C: Study Design

1C- Demonstrate an understanding of the design and development of different types of clinical research studies

Knowledge

- Clinical research process
- Common acronyms used in clinical research - Phases of clinical research – Preclinical, Phase I, II, III, IV
- Research study design including:
    - protocol design and development
    - sample size
    - inclusion and exclusion criteria
    - randomisation, blinding and unblinding
- CTIMP studies; pharmaceutical industry sponsored clinical trials, drug discovery process and licensing of medicines in the UK and beyond
- Multi-centre studies
- Qualitative and quantitative research
- Role and relevance of patient and public involvement in all stages of research process

Skills and Behaviours

- Identifies the research design and methodology used for trials/studies within the research team
- Seeks opportunities to understand the relevance of the design/methodology to their role and the wider research team

Examples of how competence may be demonstrated

Level 1

- Identifies the type and phase of a study which they support (e.g. CTIMP/non-CTIMP/ Phase I/II/III etc) and can explain how they know this and why it is relevant to know
- Discusses the design of a study that they support (e.g. ‘double- blind’, ‘randomised’, ‘placebo controlled’) and can explain what these terms mean
- Discusses different research designs and methodologies, explaining their relevance/implications for members of the research team

Level 2

- Has a comprehensive understanding of the research designs and methodologies used in clinical research

Level 3

- provides comprehensive advice and guidance for staff, researchers, patient and participants
- contributing to protocol design and review

Theme 2: Study Set-up Competency

Competency 2A: Study feasibility and Set-up

2A- Demonstrate an understanding of how studies and sites are assessed for feasibility and how they contribute to site set-up

Knowledge

- Feasibility process
- Costing and funding research
- Site preparation including site initiation visits
- Processes for participant recruitment
- Pathway planning
- Risk assessment and feasibility
- Indemnity, financial and contractual agreements

Skills and Behaviours

- Recognises the importance of planning prior to a study opening
- Identifies opportunities to observe and later contribute to feasibility assessments
- Identifies patients for pre-screening/database searches
- Attends MDT and/or clinical meetings and/or meetings with PIs/research staff
- Liaises with R&D/R&I department/support services to arrange set-up meetings (e.g. initiation visits)

Examples of how competence may be demonstrated

Level 1

- Obtains documents for study set-up
- Assists in the organisation and attends site initiation visits or meets with PIs/research staff to discuss study set-up
- Assists in the set-up of site files compliant with research governance and GCP requirements
- Observes feasibility
- Assists in the organisation of trial documentation for study set-up

Level 2

- Participates in feasibility assessments/meetings
- Identifies research activities in different cost categories

Level 3

- Undertakes risk and feasibility assessments
- Acts as a knowledgeable resource for staff and researchers involved in assessing feasibility and setting-up new studies
- liaising with sponsor representatives and responding to feedback regarding feasibility and/or set-up

Competency 2B: Study Set-up

2B-Identify and discuss the approvals required to conduct research in the NHS

Knowledge

- Role and responsibilities of the Health Research Authority (HRA), including Research Ethics Service (RES) and Research Ethics Committees (RECs).
- Role and responsibilities of R&D/R&I departments in assessing, arranging and confirming capacity and capability to deliver research projects
- NIHR CRN Study Support Service specific elements relating to study set-up
- Process of applying for an assessment of governance and legal compliance and independent ethical opinion (e.g. HRA, REC, R&D/R&I, MHRA/Confidentiality Advisory Group/Her Majesty's Prison and Probation Service)
- Key documentation required for HRA Approval
- National policies and procedures related to HRA approval including the assessment criteria and standards for UK study wide governance
- Regulatory requirements for protocol amendments (substantial and non-substantial) termination and/or closure of a trial
- Regulatory reporting procedures when breaches of protocol are identified or when fraud/misconduct is suspected

Skills and Behaviours

- Recognises the need to ensure that HRA approval, which may include appropriate and proportionate ethical opinion, is obtained before any research activities are undertaken in the NHS
- Understands/utilises systems to apply for HRA approval/REC favourable opinion and other regulatory approvals (e.g. IRAS)
- Assists with the acquisition/distribution/tracking of relevant trial documentation required for study set-up
- Recognises the importance of clear, complete and accurate applications to the HRA and is able to advise on this

