
Ethics Submissions Guide

Index

| | |
|--|----|
| 1. High-Risk Ethics Applications | |
| 1.1. New Ethics Applications | |
| 1.1.1. HREA Form & ERM | 2 |
| 1.1.2. Victorian Specific Module | 2 |
| 1.1.3. Use of Ionising Radiation | 2 |
| 1.1.3.1. Notification Safety Letter | 2 |
| 1.1.3.2. Medical Physicist Report | 3 |
| 1.1.4. Master Participant Information and Consent Forms (PICF) | 3 |
| 1.1.5. Protocol or Research Plan | 4 |
| 1.1.6. Investigator's Brochure | 4 |
| 1.1.7. Budget | 4 |
| 1.1.8. Patient Facing Materials | 5 |
| 1.1.9. HREC Review Only Indemnity | 5 |
| 1.1.10. Clinical Trial Notification Form (CTN) | 5 |
| 1.1.11. Certificate of Insurance | 6 |
| 1.1.12. Letter of Support from Head of Department | 6 |
| 1.1.13. Good Clinical Practice (GCP) Certificates | 6 |
| 1.1.14. Curriculum Vitae (CVs) | 7 |
| 1.2. New Governance Applications | |
| 1.2.1. Site Specific Assessment (SSA) Form | 8 |
| 1.2.2. Site Specific Participant Information and Consent Form (PICF) | 8 |
| 1.2.3. Standard Indemnity | 8 |
| 1.2.4. Clinical Trial Research Agreement (CTRA) or Research Collaboration Agreement (RCA) | 9 |
| 1.2.5. Material Transfer Agreement | 10 |
| 2. Low Risk Ethics Applications | 11 |
| 2.1.1. Commercially Sponsored | 11 |
| 3. Quality Assurance/Audit | 12 |
| 4. Ethics vs. Governance Document List | 13 |
| 5. WebLinks | 14 |

New Ethics Applications

HREA

What is a HREA?

The Human Research Ethics Application (HREA) is a web-based form that enables researchers to complete their research ethics proposals on ERM (Ethical Review Manager) for submission to the HREC. It includes all the integral information relating to the study and allows for attachment of supporting documents.

Do I need a HREA?

The HREA is a compulsory form that must be submitted as part of the ethics application process for all studies seeking ethical approval at SVHM.

Victorian Specific Module (VSM)

What is a VSM?

The VSM is an ethics requirement that is a state specific form designed to ensure compliance with Victorian legislation on human research. The VSM covers information privacy, health information, the use of ionising radiation, removal of human tissues and the use of poisons and controlled substances as well as issues arising from ability to give consent.

Do I need a VSM?

A VSM is an ethics requirement and must be completed for every high-risk study that has a site in Victoria. In addition, a VSM is an ethics requirement for all studies seeking a waiver of consent.

Use of Ionising Radiation

What is Ionising Radiation?

Ionising Radiation is a type of energy produced by unstable atoms that travel in the form of electromagnetic waves or particles. These unstable atoms emit an excess of energy and/or mass, these energy emissions are known as radiation. When this radiation interacts with other atoms, it ionises atoms which alter their chemical properties by breaking chemical bonds.

This effect can cause damage to living tissue, however everyone is exposed to low levels of ionising radiation in everyday life from sources such as in air, soil, water and vegetation, consumer electronics as well as medical devices; such as CT Scans, MRI's, X-rays, Ultrasound, DEXA, fluoroscopy, PET scans, MUGA and Chemotherapy among others.

What is an Ionising Radiation Notification Safety Letter?

The Ionising Radiation Notification Safety Letter is to notify the reviewing HREC that the ionising radiation that is included in the protocol is NOT additional to the current standard of care that is to be provided to the potential participants. This letter is to be signed by the site PI declaring that the appropriately certified medical physicist at the site and/or Radiation Safety Officer (RSO) has been consulted in relation to the protocol.

Do I need an Ionising Radiation Notification Safety Letter?

All trials where ionising radiation (ie. X-rays, CT scans, MRI's, Ultrasounds, Chemo etc) is to be used will require a letter from each participating site.

Medical Physicist Report

What is a Medical Physicist Report?

A Medical Physicist Report is a radiation dose and risk assessment that is completed by a medical physicist stating that the radiation is deemed to be additional to standard to care. This report will review and outline the anticipated radiation doses for each participant as part of their participation in the trial and its relative risk and necessary precautions that will need to be implemented.

The medical physicist will also determine if the radiation level exceeds the dose constraints outlined in the Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes (2005). In this case, it will be a governance requirement to submit this application to the Department of Health and Human Resources.

