

# Research Support Services

## Overview

of

## Ethics and Governance

Michael Kios



# Ethics and Governance – 4 Part Series

<b>Date &amp; Time</b>	<b>Topics to be Covered</b>
<p>Thursday</p> <p>29 October 2020</p> <p>12.30 pm – 1.30 pm</p>	<p>Overview of Ethics and Governance Guidelines, Legislation, Polices, Procedures Human Research Ethics Applications Low Risk Applications - Quality Assurance</p> <p><a href="https://us02web.zoom.us/j/89494009527?pwd=K29YYWNOtmxvV2xBbnNsdv9mSWhPZz09">https://us02web.zoom.us/j/89494009527?pwd=K29YYWNOtmxvV2xBbnNsdv9mSWhPZz09</a></p> <p>Meeting ID: 894 9400 9527      Passcode: 920776</p>
<p>Thursday</p> <p>12 November 2020</p> <p>12.30 pm – 1.45 pm</p>	<p>Site Specific Assessment Applications Governance Supporting Departments Good Clinical Practice Training Legal Documents</p> <p><a href="https://us02web.zoom.us/j/89294836899?pwd=VytsdlRzUIRrUlo0cUxMRTBWTzkwZz09">https://us02web.zoom.us/j/89294836899?pwd=VytsdlRzUIRrUlo0cUxMRTBWTzkwZz09</a></p> <p>Meeting ID: 892 9483 6899      Passcode: 279765</p>
<p>Tuesday</p> <p>24 November 2020</p> <p>12.30 pm – 2.00 pm</p>	<p>Study Site Master File Essential Documents Data, Privacy and Recruitment Informed Consent Witnesses, Interpreters, Incompetent Patients</p> <p><a href="https://us02web.zoom.us/j/82665006872?pwd=cXA0ODM3SVJvc3p6Z1FWVWZ0d0ZlZz09">https://us02web.zoom.us/j/82665006872?pwd=cXA0ODM3SVJvc3p6Z1FWVWZ0d0ZlZz09</a></p> <p>Meeting ID: 826 6500 6872      Passcode: 002481</p>
<p>Monday</p> <p>30 November 2020</p> <p>12.30 pm – 2.00 pm</p>	<p>Post Approval Submissions HREC Amendments Safety Reporting Protocol Breaches – Protocol Deviations Post Approval Monitoring - Research Progress Reports - Audits Intellectual Property Supplementary Information</p> <p><a href="https://us02web.zoom.us/j/86720721416?pwd=V2hkNVIUYU9qV0QwSWhkdENBc09ydz09">https://us02web.zoom.us/j/86720721416?pwd=V2hkNVIUYU9qV0QwSWhkdENBc09ydz09</a></p> <p>Meeting ID: 867 2072 1416      Passcode: 423386</p>



**Overview of Ethics and Governance**  
**Guidelines, Legislation, Polices, Procedures**  
**Human Research Ethics Applications**  
**Low Risk Applications**  
**Quality Assurance**  
**Site Specific Assessment Applications**  
**Legal Documents**  
**Study Site Master file & Essential Documents**  
**Privacy**  
**Informed Consent**  
**Post Approval Submissions**  
**HREC Amendments**  
**Safety Reporting**  
**Protocol Breaches – Protocol Deviations**  
**Post Approval Monitoring**  
**Research Progress Reports**  
**Audits**  
**Intellectual Property**  
**Supplementary Information**

# Research Support Services

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Chief Medical officer

**Prof Bill Sievert**  
Director, Clinical Research

**Deborah Dell**  
Manager, Research Support Services  
& Human Research Ethics Committee

**Michael Kios**  
Research Governance Manager  
Agreements, Progress Reports, Research Policies

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SSA Coordinator  
Governance - Site Specific Authorisation

**Brinda Kinakkal**  
SSA Coordinator  
Governance - Site Specific Authorisation

**Joan Angello**  
Administrative Assistant  
Annual Reports – Agreements - QA



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HREC Coordinator  
Low Risk – Quality Assurance

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New HREC Applications

**Katharine Mahoney**  
HREC & SSA Coordinator  
Post-Approval Amendments

**Heather Jackson**  
Administrative Assistant  
HREC – Governance - Invoicing



# Human Research Ethics and Governance

## History, Guidelines, Legislation, Policies and Procedures

# Historical setting – Human Research

- **1947 - Nuremberg Code**

A set of 10 principles developed for human research as a result of the Nuremberg Trials post World War 2 with the opening statement:

**“The voluntary consent of the human subject is absolutely essential”**

- **1964 Declaration of Helsinki**

A set of ethical principles for human research.

