UNIVERSITY OF WOLLONGONG AUSTRALIA

University of Wollongong & Illawarra Shoalhaven Local Health District

Human Research Ethics Committee

STANDARD OPERATING PROCEDURES

Version 4 April 2019

Contents

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PURPOSE OF THIS DOCUMENT

This document provides standard operating procedures for the University of Wollongong & Illawarra Shoalhaven Local Health District Health and Medical Human Research Ethics Committee (HREC) and Social Sciences HREC.

This document is based on NSW Ministry of Health document number GL2013_009: Human Research Ethics Committees: Standard Operating Procedures for NSW Public Health Organisations.

SCOPE

The HRECs are jointly convened by the University of Wollongong and the Illawarra Shoalhaven Local Health District. The University of Wollongong maintains the administrative responsibility for the HRECs, and liaises with the appropriate individuals at the Illawarra Shoalhaven Local Health District as required.

The Health and Medical HREC is accredited in NSW as a lead HREC for multi-centre research ethical review in the category of general research. The University of Wollongong is certified by the NHMRC for its multi-centre review processes in relation to the Health and Medical HREC under the national approach to Single Ethical Review.

Definitions & abbreviations:

Adverse event:	A physical reaction to a drug or other interventional procedure, but also emotional and/or psychological distress due, for example, to the nature of questions in a questionnaire; or a breach of privacy
Chairperson:	Chairperson, Human Research Ethics Committee
Contact Person:	The person nominated by the Co-ordinating Principal Investigator / Principal Investigator that the HREC should correspond with in relation to this ethics application
Co-ordinating Principal Investigator:	The individual who takes overall responsibility for the research project and submits the project for ethical and scientific review. They are responsible for ongoing communication with the HREC and passing on any outcomes from this to the Principal Investigators
Epidemiological Research:	Research that is the study of the distribution and determinants of health-related states or events in specified populations, and the application of this study to the control of health problems
Executive Director, OHMR:	Executive Director, Office for Health and Medical Research (OHMR), New South Wales Ministry of Health or their delegate

Executive Officer:	Executive Officer, University of Wollongong & Illawarra Shoalhaven Local Health District Human Research Ethics Committee
Health Services Research:	Human research involving the integration of epidemiologic, sociologic, economic and other analytic sciences to study health services
HREA:	Human Research Ethics Application
HREC:	Human Research Ethics Committee, a committee constituted in accordance with the National Statement to review and where appropriate approve and monitor the ethical and scientific aspects of human research
Lead Committee / Lead HREC:	A Human Research Ethics Committee accredited by NSW Health to conduct the single ethical and scientific review of multi-centre research projects
Low risk research:	Research where the only foreseeable risk to the participant is one of discomfort
Multi-centre research:	Research that is conducted at more than one site within the NSW public health system, where the sites are within the jurisdiction of more than one NSW Ministry of Health HREC.
National Statement:	*National Statement on Ethical Conduct in Human Research 2007, updated 2018,* or replacement
Negligible risk research:	Research where there is no foreseeable risk of harm or discomfort and any foreseeable risk is not more that inconvenience to the participants
NHMRC:	National Health and Medical Research Council
OHMR:	Office of Health and Medical Research
Online Forms website:	An online system that enables users to electronically complete their applications for ethical and scientific review and site authorisation
Principal Investigator:	The individual who takes responsibility for the overall conduct, management, monitoring and reporting of research conducted at a site and submits the research project for site authorisation. For single centre research, Co-ordinating Principal Investigator and

	Principal Investigator are synonymous
Public health organisation:	As defined by section 7 of the *Health Services Act 1997(NSW): a local health district, a statutory health corporation or an affiliated health organisation in respect of its recognised establishments and recognised services*
Research Governance:	A framework through which research is effectively oversighted, such that it meets appropriate standards of quality, safety, privacy, risk management and financial management
Research Governance Officer:	The individual appointed within a Public Health Organisation who is responsible for the management of applications for site authorisation and oversight of authorised research projects
Research protocol:	A document that details the objectives, design, methodology statistical considerations and organisation of a research project
Research:	Original investigation undertaken to gain knowledge, understanding and insight as described in the *Australian Code for the Responsible Conduct of Research 2018*
Site:	A facility, location or service where the research is being conducted
Site authorisation:	The authorisation granted by the Chief Executive or delegate of the Public Health Organisation for the commencement of a research project
SSA:	Site Specific Assessment – a mechanism used by Public Health Organisations to ensure that the proposed research project complies with minimum governance requirements, and to consider whether the research should be conducted and supported at a site
UOW/ISLHD HREC:	University of Wollongong & Illawarra Shoalhaven Local Health District Human Research Ethics Committee

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SOP 001: HREC function

Objectives

1.1. The UOW/ISLHD operate two HRECs to manage the volume of ethics applications received. These are separated into the Health & Medical HREC and the Social Sciences HREC.

