

Research Support Services

Overview

of

Ethics and Governance

Session No. 4

Michael Kios



Ethics and Governance – 4 Part Series

Date & Time	Topics to be Covered
<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>https://us02web.zoom.us/j/89494009527?pwd=K29YYWNOtmsxV2xBbnNsdv9mSWhPZz09</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>https://us02web.zoom.us/j/89294836899?pwd=VytsdlRzUIRrUlo0cUxMRTBWTzkwZz09</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>https://us02web.zoom.us/j/82665006872?pwd=cXA0ODM3SVJvc3p6Z1FWVWZ0d0ZlZz09</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>https://us02web.zoom.us/j/86720721416?pwd=V2hkNVIUYU9qV0QwSWhkdENBc09ydz09</p> <p>Meeting ID: 867 2072 1416 Passcode: 423386</p>



Research Support Services

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Chief Medical officer

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Director, Clinical Research

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Agreements, Progress Reports, Research Policies

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Governance - Site Specific Authorisation

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Annual Reports – Agreements - QA



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New HREC Applications

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Post-Approval Amendments

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HREC – Governance - Invoicing



Post Approval Submissions

Michael Kios



Post Approval Submissions

What?

HREC or SSA Amendments eg:

- **Change in Principal Investigator**
- **Protocol Amendments**
- **Amendments to Participant Information and Consent Forms**
- **Protocol Breaches – Protocol Violations or Deviations**
- **Safety Reporting**
- **Annual Progress Reports**

Where?

- **Submissions to HREC or RGO?**
- **Submissions to TGA or VMIA?**
- **Submissions to Lead Site or Participating Sites?**



HREC Amendments

SSA Amendments

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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

Log in

Email Address

Password

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



ERM – HREC or Ethics Amendments

Create Sub-form [x]

Select Jurisdiction

Victoria [v]

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

Please Select... [v]

- Please Select...
- Annual Safety Report VIC
- Ethics Amendment Request VIC
- Project Final Report VIC
- Project Notification Form VIC
- Project Progress Report VIC
- Safety Report VIC
- Serious Breach Report VIC
- Site Closure Report VIC
- Site Specific Assessment (SSA) VIC
- Suspected Breach Report VIC

Close

HREC/ Ethics amendments are amendments relevant to all sites participating in a study.

The following forms can be created as a 'Sub-Form' from the HREA application.

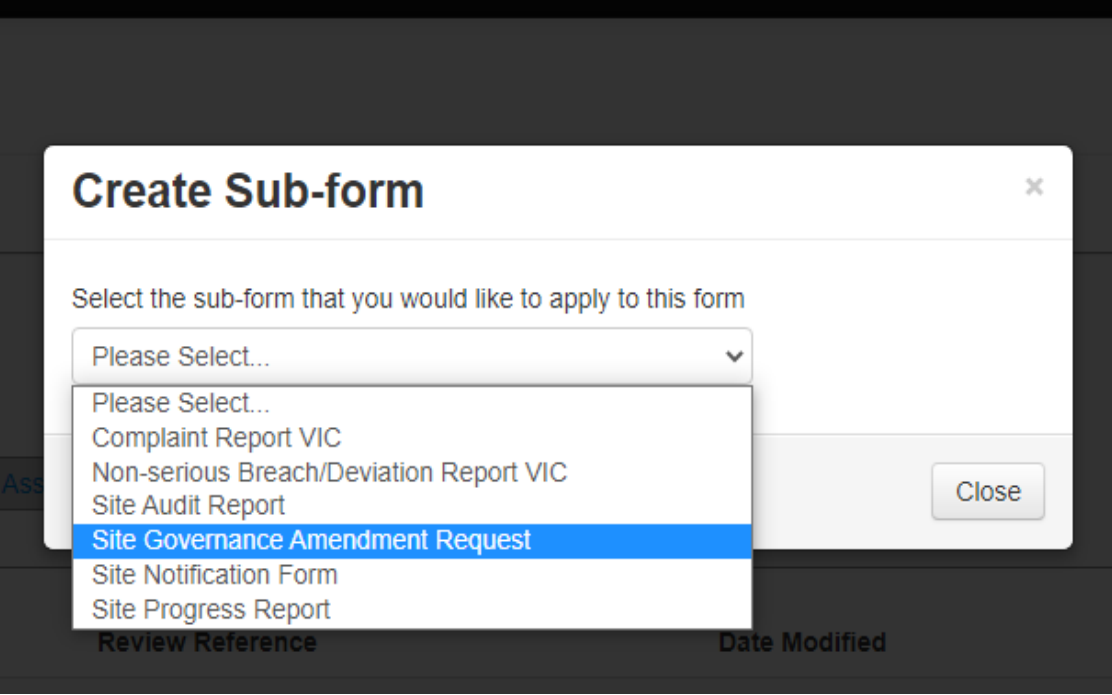
- Click on the HREA application.
- Click on 'Create Sub-Form'.
- Choose relevant jurisdiction.
- Choose form to complete, complete all questions and submit electronically.



SSA Amendment Submission

Site Governance Amendment Request Form is to be used to submit a governance only amendment

Please note fees are applicable for some Governance amendment submissions



The screenshot shows a 'Create Sub-form' dialog box with a close button (X) in the top right corner. Below the title, there is a text prompt: 'Select the sub-form that you would like to apply to this form'. A dropdown menu is open, displaying a list of options: 'Please Select...', 'Complaint Report VIC', 'Non-serious Breach/Deviation Report VIC', 'Site Audit Report', 'Site Governance Amendment Request' (highlighted in blue), 'Site Notification Form', and 'Site Progress Report'. A 'Close' button is located to the right of the dropdown menu. In the background, a table with columns 'Review Reference' and 'Date Modified' is partially visible.

****Previously 'Site Notification Form' was the only form available for submitting governance amendments. Site Notification Forms are to be used for all other site related notifications only.**



ERM – Applicant: Submission

Once any ERM Application to Monash Health has been electronically submitted:

- Email Research Support Services at Research@monashhealth.org
- Include ERM Project ID, Application Reference Number, Monash Health Reference Number, Study title, Covering Email.
- Include zip file of ERM Application with email.



HREC Amendments

HREC Amendments should be submitted for any of the following:

- Protocol amendments
- Investigator Brochure amendments
- Participant Information and Consent Form amendments
- Changes to study materials
- Change of Principal Investigator
- Other matters in consultation with Research Support Services



SSA Amendment Submissions

Requirements:

- Lead HREC approval letter
- Copy of all HREC approved documents
- Submission of any Sites Specific amendments based on the master HREC approved documents.

SSA amendments must be submitted by ERM and notification emailed to research@monashhealth.org with the following details:

- Monash Health Reference number
- ERM Reference number
- Title of project

Research Support Services can supply the former DHHS templates if there are issues with ERM



Safety Reporting

Michael Kios



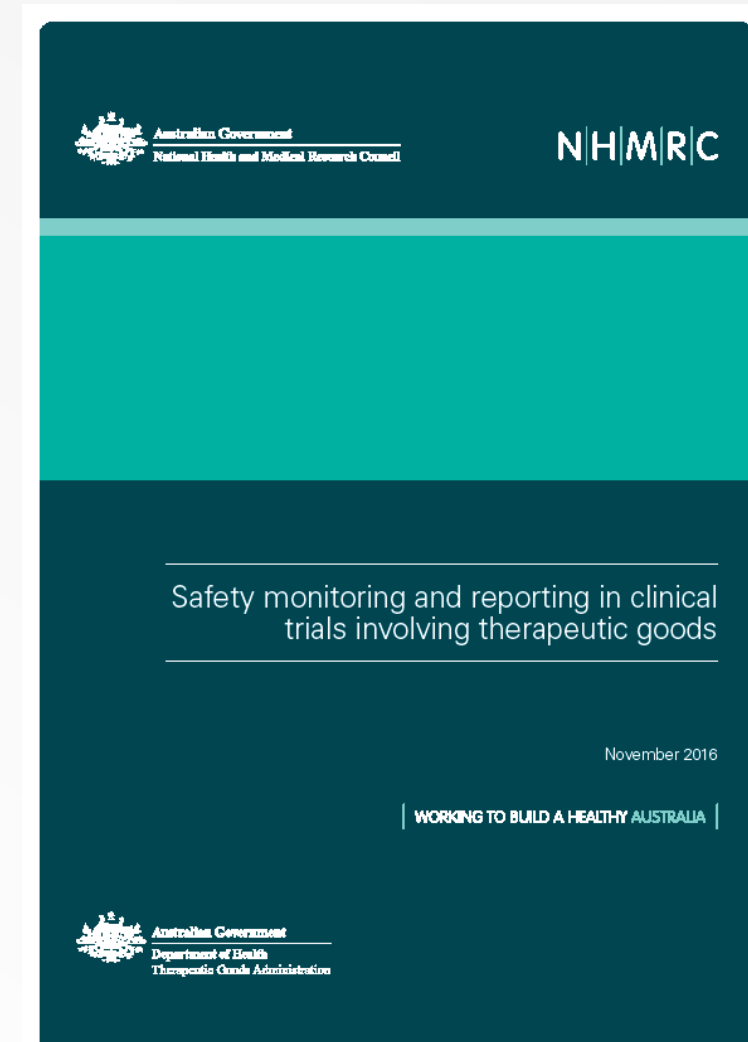
Safety Reporting: Regulatory Guidelines

<https://monashhealth.org/research/research-ethics-and-governance-forms/adverse-events/>

