# Department of Research

## Minimal & Low Risk Research Cover Sheet

## Project Details

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Project PRN:** | Enter PRN | **Date of Submission:** | | \_\_/\_\_/\_\_ |
| **Project Title:**  Enter Title | | | | |
| **CPI:** | Name | **Email:** | Enter Email | |
| **Department / role in SCGOPHCG** | | Enter role & department | | |
| **PI (if different from CPI):** | Enter name | **Email:** | Enter Email | |
| **Department / role in SCGOPHCG (if applicable)** | | Enter role & department | | |

**Project Summary**

Enter Text

Aims: Enter Text

Methods: Enter Text

Outcomes: Enter Text

## Ethics Assessment

Is this project application a Registry, Databank or Biobank?

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** |  | **No** |

### Minimal Risk Checklist

|  |  |  |  |
| --- | --- | --- | --- |
| Does the research project involve ANY of the following? (Tick all that apply) | | YES | NO |
|  | Is there risk of harm or discomfort? |  |  |
|  | Is there foreseeable risk more than an inconvenience |  |  |
|  | Is any data identifiable? |  |  |
|  | Is there any involvement of external sites? |  |  |
| WA Public Health Hospitals | | | |
| WA Universities  (Minimal Risk with Data Transfer/Confidentiality Agreement) | | | |
| Private Health Hospitals  Data only - Minimal Risk with Data Transfer Agreement  Participant Involvement - Consider Low Risk Pathway | | | |
|  | Will there be any financial burden on the institution?  (Funding provided by SCGOPHCG) |  |  |
|  | Is there any grant/funding provided by an external site or sponsor?  (Either received in advance or post approvals) |  |  |
| * If ticked “Yes” to item 4, ensure DTA is provided (WA sites) or assess for low-risk pathway (private hospitals). * If ticked “Yes” to any other item in the list, consider low risk, alternatively a full HREC review may be required. | | | |
| * If ticked “No” to ALL items your submission qualifies for review by the SCGOPHCG Ethics Office.   Note: there are No deadlines for Ethics Office review. | | | |

### Low Risk Checklist

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 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) |  | |  | |
|  | 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 Opt-Out Approach, NS 2.3.6 MUST be addressed (HREC review is required) |  | |  | |
|  | Exposure to ionizing radiation additional to standard care  [NMHS Radiation Management Plan](https://wahealthdept.sharepoint.com/sites/SCGOPHCGDepartmentofResearch652/Shared%20Documents/HREC/Administration/Procedure%20Guides/NMHS%20Radiation%20Management%20Plan.pdf) |  | |  | |
|  | Research conducted in another country, where additional ethical considerations may arise. Please complete Conducting Research in Another Country  (consider NS 4.8) |  | |  | |
| * If ticked “Yes” to any item in the list, then a full HREC review is required. * If ticked “Yes” to any of Question 7 or 8, then review by a Scientific Review subcommittee is required first.   Note: there are deadline dates for these meetings. Refer to [2024 Meeting Calendar](https://wahealthdept.sharepoint.com/sites/SCGOPHCGDepartmentofResearch652/Shared%20Documents/HREC/Administration/Calendars/2024/2024%20Meeting%20Calendar%20-%20V2.pdf) | | | | | |
| * If ticked “No” to ALL items your submission qualifies for review by the SCGOPHCG Research Panel Review.   Note: there are No deadlines for low-risk 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) / contact SCGH RGO for assistance. | | | | | |

|  |  |
| --- | --- |
| Consent | Intervention |
| Informed consent (participant)  Waiver of consent   * See separate Waiver of Consent form   OptOut consent  Guardianship and Administration Act (GAA) | Survey or questionnaire  Review of clinical notes  Retrospective  Prospective  Pharmaceutical  Procedure  Device |

### PI Sign Off and Declaration

I declare the information entered in this report is true and accurate.

|  |  |  |
| --- | --- | --- |
| **Form completed by** | **Signature** | **Date** |
| Enter Name | Enter Signature | Enter Date |

*(an electronic signature is accepted)*

### (FOR OFFICE USE ONLY)

### Overall Ethical Assessment of Risk

|  |  |  |
| --- | --- | --- |
| **LOW RISK** | | **HIGHER RISK** |
| **Minimal risk**  *No risk of harm or discomfort; potential for minor burden or inconvenience* | **Low risk**  *No risk of harm; risk of discomfort (+/- foreseeable burden)* | **Greater than low risk**  *Risk of harm; (+/- foreseeable burden)* |
| Out of session approval by HREC Chair or delegate. | Internal ethical review within the Department of Research | Full HREC committee review |
| **Comments:** | | |

### Request for Endorsement of Waiver of Consent

Does this project request a waiver?