1.2. The objectives of the HRECs are to:

a) Protect the mental and physical welfare, rights, dignity and safety of participants of research;
b) Promote ethical principles in human research;
c) Review research in accordance with the National Statement on Ethical Conduct in Human Research (2007) incorporating all updates [National Statement]; and
d) Facilitate ethical research through efficient and effective review processes.

Functions

1.3. The HRECs function on behalf of the University of Wollongong and Illawarra Shoalhaven Local Health District to:

a) Provide independent oversight of human research projects;

b) 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;

c) Determine the compliance of a human research project with the National Statement and grant, withhold or withdraw ethical approval; and

d) Provide advice to the ISLHD and the UOW on strategies to promote awareness of the ethical conduct of human research.

Accountability

1.4. The HRECs are accountable to the ISLHD Chief Executive through the Chief Executive's nominee, the Area Director of Research Management, in the conduct of its business. The minutes of the Health & Medical HREC meeting shall be forwarded to the Area Director, following confirmation. A copy of all correspondence from the Ethics Unit to researchers on applications involving the ISLHD will be sent to the ISLHD Research Directorate Office.

1.5. The HREC is accountable to the Deputy Vice Chancellor (Research & Innovation) (DVC (R&I)) and the URC (through the Research Integrity Committee) of the University of Wollongong in the conduct of its business.

1.6. The HREC shall provide regular reports, at least on an annual basis, to the Chief Executive, the DVC(R&I) and the Research Integrity Committee (RIC), which will include information on membership, the number of proposals

reviewed, status of proposals, a description of any complaints received and their outcome, and general issues raised.

1.7. The HREC may from time to time bring to the attention of the Chief Executive/RIC/DVC(R&I) or delegate issues of significant concern.

1.8. The HREC will provide reports to the:

- Australian Health Ethics Committee (AHEC) in accordance with the requirements of the National Health and Medical Research Council (NHMRC); and
- NSW Privacy Commissioner in accordance with the requirements of the Health Records and Information Privacy Act 2002 (NSW).

1.9. The HREC will undertake its review in a timely and efficient manner and have mechanisms to monitor and evaluate its performance.

1.10. The following information about the HREC available upon request to the general public and will be posted on the University of Wollongong website:

- HREC contact details;
- HREC Terms of Reference;
- Standard Operating Procedures;
- HREC membership;
- HREC meeting dates.

Scope of Responsibility

The responsibilities of the UOW & ISLHD HRECs are to:

1.11. Review human research applications where the research involves patients, staff or students of the ISLHD or the UOW.

1.12. Review human research applications where the research takes place at:

- any institutions governed by ISLHD; and/or
- any institutions governed by UOW; and/or
- any institutions governed by NSW Public Health organisations for multi-centre studies; and/or
- external institutions/organisations and researchers in accordance with NSW Health policy (PD2008_046 or subsequent updates); and/or
- interstate institutions/organisations within the scope of a scheme of mutual acceptance of ethical and scientific review entered into by NSW Ministry of Health on behalf of the HREC.

This operating procedure does not prohibit the institution from accepting an ethical approval undertaken by another HREC as a sufficient ethical approval to allow the institution to approve the commencement of the project, provided

that such other HREC is registered with the Australian Health Ethics Committee. For research involving the ISLHD, the HREC must be on the approved NSW Health HREC list available at http://www.health.nsw.gov.au/ethics/research/contactshrec.asp

Role of the Chairperson

1.13. The Chairperson is responsible for the conduct of HREC business and for ensuring that the HREC reaches decisions on all matters. Where the Chairperson is not available, the meeting will be chaired by a Deputy Chairperson, or their delegate.

