HUMAN RESEARCH ETHICS COMMITTEES SOP

PURPOSE OF THIS DOCUMENT

This document provides standard operating procedures for the University of Technology Sydney (UTS) Human Research Ethics Committees (HRECs), their subcommittees, and the Ethics Secretariat.

HREC 01: Human Research Ethics Committees

Objectives

1.1. The UTS HRECs exist to consider the ethical implications of proposed human research projects in accordance with the National Statement on Ethical Conduct in Human Research (2023) (National Statement) and to promote ethical principles in human research.

1.2. UTS recognises and supports the responsibilities set out in the Australian Code for the Responsible Conduct of Research (2018) (The Code).

1.3. UTS recognises and supports the following values and principles of the National Statement

- Research merit and integrity
- Justice
- Beneficence
- Respect

Functions

1.4. Protect the mental and physical welfare, rights, dignity and safety of human research participants, their data and/or human tissue.

1.5. Promote compliance with the National Statement, The Code, applicable State and Commonwealth requirements, and all applicable legislation.

1.6. Protect the reputation of UTS as a place of ethical research by providing independent, competent, timely review and monitoring of human research projects with respect to their ethical acceptability for as long as the projects are active.

1.7. Protect the privacy and confidentiality of research participants by ensuring that researchers appropriately manage the security, storage and disposal of confidential data and primary materials (e.g. biological samples) collected during the conduct of research involving humans in accordance with Research Data Management Procedure and Research Policy.

1.8. Review proposals from UTS staff members, students and UTS-affiliated researchers for human research projects withthe intent to identify potential risk and/or harm to the UTS-affiliated researchers, UTS staff members and/or students undertaking the research so these can be minimised.

1.9. Protect the integrity of research by assessing researchers' justifications, integrity, and competence in line with their research objectives. Additionally, the functions to safeguard ethical standards while facilitating transparent dissemination of research findings, ensuring the protection of participants and the public interest.

Scope of responsibility

1.10. Receive and review proposals for:

a) All non-health and medical human research projects (i.e., those not involving health care including mental health, clinical trials, health information, genomic research and human tissues) - Human Research Ethics Committee (HREC).

b) All health and medical human research projects (i.e., those involving health care including mental health, clinical trials, health information, genomic research and human tissues) - Health and Medical Research Ethics Committee (MREC).

1.11. Develop and provide input on UTS policies and guidelines for human research ethics.

1.12. Educate and guide UTS staff members and/or students on the ethical conduct of research and processes/requirements for ethical review and approval.

1.13. Provide advice to the University, through the Deputy Vice-Chancellor (Research), on strategies to promote awareness of the ethical conduct of human research and on ethical issues including the ethical aspects of complaints against researchers or research projects and teaching protocols.

1.14. To monitor research projects to verify their conformity with approval terms and to safeguard the rights, safety, and well-being of participants.

1.15. Commitment to supporting a research culture that encourages responsible research practices based on the principles of research integrity in the code and National Statement.

Accountability

1.16. The UTS HRECs are Vice-Chancellor's advisory committees that report to the Deputy Vice-Chancellor (Research).

1.17. The HRECs provide an annual report to the Vice-Chancellor and Deputy Vice-Chancellor (Research).

1.18. The HRECs will bring to the attention of the Director, Research Office any issues of significant concern.

1.19. The HRECs on behalf of UTS will provide reports for Human Research Ethics Committees (HRECs) in accordance with the requirements of the National Health and Medical Research Council (NHMRC) annually (or as requested), and other reports (as required).

1.20. The HRECs will undertake their reviews in a timely and efficient manner and have mechanisms to monitor and evaluate their performance.

Role of the Chairperson

1.21. The Chairpersons are responsible for the conduct of HREC business and for ensuring that the HRECs reach decisions by consensus on all matters referred to them. Where the Chairperson is not available, the meeting will be chaired by a Deputy Chairperson or an appointed delegate.

Executive Review Committee

1.22. A subcommittee called the Executive Review Committee (ERC) will meet monthly to discuss committee business and any urgent matters.

1.23. The Membership of the ERC will be as follows: Chairperson of the HREC, Chairperson of the MREC, Deputy Chairperson of the HREC, Deputy Chairperson of the MREC, and the Manager, Research Ethics (or delegate).

1.24. The decisions of the ERC will be noted on the Agenda of the next corresponding meeting of the HREC or MREC as appropriate.

