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

|  |  |
| --- | --- |
| **HREC Reference Number**  **Obtained prior to submission:**  [**PRE-SUBMISSION FORM**](https://redcap.mcri.edu.au/surveys/?s=TPK3M8CHHK) |  |
| **Project Title** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **SECTION A: Does the research project involve ANY of the following? (Tick all that apply)** | | **YES** | **NO** |
|  | Use of a product (drug or device) that is not registered with the Therapeutic Goods Administration (TGA) |  |  |
|  | 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 |  |  |
|  | 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 3.3)** |  |  |
|  | Any risk (or the potential for risk) of physical or psychological harm to the participant, beyond that imposed in routine clinical care |  |  |
|  | 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 4.3 & 4.4)** |  |  |
|  | 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 **(consider NS 3.2 & 3.4)** |  |  |
|  | Genetic testing or use of Stem Cells **(consider NS 3.5)** |  |  |
|  | Examining potentially sensitive or contentious issues or deception of participants, concealment or covert observation |  |  |
|  | Any of the following: Assisted Reproductive Technology (ART); Xenotransplantation; Genetically Modified Organisms; Toxins, mutagens, teratogens or carcinogens |  |  |
|  | Research which may show unknown disabilities; disease status or risk; or have the potential for the discovery of non-paternity |  |  |
|  | Request for a [**Waiver of Consent**](http://www.rch.org.au/uploadedFiles/Main/Content/ethics/Application%20for%20Waiver%20of%20Consent.pdf) **(NS 2.3.10 MUST be addressed)**  *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**](http://www.rch.org.au/uploadedFiles/Main/Content/ethics/Use%20of%20Opt-out%20Approach%20in%20Research.pdf) **(NS 2.3.6 MUST be addressed)** |  |  |
|  | Exposure to ionizing radiation additional to standard care; refer to [Radiation Safety in Research](https://www.rch.org.au/policy/policies/Radiation_safety_in_research/) |  |  |
|  | 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 A – please submit a High Risk review application  If you ticked “No” to all items in Section A - proceed to Section B | | | |

|  |  |  |  |
| --- | --- | --- | --- |
| **SECTION B: Does the research project involve ANY of the following? (Tick all that apply)** | | **YES** | **NO** |
|  | Any risk (or the potential for risk) of physical or psychological discomfort to the participant |  |  |
|  | Any foreseeable risk to the participant is no more than inconvenience |  |  |
|  | Aims to establish new knowledge about a disease by collection of information via surveys or interviews **(consider NS 3.1)** |  |  |
|  | Aims to establish new knowledge about a disease by collection of information that has already been collected and is stored by the Melbourne Children’s Campus only, such as medical record review or database review |  |  |
| If you ticked “Yes” to any item in Section B – please submit a [Low and Negligible Risk review application](https://www.rch.org.au/ethics/new-applications/Low_and_negligible_risk_research/)  If you ticked “No” to all items in Section B - proceed to Section C | | | |
| **SECTION C: Does the research project involve ANY of the following? (Tick all that apply)** | | | |
|  | Aims to identify and/or quantify problems within, or impediments to, good health care delivery and to identify ways of improving those problems |  |  |
|  | Aims to evaluate current health practices or to monitor the introduction of a new practice |  |  |
| If you ticked “Yes” to any item in Section C – please submit a [Quality application](https://www.rch.org.au/project-management/getting-started/) | | | |

* **Disclaimer: This checklist constitutes guidance only and is not definitive. Please direct any queries to the Research Ethics and Governance Office**
* **For Governance Applications this checklist is an FYI only (i.e. it does not change the review process.**

|  |
| --- |
| **SUBMITTING YOUR APPLICATION** |
| When submitting applications please check you have included copies of all required supplementary documentation e.g. Protocol, Participant Information & Consent Form, Budget, all participant information (e.g. posters, flyers), questionnaires and all required signatures.  **Please submit a full electronic copy to** [rch.ethics@rch.org.au](mailto:rch.ethics@rch.org.au) and **one (1) hard copy with signatures to** Research Ethics & Governance, Level 4, South Building, The Royal Children’s Hospital, 50 Flemington Road, Parkville, VIC 3052.  **If a fee applies to this submission**, as per the [schedule](http://www.rch.org.au/uploadedFiles/Main/Content/ethics/SubmissionFees.pdf), please ensure that you complete the [Invoicing Authorisation form](file:///C:\Users\lande\AppData\Local\Microsoft\Windows\Temporary%20Internet%20Files\Content.Outlook\3AAFFBTY\RCH%20Invoicing%20authorisation%20form%20-%20DRAFT%20(28.10.2016).docx). Please note that you do no need to submit this form if no fee apply. |

|  |  |  |  |
| --- | --- | --- | --- |
| **Section 1: Supporting Documents** | | | |
| **Please list ALL documents submitted as part of this application** (please add rows as required)   * Include ALL participant information i.e. advertisements, questionnaires, surveys, letters etc * Attach the complete research protocol as a standalone/separate document * Ensure ALL documents have version numbers, dates and page numbers (other than copyright material) * Attach ALL review forms * Attach ALL supporting department signatures | | | |
| **Name of document** | | **Version** | **Date** |
| ***Example:*** *Research Protocol* | | *3.0* | *04Jul10* |
| **1** |  |  |  |
| **2** |  |  |  |
| **3** |  |  |  |
| **4** |  |  |  |
| **5** |  |  |  |

