ANZCCM
The Australian & New Zealand College of Cannabinoid Medicine

The Australian and New Zealand College of Cannabinoid Medicine Human Research Ethics Committee

TERMS OF REFERENCE (TOR)

1. Background

1.1 *The Australian and New Zealand College of Cannabinoid Medicine (ANZCCM)* Human Research Ethics Committee (HREC) has been established by ANZCCM in exercise of its commitment to the conduct of human research according to the highest scientific and ethical standards.

1.2 The ANZCCM HREC is established by the Board of Directors of ANZCCM in the exercise of its power to control and manage the affairs of the College, and not by way of delegation of a function of the Board. The HREC exercises the functions detailed in these Terms of Reference. The Board may appoint to the HREC such persons, whether or not they are members of ANZCCM, as are required to satisfy the minimum membership prescribed by the National Statement.

1.3 The Board of Directors may, consider, recommend and implement changes to the structure and operations of the ANZCCM HRECs including dissolution, streamlining, re-configuration and establishment as deemed appropriate from time to time, provided that any changes do not compromise the capacity of the HREC to meet all relevant standards and procedures.

1.4 The duly constituted ANZCCM HREC shall operate in accordance with these TOR as amended from time to time.

2. What is human research?

2.1 From the National Health and Medical Research Council (NHMRC) National Statement on Ethical Conduct in Human Research (National Statement), as in force from time to time, human research is described as research conducted with or about people or their data or tissue. There is no generally agreed definition but human research can be understood broadly to include the involvement of human beings through:

- taking part in surveys, interviews or focus groups;
- undergoing psychological, physiological or medical testing or treatment;
- being observed by researchers;
- researchers having access to people's personal documents or other material;
- the collection and use of their body organs, tissues or fluids or exhaled breath;

The Australian and New Zealand College of Cannabinoid Medicine Inc.
192A Great Western Highway
Hazelbrook NSW 2779
ANZCCM HREC email: HREC@anzccp.org P: 0426237212

- access to people's information, in individually identifiable, re-identifiable or non-identifiable form, as part of an existing published or unpublished source or database

3. Roles and responsibilities

3.1 The HREC has been established to conduct scientific and ethical reviews of:

3.1.1 proposals for human research to be undertaken at or under the guidance of ANZCCM; and

3.1.2 proposals for human research received by the HREC in the performing of its function as an HREC within the streamlined ethical review of multi-site research; and

3.1.3 proposals for human research received by the HREC in the performance of review processes accepted for the purposes of any other system designed to eliminate unnecessary duplication of ethics review of human research.

3.1.4 Medical practitioners' Authorised Prescriber applications 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), in accordance with the Therapeutic Goods Act 1989, Therapeutic Goods Regulations 1990 and Therapeutic Goods (Medical Devices) Regulations 2002 and if approved, to provide the medical practitioner with a letter of endorsement from the HREC. The assessment process is detailed in the Standard Operating Procedures (SOP) document, section 9.

3.2 The role of ANZCCM HREC shall be to:

3.2.1 promote ethical, high-quality human research and this includes:

i. ensuring participants be accorded the respect and protection that is due to them, and
ii. fostering research that is of benefit to the community.

3.2.2 Ensure that the design and conduct of any human research that it reviews within the scope of its responsibilities conforms with the National Statement (as in force from time to time) and also with the ethical standards that ANZCCM is committed to.

3.2.3 Ensure that participants in any human research that the ANZCCM HREC reviews and approves are accorded the respect and protection

The Australian and New Zealand College of Cannabinoid Medicine Inc.
192A Great Western Highway
Hazelbrook NSW 2779
ANZCCM HREC email: HREC@anzccp.org P: 0426237212

that is due to them.

3.2.4 Ensure that any decision it makes complies with relevant Australian laws.

3.3 The HREC is accountable to the ANZCCM Board of Directors for the exercise of its functions and the fulfilment of its roles, save that the Board must not direct the HREC as to the outcome of any individual review.

3.4 The HREC, through the Chair, may at any time bring to the attention of the ANZCCM president and board any issues of significant concern that merit prompt consideration and attention.

