

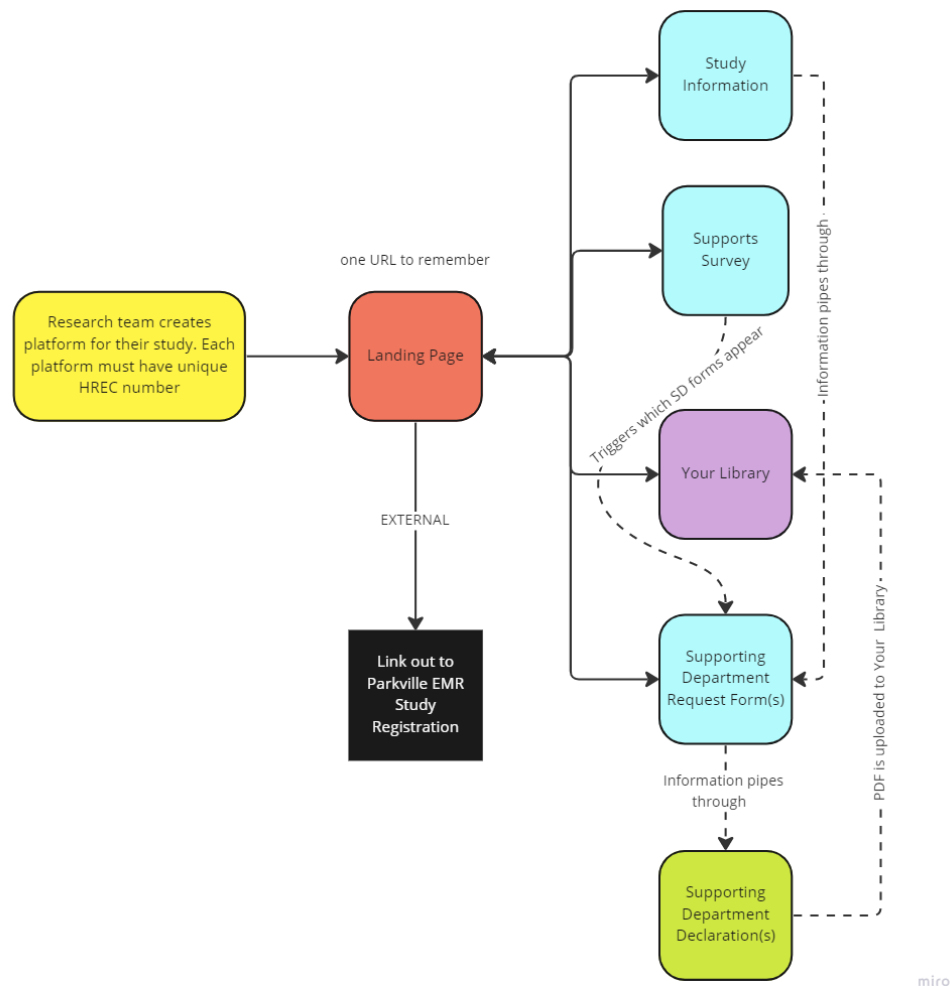
# Melbourne Children's Campus – Department and Ethics Research Platform (DERP) User Guide for Researchers

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## Overview

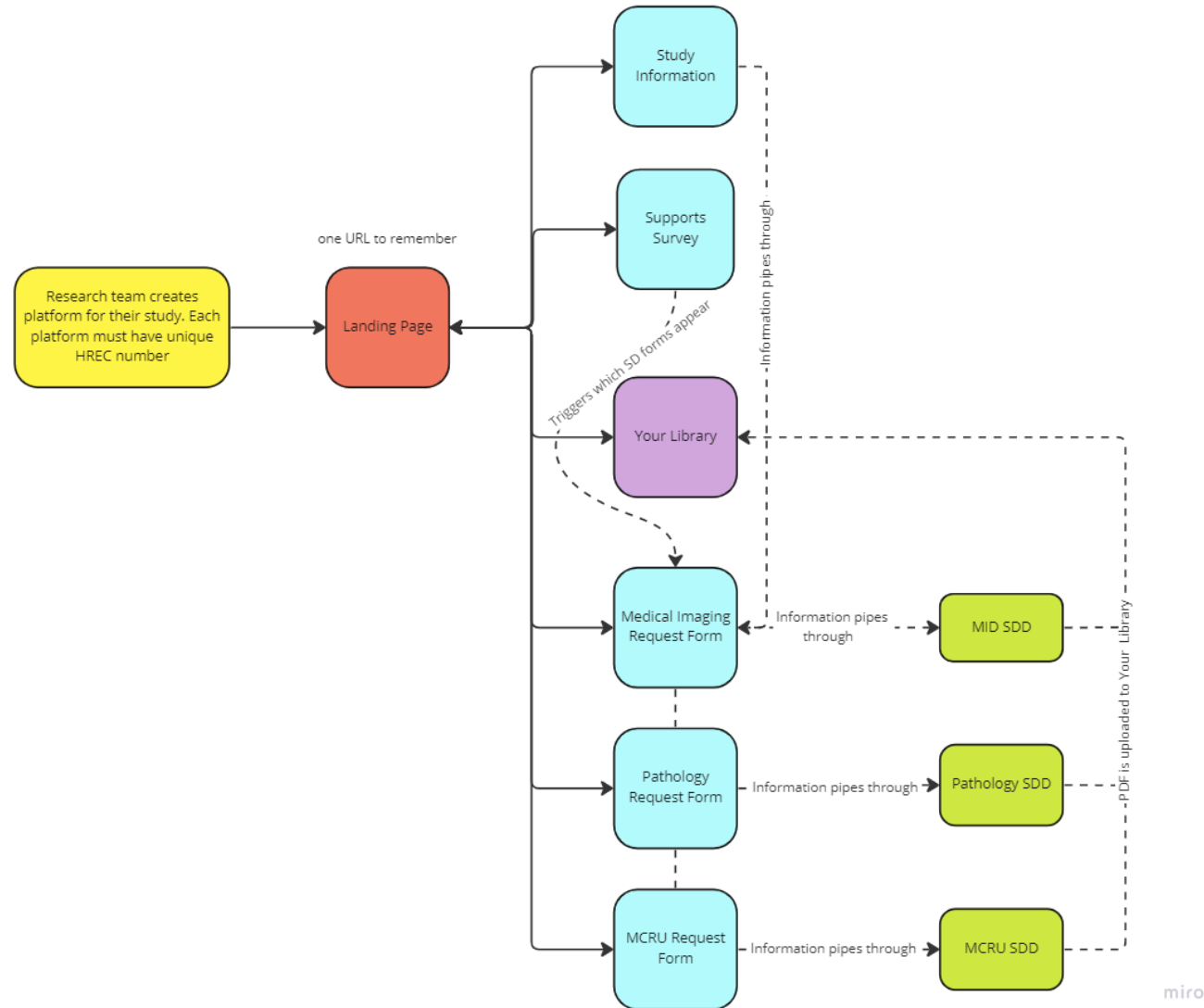
Here is an overview of how the surveys in this Platform fit together:



