ST VINCENT'S HOSPITAL MELBOURNE
A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

RESEARCH GOVERNANCE UNIT
St. Vincent's Hospital (Melbourne)
Caritas Christi Hospice
St. George's Health Service
Prague House
Cambridge House
DePaul House

INTERVENTIONS AND THERAPIES

Statement of Intent and Outcomes

The St Vincent's Hospital Human Research Ethics Committee is committed to fulfilling Section 3.3 of The National Statement on Ethical Conduct in Human Research (2007, updated 2018) by ensuring that clinical trials and non-clinical trials involving risk are reviewed by a fully constituted Human Research Ethics Committee.

Definitions

Clinical Trial is defined as a form of human research designed to find out the effects of an intervention, including a treatment of diagnostic procedure. A clinical trial may involve testing a drug, a surgical device or procedure, other therapeutic procedures and devices, a preventative procedure or a diagnostic device or procedure.

Procedure

To ensure the appropriate assessment of clinical and non-clinical trials which involve risk, all members of the St Vincent's Hospital Human Research Ethics Committee must be familiar with, and apply the principles of The National Statement on Ethical Conduct in Human Research (2007, updated 2018), and in particular, Section 3.3, to the ethical review of research.

To ensure the appropriate assessment of risk, the Committee must remain compliant with the minimum composition requirements as stipulated within the National Statement. Furthermore, all members of the Human Research Ethics Committee must be familiar with The National Statement on Ethical Conduct in Human Research (2007, updated 2018), and in particular, Sections 2.1.1 to 2.1.8.

All research involving a drug, device, imaging technique, surgical procedure or other intervention that is deemed to carry risk must be referred to the HREC for assessment. In the event further expertise is required, the HREC and / or Chair may co-opt individuals both internally and externally to obtain advice.

The HREC must also review the Participant Information and Consent Form to ensure participants are fully informed of the risks, benefits, study procedures and legal/administrative implications prior to consenting to participate, as per procedures 2.1, and 2.2.

For all clinical trials which require Clinical Trial Notification (CTN) to the Therapeutic Goods Administration, a CTN Draft form must be submitted at the time of review.

For all multisite clinical trials which have been approved by the streamlined ethical review process, procedure 5.2 must be followed to ensure adherence to local, national and international guidelines are followed.

Associated Procedures/Instructions

Procedure 2.2 – Obtaining and Honouring Consent
Procedure 2.3 – Qualifying or Waiving Conditions for Consent

Reference Documents

- The National Statement on Ethical Conduct in Research Involving Humans in accordance with the NHMRC Act, 2007 (Cth) – Updated 2018
- Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders (2018)
- Australian Code for the Responsible Conduct of Research (2007)

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