3.5 The HREC will establish an Executive Committee comprising at least the Chair or Deputy Chair, the HREC administrator, and two members of the HREC, one of which must have experience in research.

3.6 The ANZCCM HREC may delegate to the HREC Executive and HREC Administrator any of its powers and functions which are capable of being delegated in order to assist in the expeditious ethical review of a research proposal.

3.6.1 The ANZCCM HREC delegates to the HREC Executive the authority to review and approve low and negligible risk research projects. Any decisions of the HREC Executive will be ratified at the next HREC meeting.

3.6.2 The HREC Executive will undertake expedited review of business that does not require full HREC Review, including:

i. minor amendments to current HREC approved projects;
ii. responses to HREC queries, as approved by the full HREC for Executive review and approval.

4. Functions of ANZCCM HREC

4.1 In fulfilling these roles, the ANZCCM HREC will:

4.1.1 conduct ethical and scientific review of research projects in a timely fashion and ensure that the proposed research project strikes an appropriate balance between protecting the rights and wellbeing of research participants and facilitating research;

4.1.2 operate and act at all times in accordance with the National Statement and other relevant NHMRC guidelines and legislation as amended from time to time;

The Australian and New Zealand College of Cannabinoid Medicine Inc.
192A Great Western Highway
Hazelbrook NSW 2779
ANZCCM HREC email: HREC@anzccp.org P: 0426237212

4.1.3 decide whether participants in all reviewed and approved human research projects will be accorded the protection and respect that is due to them;

4.1.4 ensure that they are sufficiently informed on all aspects of a research proposal, including its scientific and statistical validity, before deciding whether a proposal is both acceptable on ethical grounds and conforms with the National Statement;

4.1.5 receive advice and reports including from expert reviewers to assist in determining if a research project is acceptable on ethical grounds and meets all necessary scientific, legal, insurance and regulatory requirements;

4.1.6 determine, in relation to each reviewed and approved research project, that there will be mechanisms to monitor the conduct of the research and that the frequency and type of those mechanisms reflect the degree of risk to participants;

4.1.7 advise ANZCCM and researcher applicants whether or not reviewed research proposals meet relevant ethical standards and have or have not been approved and provide reasons;

4.1.8 monitor approved research projects;

4.1.9 provide an avenue for handling queries and complaints in relation to approved research projects;

4.1.10 submit a report of its activities on an annual basis to the Board of ANZCCM;

4.1.11 have the authority to delegate to a subcommittee any of its powers and functions that are capable of being delegated in order to assist in the expeditious and effective ethical review of research proposals. The HREC will remain responsible and accountable for the activities and recommendations of any subcommittees;

4.1.12 consider issues referred by the Board of Directors of the ANZCCM and, where appropriate, provide advice to the Board of Directors especially on policy issues with ethical implications;

4.1.13 provide a forum in which staff, patient, carer and/or student concerns regarding ethical issues in research can be considered and investigated; and

The Australian and New Zealand College of Cannabinoid Medicine Inc.
192A Great Western Highway
Hazelbrook NSW 2779
ANZCCM HREC email: HREC@anzccp.org P: 0426237212

4.1.14 promote a deeper understanding of ethical issues related to research within ANZCCM through educational activities.

5. Membership

5.1 ANZCCM HREC shall be constituted as prescribed by the National Statement and will include at least eight (8) members, namely:

5.1.1 a Chairperson, appointed by the ANZCCM Board of Directors, with suitable experience including previous membership of an HREC, whose other responsibilities will not impair the HREC's capacity to carry out its obligations under the National Statement;

5.1.2 at least two (2) members of the public, who bring a broad community or consumer perspective and who have no paid affiliation with ANZCCM;

5.1.3 at least two (2) members with knowledge of, and current experience in, the areas of research that are regularly considered by the HREC;

5.1.4 at least one (1) member with knowledge of, and current experience in, the professional care or treatment of people; for example, a nurse, counsellor or allied health professional;

5.1.5 at least one (1) member who performs a pastoral care role in a community including, but not limited to, an Aboriginal and/or Torres Strait Islander elder or community leader, a chaplain or a minister of religion or other religious leader;

5.1.6 at least one (1) member who is a lawyer.

