



SITE SPECIFIC REQUIREMENTS

St Vincent's Hospital has several site specific requirements which must be addressed when submitting an application. The below information has been divided into the following sections:

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1. HUMAN RESEARCH ETHICS APPLICATION FORM (HREA)

The purpose of the ethics application form is to enable the HREC to consider whether the research project is ethically and scientifically acceptable, and whether it meets the requirements of the National Statement on Ethical Conduct in Human Research (2007).

There are currently two versions of the HREA available.

- **ERM Version:** <https://au.forms.ethicalreviewmanager.com/Account/Login>
- **NHMRC Version:** <https://hrea.gov.au/>

Both forms are the same 'HREA' forms, which mean you must log in, complete the form electronically, and save it on the server – it cannot be saved to your local computer for amendment.

Only the NHMRC Version is able to generate the XML File that can be imported to both the ERM and Online Forms.

Please note SVHM HREC will only accept the ERM version of the HREA. All Ethics application must be submitted via the ERM.

HREA Project Overview Section

Section 1 – Core Information

Section 2 – Research Details and Participants

Section 3 - Data and Privacy

Section 4 - Attachments and Declaration

Section 1

Include the site(s) St Vincent's Hospital (Melbourne) (SVHM) HREC is responsible for:

- SVHM
- St Vincent's Private Hospital**
- Other (please specify)

**Researchers are required to submit a Governance application to St Vincent's Private Hospital once ethics approval has been granted by SVHM HREC.

Researchers are reminded that:

1. Prospective study participants at St Vincent's Hospital (Melbourne) must be approached in the first instance by a staff member of St Vincent's and only with the permission of the patient's treating clinician.
2. Only those investigators who are specifically listed within the application form as being able to obtain informed consent should do so. Obtaining informed consent must not be delegated to anyone else.

Section 2

- *Guidance on answering: "Will your research involve participation of any of the following?"*

Participation of members of defined populations in research occurs as a consequence of recruiting them as a research cohort or as individuals whose participation can be anticipated as being likely or foreseeable. For example, a research project may target people who have a specific disease, disability or impairment or who are migrants from a particular country or it may, because of the setting and nature of the research, be likely to include individuals from these groups.

It is also possible that individuals from a defined population will be recruited into a research project without in any way being targeted by virtue of their being present in the general population from which the participants are being recruited. This is often referred to as 'coincidental' recruitment.

This distinction is important, as the purpose of considering the ethical implications of recruiting members of defined populations, whether they are considered to be 'vulnerable populations' or not, is to address those implications as they relate to the likely or foreseeable recruitment of these individuals, not as they relate to the coincidental recruitment of these individuals.

Researchers should use common sense and a 'project-specific' approach in applying this principle: if it is foreseeable that a portion of the projected participants in a specific research project will be eligible for recruitment as a result of a defined population being specifically targeted or as a result of demographic or other factors, then those ethical considerations that are specific to that group should be addressed. Whereas, if this is not the case, then the fact that it is conceivably possible that individuals who are members of a group will be recruited, but the project is not directed toward that group and the numbers of these individuals will be small, then the ethical considerations that are specific to that group may not need to be addressed.

In Australia, the issue of intended, likely, foreseeable or coincidental recruitment is of particular importance when considering the inclusion of Aboriginal and Torres Strait Islander people in research. The ethics committees that are established to perform review of research that targets or is likely to involve Aboriginal and Torres Strait Islander people have valuable guidance on when and how to apply the guidelines that are appropriate to this research, including definitions that may be useful for researchers.

- *HREA Risk Section*

Research teams should be aware of the *St Vincent's Monitoring Human Research Policy* which details the requirements for safety reporting

Section 3

- a) **Personal information** is defined in the [Privacy Act 1988](#) as information or an opinion about an identified individual, or an individual who is reasonably identifiable:
 - Whether the information or opinion is true or not; and
 - Whether the information or opinion is recorded in a material form or not.

- b) **Sensitive information** is defined in the [Privacy Act 1988](#) as:
 - information or an opinion about an individual's:
 - racial or ethnic origin; or
 - political opinions; or
 - membership of a political association; or
 - religious beliefs or affiliations; or
 - philosophical beliefs; or

- membership of a professional or trade association; or
 - membership of a trade union; or sexual orientation or practices; or
 - criminal record; that is also personal information; or
 - health information about an individual; or
 - genetic information about an individual that is not otherwise health information; or ○ biometric information that is to be used for the purpose of automated biometric verification or biometric identification; or
 - biometric templates
- c) **Health information** is defined in the [Privacy Act 1988](#) as:
- information or an opinion about:
 - the health, including an illness, disability or injury, (at any time) of an individual; or
 - an individual’s expressed wishes about the future provision of health services to the individual; or
 - a health service provided, or to be provided, to an individual; that is also personal information;
 - other personal information collected to provide, or in providing, a health service to an individual;
 - other personal information collected in connection with the donation, or intended donation, by an individual of his or her body parts, organs or body substances;
 - genetic information about an individual in a form that is, or could be, predictive of the health of the individual or a genetic relative of the individual.

