



APPEALING AGAINST A GV HEALTH'S HUMAN RESEARCH ETHICS COMMITTEE DECISION

Introduction

Goulburn Valley Health (GV Health) provides the high standards of ethical review, ethics application approval, ethical monitoring and audit review.

We have strong governance of research projects and we are committed to ongoing integrity and clarity within ethics and research governance.

The Human Research Ethics Committee (HREC) at GV Health strictly adheres to the national guidelines (NHMRC), Australian Code for the Responsible Conduct of Research 2018 and the National Statement on Ethical Conduct in Human Research 2023. The HREC, GV Health adopts, accepts and follows their Terms of Reference.

Applicants will have the right to appeal a GV Health HREC decision. Applicants must follow the following procedure if they wish to appeal against a HREC decision in relation to their research or quality assurance application or project.

Process:

Who is entitled to appeal, how and when to appeal against the GV Health's HREC decision?

Applicants seeking approvals for Research and QA may appeal. These include major, substantial and minor amendments to approvals for new/fresh applications.

The appeal will apply against a decision made by the GV Health HREC if the applicants have any concern regarding improper judgement or review, unfair or unwarranted decision in refusing approval for amendment, substantial change, resubmission and new applications.

Appeal Step by Step process:

- ⇒ First appeal: Initially, consult with the Secretary or the Chair, HREC for clarification of the decision.
- ⇒ Second written appeal: If the Secretary and the Chair, HREC are unable to satisfy the applicants then the applicants can appeal in writing with to the HREC for consideration. This will be placed on the Agenda of a suited HREC meeting. The Committee may invite the applicants for a demonstration of their concern or to attend a Q and A session with the Committee at the Ethics Committee meeting.
- ⇒ The appellant will be notified the outcome in two weeks from the date of the Ethics Committee meeting where the appeal was discussed.
- ⇒ Third Written appeal: If the appellant is still unsatisfied as to the Committee's decision or felt they wish to submit a further appeal to the Chief Executive Officer of GV Health for reconsideration of the HREC decision.



- ⇒ The Chief Executive Officer will discuss the matter with the Chair, HREC and may then take the following steps:
 - ✦ Request the HREC through the Chair for a second review of the appeal referring to the relevant national guideline
 - ✦ May form an Extraordinary Appeal Review Panel including the Chief Executive Officer / nominated delegate, one or two nominees other than the membership of the HREC and an external expert in the field of the proposed study that is under appeal.
- ⇒ The Extraordinary Ethics Appeal Review panel will review the appeal based on NHMRC and other national relevant guidelines. This panel will recommend their actions to the next sitting of the Ethics Committee.
- ⇒ Thereafter, the HREC will accept or refuse the recommendations of the panel
- ⇒ Both refusal or acceptance and subsequent implementation of the decision made on the third appeal will be the final outcome.
- ⇒ The Chief Executive Officer will not thereafter reverse the final decision taken by the HREC on the third appeal.