Guidance Document: Training requirements for conducting research at Grampians Health

Last updated January 2024

Target Audience

This document applies to personnel involved in clinical research (human research involving patients, participants, facilities and/or staff) or who propose to undertake, administrate, review and/or govern clinical research at Grampians Health.

All study personnel involved in clinical research studies must operate within their scope of practice.

Purpose

- Personnel must be appropriately qualified by training, experience and education to perform their responsibilities competently and be trained in their respective study protocol(s).
- The purpose of this document is to describe the minimum requirements for personnel involved in clinical research at Grampians Health
- To ensure that research undertaken at Grampians Health is in accordance with the principals of ICH-GCP, the TGA Australian Clinical Trial Handbook, the NHMRC National Statement and the requirements of the National Clinical Trials Governance Framework
- To ensure the appropriate documentation of clinical trial site staff qualifications and training records are completed and maintained up to date.

Scope: This document applies to all researchers, investigators, sponsors, and relevant personnel involved in planning, conducting, and reporting clinical research at Grampians Health.

Mandatory Clinical Research Training Requirements:

All personnel involved in clinical research at Grampians Health must complete the following mandatory training prior to starting work on any clinical research studies/projects:

Personnel	Required Training Course	Course Details	Frequency	Evidence Location
All staff undertaking clinical research***	ICH Good Clinical Practice (GCP)	Full course (TransCelerate approved)	Once only*	Investigator Site File AND Grampians learning hub
All staff undertaking clinical research***	ICH-GCP Refresher (online)	ICH-GCP Refresher (online) OR A-CTEC Trial Essentials (topics covered adequate for GCP refresher)	Every 3 years	Investigator Site File AND Grampians learning hub
Staff undertaking clinical trials including: - Principal Investigators - Study Coordinators - Research Support staff including (RGO, research assistant)	A-CTEC Trial Essentials for Investigators (online)** OR A-CTEC Trial Essentials for Research Support Team (online)**	A-CTEC Trial Essentials (online)	Once only then Transcelerate ICH-GCP as per usual 3-year cycle	Investigator Site File AND Grampians learning Hub
Staff undertaking clinical trials including: - Associate Investigators**** - Trial Pharmacists	As per all staff undertaking clinical research: i.e. GCP only	Full course (TransCelerate approved)	Once only then Transcelerate ICH-GCP as per usual 3-year cycle	Investigator Site File AND Grampians learning Hub

Staff undertaking clinical trials including - Principal & Associate Investigators - Study Coordinators - Research Support staff including (RGO, research assistant) - Trial Pharmacists	Grampians Health Clinical Trial SOPs (adopted fully from the National SOPs for clinical trials, including teletrials, in Australia)	Available via GovDocs	Every 2 years and/or when revised	Investigator Site File AND Grampians learning Hub

* For personnel requiring GCP training for the first time, the full course certification is required. Full course may be required for existing personnel at the request of the individual's manager, Director of Research Operations or Chief Medical Officer.

**Staff undertaking clinical trials should note that both A-CTEC course packages are mutually recognised and listed by TransCelerate as meeting the minimum requirements of ICH E6(R2) GCP.

***Requests for exemptions for non-interventional studies will be reviewed on a case-by-case basis.

**** Certain studies may require Associate Investigators to complete the full A-CTEC investigator training. GH REGO will advise on submission of governance package

Procedure

Policy Introduction Phase: January 2024 to 30th April 2024

- During the policy introduction phase, existing Principal Investigators (PIs), research support staff and staff participating in clinical research at Grampians Health are expected to complete all mandatory clinical research training

From 1st May 2024

- All training will be mandatory for existing and new clinical research personnel at Grampians Health
- Non-compliance from study staff may result in the following:
    - Existing clinical research studies/projects will be placed on hold or individuals with incomplete training removed from project involvement
    - New clinical research studies/trials/projects will not be granted Research Governance Office (RGO) approval until training is completed by the Principal Investigator (PI), research support staff and staff participating in the clinical research study

Note: It is the responsibility of the clinical research study/project/trial PI and delegated study personnel to ensure that all personnel listed on the study/project/trial's Delegation of Duties Log have completed their mandatory clinical research training, training on study protocol and any role-relevant study related materials and provided documented evidence of the training/s before any study related activity is undertaken.