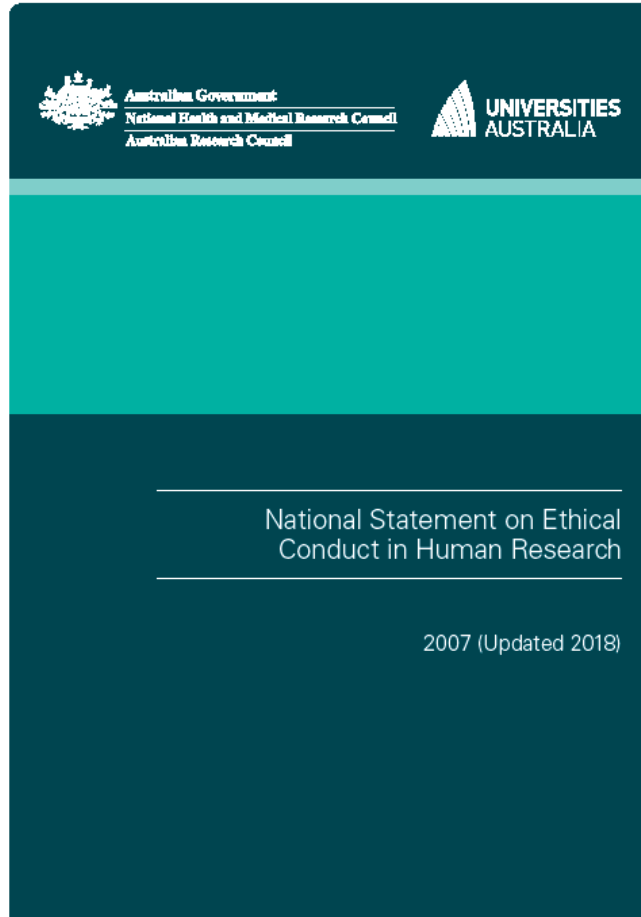
7 revisions up to 2013 including a section on Informed Consent.

- **1996 ICH Guideline for Good Clinical Practice**

Internationally accepted standard for conducting clinical trials. Revised 2016.



<https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018#block-views-block-file-attachments-content-block-1>



INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL  
REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE (ICH)

ICH HARMONISED GUIDELINE

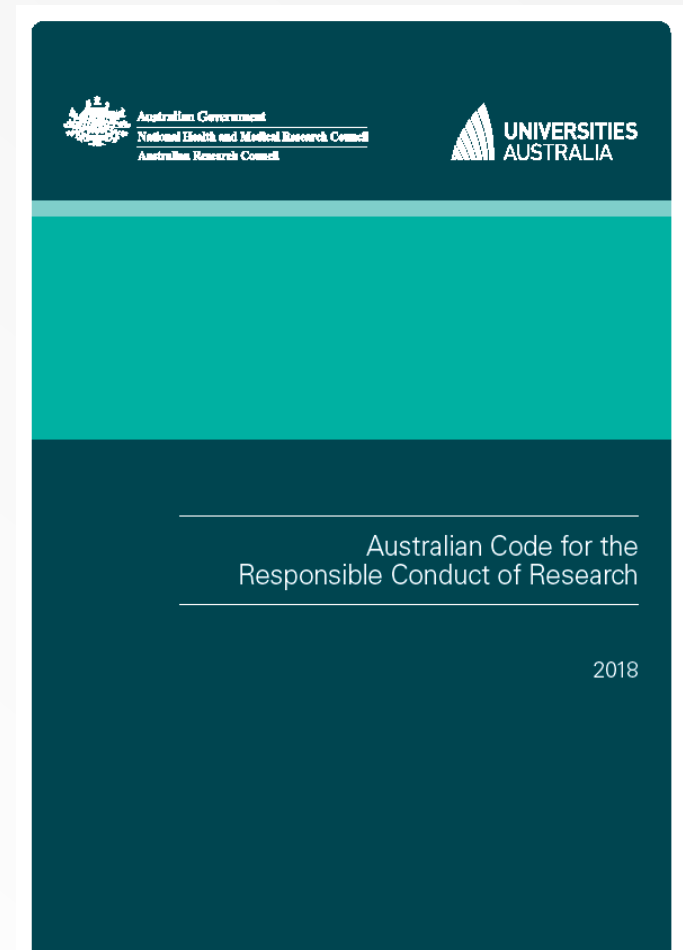
INTEGRATED ADDENDUM TO ICH E6(R1):  
GUIDELINE FOR GOOD CLINICAL PRACTICE  
E6(R2)

Current *Step 4* version  
dated 9 November 2016

[https://database.ich.org/sites/default/files/E6\\_R2\\_Addendum.pdf](https://database.ich.org/sites/default/files/E6_R2_Addendum.pdf)

