

Research Support Services

Overview

of

Ethics and Governance

Session No. 2

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=K29YYWNOtmxV2xBbnNsdv9mSWhPZz09</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=cXA0ODM3SVJvc3p6Z1FWVWZ0d0Zldz09</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>



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

Dr Anjali Dhulia
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



Site Specific Assessment

(Governance) Applications

Human Research Ethics Approval – What Next?

- Yay - HREC Approval – Now we can start!

NO

Governance Required:

Site Specific Assessment (SSA) Application



Historically....

- Before 2007, HRECs were typically responsible for both HREC and governance oversight
- National Statement (2007) created a vehicle for recognising that HREC and governance issues are separate
- HRECs are concerned with the scientific and ethical aspects of research
- Governance is the running of research and it's oversight at a local level



What is Site Specific Assessment (SSA)?

Site Specific Assessment is an assessment of whether the project can be conducted at a specific site.

This is essentially research governance.

It addresses the resources and the capability of the site to make sure the project can proceed in accordance with the ethical approval of the study.



What is HREC versus Governance

HREC	Governance
Ethical and review of Research Application	Review of resource aspects at site;
Review of the study protocol from a scientific perspective	Review of the resource aspects of the study
Review of qualifications of the staff involved	Review of the credentials of the local investigators involved in the study
Review of participant recruitment and consent	Review of insurance, contracts and indemnities
Review of any material/procedures involving participants	Review of any safety issues which could arise from doing the study on site. Eg. Access to ICU.
Review of Privacy, Data Retention etc	Review of the study budget
Review of Ongoing acceptability of study	Monitoring conduct of the study



Governance Applications - SSA

If a project is reviewed by Monash Health HREC

- **Site Specific Assessment Authorisation (SSA Authorisation) is still required to commence the study**

If a project is reviewed by another Hospital's HREC and the HREC is accredited to provide ethics review under the National Mutual Acceptance Scheme:

- **Monash Health accepts HREC review**
- **Site Specific Assessment (SSA) is required**



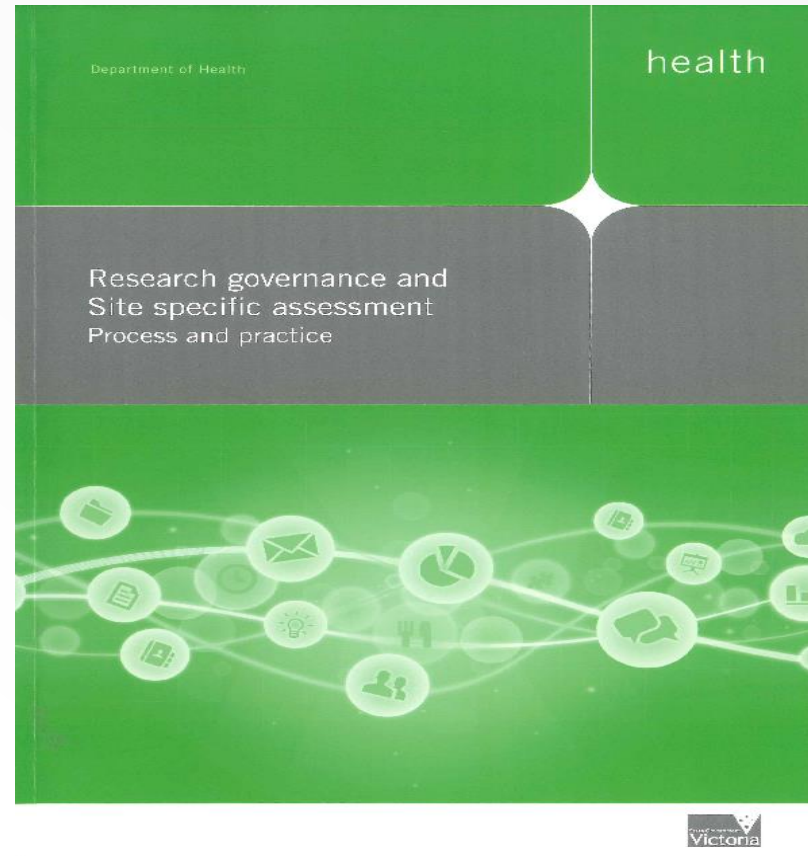
National Mutual Acceptance

“ National Mutual Acceptance (NMA) is a national system for mutual acceptance of scientific and ethical review of multi-centre human research projects conducted in publicly funded health services across jurisdictions. The **Australian Capital Territory, New South Wales, Queensland, South Australia, Victoria and Western Australia** participate in NMA. Single ethical and scientific review for a multi-centre human research project can be provided across the six participating states/territories ”

<https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/national-mutual-acceptance>



Research Governance and Site Specific Assessment Process and Practice



https://www.clinicaltrialsandresearch.vic.gov.au/__data/assets/pdf_file/0020/171146/Research-Governance-SSA-Process-and-Practice-Jun22.pdf



Ethics & Governance Submission Information

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

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

Human research ethics <https://monashhealth.org/research/human-research-ethics-committee/>

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/>



Ethical Review by External HREC – Site Specific Application Docs

Documentation required:

- SSA Application via Ethical Review Manager (ERM)
- HREC Approval Letter listing 'Monash Health' as the approved site
- HREC Approved Master documents including HREA and VSM
- Monash Health versions of documents to be based on Master versions (where applicable)
- Radiation Statement
 - *as directed by Monash Health Medical Physicist*
- Certification by Heads of Departments
- Current GCP training certificates for all researchers involved
- Monash Health fee form for HREC and/ or Governance review
- Agreements and Indemnities
- Certificate of Insurance



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 – Site Specific Assessment (SSA) Application for VIC site where Monash Health is the reviewing HREC

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
- Victorian Specific Module (VSM)

