ANZCCM
The Australian & New Zealand College of Cannabinoid Medicine

Australian and New Zealand College of Cannabinoid Medicine (ANZCCM) Human Research Ethics Committee (HREC)

STANDARD OPERATING PROCEDURES (SOP)

1. Background

1.1 The HREC conducts its business in accordance with the Terms of Reference (TOR) and this SOP manual.

1.2 The HREC TOR and SOP are made publicly available.

2. Meetings

2.1 The HREC meets on a regular basis at least every 3 months. The HREC holds at least 4 scheduled meetings in each year for the purpose of reviewing new applications.

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

2.3 A quorum is required at each meeting for the HREC to reach a final decision on any agenda item. The quorum for a meeting is at least one member from each of the categories of the minimum membership prescribed by the National Statement on Ethical Conduct in Human Research (National Statement) as in force from time to time, attending in person or via telephone or videoconference.

2.4 A meeting of the HREC 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 (National Statement).

3. Declaration of interest

3.1 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 the meeting. Conflict of interest includes financial

interests, personal, professional or institutional benefits or advantages that depend significantly on the research outcomes.

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

4. Confidentiality

4.1 HREC meetings are held in private. The agenda and minutes of meetings, applications, supporting documentation and correspondences are all treated confidentially.

5. Decision making

5.1 The HREC endeavours to reach a decision concerning the ethical and scientific acceptability of an application by general agreement, which need not involve unanimity.

5.2 Where general agreement is not immediately apparent, the Chair will 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.

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

6. Records and documentation

6.1 Written records of all meetings of the HREC are maintained (including agendas and minutes).

6.2 Files are kept securely and confidentially in accordance with applicable Commonwealth, state, territory and New Zealand privacy, records management and data protection legislation.

6.3 The HREC maintains a register of all the applications received and reviewed in accordance with the National Statement.

6.4 HREC decisions will be notified promptly in writing to successful and unsuccessful applicants.

6.4.1 Letters of approval to applicants will be delivered promptly and

specify conditions of the approval; reporting and monitoring requirements and the duration of the approval.

6.5 Copies of applications, associated documents and correspondence will be retained by the Secretary of the HREC.

6.6 Where possible email will be used to communicate with HREC members and applicants.

6.6.1 Administrative assistant for the HREC to ensure all communication between researchers, applicants and the HREC is streamlined and followed-up appropriately in time and manner.

6.6.2 HREC contact details will be clearly published on the HREC website and as part of email signatures in any communications from the HREC.

a. Text
b. Phone
c. Email
d. In writing

6.7 The emphasis in communication will be open and transparent, ideally verbally and/or face to face, with follow-up in writing.

6.7.1 Open and supportive communication will be encouraged, and any adversarial dynamics will be addressed consciously with de-escalation, utilising the HREC's broad interpersonal skill set as required.

6.8 Any issues requiring HREC input will be escalated to the dedicated HREC Researcher Liaison Member (HREC RLM).

6.8.1 The HREC RLM will table any issues at the relevant HREC meetings and/or present them sooner as required.

6.9 The review process (timing, manner, reporting requirements) for any project approved by the HREC will be determined in collaboration with the relevant researchers prior to commencement.

7. Monitoring research projects

7.1 The HREC monitors approved research projects to ensure compliance with the conditions of approval and to protect the rights, safety and welfare of participants. This includes review of annual progress reports and final

reports, safety reports, reports of protocol violations and reports of serious adverse events and suspected unexpected serious adverse reactions.

7.2 Adverse events reporting and handling will be dealt with by the research team in accordance with TGA guidelines https://www.tga.gov.au/reporting-adverse-events

7.2.1 Through reporting to the HREC in accordance with the pre-arranged reporting guidelines.

7.2.2 Adverse event frequency and seriousness will be monitored for and with each project with a low threshold for further investigation as required, including the possibility of pausing or ceasing the project if the risk to participants' welfare is determined to be too great.

7.3 The HREC has the discretion to adopt other appropriate mechanisms for monitoring depending on the complexity, design and risk perceived, including:

7.3.1 discussion of relevant aspects of the project with investigators, at any time;

7.3.2 random inspection of research sites, data, or consent documentation;

7.3.3 interview with research participants or other forms of feedback from them;

7.3.4 request and review reports from independent agencies such as a Data and Safety Monitoring Board; and

7.3.5 for research conducted during natural disasters, public health emergencies or other crises and research that may discover illegal activity.

7.4 The HREC also has the discretion to recommend in the letter of approval that the site coordinates onsite monitoring at recommended intervals or randomly throughout the project.

7.5 A decision to withdraw ethical approval may occur if:

7.5.1 There are or have been substantial deviations from the trial

protocol.

