|  |
| --- |
| **APPLICATION COVERSHEET**RCH letterhead_GENERIC header VERSION 2.png**RESEARCH ETHICS & GOVERNANCE** |

|  |  |
| --- | --- |
| **Project Reference Number:** | Please note this is the **ERM Project ID**. Please also refer to the guidance material on **"****How to get a project reference number****."** |
| Has a [**pre-registration form**](https://redcap.mcri.edu.au/surveys/?s=CHHH748AWW)been completed?  | Yes [ ]  No [ ]  |
| **Project Title:** |  |

|  |  |  |
| --- | --- | --- |
| **SECTION 1: Does the research project involve ANY of the following? (Tick all that apply)** | **YES** | **NO** |
|  | **A)** Use of a product (drug or device) that is not registered with the Therapeutic Goods Administration (TGA) | [ ]  | [ ]  |
| **B)** Use of a drug or device in a clinical trial, when the product is being used in the trial for an unapproved indication, in an unapproved age group or at an unapproved dose  | [ ]  | [ ]  |
| **C)** Use of a drug or device in a clinical trial, when such use in the trial is to gain further information about an approved use (e.g. pharmacokinetic or pharmacodynamic research) | [ ]  | [ ]  |
|  | A randomised and/or control group trial assessing an intervention(s) i.e. drug/device, clinical, surgical, diagnostic, public health or mental health **(consider NS 3.1)** | [ ]  | [ ]  |
|  | Any risk (or the potential for risk) of physical or psychological harm to the participant, beyond that imposed in routine clinical care **(consider NS 4.2)** | [ ]  | [ ]  |
|  | Targeted recruitment of Aboriginal or Torres Strait Islander people **(consider NS 4.7)** | [ ]  | [ ]  |
|  | Targeted recruitment of vulnerable groups e.g. children in the ICU, people with mental illness or those who may have been involved in criminal activities **(consider NS 4.2, 4.3 & 4.4, 4.5)**  | [ ]  | [ ]  |
|  | Invasive procedures outside of standard care e.g. collection of blood or tissue samples **(consider NS 3.4)** | [ ]  | [ ]  |
|  | Establishment of a Register, Databank or [Biobank](https://intranet.mcri.edu.au/research-and-science/biobanking) **(consider NS 3.2 & 3.4)** | [ ]  | [ ]  |
|  | Genetic testing or use of Stem Cells **(consider NS 3.3)** | [ ]  | [ ]  |
|  | Examining potentially sensitive or contentious issues or deception of participants, concealment or covert observation **(consider NS 2.3.1-2)** | [ ]  | [ ]  |
|  | Any of the following: Assisted Reproductive Technology (ART); Xenotransplantation; Genetically Modified Organisms **(consider NS 3.2 & 3.4)** | [ ]  | [ ]  |
|  | Research which may show unknown disabilities; disease status or risk; or have the potential for the discovery of non-paternity **(consider NS 3.1 Element 5, NS 3.3)** | [ ]  | [ ]  |
|  | Request for a [**Waiver of Consent**](https://www.rch.org.au/ethics/informed_consent_and_plain_language/Waiver_of_consent_projects/) **(NS 2.3.10 MUST be addressed, and researchers must identify the applicable APP’s)***Note: Retrospective chart review by the clinician is able to be done without consent for the purposes of improvement or evaluation of health services as per Health Privacy Principles 2.2 (f) (i) & (iv) & (v) & (vi) therefore a Waiver is not required in this instance* | [ ]  | [ ]  |
|  | Request for [**Opt-Out Approach**](https://www.rch.org.au/ethics/informed_consent_and_plain_language/Opt_Out_Approach/) **(NS 2.3.6 MUST be addressed, and researchers must identify the applicable APP’s)** | [ ]  | [ ]  |
|  | Exposure to ionizing radiation additional to standard care; [Medical Imaging Research Support.](https://www.rch.org.au/policy/policies/Medical_Imaging_Research_Support/) | [ ]  | [ ]  |
|  | Research conducted in another country, where additional ethical considerations may arise. Please complete [Conducting Research in Another Country](https://www.rch.org.au/uploadedFiles/Main/Content/ethics/Research%20in%20other%20countries.pdf) **(consider NS 4.8)** | [ ]  | [ ]  |
| If you ticked “Yes” to any item in Section 1 then HREC review is required; please see [**Meeting Deadlines**](http://www.rch.org.au/ethics/meeting-dates/Meeting_dates/) Note: If you ticked “Yes” to any of Question 1 then review by the Drug & Device Trials Subcommittee will occur |
| If you ticked “No” to ALL items in Section 1 please submit a [**Low & Negligible Risk Application**](https://www.rch.org.au/ethics/new-applications/Low_and_negligible_risk_research/). Note: there are NO deadlines for LNR applications, please submit when ready. |
| If the application is for Governance Only the above will be used as information only by the REG office. |