Delegation of review to Ethics Secretariat

1.25. The Chairpersons have the discretion to delegate to the Ethics Secretariat the authority to undertake review of business that is considered administrative or within the capacity of the Secretariat such as:

a) Changes to project personnel;

b) Minor administrative amendments to current projects and participant materials (as per the approved amendment matrix);

c) Ratification submissions from external HRECS;

d) Approved ethics transfer applications from UTS personnel;

e) Responses to HREC outcomes and queries;

f) Annual progress reports and final reports; and

g) Other issues, on a case-by-case basis, at the discretion of the Chairpersons.

Review of exempt from ethical review applications

1.26. Research that may be eligible for exemption from ethics review includes research that carries a lower risk to participants or the community (National Statement 2023 5.1.17), assessed by means of a risk assessment algorithm in the online system (Research Master).

1.27. Projects which are assessed as exempt, as per the risk assessment algorithm in Research Master, will be reviewed by the Ethics Secretariat to ensure that the risk assessment process is undertaken correctly. Once complete, applicants will receive a letter of noting that should be retained for their records.

1.28. Exempt from ethical review applications will be noted on the Agenda at the next meeting of the HREC.

Review of low risk research applications

1.29. Low risk research describes research, including some types of clinical trials, in which the only foreseeable risk is no greater than discomfort (Chapter 2.1) and will be assessed via the risk assessment algorithm in the online system (ResearchMaster).

1.30. The ethics review and approval process for low risk research shall be undertaken at the Faculty/School level in accordance with the UTS Low Risk Terms of Reference and National Statement (section 5.1.11 to 5.1.14).

1.31. Low risk applications will be noted on the Agenda at the next meeting of each respective HREC.

Out-of-session review

1.32. Applications must be submitted by the closing date unless there are extenuating or unusual circumstances beyond the control of the research team. In the case of unusual or extenuating circumstances, requests for out-of-session review should be directed in the first instance to the Ethics Secretariat via email and addressed to the Committee Chairperson for consideration.

1.33. Chairpersons have the discretion to review applications and major amendments out-of-session i.e., between committee meetings, where sufficient justification has been provided by the applicant.

1.34. Research with more than a low level of risk as specified in the National Statement must be reviewed by an HREC. Out-of-session review of research identified as more than low risk will occur via quorum (refer to HREC SOP 09).

Indigenous Research Advisory Panel (IRAP)

1.35. The Indigenous Research Advisory Panel (IRAP) is a sub-committee of the UTS HRECs. The IRAP has been constituted to review applications and provide specific advice to researchers proposing to conduct research with and/or pertaining to Aboriginal and Torres Strait Islander peoples. The UTS Indigenous Research Committee (IRC) endorsed the establishment of the Panel at its October 2013 meeting.

1.36. Record keeping and reporting, as well as complaints handling, will be managed at the HREC level in accordance with the UTS HRECs and IRAP TOR.

Communication with researchers

1.37. Informal communication with researchers is encouraged. The HRECs and Ethics Secretariat offer a range of informal communication options including scheduled clinics and face-to-face meetings to resolve issues about research proposals that have not been resolved by written or telephone communication alone.

HREC 02: HREC Composition

2.1. The membership of the HRECs is in accordance with the National Statement. Minimum membership comprises eight members. As far as possible, the HREC will be gender diverse and at least one third of the members are external to the institution for which the HREC is reviewing research. The membership comprises representatives from the following categories:

a) a chairperson, with suitable experience, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National

Statement;

b) at least two lay people, who have no paid affiliation with the institution and do not currently engage in medical, scientific, legal or academic work;

c) at least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional;

d) at least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, community leader, a chaplain, a minister of religion;

e) at least one lawyer, where possible one who is not engaged to advise the institution; and

f) at least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant expertise.

2.2. To ensure the HRECs are equipped to address all the relevant considerations arising from the categories of research, some or all of the above membership categories may be represented by more than one person.

2.3. No member is appointed in more than one of the membership categories.

2.4. The HRECs are free to consult person(s) considered by the HRECs to be qualified to advise and assist in reviewing applications provided that there is no conflict of interest and an undertaking of confidentiality is given. Such person(s) are not entitled to vote on any matter.

2.5. The HRECs may have ancillary members in addition to the categories above which can be invited to meetings for specific expertise, additional membership to meet quorum or to ensure consistency across faculty review.

2.6. Observers are invited to attend the meeting at the discretion of the HREC Chairperson (refer to HREC SOP 12.4). Observers sign a declaration of interest and confidentiality statement prior to observing.

