GOOD CLINICAL PRACTICE TRAINING

FOR STAFF INVOLVED IN CLINICAL RESEARCH

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Date approved:	**07/02/2022**	
Date for Review:	**07/02/2025**	
	V3.0	• **Include reference to Learnpro module** • **Update policy reference** • **Update website reference**
Replaces previous version:	**V2.0 Dec 2017**	• **Further definition of levels of training and training matrix** • **Inclusion of assessment of training guidance** • **Updated courses** • **Reference to Sponsor-specific training**
	V1.0 Mar 2009	• **Document release**

1. Introduction

NHS Greater Glasgow & Clyde (NHS GGC) have the responsibility for developing and promoting a high quality research culture and for ensuring that staff conducting clinical research are supported, and held accountable for, the professional conduct of clinical research.

The Medicines for Human Use (Clinical Trials) Regulations 2004 & Amendments detail the statutory requirements that apply to Clinical Trials of Investigational Medicinal Products (CTIMPs).

The UK Policy Framework for Health and Social Care Research sets out the standards and requirements for the conduct of all other clinical and social care research undertaken by NHS staff using the resources of the NHS and any research undertaken by universities and external organisations within the NHS system that might have an impact on the quality of those services.

All researchers are required to adhere to the relevant legislation, frameworks and principles and take responsibility for ensuring staff & students involved in the research are familiar with the appropriate requirements. Good Clinical Practice (GCP) is the international ethical, scientific and practical standard to protect the rights, safety and well-being of study participants. To achieve working to this level this policy outlines the expectation for students and staff to undertake GCP training, which is integral to the research experience and culture within NHSGGC. Each person involved in a clinical trial must receive training in GCP appropriate to their roles and responsibilities.

This policy aims to ensure that:

- Patient safety and well-being are maintained at all times when participating in a clinical trial
- Staff involved in clinical research are qualified and trained to comply with GCP and applicable regulations
- Staff members involved in supporting activities have an awareness of GCP

2. Scope

This policy applies to all staff that hold a substantive or honorary contract with NHSGGC, and those who have a Letter of Access for research.

All staff who manage patients in clinical trials must understand what awareness and/or training they require to carry out their role. There are two specific areas of awareness and training; the principles of GCP and the specific protocol(s) for the trial(s) on which they are working. The levels of awareness or training in each of these domains will depend upon the nature of the activities that they are intended to perform. These levels

are targeted at all individuals who may perform activities within clinical trials, for example (but not limited to): radiographers, pharmacy staff, auxiliary staff, doctors, nurses.

3. Roles and Responsibilities

The policy sets out levels of GCP training or awareness required by staff according to the type of project and level of involvement in clinical research.

4. Project Categories

The level of training required will be commensurate with the category of research study, as per Integrated Research Application System (IRAS) project categorisation, and role in the study team.

Category 1: CTIMP's or High Risk Studies

This includes but is not limited to:

- Clinical Trials of Investigational Medicinal Products (CTIMPs).
- Clinical investigation or other study of a medical device.
- Combined trial of an investigational medicinal product and an investigational medical device.
- Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.
- Study defined as high risk after completion of risk assessment by R&I/ Research Governance Team (SOP 51.004/ Form 51.004A), e.g. some Non-CTIMPS involving medicines.

Category 2: Any Other Research Project

This includes but is not limited to:

- Basic science study involving procedures with human participants.
- Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology.
- Study involving qualitative methods only.
- Study limited to working with human tissue samples (or other human biological samples) and data (specific project only).
- Study limited to working with data (specific project only).
- Research tissue bank.
- Research database.

5. Levels of Trial Involvement

There are 3 levels of involvement for staff that manage patients within clinical trials.

- **Level 1**
  - Activity that is specified in the trial protocol, but which is conducted in exactly the same way as in routine care, e.g. recording of BP or ECG, and is conducted by an individual who would normally perform these activities during routine care.

- **Level 2:**
  - Activity that is specified within the trial protocol and is unique to the trial, but which is within the normal remit of clinical responsibility for that member of staff. For example:
    - The administration of IV Investigational Medicinal Product (IMP) by a nurse trained in the administration of IV drugs.
    - Following an approved local dispensing procedure by pharmacy staff.
- **Level 3:**
  - Activity that is trial-specific and does not fall within the normal remit of clinical responsibility for the individual. Many activities performed by sub-investigators, research nurses and lead pharmacy contacts will fall into this category. **Prescription of IMP will always be considered a level 3 activity.**

Appendix I contains a list of examples of duties that would be performed at the above levels.

6. Levels of GCP Training/Awareness

The following training levels are the minimum required for the levels of activity and categories of study described above.

- **Level 1**
  - GCP Training – Individuals should *either:* i. undertake Good Research Practice Awareness sessions. No certificate of attendance will be issued for sessions but a record of attendance will be documented by the training team; *or,* ii. Complete the Good Research Practice Awareness LearnPro module; *or* iii. be in receipt of a brief GCP Awareness document which will be available to these staff members in their area of activity. No record will be kept as to whether or not the GCP Awareness document has been received by these individuals.