HREC Executive Committee

1.14. The HREC has an Executive Committee comprising at least the HREC Chairperson or their delegate and a member of the research office.

1.15. The HREC Executive Committee is delegated to undertake expedited review and approval of business that does not require full HREC review, including some or all of the following:

- Low and negligible risk research applications;
- Amendments to current HREC approved research projects;
- Responses to HREC queries, as approved by the full HREC for HREC Executive Committee review and approval;
- Annual progress reports and final reports; and
- Serious adverse events and suspected unexpected serious adverse reactions reports.

1.16. The minutes and decisions of the HREC Executive Committee are noted at the next HREC meeting.

SOP 002: Membership composition

2.1. The composition of each HREC shall be in accordance with the *National Statement*. Minimum membership shall be eight members, including men and women, comprising:

- a chairperson;
- at least two members who are lay people, one man and one woman, who have no affiliation with the institution or organisation, and who are not currently involved in medical, scientific, or legal work.
- at least two members with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC;
- at least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people;
- at least one member who is a minister of religion, or a person who performs a similar role in the community;
- at least one member who is a lawyer.

2.2. At least one third of the membership must be from outside of the institution for which the HREC is reviewing the research.

2.3. To ensure the membership will equip the HREC to address all the relevant considerations arising from the categories of research likely to be submitted, some or all of the above categories may be represented by more than one person. The Health and Medical HREC will include representatives from specialist areas in the ISLHD relevant to the research proposals reviewed by the HREC.

2.4. Where required, the HREC may seek advice and assistance from appropriate experts to assist with the review of a project. However, the HREC must be satisfied that such experts have no conflicts of interest in relation to the project under consideration arising from any personal involvement or participation in the project, any financial interest in the outcome or any involvement in competing research. Such person(s) shall be required to provide an undertaking of confidentiality and shall not be entitled to vote on any matter.

2.5. Additional members may be appointed to ensure the HREC has the expertise required to assess the applications submitted to it for consideration. If additional members are appointed the composition of the HREC shall continue to reflect diversity and balance in its membership, including in gender and the relative proportion of institutional and non-institutional members.

SOP 003: Appointment of members

3.1. Members are appointed as individuals rather than in a representative capacity.

3.2. Prospective members of the HREC may be recruited by direct approach, nomination or by advertisement. Prospective members shall be asked to provide a copy of their Curriculum Vitae to the selection committee. Members must agree to their name and profession being made available to the public, including being published on the institutions websites.

3.3. A selection committee, consisting of the Chairperson, Executive Officer and at least one other HREC member shall interview the prospective member, consult with the HREC members and make a recommendation to the Chief Executive and/or DVC(R&I). Prospective members may be invited to attend a meeting of the HREC as an observer prior to considering an appointment.

3.4. Members are appointed by the Chief Executive and/or DVC(R&I) in consultation with the HREC and will receive a formal notice of appointment.

3.5. The Chairperson and Deputy Chairperson/s will be appointed by the Chief Executive and DVC(R&I). In the absence of the Chairperson, the Deputy Chairperson will perform the role and duties of the Chairperson.

3.6. The letter of appointment shall include the date of appointment, length of tenure, assurance that indemnity will be provided in respect of liabilities that may arise in the course of bona fide conduct of their duties as a HREC member, the circumstances whereby membership may be terminated and the conditions of their appointment.

3.7. Members will be required to sign a confidentiality undertaking upon appointment, stating that all matters of which he/she becomes aware during the course of his/her work on the HREC will be kept confidential; that any conflicts of interest, which exist or may arise during his/her tenure on the HREC will be declared; and that he/she has not been subject to any criminal conviction or disciplinary action, which may prejudice his/her standing as a HREC member.

3.8. Upon appointment, members shall be provided with the following documentation:

- HREC Terms of Reference;
- HREC Standard Operating Procedures;
- list of members' names and contact information including that of the Executive Officer;

- NHMRC National Statement on Ethical Conduct in Human Research; and
- any other relevant information about the HREC's processes, procedures and protocols.

3.9. Members are appointed for a period of two years and may serve three consecutive terms only unless otherwise approved by the Chief Executive and DVCR. The Chair, Deputy Chair and Chair of any subcommittee may serve longer terms with the approval of the Chief Executive and DVC(R&I). Members will be advised when his/her term is due to expire. Reappointment is on invitation from Chief Executive and/or DVC(R&I) based on a recommendation from the Chairperson of the HREC.