- The **Landing Page** is your 'to-do' list. Everything else you are required to complete or access will be on this page. To help you keep track of why things are required, we've split this up into sections:
  - **Tell us about your project**
    - **What type of project is this?** Which determines if your project needs ethics review, governance authorisation, or both
    - **Project Information**, which should be your current study details. You can go back and edit this at any time
  - **The Research Ethics Step**
    - **Research Ethics Risk Assessment** which was historically the first page of the REG Application Coversheet. This determines the level of risk of your project
    - **Peer Review Proforma** for projects where this is applicable
  - The Research Governance Step
    - **Research Governance Risk Assessment** to determine which MCC departments/servicers you should engage as part of your submission

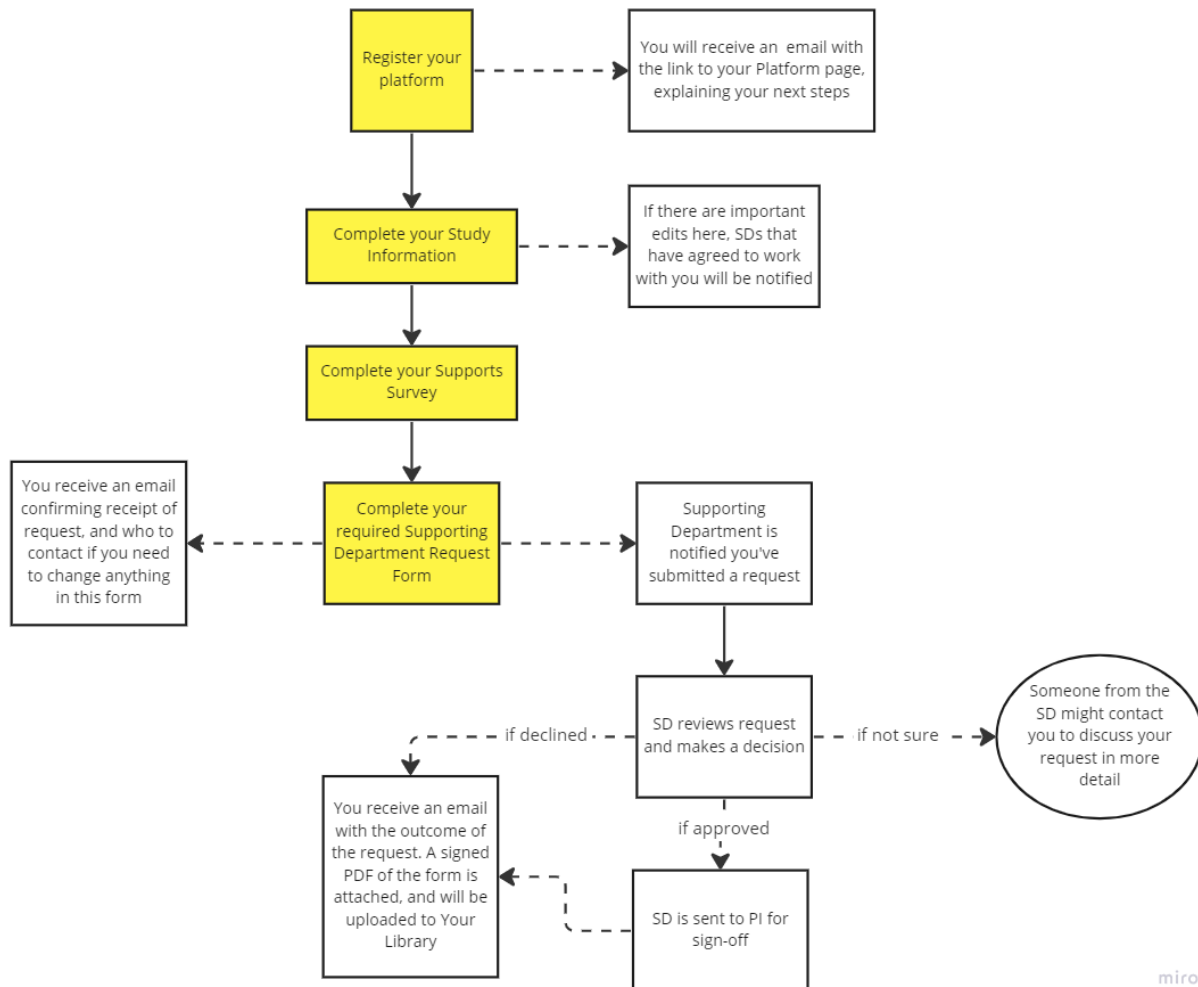
- **RCH Supporting Departments Survey** which determines which Supporting Department Request Forms appear on your to-do list. You can go back and edit this at any time
- **MCRI Sponsorship** where applicable
- The **Parkville EMR Study Registration** page, an external survey that everyone in the precinct must complete
- **The Research Governance step – RCH Supporting Departments**, where request forms will appear in your to-do list based on your response to the **Supports Survey**. This will pre-fill with all the relevant information from the Study Information, reducing the amount of information you need to complete. Their status will change based on where they are up to in the request/approval process
- **Final steps**
  - **Head of Department Declaration** to send your project for sign-off
  - **Your Library** is a list of all the Request Forms you've submitted, and SDDs you've received. This will only list the most recent SDD.