Clinical Trials: Evidence of GCP training must be retained in the dedicated section of the Trial Master File (TMF) and/or Investigator Site File (ISF). Evidence of expired GCP training must also be retained on file to demonstrate that members of the study team were GCP training throughout the whole period of their delegation on the study.

Evidence of A-CTEC training, SOP training and GCP will be saved within the personnel's Learning Management System (LMS) at Grampians Health.

Evidence of training on study protocols will be saved and maintained by research teams.

All study personnel involved must operated within their scope of practice.

Related policies:
Grampians Health Research Policy POL0080
Grampians Health Research Integrity Guideline NCG0092
GH Clinical Trials Standard Operating Procedures

References
Integrated Addendum to ICH E6 (R1) Guideline for Good Clinical Practice E6R2* annotated with TGA comments
National Health and Medical Research Council (NHMRC) *National Statement on Ethical Conduct in Human Research 2007 (and as amended)*
National Clinical Trial Governance Framework (ACSQHC)
National Standard Operating Procedures for Clinical Trials, including Teletrials, in Australia

Appendix 1: Good Clinical Practice (ICH GCP) in research

What is Good Clinical Practice?

Good Clinical Practice (GCP) is the international standard for conducting clinical research and provides a framework for ensuring participants' rights, safety and well-being are protected and the data generated is credible.

Originally developed for pharmaceutical trials, this guidance has become known as the "Good Clinical Practice" (GCP) guideline and is becoming widely adopted as the standard for all clinical research. The GCP guideline details the requirements for stakeholder responsibilities, participant consent, documentation, protocols and amendments, requirements such as indemnity, reporting lines for adverse events and provision of medical care for research (trial) participants.

Origin

The principles of GCP have their origin in the World Medical Association's Declaration of Helsinki. The Declaration of Helsinki was responsive to the revelations of the Nuremberg trials conducted after World War II, and its drafters sought to ensure that human subjects involved in clinical research would, in future, have their rights, safety and well-being placed above all other considerations in clinical research. The document has been revised several times since it was first published in 1964.

The Declaration of Helsinki was used as a basis for the development of guidance for the conduct of clinical trials by the International Conference on Harmonisation (ICH). Originally developed for commercially sponsored late phase drug trials, this guidance has become known as the "Good Clinical Practice" (GCP) guidelines, even though the guidelines apply to clinical research rather than clinical practice.

Current ICH GCP Guideline

Course components include:

- Principles of ICH GCP
- Study set up – responsibilities, approvals and essential documents
- The process of informed consent
- Case Report Form, source data and data entry completion
- Safety reporting

The GCP guidelines seeks to address issues relating to patient safety, risk management and research quality. There are currently 13 principles of ICH GCP as per the ICH harmonised guideline.

1. Clinical trials should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with GCP and the applicable regulatory requirement(s). The three basic ethical principles are of equal importance: respect for persons, beneficence and justice and permeate all other GCP principles listed below.
2. Before a trial is initiated, foreseeable risks and inconveniences should be weighed against the anticipated benefit for the individual trial subject and society. A trial should be initiated and continued only if the anticipated benefits justify the risks.
3. The rights, safety, and well-being of the trial subjects are the most important considerations and should prevail over interests of science and society.

