| Human Ethics Committee  Standard Operating Procedures  **January 2024 Version 11** |
| --- |
|  |

**Contents**

[1. Scope](#_Toc152014005) 1

2. Procedures 2

[2.1 LEVELS OF ETHICAL REVIEW](#_Toc152014009) 2

[2.1.1 Greater than low risk applications](#_Toc152014009) 2

[2.1.2 Lower risk applications](#_Toc152014009) 2

[2.1.3 Minimal risk applications](#_Toc152014009) 2

[2.1.4 Exemption from ethical reivew](#_Toc152014009) 2

[2.1.5 Quality assurance/improvement](#_Toc152014009) 2

[2.1.6 Amendments](#_Toc152014009) 2

2.1.7 Minimising duplication of ethical review 3

2.2 APPLICATIONS AND SUBMISSIONS 3

2.2.1 Application process 3

2.2.2 Additional/regulatory approvals 4

2.2.2.1 Coroner approval 4

2.2.2.2 Public Health Act approval 4

2.2.2.3 Site authorisation / research governance approval 4

2.3 MEETINGS 4

2.3.1 Meeting procedures 5

2.3.2 Decisions available to the FSS-HEC 5

2.3.3 Duration of approval 5

2.3.4 Documentation and records 6

2.4 PROJECT MONITORING 6

2.5 COMPLAINTS 6

2.5.1 Complaints about the operation of the FSS-HEC 6

2.5.2 Complaints regarding the conduct of projects approved by the FSS-HEC 7

2.5.2.1 Responding to complaints 7

2.6 ALLEGED BREACHES OF THE AUSTRALIAN CODE FOR THE RESPONSIBLE CONDUCT OF THE RESEARCH (THE CODE) 7

3. [References](#_Toc152014021) 8

# Scope

Human Research Ethics Review is a process to explore the ethical issues presented by, and implications of, a research project involving humans. Human Research Ethics Committees (HRECs) play a central role in the Australian system of ethical oversight of research. HRECs review research proposals involving human participants to ensure that they are ethically acceptable, have scientific merit, protect the rights, safety and privacy of participants and are beneficial and just, in accordance with relevant standards and guidelines, including the National Statement on Ethical Conduct in Human Research 2007 (Updated 2018) (National Statement)

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).

In addition to its role as a HREC, 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.

The purpose of this document is to provide standard operating procedures (SOPs) for FSS-HEC. The SOPs are designed to ensure the Committee operates in accordance with the National Statement and the National Health and Medical Research Council (NHMRC) Australian Code for the Responsible Conduct of Research, 2018

# Procedures

# LEVELS OF ETHICAL REVIEW

# Greater than low risk applications

All applications for research that involve more than low risk will be reviewed by the full committee (NS, 5.1.11).

* + 1. **Lower risk applications**
* Low-risk applications (as defined by NS, 2.1) will be considered out of session by the Chairperson or Deputy Chairperson and two members of the FSS-HEC and noted by the full committee (NS 5.1.12).
* If an application that has been reviewed through the low-risk review process and involves a waiver of consent for research using personal health information1 or personal information2 in medical research, review of the waiver will be referred to the full committee for consideration against NS 2.3.10 (NS 2.3.9)
* If, in the process of a low-risk review, it is identified that the research risk is greater than low-risk, the application will be referred to the full committee. (NS, 5.1.21).
  + 1. **Minimal risk applications**
* Minimal risk applications that do not meet the criteria for exemption (as per 1.4 below) will be considered out of session by the Chairperson or Deputy Chairperson and noted by the full committee (NS 5.1.12).
* An application that has been reviewed through the minimal risk review process that involves a waiver of consent for research using personal health information or personal information in medical research, review of the waiver will be referred to the full committee for consideration against NS 2.3.10 (NS 2.3.9)
* If, in the process of a minimal risk review, it is identified that the research risk is more than minimal, the application will be transferred to the low-risk review pathway or referred to the full committee, whichever is appropriate (NS, 5.1.14(c)).
  + 1. **Exemption from ethical review**

Requests for exemption from ethical review may be considered by the FSS-HEC Secretary and noted by the full committee. Requests for exemption from ethical review will only be granted where the proposal meets the conditions for eligibility as set out in the National Statement, paragraph (5.1.16 -17).