Here is an example of what your platform will look like if you request support from Medical Imaging, Pathology and MCRU. When you open **Your Library** you will see your three request forms, and three Supporting Department Declarations



## Automatic notifications

An important part of this platform is how it will be used to communicate to Supporting Departments. Rather than needing to check this system regularly, email alerts have been setup to notify teams when things that impact them have changed. For example: if Medical Imaging has agreed to support your project, they will receive a notification if you change your total target recruitment number.



Supporting Departments get an email when:

1. Recruitment start date changes
2. Recruitment target at MCC changes
3. Changes to PI/Study Coordinator/Study Team
4. A study opens (Governance Authorisation granted) or closes (Final Report submitted)

Study Teams get an email when:

1. A request for support is submitted
2. An SDD is fully signed
3. Lab slips are uploaded (if applicable, once Governance is authorised)

## Create your platform

Start the process via the registration link available on the RCH Research Ethics and Governance website:  
<https://redcap.mcricri.edu.au/surveys/?s=RMMECTXFCC8LPHL>



AAA  


## Welcome to the Melbourne Children's Campus Departments and Ethics Research Platform!

What best describes what you have come to DERP for?

**1. I/my team would like to lodge a project (quality or research) that will either:**

- be run at the Melbourne Children's Campus (MCRI/VCGS, RCH, UniMelb)
  - E.g. an audit of EMR data or a clinical trial run by Population Allergy

**OR**

- be sponsored one of the organisations of the Melbourne Children's Campus, but will run somewhere other than the Melbourne Children's Campus
  - E.g. a project being run by MCRI that is taking place in the Phillipines

**2. I/my team am using DERP for an alternative purpose**

- Requesting support from RCH Pathology/Lab Services for projects that are external to our campus
- Requesting review for Medical Physics Risk Assessment (MPRA) for projects being reviewed by a different HREC

1. I would like to lodge a project that will either be run at, or by at the MCC

2. I am using DERP for an alternative purpose

[reset](#)

Your answers on this page will begin to put together your personalised to-do list for your application. Select '1' on this question **unless** your project is one of the following:

- Your project is not running at the Melbourne Children's Campus (e.g. Royal Women's Hospital, La Trobe University, Garvan Institute) but you will need assistance from RCH Pathology. There will be no local RCH HREC/ERM number
  - **You will only be able to submit requests to RCH Pathology/Lab Services**
- Your project is currently being reviewed by another HREC (e.g. Sydney Children's Hospital Network) and you require an RCH Medical Physics Risk Assessment (MPRA) for this application. You will have a local RCH HREC/ERM number, but you don't yet.
  - **You will only be able to submit a request for a MPRA until you enter your local RCH HREC/ERM number**

The next prompt is regarding the risk of your project:

Melbourne Children's DERP User Guide for Researchers\_12Feb2024  
 Direct questions to the RCH REG Office – [rch.ethics@rch.org.au](mailto:rch.ethics@rch.org.au)

### What type of project are you lodging?

**NOTE:** If you are unsure in which category your project falls, that is OK, you will have the opportunity to change your answer later.

#### 1. A low or high risk research project

- These are research projects that have a risk greater than inconvenience to participants, their data or samples
- Research projects that have this level of risk, require review from an accredited HREC
- These research projects are also required to submit some information and documents through ERM, so they will have an ERM number that identifies their project

#### 2. Something else

- A **minimal risk** research project. These are projects that have no more risk than inconvenience to participants, their data or samples. These projects do not require review from an accredited HREC.
- A **quality** project of any level risk. Quality projects may be high risk, but the research ethics committee do not review them, the risk is assessed and managed through other committees.

#### 3. I'm not sure yet

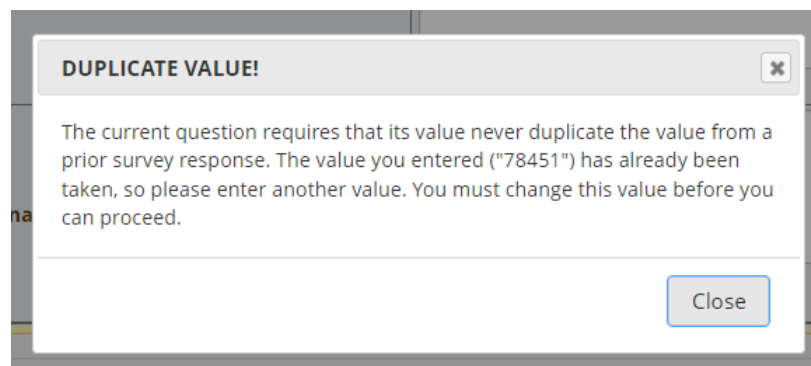
- Select this option if you need to proceed to further risk assessment questions
- You will be prompted to create your project in ERM if your project is greater than minimal risk
- You can then come back and enter an ERM number

1. A low or high-risk research project
2. Something else e.g. **minimal risk** research or a **quality** project
3. I'm not sure yet

[reset](#)

You may know the answer to this question, you may not. What you answer here can be changed later! If you select a low or high risk project you will be asked to enter your HREC/ERM number to proceed.

Your platform is connected to your HREC number. To avoid duplicates, each HREC number can only be used **once**, and you will get this error if it has already been used.



If you cannot submit using your HREC number, contact the RCH REG Office ([rch.ethics@rch.org.au](mailto:rch.ethics@rch.org.au))

Complete the registration page with your basic study details, PI and Study Coordinator contact information. Whoever is listed here will receive email notifications on their next steps.