Latest version via EMA link:  
<https://www.ema.europa.eu/en/ich-e6-r2-good-clinical-practice#current-version---revision-2-section>


<https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018>



Search Department - Internet Explorer  
 http://prompt/Search/SearchLibrary.aspx

File Edit View Favorites Tools Help

Intranet MonH Self Service RSS Tracker ERM Victoria Sign In Google NIDA Roche GCP GCP MCHRI GHTC ICH-GCP E6-R2 DHHS Forms DHHS PICF DHHS TGA CTN eRecruit Legal

 documents  
 Monash Health  
 Logged in as:  
 General Staff User  
 (connected to SNH)

Search Help Logout

Enter your search criteria here then click the Search button...

Enter Search Expression  
 [Advanced Search](#)

Search Clear the form Syntax Help

**External PROMPT Log-in details**

Username: MHprompt@snh  
 Password: MHprocedure123

For any Policy or Procedure related enquiries, please contact the Corporate Services team - [policiesandprocedures@monashhealth.org](mailto:policiesandprocedures@monashhealth.org)

**NEW MAY 2019 NEW TEMPLATES** now available on PROMPT, as part of the revised [Monash Health Policy, Procedure and Guideline Framework](#)

For any Clinical Guideline related enquiries, please contact the CCE team at [ClinicalGuidelines@monashhealth.org](mailto:ClinicalGuidelines@monashhealth.org)

Please refer to the Monthly Document Management Newsletter for information on updated policies, procedures and clinical guidelines















*Prompt Newsletter January 2020*

**Additional Resources:**


Additional Paediatric or Neonatal procedures available [RCH Clinical Practice Guideline](#) and [Neonatal Handbook](#)

A maximum of 500 results will be presented. Refining your search will result in a faster search and less documents.

Results (384 documents displayed)

<b>Research Governance</b>	Monash Health \ Research and Ethics \ Research ethics [Procedure]	 
<b>Research Ethics and Governance- Authorship for Research</b>	Monash Health \ Research and Ethics \ Research ethics [Procedure]	 
<b>Publication and dissemination of research findings</b>	Monash Health \ Research and Ethics \ Research ethics [Procedure]	 
<b>Research Related Complaint Resolution</b>	Monash Health \ Research and Ethics \ Research ethics [Procedure]	 
<b>Research and Ethics data and records</b>	Monash Health \ Research and Ethics \ Research ethics [Procedure]	 
<b>Privacy and Confidentiality in Research</b>	Monash Health \ Research and Ethics \ Research ethics [Procedure]	 
<b>Use of Human Tissue in Research</b>	Monash Health \ Research and Ethics \ Research ethics [Procedure]	 

100%

Start  6:24 PM



<b>Authorship for Research</b>	<b>Procedure</b>	<b>Peer Review</b>	<b>Procedure</b>
<b>Case Report Forms, Source Documents, Record Keeping, Archiving Procedure</b>	<b>Procedure</b>	<b>Privacy and Confidentiality in Research</b>	<b>Procedure</b>
<b>Collaborative research across institutions</b>	<b>Procedure</b>	<b>Protocol &amp; Investigational brochure Content, Design, Amendments &amp; Compliance</b>	<b>Procedure</b>
<b>Communication with Human Research Ethics Committee, Trial Sponsor &amp; Insurer</b>	<b>Procedure</b>	<b>Publication and dissemination of research findings</b>	<b>Procedure</b>
<b>Data and records</b>	<b>Procedure</b>	<b>Quality Assurance Policy and Procedure</b>	<b>Procedure</b>
<b>Investigation Site Qualifications, Adequacy of Resources &amp; Training</b>	<b>Procedure</b>	<b>Receipt and handling of investigational product</b>	<b>Procedure</b>
<b>Early Phase Clinical Trials - Human Research Ethics Review Policy &amp; Procedure</b>	<b>Procedure</b>	<b>Recruitment of incompetent patients into research</b>	<b>Procedure</b>
<b>Good clinical practice training research</b>	<b>Procedure</b>	<b>Remote Access to Electronic Medical Records (EMR) by Sponsors</b>	<b>Procedure</b>
<b>Handling and shipping of infectious substances for clinical trials</b>	<b>Procedure</b>	<b>Research at Jessie McPherson Private Hospital</b>	<b>Procedure</b>
<b>Handling of Research Misconduct and Resolving Allegations</b>	<b>Procedure</b>	<b>Research Governance</b>	<b>Procedure</b>
<b>Home Visits to Clinical Trial Participants</b>	<b>Procedure</b>	<b>Research Related Complaint Resolution</b>	<b>Procedure</b>
<b>Human Research</b>	<b>Policy</b>	<b>Site initiation and close out</b>	<b>Procedure</b>
<b>Human Research Ethics Review and Site Authorisation</b>	<b>Procedure</b>	<b>Sponsor Responsibilities in Investigator Initiated Studies</b>	<b>Procedure</b>
<b>Informed Consent and Writing Patient Informed Consent Forms</b>	<b>Procedure</b>	<b>Study site master File and documents</b>	<b>Procedure</b>
<b>Investigator Responsibilities</b>	<b>Procedure</b>	<b>Supervision of research trainees</b>	<b>Procedure</b>
<b>Low Risk Human Research Ethics Review and Site Authorisation</b>	<b>Procedure</b>	<b>Therapeutic goods administration notification &amp; serious adverse event reporting</b>	<b>Procedure</b>
<b>Medicare Eligibility for trial participation (Operational)</b>	<b>Policy</b>	<b>Use of Human Tissue in Research</b>	<b>Procedure</b>
<b>Monitoring and Auditing Approved Research</b>	<b>Procedure</b>		