Monash Health has adopted the NHMRC “Safety monitoring and reporting in clinical trials involving therapeutic goods” Position Statement (November 2016). <https://www.nhmrc.gov.au/guidelines-publications/eh59>

Sponsors must also abide by the TGA “Pharmacovigilance responsibilities of medicine sponsors” Australian recommendations and requirements (September 2017)

<https://www.tga.gov.au/publication/pharmacovigilance-responsibilities-medicine-sponsors>



Common Safety Reporting Terms

AE = Adverse Event

SAE = Serious Adverse Event

SUSAR = Suspected Unexpected Serious Adverse Reaction

USADE = Unanticipated Serious Adverse Device Effect

SSI = Significant Safety Issue

USM = Urgent Safety Measure



Adverse Event - AE

ICH-GCP Glossary

Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An adverse event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product (see the ICH Guideline for Clinical Safety Data Management: Definitions and Standards for Expedited Reporting).

These are to be kept in the study site files – not to be submitted to HREC



Serious Adverse Event (Reaction)- SAE (SAR)

- Any adverse event/adverse reaction that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect.
- Note: Life-threatening in the definition of a serious adverse event or serious adverse reaction refers to an event in which the participant was at risk of death at the time of the event. It does not refer to an event that hypothetically might have caused death if it were more severe.

These are to be kept in the study site files – not to be submitted to HREC



SUSAR - Suspected Unexpected Serious Adverse Reaction

USADE - Unanticipated Serious Adverse Device Effect

SUSAR:

A serious adverse event for which there is some degree of probability that the event is an adverse reaction to the administered drug, and the adverse reaction is unexpected.

USADE:

Serious adverse device effect which by its nature, incidence, severity or outcome has not been identified in the current version of the risk analysis report.



SSI - Significant Safety issue

USM - Urgent Safety Measure

SSI = Significant Safety Issue

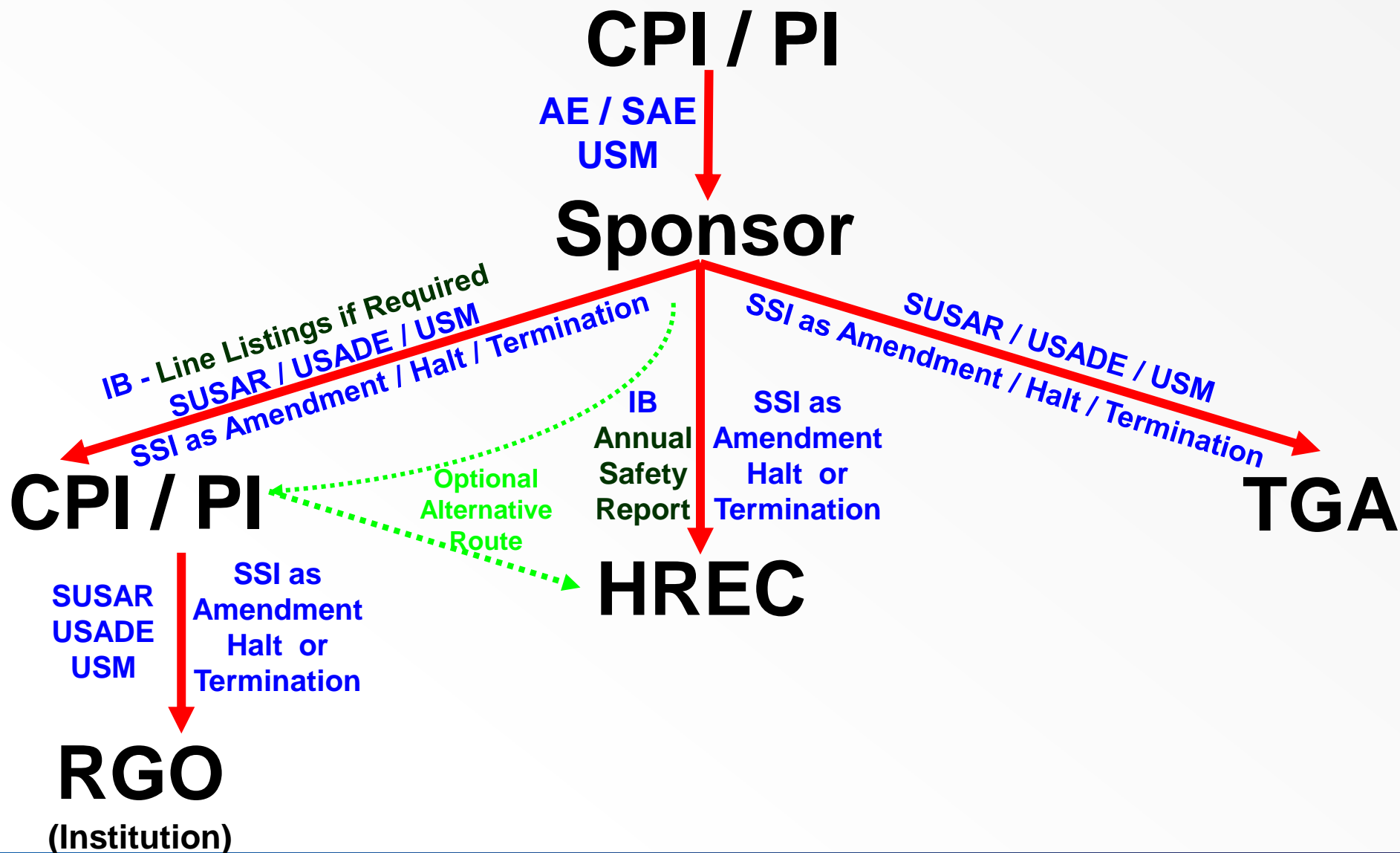
A safety issue that could adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial.

USM = Urgent Safety Measure

- A measure required to be taken in order to eliminate an immediate hazard to a participant's health or safety.
- Note: This type of significant safety issue can be instigated by either the investigator or sponsor and can be implemented before seeking approval from HRECs or institutions.



Safety Reporting Summary



Safety Reporting – Principal Investigators

The Principal Investigator should:

- a. capture and assess all AEs that occur at the site as required and in accordance with the protocol
- b. report to the sponsor **within 24 hours of becoming aware of the event**:
 - all SAEs, except those that are identified in the protocol as not needing immediate reporting
 - any occurrences of congenital anomaly/birth defect arising from any pregnancy of a participant (or partner)
 - all urgent safety measure instigated by the site
- c. report to the sponsor as specified in the protocol:
 - all safety critical events
 - any additional requested information relating to reported deaths
- d. report to the institution **within 72 hours** of becoming aware of the event:
 - all significant safety issues
 - SUSARs arising from the local site.



Safety Reporting of SUSARS – Sponsors

Sponsors keep detailed records of all reported **adverse events** and maintain up-to-date tabulations and/or line listings

Sponsors assess and categorise the safety reports received from investigators, and report all **suspected unexpected serious adverse reactions** occurring in Australian participants to the Therapeutic Goods Administration for fatal or life threatening Australian SUSARs, immediately, but no later than **7 calendar days** after being made aware of the case, with any follow-up information within a further 8 calendar days.

For all other Australian SUSARs, no later than **15 calendar days** after being made aware of the case.

When determining whether a SUSAR has occurred, where the sponsor's causality assessment conflicts with the assessment made by the site investigator, the site investigator's assessment cannot be downgraded by the sponsor (i.e. altered from 'related' to 'not related'). In this case, if an investigator's judgment triggers the reporting of a SUSAR, the opinion of both the investigator and the sponsor should be provided with any SUSAR report sent to the TGA.