5.2 Additional members may be appointed as required from time to time to assist in ethical decision-making. These will be additional to the minimum membership requirements as described in section 5.1.

5.3 The Board of Directors will ensure that wherever possible, one or more members of the HREC should be experienced in reflecting on and analysing ethical decision-making.

5.4 ANZCCM may recruit members for an HREC in such manner and shall appoint them for such a period and on such terms and conditions as it determines, however in ordinary circumstances:

The Australian and New Zealand College of Cannabinoid Medicine Inc.
192A Great Western Highway
Hazelbrook NSW 2779
ANZCCM HREC email: HREC@anzccp.org P: 0426237212

5.5 ANZCCM will adopt open and transparent processes including advertising for applications for membership and making appointments of members.

5.6 Members will receive a formal notice of appointment. The notice of appointment is to include an outline of (1) responsibilities including participation, training, confidentiality, disclosure of interests; (2) the category/categories of membership; (3) term of appointment; (4) remuneration/benefits; and (5) legal protection assurance.

5.7 The term of office shall be three (3) years, with the option for renewal of membership by the Board of Directors.

5.8 ANZCCM shall appoint HREC members for their expertise and not in a representative capacity.

5.9 ANZCCM may add to the membership such other persons as is necessary to ensure that the HREC has access to the expertise necessary to enable it to address the ethical issues arising from the categories of research it is likely to consider.

5.10 Members will receive formal communication of their appointment to the HREC from the ANZCCM Board of Directors.

5.10.1 Members may resign their membership by written notice to the HREC administrator.

6. Standing arrangements

6.1 As far as possible, each HREC meeting should be arranged to enable at least one member in each category to attend. The quorum for a meeting of the ANZCCM HREC is at least one member from each of the categories of the minimum membership prescribed by the National Statement, as in force from time to time, attending in person or via telephone, videoconference or other electronic means. A member attending by electronic means is counted as in attendance. In order for the meeting to proceed the Chairperson needs to be 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. Where a quorum is not reached and the Chairperson is not satisfied that the views of absent members of the minimum membership have been received and considered, the meeting will be adjourned to another date.

6.2 The Secretary will circulate an agenda and meetings papers at least five working days before the meeting.

The Australian and New Zealand College of Cannabinoid Medicine Inc.
192A Great Western Highway
Hazelbrook NSW 2779
ANZCCM HREC email: HREC@anzccp.org P: 0426237212

6.3 Conduct of meetings

6.3.1 The Chair shall conduct the meeting according to the standing orders; ensure order is maintained, and give members an opportunity to speak and vote on matters tabled at the meeting.

6.3.2 The order of business shall follow the agenda unless agreed otherwise.

6.3.3 Matters for discussion or to move a motion must be on the agenda and seconded, unless otherwise approved.

6.3.4 Decisions at meetings must be made following an exchange of opinions from each of the members who constitute the minimum membership, whether present at a face to face meeting, by teleconference or videoconference.

6.3.5 The HREC will endeavour to reach decisions by general agreement, which need not involve unanimity.

6.3.6 Voting shall be by show of hands. Each member has one vote.

6.3.7 Members may vote by proxy if they are unable to attend. Notice of proxy must be submitted in writing 5 days before the meeting.

6.3.8 Matters will be passed by a majority of members.

6.3.9 The Chair shall have the deciding vote if there is a tie.

6.3.10 Members may speak more than once at the discretion of the Chair.

6.4 Minutes

6.4.1 The Secretary shall accurately record the minutes of each meeting. The following details shall be recorded in the minutes:

6.4.1.1 Date, time and venue of the meeting.

6.4.1.2 Names of members present and apologies and the name of the Chair.

6.4.1.3 An overview of discussions and business conducted; decisions about approval, amendment or rejection of proposals in written or electronic form; action items and persons responsible.