Do I need a Medical Physicist Report?

A Medical Physicist Report is compulsory for all trials that are using radiation and that this radiation IS additional to standard of care.

Master Participant Information and Consent Forms (PICF)

What is a PICF?

A PICF is one of the most important project documents as it communicates to potential participants exactly what the research entails, the investigator's and participants role, outlines possible risks and benefits and allows the participant to be able to give informed consent to participate in the trial. The PICF should be written in lay terms (i.e. avoid medical terminology) and be easily understandable at a general 14 year old reading level.

What is a Master PICF?

A Master PICF is generally used in multi-site trials and is the master version that forms the basis for all subsequent site specific PICF's. The Master PICF will not include such details such as site name, PI details, local contact persons or site logos but will have optional editable sections highlighted for site

PI's to add such information. If a multi-site study is to include a Catholic site, the Master PICF must include the pre-approved optional Catholic wording in regards to pregnancy.

Protocol or Research Plan

What is a Protocol or Research Plan?

A protocol, also known as a research plan, study protocol, study outline and various other terms is a comprehensive overview of the research aims, justifications, methods, risks and perceived outcome of the proposed research. The protocol should contain a thorough analysis of literature and previously conducted studies and discuss their findings and their relationship to the proposed research. The protocol will also outline the methods of obtaining data and the anticipated risks and appropriate mitigation measures that may present in the conduction of the study.

Investigator's Brochure (IB)

What is an IB?

An investigator's Brochure is a document that contains all relevant information regarding the safety and efficacy of the pharmacology, pharmacokinetics, pharmacodynamics and toxicological history of the investigational drug and/or device in both animal and human studies.

The IB is distributed to all the investigators involved in the study to ensure they are appropriately informed and educated before administering/implementing the drug/device to participants.

Do I need an IB?

An IB is required for all drug and/or device trials.

Budget

What is a Budget?

A budget is a breakdown of the anticipated costs of conducting the trial. It is important for researchers to adequately plan for the incidentals incurred during the course of the study and ensure they have adequate funds to successfully complete the project.

Patient Facing Materials

What are Patient Facing Materials?

Patient Facing Materials are all documents that will be presented to the patient/participant. This includes but is not limited to; flyers, posters, pamphlets, advertisements, phone scripts, SMS scripts, social media advertisements, surveys, questionnaires, ID cards, name tags, appreciation items, educational slides, and information brochures/booklets.

Do I need to submit Patient Facing Materials?

All Patient Facing Materials will need to be submitted to the HREC for review and approval.

HREC Review Only Indemnity

What is an Indemnity?

An Indemnity is a legal document that provides written assurance to the investigator and the relevant ethics committee that the sponsor will provide compensation for any injury caused by participation in a clinical trial. There are two types of indemnities, HREC Review Only and the Standard Indemnity. The HREC Review Only is an ethics document and should be requested at the ethical review stage. The Standard is a governance document and will be requested at the governance review stage (if applicable).

What is a HREC Review Only Indemnity?

The HREC Review Only Indemnity is used for all commercially sponsored clinical trials whereby the HREC is providing overarching ethical review for the study to be conducted at hospitals, institutions or sites that are independent from the indemnified party.

Do I need a HREC Review Only Indemnity?

A HREC Review Only Indemnity is required for all commercially sponsored trials where SVHM is the reviewing HREC.

Clinical Trial Notification Form (CTN)

What is a CTN?

A CTN is proof of notification of an unapproved investigational drug or device with the Therapeutic Goods Administration of Australia (TGA) for use within a clinical trial. The CTN must contain all the sites, site PI's, and reviewing HREC details where the unapproved device/drug is to be trialled.

Who are the TGA?

The TGA is part of the Australian Government Department of Health, and is responsible for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products.

Do I need a CTN?

A CTN is compulsory for all drug and devices that are unapproved by the TGA.

Certificate of Insurance

What is a Certificate of Insurance?

A certificate of insurance is a legal document from an appropriate insurance agency that provides coverage in the case of an insurance claim. The coverage must be a minimum of 10 million dollars (AU\$10 000 000).

Do I need a Certificate of Insurance?

A Certificate of Insurance is compulsory for all commercially sponsored high-risk drug and device trials.

Letter of Support from Head of Department

What is a Letter of Support?

A Letter of Support is an ethics and governance requirement from the relevant Head of Department where the trial is to be conducted stating that they have read the research protocol and agree to provide the relevant resources and support for the conduction for the trial.

What if the Head of Department is the PI or an AI?