The same as above goes for USADEs



Safety Reporting of SSI's - Sponsors

The Sponsor should:

- Notify the TGA, HREC and investigators of all **significant safety issues** that adversely affect the safety of participants or materially impact on the continued ethical acceptability or conduct of the trial. Significant safety issues that meet the definition of an urgent safety measure should be notified **within 72 hours**, and all other significant safety issues should be notified **within 15 calendar days** of the sponsor instigating or being made aware of the issue.
- **Note 1:** Often, significant safety issues (SSIs) do not fall within the definition of a SUSAR and thus are not subject to the reporting requirements for SUSARs. SSIs usually require other action, such as the reporting of an urgent safety measure, an amendment, a temporary halt or an early termination of a trial. In addition, SSIs often result in safety-related changes to trial documentation. These amendments should be submitted to the HREC **without undue delay**.
-
- **Note 2:** Urgent Safety Measures (USMs) are one type of significant safety issue where sponsors or trial investigators act immediately to protect participants from an immediate hazard to their health and safety. Consequently, USMs are often instigated before the TGA and HREC are notified. In these cases, it is strongly recommended that the sponsor **contact the TGA within 24 hours** of the measure being taken.



Annual Safety Reports

The Sponsor should:

- Provide the HREC with an **annual safety report** including a clear summary of the evolving safety profile of the trial. This report should allow the HRECs to assess whether ongoing safety monitoring is being conducted appropriately and that the trial's safety monitoring plans are being followed and where necessary, are being adapted to take into account new findings as the trial progresses
- The Executive Summary of safety information produced for international regulators, such as a Development Safety Update Report (DSUR), may serve as the annual safety report sent to HRECs (a full DSUR is not required). The timing of the annual safety report may be aligned with the reporting cycles of global companies or aligned with the annual progress report sent to the HREC.



Safety Reporting: Sponsor Submission to HREC

Submission is via ERM but an email needs to be sent to:
Research@monashhealth.org

Email must include:

- Monash Health local reference number
- ERM number
- Title of Project
- Coordinating Principal Investigator or local Principal Investigator

Safety reporting forms have been removed from the DHHS site. If any issues are encountered in submitting through ERM, the DHHS templates are available by request from Research Support Services.



Annual Safety Report

for a clinical trial involving an investigational medicinal product or investigational medical device

This form should be used by the sponsor to provide the reviewing Human Research Ethics Committee (HREC) with a summary of the evolving safety profile of the project.

The sponsor is responsible for reporting to the reviewing HREC, in accordance with *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (NHMRC, 2016).

Research Project

HREC reference number	<input type="text" value="e.g. HREC/17/Abc/123"/>	HREC approval date	<input type="text" value="Select date"/>
Local reference number	<input type="text" value="Enter text"/>	Date of this report	<input type="text" value="Select date"/>
Project title	<input type="text" value="Enter text"/>		
Sponsor	<input type="text" value="Enter text"/>	Sponsor telephone	<input type="text" value="Enter text"/>
Sponsor contact (Aus)	<input type="text" value="Enter text"/>	Sponsor email	<input type="text" value="Enter text"/>
Coordinating Principal Investigator (CPI) for project	<input type="text" value="Enter text"/>		
Study coordinator name	<input type="text" value="Enter text"/>	Study coordinator email	<input type="text" value="Enter text"/>

Safety Profile

Description and analysis of new/relevant safety findings	<input type="text" value="Enter text"/>
Implications of the safety findings on the risk and benefit of the project	<input type="text" value="Enter text"/>
Describe any measures, taken or proposed, to minimise risk	<input type="text" value="Enter text"/>
Comment from sponsor	<input type="text" value="Enter text"/>

Safety Monitoring

Has the safety monitoring plan been reviewed or adapted in the past 12 months?	<input type="text" value="Select one"/>
<i>If changes are made to any documents approved by the HREC, submit the amended document(s) together with an Amendment Request Form (available from www2.health.vic.gov.au/about/clinical-trials-and-research) for review by the HREC.</i>	
Has the safety monitoring plan been implemented?	<input type="text" value="Select one"/>
Does the project have a Data and Safety Monitoring Board (DSMB) or safety monitor?	<input type="text" value="Select one"/>
How many times has the DSMB or safety monitor reviewed the project in the past 12 months?	<input type="text" value="Enter number"/>
Have all relevant communications from the DSMB or safety monitor been submitted to the reviewing HREC?	<input type="text" value="Select one"/>
<i>If the recommendation of the DSMB or safety monitor has not yet been submitted to the reviewing HREC, attach it to this report.</i>	
Comment on safety monitoring (optional)	<input type="text" value="Enter text"/>

Investigator's Brochure (or Other Reference Safety Information)

The reference safety information for a research project may be contained in an investigator's brochure, product information, instructions for use or clinical investigational plan.

Has the investigator's brochure (or other reference safety information) been reviewed?

Does the investigator's brochure (or other reference safety information) require an update with new and relevant information?

If changes are made to any documents approved by the HREC, submit the amended document(s) together with an Amendment Request Form (available from www2.health.vic.gov.au/about/clinical-trials-and-research) for review by the HREC.

Investigational Medicinal Product

Is the investigational product on the Australian Register of Therapeutic Goods (ARTG)?

If No, describe the safety profile of the investigational medicinal product

Declaration

To be completed by the Sponsor/CRO, or the Coordinating Principal Investigator (CPI) for a multi-site project, or the Principal Investigator (PI) for a single-site project.

The information provided in this report is complete and correct. The project is being conducted in accordance with the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007) and *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (NHMRC, 2016), or as amended.

Name	<input type="text" value="Enter text"/>	Email	<input type="text" value="Enter text"/>
Organisation	<input type="text" value="Enter text"/>	Telephone	<input type="text" value="Enter number"/>
Signature	<input type="text" value="Signature"/>		
Date	<input type="text" value="Select date"/>		

Office use only

Research office acknowledgement - HREC

Name	<input type="text" value="Enter text"/>	Position	<input type="text" value="Enter text"/>
Comment	<input type="text" value="Enter text"/>		
Signature	<input type="text" value="Signature"/>		
Date	<input type="text" value="Select date"/>		

Research office acknowledgement - RGO

Name	<input type="text" value="Enter text"/>	Position	<input type="text" value="Enter text"/>
Comment	<input type="text" value="Enter text"/>		
Signature	<input type="text" value="Signature"/>		
Date	<input type="text" value="Select date"/>		

Safety-Report

This form should be used for reporting any type of safety event that occurs during the conduct of a clinical trial or health/medical research project.

The sponsor is responsible for reporting a safety event to the reviewing Human Research Ethics Committee (HREC), in accordance with *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (NHMRC, 2016).

The site Principal Investigator (PI) should provide a copy to the site Research Governance Officer (RGO) as required.

Research-Project

HREC reference number	<input type="text" value="e.g. HREC/17/Abc/123"/>	HREC approval date	<input type="text" value="Select date"/>
Local reference number	<input type="text" value="Enter text"/>	Date of this report	<input type="text" value="Select date"/>
Project title	<input type="text" value="Enter text"/>		
Sponsor	<input type="text" value="Enter text"/>	Sponsor telephone	<input type="text" value="Enter text"/>
Sponsor contact (Aus)	<input type="text" value="Enter text"/>	Sponsor email	<input type="text" value="Enter text"/>
Coordinating Principal Investigator (CPI) for project	<input type="text" value="Enter text"/>		
Study coordinator	<input type="text" value="Enter text"/>	Study coordinator email	<input type="text" value="Enter text"/>
Is the project a clinical trial?	<input type="text" value="Select one"/>		

Site

Site name (organisation)	<input type="text" value="Enter text"/>	Principal Investigator (PI)	<input type="text" value="Enter text"/>
State/Territory	<input type="text" value="Enter text"/>		

Safety-Event

Type of safety event	<input type="text" value="Select one"/>		
Action taken	<input type="text" value="Select one"/>		
Event ID (local reference)	<input type="text" value="Enter text"/>	Status of event	<input type="text" value="Select one"/>
Start date of event	<input type="text" value="Select date"/>	End date of event	<input type="text" value="Select date"/>
Description of event	<input type="text" value="Enter text"/>		
Relationship to investigational product (clinical trial only)	<input type="text" value="Select one"/>		
Could the event adversely affect safety of participants, or materially impact the continued ethical acceptability or conduct of the research project?	<input type="text" value="Select one"/>		
Impact on participant safety	<input type="text" value="Enter text"/>		
Impact on conduct of the research project	<input type="text" value="Enter text"/>		
Impact on documentation for the research project	<input type="text" value="Enter text"/>		
Action(s) recommended	<input type="text" value="Enter text"/>		

If changes are made to any documents approved by the HREC, submit the amended document(s) together with an

Amendment-Request-Form-(available-from-www2.health.vic.gov.au/about/clinical-trials-and-research)-for-review-by-the-HREC.

