Metro South Health

Queensland Government

MEMORANDUM

To:	Metro South Research Community		
Copies to:	MSH Executive Directors, Divisional Chairs, Research Directors and Research Managers		
From:	Prof John Upham, Metro South Research Chair	**Contact No:**	3443 8065
Subject:	Requirement for Good Clinical Practice Certification in Metro South Health	**File Ref:**	GCP Training

Dear Metro South Researchers,

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. Metro South Research Council has endorsed a mandate for all researchers involved in clinical trials to undertake accredited GCP training.

Clinical Trials are not just pharmaceutical trials but any research investigations involving human participants to test new treatments, interventions or tests. These types of studies would ordinarily require full ethical review by a NHMRC Certified Human Research Ethics Committee (HREC).

New Clinical Trials:
From **1 February 2020**, all Principal Investigators (PI's) and research personnel submitting a **new** clinical trial for research governance authorisation within Metro South must provide evidence of accredited GCP certification undertaken within the previous 3 years. Evidence of GCP certification will form a requirement for Site-Specific Assessment (SSA) authorisation. The responsibility for ensuring that all members of the research team undertake GCP training prior to the commencement of the study, rests with the PI at the site.

Existing Clinical Trials:
From **1st June 2020,** all researchers conducting clinical trials authorised prior to 1 February 2020 must provide evidence of GCP certification.

Free online GCP training can be completed via Global Health Training Centre.

Researchers intending for Metro South Health to act as Sponsor for clinical trials utilising unapproved therapeutic goods, **must** complete a face to face GCP Course following completion of the online GCP course. Registration for these sessions will be facilitated by the Metro South Research office.

Should researchers wishing to submit a new application after 1 February 2020 have any difficulty in completing the online training, please contact the Manager - Research Integrity and Compliance, Sonia Hancock via 07 3443 8046. Further details on the requirements can be found in the attached Frequently Asked Questions.

Kind regards,

Prof John Upham
Metro South Research
7/11/2019

Prepared by:	Sonia Hancock Manager, Research Integrity and Compliance Metro South Research 3443 8046 21.10.19
Submitted through:	Paul Dall'Alba Director, Research Development Metro South Research 3443 8064
Cleared by:	Prof John Upham Chair, Research Metro South Research 3443 8064

Frequently Asked Questions (FAQ's)

What is Good Clinical Practice (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.

What is the purpose of GCP?

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 are 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 provides 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) clarifications can be found here https://www.tga.gov.au/publication/note-guidance-good-clinical-practice

GCP Training Requirements at MSHHS

All clinical trials being conducted in Metro South will need to adhere to the GCP principles. Clinical trials comprise not just pharmaceutical trials, but any research investigations involving human participants to test new treatments, interventions or tests. For those clinical trials involving an unapproved drug or device to adhere to GCP guidelines, there is a legal requirement for the trial to be conducted according to GCP.

From **1 February 2020**, all site Principal Investigators (PIs) of *new* clinical trials being conducted at Metro South must provide evidence of accredited GCP certification undertaken within the previous 3 years. The site PI is then responsible for ensuring respective members of the research team undertake GCP training prior to the commencement of the study.

In addition, all researchers conducting clinical trials authorised prior to 1 February 2020 (i.e. *existing*) must provide evidence of GCP certification by **1st June 2020**

When do I have to provide evidence of GCP training?

Evidence of completion of a GCP training course recognised by TransCelerate Biopharma Inc must be submitted to the Metro South Research Governance Officer (RGO) with the Site-Specific Assessment (SSA) application. TransCelerate Biopharma Inc is a global group comprising representatives from leading pharmaceutical companies that provides minimal criteria for GCP courses and provides a framework for mutual recognition of GCP training by pharmaceutical Sponsors. The certificate should be uploaded to ERM as a supporting document.

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

Yes. MSH will accept all GCP certificates so long as they are still valid (i.e within 3 years) and have been obtained through a Transcelerate BioPharma Inc accredited training organisation.

Do I only have to complete GCP training once?

You will need to ensure that your GCP certification is current and valid during the course of the conduct of the clinical trial. Whilst GCP certification is valid for a three-year period, ongoing certification via completion of a refresher or updated Transcelerate recognised GCP training is required.

What GCP course options exist for MSHHS employees?

Level 1: Minimum Requirement (all researchers conducting clinical trials):

Completion of a **free** online GCP course is acceptable as a minimum requirement. The MSH recommended option is the Global Health Training Centre which takes on average 45-60 minutes to complete. This free ICH E6 (R2) GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.

Level 2: Where MSH is the nominated Sponsor of a clinical trial OR the clinical trial is considered high risk

When the research team requests MSH to act as the Sponsor in accordance with ICH GCP Section 5.0, face to face (F2F) GCP course completion and certification will be required. Similarly, F2F GCP training is required when researchers are conducting a clinical trial considered to be high risk in accordance with Metro South's Risk Assessment Matrix. These are offered by accredited training organisations. Please contact the Metro South Research – Research Governance Office on 3443 8050 or MSH-RGO@health.qld.gov.au for further Information.

When do I need to complete my GCP training by?

Type of study	Certification Required By	Level 1 Online GCP training	Level 2 F2F GCP training
MSH acting as Sponsor (new)	**1st February 2020**	Required	Required
MSH Sponsor (existing)	**1st June 2020**	Required	Required
High risk clinical trial (new)	**1st February2020**	Required	Required
High risk clinical trial (existing)	**1st June 2020**	Required	Required
Medium/low risk clinical trial (new) including comparison of approved therapies	**1st February 2020**	Required	Optional
Medium/low risk clinical trial(existing) including comparison of approved therapies	**1st June 2020**	Required	Optional