Close

19/10/202

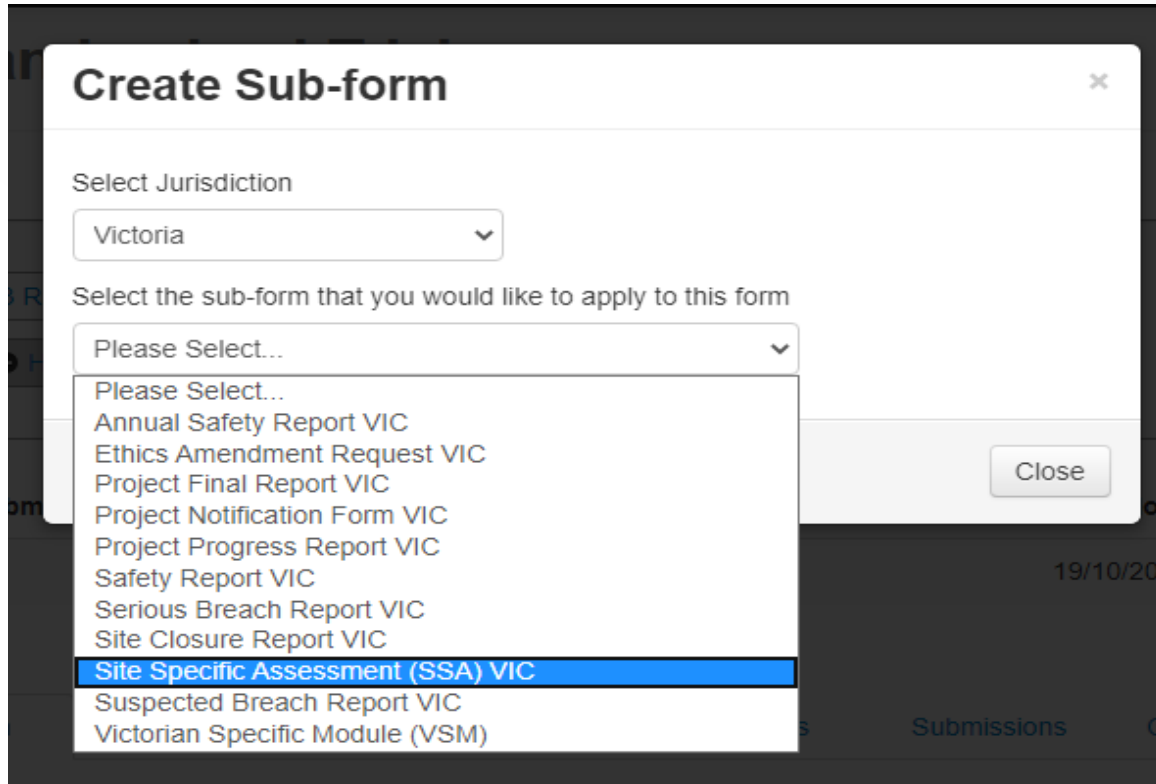
Submissions

SSA Application/ Governance Application when study is Ethically reviewed by Monash Health

A New Site Specific Assessment (SSA) application can be created from the HREA Application.

- Click on Create Sub-Form and choose Victoria as jurisdiction
- Choose Sub-Form Site Specific Assessment (SSA) VIC, complete all questions and arrange for all investigators to sign.
- Email copy of the SSA application and zip file of all study documents to research@monashhealth.org

ERM – Site Specific Assessment (SSA) Application for VIC site



Create Sub-form

Select Jurisdiction

Victoria

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

Please Select...

- 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
- Victorian Specific Module (VSM)

Close

SSA Application/ Governance Application when study is Ethically reviewed outside of Monash Health

A New Site Specific Assessment (SSA) application can be created from the HREA Application.

- Request lead site to create a SSA application on ERM.
- Request transfer of SSA application to Monash Health research team contact person.
- Monash Health Research team complete SSA Application and electronically submit to Monash Health RGO.
- Email copy of the SSA application and zip file of all study documents to research@monashhealth.org



ERM – Transfer of Application

- If you are the current owner of the project and wish to transfer ownership to another ERM account holder, click on the "Home" link and click "Transfer" in the Actions pane on the left side of the screen.
- Enter the email address of the person you wish to transfer to.
- Select the projects you wish to transfer and click "Transfer".

More details available on Researcher Guide on:

1. How to cancel transfer
2. How to share application



ERM - Transfer of Application

The screenshot displays the ERM Applications interface. On the left, the 'Actions' menu is visible, with the 'Transfer' icon highlighted by a red box. A red arrow points from this icon to a modal dialog box titled 'Transfer Form To Another User'. The dialog box contains a text input field with the email address 'research@monashhealth.org' and a checked checkbox labeled 'Transfer Sub Forms'. At the bottom right of the dialog are 'Transfer' and 'Close' buttons.

Work Area

Home Notifications

Actions

Create Folder Delete Folder Create Project

Delete Project Duplicate Project **Transfer**

General

Notifications Signatures Transfers Shared

0 0 0 0

Projects

Search Projects

Project Title	Project ID	Owner	Date Created	Date Modified
12345	48308	Ms Brinda kinakkal	02/11/2018 14:08	02/11/2018 14:47
ABCD	48287	Ms Brinda kinakkal	02/11/2018 08:50	02/11/2018 09:54
TEST HREC APPLICATION	46372	Ms Brinda kinakkal	10/09/2018 12:41	20/09/2018 12:17

Showing 1 to 3 of 3 entries



Ethics and SSA Applications created for studies prior to July 2018

- All Ethics and Governance applications prior to 2018 were either submitted in hard copy, via email or via Online Forms.
- All applications registered prior to 2018 on Online Forms have now been migrated onto ERM.
- All registered applications have a Minimal Data Set (**MDF**) application that exists on ERM.
- The lead HREC or local RGO is able to locate the MDF and provide the research team with the ERM reference number.
- An SSA application can be created via the MDF for sites in VIC, Queensland and for Mater Mesericordiae.



ERM - Minimal Dataset Form (MDF)

MDF is a base application with minimal information, which allows a research project to be registered onto ERM.

<p>Who can use MDF</p>	<p>Australian researchers from all states wishing to create an online presence for their research application.</p>
<p>When to make MDF</p>	<ul style="list-style-type: none"> • An MDF can be created for NMA projects that were Ethically reviewed outside VIC, QLD Health, Mater Health. • If an NMA project has no presence on ERM or was not submitted via Online Forms and migrated onto ERM.
<p>What can be done with MDF</p>	<ul style="list-style-type: none"> • The MDF allows you to create a base application from which SSA Applications for VIC, QLD Health and Mater Mesericordiae Ltd can be created. • Only 1 MDF is required per research project.



ERM – Site Specific Application (SSA) for VIC site

Ethical review by External HREC (from VIC, QLD, Mater Misericordiae Ltd)

(Ethical review by an HREC outside of Monash Health)

When MDF is created <i>(If study was <u>not</u> submitted via Online Forms prior to 2018 and <u>not</u> migrated to ERM)</i>	When NEAF/ HREA was/ is created <i>(If study was submitted via Online Forms prior to 2018 OR study is current)</i>
<ol style="list-style-type: none">1. If the project has no presence on ERM, request lead site to create MDF or this can be created by anyone with an ERM account.2. Choose the jurisdiction of reviewing HREC and complete MDF application.3. Create SSA application via MDF for Monash Health RGO and Submit.	<ol style="list-style-type: none">1. If study was migrated from Online Forms or a new HREA application is created, contact lead site to create SSA Application for Monash Health as a participating site and request transfer of application to Monash Health researcher to complete and submit to Monash Health RGO. <p><i>SSA Application process is the same even if site is a late addition to an existing project.</i></p>



ERM – Site Specific Application (SSA) for VIC site

Ethical review by External HREC (from ACT, NSW, SA, WA)

(Ethical review by an HREC outside of Monash Health)

- 1. Create MDF Application** in order to register the study on ERM
 - Choose which jurisdiction the Ethics application was submitted for review and answer all questions.
 - Fill out VSM Word document (*v2018 available on DHHS website*) and upload onto MDF
https://www.clinicaltrialsandresearch.vic.gov.au/data/assets/pdf_file/0020/171029/VSM-in-ERM-guide.pdf
- 2. Create SSA Application Form**
 - Submit SSA Application to respective governance office in VIC



ERM – Applicant: Minimal Dataset Form (MDF)

Create Project

Project Title:*
NEW MDF

Select Jurisdiction
Victoria

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

Close

ERM Applications Work Area Contacts Help Ms Brinda kinakkal (brinda.kinakkal@monashhealth.org) 67683

Actions
Project Create Sub-form Share
Completeness Check Submit NMA Project
Print Correspond

NEW MDF
MDF

Form Status	Review Reference	Date Modified	NMA
Not Submitted	N/A	06/08/2020 10:42	Project is not for NMA

Navigation Documents Signatures Collaborators Submissions Correspondence History

MDF Show Inactive Sections

Section Questions
Minimal Dataset Form Minimal Dataset Form

FOR NMA PROJECTS ONLY

Only **one** MDF is required for a research project.

