

Who must comply with this procedure?

Principal Investigators and staff conducting research at, or under the auspices of Monash Health.

Training requirements are Mandatory for Monash Health staff and personnel who have honorary appointments at Monash Health. Non-Monash Health Principal Investigators who submit projects that are reviewed by the Monash Health Human Research Ethics Committee (HREC) are also required to undertake GCP training.

This policy applies in the following setting:

This procedure is applicable to all Monash Health staff involved in interventional research projects and Non Monash Health Principal Investigators staff who have received ethical approval for interventional research.

1. All researchers listed on a research application submitted for ethics or governance approval from 1st January 2018 must submit a certificate attesting to the successful completion of a Good Clinical Practice (GCP) course.
2. The type of certificate must be in accordance with the framework listed below and all investigator GCP certificates must be received by Research Support Services in order for the project to receive ethics or governance approval.
3. Personnel who are listed on the National Ethics Application Form (NEAF), Human Research Ethics Application (HREA) or Site Specific Application Form (SSA) as well as researchers who join the project after approval will be required to undertake GCP training.
4. Validity of GCP certificates will be taken as being either the expiry date listed on the certificate or 3 years from the date of issue of the certificate if no expiry date is listed.
5. If a project is continuing beyond the expiry date of the GCP certificate, resubmission of a new certificate will only be required if a new project is submitted by the investigator(s) for ethics or governance approval.
6. The framework under which GCP training is required is listed below.
7. **Interventional Clinical Drug or Device Trials**
TransCelerate accredited International Council on Harmonisation – Good Clinical Practice (ICH-GCP) course.
8. A [full list](#) of providers is available
9. **Australian TransCelerate accredited courses include:**
[Monash Partners – Monash University](#) -This hands on course is currently funded by Monash Partners for Monash Health employees.

[ARCS](#) This online course incurs a fee.

[Peter MacCallum Cancer Centre](#) This hands on course incurs a fee.

[Research Excellence Training](#) This hands on course incurs a fee.

[Murdoch Children's Research Institute](#) This hands on course incurs a fee.

10. **Non Drug or Device Interventional Research**

Any TransCelerate accredited ICH-GCP course listed above or

[National Institute of Health course](#). This is a free online course.

Researchers may apply for assessment of GCP courses required to be undertaken for projects on a case by case basis by application to the Research Governance Manager. This may include university or research institute courses that will be considered on a case by case basis.

11. **Non Interventional Research**

This procedure does not currently apply to non-interventional research.

Monash Partners are developing courses to include aspects of non interventional research which are likely to be acceptable when these courses become available.

An amendment may be made to this policy to incorporate non interventional research.

Where researchers from partner organisations (e.g Monash University, Deakin University) submit GCP certificates, they will be considered on a case by case basis.

Keywords or tags

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

Document Management

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