TAYSIDE MEDICAL SCIENCE CENTRE POLICY

GOOD CLINICAL PRACTICE TRAINING FOR PERSONNEL INVOLVED IN CLINICAL RESEARCH

POLICY NUMBER:	TASC POLICY 005 v10
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Good Clinical Practice

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording and reporting studies that involve human participants.

Regulations

The Medicines for Human Use (Clinical Trials) Regulations (2004) and subsequent amendments implement the EU Clinical Trials Directive 2001/20/EC and the EU GCP Directive 2005/28/EC and are based on the principles of International Council for Harmonisation (ICH) GCP (1996).

Background

1. In October 2017, the UK Policy Framework for Health and Social Care Research replaced the research governance frameworks in each of the four nations. It states:
"The UK policy framework for health and social care research sets out principles of good practice in the management and conduct of health and social care research that take account of legal requirements and other standards."

"All the people involved in managing and conducting a research project are qualified by education, training and experience, or otherwise competent under the supervision of a suitably qualified person, to perform their tasks."

2. The Health Research Authority (HRA) and the Medicines and Healthcare products Regulatory Agency (MHRA) released a joint statement on the Application of Good Clinical Practice Training for Researchers (v1.1 October 2017) to clarify requirements for GCP training. This has been endorsed by all four UK nations.

Purpose of this Policy

It is expected that all researchers involved in clinical research in Tayside should be trained in GCP.

1. To describe the GCP training requirements for studies sponsored and/or co-sponsored by NHS Tayside and/or the University of Dundee so as to ensure that the safety, rights and

well-being of research subjects are protected and respected, in line with the principles enunciated in the Declaration of Helsinki and other internationally recognized ethical guidelines.

2. To describe the requirements of NHS Tayside Research & Development (R&D) when giving Management approval for Clinical Trials of Investigational Medicinal Products (CTIMPs).
At the time of implementation of this Policy it was compliant with all applicable UK legislation. Should new legislation come into force this Policy will be updated to take account of the changes at the earliest opportunity.

Applicability

- All personnel involved in delivering clinical research (commercial or non-commercial) sponsored and/or co-sponsored by the University of Dundee and NHS Tayside.
- Staff recorded on the study delegation logs filed in Trial Master Files (TMF) and Investigator Site Files (ISF) for commercial or non-commercial studies sponsored and/or co-sponsored by the University of Dundee and NHS Tayside.
- Researchers named on the Integrated Research Application System (IRAS) form of commercial or non-commercial studies sponsored and/or co-sponsored by the University of Dundee and NHS Tayside who will be delegated significant trial related activities.

Training requirements

<u>Category 1. CTIMPs</u>

Evidence of attendance or completion of a full day, half day or online recognised GCP training course* is essential.

No delegated task can be undertaken without documented evidence of training. This training may include but not be limited to:

- Study specific Protocol
- Study specific Inclusion/Exclusion criteria
- Process of informed consent
- IMP reference safety information
- Expected Serious Adverse Events
- Safety reporting
- Source data recording
- Data entry
- Breach reporting
- Case report form completion
- Archiving.

Training at all times should be appropriate and proportionate, relevant to specific research roles and activities undertaken by staff.

Category 2. Research staff involved in Clinical Research (not including CTIMPs)

Attendance at a recognised GCP training course* is highly recommended.
No delegated task should be undertaken without documented evidence of training.

This training may include but not be limited to:

- Protocol
- Inclusion/Exclusion criteria
- Process of informed consent
- IMP reference safety information
- Breach reporting
- Case report form completion
- Archiving.

Training at all times should be appropriate and proportionate, relevant to specific research roles and activities undertaken by staff.

Category 3. Vendors

For third party vendors, it is the responsibility of the Sponsor to ensure that staff involved in a clinical research study are appropriately trained and complying with the principles of GCP and legislation. This should be documented in the vendor agreement between the University of Dundee and/or NHS Tayside.

Training updates
There is no prescribed timing for updating GCP.

Re-training may be required when:

- There is an update or change to legislation
- New policies or practices have been implemented
- Different research activities are undertaken.

The Sponsor retains the right to require a researcher to update their training should there be evidence that this would be beneficial i.e. following a breach of GCP or a significant period of time has elapsed since an individual was actively involved in research.

Re-training does not need to follow a generic syllabus, or format but must be approved by the Sponsor.

Evidence of re-training must be retained in an individual's Training Record and provided to Sponsor if requested.

Approvals

- NHS Tayside/University of Dundee will only confirm sponsorship for CTIMPs where the Chief Investigator and other researchers named on IRAS can show evidence of GCP training.

- NHS Tayside R&D Management approval for a CTIMP will only be given if the Chief Investigators and Principal Investigator(s) and other researchers named on the IRAS form who will be delegated significant trial related activities can produce evidence of undertaking GCP training as per Sponsor's requirements.

Evidence of Training

- Evidence of recognised GCP training for all research personnel in Category 1, at all Sites, is a mandatory requirement for sponsorship and co-sponsorship of CTIMPs by University of Dundee and/or NHS Tayside.
- Certificates of evidence of GCP training for all researchers named on the delegation log must be kept in the TMF or ISF.
- Curriculum Vitaes (CVs) for all researchers named on the Delegation Log must be kept in the TMF or ISF. CVs must clearly show the individual's relevant training to enable them to undertake their delegated tasks.

Courses

- *Recognised courses are those that are part of the Transcelerate GCP Training Mutual Recognition programme, or otherwise agreed with the Sponsor on a per study basis.
- For information regarding GCP training courses, please refer to the TASC website.

DOCUMENT HISTORY

History prior to 2021 is in the archived Policies available from TASC Quality Assurance Dept.

Version Number:	**Reviewed By (Job Title):**	**Effective Date:**	**Details of editions made:**
10	Patricia Burns (Senior Research Governance Manager)	26/09/2024	ICH and IRAS acronyms explained.

APPROVALS

Approved by:	**Date:**
Professor Linda Martindale, Dean, School of Health Sciences, University of Dundee, on behalf of TASC Research Governance and Oversight Committee	17 Sept 2024
Approved by:	**Date:**
Professor Russell Petty, R&D Director, NHS Tayside	16 Sept 2024