The MDF is not an ethics application form.

The MDF allows you to create Site Specific Assessment (SSA) forms to address research governance at sites in Queensland and/or Victoria and/or Mater.

One SSA form is required for each site in Queensland, Victoria or Mater.

Answer the questions in this MDF.

Once the MDF is complete, select 'Submit'.

Select 'Create Sub-form' to create a Queensland, Victorian or Mater SSA.

In the SSA form, select 'Share', enter the email address of the site Principal Investigator (or their delegate), check all boxes and select 'Share'.

Create Sub-form

Select Jurisdiction
Victoria

Select the sub-form that you would like to apply to this form
Site Specific Assessment (SSA) VIC

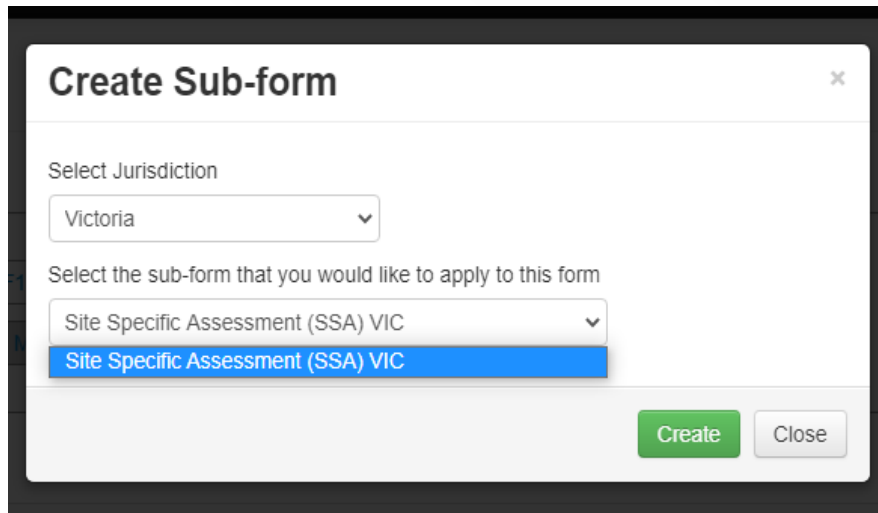
Create Close



ERM – Minimal Dataset Form (MDF)

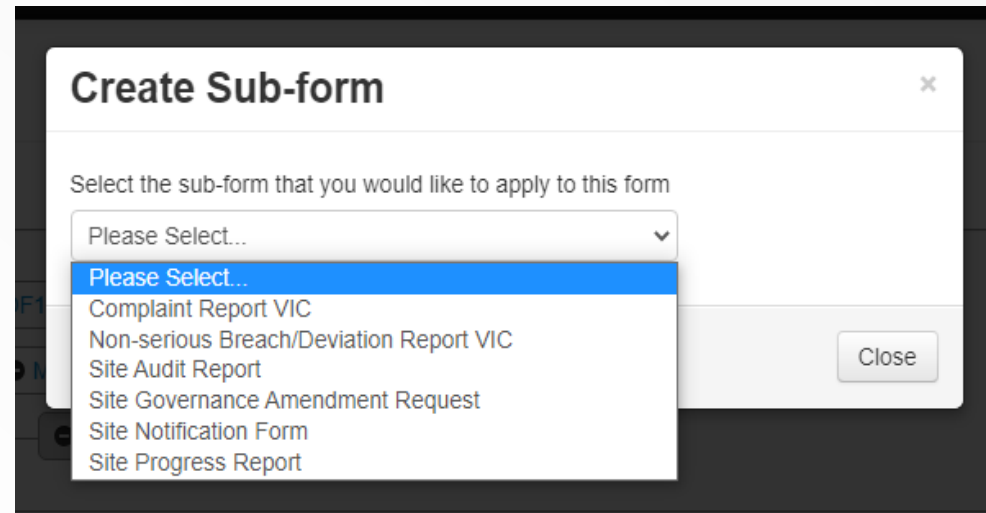
What Forms can be populated once an MDF is created?

For VIC sites, only a Site Specific Application Form can be created.



The screenshot shows a 'Create Sub-form' dialog box with a close button (X) in the top right corner. It contains two dropdown menus. The first is labeled 'Select Jurisdiction' and has 'Victoria' selected. The second is labeled 'Select the sub-form that you would like to apply to this form' and has 'Site Specific Assessment (SSA) VIC' selected. Below the second dropdown, the same option is highlighted in blue. At the bottom right, there are two buttons: a green 'Create' button and a grey 'Close' button.

Various other Forms can be populated from the SSA Application Form.



The screenshot shows a 'Create Sub-form' dialog box with a close button (X) in the top right corner. It contains a dropdown menu labeled 'Select the sub-form that you would like to apply to this form' with 'Please Select...' selected. A list of options is displayed below the dropdown, including 'Please Select...', 'Complaint Report VIC', 'Non-serious Breach/Deviation Report VIC', 'Site Audit Report', 'Site Governance Amendment Request', 'Site Notification Form', and 'Site Progress Report'. A 'Close' button is visible on the right side of the dialog box.



Legacy Application Replacement Form (LARF)

Legacy Application Replacement Form (LARF) Guidance

The Legacy Application Replacement Form (LARF) is required when a Victorian research project's original ethics application was not in the old AU RED system (database used by research offices).

The LARF is not an ethics application form; it is a proxy form that will allow you to create and submit post-approval forms (e.g. Amendment Request) in the Ethical Review Manager (ERM) system.

Always consult the reviewing organisation's research office **before** creating a LARF; they will advise you whether the form is required.

Only one LARF is required for any research project. Once a LARF has been created and submitted, all post-approval forms for that project are created from the same LARF.

1. Log in to ERM <https://au.forms.ethicalreviewmanager.com>.
 - If you had an *Online Forms* account, use the same login details (or select 'Forgotten Password' if required).
 - If you did not have an *Online Forms* account, select 'New User'.
2. Select 'Create Project'.
 - Jurisdiction = Victoria
 - Main Form = Legacy Application Replacement Form
3. Complete the questions in the LARF.
4. Submit the LARF.
5. Select 'Create Sub-form' and choose the desired post-approval form (e.g. Amendment Request).
6. Complete the questions in the post-approval form.
7. Sign the post-approval form.
8. Submit the post-approval form.

Help

Coordinating Office for Clinical Trial Research (Department of Health and Human Services, Victoria)
Phone: 03 9096 7394

Email: multisite.ethics@dhhs.vic.gov.au

Infonetica Helpdesk

Phone: 02 9037 8404

Email: helpdesk@infonetica.net

Legacy Application Replacement Form (LARF) Guidance
January 2019

The Legacy Application Replacement Form (LARF) is required when a Victorian research project's original ethics application was not in the old AuRed (Online Forms) system.