Once you submit this form, the PI and Study Coordinator will receive an email with a link to your Platform. This link can be shared with other members of your team involved in Study Management to track your progress

## Your Platform Landing Page (your Home Page)

Your Platform Landing Page (think of this like your home page) is your one-stop-shop for all outstanding tasks for your project. **You should save this link** and share it with any other members of your Study Team who will be assisting the submission process, or Study Coordination. If you reach out to any departments that use this platform, they will ask you to return to this Landing Page to place requests for them to review.

The top of this page displays your current project information and your current ERM status. The ERM status is **manually** updated by the Research Ethics and Governance team, so it will not automatically update as soon as you submit something on ERM

Below this, you will see what needs to be completed next. Your Landing Page will keep updating with what tasks are required for your project as you work down the list. Each task will also have a contact person if you need help with that particular step. We've colour coded each of your tasks to make it easier for you to keep track of what is outstanding for your project:

- Outstanding tasks appear in **orange**
- Tasks you have completed appear in **green**
- Tasks that are waiting for review by another party are **blue**
- Requests that have been denied or are blocked will appear in **red**

<p><b>Melbourne Children's ReseaRCH Unit</b></p> <p>If you have had a study amendment and need to update this request form, please contact Jaclyn Dorland (<a href="mailto:jaclyn.dorland@rch.org.au">jaclyn.dorland@rch.org.au</a>)</p>	<p><b>Reviewed - approved!</b></p>
<p><b>RCH Day Medical Unit</b></p> <p>Please contact Kate Schurmann (<a href="mailto:kate.schurmann@rch.org.au">kate.schurmann@rch.org.au</a>) for further discussion</p>	<p><b>Reviewed - declined</b></p>
<p><b>Pathology/Lab Services</b></p> <p>If you need assistance with this survey please contact Lab Services (<a href="mailto:labservices.trials@rch.org.au">labservices.trials@rch.org.au</a>)</p>	<p><b>To be completed</b></p>
<p><b>RCH Theatres</b></p> <p>If you have had a study amendment and need to update this request form, please contact Rosemary Aisbett (<a href="mailto:rosemary.aisbett@rch.org.au">rosemary.aisbett@rch.org.au</a>)</p>	<p><b>Reviewed - approved!</b></p>
<p><b>Audiology</b></p> <p>For further discussion please contact Christine Poulis on 9345 5566</p> <p><b>Need to upload a revised Reference Manual? <a href="#">Click here!</a></b></p>	<p><b>Submitted - sent to Principal Investigator</b></p> <p>Form submitted by Greg on 16-11-2022</p>



## Tell us about your project

### What type of project are you lodging?

The first task on your list asks **What type of project are you lodging?** This is a screening survey that determines if your project needs ethics review, governance review or both at the MCC. It will determine:

- Is your project research or quality?
- Has a research project undergone ethical review elsewhere?
- What level of involvement is there at MCC?

**You need to come back to this page if what you're planning in your project changes.** If you're not sure how to answer some of these questions, talk to the REG Office ([rch.ethics@rch.org.au](mailto:rch.ethics@rch.org.au)) or call them on 9345 5044

### Project Information

Information you have already provided when you registered the platform will pre-fill in this form, to avoid you entering the same information over and over again.

**Key Details**

All information here will be editable for the life of your project.

Questions marked with an \* are programmed with alerts to notify supporting departments of any changes

<b>Full study name</b>	Are Pirates Predetermined to Loot Everything - an investigation into the behaviors of Blackbeard's motley crew considering concentrations of rum readily available <div style="text-align: right; font-size: small;">Expand</div>
<b>Short (everyday) name</b>	APPLE <div style="font-size: x-small;">4 words remaining</div>

It is likely you can't complete all this information at once. You cannot submit the form until it is complete - if you try and submit an incomplete form you will get an error message, but your responses will still be saved! At the bottom of the page you can click **Save & Return Later**. You can access this form again any time via your Landing Page. This task will remain orange until you've entered all information

### The Research Ethics Step (if required)

When you return to your Landing Page you will see a new section **The Research Ethics Step**. If you are doing a quality project you will not see this section, as you are no longer required to submit quality projects for ethical review after 17<sup>th</sup> February 2024.

## The Research Ethics Step

### Research Ethics Risk Assessment

These questions will help refine the risk review pathway of your submission. You can update this form as your project evolves, up until the point of submission

To be completed

### Research Ethics Risk Assessment

You will recognise these questions as part of the historic REG Application Coversheet. Completing these questions will determine the risk profile of your project, and which review pathway it will be submitted under. If the nature of your project changes you can come back to this form and update your responses.

There are some projects that will have unique requirements that still require a conversation with the REG Office to determine the appropriate risk pathway. You will be prompted to contact the REG Office if your project is in this category.

### Peer Review Proforma (if applicable)

Projects that need ethics review and are Investigator initiated are **required** to have their protocol reviewed by an expert in the field prior to being submitted to the RCH HREC. Minimal risk projects (that are no longer being submitted for ethics review) may also send their protocol for Peer Review if they choose.

On this form you need to nominate your reviewer and upload your most recent version of the protocol for them to review.

**Your chosen Reviewer** ^

**Who will be doing your Peer Review?**  
*This person will be sent a copy of your protocol for review.*

<b>Name</b>	<input type="text"/>
<b>Email</b> <i>This is where the review proforma will be sent, please ensure this is correct</i>	<input type="text"/>
<b>Position title</b>	<input type="text"/>
<b>Department/Group</b>	<input type="text"/>
<b>Institution</b>	<input type="text"/>
<b>Protocol version for review</b> <i>This is the version that will be sent, please ensure it is correct.</i>	<a href="#">Upload file</a>

**Is your chosen reviewer:**

<b>Independent?</b> <i>They cannot be an Investigator on this project, nor report to any of the Investigators listed on this project</i>	<input type="radio"/> Yes <input type="radio"/> No <span style="float: right;">reset</span>
<b>An expert in this field?</b>	<input type="radio"/> Yes <input type="radio"/> No <span style="float: right;">reset</span>

When you save this form, an email will be sent to your nominated reviewer with a copy of your protocol and a digital version of the review proforma for them to complete. Your Landing Page will update with the new status of this task