<b>Legislative Compliance - Document Title</b>	<b>Doc Type</b>
<b>Legislative Compliance - Clinical trials</b>	Procedure
<b>legislative compliance - Consent</b>	Procedure
<b>Legislative Compliance – Exporting</b>	Procedure
<b>Legislative Compliance – Funding</b>	Procedure
<b>Legislative Compliance – Gene technology</b>	Procedure
<b>Legislative Compliance – Information</b>	Procedure
<b>Legislative Compliance – Miscellaneous Offences</b>	Procedure
<b>Legislative Compliance – Prevention of Cruelty to Animals</b>	Procedure
<b>Legislative Compliance – Registration</b>	Procedure
<b>Legislative Compliance –Tissue Removal, Donation and Experimentation</b>	Procedure
<b>Legislative Compliance –Tissue Removal, Donation and Experimentation - National</b>	Procedure



# What makes Ethical Research

1. Research is justifiable by its potential benefit and to the skill and expertise of the researchers.
2. Uses appropriate methods for achieving the aims.
3. Based on thorough study of current literature and previous studies.
4. Design to ensure respect for the participants.
5. Research team has experience, qualifications and competence.
6. Uses facilities and resources appropriate for the research.
7. Commitment to upholding principles of research conduct.
8. Disseminate and communicate results – whether favourable or unfavourable.
9. Conduct research honestly (for example declare conflicts of interest).



# Human Research

## Getting Started

Michael Kios



# Research Projects: Getting Started

- Researchers need to be aware of processes policies and procedures in conducting human research
- PROMPT – Policies and Procedures
- PROMPT – Legislative compliance documentation
- Monash Health website research pages



# Ethics & Governance Submission Information

**Monash Health Home Page:** <https://monashhealth.org/>

**Research** <https://monashhealth.org/research/>

**Human research ethics** <https://monashhealth.org/research/resources/human-research-ethics-and-site-authorisation/>

**Human Research Ethics Committee (HREC) Submissions**

<https://monashhealth.org/research/resources/human-research-ethics-and-site-authorisation/human-research-ethics-application/>

**Low and Negligible Risk Research (LNR) Submissions**

<https://monashhealth.org/research/resources/human-research-ethics-and-site-authorisation/human-research-ethics-application/>

**Quality Assurance (QA) / Quality Improvement (QI) Submissions**

<https://monashhealth.org/research/resources/human-research-ethics-and-site-authorisation/application-for-quality-assurance-and-negligible-risk-projects/>

**Site specific assessments (SSA) for Monash Health HREC approved studies (Governance)**

<https://monashhealth.org/research/resources/human-research-ethics-and-site-authorisation/application-guidance-for-site-specific-assessments/>

**Site specific assessments (SSA) for projects reviewed by another institution (Governance)**

<https://monashhealth.org/research/resources/human-research-ethics-and-site-authorisation/application-guidance-for-site-specific-assessments/>



# Research Planning: Pre-Submission

**Develop the hypotheses**

**Draft the Protocol**

**Determine the roles and responsibilities of the researchers**

- Investigators should be qualified by education, training, and experience to assume responsibility for the proper conduct of the trial.
- Maintain a list of appropriately qualified persons to whom the investigator has delegated significant trial-related duties.