4. The available nonclinical and clinical information on an investigational product should be adequate to support the proposed clinical trial.
5. Clinical trials should be scientifically sound, and described in a clear, detailed protocol.
6. A trial should be conducted in compliance with the protocol that has received prior institutional review board (IRB)/independent ethics committee (IEC) approval/favourable opinion.
7. The medical care given to, and medical decisions made on behalf of, subjects should always be the responsibility of a qualified physician or, when appropriate, of a qualified dentist.
8. Each individual involved in conducting a trial should be qualified by education, training, and experience to perform his or her respective task(s).
9. Freely given informed consent should be obtained from every subject prior to clinical trial participation.
10. All clinical trial information should be recorded, handled, and stored in a way that allows its accurate reporting, interpretation and verification.
11. The confidentiality of records that could identify subjects should be protected, respecting the privacy and confidentiality rules in accordance with the applicable regulatory requirement(s).
12. Investigational products should be manufactured, handled, and stored in accordance with applicable good manufacturing practice (GMP). They should be used in accordance with the approved protocol.
13. Systems with procedures that assure the quality of every aspect of the trial should be implemented.

Providers of ICH GCP Training

There are hundreds of online and in-person Transcelerate ICH GCP accredited providers

All providers can be found here: https://www.transcelerate-gcp-mutual-recognition.com/view-course

The duration of the course varies depending on provider. Most online providers recommend 2 – 4 hours and in-person sessions average 4 – 6 hours time commitment.

ICH GCP certification is valid for 3 years.

(Selected) Providers of Online Transcelerate-approved ICH GCP

- Australian Clinical Trials Education Centre (A-CTEC): https://actec.myopenlms.net/
- Genesis Research Services https://genesisresearchservices.com/product/good-clinical-practice-ich-gcp-course/
- Global Health Network – Global Health Training Centre: https://globalhealthtrainingcentre.tghn.org/elearning/
- NIDA Clinical Trials Network (part of the National Institutes of Health in the US) https://gcp.nidatraining.org/

Appendix 2: Clinical Trials Education - Australian Clinical Trials Education Centre (A-CTEC)

Who is A-CTEC?

A-CTEC is a not-for-profit, Victorian developed, Australia-wide education centre, with a dedicated Learning Management System (LMS) hosting a suite of evidence-based, interactive clinical trials education opportunities suitable for a range of learning needs.

Originally led by the Victorian Research Translation Centres of Melbourne Academic Centre for Health, Monash Partners Academic Health Science Centre, and Western Alliance Academic Health Science Centre, and supported by the Victorian Comprehensive Cancer Centre, Parkville Cancer Clinical Trials Unit, Melbourne Children's Trials Centre and Alfred Health. This initiative was established to address the need for high quality and easy access to clinical trial education and build capacity, particularly in regional and rural areas.

For further information visit: https://machaustralia.org/resource/actec/

What do you need to do?

As part of the implementation of the National Clinical Trials Governance Framework at Grampians Health **all staff involved in clinical trials** at Grampians Health must complete the relevant education package through A-CTEC. There are two options:

Trial Essentials for Investigators (ICH E6 R2 GCP included)

This introductory package of 5 courses will equip trial investigators (PIs and AIs/SIs) with foundational knowledge about overseeing and managing clinical trials in Australia

Course elements:

- Trial regulatory requirements in Australia
- Trial feasibility and start-up process
- Safety monitoring and reporting in trials
- Protocol compliance and serious breaches
- PI oversight and trial management

Completion of this course is equivalent to 10 active learning hours towards CPD points AND satisfies the requirements of GCP

OR

Trial Essentials for Research Support Team (ICH E6 R2 GCP included)

This introductory package of 6 courses will equip research support personnel (study coordinators, clinical trial assistants, RGO staff, pharmacy staff) with foundational knowledge about running clinical trials in Australia.

Course elements:

- Introduction to clinical trials
- Running clinical trials from start to finish
- The regulatory environment of clinical trials
- Ethics and governance application process
- Safety reporting in clinical trials
- Monitoring and auditing clinical trials

Completion of this course is equivalent to 15 active learning hours towards CPD points AND satisfies the requirements of GCP

Register your Training

Once you have completed the appropriate package above send your certificates of completion to: researchethics@gh.org.au