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** |  | **No – continue to Governance Assessment** |

|  |  |
| --- | --- |
| **Scope of Waiver:** | *Enter waiver reasoning* |
| **Standard of Care** | *E*.g. *- No deviation from standard care as data is retrospective and already exists.* |
| **Site Involved** | 1. Sir Charles Gairdner Hospital |
| **Additional Comments** | *? QI / Disclosure of data / External parties?* |
| **Recommendation** | E.g. - Recommend the waiver be approved given (1) no personal information is being used in the study (2) not data is being disclosed to an external party (3) the waiver is justified under section 2.3.10 of the National Statement. |

Please find attached:

WAHEAF

Research Protocol

Waiver of Consent Criteria

|  |  |  |
| --- | --- | --- |
| **Executive Endorsement** | **Signature** | **Date** |
| Enter Name | Enter Signature | Enter Date |

### Governance Assessment

Is this a multi-site study?

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | **Yes** | |  | **No – conducted at SCGH and/or OPH only** | | |
| **Other sites (state):** Enter Name | | | | | | |
| **Assessment Criteria** | | | | | | **Comments** |
| **Legal** | | **Within Western Australian law**  **Outside of Western Australian law or other legal concern requiring legal advice** | | | |  |
| **Funding** | | **No funding required**  **Fully funded by an external party**  **Funding required by SCGOPHCG** | | | |  |
| **Insurance** | | **Covered by SCGOPHCG insurance**  **External insurance provider** | | | |  |
| *ICWA referral required?* | | **No** | | | **Yes** |  |
| **Data management risk** | | **De-identified data**  **Re-identifiable data** | | | |  |
| *Data management system* | | **REDCap** *(preferred)*  **Another data management system** *(provide comment)* | | | |  |
| *Data being sent outside SCGOPHCG?* | | **No** | | | **Yes** |  |
| **Good Clinical Practice (GCP) Qualification**  *NB. All CPI and PIs are required to have GCP qualification for clinical trials* | | **Not required**  **Required and held by researchers**  **Required but not held by researchers** | | | |  |

**Overall Governance Assessment of Risk**

|  |  |  |
| --- | --- | --- |
| **LOW RISK** | | **HIGHER RISK** |
| **Minimal risk** | **Low risk** | **Greater than low risk** |
| Managed through minimal risk site authorisation process. | Site authorisation through RGO and panel review process. | Site authorisation through RGO, in consultation with Director of Research +/- advisory bodies (Legal and/or ICWA) |
| **Comments:** | | |

**Final Comments**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Estimated time to approval:** | | <10 days | | | 10-20 days | | 20-40 days | |
| **Research Navigator to discuss project with the CPI or PI:** | | | | | | **Yes** | | **No** |
| **Input from DOR teams to CPI recommended prior to full ethics / RGO assessment:** | | | | | | | | |
|  | **Director of Research** | |  | **Statistician Service** | | | | |
|  | **Scientific Review Subcommittee** | |  | **Business Information Support** | | | | |
|  | **Ethics Coordinator (delegate HREC chair)** | |  | **Human Research and Ethics Committee** | | | | |
|  | **Research Governance Officer** | |  | **Compliance and monitoring** | | | | |
|  | **Pharmacy Review** | |  |  | | | | |

**Comment for referral:**

**Sign Off and Declaration**

I declare the information entered in this report is true and an accurate reflection of the consensus of the panel.

Panel members:

|  |  |  |
| --- | --- | --- |
| **Form completed by** | **Signature** | **Date** |
| Enter Name | Enter Signature | Enter Date |

*(an electronic signature is accepted)*