Research Ethics Committees Appeals Procedure



Policy owner UCD Research Approval date and body Research Ethics Committee,
Ethics Committee 26th September 2024

1. Purpose

This Appeals Procedure applies to a Lead Principal Investigator (PI) who wishes to appeal a decision of a Research Ethics subcommittee.

The Appeals Procedure is evidence based. Supporting evidence must be submitted to substantiate all appeals.

2. Definitions

Appeals Committee – A committee established by the Chair of Research Ethics Committee (REC) to consider the appeal.

Independent Person – A person who has had no prior involvement with the application under appeal, has no conflict of interest in the research under review, has not collaborated in a research capacity or similar with the PI/Appellant within the last five years, and who other than a professional / collegiate relationship, has no other personal or professional relationship with the PI/Appellant.

Lead Principal Investigator (PI)/Appellant – The lead investigator who is named on the ethics application form under consideration and who is making the appeal.

Research Ethics Committee (REC) – The University's Research Ethics Committee. This committee oversees the activities of subcommittees, and all schools-based undergraduate and postgraduate committees.

Research Ethics Subcommittee – Three subcommittees of the REC: Animal Research Ethics Committee (AREC); Human Research Ethics Committee – Life Sciences (HREC-LS); Human Research Ethics Committee – Human Sciences (HREC-HS). These subcommittees review applications and deliver decisions on applications received.

Respondent Ethics Subcommittee – The Research Ethics Subcommittee or schools-based research ethics committee that reviewed the application and made the decision which is being appealed.

Office of Research Ethics (ORE) – The administrative office in UCD tasked with overseeing the research ethics application and review processes, and with providing secretariat support to the REC and the Research Ethics Subcommittees (it does not provide these services to schools-based research ethics committees).

Schools-based research ethics committees – These are Taught Masters Research Ethics Committee (TMREC) and Undergraduate Research Ethics Committee (UREC) under the authority of the relevant subcommittee.

3. Scope

Only the Lead PI as named on the application under consideration can make an appeal and is referred to in this procedure as "the Appellant".

There is no appeal regarding the decisions of the Research Ethics Committee (REC).

4. Procedure

4.1. Pre-Appeal Informal Process

In the first instance, an Appellant who wishes to query or question a decision of a Respondent Ethics Subcommittee (i.e., the subcommittee that reviewed the application – see definitions), is strongly encouraged to contact the Chair of the relevant committee as soon as possible via the ORE with details of their concerns. The Chair of the committee that reviewed the Appellant's submission will be best placed to explain why the committee made the decision that it did.

4.2. Formal Appeal - Permitted Grounds of Appeal

If the Appellant is not satisfied with the outcome of 4.1 above, the Appellant can make a formal appeal regarding any decision of a Respondent Ethics Subcommittee to the REC under the following grounds –

- A. There were procedural irregularities in the review process where the Respondent Ethics Subcommittee may not have reached the same conclusion had these not occurred and / or
- B. There is evidence or grounds for allegation of inadequacy in the review conducted.

4.3. Submitting A Formal Appeal

The Appellant must make an appeal within 28 days of the date of the decision letter from the Respondent Ethics Subcommittee notifying the REC of their appeal to the decision of the Respondent Ethics Subcommittee. Appeals must be submitted on the appropriate form and emailed to research.ethics@ucd.ie. The appeal must include the grounds of appeal and evidence to support the appeal.

4.4. Establishment of An Appeals Committee

Once an appeal is submitted an Appeals Committee will be established as per below. The establishment of the Appeals Committee will be done as expediently as possible. The Appeals Committee shall be supported by ORE acting as Secretary to the Appeals Committee.

This Appeals Committee will be composed of –

The Chair of the REC or their nominee from the current membership of the REC. This person shall act as Chair of the Appeals Committee. In the event that a non-conflicted Chair cannot be nominated from the REC then an alternate Chair shall be nominated by the President.

