Clinical Trials Policy MPF1352

Schedule 1

Applicable Commonwealth and State or Territory laws, University policies and processes, guidelines, codes of conduct and contractual requirements and any requirements of regulatory authorities or responsible HREC relevant to the particular Clinical Trial Activity, including:

a) any laws, guidelines or codes of conduct in relation to the collection, use, storage and security or disclosure of any personal information and/or health information;

b) ICH Guideline for Good Clinical Practice;

c) ISO 14155: Clinical investigation of medical devices for human subjects - Good clinical practice;

d) the NHMRC National Statement on Ethical Conduct in Human Research (2007 and all updates), and any other relevant NHMRC publication or guideline that relates to human research;

e) AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research

f) Good Clinical Data Management Practices standard; and

g) the principles that have their origins in the Declaration of Helsinki adopted by the World Medical Association in October 1996 (as accepted by the Australian Government).

Governance of Clinical Trials in Australia is complex and involves compliance with multiple acts and authorities depending on the nature of the trial, https://www.australianclinicaltrials.gov.au/clinical-trials-toolkit#overlay-context=home

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