3.10. Appointments shall allow for continuity, the development of expertise within the HREC, and the regular input of fresh ideas and approaches.

3.11. New members are expected to attend formal training sessions as soon as practicable after their appointment. All members are expected to attend education and training sessions at least annually. Reasonable costs associated with attendance at training and education sessions will be met by the host institutions.

3.12. Members shall not be remunerated except under exceptional circumstances, which must be approved on a case by case basis by the DVC(R&I) and/or Chief Executive. Members will be reimbursed for legitimate expenses incurred in attending HREC meetings, such as travelling and parking expenses.

3.13. Members may seek a leave of absence from the HREC for extended periods. Steps shall be taken to fill the vacancy.

3.14. Membership will lapse if a member fails to attend three consecutive meetings of the HREC without reasonable excuse/apology, unless exceptional circumstances exist. The Chairperson will notify the member of such lapse of membership in writing. Steps shall be taken to fill the vacancy which may arise.

3.15. Membership will lapse if a member fails to attend in full at least two thirds of all scheduled HREC meetings in each year, barring exceptional circumstances.

3.16. Members will be expected to participate in relevant specialised working groups as required. The Chairperson and Deputy Chairperson/s will be expected to be available between meetings to participate in Executive meetings.

3.17. A member may resign from the HREC at any time upon giving notice in writing to the Chairperson.

SOP 004: Orientation of new members

4.1. New HREC members must be provided with adequate orientation.

4.2. Orientation may involve all or some of the following:

- Introduction to other HREC members prior to the HREC meeting.
- Informal meeting with Chair and Executive Officer to explain their responsibilities as an HREC member, the HREC processes and procedures.
- An opportunity to sit in on HREC meetings before their appointment takes effect.
- 'Partnering' with another HREC member in the same category.
- Priority given to participate in training sessions.

4.3. Each member is:

- expected to become familiar with the *National Statement* and consult other guidelines relevant to the review of specific research applications; and
- encouraged to attend continuing education or professional development activities in research ethics once in each period of appointment.

SOP 005: Meeting schedules

5.1. The HREC meets on a regular basis, which will normally be at monthly intervals. The HREC holds at least 8 scheduled meetings in each year for the purposes of reviewing new applications.

5.2. Meeting dates and application closing dates are made publicly available.

5.3. Additional meetings are held where necessary to ensure that reviews are completed within a timely fashion, to discuss matters relating to the establishment or operating procedures of the HREC or for training purposes.

5.4. The schedule of HREC meetings for the calendar year commencing 1 January is ratified by the HREC before or at the last meeting of the previous year. The schedule sets out the dates, times and venues of meetings, and the closing date for submission of applications.

SOP 006: Agenda

18.1. The Executive Officer prepares an agenda for each HREC meeting.

18.2. The meeting agenda and associated documents are circulated to HREC members at least 7 days prior to the next meeting electronically and/or as paper copies.

18.3. Documentation received after the closing date are included on the agenda and/or tabled at the meeting at the discretion of the Executive Officer and/or Chairperson.

18.4. New applications received after the closing date are not tabled at the meeting.

18.5. As a minimum, the agenda includes the following items:

- Attendance and apologies;
- Declarations of conflicts of interest relating to agenda items;
- Confirmation of minutes of the previous HREC meeting;
- Business arising since the previous meeting(s) that the HREC indicated it wished to reconsider;
- Minutes of meetings and any issues for noting and/or approving from the HREC Executive Committee, subcommittees and external expert reviewers for example:
- Amendments to documents or modifications to applications and research projects;
- Annual progress reports and final reports;
- Reports of serious adverse events and suspected unexpected serious adverse reactions;
- New applications for review and, if applicable, the spokesperson or lead reviewer nominated by the HREC to lead the discussion on each application;
- General business; and
- Notification of the date, time and venue of the next scheduled meeting.

18.6. The agenda and all documentation are confidential.

SOP 007: Lead reviewers

7.1. The HREC has the discretion to appoint one or more members as lead reviewers for the HREC meeting or the subcommittee meeting for each application.

7.2. Allocation of applications to lead reviewers is made by the Executive Officer in consultation with the Chairperson, as necessary.

