Deakin University Human Research Ethics Committee (DUHREC) TERMS OF REFERENCE

PURPOSE

DUHREC is responsible to the Deputy Vice-Chancellor Research and Innovation (DVCRI) for the ethics review of human research projects under the terms of the <u>National Statement on Ethical Conduct in Human Research 2023</u> (the National Statement).

SCOPE OF RESPONSIBILITY

1. DUHREC will provide ethics review and/or monitoring for human research applications conducted by Deakin University staff and students as described in the Human Research Ethics Procedure (section 11), and as per the National Statement (NS) Chapter 2.1: Introduction, 5.1.11. This includes projects that may be conducted at another site and/or involve research collaborators external to the University. Where Deakin staff or students intend to conduct lower risk human research, i.e. research in which there is no risk of harm (NS page 110, HEAG Terms of Reference item 5), they should submit a lower risk application for review by the Human Ethics Advisory Group (HEAG). This aligns with NS 5.1.12, the Human Research Ethics Procedure sections 13-14 and the HEAG Terms of Reference.

COMPOSITION OF DUHREC

- 2. DUHREC consists of three panels, one in Geelong (Waurn Ponds campus), and two in Melbourne (one at the Burwood campus and the other at Deakin Downtown). All panels are fully constituted HRECs as required by the NS 5.1.24 5.1.28. Minimum membership of each panel is set out in the NS 5.1.30. Each panel of DUHREC minimally includes:
 - a. Chair/Deputy Chair, who should be from different faculties, or at least not from the same School or Institute.
 - b. at least two community/consumer members who have no paid affiliation with the University.
 - c. at least one person with knowledge of, and current experience in, the professional care, counselling, or treatment of people.
 - d. at least one person who performs a pastoral care role in a community including an Aboriginal and/or Torres Strait Islander elder or community leader, a chaplain or a minister of religion or other religious leader.
 - e. at least one lawyer, who may or may not be currently practicing and where possible is not engaged to advise the institution on research-related or other matters.
 - f. at least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend.

DUHREC MEETINGS

- 3. At least one Adviser from the Research Ethics (HRE) team will have a standing invitation to attend DUHREC meetings with right of audience and debate.
- 4. Where possible, each panel will include at least one researcher from each of Deakin's four faculties (Arts & Education; Business & Law; Health; Science, Engineering & Built Environment) or a researcher with expertise in the areas of research undertaken in the faculties.
- 5. The HEAG Chairs will be members of DUHREC, on the panel of their choice.
- 6. Where the panel does not include a member who is an Indigenous person, a reviewer with relevant experience will be appointed to review research involving Aboriginal and Torres Strait Islander people or issues.

- 7. Additional members may be co-opted by the Committee from time to time for particular purposes and specified periods. The University may access a pool of appointed HREC members as needed (NS 5.1.34 a & b) to ensure minimum membership and/or to access expertise.
- 8. Minimum membership can be confirmed once applications for the upcoming DUHREC meeting have been reviewed. The Chair will then confirm at the beginning of the meeting, that the views of any absent members have been received and considered.
- 9. The Research Ethics team will provide administrative support to DUHREC including the preparation of meeting agendas, minutes and post meeting outcomes to Deakin researchers.
- 10. Researchers may be invited to attend a DUHREC meeting to respond to significant concerns about their application. Invitations are only extended under certain circumstances e.g., where there are exceptionally tight timelines or concerns that require direct discussion between the committee and researchers.

FUNCTIONS

- 11. To consider the ethical implications of proposed human research projects, and to determine whether the projects comply with the NS and other relevant guidelines e.g. the <u>Australian Code for the Responsible Conduct of Research</u>, 2018 (the Code) and legislation e.g. Privacy Act 1988 and are ethically acceptable. In assessing Clinical Trials, DUHREC operates in line with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), Australian Clinical Trial Handbook (Aug 2021) and all subsequent updates, and applicable Australian and Victorian legislation/guidelines.
- 12. To monitor the progress and continued ethical feasibility of approved human research projects.
- 13. To manage adverse incidents, events, or reactions arising from approved human research projects in accordance with the <u>Human Research Ethics Procedure</u>.
- 14. To manage allegations of research code breaches related to human research that raise ethical concerns or involve the ethical review process in accordance with the Human Ethics Breach Process.
- 15. To provide reports on DUHREC's operations as required annually by the NHMRC, the Health Complaints Commissioner or other duly appointed authorities.
- 16. To report at least annually to the DVCRI and Research & Research Training Committee (RRTC) on DUHREC's activities.
- 17. To provide oversight, leadership, and support to the HEAG Chairs.

HREC DECISIONS

- 18. Each member of DUHREC is responsible for deciding whether, in their judgement, a proposal submitted to DUHREC meets the requirements of the NS and is ethically acceptable. To fulfil that responsibility each member should:
 - a. become familiar with the NS and consult other guidelines e.g. the Code and legislation e.g. Privacy Act, relevant to the review of specific research proposals.
 - b. prepare for and attend scheduled meetings of the review body or, if unavailable, provide their review on the ethical acceptability of research applications ahead of the scheduled meeting.
- 19. Decisions should be made on the basis of consensus and on a thorough, fair and inclusive process of discussion and deliberation by DUHREC members. Where consensus cannot be

reached after reasonable efforts to resolve differences, DUHREC may proceed with a majority decision.