Section 4

Attachments - Study team will be required to upload the protocol to the ERM

Signature – The Coordinating Principal Investigator signature is only required if the study team has selected the yes to the following question in section 1:

“Does this person have authorisation to sign the application on behalf of all members of the research team?”

If the study team does not select yes to the above question all Investigators signature will need to be collected for the study

Who can I contact for advice?

- Co-ordinating Office for Clinical Trial Research, Victorian Department of Health and Human Services (DHHS)
 Web: <https://www2.health.vic.gov.au/about/clinical-trials-and-research>
 Telephone: 03 9096 7394
 Email: multisite.ethics@dhhs.vic.gov.au
- Online Forms Helpdesk Telephone: 02 9037 8404 Email: helpdesk@infonetica.net

2. SITE SPECIFIC ASSESSMENT FORM (SSA)

The purpose of the SSA application form is to allow the SVHM Research Governance Unit to elicit information about the research project, thereby enabling it to consider whether the research meets its research governance requirements.

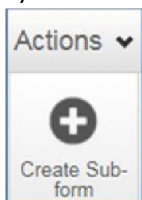
These requirements are additional to the ethical and scientific acceptability of research and include consideration of:

- the investigator's skills, training and experience
- availability and suitability of facilities and resources for the proposed research
- funding for the project
- insurance
- indemnity arrangements
- contractual arrangements
- compliance with legislative requirements.

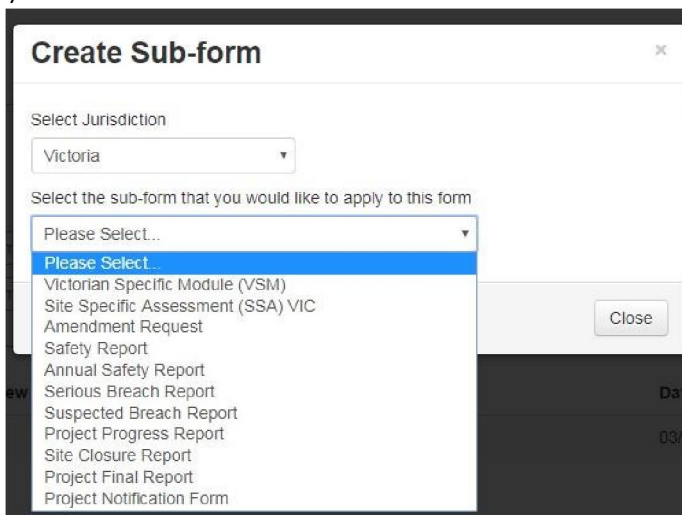
It is necessary for the investigator to complete a separate SSA application form, in addition to the ethics application form, as they seek different information and only Research Governance has responsibility for considering matters of research governance (not the HREC).

The SSA is generated via the ERM as follow:

1) Select the Create Sub Form icon



2) Select the Jurisdiction and Select SSA from the sub form

A screenshot of a 'Create Sub-form' dialog box. At the top, it says 'Create Sub-form' with a close button (X). Below that is a 'Select Jurisdiction' dropdown menu with 'Victoria' selected. Underneath is the instruction 'Select the sub-form that you would like to apply to this form'. A dropdown menu is open, showing a list of options: 'Please Select...', 'Please Select...', 'Victorian Specific Module (VSM)', 'Site Specific Assessment (SSA) VIC', 'Amendment Request', 'Safety Report', 'Annual Safety Report', 'Serious Breach Report', 'Suspected Breach Report', 'Project Progress Report', 'Site Closure Report', 'Project Final Report', and 'Project Notification Form'. A 'Close' button is visible on the right side of the dialog box.