Examples of how competence may be demonstrated

Level 1

- Identifies the regulatory approvals that have been obtained/or need to be obtained for studies which they currently support
- Explains the process for gaining approval to conduct clinical research
- Demonstrates familiarity with regulatory requirements of CTIMP and non-CTIMP studies and the processes by which these approvals are obtained
- Discusses the role and remit of the HRA in England

Level 2

- Advises on/actively contributes to the preparation of applications for HRA approval

Level 3

- Acts as a knowledgeable resource for staff and researchers making applications for regulatory approvals

- Contributing to the supervision and educational needs of staff involved in the preparation of regulatory applications

Theme 3: Study Conduct Competency

Competency 3A: Key Personnel

3A- Demonstrate an awareness of the roles and responsibilities of key personnel involved in clinical research

Knowledge

- Role and responsibilities of Sponsor and Chief Investigator (CI)
- Site staff and their responsibilities including Principal Investigator (PI), research delivery staff and research participants
- Delegation of duties and documentation of this process
- The role and remit of sponsor delegates: Contract Research Organisations (CRO); Clinical Trials Units (CTU)
- Trial Management, Trial Steering Groups, Data Monitoring and Safety Committees

Skills and Behaviours

- Contributes to the delivery of clinical research protocols as a member of the research team
- Identifies and consistently works within the scope of their own role and delegates duties
- Aware of the limitations of their own role and seeks help and support appropriately
- Maintains up-to-date delegation of duties log, records CVs and training
- Establishes and maintains effective working relationships with relevant individuals and organisations

Examples of how competence may be demonstrated

Level 1

- Articulates their own responsibilities and recognises the boundaries of their own role and when to refer to others
- Attends relevant training in relation to the requirements of the study protocol
- Able to differentiate between the roles and delegated duties of key personnel within the clinical research team

Level 2

- Consistently works within the scope of their own role and delegated duties
- Promotes team working
- Demonstrates a comprehensive understanding of the roles and responsibilities of key personnel within the clinical research environment

Level 3

- Ensures comprehensive induction is provided for all new staff
- contributes to the development and training of colleagues
- Proactively monitoring and dealing with issues appropriately

Competency 3B: Consent

3B-Demonstrate an understanding of valid informed consent in clinical research and acknowledge this as an ongoing process

Knowledge

- Principles of informed consent for participation in research – legal and governance requirements
- Information and key components of patient information sheets (PIS) and consent forms
- Preparation of PIS and informed consent forms for local use (version control, Trust 'headed paper' etc.)
- Study specific documentation – what signatures are required; copies – how many and to whom; documenting the process of informed consent
- Storage of the signed informed consent form
- Team roles and responsibilities in gaining and maintaining informed consent
- The need to reaffirm willingness to continue throughout the study

Skills and Behaviours

- Recognises the need to ensure that informed consent has been obtained and maintained; proactively seeks information to support this before undertaking study-related activities
- Prepares/tracks patient information sheets (PIS) and informed consent forms with attention to version control
- Assures patient safety by recognising and raising any concerns with the informed consent process
- Understands and administers capacity assessments as appropriate (formal and informal)
- Attends and maintains valid informed consent training as per Trust/Network policy

Examples of how competence may be demonstrated

Level 1

- Acknowledges the need for consent in clinical research
- Identifies evidence of the consent process in source data
- Provides a brief overview of the consent process for a specified study and can explain who can be involved and how informed consent is documented
- Can describe their role in the process of obtaining informed consent
- Proactively seeks documentation to confirm informed consent has been provided by the participant
- Identifies errors/cause for concern in documents

Level 2

- Clearly articulates their role and the roles of other team members in the informed consent process
- Reports any concerns with informed consent processes in a timely and appropriate manner
- Can identify immediate action which may need to be taken
- Applies capacity assessment process on each study contact

Level 3

- Acts as a knowledgeable resource and role model for staff and researchers regarding the contribution of research delivery staff to the informed consent process
- Recognised as a staff support for valid informed consent issues