- 20. After reviewing an application, DUHREC may recommend:
 - a. Approval;
 - b. Approval subject to amendments/clarifications;
 - c. Resubmission, i.e. a new research proposal is required due to the extensive nature of amendments, or to
 - d. Reject a research application.
- 21. Decisions of DUHREC must be clearly communicated to researchers as promptly as possible and include reasons for its decision. Where relevant, reference to the NS should be included, for instance where an application is judged not to be compliant with a section of the guidelines.

DUHREC DOCUMENTATION/RECORD KEEPING

- 22. DUHREC will comply with the NS requirements for documentation and record keeping (NS 5.2.15-5.2.20).
- 23. Discussions and decisions of DUHREC meetings will be documented as minutes by the Research Ethics team. Minutes of meetings will be confirmed by the Chair within 7 days. The Chair and/or Deputy Chair will be provided the opportunity to review post meeting responses before they are sent to researchers. Minutes will be confirmed at the next meeting of the applicable DUHREC panel and will be noted by the alternative panels.

DUHREC EXECUTIVE

24. DUHREC has established an Executive Committee that consists of at least one DUHREC Chair/Deputy Chair and one member of the Research Ethics team. The DUHREC Chair/Deputy Chair may invite or delegate responsibility to others with relevant experience, including DUHREC members.

The DUHREC Executive Committee may be delegated to assess and address matters out of session including:

- a. Assessment of adverse incidents, events or reactions in accordance with the <u>Human</u> <u>Research Ethics Procedure</u>.
- b. Review of allegations of research code breaches in accordance with the terms of the Human Ethics Breach Process .
- c. Provision of guidance and assistance with ethical decision making regarding the handling of complaints related to human research conducted by Deakin staff or students as outlined in the Complaints Handling process.
- d. Approval of modifications and transfers of projects to Deakin.
- e. New applications requiring expedited review, in exceptional circumstances only.
- 25. Out of session decisions by the DUHREC Executive will be ratified by DUHREC at the next committee meeting (NS 5.2.9, 5.2.10).

REQUIREMENTS OF MEMBERSHIP

- 26. The DUHREC Chair and Deputy Chairs are appointed by the DVCRI or nominee for 2 years following an expression of interest process relating to a position description. The DVCRI may appoint a Chair and 2 Deputy Chairs. The Deputy Chairs will provide support to the DUHREC Chair e.g. by chairing DUHREC meetings, attending DUHREC Executive and Ethics Chairs meetings and undertaking other duties as required, for instance when the Chair is absent/on leave. DUHREC Chairs may nominate the DUHREC panel meetings they will chair during their appointment.
- 27. In the event that the Chair/Deputy Chair of DUHREC resigns prior to the appointment of a replacement Chair/Deputy Chair, the DVCRI or nominee may request that the Deputy Chair or a Deakin University DUHREC Terms of Reference

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- current DUHREC member become Acting Chair/Acting Deputy Chair, until such time that a formal appointment process can be undertaken.
- 28. Members are appointed by the DVCRI or nominee and will be interviewed by the DUHREC Chair or Deputy Chair, supported where possible by an Ethics Adviser. The usual term of appointment is 2 years, and members are eligible for reappointment for a maximum of three terms, or longer at the discretion of the DVCRI.
- 29. Members are asked to notify the Research Ethics team in advance if they are unavailable to review applications and/or attend meetings due to planned absence/leave.
- 30. Members must declare any perceived, potential, or actual conflicts of interest at the start of each committee meeting. For DUHREC decision making, members with a conflict of interest must withdraw from the meeting on matters that relate to an actual conflict of interest and may be required to withdraw on matters that relate to a perceived or potential conflict at the discretion of the Chair/Deputy Chair.
- 31. Members must agree in writing to maintain the confidentiality of all DUHREC proceedings.
- 32. All members are required to attend continuing education or training in human research ethics (NS 5.1.26 c i, ii) at least every three years, for example attending DUHREC Induction training (prior to commencing reviewing), attending Victorian Ethics Network (VEN) seminar/s, attending in-meeting training provided by an Ethics Adviser.
- 33. Members may be asked to leave DUHREC by the DVCRI on the recommendation of the Chair or Deputy Chair.
- 34. Members may resign from DUHREC by notifying the Chair or Research Ethics Office in writing.

REMUNERATION OF EXTERNAL MEMBERS

35. Members who are external to the University will be provided with an annual honorarium in recognition of their service.

RELATIONSHIP TO OTHER RESEARCH REVIEW PROCESSES

- 36. DUHREC will have oversight of the ethics review process of the HEAG and provide advice on the recruitment of the HEAG Chair and Deputy Chair who are appointed by the DVCRI. Selection panels for HEAG Chair and Deputy Chair should include the DUHREC Chair/Deputy Chair, a member of the Research Ethics Office and a faculty representative (e.g., faculty Executive Dean/Associate Dean Research). The DUHREC Executive Committee is responsible for auditing the HEAG at least every five years, or sooner if required. Audits will determine whether:
 - a. No more than lower risk research is reviewed by the HEAG (see NS Chapter 2.1, 5.1.11) and
 - b. The work of the HEAG is otherwise compliant with the requirements of the NS.
 - c. Audits may result in directives or recommended actions.
- 37. DUHREC will only review projects involving participant exposure to ionising radiation after approval has been granted by the Deakin Radiation Safety Officer.

Effective Date: 28 February 2024