

MEMORANDUM

To: Metro South Health Executive Directors, Divisional/Departmental Leads, Principal Investigators and Research Teams

Copies to: Metro South Health Research Council and Metro South Health Research Committee

From: Professor John Upham,
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Subject: Requirement for Good Clinical Practice (GCP) Certification in Metro South Health - 2023 Update

File Ref: GCP Training 2023

This Memorandum updates training requirements mandated by Metro South Health (MSH) Research Council for all researchers involved in clinical trials. Also detailed are the actions required of Principal Investigators and research teams.

Background

Since 1 February 2020, all MSH researchers have been required to provide evidence of TransCelerate accredited GCP Training¹ undertaken within the previous three years as part of the Site-Specific Authorisation (SSA) process. The Principal Investigator (PI) at the site is responsible for ensuring that all members of the research team undertake GCP Training prior to the commencement of the study.

In addition, research teams conducting clinical trials with MSH acting as Sponsor have been required to complete a more detailed face-to-face GCP course. To support this mandate, MSH Study, Education and Research Trust Account (SERTA) Committee funded face-to-face GCP Training sessions between 2020 and 2022.

In March 2023, Metro South Research developed its own TransCelerate accredited² online MSH GCP Training course which is available on MSHLearn. MSH GCP Training satisfies the Minimum Criteria for ICH E6 (R2) GCP Investigator Site Personnel Training³ and an accredited GCP Certificate is provided at the completion of the course. A three (3) yearly renewal is required for the MSH GCP Training course.

New GCP Training Requirements for Researchers

On 18 April 2023, Metro South Health Research Committee endorsed the MSH GCP Training online module and mandated the following requirements from 1 July 2023.

MSH Sponsored Clinical Trials

If MSH is the intended act as the Sponsor⁴ the research team must provide a certificate of completion of:

- The MSH GCP Training online course (i.e. other online GCP training is not acceptable), or
- A more detailed TransCelerate accredited GCP Training course (e.g. a Sponsor-paid GCP Course, or face-to-face accredited GCP course).

¹ [Memorandum Requirement for Good Clinical Practice \(GCP\) Certification in Metro South Health - 7 November 2019](#)

² [TransCelerate Biopharma Inc. GCP Mutual Recognition Program](#)

³ [Minimum Criteria for ICH E6 \(R2\) GCP Investigator Site Personnel Training](#)

⁴ [Integrated Addendum to ICH E6\(R1\): Guideline for Good Clinical Practice ICH E6\(R2\) - Annotated with TGA comments Section 5.0](#)

All Research

All researchers must continue to submit evidence of the following as part of the SSA process:

- TransCelerate accredited GCP certification completed prior to 1 July 2023; or
- MSH GCP Training online course (i.e. other online GCP training is not acceptable from 30 June 2023); or
- A more detailed face-to-face TransCelerate accredited GCP Training course.

Please note: three-year renewal of GCP Training still applies.

Actions Required

Principal Investigators and research teams are required to:

- Be aware of these GCP Training requirements and circulate to all research-active staff within their Metro South Health networks.
- Announce and discuss in relevant division/departmental research meetings.
- Provide relevant evidence of GCP Training as part of the SSA process.

Some updated Frequently Asked Questions (FAQs) regarding GCP are provided below:

Thank you, if you have any questions regarding GCP Training requirements in MSH please contact the Metro South Research office via MSH-Research@health.qld.gov.au.



Professor John Upham
Executive Director
Metro South Research
05/06/2023

Frequently Asked Questions

What is a clinical trial?

A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials include but are not limited to:

- Surgical and medical treatments and procedures
- Experimental drugs and diagnostics
- Biological products
- Medical devices
- Health-related service changes
- Health-related preventative strategies
- Health-related educational interventions⁵

What is GCP?

The guideline for Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, conducting, recording, and reporting of clinical trials that involve human participants. It relates specifically to research and should not be confused with clinicians generally applying good clinical practice in the care of their patients.

Adherence to GCP serves as a best-practice standard for all clinical trials to protect the rights, safety and well-being of participants and provides assurance that the clinical trial data is credible. As GCP is an international standard, it facilitates mutual acceptance of data from clinical trials by regulatory authorities.

What does GCP specify?

The GCP Guideline details and delineates the respective responsibilities of those involved in the conduct of clinical trials. It also specifies requirements, including those related to participant consent, protocol and associated amendments, the investigational product, essential documentation, safety reporting and quality management.

GCP provided best-practice processes, many of which can be applied to all types of research, not just clinical trials. The GCP Guidelines, with the Therapeutic Goods Administration (TGA) annotated comments is referenced in MSH's online GCP Training module⁶.

When do I have to provide evidence of GCP training?

All researchers must continue submit evidence of accredited GCP certification undertaken within the previous 3 years as part of the SSA process. This requirement is for all project team members listed on the study. Evidence is a GCP Certificate provided by a TransCelerate accredited training provider. GCP Certificates for each research project team member must be uploaded to ERM as a supporting document to the SSA for review by the Metro South Research Governance Office (RGO).

What does accredited mean?

TransCelerate Biopharma Inc. is a global group comprising of representatives from leading pharmaceutical companies that provided minimal criteria for GCP courses and provides a framework for mutual recognition of GCP training by pharmaceutical Sponsors.

Is MSH's GCP Training online course accredited?

Yes, the MSH GCP Training course is TransCelerate accredited.

⁵ [National Clinical Trials Governance Framework](#)

⁶ [Integrated Addendum to ICH E6\(R1\): Guideline for Good Clinical Practice ICH E6\(R2\) - Annotated with TGA comments](#)

If I have done a GCP course elsewhere, can that certificate be provided?

Yes, MSH will accept all GCP certificates for non-MSH Sponsored studies as long as it is still valid within 3 years as has been obtained through a TransCelerate accredited training organisation. If you are required to complete GCP Training again once your current training has expired, then you must complete the MSH GCP Training online course.

The Sponsor has requested that I complete a particular GCP course and will pay my registration fees, do I still need to complete the MSH GCP Training course?

No, generally any paid GCP courses will be more extensive than a free to access accredited GCP course so completion of the MSH GCP Training online course is not an additional requirement.

If the Sponsor asks that you provide evidence of GCP certification without stipulating a provider, then the preference is to utilise the MSH GCP Training course as opposed to an external provider. MSH is listed on the TransCelerate website and can be provided to the Sponsor.

I have a MSH Sponsored study, what does this mean for my GCP Training?

You and your research team must complete the MSH GCP Training online course and have valid MSH GCP Certificates included as part of your SSA.

I have external researchers on my study, are they required to complete the MSH GCP Training course?

No, external researchers are not required to complete the MSH GCP Training course and may provide a copy of any valid accredited GCP Certificate with the SSA application. If the external researcher would like to complete the MSH GCP Training course, please contact Metro South Research via email MSH-Research@health.qld.gov.au to organise access.

I have completed face-to-face GCP training, do I still need to complete the MSH GCP Training?

No, GCP Training facilitated in a face-to-face format supersedes online training and valid certificates will be accepted for all research studies including MSH Sponsored studies. Please note, MSH will not be offering face-to-face GCP Training programs in 2023.