Competency 3C: Protocol Specific

3C- Demonstrate an understanding of study-specific protocol requirements

Knowledge

- Protocol – main sections; extracting information
- Protocol – study specific requirements including eligibility criteria and schedule of events
- Randomisation process
- Screening and eligibility
- Safe handling of samples, including storage as per protocol (Human Tissues Act)
- Ordering couriers, packaging and shipment of samples (handling of dry ice if applicable) as per protocol
- Processes for participant recruitment – screening, randomisation and patient pathway Equipment and supplies including investigational medicinal product

Skills and Behaviours

- Understands the rationale behind adherence to ethically approved study protocols
- Verifies inclusion/exclusion criteria of subjects recruited into trials and ensures that all relevant baseline data has been recorded
- Randomises/registers patients to trials according to the protocol requirements
- Assists in ensuring protocol required tests/procedures are done according to the protocol schedule
- Liaises with support services to book tests/procedures
- Plans study visits/follow-up schedules
- Identifies protocol schedule of events
- Develops checklists/workbooks/flowcharts
- Arranges couriering of samples

Examples of how competence may be demonstrated

Level 1

- Demonstrates an awareness of the eligibility criteria of a protocol(s)
- Demonstrates effective use of protocols by referring to appropriate sections as required
- Aware of how to raise concerns and report instances of suspected protocol deviation

- Plans and implements a recruitment strategy to ensure recruitment adheres to time and target

Level 2

- Consistently adheres to the study protocol
- Contributes to the development of policies and standard operating procedures (SOPs) to support adherence to protocols
- Identifies and actions protocol deviation or violation

Level 3

- Provides comprehensive guidance and contributing to the training and development of colleagues
- Corrective action planning for any deviations or violation

Competency 3D: Managing Priorities

3D- Identify and prioritise tasks within studies

Knowledge

- Prioritising work
- Planning workload
- Time management
- Reviewing and reassessing priorities and workload
- Implications of tasks on study timelines and workload

Skills and Behaviours

- Identifies workload priorities
- Plans workload
- Identifies and alerts team members to expected delays or competing priorities
- Identifies skills required to complete a task successfully
- Undertakes appropriate delegation of study responsibilities

Examples of how competence may be demonstrated

Level 1

- Plans work and identifies priorities
- Anticipates workload (e.g. monthly/recurring tasks)
- Aware of need to have a recruitment strategy

Level 2

- Recognises changing demands and is able to respond efficiently
- Delegates appropriately

- Aware of need to have a recruitment strategy and why this should be amended

Level 3

- Provides comprehensive advice and guidance
- Delegates tasks appropriately and providing constructive feedback
- Proactively working with the research team; taking action when the recruitment strategy is not effective

Theme 4: Data Management Competency

Competency 4A: Data Protection

4A- Apply the principles of data protection and secure handling of data and demonstrates accurate data capture and case report form (CRF) completion

Knowledge

- Local and national policies and procedures relating to data collection, storing and secure transfer including:
  - Data Protection Act
  - Confidentiality NHS Code of Practice
  - Caldicott report and local Caldicott guardian
  - Freedom of Information
  - Human Rights Act
  - Information Governance
  - GDPR
- Maintaining confidentiality for patients in clinical trials
- Actions required when data protection processes are not adhered to

Skills and Behaviours

- Respects participant confidentiality
- Ensures participant confidentiality is maintained
- Takes responsibility for the safe and secure storage of data
- Raises concerns about poor data storage
- Accurate completion of CRFs (paper and electronic)
- Transcribes/exports data from medical records to CRF (paper and electronic)
- Liaises with research nurses and clinicians to ensure accurate and complete data collection
- Identifies and resolves missing data and/or discrepancies in data

Examples of how competence may be demonstrated

Level 1

- Understands and explains own role in maintaining confidentiality and protecting data
- Contributes to the safe and secure storage of data by returning documents to their storage location after use

- Identifies and describes measures taken to maintain confidentiality of data
- Evidence of accurate and complete data entry
- Raises concerns and seeks to address incomplete, inaccurate or misleading data entry
- Manages the collection and reporting
- Contributes to the collection and reporting of local recruitment data