HREC 03: Appointment of members

3.1. HREC members are recruited by direct approach, nomination or by advertisement through an open and transparent process.

3.2. Prospective members may be invited to observe a meeting of the HREC.

3.3. Prospective members are asked to provide a copy of their curriculum vitae to a selection committee comprising the Chairperson and Manager, Research Ethics (or delegate). The selection committee interviews prospective members, consults with HREC membersand makes a recommendation on new appointments to the Deputy Vice Chancellor (Research).

3.4. All members including the Chairpersons and Deputy Chairpersons are appointed by the Deputy Vice-Chancellor (Research), and will receive a letter of appointment including the date of appointment, length of appointment, and responsibilities as an HREC member.

3.5. Members are required to sign a declaration of interest and confidentiality statement ensuring:

a) That all matters of which they become aware during the course of theirwork on the HREC will be kept confidential; and

b) That any conflicts of interest, which exist or may arise during their tenure on the HREC, will be declared;

3.6. Members are appointed for an initial period of one year. Thereafter, members may be appointed for a further two year term, and may then be re-appointed for a consecutive 3 year term. All appointments are renewable at the discretion of the Ethics Secretariat and the Deputy Vice-Chancellor (Research).

3.7. Members are required to attend at least 75% of the meetings held during each year of their appointment alongside the provision of written comments on the majority of the ethics applications being reviewed.

3.8. The appointment of any member of the HREC may be terminated if the Deputy Vice-Chancellor (Research) or their delegate is of the opinion that:

a) It is necessary for the proper and effective functioning of the HREC;

b) The person is not a fit and proper person to serve on an HREC; or

c) The person has failed to carry out their duties as an HREC member as agreed to in the terms of reference (TOR).

3.9. Lay members and non-institutional members will be reimbursed honoraria per meeting for their travel costs.

HREC 04: Orientation and training of members

4.1. A formal induction session and support will be provided to all new members in accordance with the requirements of the National Statement.

4.2. Each member is expected to become familiar with the Australian Code for the Responsible Conduct of Research (the Code), the National Statement, and ICH Good Clinical Practice (MREC), and to have sincere and strong commitment to upholding these documents.

4.3. During their membership on the HRECs, members will be provided with opportunities to attend training and professional development relevant to their work on the committee.

HREC 05: Meeting schedules

5.1. The HRECs meet on a regular basis monthly (with the exception of January) usually 11 times per year.

5.2. The schedule of meeting dates and submission deadlines are made available on the UTS Ethics SharePoint and shared with the HREC over email when finalised.

5.3. The Chairperson, in initial consultation with the Ethics Secretariat, may recommend the cancellation or postponement of a scheduled meeting for reasons such as a quorum not being achievable or no applications for review (refer HREC 09).

HREC 06: Agenda

6.1. The Ethics Secretariat prepares an agenda for each HREC meeting.

6.2. The meeting agenda and associated documents are circulated to HREC members at least 10 business days prior to the next meeting.

6.3. Documentation received after the closing date are included on the agenda and/or tabled at the meeting at the discretion of the Ethics Secretariat and/or Chairperson.

6.4. New applications received after the closing date are not tabled at the meeting, unless exceptional circumstances exist, as confirmed by the Chairperson.

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

a) Attendance, quorum, and apologies;

b) Declarations of conflicts of interest relating to agenda items;

c) Confirmation of minutes of the previous HREC meeting;

d) Business arising from the previous minutes;

e) Minutes of meetings and any issues for noting and/or approving from the ERC, subcommittees and external expert reviewers

f) New applications for review and primary reviewer nominated to lead the discussion on each application (and listed secondary reviewer);

g) Requested amendments to existing approvals;

h) Reports of serious adverse events and suspected unexpected serious adverse reactions;

i) Correspondence and other business; and

j) Notification of the date, time and venue of the next scheduled meeting.

6.6. The agenda and all accompanying documentation are regarded as confidential.

HREC 07: Primary and Secondary reviewers

7.1. The HRECs have the discretion to appoint one or more members as Primary or Secondary Reviewers for the HREC meetings for each application.

7.2. Allocation of applications to Primary and Secondary Reviewers is made by the Ethics Secretariat in consultation with the Chairpersons, as necessary.

7.3. The Primary Reviewer undertakes a thorough review of the application, provides detailed comments in the online system (ResearchMaster) and presents at the meeting. The Secondary Reviewer undertakes a thorough review of the application, provides detailed comments in the online system (ResearchMaster) and presents any additional comments at the meeting (i.e., those not covered by the Primary reviewer).