Clinical-trial-participant-notification-(Victoria)

If the event is a Suspected Unexpected Serious Adverse Reaction (SUSAR) or Unanticipated Serious Adverse Device Effect (USADE) that affected a participant at a site in Victoria, the Victorian Managed Insurance Authority (VMIA) must be notified of the event using this form. When notifying VMIA, include the participant's initials, date of birth and UR number. Refer to the VMIA website www.vmia.vic.gov.au.

Declaration

The information provided in this report is complete and correct. The project is being conducted in keeping with the conditions of approval of the reviewing HREC (and subject to any changes subsequently approved). The project is being conducted in compliance with the *National Statement on Ethical Conduct in Human Research* (NHMRC, 2007) and *Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods* (NHMRC, 2016), or as amended.

Name	<input type="text" value="Enter text"/>	Email	<input type="text" value="Enter text"/>
Organisation	<input type="text" value="Enter text"/>	Telephone	<input type="text" value="Enter number"/>
Signature	<input type="text" value="Signature"/>		
Date	<input type="text" value="Select date"/>		

Office-use-only

Research-office-acknowledgement--HREC

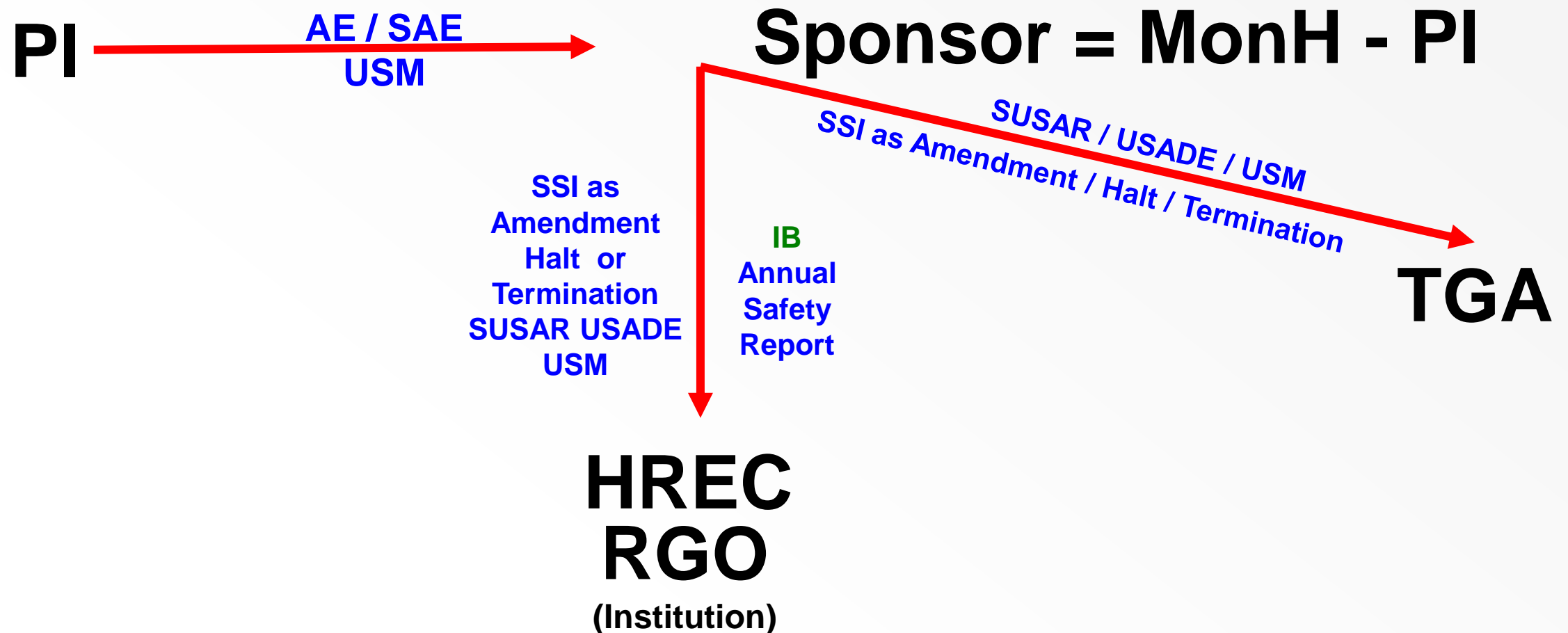
Name	<input type="text" value="Enter text"/>	Position	<input type="text" value="Enter text"/>
Comment	<input type="text" value="Enter text"/>		
Signature	<input type="text" value="Signature"/>		
Date	<input type="text" value="Select date"/>		

Research-office-acknowledgement--RGO

Name	<input type="text" value="Enter text"/>	Position	<input type="text" value="Enter text"/>
Comment	<input type="text" value="Enter text"/>		
Signature	<input type="text" value="Signature"/>		
Date	<input type="text" value="Select date"/>		

Safety Reporting Summary – Investigator Initiated Trial

Investigator Initiated Studies where the PI / Institution are the Sponsors



Protocol Breaches

Protocol Deviations

Michael Kios



Protocol Deviations – ICH Guidelines

4.5.2 The investigator should not implement any deviation from, or changes of the protocol without agreement by the sponsor and prior review and documented approval/favourable opinion from the IRB/IEC of an amendment, except where necessary to eliminate an immediate hazard(s) to trial subjects, or when the change(s) involves only logistical or administrative aspects of the trial (e.g., change in monitor(s), change of telephone number(s)).

4.5.4 The investigator may implement a deviation from, or a change of, the protocol to eliminate an immediate hazard(s) to trial subjects without prior IRB/IEC approval/favourable opinion. As soon as possible, the implemented deviation or change, the reasons for it, and, if appropriate, the proposed protocol amendment(s) should be submitted:

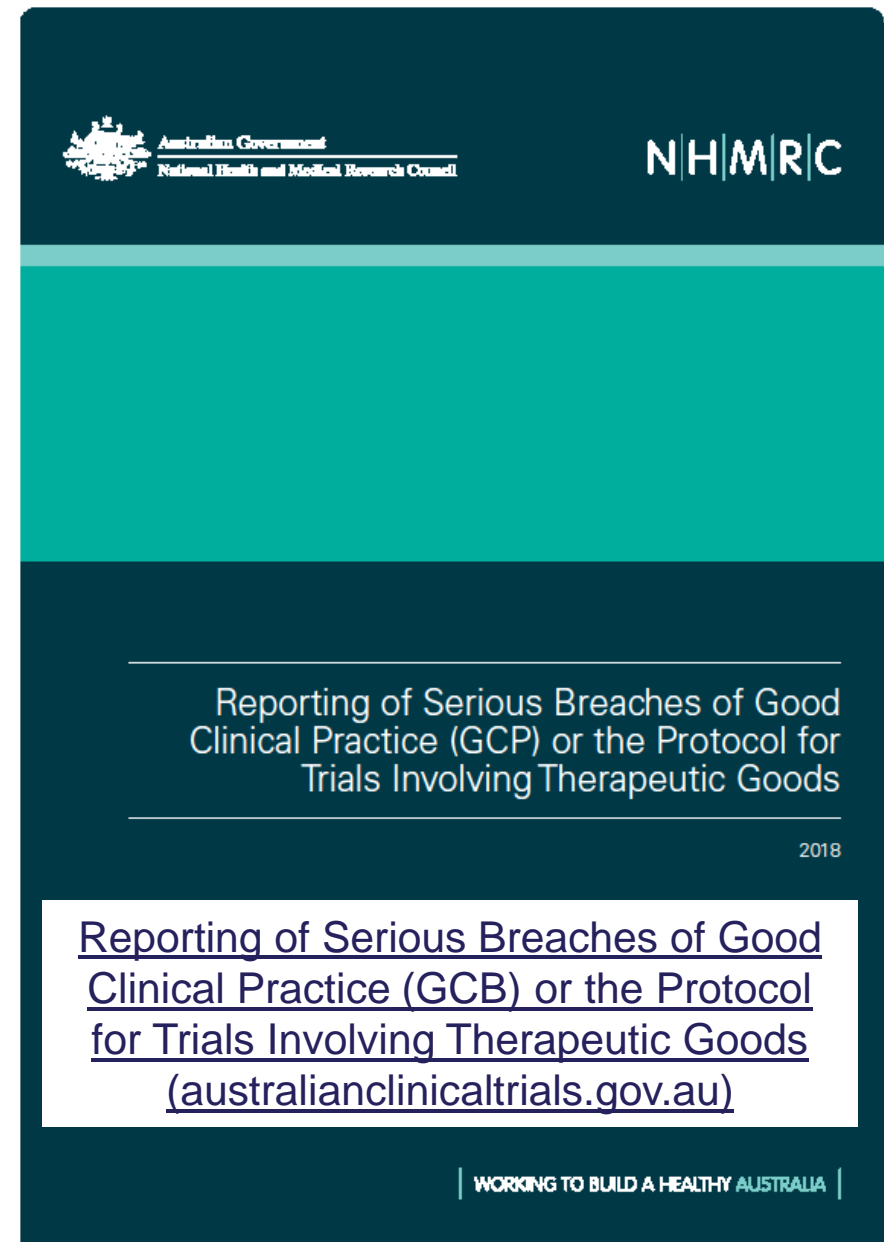
- (a) to the IRB/IEC for review and approval/favourable opinion,
- (b) to the sponsor for agreement and, if required,
- (c) to the regulatory authority(ies).



