

DEPARTMENT OF GENERAL PRACTICE & RURAL HEALTH

GUIDANCE ON SEEKING ETHICAL APPROVAL FOR RESEARCH AND SCIENTIFIC PEER REVIEW

ETHICAL APPROVAL FOR RESEARCH – OTAGO PROCESS

- All research involving human participants undertaken by University of Otago staff or students should be reviewed by a research ethics committee.
- The researcher has the primary responsibility for maintaining the highest ethical standards inherent in a culture of research excellence. An ethics committee should be used as a tool for researchers to help establish, maintain and review those standards. The responsibility of the researcher extends right throughout the life of the research project. It does not begin and end with the ethical review process.
- Departmental staff and students conducting research need to be familiar with the current guidance for ethics committee approval for research as set out on the UoO Human Ethics Committee website:
<https://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html>
- It is the responsibility of staff/students to follow these processes and choose the correct ethics approval route. Guidance on which route to take is summarised below. There may be grey areas as to which route should actually be taken and, if in doubt, the staff/students need to discuss this directly with the UoO Ethics Committee Team (current staff to consult with are listed on the website).

1. TYPES OF ETHICS COMMITTEE APPROVAL

- The Health and Disability Ethics Committee (HDEC) - administered by the Ministry of Health. For research that involves: ***Human participants recruited in their capacity as consumers of health and disability support services (patients) or relatives or caregivers of such consumers or volunteers in clinical trials:*** (<https://ethics.health.govt.nz/hdec-review-and-approvals/find-out-if-your-study-requires-hdec-review>).
- UOHEC (Health) – University of Otago Human Ethics Committee (Health). For research that involves: Health Research (observational and intervention studies) involving ***consumers of health and disability services (patients) but deemed exempt from HDEC review***. Studies exempt from HDEC review include: studies on low-risk device; minimal-risk observational studies; audits and related activities; student-led research (<https://ethics.health.govt.nz/hdec-review-and-approvals/find-out-if-your-study-requires-hdec-review##exempt>)

- Application form: **UOHEC (Health) - application form**
(<https://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html>)
- Ethics applications to UOHEC (Health) require submission of the study research protocol as well as confirmation of satisfactory peer review.
- For research involving minimal risk health research:
 - **When the previously collected and stored health data is de-identified**
 - **When identifiable health information is being used for audit of health provision, process or outcomes and there is no health information being obtained through contact with patients**
- A minimal risk short application may be made to the UOHEC (Health):
Minimal Risk Health Research - Audit and audit related studies
(<https://www.otago.ac.nz/council/committees/committees/HumanEthicsCommittees.html>)
- UOHEC - University of Otago Human Ethics Committee. For research that involves: Human participants but which falls outside the jurisdiction of the University of Otago Human Ethics Committee (Health) and the Health and Disability Ethics Committee (HDEC) (i.e. is not considered health research, does not involve patients)
 - The University of Otago Human Ethics Committee has two categories of application; **Category A and Category B**. Category A applications are considered and approved by the Committee; whereas Category B Reporting Sheets are audited by the Committee after having been approved by the Head of Department on the Committee's behalf.
 - The Human Ethics Committee has delegated authority to Heads of Department to approve low risk research involving human participants *who are NOT recruited in their capacity as patients*.
 - **A proposal can *only* be classified as Category B if NONE of the following is involved:**
 - Personal information - any information about an individual who may be identifiable from the data once it has been recorded in some lasting and usable format, or from any completed research
 - The taking or handling of any form of tissue or fluid sample from humans or cadavers (*refer to UOHEC (Health)*)
 - Any form of physical or psychological stress
 - Situations which might place the safety of either participants or researchers at any risk
 - The administration or restriction of food, fluid or a drug to a participant
 - A potential conflict between the applicant's activities as a researcher, clinician or teacher and their interests as a professional or private individual
 - The participation of minors (children and young people)
 - The participation of any other vulnerable individuals, in particular patients (*refer to UOHEC (Health)*)

- Any form of deception
- The research is being undertaken overseas by students.

2. DEPARTMENTAL ETHICS APPROVAL PROCESS

- Needs to be progressed by researcher *after* satisfying scientific research peer review (as set out below)
- Researchers must also submit all other requested/required documentation (e.g., Māori Consultation - <https://www.otago.ac.nz/research/maoriconsultation/index.html> ; Locality Authorisation - <https://www.otago.ac.nz/health-research-south/authorisation/index.html>).
- Departmental governance is provided by the Head of Department (Dr Carol Atmore), who is required to review and sign off on all applications (with the exception of HDEC applications).

