

HREC Standard Operating Procedure

2.3 Qualifying or Waiving Conditions for Consent

Statement of Intent and Outcomes

The St Vincent's Hospital Melbourne (SVHM) Human Research Ethics Committee (HREC) is committed to fulfilling Section 2.3 of the National Statement on Ethical Conduct in Human Research (2023) by ensuring that the obtainment of consent is appropriate. However, in some cases, it may be more appropriate for the Ethics Committee to waive consent, or provide limited disclosure.

Definitions

Consent is defined as a voluntary decision based on the provision of sufficient information and adequate understanding of both the proposed research, and the implications of participation.

Limited disclosure is defined as not describing the aims of methods of observational research in public contexts, to actively conceal information and planning deception of participants.

Procedure

Section 1 of the National Statement on Ethical Conduct in Human Research (2023) requires that the principles and values of respect be extrapolated to the consent process, to ensure that research participants have the ability to make their own decisions, based on the provision of sufficient, accurate and comprehensible information.

However, the requirement for consent may be justifiably waived in certain circumstances. In this case, research participants will not know that they (or their tissue/data) are involved in a research project. Waiving of consent for research purposes must be considered on an individualised basis by the HREC in line with the Privacy Act (1988) and the Health Records Act (2001) (Vic).

A request can be made to waive the need to obtain participant consent; however, the application must contain an appropriate justification in line with sections 2.3.5 to 2.3.12 of The National Statement.

Limited disclosure of the aim and method may also be justified for certain studies, when full disclosure of the research may jeopardise the outcomes. All requests for limited disclosure must be considered individually by the HREC, in line with sections 2.3.1 to 2.3.4 of the National Statement.

To ensure the appropriate ethical assessment of the consenting process and those circumstances where consent may be justifiably waived, all members of the SVHM HREC must be familiar with, and apply the principles of the National Statement, and in particular, Sections 2.3.1 to 2.3.12 to the ethical review of research.

The decision of approve a waiver of consent must be specifically discussed at the HREC meeting, and formally minuted. The approval letter must also specifically mention the approval of a waiver of consent.

In accordance with the National Statement 2.3.12 and to ensure transparency, the title of every project that involves a waiver of consent will be published on the Research Governance Unit website, with a summary submitted to the Health Services Commissioner of Victoria through the mandated process of annual reporting.

Associated Procedures/Instructions

Procedure 1.1 – Application of Values and Ethical Conduct

Procedure 2.1 – Obtaining and Honouring 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)
- Privacy Act (1988)
- Health Records Act (2001) (Vic)

Authorised by: Dr Megan Robertson, Director of Research



Megan ROBERTSON (Jul 1, 2024 09:54 GMT+10)

Author: Alexandra Braun, HREC Executive Officer

Date Issued: 2011

Date Revised: 2024

Next Review: 2027






2.3 Qualifying or Waiving Conditions for Consent

Final Audit Report

2024-06-30

Created:	2024-06-30
By:	Sue Ngeow (sue.ngeow@svha.org.au)
Status:	Signed
Transaction ID:	CBJCHBCAABAA-RTF271bTKDwajlKvim9Ludm2fEZo3GA

"2.3 Qualifying or Waiving Conditions for Consent" History

-  Document created by Sue Ngeow (sue.ngeow@svha.org.au)
2024-06-30 - 11:17:10 PM GMT
-  Document emailed to Megan ROBERTSON (megan.robertson@svha.org.au) for signature
2024-06-30 - 11:17:29 PM GMT
-  Email viewed by Megan ROBERTSON (megan.robertson@svha.org.au)
2024-06-30 - 11:54:23 PM GMT
-  Document e-signed by Megan ROBERTSON (megan.robertson@svha.org.au)
Signature Date: 2024-06-30 - 11:54:31 PM GMT - Time Source: server
-  Agreement completed.
2024-06-30 - 11:54:31 PM GMT