Due to the conflict of interest, a PI or AI on a study who is also the head of the department cannot provide a letter of support for their own study. In this instance, a letter of support can be requested from the Chief Medical Officer – Wilma Beswick at SVHM. For SVPHM governance submissions a letter of support is compulsory from Kate Worsley at SVPHM.

Good Clinical Practice (GCP) Certificates

What is GCP?

Good Clinical Practice (GCP) is an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials. It also serves to protect and respect the rights, integrity and confidentiality of trial subjects. GCP compliance certificates are typically valid for 3 years from the date of completion.

Do I Need a GCP?

GCP compliance is compulsory for all lead investigators on ethics submissions, and must be current at the time of submission. GCP is also compulsory for all investigators based at SVHM, this is inclusive of all principal investigators and associate investigators.

Curriculum Vitae (CVs)

Why do I need to submit a CV?

CV's are required to be submitted to ensure the researchers involved in a study are adequately educated and experienced in the field they are wishing to study and is a compulsory component of the ethical review process.

New Governance Applications

Site-Specific Assessment (SSA) Form

What is an SSA Form?

An SSA Form is a requirement for all governance submissions at SVHM and is part of the ERM online submission system. The SSA provides additional site-specific information not included on the HREA and allows for the uploading of site-specific documentation.

Do I need an SSA Form?

An SSA Form is compulsory for all high-risk governance applications. An SSA Form is also required for all low risk governance applications where SVHM is NOT the reviewing HREC.

The only instance where an SSA Form is not required is for a low risk research project that is singlesite and SVHM is the reviewing HREC and the participating site.

Site Specific Participant Information and Consent Form (SSA PICF)

What is an SSA PICF?

An SSA PICF is a governance submission of the consent form intended for use at SVHM. The SSA PICF is the only PICF that is authorised to be used at SVHM.

For multi-site trials, a master PICF would have been submitted at ethical review and the SSA PICF is based upon this. For SVHM PICF's, the SVHM logo will be present on the front page, PI and/or AI names will be listed, include the relevant approved Catholic wording in regards to pregnancy and also contain the local contacts for the study.

Do I need an SSA PICF?

An SSA PICF is compulsory for all trials where SVHM is a participating site.

Standard Indemnity

What is a Standard Indemnity?

A Standard Indemnity is a governance legal document where the indemnified party (SVHM) is providing premises for the conduct of the study. This is required even if SVHM is not the reviewing HREC but is a participating site in a trial.

Do I need a Standard Indemnity?

A Standard Indemnity is required for all commercially sponsored trials where SVHM is a participating site.

Research Collaboration Agreement (RCA) or Clinical Trial Research Agreement (CTRA)

What is an RCA?

An RCA is a formalised collaboration agreement between researchers and their respective institutions to ensure specific issues such as; sharing intellectual property, managing research findings, managing conflicts of interest, publication rights and commercialising research outcomes.

Do I need an RCA?

An RCA is a compulsory governance requirement for investigator-initiated, multi-site non-clinical trials in line with the NHMRC, Australian Code for the Responsible Conduct of Research (2018).

What is a CTRA?

A CTRA is similar in function to the RCA but provides more detailed operative provisions such as; adverse events, biological samples, TGA approved and non-approved investigational drugs and devices. There are two main common types of CTRA's, the Standard and the Collaborative Research Group (CRG).

The CRG CTRA differs from the Standard in that the collaborative research group in question is a non-commercial/academic research group who are responsible for sponsoring, initiating, managing, developing and coordinating the study.

Do I need a CTRA?

A CTRA is a compulsory governance requirement for all commercially sponsored clinical trials, inclusive of all drug and device trials. A CTRA is also compulsory for low risk non-interventional studies where the study is commercially sponsored by pharmaceuticals.

RCA, CTRA (Standard) or CTRA (CRG)?

| RCA | CTRA (Standard) | CTRA (CRG) |
|-----------------------------|------------------------|---------------------------------|
| Investigator-Initiated | Commercially Sponsored | Academic/Non-Commercial Sponsor |
| Multi-site | Multi-site | Multi-site |
| No Drug/Device Trials | Drug/Device Trials | Drug/Device Trials |
| Typically Low-risk Research | Typically High-Risk | Typically High-Risk |

Material Transfer Agreement

What is a Material Transfer Agreement?

A Material Transfer Agreement is a legal governance requirement where bio-specimens collected during the course of a study are to be transferred externally from SVHM. The MTA assumes that the recipient may develop a derivative or new intellectual property based on this material and that SVHM will not own any interest in this derivative or discovery. Bio-specimens are defined as any biological sample of material such as; urine, blood, tissue, cells, DNA, RNA and protein from humans, animals or plants.