7.3. The lead reviewer is provided with a copy of the application and other supporting documentation which they have been allocated to review.

7.4. The specific role undertaken by the lead reviewer both at the meeting and following the meeting is at the discretion of the HREC.

SOP 008: Attendance of the Co-ordinating Investigator

8.1. At the request of the HREC Chairperson, the Co-ordinating Investigator is invited to make formal presentation or to respond directly to requests from the HREC for further information, clarification or reassurance.

8.2. Where the Co-ordinating Investigator is unable to attend, another key investigator or collaborator is invited to attend, if appropriate. Representatives of the sponsor are not to attend the meeting in place of the Co-ordinating Investigator. Other members of the research team may attend with the Co-ordinating Investigator.

8.3. The Co-ordinating Investigator attends the meeting in person or via telephone or videoconference.

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SOP 009: Quorum requirements

9.1. A quorum is required at each meeting for the HREC to reach a final decision on any agenda item. The quorum for meetings is at least one member from each category as specified in the *National Statement* attending in person or via telephone or videoconference.

9.2. A meeting can proceed where there is less than a full attendance of the minimum membership at a meeting but only if the Chairperson is satisfied "that the views of those absent who belong to the minimum membership have been received and considered", for instance through prior submission of written comments.

9.3. Where a quorum is not reached, the HREC will not commence, continue or conclude discussion with the purpose of reviewing an application. The HREC has the discretion to proceed with other business on the agenda as if it were an HREC Executive Committee meeting, provided that the Chairperson (or Deputy Chairperson or alternate Deputy Chairperson) and at least one other member is present.

9.4. Where the Executive Officer of an HREC is concerned that a forthcoming meeting will not be attended by a quorum of members the Executive Officer notifies the Chairperson and the following options are considered:

a) Postponing and re-arranging the meeting; or

b) Cancelling the meeting.

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SOP 010: External expert reviewers

10.1. An HREC unable to make a decision on an application or without the necessary expertise is able to consult experts identified in the area by the Chairperson and/or the Executive Officer.

10.2. Advice from other external expert reviewers is sought through the following procedures

a) Notification is sent to the Co-ordinating Investigator either before or following the HREC meeting explaining that a final decision will not be made on the application until advice is obtained from an expert reviewer. The letter notifies the Co-ordinating Investigator of the issues of concern to the HREC, but does not request further information or clarification. In circumstances where expert scientific opinion is sought, the Co-ordinating Investigator is given the option to identify experts to whom they object.

b) A suitable expert reviewer is identified by the Chairperson/Executive Officer or by the HREC during the meeting.

c) The Chairperson or Executive Officer initially contacts the prospective expert reviewer(s) by telephone or email to establish whether they are available to provide expert advice within the required time frame and that they have no connection with the research that might give rise to a conflict of interest. The expert reviewer is advised about confidentiality requirements.

d) The Executive Officer specifies in writing the issues of concern to the HREC and the expert advice required, and requests written advice and/or attendance (but not voting) at the HREC meeting. The Executive Officer ensures that the expert reviewer declares any conflict of interest and signs a declaration and confidentiality agreement.

10.3. A copy of the application form is provided together with any supporting documentation required by the expert reviewer. The HREC, or HREC Executive Committee or subcommittee as appropriate, considers the advice of the expert reviewer and makes an independent decision on the ethical and scientific acceptability of the application. The advice is recorded in the minutes.

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SOP 011: Declaration of interest

11.1. An HREC member declares to the HREC any conflicts of interest they have in relation to an application for ethical and scientific review or any other matter for consideration at that meeting. Conflict of interest includes financial interests, personal, professional or institutional benefits or advantages that depend significantly on the research outcomes.

11.2. Declarations are made orally at the meeting prior to the matter being considered or in writing to the Chairperson prior to the meeting. The HREC determines whether the level of interest results in:

a) A substantial conflict of interest: a member is excluded from the meeting where there is a substantial conflict of interest until the HREC has concluded consideration of the matter. Being an investigator on a research project is considered to represent a substantial conflict of interest.

b) A non-substantial conflict of interest: the member has the discretion to leave during the discussion of the matter.

11.3. The minutes record declaration of interest and the decision of the HREC on the procedures to be followed.

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SOP 012: Confidentiality

Confidentiality of meetings

12.1. The confidentiality of HREC proceedings is essential as:

a) Members do not sit on the HREC in a representative capacity;

b) Applications need to be discussed freely; and

c) Applications may have commercial implications.