**Peer Review Proforma**

Your research protocol must be reviewed before submission to the RCH HREC

**Out for review by [Arianna Mackay](#)**

Sent to [arianna.mackay@rch.org.au](#) on 23-11-2023

When the review is complete the Study Team will receive an email that there are reviewer comments to respond to. Your Landing Page will update to reflect this:

**Peer Review Proforma**

Your research protocol must be reviewed before submission to the RCH HREC

**Peer Review complete!**  
[View comments to be responded to](#)

This takes you to a digital summary of the review proforma:

Plan of investigation:	Response	Notes where applicable
<b>Design:</b> is the design appropriate to the aim? Will the study address the question being asked and is it likely to produce an answer?	Yes	_____
<b>Bias and confounding:</b> Has the study been designed to minimise the risk of bias? Have the investigators adequately accounted for the influence of potential confounders?	No	<b>no mention of confounders in the statistics section</b>
<b>Randomisation and Blinding:</b> Where applicable, is enough detail provided on exactly how randomisation and blinding will be achieved, including who is responsible?	Yes	_____
<b>Sampling issues:</b> Will the proposed study group be large enough to provide sufficient statistical precision or power, where appropriate? Is there a reasonable justification for the proposed sample size? Will the sample collected be reasonably representative of the population in question?	Yes	_____
<b>Feasibility:</b> Is there sufficient evidence to indicate that it will be possible to obtain the numbers required for the study? Is the study feasible in terms of funds, time and other resources?	No	<b>the recruitment target seems high for this population</b>

Towards the bottom of this form are the comments the Study Team are required to respond to. You **cannot** submit this form for review until all outstanding comments are responded to:

**Required Changes** (Points that the investigator must address by either making the required change, or producing a cogent argument against the change): ^

**Provide a response to the following comment**

**Reviewer comment:** In terms of study population, it is mentioned that one parent/caregiver will participate. One significant thing to consider about this is that caregiver sex will also be a confounder. Mothers have been consistently found to be more anxious in populations of sick kids, and since anxiety is your main outcome, it will be important to account for this. I notice there is no mention of confounders in your statistical analysis section

\* must provide value

Expand

---

**Provide a response to the following comment**

**Reviewer comment:** Add verbal consent record form for researchers who are collecting consent on behalf of participants just prior to interview/focus groups.

\* must provide value

Expand

Submitting this form submits the form to the RCH HREC for review – **you no longer need to upload anything to ERM for this step**

### Ethics Assessment for Minimal Risk projects (if applicable)

For projects that are no longer required to be submitted for research ethics review (i.e. minimal risk projects), a survey will appear on your to-do list to assess your own project for merit.

This series of questions will ask you to assess the merit, justice, beneficence and respect of your project according to the relevant sections of the National Statement. If you need help with this step, reach out to the REG Office.

A copy of your answers will be send to your Head of Department as part of your request for Head of Department sign-off.

### The Research Governance Step (if applicable)

A separate section will appear on your Landing Page with tasks related to seeking Governance Authorisation at MCC. Depending on your answers in the first section, you may already have outstanding tasks here.

### Governance Risk Assessment

This form will ask you specific questions about your project to determine your Governance requirements for submission. As more departments/teams from across campus join this platform the list of questions will grow. What you answer on this form will determine what tasks appear in your **Research Governance Step** section

### RCH Supporting Departments involved

Over the course of 2023, nine departments were added to this platform allowing you to request SDDs through REDCap rather than emailing word documents back and forth. Think carefully about which departments you will need to contact to request support for your study. If you're not sure, contact the department directly to discuss.

### MCRI Sponsorship

For interventional studies that are investigator-initiated at the Melbourne Children's Campus, you need to request MCRI acts as the Sponsor for your project. If your project fulfils this criteria, Sponsorship will appear as a task on your to-do list. Rather than have a series of questions here, we have a set of instructions for how to contact this department:

## What do I need to do?

1. Check the CRDO website for current details about how to apply for MCRI Sponsorship from the Sponsorship Committee.
  - You can access it [here](#). You do not need an MCRI appointment to access this web page
2. Send your submission to [mctc@mcri.edu.au](mailto:mctc@mcri.edu.au). You will need to include:
  - Your **protocol**
  - A completed version of the **Sponsorship Application form and Risk Matrix** (this is on the CRDO website linked above and available on [METIS](#))
  - Your **budget** (if available)
3. Below, you can make a note of when this submission was sent to keep track of the request progress
4. You will be notified of the outcome of your request via email.
  - If you are issued a Certificate of Sponsorship this will be emailed to you, and available in **Your Library**
  - The Research Ethics and Governance Office has access to all documents in **Your Library**. You don't need to upload this to ERM
5. If you have any questions about this process, please contact Iona Walton via [mctc@mcri.edu.au](mailto:mctc@mcri.edu.au)

Date Sponsorship approval requested

Today D-M-Y

You can track the date you sent your email to MCTC, which will be reflected on your Landing Page to stay across your outstanding tasks:

Certificate of MCRI Sponsorship

Requested, awaiting outcome

Requested on 10-01-2024

Investigator-initiated clinical trials (i.e. initiated and organised by an individual rather than an external collaborative network, company or organisation) need to request the Murdoch Childrens Research Institute act as the legal representative for a trial, acting as the Sponsor. Details of this process are on the [CRDO website](#)

The outcome of this request will be sent to you via email and reflected on your Landing Page. If MCRI agrees to sponsor your study, the Certificate of MCRI Sponsorship will be uploaded to Your Library for your records **and sent to the REG Office as part of your application. You no longer need to upload this to ERM for review.**

Certificate of MCRI Sponsorship

**Done!**  
 Outcome also uploaded in Your Library

Requested on 23-01-2024

Investigator-initiated clinical trials (i.e. initiated and organised by an individual rather than an external collaborative network, company or organisation) need to request the Murdoch Childrens Research Institute act as the legal representative for a trial, acting as the Sponsor. Details of this process are on the [CRDO website](#)

Certificate of MCRI Sponsorship

**Declined: Sponsorship is not required**

**Outcome on 23-01-2024**

To discuss please contact Iona Walton at [mctc@mcri.ed.au](mailto:mctc@mcri.ed.au)



## MCRI Supporting services such as CCRAC and CAB

As we include more services in this platform, they will begin to appear on your Landing Page to-do list. Not all committees will have their approvals done in DERP, but you can track where things are up to for your own reference.

