Human Ethics Committee

Terms of Reference

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# Scope

The Forensic and Scientific Service Human Ethics Committee (FSS-HEC) is registered with the National Health and Medical Research Council (NHMRC) (Registration number EC00305) and is constituted and functions in accordance with the NHMRC *National Statement on Ethical Conduct in Human Research* *2023* (NS).

The FSS-HEC:

* undertakes ethical reviews and provides oversight of human research and other work involving the non-diagnostic use of human tissue and confidential data
* provides FSS executive with independent advice on human ethical issues affecting FSS and its clients, and
* has a special responsibility to review and consider applications for ethical review of research conducted in any/all Queensland Health Sites that involve use of coronial material or data.

# Objectives

The objectives of the HEC are to:

* protect the welfare, rights, dignity and safety of participants of research.
* promote ethical principles in human research.
* review research in accordance with the National Statement.
* facilitate ethical research through efficient and effective review processes.

# Functions

The HEC functions on behalf of the Department of Health (Forensic and Scientific Services) to:

* provide independent oversight of human research projects.
* provide competent, timely review and monitoring of human research projects in respect of their ethical and scientific acceptability for as long as projects are active.
* determine the compliance of a human research project with theNational Statement and grant, withhold or withdraw ethics approval.
* provide advice to the department on strategies to promote awareness of the ethical conduct of human research.

Using established ethical principles, and with reference to the relevant ethical codes and guidelines, the FSS-HEC will also provide advice and review proposals which entail:

* retention of, and use of autopsy tissues, organs and fluids for research and other non-diagnostic purposes under the [*Transplantation and Anatomy Act 1979*](http://www.austlii.edu.au/au/legis/qld/consol_act/taaa1979298/)*.*
* the use of diagnostic/evidentiary material held or obtained by FSS (i.e. human tissues etc. originating from coronial autopsies, forensic cases, public health testing and other sources) for research and other non-diagnostic/non-forensic purposes.
* the use of documents, records, reports and statistical data held at FSS (including those relating to coronial cases) for research and other purposes not originally envisaged.

# Roles and responsibilities

## 4.1 HEC CHAIR

The Chair is responsible for ensuring an efficient ethical review process. The Chair ensures Human Research Ethics Committee decisions are informed by an exchange of views from those members who comprise the minimum membership, whether in full attendance or through the receipt and consideration from some of those members who cannot be present.

In addition to the Chair’s role at the meetings, the Chair has a role in supporting ethical practice at FSS, including:

* providing advice to the FSS executive on issues affecting the organisation that raise difficult human ethical issues.
* reviewing and endorsing applications for genuine researcher approval and requests to publish coronial information prior to submission to the Coroner.

The Deputy Chair supports the Chair in the performance of their duties including fulfilling the responsibilities of the Chair whenever the Chair cannot attend meetings or perform any other functions.

## 4.2 HEC EXECUTIVE COMMITTEE

The HEC Executive Committee comprises of the HEC Chair/delegate and the Secretary.

The HEC Executive Committee is delegated to:

* + undertake expedited review and approval of business that does not require full Committee review, including:
  + negligible risk research applications, including those involving a waiver of consent provided the project does not involve personal health information[[1]](#footnote-2) or personal information[[2]](#footnote-3) in medical research
  + case reports
  + amendments to current HEC approved projects
  + responses to HEC queries
  + annual progress reports and final reports and
  + adverse events
* provide advice about the level of review required for the use of human material and data for quality assurance and process improvement activities.
* establish a procedural framework to review proposals for use of human tissue and data. This will include oversight and monitoring of ongoing projects (NS 5.4).
* advise the FSS executive of the ethical acceptability of projects reviewed in an annual report or when requested.
* provide an annual report to National Health and Medical Research Council (NHMRC) on HEC activities of the prior calendar year.
* provide advice to researchers about obligations to ensure that all research involving human material and data complies with the NS and relevant legislation.
* advise an external approving HREC if the FSS-HEC considers that ethical approval for research projects involving FSS staff or resources should be reviewed/withdrawn.
* consider options for, and make recommendations on, procedural guidelines for any activities that raise difficult human ethical issues. These may include autopsies, the handling of human tissues, facilitating coronial tissue donations, complaints, policy implementation, responding to commissions of inquiry, use of public health data collected for business-as-usual activities and donation of personal human specimens by staff.

The Executive Committee will refer any matters to other members, or the full Committee, where they feel this is necessary for full ethical consideration.

## 4.3 HEC MEMBERS

HEC member responsibilities are outlined in the National Statement on Ethical Conduct in Human Research at 5.2.21-5.2.24.