Level 2

- Raises concerns when processes to ensure confidentiality are not adhered to
- Responds to concerns if inaccurate or incomplete data entry is identified
- Manages the collection and reporting of local recruitment data

Level 3

- Ensures processes and procedures for maintaining participant confidentiality are developed and adhered to by all members of the research team
- providing advice on different methods for transferring patient identifiable information
- Supervising and managing the accurate and complete collection and transcription of data
- Strategic planning to promote effective recruitment in line with time and target
- Ensuring that local policies and standard operating procedures (SOPs) are followed by all members of the research team

Competency 4B: Essential Documents

4B-Identify and appropriately utilise essential documents in the conduct of research studies

Knowledge

- Title, purpose and storage location of essential documents including:
  - Source documents
  - Protocol
  - Case Report Forms (CRFs)
  - Investigator Brochure
  - Regulatory approvals
  - Patient information literature
  - Screening logs
  - Participant ID logs
  - Contracts
  - Reports and Communications
- Version control and document tracking

Skills and Behaviours

- Establishes trial site files that are compliant with research governance and GCP requirements
- Maintains and updates essential documents in the site file
- Recognises the importance of accurate and comprehensive documentation and source data verification

Examples of how competence may be demonstrated

Level 1

- Identifies and discusses the purpose of key research documents (site files, CRFs, investigator brochure, source data)
- Raises concerns if incomplete, inaccurate or misleading documentation is identified Demonstrates the use of correct versions of documentation and implements document tracking according to local SOPs

Level 2

- Creates and maintains research files according to local SOPs
- Responds to concerns if inaccurate or incomplete documentation is identified

Level 3

- Acts as a knowledgeable resource for staff
- Meet the supervision and educational needs of research staff utilising essential documents
- Ensure processes, policies and SOPs are developed and reviewed to support compliance with regulatory requirements

Competency 4C: Data Quality

4C-Manage data queries and demonstrate an understanding of the role of monitoring, audit and inspection in the maintenance of data quality

Knowledge

- Monitoring visits and the role of monitor
- Audit and inspections
- Data queries
- Protocol deviation/violation

Skills and Behaviours

- Acknowledges the purpose of monitoring visits and responds to recommendations appropriately
- Organises and prepares visits by trial monitors (as per protocol)
- Checks and resolves data queries
- Conducts quality assurance of documentation and/or audit as necessary
- Recognises the importance of accurate and comprehensive documentation and source data verification

Examples of how competence may be demonstrated

Level 1

- Identifies errors and inconsistencies between case report forms (CRFs) and source data and seeks to resolve these

- Prepares documents and facilities for monitoring visits and works with the study monitor during visit
- Responds to data queries in a timely manner and seeks to resolve them
- Responds to audit/monitoring recommendations

Level 2

- Proactively manages errors/inconsistencies between CRFs and source data to avoid data queries
- patterns/trends in missing data to prevent recurrence
- Participates in the auditing and monitoring of research studies

Level 3

- Contributes to the auditing and monitoring of research studies and proposes recommendations
- Supervises and manages the accurate and complete collection/transcription of data
- Contributes to the development of and ensuring that local policies and standard operating procedures (SOPs) are followed by all members of the research team
- Proactively monitors the frequency and nature of data queries and seeks to reduce team data query rates

Competency 4D: Safety Reporting

4D-Demonstrate an understanding of the principles and process of Adverse Event reporting (AEs, SAEs and SUSARs)

Knowledge

- Definition of AE/SAE/SUSAR; timelines for reporting to sponsor and host
- Preparation of safety reports

Skills and Behaviours

- Recognises the importance of safety reporting in clinical research
- Prepares adverse event forms in liaison with clinical staff and recognises the importance of ensuring the process continues through to completion
- Works with the research team to ensure safety reporting timelines are adhered to
- Demonstrates effective communication with wider clinical teams

Examples of how competence may be demonstrated

Level 1

- Describes the difference between AEs, SAEs, and SUSARs citing examples from practice
- Consistently takes appropriate action (within scope of delegated duties) when an adverse event occurs or is discovered, including timely and appropriate referral