For example the Community & Clinical Research Advisory Committee (CCRAC) task will appear if your project involves MCRI staff face-to-face with participants. Opening this task will give you instructions on how to seek approval from this committee, fields to track when you submitted a request and when it was approved:

**Why does this need to be completed?**  
 The Participant Research form and COVIDSafe Subplan need to be completed to ensure key operational and COVIDSafe practices are in place for your project. For example for on-site research that you can be accommodated in the MCTC or another area, and that the study team has access to the appropriate one page COVIDSafe Subplan to ensure study staff and participants are safe.

**How do I complete the Participant Research form and COVIDSafe Subplan?**  
 Follow the actions as outlined in the table on the MCRI Intranet [here](#)

<b>Date requested</b> * must provide value	<input type="text"/>		Today	D-M-Y
<b>Date approval received</b> * must provide value	<input type="text"/>		Today	D-M-Y
<b>Enter your CCRAC approval number</b> This should follow the format CAXXXXXX * must provide value	<input type="text"/>			

The approval date and outcome (CCRAC number for example) **will be reviewed here by the REG Office as part of your application.** You no longer need to upload this to ERM for review.

## Parkville EMR Registration (historically called the pre-submission survey)

All studies involving patients in the Parkville Precinct must be registered with Parkville EMR. This link will take you to the Parkville EMR Study Registration survey, which is managed by the Parkville EMR team (it is external to this platform).



## EMR PRE-SUBMISSION SURVEY

Welcome to the EMR Pre-Submission survey. This survey is a required step in the process of submitting an application to your Office of Research Governance and Ethics.

The pre-submission survey is divided into two parts:

1. Study Registration (2 minutes)
2. Completion of the EMR Research Study Questionnaire (5-10 minutes)

Before proceeding to register your study, you must know your project's 5-digit ERM (ethical review manager) identifier. This number is assigned as soon as you initiate an application in the ERM.

**This survey should only be used for projects that were assigned a Project ID on or after the 1st January 2020. For older projects, please lodge a Service Request via ServiceNow.**

<https://rchauprod.service-now.com/phssp>

To begin, click on the "Next Page" arrow below.

Should you have any questions regarding this questionnaire or EMR-specific queries, please contact the Parkville EMR Research Team by lodging a ServiceNow Research request via link above.

For users outside of the Parkville Precinct, please email: [epic.research@rch.org.au](mailto:epic.research@rch.org.au).

Next Page >>

You may have already answered some of these questions in the Study Information form to assist the RCH Supporting Departments, but it's important you answer them again for the Parkville EMR team. Just like your platform, this survey is connected to your HREC number so you can only complete it once.

You will need to provide:

- Current Study Contact details
- Planned recruitment start date
- Basic study information including title, description, and study design (your intervention if applicable, type of observational study)
- Whether you will need the help of RCH Supporting Departments

If you need help with this step please contact the RCH REG Office ([rch.ethics@rch.org.au](mailto:rch.ethics@rch.org.au))

### The Research Governance step – RCH Supporting Departments

Each department you have indicated you will need to contact from in your previous task has a request for that needs to be submitted to the Department for review. These will appear in their own section of The Research Governance Step



**Melbourne Children's ReseaRCH Unit**

To be completed

If you need help with this survey, please reach out to Kaya Gardiner ([kaya.gardiner@rch.org.au](mailto:kaya.gardiner@rch.org.au))

**Medical Physics and Medical Imaging**

To be completed

If you need assistance with this survey, please contact Mariz Hanna ([mid.research@rch.org.au](mailto:mid.research@rch.org.au))

**Pathology/Lab Services**

To be completed

If you need assistance with this survey please email [labservices.trials@rch.org.au](mailto:labservices.trials@rch.org.au)

Each Supporting Department has designed their own form depending on what information they require. Relevant information you have already completed in the Project Information will pre-fill in this form.

- If the information here is incorrect, you need to go back to **your Project Information** and update it

For example here is the start of the Melbourne Children's ReseaRCH Unit (MCRU) Request Form. A link is here to take you back to your Study Information to make edits if required

**Here is your current Study Information**

If anything is no longer correct or is missing, [click here to head back to your Study Information page](#) and fix it up :)

<b>ERM number</b>	65432	<b>Study short title</b>	tone
<b>PI name</b>	Anthea Greenway _____	<b>Coordinator name</b>	coord name
<b>PI email</b>	abc@de.com	<b>Coordinator email</b>	abc@de.com
<b>PI phone</b>	0402121212	<b>Coordinator phone</b>	0402121212

<b>Sponsor type</b>	Commercial (e.g. GlaxoSmithKline, Pfizer)	<b>Which campus partner is the local 'lead' site</b>	MCRU/VCGS
<b>Interventional study</b>	Yes	<b>What type of trial</b>	Drug Trial
<b>Intervention being investigated</b>	Drug	<b>What phase trial is the study</b>	Phase I/II

<b>Study recruitment status at Melbourne Children's Campus</b>		Recruiting	
<b>Planned recruitment start date</b>	08-12-2022	<b>Planned recruitment completion date</b>	_____
<b>Estimated final study visit date</b>	_____	<b>Length of study involvement for participants (in months)</b>	_____
<b>Planned participant number overall</b>	_____	<b>Planned participant number at RCH</b>	100

You may have already answered some of these questions in the Project Information form, but they are asked here again to inform the Department how trial activity will directly impact them.

