HREC Standard Operating Procedure

2.2 Obtaining and Honouring Consent

Statement of Intent and Outcomes

The St Vincent's Hospital Melbourne (SVHM) Human Research Ethics Committee (HREC) is committed to fulfilling Sections 2.1 and 2.2 of the National Statement on Ethical Conduct in Human Research (2023) by ensuring that all research protocols include an appropriate method of obtaining and honouring the informed consent of participants.

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.

Unspecified consent is defined as the consent to use collected data or tissue for unrestricted future use.

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 ensure research participants have the ability to make decisions based on the provision of sufficient, accurate and comprehendible information.

To ensure the appropriate assessment of the consent process, 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 2.2.1 to 2.3.8, to the ethical review of research.

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 on Ethical Conduct in Human Research (2023). Please see procedure 2.3 – Qualifying or Waiving Conditions for Consent.

Research projects at SVHM must obtain written informed consent using a Participant Information and Consent Form (PICF). The PICF must be written using the applicable standard template as per the Victorian Department of Health. Exceptions include projects which involve implied consent through the return of a questionnaire, or other scenarios which are appropriately justified and deemed appropriate by the HREC.

Discretion may be used by the HREC and/or Chair in determining the appropriateness of each individual method of obtaining informed consent, due to the differing requirements of each participant cohort. Generally however, it must be ensured that the PICF is written using

a reading age of 14 years to ensure participants have a reasonable chance of understanding the information provided. Further assistance should also be provided to participants where applicable, including the use of an interpreter, or assistance to read and discuss the document.

Potential participants must be provided with sufficient time to make an informed decision, and to discuss the document with family, friends or other professionals as appropriate. If the participant will not be provided with at least 24 hours, a justification should be provided.

All PICF's must specifically state that research is voluntary, and that participants are free to withdraw at any stage without having to provide a reason, and without detriment.

Consent to enter a research study must be obtained in writing on an ethically approved PICF prior to the commencement of any research related activities (unless previously approved by the HREC). This consent must be honoured at all times by all parties involved in the research.

Consent may be:

1. Specific and limited to the project under consideration
2. Extended and given for the use of data and tissue for future use. This must be closely related to the original project and/or the general area of the initial research.
3. Unspecified for the use of information for unrestricted future research.

Where unspecified consent is sought, the PICF must detail the terms and wide-ranging implications associated with participation as comprehensively as possible (including examples). This must also be accompanied by a statement which informs participants that the complete scope of potential use is unknown, but that all subsequent, unrelated work involving the information in question will be reviewed and approved by an appropriately constituted HREC prior to use.

If any changes are made to the research protocol which involves the participant in any way, an amendment to the PICF must be submitted for ethical review and approval, and the participant re-consented in a timely manner. The use of an addendum is strongly encouraged for all safety and procedural/administrative updates to avoid the duplication of irrelevant information.

For all research involving optional sub-components, it is encouraged that an additional PICF be used to ensure information is communicated and consented to with specificity. However, discretion may be used if the additional components are related and well communicated in the main PICF using specific subheadings for the consent of optional components. This must also be reflected within the consent form.

For all research involving an optional sub-component for genetic analyses (regardless of capacity) a separate PICF must be created and submitted to the HREC for approval.

Once consent has been obtained, the original document must be kept in the site study file, with a copy provided to the participant for their records. A copy should also be kept in the patient's medical record. The retention of these documents must comply with the most recent State and Commonwealth regulations at the time, which specifies a minimum of 7 years for qualitative research and 15 years for quantitative/clinical research.

Site Specific Consent Requirements

All site specific PICF's must display the SVHM logo both on the top right hand corner of the front page and again on the consent form.

Site Specific PICF's must be written in second person singular (i.e. as if you were speaking to the reader) using simple language consistent with a reading age of 14. All medical, scientific or technical terms must be explained.

A separate PICF must be written for any additional and optional genetic analysis (pharmacokinetics, pharmacogenetics/genomics, pharmacodynamics etc), as well as additional and optional tissue collection/banking or procedures which are in addition to the core study protocol. It must clearly state that these types of procedures are optional and additional to the main study, and that participants can still take part in the main study without having to participate in the optional components.

As SVHM is a Roman Catholic Hospital, the Code of Ethical Standards for Catholic Health and Aged Care Service in Australia (2001) must be followed. As a result, the following standard phrase must be used in all site specific PICF's where the avoidance of pregnancy is required:

"The effects of [Name of investigational product] on the unborn child and on the newborn baby are not known. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant or trying to become pregnant, or breast-feeding. If you are female and child-bearing is a possibility, you will be required to undergo a pregnancy test prior to commencing the research project. If you are male, you should not father a child or donate sperm for at least [number] months after the last dose of study medication.