7.5.2 Adverse effects of unexpected type, severity, or frequency are encountered.

7.5.3 As the trial progresses, the continuation of the trial would disadvantage some of the participants as determined by the researchers or others monitoring the trial.

7.5.4 Any consideration of withdrawal of approval will closely involve the research team and any other relevant stakeholders.

7.6 The HREC may invite researchers and researchers may request to be present for discussion of their proposed research.

7.7 Fees for application will be clearly published and provisions made for possible submission without a fee if the applicant is deemed unable to pay.

8. Appeals and complaints

8.1 Appeals regarding HREC rejection

8.1.1 Where the HREC has rejected an application, the Investigator has the discretion to:

a. submit a new application to the same HREC, taking due account of the HREC's concerns; or
b. lodge an appeal with the HREC Chairperson specifying the grounds of the appeal in writing.

8.2 Appeals regarding HREC approval

8.2.1 Where the HREC has given a favourable decision on an application and

- an ethical or scientific issue is subsequently identified by any party; or
- it has become apparent that the decision was based on inconsistent application of policy and guidelines.

A written appeal is lodged with the Chairperson in the first instance.

8.3 Appeals to the Board of Directors

8.3.1 If the appellant considers that the HREC has failed to follow due

process after making an appeal in line with 8.1 and 8.2 and remains unsatisfied with the outcome, they have the discretion to lodge an appeal with the Board of Directors.

8.3.2 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.

8.3.3 An independent academic will be appointed by the Board of Directors as an Independent adjudicator to investigate and make decisions in relation to appeals against HREC decisions, as stipulated at section 4.4 of the TOR Attachment 1.

8.4 Complaints about the conduct of HREC members

8.4.1 Complaints about the conduct of an HREC member are managed by the Board of Directors or delegate who informs the Chairperson of the complaint.

8.5 Complaints about the conduct of an approved research project.

8.5.1 Complaints about the conduct of an authorised research project, including allegations of research misconduct, are managed in accordance with the ANZCCM complaint handling procedures.

8.5.2 Complaints may be made about the conduct of authorised research activities by participants, researchers, staff or others. Complaints may be made in relation to:

- Breaches of privacy/confidentiality;
- conflicts of interest;
- failure to obtain informed consent;
- careless or inappropriate recording of data;
- falsifying data, plagiarism or misrepresentation or misappropriation of data; or
- other departures from good research practice or concerns in relation to the conduct of research complaint management process.

8.5.3 All complaints are dealt with in a serious and impartial manner. Complaints should be directed in writing to the Secretary of the ANZCCM HREC. In order to respond to complaints,

complainants are requested to include their name and contact details. This information is treated confidentially. Complaints are recorded by the Secretary on behalf of the ANZCCM HREC. The complaint will be directed to the ANZCCM HREC Chair for management.

8.6 Management of a complaint against a Researcher

8.6.1 The ANZCCM HREC Chair or delegate will investigate the matter as expediently as possible. All parties to the complaint will be informed of the nature of the complaint within 7 working days of receipt of the complaint. Time-frames for the duration of management of the complaint will depend on the nature of the complaint, investigation process, response from all parties, and appeals process. Parties may contact the HREC Secretary for a status update on the progress of the matter. The complainant will be notified of the outcome of the investigation relating to their complaint.

9. Authorised prescriber applications

9.1 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’) and no approval from the TGA is required for each individual patient. Full details of Authorised Prescribers are available from the TGA website.

9.2 The legislation specifies that only medical practitioners can apply to become Authorised Prescribers under the Therapeutic Goods Act 1989. The therapeutic goods legislation defines a medical practitioner as 'a person who is registered, in a state or internal territory, as a medical practitioner’. In addition, the HREC (if applicable) and TGA Delegate must be assured that the medical practitioner has the qualifications and experience necessary to appropriately manage the medical condition and use the product.

In accordance with the TGA guidelines, to become an Authorised Prescriber, applicants must:

9.2.1 Be a medical practitioner with specialist registration or general

registration with the Medical Board of Australia.

- Generally, applications from medical practitioners with non-practising, limited, student, provisional registration (requiring supervised practice), or conditions placed on their registration will not be considered for the Authorised Prescriber scheme.

9.2.2 Have the training and expertise appropriate for the condition being treated and the proposed use of the product;

9.2.3 be able to best determine the needs of the patient;

9.2.4 be able to monitor the outcome of therapy.

9.3 The application should specify the medical practitioner's registration number in the national Register of practitioners(link is external) on the Australian Health Practitioner Regulation Agency (AHPRA) website. Other health practitioners, including dentists, are not eligible to become Authorised Prescribers. These practitioners may be able to access 'unapproved' therapeutic goods for individual patients under the Special Access Scheme.