**The Principal Investigator should:**

- Be able to demonstrate a potential for recruiting the required number of suitable participants within the agreed recruitment period.
- Have sufficient time to properly conduct and complete the trial within the agreed trial period
- Have adequacy of resources that are normally determined by a site feasibility assessment

**Prepare documentation for ethics and governance submissions**



# Human Research Ethics Applications

Michael Kios



# Commencing Human Research Ethics Applications

**Application guidance for HREC Review of Clinical Research and Trial Projects is via:**

**<https://monashhealth.org/research/resources/human-research-ethics-and-site-authorisation/human-research-ethics-application/>**

**The Human Research Ethics Application Form is created on ERM:**

**<https://au.forms.ethicalreviewmanager.com/Account/Login>**

## **Submission to Research Support Services:**

- Following lodgement of the HREC application in ERM please send an email to **[research@monashhealth.org](mailto:research@monashhealth.org)** .
- In the email please advise of the ERM Reference Number along with the study title.
- Research Support Services will respond with a local reference number



# ERM

<https://au.forms.ethicalreviewmanager.com/Account/Login>



QLD LNR form to be phased out shortly. HREA to be used for all research. Consult local research office for assistance.

[https://www.health.qld.gov.au/hiiro/html/regu/hrec\\_contacts](https://www.health.qld.gov.au/hiiro/html/regu/hrec_contacts)

**Log in**

Email Address

Password

[Log in](#) [New User](#) [Forgotten Password](#)



# ERM Applicant – Create a Project HREA

ERM Applications Home Contacts Help

Work Area

Home Notifications

Actions

Create Folder Delete Folder **Create Project**

Delete Project Duplicate Project Transfer

Work Area

General

Notifications 0 Signatures 0 Transfers 0 Shared 0

Projects

Search Projects

Project Title Project ID Owner Date Created

There are currently no projects listed

Showing 0 to 0 of 0 entries

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**Create Project**

Project Title (maximum 200 characters):\*

TEST HREC APPLICATION

Select Jurisdiction

Victoria

Main Form

HREA

Create Close

ERM Applications

Work Area

Home Notifications

Actions

Project **Create Sub-form** Share

Roles **Submit** Completeness Check

NMA Project Print Correspond

Import Xml



# ERM – Human Research Ethics Application (HREA)

## Create Project

Project Title:\*  
123 Randomised Trial

Select Jurisdiction  
Victoria

Main Form  
Please Select...  
Please Select...  
**HREA**  
Legacy Application Replacement Form VIC  
LNR VIC  
MDF  
Quality Assurance (QA) VIC

Close

kinakkal 20/09/2020 11:23

Navigation Documents Signatures Collaborators Submissions Correspondence History

## HREA

Show Inactive Sections

**Section** **Questions**

ERM Module: [ERM Filter Questions](#)

HREA Introduction: [Introduction](#) [HREC Directory](#)

Project Overview: [Project Overview](#)

Project Team: [Project Team](#)

Disclosure of Interests: [Disclosure of Interests](#)

Restrictions: [Restrictions](#)

Evaluations: [Evaluations](#)

Location: [Location](#)

Methods: [Methods](#)

Participants: [Participants](#)

Method Specific: [Method Specific](#) | [M1](#) | [M2](#) | [M3](#) | [M4](#) | [M5](#) | [M6](#) | [M6 - Clinical Trial Drugs](#) | [M6 - Clinical Trial Device](#) | [M6 - Xenotransplantation](#) | [M6 - Clinical Trial](#) | [M7](#) | [M8](#) | [M9](#)

Participant Specific: [Participant Specific](#) | [P1](#) | [P2](#) | [P3](#) | [P4](#) | [P5](#) | [P6](#) | [P7](#) | [P8](#)

Project Details: [Recruitment - General](#) | [Recruitment - Action Research](#) | [Recruitment - Observational Research](#)

Consent: [Consent 1](#) | [Consent 2](#) | [Alternatives to Consent](#) | [Consent - Ethnographic Research](#) | [Consent - Children and young people](#) | [Consent - Highly dependent on medical care](#) | [Consent - People with a cognitive impairment](#) | [Consent - Involvement in illegal activities](#)

Risk: [Risk - General](#) | [Risk - Dependent or unequal relationships](#)

Benefit: [Benefit](#)

Data and Privacy: [Data Characteristics](#) | [Activities with Data](#)

Generate HREA document: [Generate HREA document](#) | [Upload](#) | [HREC](#) | [Declaration](#) | [Declaration - CI/CP/Lead Investigator](#) | [Declaration - PI](#) | [Declaration - AI/Investigator](#) | [Declaration - Other](#) | [Generate HREA document](#)

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# Create Sub-Forms – Eg: VSM

## Create Sub-form ✕

Select Jurisdiction

Victoria ▼

Select the sub-form that you would like to apply to this form

- 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
- Project Notification Form

submissions Correspo

Close



# What should be submitted in a Human Research Ethics Application?

- **Human Research Ethics Application Form (HREA) – Online at ERM**
- **Victorian Specific Module (VSM) – Online at ERM**
- **Protocol**
- **Product Information (Investigator Brochure) (if relevant)**
- **Participant Information & Consent Form (PICF) – DHHS Templates**
- **Any questionnaires / participant diaries/ advertising**
- **Any document which will assist in the scientific and ethical review of the study**
- **Radiation – Medical Physicist Report (if relevant)**
- **HREC Review Only Indemnity & Insurance Certificate (if relevant)**



# Human Research Ethics Application - HREA

The **HREA** provides sufficient detail about the research project to allow an HREC to make an informed decision about the ethical & scientific acceptability of the study.