Both male and female participants must avoid pregnancy during the course of the research and for a period of [number] months after completion of the research project. You should discuss effective methods of avoiding pregnancy with your study doctor.

[For female participants] If you do become pregnant whilst participating in the research project, you should advise your study doctor immediately. Your study doctor will withdraw you from the research project and advise on further medical attention should this be necessary. You must not continue in the research if you become pregnant.

[For male participants] You should advise your study doctor if you father a child while participating in the research project. Your study doctor will advise on medical attention for your partner should this be necessary."

The following optional wording will be accepted on SVHM site-specific PICFs. This wording has been noted by SVHS Bioethics Committee and is acceptable to SVHM HREC:

"Because of the unknown risks of this study medication, it is important that you do not become pregnant during this trial. For legal reasons, the pharmaceutical company requires us to provide you with the following information about methods of avoiding pregnancy. Not all of this information is endorsed by [insert site name] nor reflects its ethical standards as a Catholic hospital. You should discuss with the study doctor and/or your own doctor and ethical advisor an effective way for you to avoid pregnancy that is in keeping with your beliefs and values"

Only if needed, the following wording may be added to the above pregnancy clause: "*Sexually active women who are potentially fertile will be excluded unless they are using a medically reliable method of preventing conception."*(Examples of medically reliable methods of preventing conception must not be included.)

It is acceptable within Catholic teaching to counsel a woman and/or her partner to avoid becoming pregnant when either the woman or partner is undergoing treatment that might affect an embryo/foetus. It is not acceptable to counsel a woman or her partner to use a contraceptive for the express intention of making intercourse infertile. Therefore, statements to this effect must not be included.

The following standard format tables must also be used when writing a site specific PICF for SVHM:

For matters relating to research at the site at which you are participating, the details of the local site complaints person are: Clinical contact person

Position	Patient Liaison Officer at St Vincent's Hospital Melbourne
Telephone	(03) 9231 1954
Email	PLO@svhm.org.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC name	St Vincent's Hospital Melbourne HREC
Position	HREC Executive Officer
Telephone	(03) 9231 6970
Email	Research.ethics@svhm.org.au

Consent Requirements for Multisite Applications

For multisite applications the PICF must be presented for review in the format of a "master" template. This is a skeleton document which contains all study related information, but omits all site specific information including the name of the site, site personnel and contact numbers.

Once approved, this generic document should be sent to each of the other participating centres who will enter their site specific information and create a 'governance version'.

All PICF's must contain the version number, date and page number (page x of x) within the header or footer for accountability. Please note that multi-site studies should contain a reference to the master document, as well as the site specific governance version.

Example:
Master Version 1, dated xx/xx/xxxx

Local Governance Version 1, dated xx/xx/xx *Page xx of xx*

If a site has a particular requirement to deviate from the master, a site specific version should be created and submitted to the HREC for ethical review and approval prior to use. This would then become a site specific master document, with its own master version and date.

Associated Procedures/Instructions

Procedure 2.3 – Qualifying or Waiving 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 09:54 GMT+10)

Author: Alexandra Braun, HREC Executive Officer

Date Issued: 2011

Date Revised: 2024 **Next Review:** 2027

2.2 Obtaining and Honouring Consent

Final Audit Report 2024-06-30

Created:	2024-06-30
By:	Sue Ngeow (sue.ngeow@svha.org.au)
Status:	Signed
Transaction ID:	CBJCHBCAABAAS8SoobMGsDtDbkePFCFR9TWQGikAkm_4

"2.2 Obtaining and Honouring Consent" History

Document created by Sue Ngeow (sue.ngeow@svha.org.au)
2024-06-30 - 11:15:48 PM GMT

Document emailed to Megan ROBERTSON (megan.robertson@svha.org.au) for signature
2024-06-30 - 11:16:19 PM GMT

Email viewed by Megan ROBERTSON (megan.robertson@svha.org.au)
2024-06-30 - 11:54:46 PM GMT

Document e-signed by Megan ROBERTSON (megan.robertson@svha.org.au)
Signature Date: 2024-06-30 - 11:54:57 PM GMT - Time Source: server

Agreement completed.
2024-06-30 - 11:54:57 PM GMT