Non-Clinical Research Ethics

Procedure for Appealing Against a Decision Made by the University Research Ethics Committee (UREC)

A. Background Information

a) The University Research Ethics Committee (UREC) is responsible for upholding the ethical standards of practice in non-clinical research involving human participants in the University in order to protect participants and researchers from harm, preserve participants’ rights, and to provide reassurance to the public and funders regarding the ethical conduct of research at the University. It provides oversight, monitoring and guidance to the School Research Ethics Committees and acts as the first point of contact for the review and approval of proposals to access and use sensitive material for research purposes.

b) All Research Projects involving human participants must have appropriate ethical approval before they begin. For research projects governed by the University’s Code of Practice for Non-Clinical Research Ethics on Human Participants and which involve access and use of sensitive material for research purposes, ethical approval is sought by completing the relevant checklists, forms and associated documentation and submitting this to the Convener of UREC (checklists, forms and the procedure for submission are available at: https://www.dundee.ac.uk/research/governance-policy/ethicsprocedures/ethics/). UREC also undertakes ethical review and approval of cases referred to it by an SREC which was unable to reach a decision, for instance due to complexity or conflicts of interest.

c) Before considering an appeal, researchers should seek advice from the UREC Convener on how they might reformulate and resubmit their application to address the reasons provided by the reviewers for rejecting the application.

d) A researcher may appeal the UREC decision to reject an application for ethical approval on one or more of the following grounds:

   I. Evidence of procedural irregularities (including administrative errors) in the conduct of the review process of such a nature as to give rise to reasonable doubt as to whether the reviewer(s) would have reached the same conclusion had they not occurred.
   II. Evidence of prejudice or bias in the review process.
   III. Evidence of inadequate review.

e) The Convener of the Research Governance and Policy Sub-Committee will dismiss the appeal if it does not meet one of the grounds detailed in section A(d).

f) Appeals will not be accepted from researchers simply on the basis that they are dissatisfied with the outcome of an application for ethical approval.
B. Procedure

a) The researcher should submit an appeal form within 10 working days of being notified of the UREC decision.

b) The application should be submitted to the Convener of the Research Governance and Policy Sub-Committee (RGPSC). If the researcher is a student, their supervisor must sign the appeal form.

c) The Convener of the RGPSC will identify two other members of staff with appropriate expertise (who may or may not be members of the RGPSC) and no conflict of interest to form a panel to consider the appeal; as a first step the panel will determine whether the grounds for appeal are consistent with those stated in section A(d).

d) If the panel determine that the grounds for appeal are not consistent with those stated in section A(d) the appellant (and their supervisor, if the appellant is a student) will be informed that the appeal has been dismissed and the reasons for the dismissal.

e) If the panel determine that the grounds for appeal are consistent with those stated in A(d) the Convener of the RGPSC will obtain relevant information from the UREC Convener and/or UREC Administrator and, if necessary, may also request clarification or additional evidence from the appellant. The Convener of the RGPSC will share this information with the other members of the panel. Up to 15 working days will be allowed for gathering any additional information.

f) Each member of the panel will independently consider the appeal and record their recommendation (Appeal Upheld or Appeal Dismissed). If all members recommend the same outcome this will be the decision of the panel. If there are differences of opinion the panel will meet in person to discuss the case in detail. If differences in opinion persist the majority view will prevail. Up to 15 working days will be allowed for this process.

g) The Convener of the RGPSC will inform the appellant (and their supervisor, if the appellant is a student), UREC Convener and UREC Administrator of the decision and any remedial action required. Such actions may include, but are not limited to, one or more of the following:
   - Re-submission of the application for review by UREC using reviewers (with appropriate subject expertise) not involved in assessing the original application.
   - If there is not sufficient subject expertise available in members of UREC not involved in assessing the original application, review by appropriate internal or external reviewers outwith UREC.
   - Requiring amendment of procedures/controls within UREC.

Where procedural irregularities are determined to have occurred but not to have impacted on the outcome of the application, the appeal will not meet the grounds for appeal in section A(d) and will therefore be dismissed.

h) The decision of the panel will be final.