The Australian and New Zealand College of Cannabinoid Medicine Inc.
192A Great Western Highway
Hazelbrook NSW 2779
ANZCCM HREC email: HREC@anzccp.org P: 0426237212

6.4.1.4 Disclosures of interest/determinations made about potential conflicts of interest. Interests, rather than conflicts of interest will be disclosed, and a determination will be made as to whether the disclosed interests constitute a conflict of interest.

6.4.1.5 Date, time and venue of next meeting.

6.4.2 The minutes of the preceding meeting shall be circulated to members. The Chair will:

6.4.2.1 Approve the minutes for circulation as soon as possible after the meeting.

6.4.2.2 At the next meeting move that the minutes be confirmed as a true record.

6.4.2.3 Sign the confirmed minutes.

6.5 Adjournment

The Chair may adjourn the meeting from time to time with the consent of the HREC. Business at the adjourned meeting shall be confined to business that was left unfinished at the meeting where the adjournment took place. If a meeting has been adjourned for more than 10 working days, notice shall be given as for an ordinary meeting.

6.6 Code of Conduct

An HREC member shall:

6.6.1 keep their comments to matters before the HREC;

6.6.2 attend meetings and be punctual;

6.6.3 act in the best interests of the HREC and not bring the HREC into disrepute;

6.6.4 exercise appropriate care and diligence;

6.6.5 not make false statements or falsify records;

6.6.6 act appropriately to not gain advantage for themselves or others;

The Australian and New Zealand College of Cannabinoid Medicine Inc.
192A Great Western Highway
Hazelbrook NSW 2779
ANZCCM HREC email: HREC@anzccp.org P: 0426237212

6.6.7 not make offensive statements or comments or behave improperly;

6.6.8 shall cease speaking when called to order by the Chair;

6.6.9 declare any potential conflicts of interest and stand aside from discussions and voting on such matters deemed to be a conflict of interest;

6.6.10 keep all matters in confidence and not disclose any matters of business to the general public or other persons not associated with the research projects under review.

6.7 Dismissal of members

Members are required to adhere to the Code of Conduct listed above. Non-compliance with the code of conduct could result in the removal of the individual/s from the HREC. Such inappropriate conduct includes, but is not limited to:

6.7.1 not adhering to the Code of Conduct listed above

6.7.2 not attending meetings; being unreliable, or not being punctual

6.7.3 having a criminal record

6.7.4 making commercial misrepresentations

6.8 If a member's conduct is in question, and it appears to be a minor issue, then the Chair should contact the member and discuss the matter to determine if it can be resolved. If it cannot be resolved or the matter is deemed to be serious, then a formal notice should be sent by the Chair to the member outlining the issue. Evidence should be included where relevant, and/or details of a complaint if appropriate. Members should be given an opportunity to respond to the notice. After the second written notice, the member is dismissed from the HREC. Members may appeal the proposed action and should be given the opportunity to meet with the Board of Directors. Members may bring a representative to any appeal meetings. The outcome of the appeals meeting is final.

6.9 If the matter is considered extremely serious, then only one notice is necessary; such as having a criminal record that has not been disclosed. Other disciplinary action may include temporary dismissal for a period of time.

6.10 Amendment of standing orders

The Australian and New Zealand College of Cannabinoid Medicine Inc.
192A Great Western Highway
Hazelbrook NSW 2779
ANZCCM HREC email: HREC@anzccp.org P: 0426237212

6.10.1 These standing orders may be amended by a motion that has been presented according to these standing orders.

7. Meeting notices and frequency

7.1 The HREC shall meet at least every 3 months or when required.

7.2 Notices of meetings will be sent out at least two weeks prior to the meeting date. Agenda and papers will be sent out at least five days prior to the meeting date.

8. Members responsibilities and entitlements

8.1 Each member will be provided with an induction and orientation to the functions of the HREC and be offered the opportunity of being assisted by a current HREC member as a mentor.

8.2 Each member is responsible for ensuring that they have read all HREC documentation to be considered at an HREC meeting prior to the meeting;

8.3 Each member is responsible for deciding whether, in their judgment, a proposal submitted to the HREC meets the requirements of the National Statement and is ethically acceptable.