3. VICTORIA SPECIFIC MODULE (VSM)

VSM

This is a Victoria specific document and will need to be submitted to HREC for ethical review

The VSM consist of the following section:

Section 1: *Research Involving the Recruitment of Adults who may be Incompetent to Consent -*

Section 2: *Research Involving the Collection/Use/Disclosure of Information*

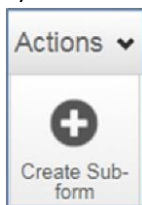
Section 3: *Research Involving the Use of Human Tissues or Blood, or Performance of Post Mortem*

There are 2 ways of obtaining the VSM form:

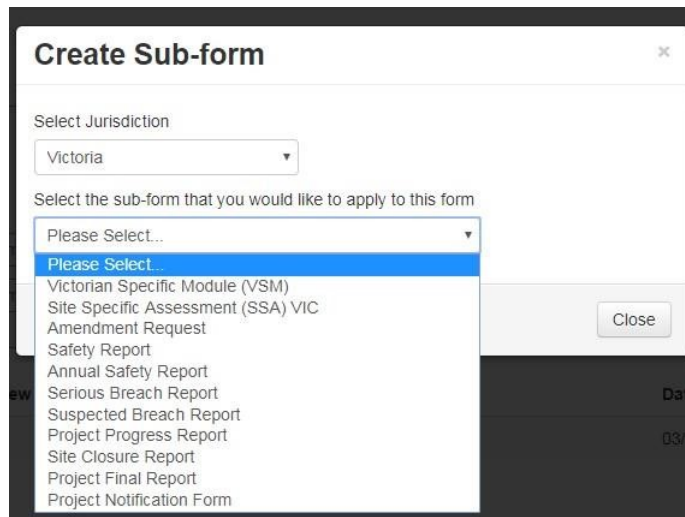
1) Download the form via the SVHM HREC website and complete the form

2) Generate and complete the VSM generated via the ERM as follow:

a) Select the Create Sub Form icon



b) Select the Jurisdiction and Select VSM from the sub form



4. USE OF IONISING RADIATION

The Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005) is designed to ensure that researchers proposing to expose research participants to ionizing radiation provide information that allows consent to be properly considered by research participants and Human Research Ethics Committees.

Section 2.1.7 of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Code of Practice: Exposure of Humans to Ionising Radiation for Research Purposes states

“The researcher must prepare a submission to the Human Research Ethics Committee (HREC) in accordance with its requirements. The submission must include the following information regarding radiation exposure:

- the reasons why it is necessary to expose research participants to ionising radiation for the purpose of the research
- the radiation dose assessment and risk assessment made by a Medical Physicist
- a statement confirming that the site at which the examination or procedure will be performed is actively involved in a relevant quality assurance program such as the programs of the Royal Australian and New Zealand College of Radiologists or of the Australian and New Zealand Association of Physicians in Nuclear Medicine
- the precautions to be taken to keep radiation exposure to a minimum
- the written information to be given to research participants relating to the doses and risks associated with the radiation exposure
- for novel uses of radiation, the arrangements for a review of radiation doses actually received and the arrangements for retention of dose records

For all studies that involve the use of Ionising Radiation the Use of Ionising Radiation Form needs to be completed.

Ionising Radiation that is NOT Addition to Standard Care

If the use of ionising radiation in research is not additional to standard care at SVHM, the following form must be used and submitted to the reviewing HREC:

- Notification to the Reviewing HREC: Use if Ionising Radiation in a Research Project

If SVHM is not the reviewing HREC - The Principal Investigator must provide a copy of the confirmation letter that the form had been reviewed by the HREC.

Ionising Radiation that is ADDITIONAL to Standard Care

If the use of Ionising radiation in research is additional to standard care at SVHM, the research team must provide a copy of the independent assessment report conducted by a Medical Physicist.

Who can I contact for advice?

- Co-ordinating Office for Clinical Trial Research, Victorian Department of Health and Human Services (DHHS)

Web: <https://www2.health.vic.gov.au/about/clinical-trials-and-research>

Telephone: 03 9096 7394 Email: multisite.ethics@dhhs.vic.gov.

5. PARTICIPANT INFORMATION & CONSENT FORM (PICF)

GENERAL

All PICFs submitted for review must incorporate the format, layout and standard phrases contained within the PICF templates available from the following website

<https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/how-to-make-an-hrec-application-for-clinical-trials>

All St Vincent's Hospital PICFs must incorporate the SVHM logo in the top right hand corner of the front page, as well as on the consent page.

All PICFs 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.

HEADERS / FOOTERS

All PICFs 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:

[Protocol No][Site] Specific PICF [type eg. Main] Ver. X.X Date DD/MM/YYYY [Site Specific Template]
[Protocol No]National Mutual Acceptance PICF Ver. X.X Date DD/MM/YYYY [Master Template]
Page xx of xx

Form for Withdrawal of Participation

All PICFS must either have the form for withdrawal of participation in the PICFs or as a separate document for submission.