  - Trial-Specific Training – no trial specific training is required, and these staff will not be listed on trial delegation logs or training logs. The responsibility for protocol compliance will lie with the member of the research team who is instructing the individual to carry out this activity. The fact that the individual carrying out the activity does so as part of a clinical job is considered sufficient evidence of training in the activity. The individual is not delegated to perform any activity within the trial that is not part of their everyday practice.

- **Level 2**
    - GCP Training – abbreviated training will be provided to all relevant staff prior to undertaking trial activity. For example:
        - for nurses administering IV IMPs that are chemotherapy, this training will be part of the Chemotherapy Course, which is mandatory for all such staff.
        - for other staff groups this will be organised by the appropriate line managers.

      This training will be documented and traceable but will not necessarily be subject to planned or documented review unless there are significant changes in training requirements. No certificate of attendance will be issued.

    - Trial-Specific Training – this will depend on the staff group. For example:
        - Nursing staff in this category will be made aware that the patient is on a clinical trial and will be informed as to whom to contact regarding that trial in the event of any concerns/AEs. The mode of this communication will be dependent on the activity, e.g. for IMP administration this information will be on the prescription.
        - Pharmacy staff in this category will undertake trial-specific training in relation to the locally approved dispensing procedures. This training will be carried out by a member of the lead pharmacy contacts team or another member of the pharmacy team, using a cascade system. This training will be documented on a training log that is stored in the pharmacy site file for the project.

  Level 2-only staff will not be required to sign a delegation log, but their signature next to the activity (e.g. on the prescription) will constitute recognition of the trial-related nature of the activity and will be filed in the source documentation but not the Investigator Site File (ISF).

  Staff who, as part of their routine clinical work, conduct protocol directed interventions and activities with subjects of CTIMPs and high risk studies who would normally perform these activities as part of routine care will:
        - be eligible to attend NHS Research Scotland (NRS) GCP courses offered by Glasgow Clinical Research Facility.
        - have access to NHS GG&C Good Research Practice Awareness sessions. No certificate of attendance will be issued; a record of attendance will be documented by the training team.
        - Have access to NHSGG&C Good Research Practice Awareness LearnPro module

- **Level 3**
    - GCP Training – Full GCP training at a recognised GCP training course for CTIMPs must be undertaken before conducting trial related activities, evidenced by certificate and updated/revalidated every two years. (see section 10). Where update/revalidation is a shorter course than a full GCP training course it must take place before or within 2 months following the expiry of the certificate. Otherwise, a full GCP training course must be undertaken.

    - Trial-Specific Training – The Principal Investigator (PI) is ultimately responsible for the training of this group in all activities within the trial delegated to each individual. Trial-Specific training logs should be maintained in the ISF and all individuals undertaking these activities will be delegated to do so by the PI and this will be recorded in the delegation log in the ISF. The delegation log must include all individuals conducting level 3 activities within the given trial.

Any member of staff who prescribes IMPs must undergo full GCP training and be listed on delegation logs as a prescriber, i.e. non-medical prescribers must not be listed as their main role only, e.g. pharmacist or nurse

Trial specific GCP training will not be accepted as valid GCP Training by NHS GGC but may be requested by the study sponsor.

7. Assessment of Level of Study Activity/Training

When a trial is reviewed via the Research and Innovation (R&I) Management Approval process, the default activity and training levels will be as above. For departments that have an approval committee, the committee will identify the level of research resource to be provided for each trial and hence the level of activity and training to be applied to the project. These decisions will be documented in the minutes of that committee. For example within the Beatson West of Scotland Cancer Centre (BWoSCC) the monthly Clinical Trials Executive Committee (CTEC) allocate trials to treatment areas dependent on study risk and activities required. The available treatment areas in BWOSCC have definitions of the level of activity and training that may be carried out in each.

8. Communication & Dissemination

This policy will be made available on the NHS GGC Research & Innovation website: all staff conducting research in NHSGGC will be able to access this policy.

Implementation and adherence to this policy will be audited as part of NHSGGC Research Governance monitoring and audit plans.

9. Review

This policy will be reviewed every three years. The next review will be December 2024 or sooner if there is a change in the legislation or frameworks governing clinical research.

10. Related documents& links

Medicines and Healthcare products Regulatory Agency (2012) Good Clinical Practice Guide. London.

Medicines for Human Use (Clinical Trials) Regulations 2004 Statutory Instrument 1031& Amendments **http://www.opsi.gov.uk/si/si2004/20041031.htm**

UK Policy Framework for Health and Social Care Research

Recognised GCP courses available:

- NRS GCP Introduction to GCP (Transcelerate® compliant)
- NRS GCP Update (Transcelerate® compliant)
- NIHR On-line GCP (Transcelerate® compliant)
- Good Research Practice (GCP for non-drug studies)

Additional training available:

- Informed Consent in Adults
- Informed Consent in Children