8.4 Where a member is not able to attend a meeting, the member is responsible for sending any comments on HREC proposals and other matters to the HREC administrator prior to the meeting, unless circumstances do not permit this.

8.5 Each member is responsible for:

8.5.1 disclosing to the HREC any conflicts of interest that may affect the HREC's review of a research proposal;

8.5.2 protecting the confidentiality of information received in the exercise of their duties;

8.5.3 becoming familiar with the National Statement and other relevant guidelines;

8.5.4 preparing for and attending HREC meetings or, if unavailable, provide opinions on the ethical acceptability of research proposals;

8.5.5 undertaking continuing education in human research ethics at least

The Australian and New Zealand College of Cannabinoid Medicine Inc.
192A Great Western Highway
Hazelbrook NSW 2779
ANZCCM HREC email: HREC@anzccp.org P: 0426237212

once every three years.

8.6 The Chairperson and Deputy Chairperson receive an honorarium as a condition of appointment, at a rate determined by the Board of Directors from time to time and recorded in their notice of appointment. Members who are not otherwise compensated for their service on the HREC receive a flat dollar sitting fee at a rate determined by the Board of Directors from time to time (and recorded in their notice of appointment) for each meeting at which they both review the applications assigned to them and attend for the full meeting. The rates are determined by the Board and reviewed annually. All members may be reimbursed for reasonable expenses incurred in attending to the business of the HREC.

9. Chair and Deputy Chair responsibilities

9.1 In addition to the responsibilities and entitlement as members, the Chair (and where relevant, in the absence of the Chair, the Deputy Chair) will have the following responsibilities as set out in clauses 9.2-9.5.

9.2 The Chair must not have other responsibilities that will impair the HREC's capacity to fulfil its obligations under the National Statement and fulfil the roles and carry out the functions set out in these TOR.

9.3 The Chair is responsible for ensuring that HREC decisions are informed by an exchange of views from those members who comprise the minimum membership, whether in full attendance or through the receipt and consideration of feedback from those members who cannot be present. Achieving such decisions requires that the Chair:

9.3.1 actively engages all members;

9.3.2 elicits their views; and

9.3.3 communicates their responses to other members.

9.4 As the HREC endeavours to reach decisions by general agreement, which need not involve unanimity (National Statement 5.2.8), the Chair will need to facilitate the expression of opinion from all members, identify points of agreement and of disagreement and judge when a sufficient degree of general agreement has been reached.

9.5 The Chair of the HREC will review and approve any reports of activities of the HREC to the NHMRC and the ANZCCM Board of Directors.

9.6 The Deputy Chair should support the Chair in the performance of, and be capable of fulfilling, the responsibilities of the Chair whenever the Chair

The Australian and New Zealand College of Cannabinoid Medicine Inc.
192A Great Western Highway
Hazelbrook NSW 2779
ANZCCM HREC email: HREC@anzccp.org P: 0426237212

cannot attend meetings or perform any other function.

10. Reporting

10.1 ANZCCM shall report annually, or upon request, to the NHMRC on the conduct of the HREC. The HREC shall report to the ANZCCM Board of Directors annually.

11. Handling of complaints and avenue of appeal against ANZCCM HREC decisions

11.1 Complaints by researchers against ANZCCM HREC decisions are handled under the Appeals Against HREC Performance and Decisions Procedures (Attachment 1).

The Australian and New Zealand College of Cannabinoid Medicine Inc.
192A Great Western Highway
Hazelbrook NSW 2779
ANZCCM HREC email: HREC@anzccp.org P: 0426237212

Attachment 1

Complaints about HREC performance and decisions procedures

1. Procedures statement

These procedures set out the processes for receiving and handling complaints against the performance of, and appeals against decisions made by, the ANZCCM Human Research Ethics Committee (HREC).

2. Scope

These procedures relate only to the management of complaints in relation to the processes, decisions and actions of the ANZCCM Human Research Ethics Committee.