NHMRC Breach Reporting Guidelines

This guidance sets out a framework for the management and reporting of serious breaches. Its purpose is to:

- clarify GCP Guideline requirements for reporting deviations
- rationalise the reporting of protocol deviations to align with GCP, which only requires the reporting of a small sub-set of deviations to review bodies
- adopt a standard term ('serious breach') to describe this sub-set • clarify the roles of key stakeholders
- define standard reporting timelines
- provide standard forms for serious breach and suspected breach reporting to Human Research Ethics Committees (HRECs) to replace the forms currently used within jurisdictions to report protocol deviations (Appendix I and II).



Protocol Breaches

- Serious Breach
- Non Serious Breach
- Suspected Breach

- To be submitted through ERM but former DHHS templates may be used if issues are encountered through ERM.

- Templates are available on request from Research Support Services



Serious Breach Report

- **Serious Breach** is a breach of Good Clinical Practice or the protocol that is likely to affect to a significant degree the safety or rights of a research participant or the reliability and robustness of the data generated in the research project.
- Serious breaches must be notified to the reviewing Human Research Ethics Committee (HREC).
- Serious breaches must be notified to Monash Health HREC.
- Serious breaches at a site should also be reported by the site Principal Investigator (PI) to their site Research Governance Officer if the project was reviewed by an external HREC.

Serious Breach Report Form (Sponsor)

Serious Breach is a breach of Good Clinical Practice or the protocol that is likely to affect to a significant degree the safety or rights of a research participant or the reliability and robustness of the data generated in the research project.

Serious breaches must be notified to the reviewing Human Research Ethics Committee (HREC).

This form must be completed by the **sponsor** when reporting a serious breach to the Human Research Ethics Committee (HREC) or when a sponsor is providing additional/follow-up information following notification by an individual / institution of a confirmed serious breach.

Serious breaches at a site should also be reported by the site Principal Investigator (PI) to their site Research Governance Officer (RGO) using this form.

Research Project

HREC reference number	<input type="text" value="e.g. HREC/17/Abc/123"/>	HREC approval date	<input type="text" value="Select date"/>
Local reference number	<input type="text" value="Enter text"/>	Date of this report	<input type="text" value="Select date"/>
Project title	<input type="text" value="Enter text"/>		
Sponsor	<input type="text" value="Enter text"/>	Sponsor telephone	<input type="text" value="Enter text"/>
Sponsor contact (Aus)	<input type="text" value="Enter text"/>	Sponsor email	<input type="text" value="Enter text"/>
Coordinating Principal Investigator (CPI) for project	<input type="text" value="Enter text"/>		
Study coordinator name	<input type="text" value="Enter text"/>	Study coordinator email	<input type="text" value="Enter text"/>
Is the project a clinical trial?	<input type="text" value="Select one"/>		

Organisation/individual committing the serious breach

Name	<input type="text" value="Enter text"/>	Principal Investigator (PI)	<input type="text" value="Enter text"/>
State/Territory	<input type="text" value="Enter text"/>		

Details of the serious breach

Has the serious breach had any impact on any of the following:

Participant safety	<input type="text" value="Select one"/>	Participant rights	<input type="text" value="Select one"/>
Reliability and robustness of data	<input type="text" value="Select one"/>		

Additional information required:

Brief explanation of the serious breach and other relevant information	<input type="text" value="Enter text"/>
--	---



Non-serious Breach - Deviation Report

- A **Deviation** is any breach, divergence or departure from the requirements of Good Clinical Practice or the clinical trial protocol and does not have a significant impact on the continued safety or rights of participants or the reliability and robustness of the data generated in the clinical trial.
- To fulfil ICH-GCP requirements any **deviations** are to be reported to the **sponsor**.
- Not all deviations require reporting to the reviewing HREC but sites should decide according to site policy.
- **Monash Health does not require Non-Serious Breaches to be reported to HREC.**

Non-serious Breach - Deviation Report

A **Deviation** is any breach, divergence or departure from the requirements of Good Clinical Practice or the clinical trial protocol and does not have a significant impact on the continued safety or rights of participants or the reliability and robustness of the data generated in the clinical trial. Deviations that are considered to be a **serious breach** should be reported using the **Serious Breach Report Form (Sponsor)**.

To fulfil ICH-GCP requirements any **deviations** are to be reported to the **sponsor**. Not all deviations require reporting to the reviewing HREC but sites should decide according to site policy. A copy of this report should be provided to the Research Governance Officer (RGO) at the Principal Investigator's site.

The **sponsor** in collaboration with the site Principal Investigator should complete this form to report a non-serious breach - deviation.

Research Project

HREC reference number	<input type="text" value="e.g. HREC/17/Abc/123"/>	HREC approval date	<input type="text" value="Select date"/>
Local reference number	<input type="text" value="Enter text"/>	Date of this report	<input type="text" value="Select date"/>
Project title	<input type="text" value="Enter text"/>		
Sponsor	<input type="text" value="Enter text"/>	Sponsor telephone	<input type="text" value="Enter text"/>
Sponsor contact (Aus)	<input type="text" value="Enter text"/>	Sponsor email	<input type="text" value="Enter text"/>
Coordinating Principal Investigator (CPI) for project	<input type="text" value="Enter text"/>		
Study coordinator name	<input type="text" value="Enter text"/>	Study coordinator email	<input type="text" value="Enter text"/>
Is the project a clinical trial?	<input type="text" value="Select one"/>		

Site

Site name (organisation)	<input type="text" value="Enter text"/>	Principal Investigator (PI)	<input type="text" value="Enter text"/>
State/Territory	<input type="text" value="Enter text"/>		

Details of Non-serious Breach - Deviation

Record the date that the non-serious breach - deviation occurred

Brief explanation of the non-serious breach – deviation and risk assessment

Were any participants directly affected by the non-serious breach - deviation



Suspected Breach Report

- **Suspected Breach** is a report that is judged by the reporter as a possible serious breach but has yet to be formally confirmed as a serious breach by the sponsor.
- Serious breaches must be notified to the reviewing Human Research Ethics Committee (HREC).
- This form must be completed when a **third party** (e.g. individual / institution) wishes to report a suspected breach of Good Clinical Practice or the protocol. This should be reported directly to the reviewing HREC without reporting through the sponsor.

Suspected Breach Report Form (Third Party)

Suspected Breach is a report that is judged by the reporter as a possible serious breach but has yet to be formally confirmed as a serious breach by the sponsor.

Serious breaches must be notified to the reviewing Human Research Ethics Committee (HREC). This form must be completed when a **third party** (e.g. individual / institution) wishes to report a suspected breach of Good Clinical Practice or the protocol. This should be reported directly to the reviewing HREC without reporting through the sponsor.

Provide the following details

HREC reference number	<input type="text" value="e.g. HREC/17/Abc/123"/>	HREC approval date	<input type="text" value="Select date"/>
Local reference number	<input type="text" value="Enter text"/>	Date of this report	<input type="text" value="Select date"/>
Project title	<input type="text" value="Enter text"/>		
Coordinating Principal Investigator (CPI) for project	<input type="text" value="Enter text"/>		
Reporter name	<input type="text" value="Enter text"/>		
Organisation	<input type="text" value="Enter text"/>	Contact details	<input type="text" value="Enter text"/>

Reporter's role in/connection to the project:

Details of the organisation/individual committing the suspected breach:

Details of the suspected breach

Provide:

1. A brief explanation of the suspected breach

2. An explanation of where, how and when the suspected breach was identified

3. Any further information



Protocol Breach Reporting by Principal Investigator

The principal investigator should:

Ensure that the trial team is aware of the process for reporting serious breaches.