* + 1. **Quality assurance/improvement**

Quality assurance and quality development/improvement activities (including those involving a waiver of consent) that require ethical oversight will be reviewed by the FSS-HEC Chairperson, Deputy Chairperson or Secretary with reference to the NHMRC document [*Ethical Considerations in Quality Assurance and Evaluation Activities*](https://www.nhmrc.gov.au/file/2821/download?token=r4lnWk6N) (ie. 2e - Triggers for ethical review).

* + 1. **Amendments**

Requests for amendments to current ethics approval applications may be reviewed and approved by the Chairperson, Deputy Chairperson or the Secretary between meetings.

Substantial amendments may require consultation with additional HEC members or full committee review.

* + 1. **Minimising duplication of ethical review**

Where another Australian Human Research Ethics Committee (HREC) has approved an application for ethical review and that HREC is either a Queensland Health HREC or a certified committee participating in the National Mutual Acceptance (NMA) Scheme, FSS will generally accept that application without further ethical review, performing governance assessment only, unless:

* the project involves access to or use of coronial material, in which case the aspects of the application which involve coronial material must be reviewed by the FSS-HEC Executive Committee (with referral to the full HEC where the Executive Committee deems this necessary); or
* during the governance assessment, ethical considerations or risks arising from local circumstances are identified. In this case, the FSS-HEC Chairperson or Deputy Chairperson will liaise with the reviewing HREC for the management and resolution of the issues.

# APPLICATIONS AND SUBMISSIONS

* + 1. **Application process**

The FSS-HEC requires applications for ethical review of research projects that are low risk or greater or those involving a waiver of consent and personal health information or personal information in medical research, to be submitted electronically using the Ethics Review Manager (ERM) system and submitted to the ‘Queensland Health Forensic and Scientific Services Human Ethics Committee’.

* Applications must include:
* a project description / plan
* consent forms and participant information sheets (where applicable)
* A data management plan that is compliant with the [Queensland Health De-identification and Anonymisation of Data Guideline](https://metrosouth.health.qld.gov.au/sites/default/files/content/de-identification-and-anonymisation-of-data-guideline.pdf), and [The Australian Code for the Responsible Conduct of Research (2018)](https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018)
* any other relevant supporting documentation, such as letters of support.
* Applicants submitting projects for FSS-HEC review must demonstrate that:
* research is planned to produce clear results intended for publication in peer-reviewed literature,
* research will be conducted or supervised by persons with experience, professional competence, and qualifications appropriate to the research, and
* for research involving coronial material or data, that the guidance provided by the FSS-HEC on [distributive justice in the coronial setting](https://www.health.qld.gov.au/public-health/forensic-and-scientific-services/research/accessing-materials-and-data) has been considered.
* Requests for exemption, quality assurance projects or ethical review of minimal risk projects that do not involve a waiver of consent and personal health information or personal information in medical research can be submitted via ERM or the short version [electronic application form.](https://forms.office.com/Pages/ResponsePage.aspx?id=CLBlC9eVvEq6_D_8IMA5wIl03H5tLBVNrTfkxAXutAZUMExLRDRMNVFQMERFNVEyOUpUR0RVRzAzNi4u)
* Internal applications for ethical review of proposed publications, eg. case reports should be submitted on the [Human Ethics Review - publications checklist](http://qis.health.qld.gov.au/DocumentManagement/Default.aspx?DocumentID=32177) and include a copy of the full draft manuscript.
* All other submissions to the FSS-HEC must be in writing. Advice regarding the format for these submissions should be sought from the Secretary of the FSS-HEC.
* The Chairperson or Deputy Chairperson and Secretary will determine if expert advice is required.
* Fees may be levied by FSS to recover costs associated with ethical review and monitoring of research projects from applicants external to Queensland Health. In addition, all costs associated with seeking coronial and next of kin consent and/or retention of autopsy tissues for approved projects must be borne by the projects.
  + 1. **Additional/regulatory approvals**

Additional approvals should be sought as required and before projects commence, including (but not limited to):

