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| **Project Reference Number:** | RGS |
| **Project Title:** |  |

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| **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](https://cahs-healthpoint.hdwa.health.wa.gov.au/directory/research/researchers/Guidelines%20Documents/Research%20Blood%20Sampling%20Guidelines.pdf) or tissue samples **(consider NS 3.4)** |  |  |
|  | Establishment of a Register, Databank or [Biobank](https://cahs-healthpoint.hdwa.health.wa.gov.au/directory/research/researchers/Guidelines%20Documents/Guidelines%20for%20human%20biobanks,%20genetic%20research%20databases%20and%20associated%20data.pdf) **(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)** |  |  |
|  | Use of data without consent - Request for a **Waiver of Consent (NS 2.3.10 MUST be addressed)** |  |  |
|  | Request for **Opt-Out Approach (NS 2.3.6 MUST be addressed)** |  |  |
|  | Exposure to ionizing radiation additional to standard care; [Radiation Safety in Research](https://pch-healthpoint.hdwa.health.wa.gov.au/directory/clinicalservices/MedicalImaging/Documents/Radiation%20Management%20Plan_2021.pdf) |  |  |
|  | Research conducted in another country, where additional ethical considerations may arise. Please complete Conducting Research in Another Country **(consider NS 4.8)** |  |  |
| **If you ticked “Yes” to any item in the list, then full HREC review is required.**  **If you ticked “Yes” to any of Question 1 or 2, then review by the Clinical Trials Subcommittee is required first.**  **Note: there are deadline dates for these meetings. Refer to** [**Meeting Deadlines**](https://cahs-healthpoint.hdwa.health.wa.gov.au/directory/research/researchers/Pages/Ethics-and-Governance.aspx) | | | |
| **If you ticked “No” to ALL items your submission qualifies for review by the Low Risk Ethics Committee.**  **Note: there are NO deadlines for LREC applications, please submit when ready.** | | | |
| **If your project has HREC approval from a certified HREC under the National Mutual Acceptance (NMA) Scheme, then a Governance-only review is required. Refer to** [**NMA Scheme**](https://www.clinicaltrialsandresearch.vic.gov.au/national-mutual-acceptance) **and contact CAHS RGO for assistance.** | | | |

**Please attach this cover sheet in your RGS Project workspace in the Applications tab titled “Cover Sheet”:**

**Applications > Ethics Approval > Active > Documents**