Report any suspected breaches to the sponsor **within 72 hours** of becoming aware of the suspected breach.

Note: Exceptionally, the investigator, in liaison with their institution, may report the suspected breach directly to the HREC.

Report all serious breaches that have been confirmed by the sponsor as occurring at the site to their institution (research governance office) **within 72 hours** of being notified of the serious breach.



Protocol Breach Reporting by Sponsor

Sponsors have primary responsibility for determining whether any suspected breach meets the definition of a serious breach. In practice, this assessment is often conducted or overseen by the group tasked with monitoring the general quality of the trial and its adherence to the protocol.

Report serious breaches to the reviewing HREC within **7 calendar days** of confirming a serious breach has occurred and provide follow-up reports when required.

For serious breaches occurring at a trial site, notify the site's principal investigator within **7 calendar days** of confirming a serious breach has occurred.



Post Approval Monitoring

Sponsors

**Annual
Research Progress Reports**

Audits

Post Approval Monitoring

- **Annual Progress Reports**
- **Desktop Audits**
- **Full or Themed Audits**

- **Commercial Sponsor Monitoring**
- **Remote Monitoring**
- **Data Safety Monitoring Boards (DSMBs)**

- **Investigator Initiated Studies – Self Audit Tool**



Remote Monitoring - EMR

- The “Remote Access to Electronic Medical Records (EMR) by Sponsors of Commercially Sponsored Clinical Trials” procedure is available on PROMPT.

This can be accessed on the Monash Health intranet via the following link: <http://prompt/Search/SearchLibrary.aspx> .

- For any sponsor that requests a copy of the procedure, it may be downloaded from PROMPT and provided as an attachment. Please note that this procedure is to satisfy the ethics and governance aspects of access to EMR.
- The physical mechanisms for access are continually being developed by IT and the EMR team to ensure all security aspects are in line with hospital policy and data security requirements.



Request for Submission of Annual Research Report

- Research annual reports are **due by 30th April Each Year**
- **For any project that has been approved prior to 1st December 2020**, the Annual Report will be due by the 30th April 2021 irrespective of the HREC approval date.
- For example projects approved in December 2020, annual reports are due 30th April 2022.



Types of Annual Research Reports

The following Annual Reports require completion where relevant:

Project final report –site closure report if project completed

Progress-report –site report (RGO) for all projects.

Progress report –site report (HREC) Only if the project is multisite where Monash Health is the reviewing HREC and other institutions are participating.

All annual reports must be submitted by ERM and notification emailed to

research_progress@monashhealth.org with the

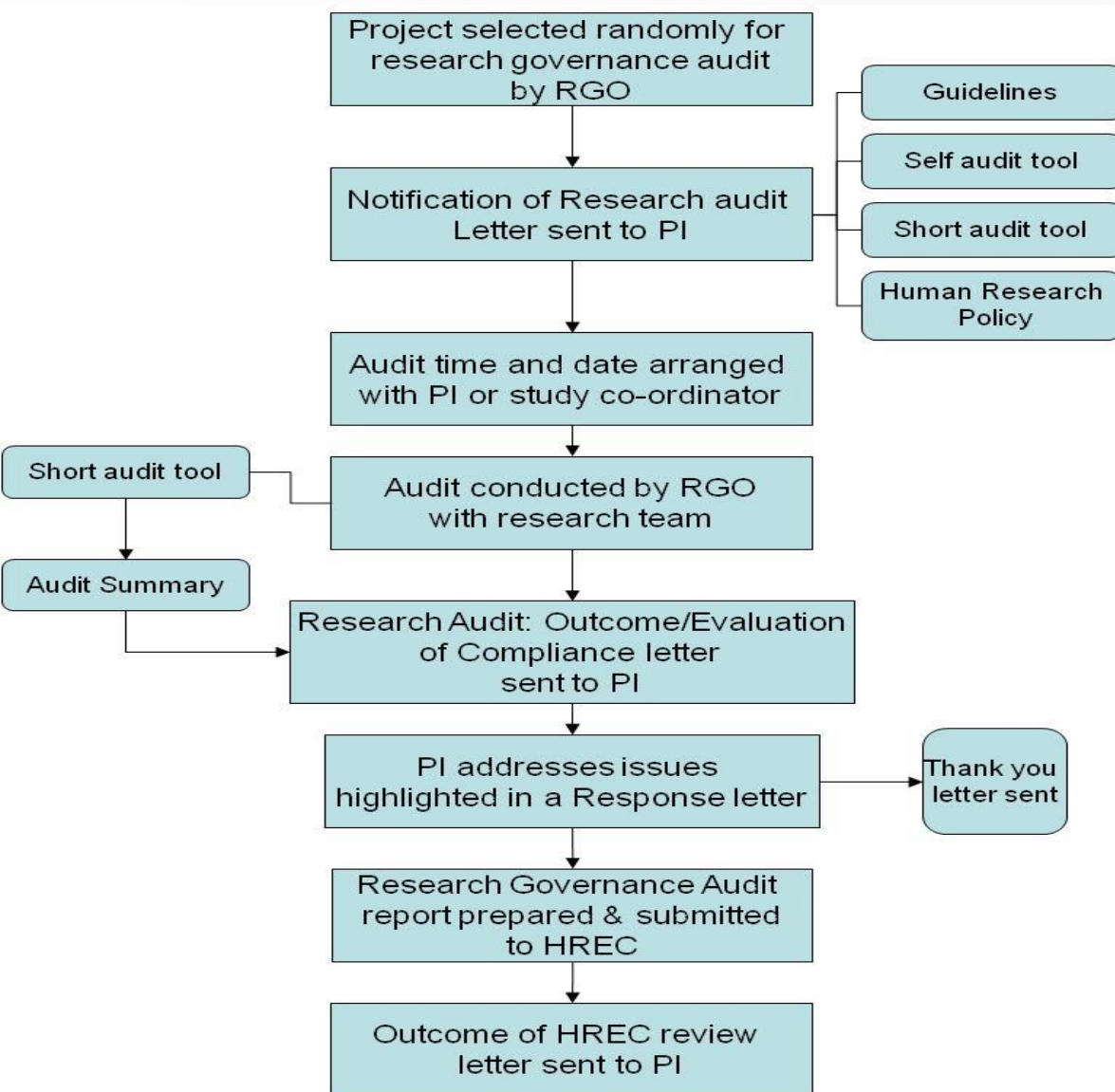
Monash Health Reference number

ERM Reference number

Title of project



Monash Health Research Audit Process



Audit Selection – Random or Reason

**Letter sent with:
Audit Guidelines
Human Research Policy
Self Audit Tool
Short Audit Tool**

Time and Date arranged with the PI & Clinical Trial Coordinator

Auditing can range from several hours to several days depending on the size of the study or the scope of the audit

Audit report sent to PI to address issues and follow up meetings may be required.



Documents to be sighted during audit

- PICF
- Case Report Forms
- Questionnaires (if applicable)
- Study site master file
- Self Audit tool
- Annual Report form



Common problem areas

- Delegation Log
- Consent requirements
- Protocol Compliance including procedures, records, privacy & confidentiality
- Participant recruitment numbers and timelines
- Notification of research participation in patient medical records
- Employment of new research staff without notifying participants
- Advertising material used to recruit participants not approved by HREC
- All changes in Researcher personnel needs to be notified via a protocol amendment or the annual research report.
- All Researchers involved with the project must be listed on original HREC application including Research co-ordinators.



Intellectual Property

Michael Kios



What is Intellectual Property?