|  |
| --- |
| **Section 2: Application Type** |
| **Please submit a full electronic copy via the** [**ERM**](http://au.forms.ethicalreviewmanager.com/Account/Login) **system with necessary signatures.**If a fee applies to this submission (see [Fee Schedule](http://www.rch.org.au/uploadedFiles/Main/Content/ethics/SubmissionFees.pdf)) please submit a completed [RCH Fee Payment Form](https://www.rch.org.au/uploadedFiles/Main/Content/ethics/RCH%20HREC%20Fee%20Payment%20Form%20%28May%202018%29.doc). |
| **2.1** | **Application type** | [ ]  Single site (RCH/MCRI/UMDP only)[ ]  Multi-site  |
| **2.2** | **Project submitted for** | **Please list ALL sites for which the RCH HREC will be providing ethical approval (please clearly indicate if any of these sites are private entities):*** Site 1: **Melbourne Children’s Campus (RCH/MCRI/UMDP)**
* Site 2:
* Site 3:
 |
| [ ]  **Ethics Approval AND Governance Authorisation** |
| [ ]  **Ethics Approval Only (study not being run at or by the Melbourne Children’s Campus)** **– Please complete section 1-4 only** |
| [ ]  **Governance Authorisation Only – Please complete sections 1-3 & 5-6 only** |

|  |
| --- |
| **Section 3: Supporting Documents** |
| **Please list ALL documents submitted as part of this application** (please add rows as required)* Attach the complete research protocol as a standalone/separate document
* Include ALL participant information i.e. advertisements, questionnaires, surveys, letters etc
* Ensure ALL documents have version numbers, dates and page numbers (other than copyright material)
* Ensure ALL required Signatures are provided
* **For Clinical Trials: Please ensure a copy of the PI and investigator team’s current GCP certificate is provided**
 |
| **Name of document** | **Version** | **Date** |
| ***Example:*** *Research Protocol* | *3.0* | *04Jul10* |
| **1** |  |  |  |
| **2** |  |  |  |
| **3** |  |  |  |
| **4** |  |  |  |

|  |
| --- |
| **Section 4: Pre-submission Peer Review**  |
| RCH HREC requires a Peer Review to be completed before the application is submitted. Refer to the [Pre-submission Peer Review Process](http://www.rch.org.au/uploadedFiles/Main/Content/ethics/Pre-submission%20Peer%20Review%20Process.docx) for more information and exemptions.Peer Reviewer should complete Pre-submission Peer Review Proforma (or attach other evidence of review). |
| **4.1** | **Has this research undergone peer review?** | [ ]  Yes  [ ]  No[ ]  Not applicable, please provide reason: |
| **4.2** | **Is the completed, signed and dated Pre-submission (Peer) Review Proforma (or equivalent) attached?** | [ ]  Yes [ ]  No, please explain:  |
| **4.3** | **Is a cover letter responding to the peer reviewer required/suggested changes attached?**  | [ ]  Yes[ ]  No, please explain: |