7.4. If for some reason the Primary Reviewer is unavailable to attend the meeting, the Secondary Reviewer will be asked to present at the meeting.

7.5. Members are not expected to provide written comments in the online system (ResearchMaster) for applications on which they are not the assigned Primary or Secondary Reviewer. However, members are expected to provide verbal comment at the meeting on any ethical issues that they identify – particularly those in relation to their membership category (for example – a lay member may identify a concern with informed consent processes that is not immediately apparent to a researcher).

HREC 08: Attendance of the Chief Investigator

8.1. At the request of the HREC Chairperson, the Chief Investigator (CI) may be invited to make a formal presentation or to respond directly to requests from the HREC for further information, clarification or reassurance. The CI may be asked to leave the meeting at the cessation of the presentation, prior to committee discussion of the application.

8.2. Where the CI is unable to attend, a delegate (e.g. co-investigator or collaborator) may be invited to attend, if appropriate. However, representatives of the Sponsor are not to attend the meeting in place of the CI. At the discretion of the HREC Chairperson, additional members of the research team may attend with the CI.

8.3. The CI (or delegate) may attend the meeting to discuss their application either in person or via telephone or videoconference.

HREC 09: 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 attending in person or via telephone or videoconference.

9.2. Where a quorum is not reached, the HREC can commence, continue, or conclude discussion for the purpose of reviewing an application, noting that the minutes of the meeting must be circulated out of session to those categories not in attendance to confirm the outcomes.

9.3. Where there is less than a full attendance of the membership at a meeting, a meeting can commence, continue, or conclude discussion for the purpose of reviewing an application ONLY where the Chairperson is satisfied “that the views of those absent and who belong to the membership have been received and considered” (for instance through prior submission of written comments).

HREC 10: External expert reviewers

10.1. Where an HREC is unable to make a decision on an application and/or when it is without the necessary expertise, it may consult experts in the relevant field/specialist area, as identified by the Chairperson and/or the Manager, Research Ethics.

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

a) Notification is sent to the CI 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 CI of the issues of concern to the HREC, but does not request further information or clarification. In circumstances where expert opinion/review is sought, the CI is also given the option to identify experts to whom they object.

b) A suitable expert reviewer is identified by the Chairperson or Ethics Secretariat or by the HREC during the meeting.

c) The Chairperson or Ethics Secretariat 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 Ethics Secretariat 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 Ethics Secretariat 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, ERC or subcommittee, as appropriate, considers the advice of the expert reviewer and makes an independent decision on the ethical acceptability of the application. The advice is recorded in the minutes.

HREC 11: 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 review or any other matter for consideration at that meeting. Conflicts of interest include financial interests, personal, professional or institutional benefits or advantages that depend significantly on the research outcomes.

11.2. Declarations are made to the Ethics Secretariat and Chairperson either in writing prior to the meeting ororally at the meeting prior to the matter being considered. The HREC determines whether the level of interest results in:

a) A substantial conflict of interest requiring the member to be excluded from the meeting 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 where the member has the discretion to leave during the discussion.

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

HREC 12: Confidentiality

Confidentiality of meetings

12.1. It is essential that HREC proceedings are kept confidential as:

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

b) The HREC must feel able to discuss applications freely; and

c) The intellectual property of applicants needs to be protected, especially where applications have declared commercial implications.

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

12.3. HREC members are obliged to keep applications and related discussions confidential in two ways:

a) Agreement to the HREC TOR; and

b) Members sign a confidentiality agreement 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 and their supporting documentation, including any correspondence, are treated confidentially by the HREC and Ethics Secretariat.

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 CI and sent to the CI or the relevant contact person identified on the application form. Correspondence is released to key researchers as necessary however not released to the Sponsor.

12.8. At their discretion, CI may choose to forward information about matters raised in the ethical review to Sponsors or other parties where necessary.

HREC 13: Decision making

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

13.2. The HREC endeavours to reach a decision concerning the ethical 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 (i.e., consensus).

13.4. Any significant minority view (i.e., two or more members) should be noted in the minutes.

13.5. Where members wish, a record of their formal dissent from the decision of the HREC should be 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 Ethics Secretariat or Chairperson prior to the meeting. Submission of written comments is recorded in the minutes.

HREC 14: HREC Decisions

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 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 subcommittee of HREC members or the Ethics Secretariat (as delegated under Executive approval).

14.4. The HREC Secretariat reports the HREC decision in writing to the CI (and primary contact) within 10 working days of the meeting, unless otherwise notified.