The LARF is not an ethics application form;
It is a proxy form that will allow you to create and submit post-approval forms in the Ethical Review Manager (ERM) system

Create Project [X]

Project Title (maximum 200 characters):*

TEST2

Select Jurisdiction

Victoria [v]

Main Form

Legacy Application Replacem [v]

Create Close



ERM : Legacy Application Replacement Form (LARF)

FOR VICTORIA HREC APPROVED PROJECTS ONLY

ERM Applications Work Area Contacts Help Ms Brinda kinakkal (brinda.kinakkal@monashhealth.org)

Actions

Project Create Sub-form Share

Completeness Check Submit NMA Project

Print Correspond

NEW LARF 67699

Project Tree

- NEW LARF
 - Legacy Application Replacement Form VIC

Form Status	Review Reference	Date Modified	NMA
Not Submitted	N/A	06/08/2020 14:52	Project is not for NMA

Navigation Documents Signatures Collaborators Submissions Correspondence History

Legacy Application Replacement Form VIC Show Inactive Sections

Section: Legacy Application Replacement Form Questions: [Details of Original Application](#)

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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.



Site Specific Assessment Form (SSA) – For Governance

- The **Site Specific Assessment Form** should be used for site specific assessment of research projects where the research proposal has been submitted for ethical and scientific review using the HREA.
- **It is completed with local site Information**
- **Signed by all Investigators**
- **Signed by Heads of participating departments**
or use
- **Department specific forms for services – Monash Partners Templates**



Supporting Department Forms

Monash Partners Forms

- Monash Partners General Service Request – Certification by Head of Supporting Department
- Monash Partners Certification by Head of Cardiology Department
- Monash Partners Certification by Head of Diagnostic Imaging Department
- Monash Partners Certification by Head of Lung Function Department
- Monash Partners Certification by Head of Pharmacy Department
- Monash Partners Certification by Head of Pathology Department
- Monash Partners Low Risk Form: Human Biospecimen Addendum (Low Risk Projects)

• Monash Health Forms

- Form 4T Clinical Trials Centre
- Form 7 Confidentiality Agreement

<https://monashhealth.org/research/resources/forms-library/>



Ionising Radiation Procedures

Radiation Statement

Always use approved radiation statement in Participant Information and Consent Forms as directed by Monash Health Medical Physicist for radiation procedures deemed above standard of care.

- ❖ Arrange for Radiation Review of Ionising Radiation procedures with Monash Health Medical Physicist via Research Support Services

Research@monashhealth.org

- Medical Physicist's Report Request Form
- Protocol
- Signed VSM Section 4
- Participant Information Sheet and Consent Form

- ❖ Where ionising radiation procedures are standard of care:

<https://www.health.vic.gov.au/radiation/research-involving-irradiation-of-people>

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



Monash Health PICFs

- ❖ Must be created from Master document
- ❖ Engage 'Tracking' before making any changes
- ❖ Insert Monash Health logo
- ❖ Insert site specific Investigator(s) and site details
- ❖ Insert footer details per guidelines or in the format:
e.g "Monash Health Main PICF V1.0 dated 27 May 2019 based on Master Main PICF V1.0 dated 01 May 2019"
- ❖ Insert Monash Health Radiation Statement (if applicable)
- ❖ Insert Monash Health reimbursement arrangement (if applicable)
- ❖ Insert Deborah Dell's details as the local complaints contact person
- ❖ Insert Michael Kios's details as Local Governance Officer



Good Clinical Practice Training in Research

- GCP training is required for all researchers participating in interventional studies.
- All researchers listed on a research application must submit a valid GCP certificate.
-
- ICH-GCP courses as listed on the TransCelerate web site are accepted.
- GCP certificates are valid until the expiry date listed on the certificate or 3 years from the date of issue.
- If a project is continuing beyond the expiry date of the GCP certificate, resubmission of a new certificate will only be required if a new project is submitted by the investigator(s) for ethics or governance approval.
- This does not currently apply to non-interventional research.



Good Clinical Practices (GCP)

A GCP Certificate is required for investigators on all interventional studies

Submission of evidence of current TransCelerate Accredited Good Clinical Practice (GCP) training for:

- All Monash Health investigators or
- Principal Investigators at other institutions where ethical approval of the study has been provided by Monash Health.

All acceptable courses are available at: <http://www.transceleratebiopharmainc.com/gcp-training-attestation/training-providers/>

The Monash Partners Course which is free to paid employees of any of the Monash Partners members satisfies this requirement. Registration for this course is accessible via the following link:

<https://www.monash.edu/medicine/sphpm/mchri/short-courses/good-clinical-practice>

The free online National Drug Abuse Treatment Clinical Trials Network Course

<https://gcp.nidatraining.org/>

or the free online Roche Good Clinical Practice course available at:

http://www.pdexternal-roche.com/translations/English/story_html5.html

are adequate.

Other course such as university based GCP courses will be considered on a case by case basis.



Legal Documents

Agreements

Michael Kios



Legal Documents

- Clinical Trial Research Agreement (CTRA), [Medicines Australia](#) - [MTAA](#) - [Monash Partners](#) - [Other](#)
- Study Budget - Part of CTRA
- Standard Form of Indemnity [Medicines Australia](#)
- HREC Form of Indemnity [Medicines Australia](#)
- Insurance Certificate for Sponsored Trials



When Are Agreements Required

- Research Agreements are required when there is collaboration or transactions between separate legal entities
- Commercially Sponsored Studies
- Collaborative Studies
- Multi-site Investigator initiated Studies



Agreements: Australian Code for the Responsible Conduct of Research

- **8.1 Establish agreements for each collaboration**
- Organisations involved in a joint research project should ensure that an agreement is reached with the partners on the management of the research.
- The agreement should be in writing.
- It must cover:
 - Intellectual property
 - Confidentiality and copyright issues
 - Sharing commercial returns
 - Responsibility for ethics and safety clearances
 - Reporting to appropriate agencies.
- It should address the protocols to be followed by the partners when disseminating the research outcomes, and the management of primary research materials and research data.



Agreements: TGA Note for Guidance on Good Clinical Practice CPMP-ICH-135-95

- 4.9.6
- The financial aspects of the trial should be documented in an agreement between the sponsor and the investigator/institution.

- 5.1.2
- The sponsor is responsible for securing agreement from all involved parties to ensure direct access to all trial related sites, source data/documents , and reports for the purpose of monitoring and auditing by the sponsor, and inspection by domestic and foreign regulatory authorities.

- 5.1.4
- Agreements, made by the sponsor with the investigator/institution and any other parties involved with the clinical trial, should be in writing, as part of the protocol or in a separate agreement.