|  |
| --- |
| **Section 5: Funding and Budget** |
| **5.1** | **Is the necessary funding and resources available to conduct this project?** | [ ]  Yes[ ]  No  |
| **5.2** | **What is the current and proposed source(s) of funding for this project?** List **all** sources of funding e.g. grants, department funds that will/may be accessed to cover costs)  | [ ]  RCH[ ]  MCRI [ ]  Other (specify): |
| **5.3** | [**HREC PAYMENT FEE**](https://www.rch.org.au/uploadedFiles/Main/Content/ethics/SubmissionFees.pdf)**:**Is a [HREC Fee Payment form](https://www.rch.org.au/uploadedFiles/Main/Content/ethics/RCH%20HREC%20Fee%20Payment%20Form%20%28May%202018%29.doc) applicable for this submission? I.e. commercially sponsored trial and external organisations.  | [ ]  Yes [ ]  No, please explain:[ ]  Not applicable, not a commercially sponsored trial |
| **5.4** | **List all Melbourne Children’s cost centres into which research funds will be placed:** Please indicate if the cost centre is RCH or MCRI e.g. P1234 (RCH) |  |
| **5.5** | **Is a detailed budget and/or if applicable Melbourne Children’s site budget attached to this application?** Including relevant salaries and other costs. | [ ]  Yes[ ]  No, please explain:  |

|  |
| --- |
| **Section 6: Affiliations & Approvals (inc Research Agreements & Conflicts of Interest)** |
| **6.1** | **Please list the organisations conducting this research** Consider affiliations of all investigators. Please ensure consistency across study documents e.g. protocol, PICF, agreement (if required) and Head of Department (HoD) sign off e.g. MCRI group leader or theme director sign off and/or RCH HoD.  | [ ]  RCH[ ]  MCRI[ ]  University of Melbourne[ ]  Other, please specify: |
| **6.2** | **Study Team:** have all the necessary signatures been obtained? CPI, PI and AI’s as listed on the HREA and/or SSA (This should be provided on the HREA for single site and SSA for multi-site)  | [ ]  Yes on HREA or SSA or on the [SSA PI or AI form](https://www.rch.org.au/ethics/researcher-resources/Forms_and_templates/)[ ]  No, still outstanding (please list): |
| **6.3** | **Head of Department:** has the PI’s HoD (or line manager) signed off on the research study(Head of RCH Department and or/ MCRI Group and cannot be a member of the research team) | [ ]  Yes, on the SSA or [HoD Form](file:///C%3A%5CUsers%5CCHAUHADE%5CAppData%5CLocal%5CMicrosoft%5CWindows%5CTemporary%20Internet%20Files%5CContent.Outlook%5C08L6J341%5CSSA%20-%20Head%20of%20Department%20Signature) [ ]  No, still outstanding (please list): |
| **6.4**  | **Supporting Departments:** have all the necessary signatures been obtained?Please consider all supporting departments that are involved in the research, including recruitment. Note: some departments have research support approval processes e.g. ICU. | [ ]  Yes, attached (please list):* **Dept 1:**
* **Dept 2:**
* **Dept 3:**

[ ]  No, still outstanding (please list):* **Dept 1:**
* **Dept 2:**
* **Dept 3:**
 |
| **6.5** | **Is this project being Sponsored by MCRI? If it is an Investigator Initiated Clinical Trial has approval been obtained from the MCTC Sponsorship Committee?**  | [ ]  Yes, please attach copy of the Sponsorship Approval Certificate. [ ]  No, please explain: |
| **6.6** | **If applicable, has this biobank been registered with the** [**MCBC Biobank Register**](https://redcap.mcri.edu.au/surveys/?s=HWYY7EAFF3)**?** See [MCRI Biobanking](https://intranet.mcri.edu.au/research-and-science/biobanking) for more information.Please ensure the relevant information is covered in the submitted protocol; see [Databank or Biobank Protocol](http://www.rch.org.au/uploadedFiles/Main/Content/ethics/Databank%20Guidelines%2029%20May%202013.pdf) for more information. | [ ]  Yes[ ]  No, please explain: |
| **6.7** | **Is research being conducted collaboratively across multiple organisation? If so, a** [**written agreement**](https://www.rch.org.au/ethics/researcher-resources/Governance_and_regulatory_documents/) **is required** e.g. CTRA, collaborative research agreement, material transfer agreement.  | [ ]  Yes, please attach copy[ ]  No |