Standards for Good Clinical Practice (GCP) Training and GCP certificates in the Monash Partners Academic Health Science Centre

1. Introduction

In Australia, the Australian Code, National Statement and ICH Good Clinical Practice Guidelines require researchers to be adequately experienced, qualified or supervised.

To assist in meeting this requirement Monash Partners mandates that all Investigators and Sub-investigators, as defined below, undergo recognised Good Clinical Practice (GCP) training to conduct clinical trials or interventional studies.

This policy sets out the standards for compliance with the code of Good Clinical Practice (GCP) with respect to training and GCP certificates for all Monash Partners staff involved in the conduct of clinical trials or interventional studies. It is applicable to all phase of clinical trials, both non-commercial (including investigator initiated and collaborative group) and commercially sponsored studies. Researchers involved in human research other than clinical trials and interventional studies are not bound by this Standard/Policy

Requirements for the conduct of clinical trials

The requirements for the conduct of all clinical trials are described in the: Therapeutic Goods Administration (TGA) Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) (2000), FDA CFR Title 21 part 312, FDA Guidance for Industry (2009), the FDA Information Sheet Guidance for Sponsors, Clinical Investigators and IRBs (2010), National Statement on Ethical Conduct in Human Research (NHMRC, 2007 as amended under rolling review), and the Australian Code for the Responsible Conduct of Research (NHMRC, 2007) and other applicable regulatory requirements.

Definitions

Accredited training: training that provides a participant with a recognised qualification on completion. This includes courses which meet the TransCelerate BioPharma Inc. Minimum Criteria for ICH Good Clinical Practice (GCP) Investigator Site Personnel Training.

Clinical trial: For the purpose of this document, a clinical trial refers to an interventional study which may involve pharmaceuticals, surgical procedures, devices, other therapeutic and preventive procedures, a diagnostic device or procedure or examination of biomedical/physiological phenomena.

FDA: Food and Drug Administration

Good Clinical Practice (GCP): A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.

Interventional study: A human research study in which participants are assigned to receive one or more interventions typically through a clinical trial, so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes.

Investigator: A person responsible for the conduct of the clinical trial at a trial site. If a trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and referred to as the Principal Investigator.

IRB/HREC: Institutional Review Board/Human Research Ethics Committee

Monash Partners Academic Health Science Centre: a collaboration between Alfred Health, Baker Heart and Diabetes Institute, Burnet Institute, Cabrini Health, Epworth Healthcare, Eastern Health, Hudson Institute of Medical Research, Monash Health, Monash University and Peninsula Health

NHMRC: National Health and Medical Research Council

TGA: Therapeutics Goods Administration

Sponsor: an individual, company, institution, or organisation that takes responsibility for the initiation, management, and/or financing of a clinical trial

Sub-investigator: Any individual member of the clinical trial team designated and supervised by the investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions. For the purposes of this policy, Research Coordinators and Research Associates are defined as Sub-investigators.

2. Responsibilities

Good Clinical Practice (GCP) guidelines and the National Statement on Ethical Conduct in Human Research (NHMRC, 2007 as amended under rolling review), and the Australian Code for the Responsible Conduct of Research (NHMRC, 2007) require researchers to be appropriately trained and credentialed.

All Principal Investigators (PIs), Associate Investigators (AIs) and Research Co-ordinators involved in the conduct of clinical trials and interventional studies at any Monash Partners institution will undergo formal GCP training or have acknowledgement of prior GCP training valid within the last 3 years. The training will be documented by a certificate detailing the date and type of GCP training received.

GCP training can encompass any of the following:

- Any training (face to face or online) that meets the criteria for ICH GCP investigator site personnel training as identified by Transcelerate Biopharma Inc. as necessary to enable mutual recognition of GCP training among trial sponsors. The list of recognised training providers can be found on their website. The following GCP training programs are included :
    - The Monash Partners accredited GCP training program (see below);
    - Research Excellence Training (RXT), ARCS, Peter MacCallum Cancer Centre or the Murdoch Children's Research Institute GCP training programs; or
    - Any of the accredited GCP Pharmaceutical sponsor training programs
- US National Institute of Health (NIH) GCP training
- Formal clinical research training (which includes GCP training) through a university or research institute to be considered on an individual basis

Staff must forward the certificate of completion to the Office for Research (or equivalent) in their Institution for its records.

Staff who have completed GCP training through these providers, and can provide evidence of course completion, will be eligible for Monash Partners GCP refresher training.

Monash University Accredited GCP Training program

Accredited GCP training is provided by Monash University through the School of Public Health and Preventive Medicine and the Monash Centre for Health Research and Implementation. This training meets the criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma Inc. as necessary to enable mutual recognition of GCP training among trial sponsors and is delivered by trained GCP facilitators.

- For staff with no prior GCP training, GCP training is offered as a 6 hour face to face interactive workshop

All staff who have undertaken face-to-face or online GCP training (as outlined above) will be able to fulfil the subsequent requirements to renew their GCP training every 3 years by:

- Attending the refresher GCP training course provided by Monash University
- Completing accredited face to face or online refresher training

GCP certificates are issued once training is completed. Certificates issued by Monash University are not individually signed, but are authenticated and approved by the Monash University School of Public Health and Preventive Medicine and the Monash Centre for Health Research and Implementation.

The Research Governance Offices of the Monash Partners organisations will maintain a database of trained staff.

3. Dissemination and Implementation

This document will be disseminated to all staff involved in clinical trials and interventional studies and to external bodies as required to clarify our regulatory compliance.

4. References

- **"Note for Guidance on Good Clinical Practice" (CPMP/ICH/135/95) Annotated with TGA comments. Therapeutic Goods Administration July 2000.**
- **"Information Sheet Guidance for Sponsors, Clinical Investigators and IRBs. Statement of Investigator (Form FDA 1572)". Food and Drug Administration May 2010.**
- **"Guidance for Industry, Investigator Responsibilities – Protecting the Rights, Safety and Welfare of Study Subjects". Food and Drug Administration October 2009.**
- **"National Statement on Ethical Conduct in Human Research" (NHMRC, 2007 as amended under rolling review). "Australian Code for the Responsible Conduct of Research" (NHMRC, 2007)**
- **"ICH Harmonised Tripartite Guideline: Guideline for Good Clinical Practice E6 (R1)" International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use 10 June 199**