- Project Summary
- Researcher details
- Resources
- Sites involved
- Project details
- Participant details
- Recruitment & consent
- Data & Privacy
- Project specific details
- Declarations



# Victorian Specific Module - VSM

The **VSM** is mandatory for all research conducted in the State of Victoria  
**For Completion in ERM**

## 3 Sections:

1. Recruitment of adult participants who do not have decision making capacity
2. Collection, use and/or disclosure of personal and/or health information
3. Removal of tissue or blood from a living or deceased adult or child

**A former hard copy version of the VSM had a Section 4 related to Ionising Radiation. Completion is required for assessment by the Monash Health Radiation Safety Officer.**

**Section 4: Use of Ionising radiation**

**Not on ERM – Available from the Research Support Services web site:**

**<https://monashhealth.org/research/resources/human-research-ethics-and-site-authorisation/ionising-radiation/>**



# Protocol /Project Description

The **Protocol** / Project **Description** is a description of the procedure to standardize a method of experimentation in order to get consistent results and ensure the safety of participants.



# Investigator Brochure (IB)

- The **Investigator Brochure** is a comprehensive document outlining the information about an investigational product.
- Dose of study drug, Frequency of dosing, Methods of administration, Safety & monitoring procedures
- Any other product information



# Participant Information and Consent Form - (PICF)

- Informed consent is documented by means of a written, signed and dated PICF.
- All PICF's must follow the NHMRC standardised templates  
<https://www.clinicaltrialsandresearch.vic.gov.au/downloads>



# Participant Information and Consent Form - (PICF)

There are 20 sections in the PICF – Delete any sections that are not relevant to your study.

<https://www.clinicaltrialsandresearch.vic.gov.au/downloads>

## 13 Different PICF Templates

- PICF Interventional for Self
- PICF Interventional for Parent and Guardian
- PICF Interventional for Person Responsible/Medical Treatment Decision Maker
- PICF Participant Partner Pregnancy
- **PICF Genetic for Self**
- **PICF Genetic for Parent and Guardian**
- **PICF Genetic for Person Responsible/Medical Treatment Decision Maker**
- PICF Non-Interventional for Self
- PICF Non- Interventional for Parent and Guardian
- PICF Non-Interventional for Person Responsible/Medical Treatment Decision Maker
- **PICF Health and Social Science for Self**
- **PICF Health and Social Science for Parent and Guardian**
- **PICF Health and Social Science for Person Responsible/Medical Treatment Decision Maker**



# Waiver of Consent

**A Waiver of Consent request to access patient identifiable information is usually made because:**

1. Researchers require access to clinical data for a large number of participants for a cohort study or clinical registry;
2. researchers wish to identify suitable participants with a view to inviting the participant into the study.

**Under the Victorian Health Privacy Principles and the National Statement on Ethical Conduct in Human Research (NHMRC 2018), only a Human Research Ethics Committee is permitted to grant a waiver of consent.**

**Ideally, all participants should be given an opportunity to provide informed consent.** However;

- This is not always possible, due to factors such as the participant may have deceased or some time has passed and is no longer contactable.
- There is a provision to apply for a waiver of consent and waiver must demonstrate that the importance of the research outweighs an individual's right to privacy.

**To apply for a Waiver of Consent, the researchers must address sections 2.2 and 3.2 of the National Statement criteria for a Waiver of Consent and ensure the relevant Australian Privacy and Victorian Health Privacy Principles are addressed.**

- <https://monashhealth.org/research/resources/forms-library/>
- <https://monashhealth.org/wp-content/uploads/2022/09/Waiver-of-Consent.pdf>



# Study Materials or Other Documentation

- Questionnaires
- Diaries
- Contact Cards
- Letters
- Translated documents
- Participant instruction or information documents
- Telephone transcripts
- Information provided to participants or products provided to participants
- Online documentation
- Case Report Forms
- Advertising
- Investigator CV's and Qualifications



# Ionising Radiation

## Radiation that involves standard care procedures:

Complete the Notification form in ERM or request a form from Research Support Services

<https://monashhealth.org/research/resources/human-research-ethics-and-site-authorisation/ionising-radiation/>

## Radiation that is beyond standard care:

**A Medical Physicist's Assessment is required.**

Please email the following to the radiation safety officer or to [research@monashhealth.org](mailto:research@monashhealth.org) for a Medical Physicist's Assessment.