12.2. HREC meetings are held in private and members are encouraged to raise matters of concern.

12.3. Confidentiality is addressed in two ways:

a) The HREC Terms of Reference; and

b) Members signing a statement of undertaking upon appointment.

12.4. Attendance of visitors or observers at a meeting, as appropriate and approved by the Chairperson, is conditional on the attendee signing a confidentiality agreement.

Confidentiality of applications

12.5. Applications, supporting documentation and correspondence are treated confidentially.

12.6. External expert reviewers providing advice to the HREC are asked to sign a confidentiality agreement.

12.7. HREC correspondence is addressed to the Co-ordinating Investigator and sent to the Co-ordinating Investigator or the relevant contact person identified on the application form. Correspondence is not released to the sponsor or any other parties.

12.8. Co-ordinating Investigators forward information about matters raised in the ethical review to sponsors or other parties where necessary.

SOP 013: Decision making

13.1. Members present are allowed reasonable opportunity to express relevant views on matters on the agenda.

13.2. The HREC endeavours to reach a decision concerning the ethical and scientific acceptability of a research project by unanimous agreement.

13.3. Where a unanimous decision is not reached, the Chair will need to facilitate the expression of opinion from all members, identify points of agreement and of disagreements and judge when a sufficient degree of general agreement has been reached.

13.4. Any significant minority view (i.e. 2 or more members) is noted in the minutes.

13.5. Discussions of significant issues and decisions are recorded in the minutes. Where members wish, a record of their formal dissent from the decision of the HREC is recorded in the minutes.

13.6. To encourage free and open discussion and to emphasise the collegiate character of the HREC, particular views are not attributed to particular individuals in the minutes, except in circumstances where a member seeks to have their opinions or objections recorded.

13.7. An HREC member unable to attend a meeting may submit comments in writing on agenda items to the Executive Officer or Chairperson prior to the meeting. Submission of written comments is recorded in the minutes.

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SOP 014: Decisions available to the HREC

14.1. The HREC selects one of the following decisions on any application reviewed at a meeting and the decision is recorded in the minutes:

a) Approve the application as being ethically and scientifically acceptable;

b) Request modification or further information/clarification;

c) Seek further advice from external expert reviewer(s); or

d) Reject the application.

14.2. The Chairperson ensures that one of the above decisions is made on every application considered at an HREC meeting.

14.3. Where the HREC decides that further information or clarification is required, the Chairperson ensures that:

a) Further information or clarification required is specifically identified at the meeting; and

b) Delegation of responsibility for considering the further information or clarification and confirming the final HREC opinion is clearly agreed, i.e. the information will need to be re-submitted to the full HREC, a number of HREC members or the HREC Executive Committee.

SOP 015: Minutes

15.1. The Executive Officer prepares the minutes of the HREC meeting in consultation with the Chairperson and other members as necessary. The minutes are subsequently approved by the Chairperson within 10 working days of the meeting.

15.2. The minutes reflect each item listed for discussion on the agenda:

a) Attendance and apologies;
b) Declarations of conflicts of interest relating to agenda items;
c) Confirmation of minutes of the previous HREC meeting;
d) Business arising since the previous meeting(s) that the HREC indicated it wished to reconsider;
e) Minutes of meetings and any issues for noting and/or approving from the HREC Executive Committee, subcommittees and external expert reviewers;
f) Amendments to documents or modifications to applications and research projects;
g) Annual progress reports and final reports; and
h) Reports of serious adverse events and suspected unexpected serious adverse reactions.
i) HREC deliberations and decisions on new applications, whether in the main text of the minutes or in attachments:
   - Submission of written comments by members;
   - Summaries of the advice given by expert or lead reviewers;
   - Summaries of the main issues considered;
   - Decisions of the HREC on the application; and
   - Formal dissent from the decision of the HREC by a member and the reason for it and/or any significant minority views (i.e. 2 or more members)
j) General business; and
k) Notification of the date, time and venue of the next scheduled meeting.

15.3. The minutes are submitted at the next meeting of the HREC for ratification as a true record. Members are given the opportunity to seek amendments to the minutes prior to their finalisation.