Each member of the FSS-HEC is responsible for:

* reviewing applications assessed as greater than low risk, contributing to Committee discussions and deciding on the ethical acceptability of proposals, based on the guidelines set out in the NS.
* considering applications for a waiver of consent for projects involving personal health information or personal information in medical research, with reference to the NS 2.3.10. These may form part of applications that have been assessed as ‘low or negligible risk’ that have been referred to the Committee for consideration of the waiver only (rather than assessment of the whole application).
* informing the Chairperson if a leave of absence is required. If unable to attend three or more consecutive meetings, members should consider their availability to remain on the committee.
* maintaining appropriate confidentiality of the content of applications and the deliberations of FSS-HEC matters (NS 5.1.37).

## 4.4 HEC ADMINISTRATOR

The role of the HEC Administrator is described in the Queensland Health HREC Administrators Standard Operating Procedures. The HEC Administrator (or their delegate) will be the Secretary of the FSS-HEC.

The HEC Administrator is an employee of FSS and reports to the Chairperson of the FSS-HEC in matters related to the activities of the committee.

The primary role of the HEC Administrator is to provide leadership in directing and managing human ethics at FSS in accordance with the National Statement and other relevant policies, guidelines and legislation pertaining to human research in Australia.

In addition, the HEC Administrator:

* provides administrative and ethical advice on the process of human ethical review of research projects and other quality assurance and process improvement activities.
* is responsible for the administration of applications made by researchers to the FSS-HEC and for the management of institutional ethical review processes.
* maintains a local register for all proposals submitted to the FSS-HEC, including any conditions of approval, monitoring and reporting requirements and the status of projects.

# Ethical framework

The FSS-HEC operates under the guidance of the following:

* National Statement on Ethical Conduct in Human Research, 2023
* Australian Code for the Responsible Conduct of Research, 2018 and underlying Guides
* Principles of ‘[Distributive justice](https://www.health.qld.gov.au/public-health/forensic-and-scientific-services/research/accessing-materials-and-data)’

FSS expects that research that involves Aboriginal and Torres Strait Islander Peoples will be designed to support and promote the ethical principles sent out in [Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities](https://www.nhmrc.gov.au/sites/default/files/documents/Indigenous%20guidelines/Indigenous-ethical-guidelines.pdf).

# Consent requirements

As a general rule, FSS expects consent to be obtained from research participants as per the National Statement on Ethical Conduct in Human Research, Chapter 2.2.

* The FSS-HEC may decide that a waiver of the requirement for consent is justified in some cases (e.g. where samples/data are non-identifiable). The FSS-HEC will consider requests for waiver of consent for a project that meets the requirements outlined in NS 2.3.10 and these must be addressed specifically, as well as section 95/95A of the *Privacy Act (Cth)*, where applicable.
* Applications for a waiver of consent for projects that do not involve personal health information or personal information in medical research may be considered by the full Committee or via the low risk or negligible risk review pathways (NS 2.3.9).
* Retrieval and/or use of tissues at autopsies must comply with the *Transplantation and Anatomy Act 1979*, which requires consent from the Coroner (in coronial cases) and next of kin, and authorisation by a designated officer.
* Consent must only be obtained for the purposes outlined in the application and approved by the FSS-HEC. This must not be materially altered without prior authorisation by the FSS-HEC.
* The FSS-HEC may approve retention of tissue for particular types of research, subject to approval from an appropriately constituted ethics committee for any project for which this tissue is subsequently used.

# Retention, use, storage and disposal of human tissue and associated records

* All human material and data should be used only for the purposes described in the written application and approved by the FSS-HEC.
* Details of arrangements for storage and the proposed method of disposal must be provided prior to release/use of material by FSS for the purposes of research. This information should be detailed in the Human Research Ethics Application (HREA) or accompanying project description.
* Remaining tissues (other than clinical waste) which have been retrieved from coronial autopsies must be returned to FSS for disposal in an appropriate manner.
* Material is not to be distributed or released to any person other than personnel under the direct supervision of the applicant; and will not be sent to any location other than that specified in the approved ethics application.
* Where access to post-mortem reports and other coronial documents has been authorised, only data that has been approved by the FSS-HEC should be used. Any electronic or paper copies made for this purpose must be destroyed, unless otherwise agreed in writing at the discretion of the FSS-HEC.

