Monash Partners
Academic Health Science Centre

Good Clinical Practice (GCP) at Monash Partners

What is GCP?

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. The GCP guideline details the requirements for trial documentation, protocol amendments, requirements such as indemnity, reporting lines for adverse events and provision of medical care for trial participants.

The Therapeutic Goods Administration (TGA) has adopted the European Union version of these guidelines in Australia. The TGA advice includes specific comments from the TGA relevant to the Australian context.

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 HREC's (Human Research Ethics Committee) mandates that all Investigators and Sub-investigators, as defined below, undergo recognised Good Clinical Practice (GCP) training to conduct 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 required to undergo GCP certification.

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.

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The Australian Clinical Trial Handbook: A simple, practical guide to the conduct of clinical trials to International standards of Good Clinical Practice (GCP) in the Australian context.

GCP training requirements at Monash Partners

Monash Partners Ethics Committees, requires that 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.

Investigators are required to indicate on the governance application cover letter whether they have undertaken any GCP training and if the training appears on the list of courses on TransCelerate Biopharma Inc. for the list of training providers. A copy of the course completion certificate should be included with the research governance application.

GCP Training at Monash Partners

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 http://www.med.monash.edu.au/sphpm/shortcourses/good-clinical-practice.html

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 http://www.med.monash.edu.au/sphpm/shortcourses/refresher-ich-good-clinical-practice.html

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.