9.4 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:

9.4.1 The indication for which the product will be prescribed;

9.4.2 efficacy and safety of the product in relation to its proposed use;

9.4.3 for medicines, the route of administration and dosage form;

9.4.4 clinical justification for use of the product;

9.4.5 suitability of the medical practitioner; and patient information about the product and the informed consent form.

9.5 The HREC will evaluate a medical practitioner's submission (where applicable) and, if appropriate, approve or endorse it.

9.5.1 If the application is approved or endorsed, provide the medical practitioner with a letter declaring they have reviewed all necessary documentation and clearly stating this approval or endorsement.

9.5.2 Monitor the medical practitioner's use of the 'unapproved' goods to ensure continued endorsement is appropriate. Examples of monitoring that have been undertaken by HRECs and specialist colleges have included the requirement for the medical practitioner to submit to them.

9.5.3 Reports outlining the number of patients who have been treated.

9.5.4 Adverse event or product defect reports.

9.5.5 Consider any new information available to determine whether it would be appropriate to continue the endorsement or approval.

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

9.6.1 inappropriate use of the product by the Authorised Prescriber;

9.6.2 safety concerns about the product;

9.6.3 failure of the Authorised Prescriber to comply with conditions imposed by the HREC; or

9.6.4 failure of the Authorised Prescriber to comply with legislation.

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

9.7.1 advise the medical practitioner of its concerns;

9.7.2 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

9.7.3 report to the TGA.

a. Upon withdrawing its approval or endorsement of an Authorised Prescriber, the HREC must promptly notify the TGA of that decision. Notification is not discretionary and is not subject to any internal determination. The Chair of the HREC is responsible for notifying the TGA in writing as soon as practicable after the decision to withdraw is made, and in any event within 5

working days, and may direct the HREC Secretary to effect the notification.

b. The HREC shall also, in consultation with the ANZCCM Board of Directors, consider whether any further steps are appropriate, including:

(i) notifying the relevant state or territory health department or professional regulator (such as AHPRA) of the circumstances that gave rise to the withdrawal; and

(ii) ensuring that appropriate arrangements are in place for the continuity of care of patients who were being treated by the Authorised Prescriber under the withdrawn endorsement.

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

9.8.1 determination by the HREC Executive Committee; and/or

9.8.2 consultation with the ANZCCM board of directors.

9.8.3 consultation with the scientific subcommittee.

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

9.10 Institutional approval

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

9.11 Application of other SOP clauses in this document to Authorised Prescriber (AP) applications

9.11.1 The sections of these SOP apply to Authorised Prescriber applications and endorsements (including initial applications, renewals, amendments, and reviews of existing endorsements) as if references to "research", "research

projects" and "research participants" were references to the Authorised Prescriber's proposed or approved clinical use of the relevant unapproved therapeutic good and to the patients who are or may be treated under that endorsement. In particular:

(a) Meetings: AP applications and endorsements may be considered at scheduled HREC meetings or, where appropriate, by the HREC Executive Committee in accordance with the delegation provisions of the Terms of Reference;

(b) Declaration of interest: members must declare any conflicts of interest in relation to an AP application, including any financial or professional relationship with the applicant or with the manufacturer or sponsor of the relevant therapeutic good;

(c) Confidentiality: applications, supporting documentation and deliberations relating to AP matters are confidential on the same basis as research ethics applications;

(d) Decision making: the HREC endeavours to reach decisions on AP matters by general agreement; where the HREC has given a favourable decision and an issue subsequently arises, or where an application is rejected, the appeal and review processes in the Appeals and Complaints section apply;

(e) Records and documentation: the HREC maintains a register of all AP applications received and decisions made, and letters of endorsement or rejection are provided promptly in writing with reasons stated;

(f) Appeals and complaints: applicants whose applications are rejected or whose endorsement is withdrawn have the same rights of appeal as researchers under the Appeals and Complaints section; complaints about the conduct of an Authorised Prescriber may be made under those procedures, with "research misconduct" to be read as including conduct inconsistent with the terms of the HREC's endorsement.

9.11.2 Where any provision of these Procedures is inconsistent with or cannot be adapted to the Authorised Prescriber context, or where this section 9 itself provides specifically for a matter, this section 9 prevails to the extent of the inconsistency.

10. Review/amendments of the procedures

10.1 These Procedures will be reviewed every year and may be amended in consultation with the HREC.

11. Termination of HREC responsibility

11.1 Where the HREC is to be merged, closed or has ceased to function, ANZCCM is to notify the NHMRC and determine the appropriate course of action, including in relation to the status of the HREC's registration with NHMRC and the monitoring and management of previously approved research.

12. Approvals summary

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