SITE SPECIFIC STANDARD PHRASES

Complaints and Research Participant Rights

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 approving this research and HREC Executive Officer details

Reviewing HREC name	St. Vincent's Hospital Melbourne HREC
Position	HREC Executive Officer
Telephone	03 9231 2394
Email	research.ethics@svhm.org.au

Local HREC Office Contact (Single Site- Research Governance Officer)

Name	St. Vincent's Hospital (Melbourne) Human Research Ethics Committee
Position	HREC Executive Officer
Telephone	(03) 9231 2394
Email	Research.ethics@svhm.org.au

Advice on Avoiding Pregnancy (if applicable)

St Vincent's Hospital (Melbourne) is a Roman Catholic health service. 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.

St Vincent's Hospital (Melbourne), therefore, does not accept any statements in the application (e.g. participant information sheet, scientific description etc) to the effect that participants must practice methods of contraception or avoid pregnancy. The National Mutual Acceptance (the NMA) of single ethical and scientific review for multi-centre clinical trials was introduced on 1 November 2013. Under the NMA, Catholic Health Australia has provided recommended wording to be used for studies which involve participants of childbearing age.

For studies where pregnancy must be avoided please use the Catholic Health Australia's approved wording outlined below (refer to Appendix 2 of the Standard Principles for Operation, NMA).

**Patient Information and Consent Form Statement where pregnancy must be avoided:
Recommended Template for Catholic Institutions**

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.

Alternative Catholic Wording for Studies Where Pregnancy Should Be Avoided

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

For further information, please refer to Research Governance Unit website, or visit www.health.vic.gov.au/clinicaltrials/mutual-acceptance.htm or contact the Unit for advice.

Retention of Records

The retention of research related records must comply with the Australian Code for the Responsible Conduct of Research (2007) and the Health Records Act which specifies that *the minimum recommended period for retention of research data is 5 years from the date of publication. However, in any particular case, the period for which data should be retained should be determined by the specific type of research. For example:*

Types of Project	Retention Period after project end
Short-term research projects that are for assessment purposes only, such as research projects completed by students	12 months
Clinical Trials	15 years or more
Areas such as gene therapy	Retained permanently
Work has community or heritage value	Kent permanently preferably within a national collection.

Please note that the Health Records Act requirement for the retention of research records is different from University requirements.

Health Records Act 2001 – More than 7 Years after completion of a study

University Requirement - 5 Years after completion of a study

St Vincent’s Hospital follows the Health Records hence all records must be retained for a minimum of seven (7) years if conducted at St Vincent’s Hospital.

Translation

When the protocol requires a professional translator to assist with the attainment of informed consent, the following sentence should be included within the consent form:

I certify that I have translated the above explanation and declaration and assisted Dr. with the oral translation to the person below in the language which the person has indicated he/she understands.

Interpreter (sign/print): Date:

Participants who require a translator must be provided with a PICF that has been translated into their language. As per Good Clinical Practice Guidelines, the PICF should be translated from English to the subject language, and then translated back to English to ensure correctness. This must also be approved by the HREC prior to use.

Collection of information relating to illegal drug use

Where applicable, the following sentence should be included within the PICF (preferably within the section detailing the participant experience):

The research project involves the collection of information about your use of drugs. Participation in the research project includes blood and or urine analysis to determine the presence of { }. The test may reveal evidence that you have previously used illegal drugs. That information will be stored in a re-identifiable (or coded) format. In the event that St Vincent's is required to disclose that information, it may be used against you in legal proceedings or otherwise.

NB. Where research project involves collection of information only, i.e. no blood or urine tests will be performed, the second and third sentence can be removed.

Tissue Banks

For projects involving banking of tissue where consent is being sought for unrelated future research the following wording must be included verbatim within the 'Research procedures' section:

We also seek your permission to hold your tissue samples and information indefinitely, in case they are of benefit for future research. Medical science is advancing very quickly, and so we are not in a position to be able to tell you exactly what form the future research might take, or the consequences of that research. Future research might involve isolating genetic markers for disease, ascertaining the effects of different drugs on different people, or [insert additional possibilities].

This research might also result in drugs or tests that are produced and marketed by private organisations for profit. St Vincent's may or may not profit from any of the revenue that such research would generate. Although knowledge acquired through medical research may lead to discoveries that are of commercial value to the researcher and his/her institution, there will be no financial benefit to yourself or your family.

