

HREC Standard Operating Procedure

3.3 Interventions and Therapies

Statement of Intent and Outcomes

The St Vincent's Hospital Melbourne (SVHM) Human Research Ethics Committee (HREC) is committed to fulfilling Section 2.1 of the National Statement on Ethical Conduct in Human Research (2023) by ensuring that clinical trials and non-clinical trials involving risk are reviewed by a fully constituted HREC.

Definitions

Clinical Trial is defined as a form of human research designed to find out the effects of an intervention, including a treatment or 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.

Procedures

To ensure the appropriate assessment of clinical and non-clinical trials which involve risk, all members of the SVHM HREC must be familiar with, and apply the principles of the National Statement on Ethical Conduct in Human Research (2023), and in particular Sections 2.1 and 3.1, to the ethical review of research.

To ensure the appropriate assessment of risk, the HREC must remain compliant with the minimum composition requirements as stipulated within the National Statement. Furthermore, all members of the HREC must be familiar with the National Statement on Ethical Conduct in Human Research (2023), and in particular, Sections 2.1.1 to 2.1.5.

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 Human Research (2023)
- 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 (2018)

Authorised by: Dr Megan Robertson, Director of Research



Megan ROBERTSON (Jul 1, 2024 09:49 GMT+10)

Author: Alexandra Braun, HREC Executive Officer

Date Issued: 2011

Date Revised: 2024

Next Review: 2027






3.3 Interventions and Therapies

Final Audit Report

2024-06-30

Created:	2024-06-30
By:	Sue Ngeow (sue.ngeow@svha.org.au)
Status:	Signed
Transaction ID:	CBJCHBCAABAAriPhD5JJsUP1I4wSvEQHgCP8BSbROKKw

"3.3 Interventions and Therapies" History

-  Document created by Sue Ngeow (sue.ngeow@svha.org.au)
2024-06-30 - 11:29:20 PM GMT
-  Document emailed to Megan ROBERTSON (megan.robertson@svha.org.au) for signature
2024-06-30 - 11:30:07 PM GMT
-  Email viewed by Megan ROBERTSON (megan.robertson@svha.org.au)
2024-06-30 - 11:49:06 PM GMT
-  Document e-signed by Megan ROBERTSON (megan.robertson@svha.org.au)
Signature Date: 2024-06-30 - 11:49:15 PM GMT - Time Source: server
-  Agreement completed.
2024-06-30 - 11:49:15 PM GMT