For example: on the Project Information you stated you would be collecting biological samples. You will be asked this again on the MCRU Request Form to confirm if you will be collecting biological samples

specifically in the MCRU space. The status of your Request Forms will update as they move through the approval process:

<p><b>Melbourne Children's ReseaRCH Unit</b></p> <p>If you have had a study amendment and need to update this request form, please contact Kaya Gardiner (<a href="mailto:kaya.gardiner@rch.org.au">kaya.gardiner@rch.org.au</a>)</p>	<p><b>Reviewed - approved!</b></p>
<p><b>Audiology</b></p> <p>If you need to change what you have submitted in this survey please contact Christine Poulis on 9345 5566</p>	<p><b>Submitted - pending review</b></p>
<p><b>Medical Physics and Medical Imaging</b></p> <p>This form includes request for Endocrinology support. If you need assistance with this survey, please contact Mariz Hanna (<a href="mailto:mid.research@rch.org.au">mid.research@rch.org.au</a>)</p>	<p><b>To be completed</b></p>

RCH Supporting Department request example: Medical Imaging Department (MID) & Medical Physics Risk Assessment (MPRA)

**Things to note before filling out the SDD:** This SDD is for trials that require Medical Imaging scans and/or Medical Physics risk Assessments.

If you're unsure whether you need a Medical Imaging SDD, consider the following:

- Will the trial require any imaging (i.e. MRI, ultrasound or X-ray) performed at the RCH radiology department?
- Do you require images of scans or radiology reports?

If you're unsure whether you need a Medical Physics Risk Assessment, consider the following:

- Will the trial use any ionising radiation in the scans? (i.e. X-rays, CT scans, Nuclear Medicine / PET scans or DEXA/pQCT)
- Please note: DEXA and pQCT require Endocrinology Supporting Department Approval. Medical Imaging can only provide the medical physics risk assessment for these scans.

To complete the form, you will need the following information:

- Patient demographics
- Imaging services required
- Schedule of imaging
- Identify which of these scans are standard of care

Further detail is provided in the description ahead of each section of questions.

Instructions for filling out the form:

Please see below for a few helpful tips when filling out the SDD.

- Begin the form by ticking all that apply to your study. This will expand the form to include all the questions relevant to your request.

**Which of the following do you require?**  
(Tick all that apply)  
*\* must provide value*

Medical Imaging Supporting Department Declaration  
 Medical Physics Risk Assessment  
 Data request (Retrospective Scans)

- The next set of questions is gathering information about the patient demographics. This information is vital in calculating the radiation doses and assist in determining whether the scans requested are feasible for our department.

Please respond to the best of your abilities when prompted for the minimum and maximum numbers. While this may seem dramatic, we do need the absolute minimum and maximum numbers. For example:

The study may only run for 12 months but require follow up for up to 5 years.

<b>What is the <i>average</i> duration of each participants time in the research study?</b>	<input type="text" value="12"/>	<input type="text" value="Months"/> ▾
<b>What is the <i>maximum</i> duration of each participants time in the research study?</b>	<input type="text" value="5"/>	<input type="text" value="Years"/> ▾

- Medical Imaging scan details are required for the scans requested as per the trial protocol. See example below of a combination of scans.

Medical Imaging scan details				
Please select the modality of the scan:	Specify which area is required for the scan (As per protocol)	What is the maximum number of occasions a patient will receive this scan?	What is the schedule of imaging for this scan? (Alternatively, please reference page number in protocol if available)	Is this scan & schedule of imaging considered Standard Care at RCH? (refer to SOC definition above)
Plain Film X-rays <input checked="" type="checkbox"/> Tick box to add another scan	Chest <small>14 words remaining</small> <small>Expand</small>	<input type="text" value="3"/>	Baseline, week 4 and week 5 <small>194 words remaining</small> <small>Expand</small>	<input type="text" value="Yes"/>
Computed Tomography (CT) <input checked="" type="checkbox"/> Tick box to add another scan	CT Chest /Abdomen /Pelvis <small>11 words remaining</small> <small>Expand</small>	<input type="text" value="1"/>	At screening only <small>197 words remaining</small> <small>Expand</small>	<input type="text" value="No"/>
Magnetic Resonance Imaging (MRI) <input checked="" type="checkbox"/> Tick box to add another scan	MRI Abdomen <small>13 words remaining</small> <small>Expand</small>	<input type="text" value="1"/>	At screening if CT contrast is contraindicated <small>193 words remaining</small> <small>Expand</small>	<input type="text" value="No"/>
Nuclear Medicine and/or PET <input checked="" type="checkbox"/> Tick box to add another scan	Bone Scan <small>13 words remaining</small> <small>Expand</small>	<input type="text" value="4"/>	Screening, Cycle 4, cycle 8 and end of treatment <small>191 words remaining</small> <small>Expand</small>	<input type="text" value="Yes"/>
Ultrasound (US) <input type="checkbox"/> Tick box to add another scan	Abdomen <small>14 words remaining</small> <small>Expand</small>	<input type="text" value="6"/>	Screening then monthly scans <small>196 words remaining</small> <small>Expand</small>	<input type="text" value="Yes"/>

- If the scans are a combination of both Standard of Care (SOC) and non-SOC, please enter as two separate rows. This assists in calculating how much radiation dose are in addition to the standard this patient would typically receive if they were not on the study. It is also used for MID to calculate the workload in addition to what would typically be performed.

<input type="text" value="Computed Tomography (CT)"/> <input checked="" type="checkbox"/> Tick box to add another scan	<input type="text" value="CT Chest /Abdomen /Pelvis"/> <small>11 words remaining</small> <small>Expand</small>	<input type="text" value="1"/>	<input type="text" value="At screening only"/> <small>197 words remaining</small> <small>Expand</small>	<input type="text" value="Yes"/>
<input type="text" value="Computed Tomography (CT)"/> <input checked="" type="checkbox"/> Tick box to add another scan	<input type="text" value="CT Chest /Abdomen /Pelvis"/> <small>11 words remaining</small> <small>Expand</small>	<input type="text" value="5"/>	<input type="text" value="Cycle 2, cycle 4, cycle 6, cycle 8 and cycle 10"/> <small>189 words remaining</small> <small>Expand</small>	<input type="text" value="No"/>

- You will find comments boxes spread throughout the survey to add in any addition information or concerns.