1. Coroner approval

* All research and case reports that involve coronial tissue or data require coronial approval, regardless of how these are to be published (eg. journal articles, posters or talks at grand rounds, meetings or conferences). Such approvals are not required for internal case presentations to other forensic staff at FSS.
* For research projects, investigators must receive approval from the State Coroner as **‘Genuine researchers’** as per s53 of the [*Coroners Act 2003*](https://www.legislation.qld.gov.au/view/html/inforce/current/act-2003-013) where access to coronial tissue or data is required for the research
* A “genuine researcher” approval covers publication of the findings/coronial material as outlined in the approved application. If additional data, images or further publication is proposed, a separate approval to publish coronial approval will be required.
* Case reports, whether an individual case or a small group of cases, require approval from the:
  + case Coroner where the coroner’s investigation is complete, or
  + State Coroner where the coroner’s investigation is not complete
  + Chief Forensic Pathologist (or delegate)
  + Chair of the FSS-HEC
  + forensic pathologist/s involved in the case.
* For case reports (but not research), the State Coroner has given general approval for all forensic pathologists and odontologists to be “genuine researchers” under section 53. Therefore, case reports with a FSS forensic pathologists or odontologist as an author do not require “genuine researcher” approval.

1. Public Health Act approval

Disclosure of confidential health information for research requires approval under chapter 6, part 4 of the [*Public Health Act 2005*](https://www.legislation.qld.gov.au/LEGISLTN/CURRENT/P/PubHealA05.pdf) (PHA) if consent is not obtained and the information is identifiable or potentially re-identifiable. The PHA does not apply to health information held by Queensland Health if its disclosure is authorised under another Act of law

1. Site authorisation/research governance approval

All research conducted at FSS or using FSS resources requires research governance assessment and authorisation, and this is separate to the ethical review.

The FSS-HEC may require applicants seek legal advice to ensure that proposed research complies with other relevant regulatory requirements.

# MEETINGS

* Meetings are scheduled monthly, except for January. Scheduled meetings may be cancelled if no submissions requiring full Committee review are received.
* A timetable of meetings will be finalised by November of the preceding year and published on the [FSS-HEC internet site](https://www.health.qld.gov.au/public-health/forensic-and-scientific-services/research/committees/human-ethics-committee/meetings). The Chairperson or Deputy Chairperson may reschedule a meeting and/or convene additional meetings to consider urgent matters.
* Notice of meeting will be given at least two weeks prior. An electronic copy of applications for consideration with all associated documentation, including the HREA, participant information sheet and consent form, questionnaires and any other relevant correspondence (where applicable) will be forwarded to all members at least one week before the meeting.
  1. **Meeting procedures**
* Members of the committee must disclose any conflict of interest in relation to matters on the agenda prior to discussion of the item. In such instances the FSS-HEC will determine whether, and to what extent, the member will be excluded from deliberations (NS 5.6.3 to 5.6.5).
* It is the responsibility of each member of the FSS-HEC to independently decide whether, in their opinion, each application submitted to the FSS-HEC conforms with established ethical principles and relevant ethical codes and guidelines (NS 5.2.21).
* Decisions by the committee about whether the research project meets the requirements of the National Statement must be informed by the exchange of opinions from each of the members who constitute the minimum membership of the FSS-HEC. This exchange should, ideally, take place at a meeting with all members present (NS 5.2.4).
* Members who are unable to attend a meeting in person may arrange to participate online or via teleconference, and/or forward their reviews in writing to the FSS-HEC Secretary or Chairperson prior to the meeting (NS 5.2.3).
* Where there is less than full attendance in person of the minimum membership at a meeting, the Chairperson should be satisfied, before any decision is reached, that the views of those absent who belong to the minimum membership have been received and considered (NS 5.2.5).
* Efforts should be made to reach decisions by general agreement. This need not involve unanimity (NS 5.2.8).
* In the absence of the Chairperson, the Chairperson/Secretary may appoint an acting Chairperson.
* It is permissible for members of other HRECs, students studying ethics components and other persons to approach the HREC Chair to request permission to attend a HEC meeting as an observer. Before this occurs, permission must be granted by the HEC Chair and a confidentiality agreement must be signed by the observer.
* To ensure informed consideration of projects/issues the FSS-HEC may invite the applicant to attend the meeting to discuss a proposal (NS 5.2.6 (c)).
  1. **Decisions available to the FSS-HEC**