15.4. The minutes are confidential to the HREC and are not disclosed to investigators or sponsors.

15.5. The minutes of HREC meetings are made available to the Chief Executive or their delegate and, upon request, to the Research Governance Officer of the site where the research is to be conducted.

SOP 016: Duration of HREC approval

16.1. HREC approval applies for a period of one year, except where action is taken to suspend or terminate the decision.

16.2. The application to extend the duration of the research project is submitted by the Co-ordinating Investigator as a progress report/renewal request for review by the Executive Committee in the first instance.

16.3. HREC approval for an extension applies for a further one year, except where action is taken to suspend or terminate the decision.

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SOP 017: HREC reporting requirements

17.1. The ratified minutes of each HREC meeting are forwarded to the Chief Executive or delegate.

17.2. The HREC provides an annual report to the Chief Executive or delegate, DVC (R&I) and RIC which includes:

a) Membership/membership changes;

b) Number of meetings;

c) Number of research projects reviewed, approved and rejected;

d) Monitoring procedures for ethical aspects of research in progress and issues identified by the HREC in undertaking its monitoring role;

e) Description of any appeals and complaints received and their outcome;

f) Description of any research where HREC approval has been suspended or withdrawn and the reasons for this action;

g) General issues including advice on strategies to promote awareness of the ethical conduct of human research in the institution; and

h) Resources to assist the HREC in fulfilling its role.

17.3. The HREC completes and submits reports on behalf of the UOW & the Public Health Organisation to the:

a) Australian Health Ethics Committee (AHEC) in accordance with the requirements of the NHMRC;

b) NSW Privacy Commissioner in accordance with the requirements of the Health Records and Information Privacy Act 2002 (NSW);

c) Certified Institution Annual Report to the National Health and Medical Research Council (NHMRC), and any other reports as required.

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SOP 018: Clinical Trial Notification and Clinical Trial Exemption schemes

18.1. Unapproved therapeutic goods have undergone limited or no evaluation of quality, safety or efficacy by the Therapeutic Goods Administration (TGA). Use of these products is considered to be experimental and potentially carries risks that have not been defined in the Australian context.

18.2. There are two schemes under which clinical trials involving a new therapeutic good or new uses of a therapeutic good can be conducted in Australia: the Clinical Trial Notification (CTN) scheme and the Clinical Trial Exemption (CTX) scheme.

18.3. The investigator's obligations under the *Therapeutic Goods Act 1989* and application forms to conduct clinical trials under the CTN or CTX scheme are detailed at: https://www.tga.gov.au/clinical-trials

CTN HREC application requirements

18.7. The CTN Scheme is a notification Scheme.

18.8. The investigator/sponsor completes and submits all sections of the CTN form online to the TGA before submission to the HREC.

18.9. The TGA does not evaluate any data relating to the clinical trial at the time of submission. The HREC reviews the scientific validity of the trial design, the balance of risk versus harm of the therapeutic good, the ethical acceptability of the trial process, and approves the trial protocol.

18.10. The following details are considered in the HREC review:

- Investigational product;
- Comparator product (if applicable);
- All other drugs administered as part of the trial (approved and unapproved);
- Trial site;
- Sponsor; and
- Investigator.

18.11. The institution or organisation at which the trial will be conducted, referred to as the 'Approving Authority', gives the final approval for the conduct of the trial at the site, having due regard to advice from the HREC.

18.12. The HREC is responsible for monitoring the conduct of the trial.

CTX HREC application requirements

18.13. The CTX Scheme is an approval process.

18.14. The application is a paper-based form, Part 1 and Part 2, which must be completed by the investigator/sponsor and submitted to the TGA via

post.

18.15. The TGA evaluates summary information about the product including relevant, but limited, scientific data prior to the start of a trial.

18.16. The HREC is responsible for considering the scientific and ethical issues of the proposed trial protocol.

For single-centre research projects

18.17. The CTX Part 2 form, signed by the Co-ordinating Investigator, is provided to the HREC at the time of submission of a new application.

18.18. If the application is approved, the HREC signs the CTX form at section 3 and returns it to the Co-ordinating Investigator or the Research Governance Officer.

For multi-centre research projects

18.19. The CTX Part 2 form, signed by each Principal Investigator for each site, is provided to the HREC at the time of submission of a new application.