No research will take place using your tissue samples and information unless that research is first reviewed and approved by a Human Research Ethics Committee, which will determine whether the benefits of the research outweigh the cost to you and your privacy.

ADDITIONAL ASSISTANCE / TRAINING

For additional information and tips on how to write a PICF, please contact the Research Governance Staff by email.

6. CONTRACTS AND AGREEMENTS

All clinical trials, human research, investigator initiated and collaborative studies must provide a research agreement for review/authorization. Depending on the type of research the following template below must be used:

Types of Research	Template	Website to download template
<ul style="list-style-type: none"> - Clinical Trials - Human Research - Collaborative Group Studies - Investigator Initiated Research 	Australia Medicines	https://medicinesaustralia.com.au/policy/clinical-trials/clinical-trials-research-agreements/
Medical Device Trial	Medical Device Medical Technology Association (MTAA)	https://www.mtaa.org.au/clinical-investigations
Research conducted in Victoria and institutions involved are part of the Melbourne Academic Centre for Health	Melbourne Academic Centre for Health (MACH)	https://www.machaustralia.org/research-collaboration-agreement

If these templates cannot be used, please contact the Research Governance Unit for advice.

The following are the details for St Vincent's Hospital to be inserted:

Name of Institution:	ST. VINCENT'S HOSPITAL (MELBOURNE) LIMITED
Address:	41 Victoria Parade, Fitzroy VIC 3065
ABN:	22 052 110 755

Please see below for the number of CTRA required to be submitted to the RGU office as part of the RGO application and the signature required to be present on the CTRA in order for the RGU to process the application:

SVHM Involvement	Hard copies	Signature to be present on CTRA
SVHM is a participating site in the study	3 hard copies	<ul style="list-style-type: none"> - Sponsor - Principal Investigator
SVHM is the Sponsor for the study	3 hard copies	<ul style="list-style-type: none"> - No signature to be present. - PI needs to ensure that the CTRA has been discussed with participating site and that mutual agreement has been reached by all parties. - Study team is required to send back one of the original fully executed CTRA to SVHM RGU

Please note that only the Director of Research and the Executive Officer can sign off on behalf of the institution.

7. INSURANCE AND INDEMNITY

All multi-site **Sponsored Clinical Trials** must provide appropriate levels of insurance/indemnity.

SVHM requires the use of the Medicines Australia Standard Indemnity Form. Where the trial is being reviewed as a multisite study, the Medicines Australia HREC Review Only Form of Indemnity is also required for each site which will accept the ethical approval issued by SVHM.

Please state Indemnified Party as follow:

St Vincent's Hospital (Melbourne) Limited, 41 Victoria Parade, Fitzroy, Victoria 3065, ABN 22 052 110 755

To comply with the minimum insurance requirements, sponsored research must provide a copy of the certificate of currency (or insurance certificate) which contains the following information:

- The type of insurance – Public and Product Liability – or equivalent such as General Liability or Clinical Trials Insurance
- The full legal name of the Australian entity acting as the sponsor
- The full legal name of the insurer (which must be approved by the Australian Prudential Regulation Authority or a foreign equivalent). All insurers are required to hold Standard & Poor's financial rating of not less than 'A-'.
- The period of insurance
- That the insurance coverage allows for a minimum of AUD\$10 million for any one occurrence and in the annual aggregate
- That the insurance coverage contains an excess/deductible, or self insured retention amount greater than AUD\$25,000 for each and every claim or series of claims arising out of one original cause.

Additional information regarding the level of insurance and indemnity required can be obtained from the Victorian Managed Insurance Authority (VMIA) Clinical Trials Guidelines

<http://www.vmia.vic.gov.au/RiskManagement/Clinical-trials/clinical-trial-notificationguidelines.aspx>

Post Marketing Study /Phase IV Clinical Trial

A Standard Indemnity is not required if the Australia Medicine Clinical Trial Research Agreement – Phase 4 is used.

An insurance covering study will not need to be provided but the general insurance covering the Sponsor Company will need to be provided.