14.5. If the HREC determines that further information, clarification or changes are required for the consideration of a project, the correspondence to the CI clearly articulates the reasons for this determination and outlines the information that is required. Where possible, requests for additional information, clarification and/or changes should refer to the National Statement or relevant pieces of legislation.

14.6. If the requested information is not received from the applicant within 90 days of the letter being sent the project may be withdrawn and the applicant may be required to re-submit the project at a later date.

14.7. The HREC endeavours to openly communicate with researchers to resolve outstanding requests for further information, clarification or changes to projects relating to ethical issues. The HREC may nominate one (or more) of its members to communicate directly with the applicant or by inviting the applicant to attend the relevant HREC meeting.

14.8. If the HREC determines that a project is ethically unacceptable, the notification of the HREC's decision will include the grounds for rejecting the project with reference to the National Statement or other relevant pieces of legislation. HREC member(s) or members of the Ethics Secretariat may be nominated to work with the researcher to assist in re-submission.

HREC 15: Minutes

15.1. The Ethics Secretariat 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, quorum and apologies;

b) Declarations of conflicts of interest relating to agenda items;

c) Confirmation of minutes of the previous HREC meeting;

d) Business arising from the previous minutes(s);

e) Minutes of meetings and any issues for noting and/or approving from the ERC, Ethics Secretariat, subcommittees and external expert reviewers;

f) 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)

g) Requested amendments to existing approvals;

h) Reports of serious adverse events and suspected unexpected serious adverse

reactions;

i) Correspondence and other business; and

j) 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 confirmation as a true and accurate record of the previous meeting. 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 Deputy Vice-Chancellor (Research).

HREC 16: Duration of HREC approval

16.1. HREC approval applies for up to a maximum of five years, subject to annual reporting as required by the National Statement. For ratification, approval will apply for the length of time specified by the Lead HREC.

16.2. The HRECs may, at their discretion, take action to suspend or terminate the decision (refer HREC 19).

16.3. Extension requests may be submitted via an annual report or an amendment application prior to the applications expiry. If expired, the extension can be granted at the discretion of the Chairperson.

16.4. Extension requests are only granted for one year at a time, for a maximum of two extensions (i.e., the project should extend to no longer than 7 years in total).

16.5. If two extensions have already been granted, clear justification will need to be provided by the researcher as to why the project needs a further extension. These requests need to be considered and approved by the Chairperson. If declined, a new application should be submitted.

HREC 17: HREC reporting requirements

17.1. The ratified minutes of each HREC meeting may be forwarded to the Deputy Vice Chancellor (Research).

17.2. The HRECs provide an annual report to the Vice-Chancellor and Deputy Vice-Chancellor (Research) 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/activities including the provision of advice and training for professional staff, academics, students, and committee members as well as new initiatives and improvements; and

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

17.3 The HRECs shall produce an Annual Report for Human Research Ethics Committees (HRECs) in accordance with the requirements of the National Health and Medical Research Council (NHMRC), and any other reports as required on behalf of UTS.

HREC 18: Clinical Trials

18.1. UTS adopts the World Health Organisation (WHO) definition of clinical trial: 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'.

18.2. The UTS MREC will review clinical trial applications in line with the requirements of the Integrated Addendum to E6(R1): *Guideline for Good Clinical Practice*, and *Safety monitoring and reporting in clinical trials involving therapeutic goods,* or any replacement or amendment thereof.

18.3. Where UTS is involved in a multi-centre clinical trial as a trial site (i.e., where a UTS staff member is a Site Principal Investigator or is part of a Collaborative Research Group or Cooperative Trials Group), the ethics approval process should be performed by a Lead HREC under National Mutual Acceptance and/or an HREC certified under the National Certification Scheme. Once this approval has been received, a subsequent application for ratification must be submitted to the UTS MREC.

18.4. In Australia, clinical trials involving unapproved therapeutic goods or new uses of a therapeutic good must be approved under one of the following schemes[1]:

- Clinical Trial Notification (CTN) scheme (i.e., generally for earlier phase studies ifthere is adequate preclinical information available, especially regarding safety)
- Clinical Trial Approval (CTA) scheme (i.e., generally for high risk or novel treatments, such as gene therapy, where there is no or limited knowledge of safety)

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

[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.