- **Intellectual Property (IP)**
- **Creations of the mind or intellect that can be legally owned**



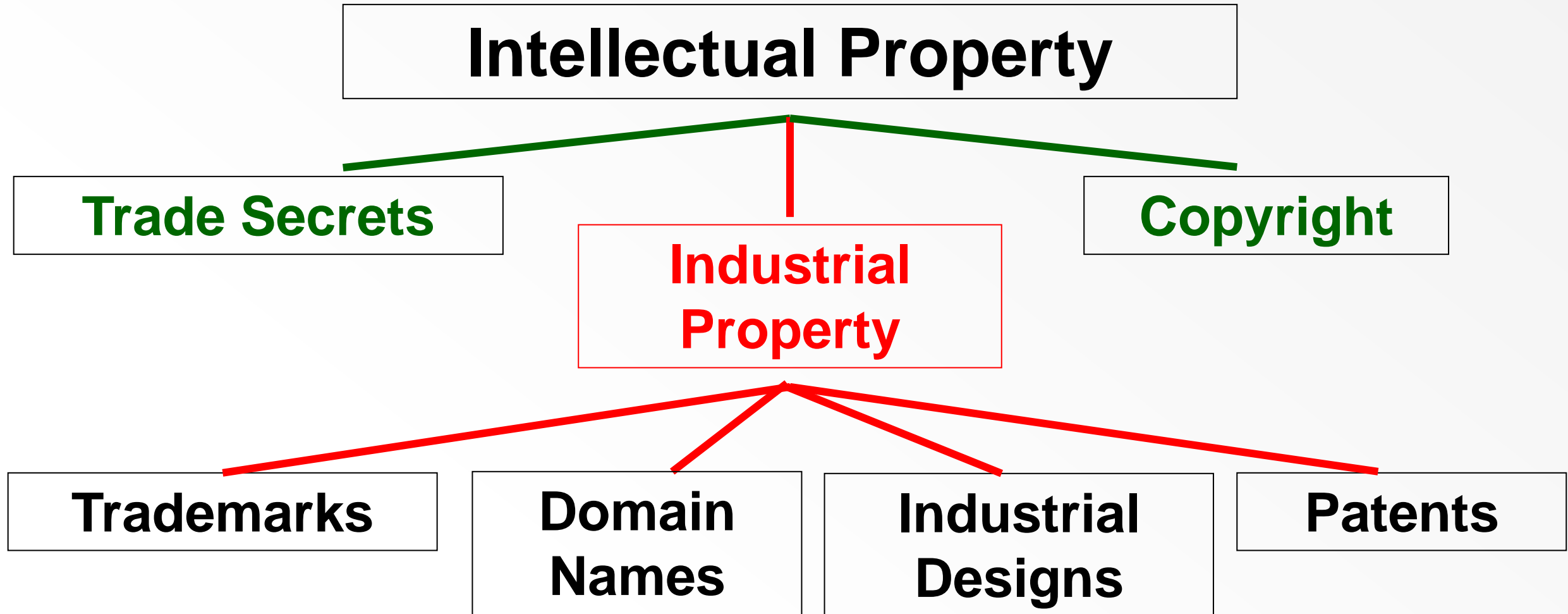
World Intellectual Property Organization (WIPO)

The World Intellectual Property Organization list of subject matter protected by intellectual property rights:

- literary, artistic and scientific works;
- performances of performing artists, phonograms, broadcasts;
- inventions in all fields of human endeavour;
- scientific discoveries;
- industrial designs;
- trademarks, service marks, commercial names & designations;



Intellectual Property



Trade Secrets

- A trade secret is a formula, practice, process, design, instrument, pattern, or compilation of information which is not generally known or reasonably ascertainable, by which a business can obtain an economic advantage over competitors or customers.
- Covered by Confidentiality Agreements



Copyright

Copyright is automatic

- There is no copyright registration process
- You do not need to claim copyright by including the copyright symbol and their name on a work ©
- Copyright owners can transfer their copyright
- An author can assign copyright to a publisher.
- If a creator made the work as part of their job, the employer will generally own copyright.



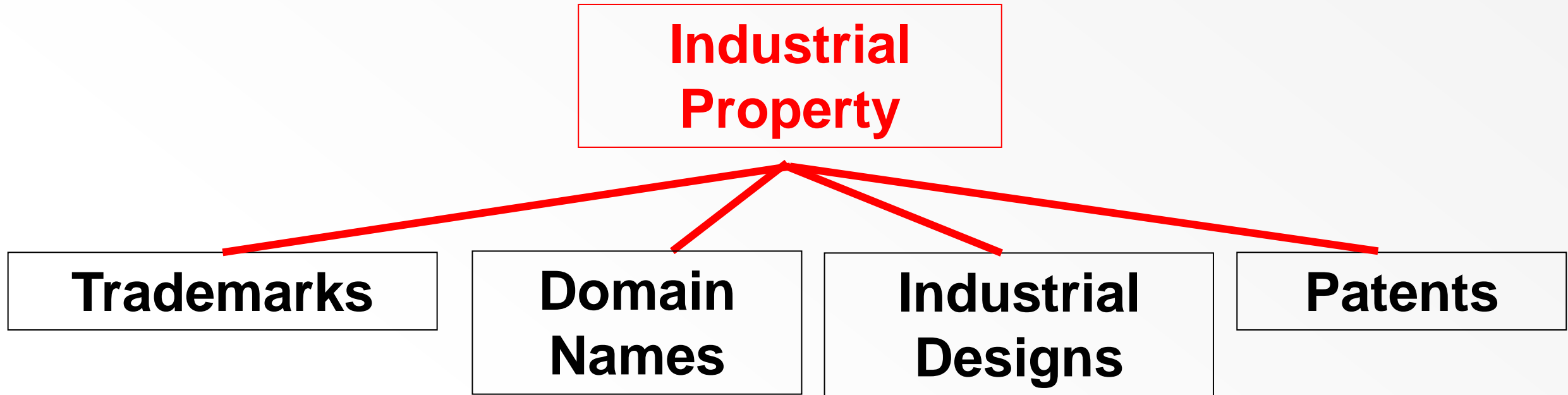
Copyright

Copyright may include works that are:

- literary, artistic, photographic, architectural, musical, computer programs
- Copyright gives the creator of an original work exclusive rights to it, usually for a limited time
- Usually 70 years after the death of the author, or the year the publication was made public.
- Time of Copyright can vary depending on jurisdictional laws



Industrial Property



Trade Marks

A trademark is a recognizable sign, design or expression which identifies products or services of a particular source from those of others.

Eg:

- Commonwealth Bank
- Cadbury



Domain Names

Domain Names are organisations identity in cyberspace.

.com - used by commercial organizations

.org - used by non-profit organizations

.net - supposed to be used by network providers

.edu - used by educational institutions

.gov - used by government



Industrial Designs

Creation of a 2 or 3 dimensional shape or pattern that has aesthetic value

Protection may be by:

- Copyright
- Industrial design right (Design Patent) that protects the visual design of the object

The initial period of registration for your design lasts for five years from the filing date of your application.

You may choose to renew your design registration for a further five years, to a maximum of 10 years.



Patents

A patent grants an inventor exclusive rights to make, use, sell, and import an invention for a limited period of time, in exchange for the public disclosure of the invention.

An invention is a solution to a specific technological problem, which may be a product or a process.

There are two types of patents in Australia



Innovation Patents

1. Innovation patents – Commenced 2001 but will be phased out

Protect innovative creations that are not necessarily new eg practical applications into marketable products.

Does not legally stop others from copying your innovation unless you have your innovation patent examined.

Useful for Small business seeking first-to-market advantage.

Protection period is 8 years



Patents

2. Standard patents

Standard patents provide long term protection and control over an invention for up to 20 years from the day you file your complete application.



Patents

Invention:

1. Patentable
2. Useful
3. Novel
4. Non-obvious

Patent Procedure:

1. Patent Attorney
2. Provisional Patent
3. PCT – Patent Cooperative Treaty
4. Jurisdictions

Commercialisation:

Partner
Investment
Yourself



Monash Health IP policy

Policy Statement

Monash Health recognises that considerable Intellectual Property is generated by its employees and it is committed to supporting the commercialisation and sharing of those Intellectual Property rights.

Who must comply with this policy?

All Monash Health employees.

For the purpose of this policy, "Monash Health employees" means all individuals:

- employed directly by Monash Health, including full time and part time employment;
- indirectly employed through Monash Health such as on grant funds administered by Monash Health;
- jointly appointed by Monash Health and one or more third parties;
- that utilise the facilities or resources of Monash Health including, without limitation, for clinical or research applications; or
- who are students that use the facilities or resources of Monash Health as part of their research or study activities.

Purpose:

This policy is designed to enable all Monash Health employees to clearly understand the circumstances in which Monash Health owns Intellectual Property and the procedure involved in protecting such Intellectual Property.

Scope

The policy and procedure applies to all Monash Health employees and visitors in any and all of the sites operated by Monash Health

List of Monash Health procedures link to this Operational Policy

[Music therapists copyright licencing](#)

[Publication and dissemination of research findings](#)

[Research ethics authorship for research](#)

Definitions

Intellectual Property means all intellectual property that includes, but is not limited to, patents and applications; know-how, confidential information and trade-secrets; computer programs; designs; copyright; trademarks and contractual rights that exist in relation to any innovation or work. It also applies to research results or inventions obtained or produced as a result of the endeavours of Monash Health employees.

Monash Health employee means any individual who is directly or indirectly employed by Monash Health, including full time and part-time employment.

