Requirement for Good Clinical Practice (GCP) training in Metro North Hospital & Health Service

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 MNHHS

All clinical trials being conducted in Metro North should 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 September 2019**, all site Principal Investigators (PIs) of clinical trials being conducted at Metro North 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. This requirement applies to new studies and does not apply retrospectively to studies that have already been granted SSA authorisation.

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 relevant Metro North 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 and submitted in hardcopy, if required by the RGO.

What GCP course options exist for MNHHS employees?

Throughout the year, the Metro North Office of Research coordinates face-to-face GCP courses with an external GCP trainer at a competitive price. Other face-to-face GCP course options are also regularly offered by other bodies

including ARCS and Datapharm Australia (these are external to Metro North). While face-to-face GCP education is highly recommended, completion of an online GCP course is also acceptable. Metro North has access to online GCP modules provided by IQVIA free of charge. Please contact the Metro North Office of Research or one of the Metro North Research Governance Officers via the contact details below for a copy of the link to online training. Other online GCP Courses are also offered by Praxis Australia and ARCS for a fee.

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

Yes, if the GCP course completed is recognised by Transcelerate Biopharma Inc.

Contacts

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