HREC 19: Suspension or withdrawal of HREC approval

19.1. The HREC will suspend ethical approval if satisfied that a research project is not, or cannot be, conducted in accordance with the approval granted and/or that the rights, safety or welfare of participants may be compromised. Suspension can relate to some or all project activities. Certain aspects of the protocol may be permitted to continue to ensure participant safety even where a project is suspended, for example, ongoing collection of safety data, administration of study drug or study procedures that are not related to the reason/s for suspension. At a minimum, suspension will involve cessation of participant recruitment. The HREC will specify what aspects of the project will cease, as well as when, and under what circumstances, activities may recommence.

19.2. Where the HREC suspends ethical approval, the CI will be notified in writing within 3 working days of the decision to suspend, unless immediate notification is required for urgent safety reasons.

19.3. Upon suspension, the HREC Chairperson, the Manager, Research Ethics, and other nominated members of the HREC, will investigate the conduct of the project and compile a report for consideration by the full HREC and the CI.

19.4. The CI will be requested to respond to the report.

19.5. The full HREC will consider the response of the CI to the report and decide on the conditions for reinstatement of approval or whether approval will bewithdrawn.

19.6. The HREC will notify the CI of its decision.

19.7. An investigator will discontinue research following suspension or withdrawal of ethical and scientific approval and will comply with the special conditions imposed by the HREC.

19.8. As required by the National Statement, any other HRECs involved in the project will be notified of the suspension or withdrawal of HREC approval. Additionally, the HREC has the discretion to notify other Investigators and/or participants as deemed appropriate.

HREC 20: Appeals and complaints

Appeals regarding HREC rejection of an application

20.1. Where the HREC has rejected an application, the investigator has the options to:

a) Submit a new application to the HREC taking due account of the HREC's concerns. This will be processed and reviewed in the same way as any other new application; or

b) Lodge an appeal with the HREC Chairperson specifying the grounds of the appeal in writing. The Chairperson will investigate the appeal and its validity and recommend to the HREC an appropriate course of action at the following meeting of the HREC.

20.2. The HREC will notify the appellant of the course of action and determination in a timely manner.

20.3. If the appellant is not satisfied with the outcome, they will have the discretion to refer the appeal to the Director, Research Office.

Complaints about the HREC's review process

20.4. A complaint about the HREC's review process will be directed to the attention of the Chairperson of the HREC, detailing the grounds of the complaint. If first submitted to the Ethics Secretariat, the complaint will be referred to the Chairperson.

20.5. The Chairperson with support from the Ethics Secretariat will investigate the complaint and its validity and recommend to the HREC an appropriate course of action. The HREC will notify the complainant of the course of action and determination in a timely manner.

20.6. If the complainant is not satisfied with the outcome, they will have the discretion to refer the complaint to the Director, Research Office.

Complaints about the conduct of an approved research project

20.7. Any concern or complaint about the ethical conduct of a research project will be directed to the Manager, Research Ethics.

20.8. Concerns or complaints from internal and external stakeholders received by email, telephone or in a face-to-face conversation will be recorded by the Manager, Research Ethics and kept in a designated file in Content Manager.

20.9. The Manager, Research Ethics will acknowledge receipt of the complaint and undertake a preliminary assessment regarding the issues raised by the complainant.

20.10. The HREC Chair will be notified about the complaint and the results of the preliminary assessment and if necessary will provide advice about the appropriate resolution of the concern or complaint.

20.11. Where a resolution is established from the consultation with appropriate stakeholders the complainant will be notified by the Manager, Research Ethics. The correspondence will be recorded into Content Manager.

20.12. Complaints relating to the ethical approval of a research project will be notified to

the UTS HREC.

20.13. Where the preliminary investigation finds that the complaint may also represent a breach of the *Australian Code for the Responsible Conduct of Research*, the Manager, ResearchEthics will refer it to the Assessment Officer who will take responsibility for assessing if a potential breach of the Code has occurred via the process detailed in the UTS Research Policy.

20.14. The outcome of assessment of the complaint will be reported back to the HREC chair, complainant and/ or other appropriate funding bodies if require.

20.15. The Chair and the HREC shall endorse the resolution of complaints relating to the ethical approval of a research project.

20.16. The complaint, and its resolution, will be notified to the Director, Research Office, the HREC, and the Faculty's Associate Dean (Research), and the Head of School. The Manager, Research Ethics will inform the complainant and the respondent of the outcome.

20.17. In exceptional cases, the HREC Chair, Deputy Chair or Manager, Research Ethics may place an immediate suspension on a project upon receipt of a complaint. The researcher will be notified immediately if this occurs.

20.18. If the complainant is not satisfied with the outcome, they will have the discretion to refer the complaint to the Director, Research Office.