# Confidentiality, privacy and de-identification of material

* FSS-HEC requires material used for non-diagnostic purposes to be non-identifiable unless applicants are able to provide compelling reasons in their applications why material should remain identifiable or potentially re-identifiable (e.g. to enable data linkage).
* Approved projects that access human data must observe confidentiality and privacy obligations to participants, and to deceased and their families, and ensure that confidential information is only used for the purposes for which ethical approval is provided. The same privacy and confidentiality laws that govern medical and health care information will apply.
* It is recognised that some agencies, because of their status under legislation may be entitled to disclose health information for various purposes.
* The FSS-HEC will utilise the [Queensland Health document Anonymisation and de-identification of data](https://metrosouth.health.qld.gov.au/sites/default/files/content/de-identification-and-anonymisation-of-data-guideline.pdf) when considering confidentiality, privacy and de-identification of material.

# Relationships

Pursuant to the [Department of Health Governance Framework](https://www.health.qld.gov.au/__data/assets/pdf_file/0025/1069153/governance-framework.pdf) all decisions made within FSS must be made by a position with the delegated authority to do so. Decisions are made by the FSS-HEC under the authority of the Executive Director, FSS.

The FSS-HEC will:

* report through its Chairperson to the FSS executive.
* liaise and consult with the Office of Research and Innovation (ORI), Queensland Health, other ethics committees, research facilities, other relevant projects, and applicants through the Chairperson and Administrator.

# Composition and appointment of FSS-HEC members

Composition and appointment of FSS-HEC members comply with section 5.1.30-5.1.43 in the National Statement on Ethical Conduct of Human Research.

A current list of members is available here <https://www.health.qld.gov.au/public-health/forensic-and-scientific-services/research/committees/human-ethics-committee/membership>

# CONDITIONS OF MEMBER APPOINTMENT

Member responsibilities are outlined in the NS 5.2.21-5.2.24.

* New members should be provided induction material and individual mentoring via the Chairperson or other member of the FSS-HEC (NS, 5.1.28(b)).
* An individuals’ membership of the FSS-HEC may be terminated at any time without notice or reason either by the member or the FSS executive.
* HEC members should be able to freely discuss with other members the applications submitted to them. For this reason, HEC meetings will be held in private, and members are encouraged to raise any matters of concern.
* Members are required to keep the business of the HEC confidential.
* Members should be provided a letter of appointment including the date of appointment, length of tenure, meeting attendance responsibilities and general responsibilities of membership (NS 5.1.42).

# INDEMNITY FOR COMMITTEE MEMBERS

Queensland Health provides indemnity for members of the FSS-HEC and external expert reviewers through Queensland Government Insurance Fund (QGIF) in accordance with the [Queensland Government Indemnity Guideline](https://www.forgov.qld.gov.au/working-in-the-public-service/directives-awards-and-legislation/search-for-directives-policies-circulars-and-guidelines/queensland-government-indemnity-guideline) for liabilities that may arise in the course of bona fide conduct of their duties in this capacity.

# References

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World Health Organization. Regional Office for the Eastern Mediterranean. *Ethical practice in laboratory medicine and forensic pathology.* WHO, 1999. <https://apps.who.int/iris/handle/10665/119604>

*Coroners Act 2003* (Qld) <https://www.legislation.qld.gov.au/view/html/inforce/current/act-2003-013>

*Hospital and Health Boards Act 2011* (Qld) <https://www.legislation.qld.gov.au/view/html/inforce/current/act-2011-032>

*Privacy Act 1988* (Cth) <https://www.legislation.gov.au/Details/C2021C00139>

*Public Health Act 2005* (Qld) <https://www.legislation.qld.gov.au/view/html/inforce/current/act-2005-048>

*Transplantation and Anatomy Act 1979* (Qld) <https://www.legislation.qld.gov.au/view/html/inforce/current/act-1979-074>

Queensland Health HREC Administrator SOPs <https://www.health.qld.gov.au/__data/assets/pdf_file/0034/147598/hrec_sop.pdf>

1. Health information is defined in schedule 5 of the IP Act as:

   *(a) personal information about the individual that includes any of the following—*

   *(i) the individual’s health at any time;*

   *(ii) a disability of the individual at any time;*

   *(iii) the individual’s expressed wishes about the future provision of health services to the individual;*

   *(iv) (iv) a health service that has been provided, or that is to be provided, to the individual; or*

   *(b) personal information about the individual collected for the purpose of providing, or in providing, a health service; or*

   *(c) personal information about the individual collected in connection with the donation, or intended donation, by the individual of any of the individual’s body parts, organs or body substances.* [↑](#footnote-ref-2)
2. ***Personal information*** is information or an opinion, including information or an opinion forming part of a database, whether true or not, and whether recorded in a material form or not, about an individual whose identity is apparent, or can reasonably be ascertained, from the information or opinion. *Information Privacy Act 2009 QLD s12* [↑](#footnote-ref-3)