**Terms of Reference October 2017**

### ALBURY WODONGA HUMAN RESEARCH ETHICS COMMITTEE

### (AWHREC)

**Role:**

The Albury Wodonga Human Research Ethics Committee (AWHREC) reviews pursuant to the national statement research projects involving humans undertaken at Albury Wodonga Health (AWH), related health providers and practitioners, students at local universities and other institutions in Southern New South Wales and North-East Victoria.

**Objectives:**

* The AWHREC primary role is to protect the welfare and the rights of participants in research in compliance with the National Statement on Ethical Conduct of Research involving Humans and relevant provisions of State and Federal Privacy legislation.
* The AWHREC can approve, require amendment of, or reject a research submission.
* Decisions by the AWHREC should ideally be reached by consensus. An extension of time may be required for reconsideration of any proposal and its possible amendment.
* The AWHREC may request advice and assistance from experts to assist with consideration of a research submission. The Chairperson must be satisfied that experts assisting in the manner have no conflict of interest in the research.
* The Chairperson must be satisfied that no member of the committee has a conflict of interest on a research application before the committee.
* The AWHREC should not communicate directly with a research sponsor except regarding insurance, administration and indemnity.
* The AWHREC will endeavour to reach a decision concerning a proposal by unanimous agreement. Any significant minority view will be noted in the minutes.
* The AWHREC will issue advice of its views in writing to the applicant.

**Applications:**

* All applications to the committee must be submitted to the AWHREC by the relevant closing date, in writing, in the format required by the National Statement and include such additional documentation as the AWHREC may specify.
* All documents and other materials intended to inform participants of the research must be approved by the AWHREC.
* Approved submissions may be required to follow conditions imposed by AWHREC.
* Special or urgent applications may be submitted to the AWHREC for expedited review, subject always to the discretion of the Committee and Chair.

**Accountability and Reporting:**

* The activities of the AWHREC are subject to audit by the National Health and Medical Research Council (NHMRC), through the Australian Health Ethics Committee (AHEC), to ensure compliance with the National Statement on Ethical Conduct in Research Involving Humans.
* The AWHREC will report information relevant to its procedures annually to the NHMRC as required, including when necessary:
* Membership / membership changes.
* Number of meetings.
* Confirmation of participation by required categories of members.
* The number of protocols presented, the number approved, and the number rejected.
* Monitoring procedures in place and any problems encountered.
* Complaints procedures and the number of complaints handled.
* The AWHREC will maintain records or applications including:
* Name of responsible organisation.
* Project identification numbers.
* Principal researcher.
* Title of project.
* Ethical approval or non- approval and date.
* Conditions of any approval.
* Whether approval was by expedited review.
* Whether the opinion of another Human Research Ethics Committee (HREC) was considered.
* Action taken by the AWHREC to monitor conduct of the research.
* The relevance, if any, of the *Guidelines for the Protection of Privacy in the Conduct of Medical Research*.
* The AWHREC will also retain in file a copy, either hard copy and/or electronic of each proposal and application for approval including any information sheets and consent forms or relevant correspondence

**Post Assessment Responsibilities:**

* It is the responsibility of the applicant to adhere to any conditions applying to approved submissions. Details of these conditions will be provided within the approval letter.

**Complaints:**

* Complaints directed to the AWHREC will be acknowledged promptly in writing.
* Complaints against the AWHREC or researcher will be handled according to the complaints procedure.

**Suspension or Discontinuation of Research**

* The AWHREC may withdraw approval for research at any time if it believes the approved protocol is not being followed.
* Written withdrawal of approval must be notified to the researcher, clearly stating the reason for withdrawal of approval and the research should be suspended or discontinued immediately unless appealed.
* Researchers have 14 days to appeal the decision of the AWHREC.
* The appeal will be referred to the Ethics committee of another comparable institution for adjudication. Both the committee and the researcher will approve the choice of the arbitrating institution.

**Mode of Operation:**

The AWHREC will perform its functions according to its Terms of Reference and any other written policies and procedures. The procedures will be reviewed periodically and amended and updated as necessary. All committee members will have access to/or be provided with copies of the procedures

**Membership:**

* Minimum membership of the committee numbers eight, preferably with equal representation of the sexes. The core membership comprises:
* A chairperson who is not from one of the other required categories.
* At least two members who are lay people, who have no affiliation with the institution or organisation, are not currently involved in medical, scientific, or legal work, and who are preferably from the community in which the institution or organisation is located.
* At least one member with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC (eg: health, medical, social, psychological, epidemiological, as appropriate).
* At least one member with knowledge of, and current experience in, the professional care, counselling or treatment of people (eg: Medical Practitioner, Clinical Psychologist, Social Worker, nurse, as appropriate).
* At least one member who is a minister of religion, or such a person who performs a similar role in the community such as an Aboriginal elder.
* At least one member who is a lawyer.
* AWHREC members are appointed for a period of up to three years but with no limitation upon the number of terms for which a member may be appointed. Terms and categories of committee members are to be regularly reviewed to ensure that they meet the statutory requirements.
* The AWHREC will provide legal protection in respect of liabilities that may arise during bona fide conduct of the duties of committee members.
* AWHREC membership is a volunteer appointment and remuneration will not be considered.
* The Chairperson will be appointed by the committee. In the absence of the Chairperson, the alternate Chairperson will perform the roles and duties of the Chairperson.
* Administrative duties will be arranged by AWH.

**Quorum:**

* The AWHREC will have a minimum of eight members and composed according to the National Statement on Ethical Conduct of Research involving Humans.
* A quorum must be present for the AWHREC to reach any final decision. A quorum shall be five members. Where there is less than full attendance at a meeting, the Chairperson must be satisfied, before a decision is reached that the minimum membership have received all papers and have had the opportunity to contribute their views. These views are to be recorded and considered.
* A researcher maybe invited to present their proposals to the AWHREC.

**Meeting Frequency:**

* AWHREC meetings will be held at least six (6) times annually.

**Any Required Standing Agenda Items:**

Item 4: Conflicts of Interest.

Any Committee member having a conflict of interest with any research application will be required to disclose that at the meeting.

**Frequency for Review of Committee Performance and Terms of Reference:**

Usually annual.

**Agenda / Minutes:**

* Agendas and minutes and associated papers to the next meeting, will be circulated at least one week prior to the scheduled date of the meeting.

**Annexes:**

**Related AWH Documents:**

**Accreditation Standards:**

**Other Relevant Information:** National Statement on Ethical Conduct in Human Research 2007

(Updated March 2014)

**References:**

**Contact Point:**  AWHREC.

**In consultation with:**

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| **TITLE / POSITION** |
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| THIS SECTION FOR QUALITY & CLINICAL GOVERNANCE OFFICE USE ONLY | | |
| **Approved by Executive / Delegate:** | **Date Approved:** | **SharePoint Location:** |
| AWHREC |  | Pending… |
| **Responsible Department:** | **Date for Review:** | **Linked Documents:** |
| AWHREC |  |  |
| **Version No:** | **Original Approval Date:** | **Previously Named As:** |
| 2 | 24 February 2015 |  |