18.20. The lead HREC is provided with either:

a) Multiple forms – a CTX form for each site at which the research project will be conducted; or

b) One CTX form with a separate page for each trial site (section 1.5), Principal Investigator (section 2), and Approving Authority (section 4).

18.21. If the application is approved, the lead HREC signs the CTN or CTX form(s) at section 3, and returns the signed form(s) to the Co-ordinating Investigator with the HREC approval letter for dissemination to Principal Investigators. The Principal Investigator submits this to the site Research Governance Officer.

18.22. Where only one CTX form has been submitted to the HREC for a multi-centre project, the trial cannot commence at any site until signatures have been obtained from all Approving Authorities.

Adding trial sites following initial notification to the TGA

18.4. For additional trial sites which have not been included in the original application to the HREC, a new complete CTX form is required. This form must indicate that its purpose is to add a trial site at section 1.3 (CTX) of the form.

SOP 019: Authorised Prescriber applications

19.1. In accordance with the Therapeutic Goods Act 1989, Therapeutic Goods Regulations 1990 and Therapeutic Goods (Medical Devices) Regulations 2002, the Therapeutic Goods Administration (TGA) is able to grant to a medical practitioner authority to prescribe a specified unapproved therapeutic good or class of unapproved therapeutic goods to specified recipients or classes of recipients (identified by their medical condition). An Authorised Prescriber can then prescribe that product for that condition (also known as the 'indication').

19.2. Once a medical practitioner becomes an Authorised Prescriber they do not need to notify the TGA each time they prescribe the unapproved product during the period of approval, however they must report to the TGA the number of patients treated every six months and use of the product must be reported twice yearly. Full details of Authorised Prescribers are available from the TGA at https://www.tga.gov.au/form/authorised-prescribers

19.3. The legislation requires that the medical practitioner obtains endorsement from the HREC at the institution at which they practise (except where the practitioner can demonstrate that he/she does not have access to an appropriate HREC, in which case endorsement from a specialist college is acceptable). The HREC is responsible for providing a letter of endorsement to be submitted by the medical practitioner to the TGA as part of the practitioner's application. Full details of the HREC responsibilities are provided at https://www.tga.gov.au/authorised-prescriber-scheme

19.4. When reviewing applications to become an Authorised Prescriber, the HREC needs to assess not only the safety of the product in relation to its proposed use, but also the suitability of the medical practitioner. The HREC considers:

a) The indication for which the product will be prescribed;

b) Efficacy and safety of the product in relation to its proposed use;

c) For medicines, the route of administration and dosage form;

d) Clinical justification for use of the product;

e) Suitability of the medical practitioner; and

f) Patient information about the product and the informed consent form.

19.5. If endorsed, the HREC provides a letter to the applicant in the format suggested by the TGA. The HREC imposes conditions on the endorsement, if required, such as:

a) Regular reports to the HREC comprising information such as the number of patients prescribed the unapproved product; and

b) Reporting of adverse events.

19.6. The HREC will review its endorsement of the Authorised Prescriber if it is aware of:

a) Inappropriate use of the product by the Authorised Prescriber;

b) Safety concerns about the product;

c) Failure of the Authorised Prescriber to comply with conditions imposed by the HREC; or

d) Failure of the Authorised Prescriber to comply with legislation.

19.7. Where the HREC is satisfied that the welfare and/or rights of patients are not or will not be protected, it will:

a) Advise the medical practitioner and the Chief Executive of its concerns;

b) Withdraw its approval of the Authorised Prescriber if it is satisfied that the welfare and/or rights of patients are not or will not be protected; and

c) Report to the TGA (Chief Executive and Chairperson to determine).

19.8. To review access to unapproved therapeutic goods via Authorised Prescribers, the HREC and ISLHD will determine the best process for considering applications. This process may consist of:

a) Determination by the HREC Executive Committee; and/or

b) Consultation with the hospital drug and therapeutics committee or delegate; and/or

c) Consultation with the scientific subcommittee.

19.9. Decisions by the HREC Executive Committee are tabled for ratification at the next HREC meeting.

Institutional approval

19.10. Final responsibility for the use of an unapproved product within an institution always rests with that institution. Medical practitioners working in a NSW Public Health Organisation should discuss the use of the unapproved therapeutic product and identify the approval process with the institution before applying for authorisation.