Good Clinical Practice Training in Research

Procedure

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TARGET AUDIENCE and SETTING

All staff and external researchers who are conducting or supporting research at, or under the auspices of, Monash Health are required to complete Good Clinical Practice (GCP) training as training requirement.

PURPOSE

To ensure that:

1. All internal and external personnel who are involved in conducting or supporting research at Monash Health hold current Good Clinical Practice (GCP) training to maintain safety and quality in research.
2. All Monash Health employees who are involved in conducting or supporting research at Monash Health maintain an up-to-date record of their current Good Clinical Practice (GCP) training certificate on the Monash Health Learning Portal http://learning.monashhealth.org.
3. All external researchers who are involved in conducting or supporting research at Monash Health maintain an up-to-date record of their current Good Clinical Practice training certificate (GCP) and provide evidence of this to Research Support Services.

STANDARD REQUIREMENTS

When undertaking any clinical interaction with a patient, staff are expected to:

- Perform routine hand hygiene. Refer to the Hand Hygiene Procedure.
- Introduce themselves to the Patient and Carer/ Family if in attendance
- Check patient identification. Refer to the Patient Identification Procedure.
- Obtain consent as per the Consent to Medical Treatment Procedure.
- Keep the patient/carer informed and involve them in decision making.
- Document interaction in the electronic medical record or health record using black pen; including date, time, signature, and designation.

PROCEDURE

1. Monash Health Employees

Upon commencing employment in a position that involves conducting or supporting research at Monash Health, it is the responsibility of the employee's line manager to:

i. Ensure the employee has completed a TransCelerate recognised Good Clinical Practice (GCP) training course. Monash Health prefers the Australian Clinical Trials Education Centre (ACTEC) GCP course, that is Transcelerate recognised and free of cost. ACTEC will be providing regular reports to Monash Health on completions. We advise all new employees to complete their training through ACTEC, and current staff to complete refresher training through ACTEC. If a staff member has completed training elsewhere this is acceptable. A list of acceptable courses is in "Related Documentation."
ii. Ensure the employee has uploaded a copy of the certificate and entered the correct date of completion on the Monash Health Learning Portal http://learning.monashhealth.org
iii. Verify the Certificate and the date completed.
iv. Ensure that the employee completes a refresher course every 3 years, and that the certificate is verified and uploaded on the Monash Health Learning Portal http://learning.monashhealth.org.

2. External Researchers (including student researchers and honorary researchers)

Prior to submission of an application for Human Research Ethics and Governance approval, a researcher must:

i. Complete a TransCelerate recognised Good Clinical Practice (GCP) course. A list of acceptable is courses is in "Related Documentation".
ii. Provide a copy of the certificate of completion with the application for Human Research Ethics and Governance review to Research Support Services.
iii. Provide a certificate of completion of refresher training every 3 years for the duration of the study, from the date of expiration.

3. Monitoring of Compliance

Managers are responsible for ensuring staff have a current GCP certificate on the Monash Health Learning Portal and that the date completed has been entered correctly. Research Council is responsible for monitoring compliance with this procedure as required under the National Clinical Trials Governance Framework.

Please note that if Monash Health employees register for the ACTEC course, they are accepting the terms and conditions of ACTEC, including Monash Health receiving regular reports on course completions for compliance monitoring.

RELATED DOCUMENTATION

A full list TransCelerate recognised Good Clinical Practice (GCP) training providers can be found through this link:
http://www.transceleratebiopharmainc.com/gcp-training-attestation/training-providers/

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

This hands-on course is currently funded by Monash Partners for Monash Health employees and incurs a fee for employees outside of Monash Partners' partner organisations.

SCRS
https://myscrs.org/membership/gcp-training/
This online course is free for SCRS members. All Monash Health staff are eligible to become members of SCRS.ARCS

https://www.arcs.com.au/
This online course incurs a fee.

Peter MacCallum Cancer Centre
https://www.petermac.org/education/research-education/clinical-research-education
This hands-on course incurs a fee.

National Institute of Health course.
https://gcp.nidatraining.org/
This is a free online course.

BACKGROUND

Good Clinical Practice is an international ethical and scientific quality standard for designing, conducting, recording, and reporting trials that involve the participation of human subjects. The standard provides public assurance that the rights, safety, and wellbeing of trial participants are protected consistent with the principles that have their origin in the Declaration of Helsinki.1

In the Australian context, personnel involved in conducting or supporting the conduct of clinical research are expected to hold current GCP training as a minimum requirement. This is detailed consistently in a range of national guideline documents (see section on Key Standards).

KEY STANDARDS, GUIDELINES OR LEGISLATION

Australian Commission on Safety and Quality in Health Care – National Clinical Trials Governance Framework and User Guide

Australian Code for the Responsible Conduct of Research

National Statement on Ethical Conduct in Human Research

Therapeutic Goods Administration – Australian Clinical Trial Handbook

KEYWORDS

Human Research, Ethics, Research Governance, Good Clinical Practice, Researchers, Human Research Ethics Committee, Training.

[1] Nuremberg Declaration of Helsinki (1964) BMJ 1996; 313 doi: https://doi.org/10.1136/bmj.313.7070.1448a (Published 07 December 1996) Cite this as: BMJ 1996;313:1448.

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