Do I need a Material Transfer Agreement?

An MTA is a compulsory governance requirement for all studies where bio-specimens are be transferred externally from SVHM.

Low Risk Ethics Applications

Low Risk research describes research in which the only foreseeable risk is one of discomfort. To be eligible for the Low Risk Pathway, the project MUST NOT INCLUDE:

- Women who are pregnant
- Children or young people under the age of 18
- Persons with an intellectual disability or mental impairment of any kind
- Persons highly dependent on medical care
- Persons incompetent to provide informed consent
- People involved in illegal activities
- Prisoners or people on parole
- Research specifically recruiting Aboriginal and / or Torres Strait Islander people
- Persons not usually considered to be vulnerable but would be considered vulnerable in the context of this research project
- Additional clinical interventions and/or therapies
- Human genetic research or gene technology
- Derivation or use of human stem cells
- Discomfort or risk beyond that of routine care
- Deception of participants, concealment or covert observation
- Examining potentially sensitive or contentious issues
- Additional Radioactive substances / ionizing radiation e.g. X-rays, DEXA
- Assisted reproductive technology (ART)
- Xenotransplantation
- Toxins / mutagens / teratogens / carcinogens
- Collection, use or disclosure of identifiable information

Commercially Sponsored

If a Low Risk study is multi-site and commercially sponsored by pharmaceuticals, the following will be required:

- CTRA
- HREC Review Only Indemnity (SVHM Reviewing HREC)
- Standard Indemnity (SVHM Governance)

Quality Assurance (QA)

Quality Assurance is defined by the NHMRC as:

“An activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation.”

QA, audit, and quality improvement are terms used interchangeably to refer to activities that fall under the auspice of Quality Assurance review. St. Vincent’s Hospital Research Governance Unit (RGU) aims to encourage and facilitate the process of Quality Assurance activities, as it is an essential process for improving health services and patient outcomes. QA aims to gain information on specific services to create better outcomes and more effective processes.

QA activities may involve patients, staff, or members of the community. Therefore, it is equally important for Quality Assurance activities to be conducted with ethical consideration of those involved.

Quality Assurance activities must be initiated by a St. Vincent’s Hospital Principal Investigator. Any applications initiated by an external principal investigator are not considered Quality Assurance

To be eligible for Quality Assurance, the project **MUST NOT**:

- Aim to generate new generalizable knowledge
- Involve any significant departure from the routine clinical care provided to patients
- Involve randomisation, control groups, or use of placebo
- Seek to gather information about the participant beyond that collected as part of routine care
- Involve additional testing, blood or tissue collection
- Involve the assessment of safety/efficacy of a new intervention/device
- Impose any additional burden, harm or risk, beyond those associated with routine care

Ethics vs. Governance Documents

| Ethics | Governance |
|------------------------------|------------------------|
| HREA | SSA |
| VSM | VSM |
| Radiation Notification | Radiation Notification |
| Master PICF | SVHM PICF |
| Protocol | Protocol |
| IB | IB |
| Budget | Budget |
| Patient Facing Docs | Patient Facing Docs |
| CTN | CTN |
| Insurance | Insurance |
| HOD Letter | HOD Letter |
| Acknowledgement Letter Sites | N/A |
| GCP C/PI | GCP PI and AI's |
| CV's all Investigators | CV's PI and AI's |
| HREC Review Only Indemnity | Standard Indemnity |
| | RCA/CTRA |
| | MTA |

WebLinks

SVHM HREC Homepage <https://www.svhm.org.au/research/researchers/human-research-ethics-committee>

SVHM Low Risk/QA Homepage <https://www.svhm.org.au/research/researchers/low-risk-research-and-quality-assurance>

SVHM Forms <https://www.svhm.org.au/research/researchers/forms>

Medicines Australia Indemnity Templates <https://medicinesaustralia.com.au/policy/clinical-trials/indemnity-and-compensation-guidelines/>

Clinical Trial Research Agreement Templates <https://medicinesaustralia.com.au/policy/clinical-trials/clinical-trials-research-agreements/>

NHMRC – Ethical considerations in quality assurance and evaluation activities

<https://www.nhmrc.gov.au/about-us/resources/ethical-considerations-quality-assurance-and-evaluation-activities>

National Statement on Ethical Conduct in Human Research (2007) – Updated 2018

<https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-humanresearch-2007-updated-2018>

Australian Code for the Responsible Conduct of Research (2018)

<https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research2018>