



University
of Dundee

TAYSIDE MEDICAL SCIENCE CENTRE POLICY

GOOD CLINICAL PRACTICE TRAINING FOR PERSONNEL INVOLVED IN CLINICAL RESEARCH

POLICY NUMBER:	TASC POLICY 005 v9
AUTHOR:	Patricia Burns
EFFECTIVE DATE:	26 Sep 2022
REVIEW DATE:	26 Sep 2024

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 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 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 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:

Category 1. CTIMPs

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 Research & Development (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 Vitae (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.


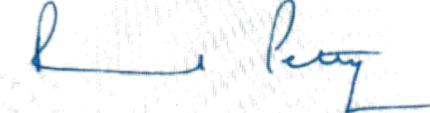
Courses

- *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

Version Number	Edited by (Job Title)	Effective Date	Details of editions made
History of reviewers prior to 2014 is detailed in the archived Policies			
3	Mark Ferguson (Training Manager)	01/12/2013	Clarifying requirements for mandatory and those recommended for GCP training.
4	Sarah Kennedy (Training Manager)	01/12/2015	Update wording to include online training and explanation of recognised courses. Remove reference to non-CTIMP GCP courses.
5	Sarah Kennedy (Training Manager)	23/06/2016	Expansion of definition of recognised courses (see page 5).
6	Catrina Forde (Senior Research Governance Manager)	06/06/2017	GCP update training may be up to 3 years out with Scotland. Sections 4, 5 and 7 removed.
7	Patricia Burns (Senior Research Governance Manager)	26/09/2018	Updated in line with MHRA/HRA joint statement. Reorganised for ease of reading. Removal of mandatory GCP updates within two years.
8	Patricia Burns (Senior Research Governance Manager)	26/09/2020	Sentence added to page 1 to state that "It is expected that all researchers involved in clinical research in Tayside should be trained in GCP.".
9	Patricia Burns (Senior Research Governance Manager)	26/09/2022	No changes required.

APPROVALS

Sign	Date
<p>RATIFIED BY: Professor Linda Martindale, Dean, School of Health Sciences, University of Dundee – on behalf of TASC Research Governance and Oversight Committee</p> <p><i>Signature</i></p> 	<p>20th September 2022</p>
<p>RATIFIED BY: Professor Russell Petty, R&D Director, NHS Tayside</p> <p><i>Signature</i></p> 	<p>22 Sep 2022</p>