- Assists in the preparation of adverse event reports

Level 2

- Identifies and consistently takes appropriate action (within scope of delegated duties) when an adverse event occurs
- Prepares initial and follow-up adverse event reports in liaison with clinical staff
- Discusses the principle of un-blinding and explains local/study specific processes

Level 3

- Demonstrates a comprehensive understanding of safety reporting requirements in clinical trials
- Provides comprehensive advice and timely guidance
- Contributes to the supervision and educational needs of research staff involved in safety reporting

Competency 4E: Storage and Archiving

4E- Apply the principles of secure storage and retention of data/study documentation

Knowledge

- Filing systems
- Site Master File/Essential Documents
- Storage of trial Site File, Case Report Forms (CRFs) and Investigator Brochure
  Storage of completed informed consent forms
- Archiving of data following study closure
- Local Trust and Trial Archiving standard operating procedures (SOPs)
- Agreed contracts and costs of archiving

Skills and Behaviours

- Ensures secure filing and storage of study documentation in accordance with research governance requirements
- Recognises the importance of maintaining secure storage and retention of data

Examples of how competence may be demonstrated

Level 1

- Contributes to study closure and preparation of documents for archiving

Level 2

- Participates in archiving of studies liaising with the sponsor and R&D/R&I

Level 3

- Provides comprehensive advice and guidance

- Ensures processes and SOPs are in place and adhered to

Appendix 6: Training Attendance Log

Research Training Attendees List

Date:
Trainer:
Location:

Name	Department	Email Address	Ext.

Appendix 7: SOP Signature Sheet

Please complete and sign this document then retain within <u>your training files</u>

	Initial the boxes
I have read and understood the contents and requirements of the SOP for SOPs (SOP-01-08) and accept to follow Trust policies implementing it.	
I have read and understood the contents and requirements of the SOP for SAEs (Sponsored) (SOP-02-09) and accept to follow by Trust policies implementing it.	
I have read and understood the contents and requirements of the SOP for 'Informed Consent' (SOP-04-07) and accept to follow by Trust policies in implementing it.	
I have read and understood the contents and requirements of the SOP for 'SAEs (Hosted)' (SOP-05-09) and accept to follow by Trust policies implementing it.	
I have read and understood the contents and requirements of the SOP for 'TMF' (SOP-06-07) and accept to follow Trust policies implementing it.	
I have read and understood the contents and requirements of the SOP for 'Research Staff Training' (SOP-07-06) and accept to follow by Trust policies implementing it.	
I have read and understood the contents and requirements of the SOP for 'Role of CI, Pharmacy, Nuclear Medicine and R&D' (SOP-08-05) and accept to follow by Trust policies in implementing it.	
I have read and understood the contents and requirements of the SOP for 'Amendments' (SOP-09-8) and accept to follow by Trust policies implementing it.	
I have read and understood the contents and requirements of the SOP for 'Serious Breaches (Sponsored)' (SOP-10-05) and accept to follow by Trust policies implementing it.	
I have read and understood the contents and requirements of the SOP for 'Sponsor Oversight' (SOP-11-05) and accept to follow the trust policies implementing it.	
I have read and understood the contents and requirements of the SOP for 'Monitoring' (SOP-12-04) and accept to follow by Trust policies implementing it.	
I have read and understood the contents and requirements of the SOP for 'Research Applications' (SOP-13-05) and accept to follow by Trust policies implementing it.	
I have read and understood the contents and requirements of the SOP for 'Writing Research Protocols' (SOP-14-05) and accept to follow by Trust policies in implementing it.	
I have read and understood the contents and requirements of the SOP for 'CRF and Data Management (Sponsored)' (SOP-15-06) and accept to follow Trust policies implementing it.	
I have read and understood the contents and requirements of the SOP for 'DSURs' (SOP-16-07) and accept to follow by Trust policies implementing it.	
I have read and understood the contents and requirements of the SOP for 'Archiving Essential Documents' (SOP-17-05) and accept to follow by Trust policies in implementing it.	