- [Section 4 of the Victorian Specific Module](#)
- [Medical Physicists Report Request Form](#)
- Participant Information and Consent Form
- Protocol



# How should the documents be submitted for Human Research Ethics Review?

1. Upload the documents on ERM

<https://au.forms.ethicalreviewmanager.com/Account/Login>

**2. Make sure you click the submit button**

3. Following submission on ERM, send an email to [research@monashhealth.org](mailto:research@monashhealth.org) with the following:

- Project Title
- ERM Reference
- Covering email



# When should documents be submitted to HREC?

2 weeks prior to the meeting date

SUBMISSION DEADLINE	MEETING DATE
21 October	05 November
18 November	03 December



# HREC Meetings - 2023

## **SUBMISSION DEADLINE**

18 January  
15 February  
22 March  
26 April  
24 May  
21 June  
19 July  
23 August  
20 September  
18 October  
22 November

## **MEETING DATE**

02 February  
02 March  
13 April  
11 May  
01 June  
06 July  
03 August  
07 September  
05 October  
02 November  
07 December



# When and How Does a Researcher Receive Feedback

- Feedback is provided in writing generally within 3 working days of meeting
- Feedback provided by email to the Principal Investigator with a copy to the Research Coordinator



# Low or Negligible Risk Projects

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# Low Risk – Negligible Risk

- The expression ‘low risk research’ describes research in which the only foreseeable risk is one of discomfort. Research in which the risk for participants is more serious than discomfort is not low risk.
- The expression ‘negligible risk research’ describes research in which there is no foreseeable risk of harm or discomfort and any foreseeable risk is no more than inconvenience.



# Inconvenience and Discomfort

**Inconvenience is less serious than discomfort.**

- Examples of inconvenience may include participating in a survey containing non-sensitive questions, observing people using a public space or analysing de-identified datasets.
- By comparison, examples of discomforts may include, the discomforts related to measuring blood pressure, and anxiety induced by an interview.



# Examples of Low Risk Research

- Short surveys where the research topic and questions are not sensitive and will not induce feelings of anxiety or have the potential to introduce emotional risks.
- Short Interviews involving a structured set of questions where the research topic and questions are not sensitive and will not induce feelings of anxiety. The interview must not collect identifying information from participants.
- Observational studies of people undertaking non-sensitive activities in a public space that will not be recorded or photographed or identify individuals.
- Research involving only the use of information from existing data collections where the identity of the person cannot be ascertained.
- Secondary use of non-identifiable data or biospecimens.
- Research involving human tissue held in a research tissue bank for which consent was obtained for its use in research at the time of its collection and storage.
- Research involving participants undertaking an activity involving no more than discomfort, is non-sensitive and where only non-identifiable data is collected.



# Low Risk Project Submissions in ERM

All Human Research Ethics Applications to the Monash Health Research Ethics Committee are submitted in the same manner.

Monash Health does not accept Low Negligible Risk (LNR) submissions via the LNR VIC form.

Regardless of whether your project is low risk or full HREC, we only accept the HREA application.

Classification as a Low or Negligible Risk project is made by Research Support Services representatives.

**Create Project**

Project Title:\*  
123 Randomised Trial

Select Jurisdiction  
Victoria

Main Form  
Please Select...  
Please Select...  
HREA  
Legacy Application Replacement Form VIC  
LNR VIC  
MDF  
Quality Assurance (QA) VIC

Close

Submissions via the LNR VIC application form is not accepted by Monash Health



## If a Project is Deemed to be Low Risk

Researchers are notified their project has been received and is a Low Risk Project and allocated to the next Low Risk Panel Meeting

**OR**

Researchers are notified their project is not a Low Risk Project and will be allocated to a to a full HREC meeting

HREC Coordinator reviews the projects allocates to the next Low Risk Panel Meeting and prepares a Schedule which is then emailed the day after the submission deadline to the Low Risk panel for review with a project allocated to each member with a request the review should be returned the day after the meeting date.