The HEC will reach one of the following decisions on any application reviewed at a meeting:

* **Final decision**. The HEC may reach a final decision on the application at the meeting. This decision may be:
  + Approved
  + Approved with specified conditions, or
  + Not Approved
* **Further information/modification requested.** The HEC may seek further information/clarification before making a final decision. The application should be given a decision of Further information/modification requested. The application should not be given a decision of Not Approved at this time.
  1. **Duration of approval**

Approvals will remain current provided the conditions of approval as specified in the approval letter are complied with, including all reporting requirements.

* 1. **Documentation and records**
* The Secretary of the FSS-HEC will arrange for minutes of the meetings to be recorded. These will include a summary of the key points arising in the discussion, any dissenting views and the conclusions/recommendations/actions agreed.
* The recommendations and actions will be documented in the minutes of the meeting.
* Minutes will be ratified at the following meeting or within 30 calendar days of the meeting.
* Decisions will be communicated to researchers in writing. When applications are not approved, reasons referencing the National Statement will be provided. Where applications are approved, the approval correspondence should state that the application meets the requirements of the National Statement (NS 5.2.7).

# PROJECT MONITORING

The FSS-HEC requires principal investigators to:

* ensure that all ethical approval, legal advice, and other relevant approvals have been obtained before a project commences
* maintain adequate records and provide access to the FSS-HEC when requested
* provide reports outlining project progress, maintenance and security of records, compliance with the approved proposal and any conditions of approval, at least annually or at intervals specified by the FSS-HEC and at completion of any project (NS 5.4.8)
* notify the Secretary of the FSS-HEC in writing of: circumstances occurring at any time during the project which may affect the ethical approval; any complaints that raise ethical issues regarding the conduct of an approved project proposed changes to an approved research protocol; and the cessation of a project prior to the expected date of completion
* provide a copy of, or links to any outputs of the research, including published results, journal articles, presentations at conferences, etc. to the FSS-HEC in the final project report.

Ethical approval will be withdrawn where the FSS-HEC has reason to believe that continuance of a project will compromise participants’ welfare (NS 5.4.14).

# COMPLAINTS

* + - 1. **Complaints about the operation of the FSS-HEC**
* Complaints and appeals about the application review process or the outcome of an application should be submitted in writing to the Secretary.
* The FSS executive expects the FSS-HEC to explain the ethical grounds for rejecting a proposal and/or to suggest modifications which would facilitate its re-submission (NS 5.7.3). Therefore, advice and decisions of the FSS-HEC on ethical matters are generally not subject to appeal.
* The National Statement, however, identifies that there may be justifiable differences of opinion as to whether a research proposal meets the requirements of the National Statement and requires organisations to provide a process for dealing with such complaints.
* The Secretary will discuss the matter with the Chairperson or Deputy Chairperson of the FSS-HEC and record this against the project in the HEC register. Generally, the Chairperson will be the person responsible for actioning the complaint. However, the Chairperson may refer the complaint to the Executive Director, FSS or other authorised officers as required.
  + 1. **Complaints regarding the conduct of projects approved by the FSS-HEC**
* Participant information sheets and consent forms for projects must include contact details where participants may lodge complaints regarding the conduct of the project. This should be an employee of Queensland Health who is independent to the research team.
* General complaints about the conduct of project/s should be directed to the person nominated in the consent form. These complaints should then be forwarded, preferably in writing, to the Secretary for referral to the Chairperson.
* If the complaint raises questions regarding the ethical acceptability of the project, the Chairperson must consider whether the project should be suspended while the matter is investigated. The Chairperson may need to seek advice from the FSS-HEC or other appropriate sources.
* Matters that involve FSS system failures will be logged as an opportunity for quality improvement (OQI) in the quality information system (QIS) within one week and investigated, actioned and followed up as per the OQI process.
* Other matters, which may involve projects external to FSS or may be more appropriately handled by other Queensland Health processes, will be referred to the relevant person/unit.
  + - 1. Responding to complaints
* Where possible, a written response will be sent to the complainant detailing the result of any investigation within one month of receipt.
* Complex matters may take longer to resolve and in these cases a letter should be sent outlining any actions being taken and the proposed time frame for a response.
* Outcomes of any investigation and the actions undertaken from this investigation must be referred to the FSS executive for ratification or noting, as appropriate.
* If the complainant does not find that the matter is satisfactorily resolved, the complainant may lodge a submission in writing to the Executive Director, FSS.
* Where complaints relate to research projects, copies of all correspondence should be forwarded to the FSS Research Office.