8. CLINICAL TRIAL NOTIFICATION (CTN)

The CTN will be required for the following:

- any medicine not entered on the Australian Register of Therapeutic Goods (ARTG), including any new formulation, strength or size, dosage form, name, indications, directions for use or type of container of a medicine already in the ARTG
- any medical device not entered in the ARTG, including any new design specification, model, technology, material or treatment modality of a medical device already in the ARTG □ any biological not entered in the ARTG:
 - including any new applicable standards, intended clinical use or principal manufacturer of a Class 1 or 2 biological already in the ARTG
 - including any new product name, dosage form, formulation or composition, therapeutic indication, type of container or principal manufacturer of a Class 3 or 4 biological already in the ARTG
- a therapeutic good already in the ARTG that is used beyond the conditions of its marketing approval including labelling.

a) For Commercially Sponsored / Investigator Initiated Study – It is the Sponsor/ Investigator responsibility to submit the CTN to the TGA. A copy of the submitted CTN will need to be submitted to the Research Governance Unit after Ethics and Governance Approval has been granted for the study.

The following are the St Vincent's Hospital Melbourne details to be entered into the CTN application

HREC Name	St Vincent's Hospital Melbourne Human Research Ethics Committee
HREC Contact Officer	Dr. Tam Nguyen, Executive Officer of Research
HREC Code	EC00343
Contact Phone Number	03 9231 2394
Contact Email	research.ethics@svhm.org.au

Approving Authority:	St Vincent's Hospital (Melbourne) Limited, 41 Victoria Parade, Fitzroy, VIC 3065
Approving Authority Officer	Dr. Megan Robertson, Director of Research
Contact Number	03 9231 2394
Contact Email:	research.ethics@svhm.org.au

b) St Vincent's Hospital Melbourne is the Sponsor – The St Vincent's Hospital Melbourne Research Governance Unit will be assisting the Investigator to make the submission to the TGA.

Please send an email to Research.ETHICS@svhm.org.au to schedule an appointment for lodging in the application.

Payment to SVHM Research Governance Unit is required by the research team for lodging a CTN application.

