RE: ICH Good Clinical Practice (E6) R2 *online module updates*

The key guidelines and frameworks within Australia that govern the setup and conduct of human research include:

- *National Statement on Ethical Conduct in Human Research* 2007 (Updated 2018). (NHMRC, the Australian Research Council and Universities Australia, 2018).

  Guidelines and tools related to assisted reproductive technology; clinical ethics; embryo research, stem cells and human cloning; organ and tissue donation and transplantation; privacy; research involving Aboriginal and Torres Strait Islander peoples can be found on the NHMRC website under ethical issues and further resources.

- *The Australian Code for the Responsible Conduct of Research* (NHMRC, the Australian Research Council and Universities Australia, 2018)

- *Australian clinical trial handbook. Guidance on conducting clinical trials in Australia using 'unapproved 'therapeutic goods (TGA, Version 2.2, October 2018)* [replaces the 2004 Access to unapproved therapeutic goods - Clinical trials in Australia].

  The document provides guidance on the legislative, regulatory and GCP requirements when conducting clinical trials in Australia using 'unapproved' therapeutic goods. This includes the two schemes under which clinical trials involving 'unapproved' therapeutic goods may be conducted in Australia:

  - Clinical Trial Notification (CTN) scheme
  - Clinical Trial Exemption (CTX) scheme

  Clinical trials that do not involve the use of 'unapproved' therapeutic goods are not subject to the requirements of the CTN and CTX schemes.

- *Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice (ICH GCP E6 (R2) Annotated with TGA comments (TGA, 2016)* [replaces the Note for guidance on good clinical practice CPMP/ICH/135/95].

- Guidance: *Safety monitoring and reporting in clinical trials involving therapeutic goods (NHMRC, 2016)*.

- *Risk-based Management and Monitoring of Clinical Trials Involving Therapeutic Goods (NHMRC, 2018)*.

- *Reporting of Serious Breaches of Good Clinical Practice (GCP) or the Protocol for Trials Involving Therapeutic Goods (NHMRC, 2018)*.

- *Data Safety Monitoring Boards (DSMBs) (NHMRC, 2018).*

- *Competencies for Australian Academic Clinical Trialists (NHMRC, 2018).*