Clinical Trial Research Agreement CTRA

Medicines Australia Clinical Trial Research Agreement (CTRA)

<https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/>

Clinical Trial Research Agreement – Medicines Australia Standard Form

- Clinical Trial Research Agreement – CTRA: Contract Research Organisation acting as the Local Sponsor
- Clinical Trial Research Agreement – Collaborative or Cooperative Research Group (CRG) Studies
- Clinical Trial Research Agreement – Phase 4 Clinical Trial (Medicines)
- Clinical Trial Research Agreement – Phase 4 Clinical Trial (Medicines) Contract Research Organisation acting as the Local Sponsor

Medical Technology Association of Australia (CTRA)

<https://www.mtaa.org.au/clinical-investigation-research-agreements>

MTAA Standard Clinical Investigation Research Agreement



Medicines Australia Agreement Templates

<https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/>

Instructions:

1. Insert your logo in the box to the left
2. Resize logo by dragging right hand corner
3. Update the footer information
4. Delete these instructions
5. Complete other information in the Form

Clinical Trial Research Agreement Medicines Australia – Standard Form

The body of this Agreement (that is from the following page to the execution clauses) is intended to be identical to the standard form a copy of which is located at <http://medicinesaustralia.com.au/issues-information/clinical-trials/clinical-trials-research-agreements>. Any textual change to the body of this Agreement is to be ignored, and reference instead had to the standard form, as amended by Schedule 7 by way of Special Conditions.

Details of the parties

Name of Institution:	
Address:	
ABN:	
Contact for Notices:	
Fax for Notices:	
Phone Number:	

Name of Sponsor:	
Address:	
ABN:	
Contact for Notices:	
Fax for Notices:	
Phone Number:	

Study Name:	
Protocol Number:	
Date of Agreement:	

Protocol Number:
Site:
Medicines Australia Standard CTRA 8 March 2017 (revised) Page 1 of 25

Instructions:

1. Insert your logo in the box to the left
2. Resize logo by dragging right hand corner
3. Update the footer information
4. Delete these instructions
5. Complete other information in the Form

Clinical Trial Research Agreement

Medicines Australia CTRA: Contract Research Organisation acting as the Local Sponsor

This agreement is to be used where a Contract Research Organisation acts as, and assumes all of the responsibilities of, a local commercial sponsor.

The body of this Agreement (that is from the following page to the execution clauses) is intended to be identical to the standard form a copy of which is located at <http://medicinesaustralia.com.au/issues-information/clinical-trials/clinical-trials-research-agreements>. Any textual change to the body of this Agreement is to be ignored, and reference instead had to the standard form, as amended by Schedule 7 by way of Special Conditions.

Details of the parties

Name of Institution:	
Address:	
ABN:	
Contact for Notices:	
Fax for Notices:	
Phone Number:	

Name of Local Sponsor:	
Address:	
ABN:	
Contact for Notices:	
Fax for Notices:	
Phone Number:	

Study name:	
Protocol Number:	
Date of Agreement:	

Protocol Number:
Site:
Medicines Australia CRO CTRA 8 March 2017 (revised) Page 1 of 25

Instructions:

1. Insert your logo in the box to the left
2. Resize logo by dragging right hand corner
3. Update the footer information
4. Delete these instructions
5. Complete other information in the Form

Clinical Trial Research Agreement

Collaborative or Cooperative Research Group (CRG) Studies – Standard Form

The body of this Agreement (that is from the following page to the execution clauses) is intended to be identical to the standard form a copy of which is located at <http://medicinesaustralia.com.au/issues-information/clinical-trials/clinical-trials-research-agreements>. Any textual change to the body of this Agreement is to be ignored, and reference instead had to the standard form, as amended by Schedule 4 by way of Special Conditions.

Details of the parties

Name of Institution:	
Address:	
ABN:	
Contact for Notices:	
Fax for Notices:	
Phone Number:	

Name of CRG:	
Address:	
ABN:	
Contact for Notices:	
Fax for Notices:	
Phone Number:	

Study Name:	
Protocol Number:	
Date of Agreement:	

Protocol Number:
Site:
Medicines Australia CRG CTRA 8 March 2017 (revised) Page 1 of 23



Monash Partners – Research Collaboration Agreement Template



Research Collaboration Agreement

For an Investigator Initiated Project

This Agreement is based on the Alfred Health Research Collaboration Agreement for an Investigator Initiated Project.

The body of this Agreement beyond the recitals should not be amended. Any proposed changes to this Agreement must be incorporated in Schedule 3 by way of Special Conditions.

Details of the Parties

[Insert name Party 1]: ((insert short form Party name))

Address:

ABN:

Contact for Notices:

Fax for Notices:

Phone Number:

[Insert name Party 2]: ((insert short form Party name))

Address:

ABN:

Contact for Notices:

Fax for Notices:

Phone Number:

Project Name:

Protocol Number or HREC Number/Local Project Number:

Date of Agreement: Date of last Party to sign

<https://monashhealth.org/research/resources/forms-library/>



Melbourne Academic Centre for Health - MACH

The Melbourne Health equivalent of the Monash Partners agreement template is the MACH Agreement.

Ensure the latest version is used

The following inclusion is required in the schedule.

Item 10 Special Conditions

Clause 10 is deleted in its entirety and replaced with the following:

10. INSURANCE AND INDEMNITIES

- 10.1 Each Party is liable for its acts and omissions in relation to the conduct of the Project.
- 10.2 Each Party must maintain such insurances as are necessary to provide indemnity to it in relation to any liability which it may incur in conducting the Project or performing its obligations under this Agreement.
- 10.3 A Party satisfies the requirements of clause 10.2 if it is entitled to indemnity under a program or scheme of insurance or indemnity that is arranged by a department or agency of a State or Territory of the Commonwealth of Australia.



Other Research Agreements

<https://monashhealth.org/research/research-information/34824-2/>

- Confidential Disclosure Agreements (CDA) / Non Disclosure Agreements (NDA)
- Material Transfer Agreement – Biological Samples
- Data Transfer Agreement
- Monash Health Investigator Initiated Agreement with Commercial Support
- Non-Standard Agreements: Other Institution Templates
 Service Agreements
 International Agreements
- **Bipartite Agreement (Medicines Australia CTRA to include Monash University as Funds Administrator)**
- **Tripartite Agreement Template (Medicines Australia CTRA to include Monash University as a party to the agreement as the Funds Administrator)**



Agreement Details

Name of Institution:	Monash Health
Address:	246 Clayton Road, Clayton, Victoria, 3168
ABN:	82 142 080 338
Contact for Notices:	Principal Investigator Name
Fax for Notices:	Principal Investigator Fax Number
Phone Number:	Principal Investigator Phone Number

- Investigators cannot sign legal agreements on behalf of Monash Health
- Collaborators need to arrange signing of agreements by representatives of the collaborating party who are authorised to sign legal agreements.



Review of Agreements

- submitted to research@monashhealth.org in word format for review.
- Review by Research Governance Manager
- Feedback or tracked change agreement returned to researchers
- Researchers send agreement to collaborator for review
- Collaborator authorised legal representative signs
- Signed agreement mailed or emailed to research@monashhealth.org
- Signing arranged by authorised legal representative

If amendments are not accepted by the collaborator or further amendments:

- Research Governance Manager re-reviews with further amendments or legal advice sought.
- Acceptance of certain clauses may require agreements to undergo a contract approval process with eventual signing by the Chief Executive.



