		TITLE: Human Research and Ethics Subcommittee (The Subcommittee)	
Document Type:	Terms of Reference	Approved by:	ECSQP
Committee:	Executive	Section:	Human Research + Ethics
Author/Prepared by:	Dr Md Rafiqul Islam	Position:	Director of Research

1. PURPOSE:

To receive, consider and assess:

- research applications that are determined by the Subcommittee to involve no more than low and or negligible risk (as defined under Clause 3); and
- quality improvement applications.

To consider any application to vary or amend an approved application.

To record final or progress reports of approved applications.

2. OBJECTIVES:

To ensure that any low and/or negligible risk application or quality improvement application meets the requirements of the National Statement on Ethical Conduct in Human Research (‘the National Statement’) and is ethically acceptable.

3. DEFINITIONS:

“Low risk research” means research in which the only foreseeable risk for participants is discomfort and the expression “negligible risk research” means research in which there is no foreseeable risk of harm or discomfort for participants and any foreseeable risk is no more than inconvenience. Low risk audits and negligible risk audits are to have similar meanings to low risk research and negligible risk research.

The following areas of research and audit are **not** to be considered to be low risk unless those areas of research or audit relate solely to collections of non-identifiable data and their use satisfies the requirements of relevant paragraphs of the National Statement:

- i. Women who are pregnant and the human foetus (Chapter 4.1 of the National Statement);
- ii. People highly dependent on medical care who may be unable to give consent (Chapter 4.4 of the National Statement);
- iii. People with a cognitive impairment, an intellectual disability, or a mental illness (Chapter 4.5 of the National Statement);
- iv. Aboriginal and Torres Strait Islander Peoples (Chapter 4.7 of the National Statement).
- v. People who may be involved in illegal activities are not to be considered low risk research, negligible risk research, low risk audits or negligible risk audits (Chapter 4.6 of the National Statement for details).

4. MEMBERSHIP:

4.1 The membership of the Subcommittee shall comprise of the following:

- i. The Chief Medical Officer (CMO)/Acting CMO (as may be applicable) who shall act as the Chairperson of the Subcommittee at all meetings at which he or she is present;
- ii. The Director of Research who shall act as acting or delegated Chairperson;
- iii. Two appropriately qualified people appointed by the Chairperson from within the institution (GV Health);
- iv. Two non-institutional members appointed by the Chairperson;
- v. The Chairperson of the GV Health HREC.



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- 4.2 A member who becomes a member of the Sub-Committee by virtue of the position he/she holds with GV Health shall cease to be a member upon that member ceasing to hold that position.
- 4.3 Co-opted Membership: The Chairperson can appoint a co-opted member when it is deemed necessary either by the Chairperson and or the Director of Research.

5. QUORUM


The quorum of the Sub-Committee shall be at least three members present either in person or by being present by participating by one of the other methods permitted by Sub-Clause 6.4. One of the members present at a meeting of the Subcommittee must be the Chairperson or acting/delegated Chairperson of the Subcommittee.

6. BUSINESS OF THE SUBCOMMITTEE

- 6.1 If the Subcommittee is unsure or divided in deciding whether an application is of low or negligible risk then the Subcommittee shall refer the application to the GV Health Human Research and Ethic Committee (GV HREC) for its consideration;
- 6.2 The Subcommittee may at any time transfer an application which comes before it to the GV HREC and must transfer any application to the GV HREC if it considers at any time that the application is beyond the powers of the Subcommittee to deal with;
- 6.3 The Sub-Committee must transfer any application which is before it to the GV HREC if directed to do so by the GV HREC;
- 6.4 A meeting of the Subcommittee may be held by:
 - i. all participating members being present in person;
 - ii. one, some or all participating members participating being present in person or by one of the methods set out in sub-clauses iii) or iv) below;
 - iii. one, some or all members participating by use of technology in the same manner as meetings and attendance at meetings of the full HREC may be permitted by use of technology with permission for the use of technology for a meeting of the Subcommittee or permission for attendance at meeting of the Subcommittee to be given by the person chairing that meeting of the Sub-Committee;
 - iv. attendance by one, some or all participating members by way of a series of telephone calls or an exchange of emails so long as the Subcommittee reaches a unanimous or majority decision as to the outcome of an application which is communicated to all participating members.

A member of the Subcommittee who attends a meeting in person shall be considered to be present at that meeting as shall a person who participates in the meeting by one of the methods set out in Sub-Clauses iii) or iv) of this Clause.

- 6.5 The Subcommittee shall provide to the HREC a copy of all its meeting outcomes as well as such verbal or written briefings, documentation and records which in any way relate to the work of the Sub-Committee and which are requested by the HREC.
- 6.6 The Subcommittee shall call meetings (physical or online or in a form permitted by sub-clause 6.4 iii) and iv) of the Subcommittee as and when required to enable the business of the Subcommittee to be conducted in a reasonably timely manner.

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7. REPORTING:

The Subcommittee will provide a copy of all approved applications to the GV HREC for inclusion in that committee's minutes.

8. ORGANISATIONAL RELATIONSHIPS:

The Subcommittee is an internally constituted committee of GV Health. GV Health has legal responsibility and liability for anything done or omitted to be done by the Subcommittee and its members including but not limited to for decisions, approvals and advice given by or made by the Subcommittee and indemnifies its members.

8.1 All members of Subcommittees including but not limited to the Low or Negligible Risk Subcommittee shall be indemnified by GV Health against legal liability for anything done or omitted to be done by a member in the course of or in connection with a member's membership of a Sub-Committee (whether or not a member of a Subcommittee is a member of the HREC) save only to the extent that a member has failed to act in good faith.

8.2 Where GV Health is obliged by this paragraph to indemnify a member of the Subcommittee, GV Health shall pay all costs and expenses incurred by a member in defending any claim made against a member and shall maintain insurance which covers all members of the HREC Subcommittee (including but not limited to members of the Subcommittee who are not employed by GV Health) against the legal liability of members for which GV Health is obliged to indemnify members pursuant to this paragraph at least to the extent of the indemnity to members provided for with an extension to cover the costs and expenses incurred by a member which by this paragraph are to be paid by GV Health.

9. MINUTES AND SECRETARY:

The Office of the Director of Research will source secretarial support for the Subcommittee by the existing HREC Administration Officer.

REFERENCES:

NHMRC National Statement 2023

Contributors to the document

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Committees:	Human Research & Ethics Committee		
	Executive Safety, Quality & Performance Committee – 12 November 2024		
	Kellie Thompson, Acting Chair – ECSQP, CNMO & EDQRIU		