Two representatives from each of the Research Ethics Subcommittees that are not the subject of the appeal, as selected by the Chair of the Appeals Committee

- if the appeal relates to a decision made by one of the three Research Ethics Subcommittees (AREC; HREC-LS or HREC-HS), then there will be four ordinary members in addition to the Chair;
- if the appeal relates to decision made by a schools-based research ethics committee (i.e., TMREC or UREC), then there will be six ordinary members in addition to the Chair (ie 2 representatives from each of AREC; HREC-LS and HREC-HS).

The Chair may co-opt a further person to act as an expert member of the Appeals Committee who shall not have a conflict of interest. This member may be internal or external to the University whom the Chair considers can bring scientific, technical or legal expertise to the Appeals Committee.

All appointed members of the Appeals Committee must meet the definition of Independent Person as outlined in Section 2.

The Chair is responsible for making all reasonable efforts to ensure appropriate gender representation on the Appeal Committee.

Members appointed to the Appeals Committee will:

- Declare and manage any conflicts of interest.
- Uphold the University's strategic commitment to Equality, Diversity and Inclusion (EDI) in the conduct of their duties; and
- Maintain confidentiality unless otherwise required by law or by UCD.

It is not the role of the Appeals Committee to substitute academic, scientific or clinical judgment.

4.5. Appeals Committee Procedure

The Secretary to the Appeals Committee (ORE) shall request and supply to the Appeal Committee all the relevant documentation and information from the Respondent Ethics Subcommittee, relevant documentation from the Appellant, documentation provided by any independent experts, as well as any additional information and documentation that may be deemed relevant.

All documentation and information shall be provided to the Secretary (ORE) within 14 days of request.

Both the Appellant and the Chair of the Respondent Ethics Subcommittee will be given the opportunity to view and to comment upon all the documentation and information provided to the Appeals Committee.

All documentation and information will be distributed by the ORE to the members of the Appeals Committee prior to the determination of the appeal.

Appeals will usually be determined on the written documentation and information provided. In the event that the Appeals Committee wish to convene an oral hearing, they will set out terms of reference to provide for this. This will be in accordance with the rules of natural justice.

The Appeals Committee may seek internal and external advice as it deems necessary as outlined in Section 4.4 above.

The members of the Appeals Committee will meet to review the appeal and will make their decision by simple majority. In the event of a tie, the Chair will have a casting vote. If deemed appropriate, more than one meeting can take place at the discretion of the Chair.

Members of the Appeals Committee shall give full consideration to the grounds of the appeal and to all of the documentation and information provided in reaching their decision.

4.6. Appeals Committee Decision

The Appeals Committee may:

Uphold the appeal, in full or in part

Not uphold the appeal

In the event an appeal is upheld in full or in part, the Appeals Committee may:

- Refer the case back to the Respondent Ethics Subcommittee for further consideration with such
 conditions as the Appeals Committee deems appropriate, which may include the constitution of a new
 temporary Subcommittee whose membership will be decided by the Appeals Committee.
- Revoke or amend the decision of the Respondent Ethics Subcommittee that made the original decision.
- Require the Appellant to meet specified conditions.

The Appeals Committee may issue a single decision or a combination of the above.

The decision of the Appeals Committee will be communicated to the Appellant and the Chair of the Respondent Ethics Subcommittee in writing within 5 days of the decision. The communication will include the reasons for the decision.

The Chair of the Appeals Committee has the right to notify research funding bodies, partner institutions or regulatory bodies of any matters relating to the appeal which may include notifying them of the appeal and the outcome as well as notifying internal stakeholders.

The decision of the Appeals Committee is final.

5. Related Documents

UCD Research Ethics Policy

UCD Code of Conduct of Research with Humans and Animals

REC Operating Procedures

Policy on the Use of Animals for Research & Teaching

6. Version History

Version	Date Approved	Approval Body
V1.1	February 2022	Research Ethics Committee
V2	26 th September 2024	Research Ethics Committee