3. Definitions

HREC - Human Research Ethics Committee

4. Appeals against HREC decisions

4.1 Researchers have the right to appeal against a decision made in relation to an HREC application.

4.2 Informal resolution should be attempted in the first instance. This may include the researcher(s) meeting with the Chair of the HREC to discuss the points of contention.

4.3 Where attempts at informal resolution are not successful, the researcher(s) should submit a complaint in writing to the Board of Directors. In the case of an appeal against a decision of the HREC, this should be within ten working days of receipt of the HREC decision.

4.4 An independent academic will be appointed by the Board of Directors as an Independent Adjudicator to investigate and determine appeals against decisions of the HREC.

4.5 The Independent Adjudicator will communicate with the researcher(s), members of the HREC and do anything reasonable to resolve the issue.

4.6 After due consideration of the facts, the Independent Adjudicator will determine whether to:

4.6.1 dismiss the appeal, or

The Australian and New Zealand College of Cannabinoid Medicine Inc.
192A Great Western Highway
Hazelbrook NSW 2779
ANZCCM HREC email: HREC@anzccp.org P: 0426237212

4.7 uphold the appeal in whole or in part.

4.8 The Independent Adjudicator will submit a report of the findings of the investigation to the Board of Directors within 10 working days of completion of the investigation.

4.9 The ANZCCM Board of Directors will communicate the findings of the investigation and the determination of the Independent Adjudicator to the researcher(s). Where an appeal is upheld in whole or in part, the matter is referred back to the HREC for reconsideration in accordance with the determination. The ANZCCM Board of Directors will not approve, endorse or permit any research project or Authorised Prescriber application that the HREC has declined to approve. This constitutes the last internal process of appeal at ANZCCM.

5. Complaints about HREC performance by the Public

5.1 The public, including participants of research, have a right to make complaints against the performance of an HREC in relation to its handling of concerns and complaints about research projects.

5.2 HREC Participant Information Forms include the contact details for correspondence and complaints in relation to research.

5.3 Complaints about the performance of the HREC are handled by an Independent Adjudicator appointed by the ANZCCM Board of Directors.

5.4 The Independent Adjudicator will communicate with the Chair of the HREC and the complainant and do anything reasonable to resolve the issue.

5.5 After due consideration of the facts, the Independent Adjudicator will make a recommendation to:

5.5.1 dismiss the complaint, or

5.5.2 uphold the complaint in whole or in part.

5.6 The Independent Adjudicator will submit a report to the ANZCCM Board of Directors in relation to their findings.

5.7 In the case where the complaint is dismissed, the ANZCCM Board of Directors will communicate the findings of the investigation and decision to the complainant. This constitutes the last internal process of appeal at ANZCCM.

The Australian and New Zealand College of Cannabinoid Medicine Inc.
192A Great Western Highway
Hazelbrook NSW 2779
ANZCCM HREC email: HREC@anzccp.org P: 0426237212

Complainants who are dissatisfied with the decision of the Independent Adjudicator may appeal to the appropriate Ombudsman or most appropriate relevant appeal body with jurisdiction.

5.8 In the case where the complaint is upheld, the ANZCCM Board of Directors will:

5.8.1 Communicate with the Chair of the HREC and the complainant the findings of the investigation and decision.

5.8.2 Initiate restorative or disciplinary action against the HREC or individual HREC member(s) where appropriate. This may include the removal of an HREC member from the HREC.

6. Approvals summary

Document Name	Australian and New Zealand College of Cannabinoid Medicine (ANZCCM) Human Research Ethics Committee (HREC) – TERMS OF REFERENCE (TOR) (including Complaints about HREC performance and decisions procedures)
Version Number	3
Date of Original Version	4/4/2021
Approving Authority	ANZCCM Board of Directors
Approval Date	15/9/2026
Next Review Date	15/9/2027
Contact Officer	President ANZCCM

The Australian and New Zealand College of Cannabinoid Medicine Inc.
192A Great Western Highway
Hazelbrook NSW 2779
ANZCCM HREC email: HREC@anzccp.org P: 0426237212