SCIENTIFIC RESEARCH PEER REVIEW

- All research conducted by staff / students that falls within the remit of the Ethics Approval Process (HDEC; UOHEC-Health; UOHEC – all categories) needs formal scientific peer review.
- Formal scientific peer review is separate from the ethics approval process and *needs to be completed before an ethics committee application is made*.
- Proposals deemed to already have recognised external peer review are exempt from departmental peer review process. This applies to research projects which have received contestible grant funding from national (e.g., HRC; Marsden, Lotteries Health) and Local (e.g., Dean’s Bequest DSM; Health Care Otago; UORG) funding bodies.
- Departmental staff and students conducting research need to be familiar with the current guidance for scientific peer review set out on the Health Research South website (<https://www.otago.ac.nz/health-research-south/authorisation/peer-review/index.html>).
- The peer review process for both research projects and higher degree proposals is in essence the same, acknowledging that a higher degrees proposal may not constitute a formal research protocol. There is a separate process for approval of higher degrees proposals (see relevant departmental guidance),
- The guidance for the peer review process from Health Research South is comprehensive. To summarise:
 - Level A – HDEC – Reviewed by the Departmental Peer Review Committee, based on a review by at least 2 peers, including a reviewer with statistical expertise (if appropriate) OR satisfactory external peer review
 - Level B – Research not requiring HDEC review (UOHEC-Health; UOHEC – all categories) – Approval by Departmental Peer Review Chairperson based on review by at least two peers confirming scientific validity OR satisfactory external peer review

- Level C – research carried out for purpose of doing research, with no intent to gain new knowledge and ethics committee review not needed – Approval by Approval by Departmental Peer Review Chairperson based on review by one peer confirming scientific validity

1. DEPARTMENTAL SCIENTIFIC PEER REVIEW PROCESS

- Departmental Scientific Peer Review is an important part of departmental research activity and all confirmation path staff at lecturer grade or above and research staff at Research Fellow level and above are expected to participate in this process at the request of the Chair of the Departmental Peer Review Committee.
- The Chair of the Departmental Peer Review Committee is Prof Tim Stokes, who is also the Departmental Research Convenor. The current Departmental Scientific Peer Review Committee membership is: Dr Katherine Hall (Higher Degrees Convenor), A/Prof Chrys Jaye. This membership aligns with that for the current Departmental *Higher Degrees Committee*.
- When the Chair of the Departmental Peer Review Committee is conflicted, e.g., if he is applicant/co-applicant for a research proposal, then another member of the committee will sign off.
- The Chair of the Departmental Peer Review Committee has delegated authority from the Head of Department to approve research proposals.
- The steps to be followed, including expected timelines for completion of each step, are shown on the attached flow chart.

Prof Tim Stokes

Chair of the Departmental Peer Review Committee

Departmental Research Convenor

24/4/20

FLOW CHART: DEPARTMENTAL SCIENTIFIC PEER REVIEW PROCESS DGPRH

FIRST STEP (preparation of research proposal and identification of peer reviewers)

- Researcher prepares research protocol (this should use a format in line with research grant applications submitted to local funding bodies, e.g., UORG, Dean's Bequest DSM, Health Care Otago).
- The researcher identifies and approaches two potential peer reviewers (these can be internal or external to department) in line with Health Research South Guidance and gets their agreement to review
- The timeframe for this stage will be variable.



SECOND STEP (peer review of research proposal)

- The Chair of the Departmental Peer Review Committee (ChDPRC) oversees the peer review process with appropriate administration support
The ChDPRC /administrator sends out research protocol for external peer review to the identified two reviewers (within 1-2 working days of receiving proposal, assuming reviewers already identified and willing).
- Peer review requested to be completed within a 10 working day timeframe
- The ChDPRC /administrator sends out received peer review comments to researcher (within 1-2 working days of receiving peer review comments) and requests a revision of the proposal (both tracked changes and untracked versions) and a rebuttal table. The researcher addresses these. The final proposal (untracked), tracked changes proposal and rebuttal table are prepared and submitted to the ChDPRC/administrator by the researcher.
- The ChDPRC reviews the submitted documentation (Level B).
- The Full Departmental Peer Review Committee reviews the submitted documentation (Level A).
- If ChDPRC / Full committee views proposal as unsatisfactory this is returned to researcher with a request for revision.



THIRD STEP (approval)

- ChDPRC approves proposal and notifies the researcher formally by letter – to be included in ethics committee submission
- Timeframe for sign off of revised proposal from receipt 1-3 working days (Level B); 5-10 working days (Level A).



PROGRESS TO ETHICS COMMITTEE APPLICATION