Following receipt of the all reviews, minutes are prepared with all reviews for review and ratification by the Chair of the Low Risk Panel.  
A “Subject to Conditions” letter is emailed to the Researchers for response

**Low Risk Approval letter issued once conditions are satisfactorily addressed**



# Low Risk Site Specific Authorisation

- Once a Low Risk project is approved it is ratified by the full HREC;
- SSA can occur in parallel to Low Risk review



# Quality Assurance (QA) Quality Improvement (QI)

## Exempt from Ethical Review

# Quality Assurance/Quality Improvement

- Quality improvement (QI) is an organised process that evaluates, assesses and seeks to improve health service delivery to improve patient and population outcomes and health service efficiency.
- Common QI activities include:
  - sentinel event monitoring,
  - incident monitoring
  - root cause analysis
  - medical record review and other forms of audit as well as peer review meetings and program evaluation.
- QI may include activities involving staff, patients or members of the community and may encompass review of practice, services, health records on a site basis only.
- **A QI study involving other institutions require their own processes to be undertaken and a collaboration agreement entered into for data collation.**



# Quality Assurance Project Submission

In order to apply for QA Approval at Monash Health. (see link to the Monash Health website) –

<https://monashhealth.org/research/resources/human-research-ethics-and-site-authorisation/application-for-quality-assurance-and-negligible-risk-projects/>

- **Step 1** – Monash Health Employee completes the Victorian Quality Assurance (QA) Application form online at: <https://au.forms.ethicalreviewmanager.com/>
- **Step 2** – Following completion of the Quality Assurance (QA) Application Form, Monash Health employee sends a courtesy email to our [research\\_qa@monashhealth.org](mailto:research_qa@monashhealth.org) advising:
  - # ERM Reference Number
  - # Project Title
- **Step 3** – The Quality Assurance (QA) Application Form will be reviewed by the HREC Manager and if required a member of the Human Research Ethics Committee.

An email will be sent to the first named investigator within 3 working days. If the study is deemed to be QA an exempt from Human Research Ethics Review, a letter will be attached to the email ,which may be used for verification purposes with journal editors/conference organisers if there is an intention to publish the results. The outcome will also be recorded on the Ethical Review Manager website.

If the activity is deemed to require human research ethics review, this advice will be communicated within 5-7 working days.



# Human Research Ethics Approval – What Next?

- Yay - HREC Approval – Now we can start!

**NO**

**Governance Required:**

**Site Specific Assessment (SSA) Application**



# Ethics and Governance – 4 Part Series

<b>Date &amp; Time</b>	<b>Topics to be Covered</b>
<p>Thursday</p> <p>29 October 2020</p> <p>12.30 pm – 1.30 pm</p>	<p>Overview of Ethics and Governance Guidelines, Legislation, Polices, Procedures Human Research Ethics Applications Low Risk Applications - Quality Assurance</p> <p><a href="https://us02web.zoom.us/j/89494009527?pwd=K29YYWNOtmxV2xBbnNsdv9mSWhPZz09">https://us02web.zoom.us/j/89494009527?pwd=K29YYWNOtmxV2xBbnNsdv9mSWhPZz09</a></p> <p>Meeting ID: 894 9400 9527      Passcode: 920776</p>
<p>Thursday</p> <p>12 November 2020</p> <p>12.30 pm – 1.45 pm</p>	<p>Site Specific Assessment Applications Governance Supporting Departments Good Clinical Practice Training Legal Documents</p> <p><a href="https://us02web.zoom.us/j/89294836899?pwd=VytsdlRzUIRrUlo0cUxMRTBWTzkwZz09">https://us02web.zoom.us/j/89294836899?pwd=VytsdlRzUIRrUlo0cUxMRTBWTzkwZz09</a></p> <p>Meeting ID: 892 9483 6899      Passcode: 279765</p>
<p>Tuesday</p> <p>24 November 2020</p> <p>12.30 pm – 2.00 pm</p>	<p>Study Site Master File Essential Documents Data, Privacy and Recruitment Informed Consent Witnesses, Interpreters, Incompetent Patients</p> <p><a href="https://us02web.zoom.us/j/82665006872?pwd=cXA0ODM3SVJvc3p6Z1FWVWVz0d0Zldz09">https://us02web.zoom.us/j/82665006872?pwd=cXA0ODM3SVJvc3p6Z1FWVWVz0d0Zldz09</a></p> <p>Meeting ID: 826 6500 6872      Passcode: 002481</p>
<p>Monday</p> <p>30 November 2020</p> <p>12.30 pm – 2.00 pm</p>	<p>Post Approval Submissions HREC Amendments Safety Reporting Protocol Breaches – Protocol Deviations Post Approval Monitoring - Research Progress Reports - Audits Intellectual Property Supplementary Information</p> <p><a href="https://us02web.zoom.us/j/86720721416?pwd=V2hkNVIUYU9qV0QwSWHkdENBc09ydz09">https://us02web.zoom.us/j/86720721416?pwd=V2hkNVIUYU9qV0QwSWHkdENBc09ydz09</a></p> <p>Meeting ID: 867 2072 1416      Passcode: 423386</p>