Non Standard Agreements

- All agreements that do not follow one of the standard templates will require preliminary review by Research Support Services team, prior to the Research Support Services submitting to the Legal Team for review.
- A multi-institutional agreement (NHMRC) that is supported by a research grant and Monash Health is not the lead site, will be accepted for review.
- In the event that Monash Health is the lead collaborator on an investigator driven or collaborative study, Monash Health will only accept an approved Collaborative Group Template.
- Researchers to allow 4 weeks for review.
- **Issues with Non Standard Agreements:**
 - Indemnities
 - International Law

Contract Approval Form

CONTRACT APPROVAL FORM	
Contract Purpose	
Other party/parties	
Term	Start Date: End Date: Optional terms:
Value of contract	Category: Expense/ Revenue/ Other (circle) Annual amount: Total value of initial term: Total value including optional terms: Cost centre:
Procurement Process	Has there been a tender? <input type="checkbox"/> yes <input type="checkbox"/> no Is there a business case paper? <input type="checkbox"/> yes <input type="checkbox"/> no
Summary of Contract	
Person responsible for contract	
Name & Position:	
Department:	Ext:
Program/Service Director/General Manager Approval	
Name & Position:	
Signed:	Date:
Executive Director Approval	
Name & Position:	
Signed:	Date:
Procurement Approval	
Name & Position:	
Comments:	
Signed:	Date:
Legal Approval	
Name & Position:	
Comments:	
Signed:	Date:
Finance Approval	
Name & Position:	
Comments:	
Signed:	Date:
Contract signatory (refer to authority delegation schedule)	
Name & Position:	
Signed:	Date:



Research Support Program (RSP)

- Monash University – Funds Administrator
- Principal Investigator – Dual appointment
- ~24% Commonwealth Government Infrastructure Funding
- Funds available after 2 years
- 90% of Infrastructure Funds to Research Unit
- 5% of Infrastructure Funds to Monash University
- 5% of Infrastructure Funds to Monash Health
- Tripartite Agreement
- Bipartite Agreement



Research Support Program Agreements

Tripartite agreement is a modified Medicines Australia agreement template that has been developed to include Monash University as a party to the agreement to act as the Funds Administrator of the project.

Bipartite agreement is a standard Medicines Australia agreement template that includes Monash University as the Funds Administrator. Monash University are not a party to the agreement.

Bipartite agreement with Monash University Acknowledgement is a standard Medicines Australia agreement template that included Monash University as the Funds Administrator. Monash University are not a party to the agreement but they sign the agreement in acknowledgement similar to sign off by the Principal Investigator.



Tripartite Agreement

This agreement has been developed to include Monash University as a party to the agreement to act as the Funds Administrator of the project.

It includes a Schedule 7 that has been approved by Monash Health and Monash University Lawyers

<https://monashhealth.org/research/resources/forms-library/>

Clinical Trial Research Agreement Based on Medicines Australia – Standard Form

The body of this Agreement (that is from the following page to the execution clauses) is intended to be identical to the standard form a copy of which is located at <http://medicinesaustralia.com.au/issues-information/clinical-trials/clinical-trials-research-agreements>. Any textual change to the body of this Agreement is to be ignored, and reference instead had to the standard form, as amended by Schedule 7 by way of Special Conditions.

Details of the parties

Name of Institution:	Monash Health
Address:	246 Clayton Road, Clayton Victoria 3168
ABN:	82 142 080 338
Contact for Notices:	
Fax or Email for Notices:	
Phone Number:	

Name of Administering Institution:	Monash University
Address:	Wellington Road, Clayton Victoria 3800
ABN	12 377 614 012
Contact for Notices:	Research Manager
Fax or Email for Notices	SCS-Clinicaltrials@monash.edu
Phone Number:	03 9903 0080

Name of Sponsor:	
Address:	
ABN:	
Contact for Notices:	
Fax or Email for Notices:	
Phone Number:	

Study Name:	
Protocol Number:	
Date of Agreement:	



Schedule 2 (or 7) – Principal Investigator Statement

The following statement is required in each agreement unless other wording is approved by Monash University Lawyers

The Principal Investigator is an employee of the Institution and a joint or adjunct appointee of Monash University. The Parties acknowledge that the designated Payee, Monash University, is authorised to receive and administer all of the payments for the services performed under this agreement.



Invoicing Details

Payment Terms

Payment terms of 30 days apply upon receipt of invoice.

Method of Payment

Payments will be made via Electronic Funds Transfer (EFT)
All payments by EFT/direct credit under this Agreement will be made as follows:

Recipient Name: Monash University
ABN: 12 377 614 012
Recipient Address: Receivables and Revenue Accounting
Level 4, 211 Wellington Road
Mulgrave, VIC, 3170
Recipient Phone: 03 9905 6152
Recipient Email: finance-corporatebanking@monash.edu

Bank: Westpac Banking Corporation
Bank Address: Campus Centre
Clayton Campus
Monash University
BSB No.: 033-289
Account No.: 630759
Account Name: Monash University General Account
SWIFT Code: WPACAU2S
IBAN: 033289630759
Duns No: 753252691

Notification of all payments by EFT/direct credit made under this Agreement will be communicated to the Executive Officer at the following address:

Monash Health: [Department Name]
[Insert correct address, ph and email if different from below]
Monash Medical Centre
246 Clayton Road, Clayton VIC, 3168
Telephone No.: +61 (3) 9594 6666
Facsimile No.: +61 (3) 9594 6111.
E-Mail Address: finance-corporatebanking@monash.edu,
SCS-Clinicaltrials@monash.edu and XXX.XXX@monashhealth.org

The notification of all payments made under this Agreement will be accompanied with documentation of the calculation of each payment.

The documentation will specify:
The Human Research Ethics Committee (HREC) project number;
The Principal Investigator's name;
What the payment is being made for;
The number of participants who have completed particular milestones;



Agreement variations

- Merck Sharp & Dohme (MSD) have a unique Tripartite Agreement
- Schedule 4 and 7 inclusions are permissible if the sponsor requires clarity of the process
- Roche will not participate in this scheme
- Phase 4 clinical trials cannot participate in this scheme
- Government body collaborations cannot participate under this scheme
- Collaborations with NHMRC or MRFF cannot participate
- Variations to agreements can occur in the invoicing sections in consultation with the sponsor, Monash Health and Monash University
- Submit the agreement to Research Support Services for review prior to arranging sign off by the sponsor



Agreement Review and Signing

- Agreements should be submitted to Research Support Services for review before arranging sign off.
- Once approved by Research Support Services, arrange signing by the sponsor
- The agreement is then emailed or delivered as 3 hard originals if the sponsor requires wet signatures.
- Electronic Signatures like DocuSign are accepted but Monash Health will only wet sign. Monash Health will be moving to electronic signing in the future.
- Once received by Research Support Services signing by the CMO or CEO will be arranged by Research Support Services.
- On occasions where Monash Health signs first, a fully executed agreement must be emailed to Research Support Services.
- Wet signed agreements can be collected by appointment.