9. CONSOLIDATING DOCUMENTS FOR ETHICS AND GOVERNANCE SUBMISSION

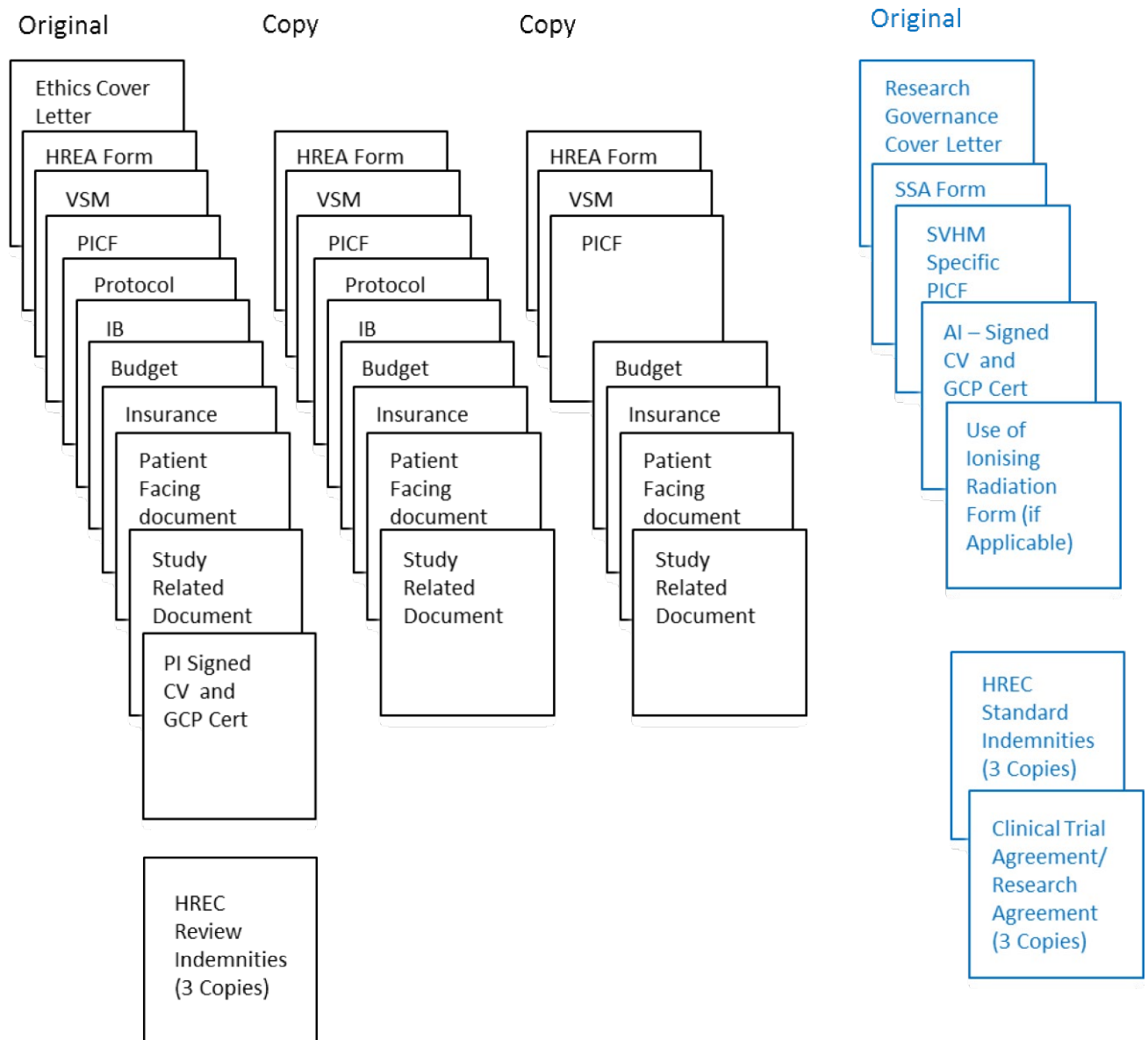
Ethical and Governance Submission

If St Vincent Hospital Melbourne (SVHM) HREC is the reviewing HREC and St Vincent Hospital Melbourne is a participating site, the following documents will be required for Ethics and Governance approval.

Please STAPLE EACH DOCUMENTS when submitting if not your application MAY BE REJECTED.

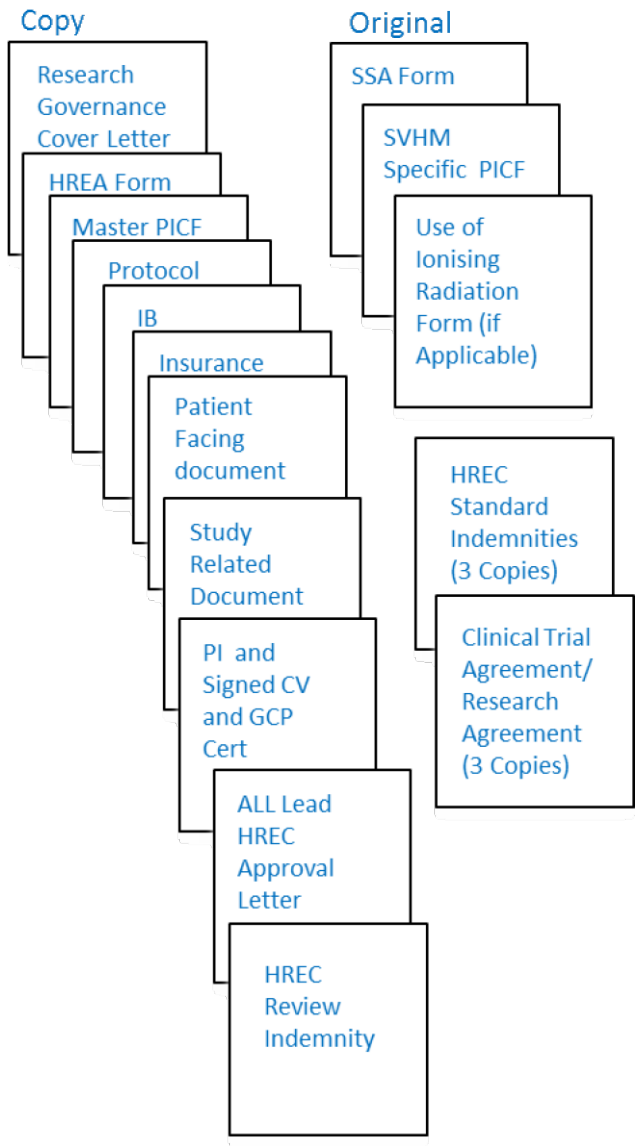
Ethics Submission Package

Governance Submission Package



Governance Submission

The following documents are required if the reviewing HREC is NOT St Vincent Hospital Melbourne and SVHM is a participating site



