Government of Western Australia
North Metropolitan Health Service
Sir Charles Gairdner Osborne Park Health Care Group

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Sir Charles Gairdner and Osborne Park Health Care Group Human Research Ethics Committee

Low Risk Pathway Guidelines

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Contents

Editor	Date	Version	Amendments
HREC Office	Pre 2023	1.0	Low Risk Review Document Low Risk Review Pathway
HREC Office	January 2024	2.0	Guidelines have been drafted from previous low risk pathway documents, merged, and updated by the HREC Office with advice from the Research Manager and Directors to create the new Low Risk Guidelines.
HREC Office	February 2024	2.1	Administrative changes, advice provided by the Department of Research Team.

Abbreviations

Sir Charles Gairdner and Osborne Park Health Care Group	SCGOPHCG
Human Research Ethics Committee	HREC
Research Governance Office	RGO
WA Health Ethics Application Form	WAHEAF
Human Research Ethics Application	HREA
Participant Information and Consent Form	PICF
North Metropolitan Health Services	NMHS
Research Governance Service	RGS
Coordinating Principal Investigator	CPI
Additional Information Required	AIR
Key Performance Indicator	KPI

Purpose

The purpose of these guidelines is to set out the process of low risk ethical review for research involving human participants within the SCGOPHCG. These include the timeframe for approval, the review format and criteria, submission requirements and the review process.

The guidelines have been written in line with the requirements of Section 2.1 of the National Statement and based on the Sydney Local Health District, low & negligible risk, Ethics Review Guide.

Overview

Research activity which the potential risks of participation pose risks no greater than 'discomfort'. Discomfort is considered less serious than harm. It can involve physical or psychological impacts, for example, minor side-effects of medication, discomfort related to non-invasive examinations or tests (such as measuring blood pressure), and mild anxiety associated with an interview.

Eligible activities are those where the risks to participants are no greater than discomfort and may include:

- Questionnaires and general surveys on non-controversial, non-personal issues that also include only basic demographic data and where respondents are not identified without questions that could result in participant distress
- Audits using non-personal data or lab work using already collected material, either with consent or using deidentified information
- Research using retrospectively collected tissue samples/specimens

- Research involving only the use and/or disclosure of information from existing deidentified data collections
- Research involving personal health information held in a research database or involving human tissue held in a research tissue bank for which consent for use in research was obtained at the time of its collection and storage
- Research requiring access to individual medical records or to information stored electronically, through the site's Medical Records Department or other department, but where participant consent is not required because, in all instances, individuals cannot be identified from data extracted or provided.

Timeframe for Approval

Low risk projects have a KPI approval of 30 business day from the original submission date to HREC and RGO. This is dependent on the 'stop clock' (time sitting with the researcher).

Review Format

This review pathway involves a pre-review with the Department of Research Review Panel, an internal review conducted by the Ethics Coordinator or HREC Office Delegate and site review/approval by the Research Governance Office.

Eligibility Criteria

In low risk research, the foreseeable risk is no more than *discomfort* and there is *no risk of harm*. Examples may include discomforts associated with measuring blood pressure or mild anxiety induced by an interview. *Note: Where a person's reactions exceed discomfort and become distress, they should be viewed as harms.*

- No risk of harm
- No foreseeable risk more than discomfort
- Retrospective de-identified data
- Prospective de-identified data
- Questionnaires or surveys
- Participant involvement
- External Sites (with Data Transfer Agreement)
- Affiliation with WA Universities (with Data Transfer Agreement)
  (Students, Interns, Resident Medical Officers, Trainees/Registrars, Fellows, and Higher Degree Research)
- On site Data Scientists, Statisticians and Bio Statisticians.
  (Some on site statisticians will have affiliation with WA Universities)
- Strong data management plan ensuring only de-identified data
  (REDCap is a secure web application and the preferred WA Health data management tool supported by a governance structure)

Submission Requirements

- Minimal & Low Risk Coversheet
- WA Health Ethics Application Form
  Or
- Human Research Ethics Application

- Research Protocol
- Waiver of Consent Request (Addressing the waiver criteria in the National Statement) Or
- Participant Information and Consent Form
- Data Management Plan
- All other necessary document specific to the project

New Application Review

The Ethics Office should review all new applications once submitted to RGS. This involves taking the task submitted at validation and reviewing each document individually.

This review should consider the following:

- Standard validation steps (version control, documents are as they are labelled etc.)
- No key components necessary for the application are omitted
  Examples include:
  - projects seeking a waiver of consent have addressed each point of 2.3.10 (please see “Waiver of consent” for further information on the review)
  - applications missing requisite state modules when seeking national approval.
- Quality of application forms (WAHEAF or HREA)
  Examples include:
  - insufficient or misleading information included in the application form
  - conflicts between application forms and other submitted documents (PICF and protocol most commonly)
  - applications submitted in other states which contradict requirements within WA
- Lack of important information in study protocols
  - the most common concern is lack of a statistical methodology, sample size justification/power calculation
    Note: it is not expected that the Ethics Coordinator review the quality of these, simply that they are in the protocol at submission
- Insufficient information in the PICF
  - these documents should be of sufficient quality to be used in the hospital and reflect the high standards expected by the institution
  - these documents should also be written in manner accessible to the cohort in which they are being used
    Note: all participant documents should be written in lay terms; content that could be understood by a reader with a year 8 level of reading comprehension.

Step by Step Review Process

Step 1: Assess Eligibility

If a project appears to be eligible for expedited low risk, it needs to be scrutinised to ensure there is no hidden risk or cost. The NMHS Risk and Complexity Assessment may assist in reviewing eligibility.

Step 2: Panel Review

An internal review is required by the Department of Research Review Panel. *Note: meetings held weekly to assess these projects on a fast-tracked timeline.*

The review panel is comprised of Clinical Director, Department Director, Department Manager, Ethics Office Staff, Compliance and Monitoring Staff, and Research Navigation Staff. The role of this panel is to assess the risk level as a group and fast-track the projects on behalf of the HREC.

Step 3: Ethical Review

The ethical review should consider all study material to ensure the principles of the National Statement are adhered to.

- Ensure the PICF (if applicable) is of sufficient quality, appropriately describes the conduct, rationale and methods of the study are described in an informative and succinct manner.
- If requesting waiver of consent, the minimal & low risk coversheet contains the request for waiver form, which requires endorsement by the Executive during the Panel Review to ensure the institution is prepared to accept any potential legal risk.

Step 4: Review Outcome

If queries have been raised during any part of the review, draft an AIR letter with the comments and send to the CPI via RGS.

- Once a response has been received, ensure required points have been addressed and tracked/clean copies have been submitted to RGS.

If there were no queries, executive endorsement has been provided (if required), and all parties agree, out of session approval can be provided in RGS and an ethics approval letter sent to the CPI.

- Advise the researcher site approvals by RGO will be required prior to conducting any research on site.

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