|  |  |  |
| --- | --- | --- |
| **Section 2: General Information** | | |
| **2.1** | **Application type** | Single site (RCH/MCRI only)  Multi-site |
| **2.2** | **Project submitted for** | **Ethics Approval AND Governance Authorisation**  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): |
| **Governance Authorisation only**  Please list the reviewing HREC: |
| **Ethics Approval only** (i.e. study not conducted at RCH/MCRI)  Please list all sites for which the RCH HREC will be providing ethical approval:  **Please complete ONLY sections: 3, 5 & 9** |

|  |  |  |
| --- | --- | --- |
| **Section 3: Pre-submission Peer Review** | | |
| **Please note:**   * 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 must complete the [Pre-submission Peer Review Proforma](http://www.rch.org.au/uploadedFiles/Main/Content/ethics/Pre-submission%20Peer%20Review%20Proforma.docx) | | |
| **3.1** | Has this research undergone peer review? | Yes  No  Not applicable, please provide reason: |
| **3.2** | Is the completed, signed and dated Pre-submission (Peer) Review Proforma (or equivalent) attached? | Yes  No, please explain: |
| **3.3** | Is a cover letter responding to each peer reviewer ‘required or suggested change’ attached? | Yes  No, please explain: |

|  |  |  |
| --- | --- | --- |
| **Section 4: Review of Standard Practice (if research involves RCH patients)** | | |
| **4.1** | Is the **standard care** described in the protocol the current standard care at RCH? E.g. frequency of CT scans, blood tests, and any treatments or drugs | Yes  No, please explain differences and level of associated risk: |
| **4.2** | Are there areas where RCH specific practice may differ from that described in the protocol? | No  Yes, please explain differences and level of associated risk: |

|  |  |  |
| --- | --- | --- |
| **Section 5: Consent** | | |
| **5.1** | Is the proposed collection, use or disclosure of the data and/or samples covered by participant (or parent/guardian) **consent?** | Yes (please attach the PICF)  No, please explain: |
| **5.2** | Does the project involve the collection and use of health or personal information from a Third Party **without their consent?** e.g. Commonwealth or State Agency or Registry  Please ensure the **VSM section 2** is completed. | Yes  No |
| **5.3** | If this protocol includes a [**Waiver of Consent**](http://www.rch.org.au/uploadedFiles/Main/Content/ethics/Application%20for%20Waiver%20of%20Consent.pdf)or an[**Opt-Out consent**](http://www.rch.org.au/uploadedFiles/Main/Content/ethics/Use%20of%20Opt-out%20Approach%20in%20Research.pdf)are responses to the relevant NS criteria attached? | Not applicable  Yes  No |

|  |  |  |
| --- | --- | --- |
| **Section 6: Bio-banking** | | |
| **6.1** | **Does the project involve a Biobanking component?** e.g. collection of tissue for storage and use in this and/or future projects | Yes  No |
| **6.2** | **If Yes, 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: |

|  |  |  |
| --- | --- | --- |
| **Section 7: Funding and Budget** | | |
| **7.1** | **Is the necessary funding and resources available to conduct this project?** | Yes  No |
| **7.2** | **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)  *Note: A response of N/A or None is not acceptable* | RCH  MCRI  Other (specify): |
| **7.3** | **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) |  |
| **7.4** | **Will the project be supported in other ways?** E.g. In-kind support/equipment by an external party | Yes, provide details:  No |
| **7.5** | **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 8: Affiliations (including Research Agreements & Conflicts of Interest)** | | |
| **8.1** | **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. | RCH  MCRI  University of Melbourne  Other, please specify: |
| **8.2** | **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 |
| **8.3** | **Do any of the researchers have a conflict of interest likely to arise in relation to this research?**  *Note: please disclose any actual or potential conflict of interest in research, including any:*  *(a) Personal (as opposed to professional) involvement or participation in the research;*  *(b) Financial or other interest or affiliation; or*  *(c) Involvement in competing research* | No  Yes, please provide details of the conflict of interest and how this will managed: |

|  |  |  |  |
| --- | --- | --- | --- |
| **Section 9: Principal Investigator Declaration** | | | |
| 1. I take full responsibility for the conduct of this research. 2. I will ensure that all research staff at this site are aware of relevant Melbourne Children’s Campus Research Policies and Procedures (where applicable). 3. I will only start this research project after obtaining both ethical approval from the responsible Human Research Ethics Committee (HREC) and governance authorisation from the relevant site. 4. I undertake to conduct this research project in accordance with the protocols and procedures as approved by the HREC and the ethical and research arrangements of the organisation(s) involved. 5. On behalf of researchers, any actual or potential conflicts of interest have been declared and I will notify the HREC of any that arise during the study period. 6. I understand and agree that study files and documents and research records and data may be subject to inspection for audit and monitoring purposes. 7. I understand that information relating to this research, and about me as a researcher, will be held by the HREC, Research Governance Manager, and on the Research Ethics & Governance Database. This information will be used for reporting purposes and managed according to the principles established in the Privacy Act 1988 (Commonwealth) and relevant laws in the States and Territories of Australia. 8. Clinical Trials only: I confirm I have completed Good Clinical Practice (GCP) training within the last three years, using a [TransCelerate accredited course](http://www.transceleratebiopharmainc.com/gcp-training-attestation/list-of-training-providers/). Please attached certificate of completion.  Note: It is strongly recommended that Associate Investigators also complete GCP training. | | | |
| **Principal Investigator (name):** |  | | |
| **Signature:** |  | **Date:** |  |