GOOD CLINICAL PRACTICE TRAINING

FOR STAFF INVOLVED IN CLINICAL RESEARCH

Lead Manager:	**Naomi Hickey** **R&I Education and Quality Lead**	
Responsible Director:	**Professor Jesse Dawson** **R&I Director**	
Approved by:	**Corporate Management Team**	
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	V4.0 Jan 2026	• **Reference to amended Clinical Trial Regulations** • **Inclusion of research engaged students** • **Appendix 1 added** • **Minor clarifications** • **Change lead manager**
Replaces previous version:	**V3.0 Jan 2023**	• **Include reference to Learnpro module** • **Update policy reference** • **Update website reference**
	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) (Amendment) Regulations 2025 detail the statutory requirements that apply to Clinical Trials of Investigational Medicinal Products (CTIMPs). This regulation comes into force on 28th April 2026. All staff members requiring GCP training as below must complete a GCP Update/Refresher course before end 2026 to ensure knowledge of new legislation (even if previous GCP training has not expired in that timeline).

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

In line with duties set out in the Equality Act 2010, NHSGGC will make all reasonable adjustments to training design and delivery to ensure the needs of staff who require additional support to access professional learning are met.

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 (including students who are specifically engaged in 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 51.004B), 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.

Staff working on projects in category 1 are required to consider their role and level of trial involvement and complete appropriate training as detailed below. Staff working on projects in category 2 should consider Good Research Practice Training to ensure that the research activity and training complies with UK Policy Framework for Health and Social care.

5. Levels of Trial Activities for Category 1 Projects

There are 3 levels of activities for staff that manage patients within category 1 projects. See appendix 1 for a list of examples.

- **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. This is not exhaustive – seek advice from R&I as required.

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 are not required to complete GCP training for level 1 trial activity and will not be listed on trial delegation logs. The responsibility for GCP compliance lies with the PI and/or the member of the research team who is instructing the individual to carry out this activity.

  - Trial-Specific Training – no trial specific training is required, and these staff will not be listed on trial training logs. The responsibility for protocol

compliance will lie with the PI and/or 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 – Good Research Practice Awareness or similar abbreviated training must be completed prior to undertaking trial activity. This may be face to face or online training. 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.

  - 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 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 will:

- be eligible to attend NHS Research Scotland (NRS) GCP courses offered by Glasgow Clinical Research Facility.
- have access NHS GG&C Good Research Practice Awareness sessions.
- have access to NHSGG&C Good Research Practice Awareness LearnPro module or equivalent.

- **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 January 2029 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.

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 UK Statutory Instruments2025 No. 538

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)
- Good Research Practice Awareness

Additional training available:

- Informed Consent in Adults
- Informed Consent in Children

Appendix 1 List of examples of duties

This list is a guide and is not an exhaustive list

Level	Duties	Staff Group
1	Vital signs (Blood Pressure, Pulse, Temperature Respirations, Pulse Oximetry)	Nursing
1	Height	Nursing
1	Weight	Nursing
1	Urinalysis	Nursing
1	Urine Pregnancy Test	Nursing
1	ECG recording	Nursing
1	Blood glucometer recording	Nursing
1	Phlebotomy	Nursing
1	Cannulation	Nursing
1	Administration of oral, sub cut, IM or IV drugs (including chemotherapy) which are non IMP (NIMP)	Nursing
2	Administration of trial drugs which are IMP	Nursing
2	Receipt of IMP	Pharmacy
2	Environmental temperature monitoring	Pharmacy
2	Dispensing of NIMP	Pharmacy
2	Dispensing of IMP for phase II-IV trials	Pharmacy
2	Accountability and reconciliation of IMP	Pharmacy
2	Destruction of IMP with sponsor approval	Pharmacy
3	Any trial activity not covered by level 1 &2	