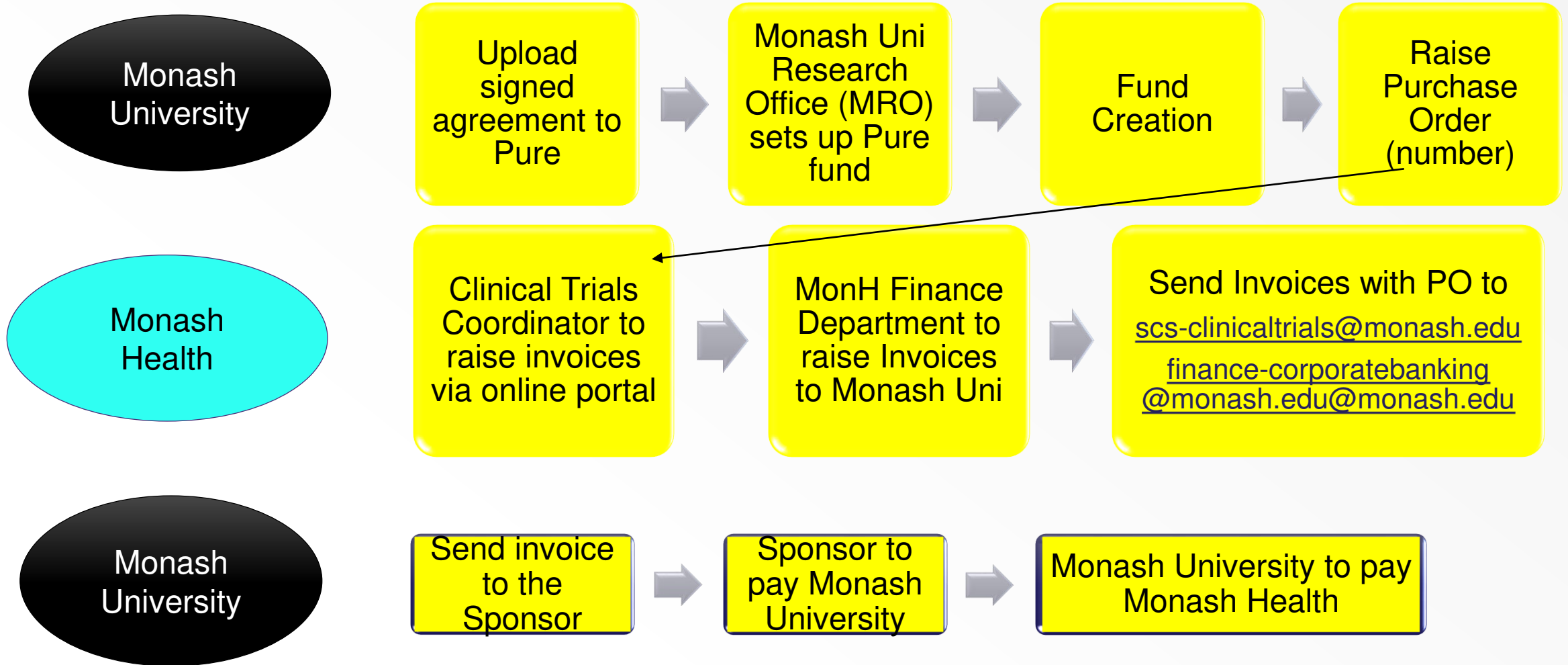
Financial Aspects

Projects Financially Administered by Monash University

Michael Kios



Monash Health Agreement & Invoicing Workflow after Agreement Signed



Sundry Debtors Charge Advice

Sundry Debtors - Internet Explorer
http://intranet.southernhealth.org.au/finance/sundry/editor/new_start4.asp

Sundry Debtors Charge Advice [Help](#)

All fields require a valid entry before the form will Submit.

1. Select your Cost Centre and then wait a moment for the form to load.
R1861

2. Select a Revenue Code and then wait another moment.
57051

2b. Sub Account Code (codes will only appear for 57201 - Car Parking.)
[]

Revenue Code : 57051
Entity & Cost Centre Code : SHS01-R1861

Contact Officer : [Robyn Hogben]
Email : [Robyn.Hogben@monashhealth.org]
Campus : [Kingston] Telephone : [9265 7939]

Please Invoice : [Purchase Order No]
Position / Title : [SCS CLINICAL TRIALS]
Company : [MONASH UNIVERSITY]
Street / PO Box : [C/N 508194]
Suburb / City : []
State : []
Period Relating To : []
Postcode : []

Description Of Charges : []
Character Count: 0 (10 Characters Minimum, 240 Maximum.)

Send Invoice To: []
Does GST Apply?: [] Does this amount include GST?: []
Total : \$ []


OK **Reset**

You can email supporting documentation on the next screen!

***'Cut-off' Date is the Last Working day of the Month at 12 Noon.**
- Contact Finance directly for late invoices (sundry.billing@monashhealth.org).

Create your own Desktop Shortcut to the Monash Health Finance On-Line Sundry Debtors Charge Advice Page!

Simply 'drag' the icon on the left off this page and drop it on your desktop. (Say Yes to any prompts)
If you can't see any part of your Desktop, you will need to reduce the size of this window.



**Include the Monash University
Coupa Purchase Order Number.
Also for Ethics and Governance
Post Approval Fee Forms**



Monash University Contact Details

E: Scs-clinicaltrials@monash.edu

Rita Tam - Finance

Senior Research and Revenue Accountant

E: Rita.tam@monash.edu

T: 03 9903 0080

Vanalysa Ly - Agreements

Research Manager

E: Vanalysa.ly@monash.edu

T: 03 9903 0639



Payment Forms

PROJECTS WILL NOT BE ACCEPTED WITHOUT COMPLETED PAYMENT FORM. PAYMENT IS PER PROJECT

Date	Monash Health HREC No. – <u>Compulsory Field:</u>	Principal Investigator Name:
Application type (note both options can be selected):		
<input type="checkbox"/> Ethics review <input type="checkbox"/> Governance review		
Principal Investigator Contact Details		
Email Address: Contact Telephone Number:		
*Required so that a copy of the receipt may be emailed for taxation/CME claim purposes		

HREC/Governance Submission Fee for:	Unit Value (\$)	GST (\$)	Total (\$)
New Research Projects			
<input type="checkbox"/> Phase I - Commercially Sponsored study – single site study	7000	700	7700
<input type="checkbox"/> Phase I - Commercially Sponsored study – multiple site study (+ charge per site)	7000	700	7700
<input type="checkbox"/> Commercially Sponsored study- single site study	6000	600	6600
<input type="checkbox"/> Commercially Sponsored study- multiple site study (+ charge per extra site)	6000	600	6600
No of sites:	500	50	550
<input type="checkbox"/> Commercially Sponsor- Sub studies	3000	300	3300
<input type="checkbox"/> Non-commercial external sponsor- e.g. collaborative group studies	550	55	605
<input type="checkbox"/> External studies (non-clinical trials) for profit entity	550	55	605
<input type="checkbox"/> External studies (non-clinical trials) not for profit entity	300	30	330
<i>New Research Project - In-house/ Investigator-Initiated studies by Monash Health staff or Monash Health Translation Precinct Partners (Monash University, Monash Institute of Medical Research, Hudson Institute of Medical Research). Excludes undergraduate student projects and investigator-driven projects where the grant funding amount is less than \$2000 per annum.</i>			
<input type="checkbox"/>	200	20	220
<input type="checkbox"/> Quality Improvement Activity	No Fee		
PLEASE ENTER AMOUNT PAYABLE HERE →			\$

PLEASE NOTE THAT THESE FEES ARE CUMULATIVE: Example: The fee for submitting a multi-site commercially sponsored trial with 2 sites will be \$6,600 for the ethics/governance review of the first site + 1 x \$550 per extra site to give a total fee of \$7,150 inc GST. Please note that each study will only be charged once. A study will be charged for either for the ethics submission or governance submission.