I have read and understood the contents and requirements of the SOP for 'Initiation' (SOP-18-06) and accept to follow the Trust policies implementing it.	
I have read and understood the contents and requirements of the SOP for 'QMS' (SOP-19-06) and accept to follow by Trust policies implementing it.	
I have read and understood the contents and requirements of the SOP for 'Patient Information' (SOP-20-06) and accept to follow by Trust policies implementing it.	
I have read and understood the contents and requirements of the SOP for 'Trial Closure' (SOP-21-05) and accept to follow by Trust policies implementing it.	
I have read and understood the contents and requirements of the SOP for 'End of Trial Study Reports' (SOP-22-06) and accept to follow the Trust policies implementing it.	
I have read and understood the contents and requirements of the SOP for 'Source Data' (SOP-28-06) and accept to follow the Trust policies in implementing it.	
I have read and understood the contents and requirements of the SOP for 'Serious Breaches (Hosted)' (SOP-31-06) and accept to follow by Trust policies implementing it.	
I have read and understood the contents and requirements of the SOP for 'Vendor Assessment' (SOP-32-06) and accept to follow by Trust policies in implementing it.	
I have read and understood the contents and requirements of the SOP for 'Risk Assessment Process' (SOP-33-04) and accept to follow by Trust policies implementing it.	
I have read and understood the contents and requirements of the SOP for 'Statistics' (SOP-34-02) and accept to follow by Trust policies in implementing it.	
I have read and understood the contents and requirements of the SOP for 'Exiting Staff Procedure' (SOP-35-02) and accept to follow by Trust policies implementing it.	

I confirm that I have read and understood all of the above listed SOPs as indicated by my initials

Recipient

Signature: ……..……..……Date: ……..……..

Name & Position:
……..……..……

Appendix 8: Escalation plan

Serious Breaches of GCP and Critical Audit Findings in Clinical Research

Summary
This paper summarises the process for escalating findings of non-compliance relating to the governance of clinical research activity.

CONTENTS

Section

1. Identification of non-compliance in clinical research

Non-compliance in clinical research may be identified through one of 3 routes:
1. By the clinical research study team conducting the trial
2. Through monitoring or auditing conducted by the R&D Department
3. Through monitoring or auditing conducted by partners

2. Categories of non-compliance in clinical research

Serious breach: A breach in compliance with clinical trial protocol or GCP regulations which is likely to affect to a significant degree the safety of the trial participant or the scientific validity of the trial.

Critical Finding: Where evidence exists through audit that significant and unjustified departure(s) from applicable legislative requirements has occurred with evidence that
- the safety or well-being of trial subjects either has been or has significant potential to be jeopardised, and/or,
- the clinical trial data is unreliable and/or,
- there are a number of Major non-compliances across areas of responsibility, indicating a systematic quality assurance failure, and/or,
- where inappropriate, insufficient or untimely corrective action has taken place regarding previously reported Major non-compliances.

3 Reporting of non-compliance in clinical research

Reports of serious breaches and critical findings will be provided to:
- The R & D Steering Group
- The Risk and Quality Committee

All potential serious breaches of GCP in Trust sponsored studies are reported to the R&D Dept in accordance with the SOP on Notification of Serious Breaches of GCP

All confirmed serious breaches of GCP in hosted studies must be reported as required by the sponsor and in accordance with the SOP. It is the sponsor's responsibility to inform the PI.

In all cases, potentially serious breaches and critical audit findings are escalated to a governance review panel comprising of the following:
- Associate Medical Director [R & D]
- Director of R & D
- Senior Research Nurse

This panel may choose to consult further with the Medical Director

If any panel member is involved in the trial being reviewed, the next most senior clinician within the management structure will be called upon for their professional opinion.

The panel is responsible for reviewing non compliance reports, agreeing and taking the appropriate managerial action and if necessary notifying the relevant regulatory authority within the appropriate period. Where notification to a regulatory authority is required, a copy of this notification will also be sent to the Medical Director.

If a risk to organisational reputation is identified, the Medical Director is responsible for alerting the communications teams as appropriate.

Additionally the RDSG will review all clinical trial audit reports generated by the R&D Department.

Incidents relating to all clinical trials are also reported to the Trust via Datix and to the R&QC. Quarterly oversight of these incidents will be undertaken by the RDSG.