Online GCP training supplement

On-Line Course Options

You must familiarise yourself with Australian research-specific requirements (see links below) as well as national and state health and privacy requirements.

Note: Any Good Clinical Practice (GCP) training completed must meet the minimum criteria set out by TransCelerate Biopharma Inc. and must appear on the list of courses located on the TransCelerate Biopharma Inc. website.

TransCelerate BioPharma is a collaboration of 20 global pharmaceutical companies aiming to streamline research).

Online GCP training courses:

Note 1: On completion of the course, print out the certificate of completion for your files and forward a copy to the Office for Research.

Note 2: For online training that is internationally focused and where some information is either incorrect or not applicable for Australian researchers, refer to the information provided on page 2 of this document for Australian updates.

The Global Health Network Training Course (free)

This ICH E6 (R2) GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate

Go to: https://globalhealthtrainingcentre.tghn.org/ich-good-clinical-practice

NIDA Clinical Trials Network (free)

The free online GCP course conducted by the NIDA Clinical Trials Network (part of the National Institutes of Health in the US) is now TransCelerate-recognised.

Go to https://gcp.nidatraining.org

ARCS Australia (Fee to be paid by the researcher staff's department)

ARCS Australia conducts on-line training and certification suitable for the Australian context.

Go to: https://www.arcs.com.au/events/events-calendar

PRAXIS Australia (Fee to be paid by the researcher staff's department)

Praxis Australia conducts on-line training and certification suitable for the Australian context.

Go to: https://praxisaustralia.com.au/learning

Mandatory Requirements for all human research:

National Statement on Ethical Conduct in Human Research (NHMRC, 2007 updated 2018) https://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

Australian Code for the Responsible Conduct of Research (NHMRC, 2018) along with several supporting guidance documents (Managing and Investigating Potential Breaches; Authorship; management of Data and Information in Research; Peer Review; Disclosure of interests and management of conflicts of interest)

https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018

The Royal Melbourne Hospital

Mandatory Requirements for drug/device clinical trials (but recommended for all research):

Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice ICH E6(R2) - annotated with TGA comments https://www.tga.gov.au/resources/publication/publications/ich-guideline-good-clinical-practice

NHMRC Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods (EH59, November 2016) https://www.nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods

Replacement Information for On-line US GCP Courses that are Incorrect and/or Not Applicable for Australia

1) Ethical review by an Institutional Review Board [IRB]

In Australia, this body is known as the Human Research Ethics Committee [HREC]

Australia adheres to national regulations. Two important areas of difference for Australian research conduct are the:

a. Data and document retention periods

The National Statement (2018 update) specifies that research data should be made available for future research projects, except where there are justifiable ethical reasons for not doing so. If data and documents are not to be retained, you must be aware of the applicable minimum retention period.

Minimum retention periods are determined by the type of research and relevant legislation, code and guidelines. Where more than one legislation/code/guideline is relevant, the one with the longest retention period applies. Examples for Australia (but discuss with the RCH Research Ethics Governance office their requirements for a particular project):

- All research – in general at least 5 years from publication [AUSTL CODE FOR RESPONSIBLE CONDUCT OF RESEARCH 2018]
- All research – retention of any new health data for at least 7 years (for adults) and until age 25 for children [VIC HRA]
- Clinical trials - must archive for at least 15 years post-trial completion [TGA] or until child aged 25 years (whichever is the later) [VIC HRA]
- Gene therapy research data- must retain permanently [AUST CODE 2018]
- Research that has community or heritage value - must retain permanently, preferably within a national collection [AUST CODE 2018]

b. Composition and processes of the independent ethical review committee

Refer instead to the National Statement.

2) Informed Consent

a. **Consent of minors**

US regulations require written assent from minors but assent is not recognised in Australia. Instead, informed consent should be obtained from mature minors (in conjunction with consent from the parent/guardian). Young children should also be provided with information in a format that is appropriate to their age and comprehension.

b. **Translation**

Where a translator is involved in obtaining consent, US regulations require that a written translation of the information and consent document be provided. In Australia:

- a written translation is not mandatory
- the translator must be accredited – for verbal translations the translator must sign the consent form
- an impartial witness (who may be the translator) must be involved in the full discussion and must sign the consent form.

c. **Illiteracy**
Under US regulation, illiterate English-speaking participants can, rather than signing, "make their mark". In Australia, where a participant or parent/legal guardian is unable to read the informed consent documents, an impartial witness must be involved in the full discussion and must sign the consent form.

d. **Privacy in research**
Reference is usually made to the following US Acts and Rules which do not apply to Australia: Health Insurance Portability and Accountability Act (HIPAA); Privacy Rule for medical records research; and the Family Educational Rights and Privacy Act (FERPA) for student education records. You must make yourself familiar with Australian national and state legislation.

e. **Safety reporting**
Those working in Australian clinical trials must be thoroughly familiar with the NHMRC guidance "Safety monitoring and reporting in clinical trials involving therapeutic goods (EH59, November 2016) https://nhmrc.gov.au/about-us/publications/safety-monitoring-and-reporting-clinical-trials-involving-therapeutic-goods