# ALLEGED BREACHES OF THE AUSTRALIAN CODE FOR THE RESPONSIBLE CONDUCT OF RESEARCH (THE CODE)

Where concerns are identified regarding the conduct of FSS research or researchers, these will be managed in accordance with the [Forensic and Scientific Services and Pathology Queensland Procedure for Handling potential breaches of the Australian Code for the Responsible Conduct of Research 2018](https://www.health.qld.gov.au/__data/assets/word_doc/0019/1103077/complaints-procedure.docx).

# References

AIATSIS. *AIATSIS Code of Ethics for Aboriginal and Torres Strait Islander Research*. Australian Institute of Aboriginal and Torres Strait Islander Studies, Canberra, 2020. <https://aiatsis.gov.au/sites/default/files/2020-10/aiatsis-code-ethics.pdf>

Forensic and Scientific Services. *Procedure for handling research complaints and allegations of research misconduct.* Queensland Government, Queensland Health. <https://www.health.qld.gov.au/__data/assets/word_doc/0019/1103077/complaints-procedure.docx>

NHMRC. *Australian Code for the Responsible Conduct of Research.* Australian Government, National Health and Medical Research Council and Universities Australia, 2018. <https://www.nhmrc.gov.au/about-us/publications/australian-code-responsible-conduct-research-2018>

NHMRC. *Ethical conduct in research with Aboriginal and Torres Strait Islander Peoples and communities: Guidelines for researchers and stakeholders.* Australian Government, National Health and Medical Research Council, 2018. <https://www.nhmrc.gov.au/about-us/resources/ethical-conduct-research-aboriginal-and-torres-strait-islander-peoples-and-communities>

NHMRC. *Ethical considerations in quality assurance and evaluation activities.* Australian Government, National Health and Medical Research Council, 2014. [https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research](https://www.nhmrc.gov.au/about-us/resources/ethical-considerations-quality-assurance-and-evaluation-activities)

NHMRC. *Guidelines approved under Section 95A of the Privacy Act 1988.* Australian Government, National Health and Medical Research Council, 2015. <https://www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95a-privacy-act-1988>

NHMRC. *Guidelines approved under Section 95AA of the Privacy Act 1988 (Cth).* Australian Government, National Health and Medical Research Council, 2014. <https://www.nhmrc.gov.au/about-us/publications/guidelines-approved-under-section-95aa-privacy-act-1988-cth>

NHMRC. *Guidelines under Section 95 of the Privacy Act 1988*. Australian Government, National Health and Medical Research Council, 2015. <https://www.nhmrc.gov.au/about-us/publications/guidelines-under-section-95-privacy-act-1988>

NHMRC. *Keeping research on track II.* Australian Government, National Health and Medical Research Council, 2018. <https://www.nhmrc.gov.au/about-us/resources/keeping-research-track-ii>

NHMRC. *National Statement on Ethical Conduct in Human Research 2023.* Australian Government, National Health and Medical Research Council, 2023.  <https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2023>

NHMRC. *Organ and tissue donation after death, for transplantation* [under review]. Australian Government, National Health and Medical Research Council, 2007.

<https://www.nhmrc.gov.au/about-us/publications/organ-and-tissue-donation-after-death-transplantation>

SA Health. *The National Code of Ethical Autopsy Practice.* Government of South Australia, South Australia Health, 2011. [https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/resources/policies/national+code+of+ethical+autopsy+practice](https://www.sahealth.sa.gov.au/wps/wcm/connect/ce458c80495485e786a0f63b73084503/Directive_National_Code+for+Ethical_Autopsy_Practice_v1.1_Oct2018.pdf?MOD=AJPERES&amp;CACHEID=ROOTWORKSPACE-ce458c80495485e786a0f63b73084503-oC.5MkK)

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>