**Please provide any further comments or questions about the study for Medical Imaging:**

There is no imaging manual, scan as per hospital protocol

300 words remaining Expand

- Submit the survey with the PI or authorised representative signature and wait for a response!

### What happens next?

The Medical Imaging department and/or Medical Physicist will gladly review this study and respond within 15 business days of receiving all relevant documentation. You may be contacted if there's any missing information. Please do not hesitate to contact us on [mid.research@rch.org.au](mailto:mid.research@rch.org.au) should you have any questions.

## Final steps – when you’ve completed the above

### Head of Department Declaration

All projects require Head of Department sign-off before they can be submitted for review. Your HoD will be sent a summary table of your project and a copy of your protocol. For minimal risk and quality projects, they will also be sent a copy of your self-assessment of merit. If you have not completed a required task on your list above, you will be blocked from completing this step.

**Head of Department Declaration**

Your must get HoD sign-off before you can submit

**You must complete the above tasks before you can send for sign-off**

**The protocol sent is what is uploaded to your Project Information. Please ensure the most up to date version has been uploaded.**

On this form you need to nominate who you would like the HoD Declaration to be sent to for sign-off:

**Your Head of Department** ^

**Who will be doing your Head of Department sign-off?**

<b>Name</b>	<input type="text"/>
<b>Email</b> <i>This is where the request for sign-off will be sent, please ensure this is correct</i>	<input type="text"/>
<b>Position title</b>	<input type="text"/>
<b>Department/Group</b>	<input type="text"/>
<b>Institution</b>	<input type="text"/>

Your HoD will be sent a digital version of the HoD sign-off form, and the status of this task on your Landing Page will update:

**Head of Department Declaration**

You must get HoD sign-off before you can submit

**Out for signature to ~~Andrew Mackay~~**

Sent to ~~andrew.mackay~~@rch.org.au on 23-11-2023

Once this is complete, your Landing Page will update to reflect this

**Head of Department Declaration**

You must get HoD sign-off before you can submit

**Done!**  
You can find the PDF in Your Library

The Study Team will receive an email with a PDF copy of their responses. This will be uploaded to Your Library **and sent to the REG Office as part of your application. You no longer need to upload this to ERM for review.**

## Your Library

Each Request Form you submit and Supporting Department Declaration that is approved will upload in PDF form to **Your Library**.

Requests you have submitted			
<table border="1"> <tr> <td><b>MCRU Request Form</b></td> </tr> <tr> <td>Submitted on 23-11-2022</td> </tr> </table>	<b>MCRU Request Form</b>	Submitted on 23-11-2022	<p><a href="#">MCRURequestForm_2022-11-2..._0728.pdf (0.05 MB)</a></p> <p><a href="#">Upload new version</a> or <a href="#">Remove file</a></p>
<b>MCRU Request Form</b>			
Submitted on 23-11-2022			
<table border="1"> <tr> <td><b>Lab Services Request Form</b></td> </tr> <tr> <td>Submitted on 23-11-2022</td> </tr> </table>	<b>Lab Services Request Form</b>	Submitted on 23-11-2022	<p><a href="#">LabServicesRequestForm_20..._0731.pdf (0.04 MB)</a></p> <p><a href="#">Upload new version</a> or <a href="#">Remove file</a></p>
<b>Lab Services Request Form</b>			
Submitted on 23-11-2022			
<table border="1"> <tr> <td><b>Audiology Request Form</b></td> </tr> <tr> <td>Submitted on 23-11-2022</td> </tr> </table>	<b>Audiology Request Form</b>	Submitted on 23-11-2022	<p><a href="#">AudiologyRequestForm_2022..._0741.pdf (0.04 MB)</a></p> <p><a href="#">Upload new version</a> or <a href="#">Remove file</a></p>
<b>Audiology Request Form</b>			
Submitted on 23-11-2022			
Supporting Department Declarations you have received			
<table border="1"> <tr> <td><b>Lab Services Supporting Department Declaration</b></td> </tr> <tr> <td>Signed on 23-11-2022</td> </tr> </table>	<b>Lab Services Supporting Department Declaration</b>	Signed on 23-11-2022	<p><a href="#">LabServicesSupportingDepa..._0837.pdf (0.05 MB)</a></p> <p><a href="#">Upload new version</a> or <a href="#">Remove file</a></p>
<b>Lab Services Supporting Department Declaration</b>			
Signed on 23-11-2022			

**You no longer need to download these and include them in your ERM submission. They will be reviewed by the RCH REG Office within DERP**

## What happens next?

At the end of your Landing Page you'll see your next steps to get an understanding of where you're up to with your project

### **ERM (Ethics Review Manager) application**

When your ERM application requests a PDF of your Supporting Department Declaration, you can find it via the 'Your Library' page. We will update the ERM project status in this platform on your behalf when approval is granted, and when you submit your final closure report.

**From 1st Jan 2024 the REG Office is transitioning to reviewing projects within DERP itself. Any files you can see in Your Library, REG has access to as well. You are still welcome to upload things to ERM as part of your submission**

### **Complete the required support request forms above**

Each supporting department/service you have indicated you require will have their own request form. If a new supporting department/service is added (ie after a protocol amendment), you can update your selections in the [RCH Supporting Departments involved](#) list. This will update which request forms you need to complete

### **Look out for Supporting Department/Service approval**

You will be emailed when a department has reviewed your request. Departments will get in contact with you if they have any questions about the requests you have made

### **Recruitment start/stop dates**

Update the Study Information page whenever there are any changes to your timeline, including recruitment start date and finishing date.

### **Project changes**

If your project changes please update the Study Information page with the relevant information. This includes changes in recruitment number, Principal Investigator and Study Coordinator and funding details. Supporting Departments will be notified of the relevant changes you make.

**If you need help from a specific department, please reach out to the relevant people listed above.**