Monash Health visitors means any visiting student, scientist or medical officer who uses Monash Health's facilities, funds or resources for research or study purposes.

Monash Health Intellectual Property Committee means the committee established by Monash Health for administration and commercialisation of Intellectual Property covered by this policy.

First Issued: 16/09/2013

Page 1 of 4

Last Reviewed: 23/03/2016

Version Changed: 23/03/2016

UNCONTROLLED WHEN DOWNLOADED

Review By: 23/03/2020



Innovation Disclosure Form

A About this form

This form is to be completed by employees of Monash Health who create Innovation, particularly innovations and results of research, in the course of their employment with Monash Health.

The information you provide in this form will assist Monash Health in the evaluation and prioritisation of the appropriate actions necessary to protect, use, manage and potentially commercialise Monash Health's interests in the Innovation/innovation. Monash Health may disclose the information provided in this form to its legal and other advisors.

B How to use this form

This form consists of Part A, which requests a brief outline of the innovation, and Part B which requests more detailed information relevant to the ownership, protection and commercial potential of the innovation.

You may complete both parts prior to submitting the form. Alternatively, if you prefer, you may complete Part A only, and the Research Governance Officer will contact you to arrange a meeting to assist you to complete Part B.

To submit this form and for further assistance, please contact the Research Governance Officer, whose details are listed below.

C Keep this information quiet!

If you disclose the innovation or research results, the opportunity to patent it or apply for design registration may be lost.

The contents of this form (once details are inserted) should not be disclosed to anyone other than your manager and Monash Health staff closely associated with the project including support staff such as the Research Governance Officer, co-innovating collaborators and legal advisors retained to advise on Innovation and commercialisation. You should discuss it with others only on a strictly confidential basis, preferably following execution of a confidentiality agreement. Keep this document in a safe place and do not save it in an accessible location on the Monash Health network. Your manager is required to forward the completed form on to the relevant Executive Director and/or the Intellectual Property Committee.



Supplementary information

Michael Kios



Monash Partners Academic Health Science Centre

- Established in 2011, Monash Partners is an innovative partnership between leading health service, teaching and research organisations, and became accredited by the National Health and Medical Research Council (NHMRC) in 2015 as an Advanced Health Research Translation Centre.
- Monash Partners is a member of the [Australian Health Research Alliance \(AHRA\)](#) encompassing all NHMRC accredited Advanced Health Research Translation Centres and Centres for Innovation in Regional Health.
- Partners include: Monash Health, Monash University, Hudson Institute of Medical Research, Alfred Health, Peninsula Health, Eastern Health, Cabrini Health, Epworth HealthCare, Burnet Institute, and Baker Heart and Diabetes Institute.
- Associate partners include: La Trobe University and Latrobe Regional Hospital.
- The purpose of Monash Partners is to connect researchers, clinicians and the community to innovate for better health for around three million Australians and beyond.



Monash Health Translation Precinct



MHTP
Monash Health
Translation Precinct



**Monash
Health**



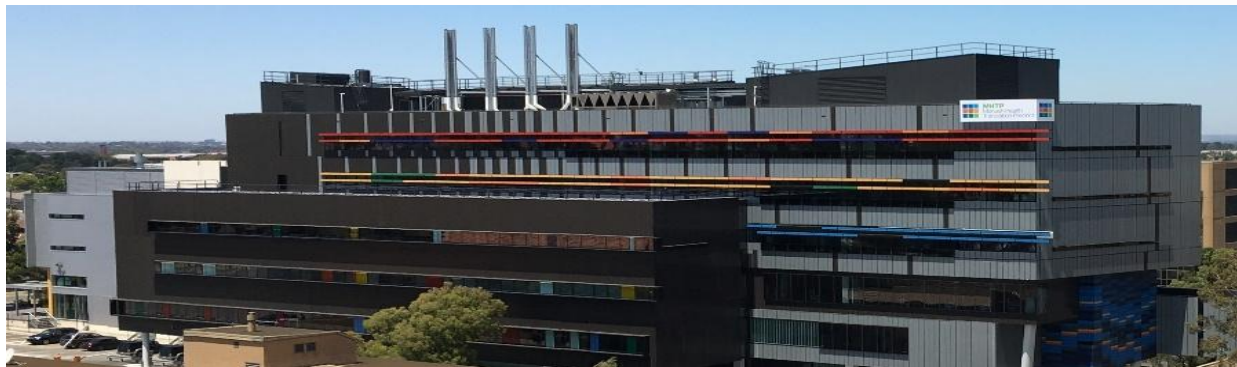
MONASH University

HUDSON
INSTITUTE OF MEDICAL RESEARCH



Clinical Trials Centre - MHTP

- 8 clinical trial beds
- 21 chairs,
- Clinical trials pharmacy
- Pathology services
- Dedicated MRI suite.
- All phases of clinical trials
- Professional clinical trials team



Monash Health Research Council

- The role of the Monash Health Research Council is to provide leadership, strategy and governance to all research at Monash Health.
- Reporting directly to the Monash Health Executive Committee, it is represented by the key research leaders at Monash Health covering all research streams and health disciplines.
- It supports the vision of the Monash Health Translation Precinct (MHTP) partners to make Monash Health the preferred site for translational research and ensures that Monash Health is an active partner of Monash Partners Academic Health Science Centre (MPAHSC).
- Above all, it will continue to advocate for the importance of research as part of Monash Health's patient-centred strategy both now and into the future.
- Chaired by the Director of Clinical Research, Professor William Sievert, the Monash Health Research Council meets monthly.



Clinical Trials Strategy and Governance Group

- The Monash Health Clinical Trials Strategy and Governance Group operates under the authority of the Monash Health Research Council.

The purpose of the Clinical Trials Strategy and Governance Group is to provide strategic direction and oversight to:

- ensure that clinical trial activity at Monash Health aligns with the Monash Health Strategic Plan 2023;
- ensure that governance arrangements for the Clinical Trials Centre support the needs of the organisation and all clinical units actively involved in clinical trials; and
- ensure that strategies and tactics used to manage the efficiency and effectiveness of the Clinical Trials Centre are appropriate and support effective utilisation of resources.



Clinical Trials Centre Operations group

The Clinical Trials Centre Operations Group acts under the direction of the Clinical Trials Centre Strategy and Governance Group to:

- Facilitate effective management of the Clinical Trials Centre through a co-operative approach and efficient operation of the Clinical Trials Centre; including but not limited to human resources management, occupational health and safety, financial management including budget management and financial sustainability.
- Provide a forum for clinical trial research staff to share knowledge and information regarding their area of expertise and in the area of clinical trials.
- Address operational concerns raised by the trial groups using the Clinical Trials Centre.
- Implement initiatives of the Strategy and Governance Group.



The Australian Commission on Safety & Quality in Health Care National Clinical Trials Governance Framework

- The Australian Commission on Safety and Quality in Health Care has developed a draft “[National Clinical Trials Governance Framework](#)” in order to have a nationally consistent accreditation approach for health service organisations undertaking clinical trials.
- The Governance Framework is aligned to the National Safety and Quality Health Service Standards (NSQHS).
- The framework is structured to come under two national standards – “Clinical Governance” and “Partnering with Consumers”.
- Monash Health is not a pilot site but will complete a self-assessment involving Research Support services and the Quality Unit.



Office of Research Integrity

<http://ori.hhs.gov/TheResearchClinic>



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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

Anusha Hingalagoda
SSA Coordinator
Governance - Site Specific Authorisation

Brinda Kinakkal
SSA Coordinator
Governance - Site Specific Authorisation

Joan Angello
Administrative Assistant
Annual Reports – Agreements - QA



Julie Gephart
HREC Coordinator
Low Risk – Quality Assurance

Sarah Niazmand
HREC & SSA Coordinator
New HREC Applications

Katharine Mahoney
HREC & SSA Coordinator
Post-Approval Amendments

Heather Jackson
Administrative Assistant
HREC – Governance - Invoicing



Ethics and Governance – 4 Part Series

Date & Time	Topics to be Covered
<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>https://us02web.zoom.us/j/89494009527?pwd=K29YYWNOtmsxV2xBbnNsdv9mSWhPZz09</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>https://us02web.zoom.us/j/89294836899?pwd=VytSDLRzUIRrUlo0cUxMRTBWTzkWZz09</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>https://us02web.zoom.us/j/82665006872?pwd=cXA0ODM3SVJvc3p6Z1FWVWZ0d0ZlZz09</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>https://us02web.zoom.us/j/86720721416?pwd=V2hkNVIUYU9qV0QwSWhkdENBc09ydz09</p> <p>Meeting ID: 867 2072 1416 Passcode: 423386</p>