New Project Fee

PROJECTS WILL NOT BE ACCEPTED WITHOUT COMPLETED PAYMENT FORM. PAYMENT IS PER PROJECT

Date	Monash Health HREC No. – <u>Compulsory Field:</u>	Principal Investigator Name:
Application type (note both options can be selected):		
<input type="checkbox"/> Ethics review <input type="checkbox"/> Governance review		
Principal Investigator Contact Details		
Email Address: Contact Telephone Number:		
*Required so that a copy of the receipt may be emailed for taxation/CME claim purposes		

Ethics/Governance Amendment Fee for:	Total (\$) Excl. GST	Total (\$) Inc. GST
Commercially sponsored projects:		
<input type="checkbox"/> Protocol amendments	650	715
<input type="checkbox"/> Updated IB	200	220
<input type="checkbox"/> Admin changes, minor PICF Changes, addition of investigator only	200	220
<input type="checkbox"/> Addition of a site to an existing clinical trial (charge per additional site) No. additional sites: <input type="checkbox"/>	500	550
<input type="checkbox"/> Non-commercial external sponsor- e.g. collaborative group studies	No Fee	No Fee
<input type="checkbox"/> External studies (non-clinical trials)	No Fee	No Fee
<input type="checkbox"/> In-house studies	No Fee	No Fee
PLEASE ENTER AMOUNT PAYABLE HERE →		\$

Example: To amend a commercially sponsored (funded) clinical trial by changing the protocol, updating the IB and adding 2 additional sites, the fee will be \$715 for the protocol amendment & IB and 2 x \$550 for each additional site (total \$2030 inc GST).

*Substantial PICF changes includes changes to the PICF due to updated safety information and/or protocol amendments. This does not include administrative changes to the PICF such as addition of investigators, syntax/typographical amendments.

Amendment Fee

Payment methods:

Complete 1 of the 3 payment options: Credit Card, Cheque, or Internal Transfer

Credit Card

Please note that many card issuers have a maximum transaction limit that may be exceeded by this payment. If so, please indicate whether a split transaction is required using the below box.

Card Type (We only accept cards below)	Credit Card Number:	Expiry Date:
<input type="checkbox"/> Visa <input type="checkbox"/> MasterCard <input type="checkbox"/> Bankcard		
Card Holder's Name:	Card Holder's Signature	
Card Holder's Address (for Receipt Purposes)		
Split payments-Please indicate the maximum transaction amount for this card and if split payment required		

Internal Transfer

• When paying by transfer please pay the amount excluding GST

Principal Investigator:	Cost Centre Number:	Cost Centre Name:
Cost Centre Manager (Print Name):	Cost Centre Manager (Signature):	

Cheque or Invoice

• Please attach the cheque / invoice to this form

Contact Name for Position/Person Responsible for HREC/RGO Fee Payments	Company/Organisation	Full Postal Address	Email & Phone
Monash University	Monash University	Receivables and Revenue Accounting Level 4, 211 Wellington Rd Mulgrave VIC 3170	SCS- Clinicaltrials@monash.edu
Coupa PO# XXXXXXXXXX			

Finance Service Use Only		
Cost Centre R-1747	AC 57819	Tax Code G1 - GSTable
Receipt Number	Date	

Monash Health - Research Support Services: ABN: 82 142 080 338
Level 7, 1 Block, Monash Medical Centre

Amendment Fee if Paid Via Monash Uni



Legal Documents

Indemnities and insurance

Indemnities

Standard Form of Indemnity

- Providing indemnity for the premises and/or HREC review

HREC Review Only Indemnity

- Providing indemnity for HREC review for multi-centre study
- **MONASH HEALTH is the Institution**

246 Clayton Road, Clayton VIC 3168 ABN: 82 142 080 338



Research Indemnities

Indemnities are only required when there is a commercial sponsor involved or a private entity undertaking an interventional clinical trial

Medicines Australia Forms of Indemnity

<https://www.medicinesaustralia.com.au/policy/clinical-trials/clinical-trial-research-agreements/>

- Form of Indemnity – Standard
- Form of Indemnity – HREC Review only

Medical Technology Association of Australia forms of Indemnity

<https://www.mtaa.org.au/clinical-investigation-research-agreements>

- The MTAA Standard Indemnity Form for a clinical investigation
- The MTAA Indemnity Form for HREC review only



Insurance – Commercial Studies

- Insurance Certificate
- Coverage for minimum \$10M
- Excess \$25k or less

- *VMIA site*



SSA Authorisation – What Next?

Yay – SSA Authorisation
Now can we start?

YES



Ready to Start

Once all ethics and governance approvals have been obtained and legal documents signed where relevant, the site should be ready to commence.

- Site initiation can proceed
- Patient recruitment can proceed

In commencing the Study Site Master File will be the repository of all documentation – even if it indicates where information is held in areas away from this File.



Ethics and Governance – 4 Part Series

<u>Date & Time</u>	<u>Topics to be Covered</u>
<p style="text-align: center;">Thursday</p> <p style="text-align: center;">29 October 2020</p> <p style="text-align: center;">12.30 pm – 1.30 pm</p>	<p style="text-align: center;">Overview of Ethics and Governance Guidelines, Legislation, Polices, Procedures Human Research Ethics Applications Low Risk Applications - Quality Assurance</p> <p style="text-align: center;">https://us02web.zoom.us/j/89494009527?pwd=K29YYWNOtmsxV2xBbnNsdv9mSWhPZz09</p> <p style="text-align: center;">Meeting ID: 894 9400 9527 Passcode: 920776</p>
<p style="text-align: center;">Thursday</p> <p style="text-align: center;">12 November 2020</p> <p style="text-align: center;">12.30 pm – 1.45 pm</p>	<p style="text-align: center;">Site Specific Assessment Applications Governance Supporting Departments Good Clinical Practice Training Legal Documents</p> <p style="text-align: center;">https://us02web.zoom.us/j/89294836899?pwd=VytsdlRzUIRrUlo0cUxMRTBWTzkwZz09</p> <p style="text-align: center;">Meeting ID: 892 9483 6899 Passcode: 279765</p>
<p style="text-align: center;">Tuesday</p> <p style="text-align: center;">24 November 2020</p> <p style="text-align: center;">12.30 pm – 2.00 pm</p>	<p style="text-align: center;">Study Site Master File Essential Documents Data, Privacy and Recruitment Informed Consent Witnesses, Interpreters, Incompetent Patients</p> <p style="text-align: center;">https://us02web.zoom.us/j/82665006872?pwd=cXA0ODM3SVJvc3p6Z1FWVWZ0d0Zldz09</p> <p style="text-align: center;">Meeting ID: 826 6500 6872 Passcode: 002481</p>
<p style="text-align: center;">Monday</p> <p style="text-align: center;">30 November 2020</p> <p style="text-align: center;">12.30 pm – 2.00 pm</p>	<p style="text-align: center;">Post Approval Submissions HREC Amendments Safety Reporting Protocol Breaches – Protocol Deviations Post Approval Monitoring - Research Progress Reports - Audits Intellectual Property Supplementary Information</p> <p style="text-align: center;">https://us02web.zoom.us/j/86720721416?pwd=V2hkNVIUYU9qV0QwSWhkdENBc09ydz09</p> <p style="text-align: center;">Meeting ID: 867 2072 1416 Passcode: 423386</p>