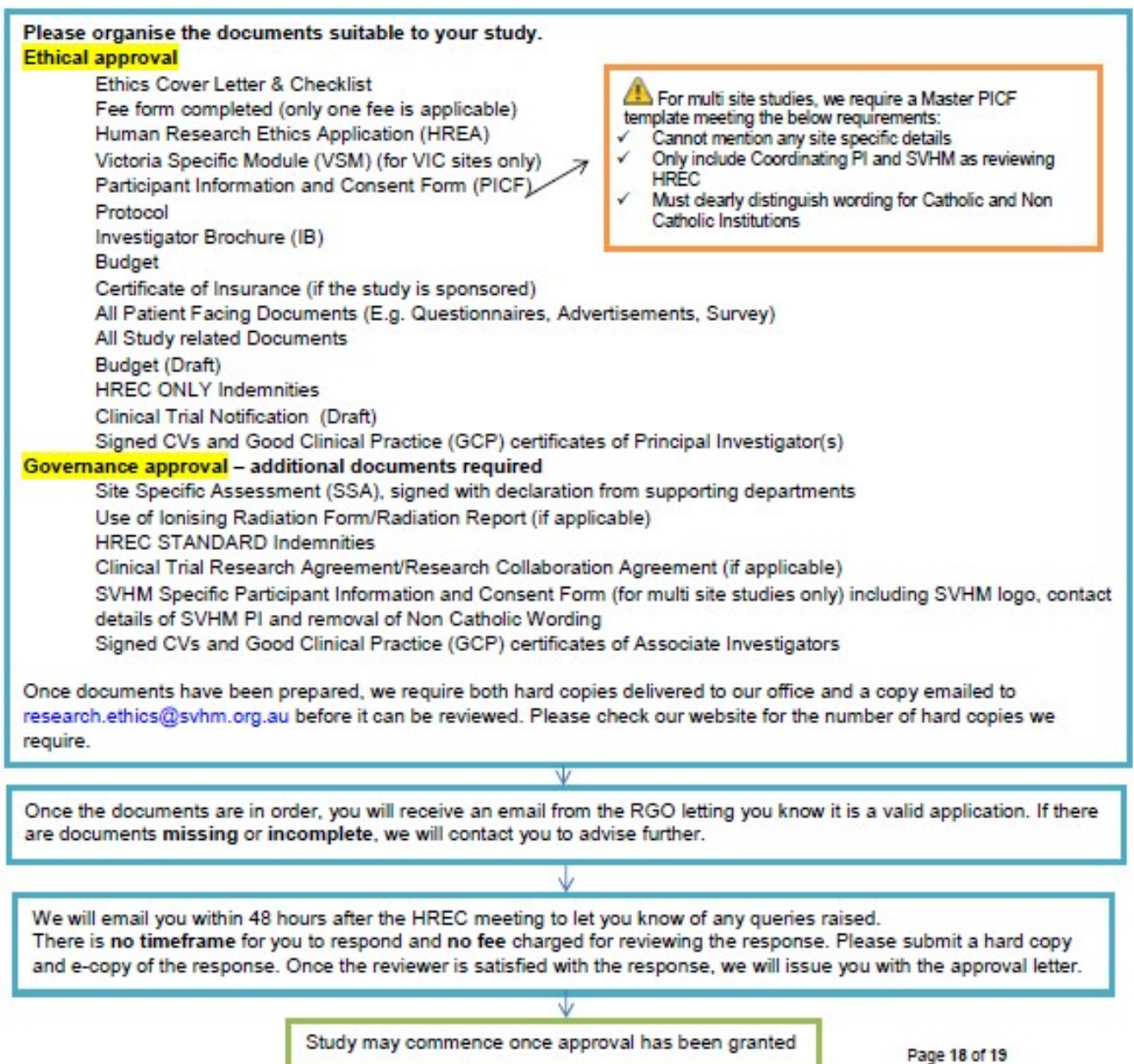
10. THE PROCESS TO OBTAINING ETHICAL AND GOVERNANCE APPROVAL FOR HIGH RISK STUDIES

When will you need Ethical Approval?

Ethical approval is required before conducting research. St Vincent's Hospital Melbourne (SVHM) is able to grant ethical approval on behalf of study sites participating in the study. SVHM will also accept approval from an accredited HREC that is part of the National Mutual Acceptance (NMA) Scheme. SVHM can issue ethical approval without being a participating site.

- If SVHM is the participating site, you will need **ethical and governance approval** from SVHM.
- If SVHM is not the participating site, you will need **ethical approval only** from SVHM. *Please check if the participating site(s) will accept ethical approval from SVHM prior.*

To obtain Ethical and Governance Approval from St Vincent's Hospital Melbourne



The Process to Obtaining Governance Approval

When will you need Governance Approval?

Governance approval is required before conducting any research at SVHM, provided ethical approval has been obtained from another accredited Human Research Ethics Committee. SVHM Human Research Ethics Committee accepts Ethical review and approval from HREC committees that are part of the National Mutual Acceptance (NMA) Scheme.

The flow chart below outlines what is required.

