

Revisions to Regulation 28: Appealing A Decision Made By Senate Research Ethics Committee (SREC)

Summary

The purpose of this paper is to ask Senate to approve proposed revisions to Regulation 28.

The Regulation has been updated to consolidate the appeals process for local Research Ethics Committees (RECs) with Regulation 28. Local RECs are currently asked to have a procedure in place for dealing with appeals, however, at present there are 13 RECs in operation all with their individual processes. This is not good practice. Consolidating the appeals process is also consistent with the approach taken by other institutions, e.g. University of Cambridge.

The revisions have been scrutinised by AGC at their meetings in February, June and October and AGC now recommends the changes to Senate.

Senate is asked to approve the proposed revisions to Regulation 28.

The revised Regulation is attached at Annex A. The current Regulation is included at Annex B for information.

One action required.

Recommended Action

Senate is asked to **approve** the proposed revisions.

Publication: Open

City, University of London
Appealing a decision made by a City Research Ethics Committee

City defines an appeal as a request from an applicant for a review of a decision in relation to significant amendments requested to or rejection of a research ethics application by one of City's Research Ethics Committees (including Senate Research Ethics Committee).

This procedure applies to all staff and students engaged in a research project which falls under the institution's policies and procedures for research involving human participants, personal data or projects involving animals. Appeals against the decision of any City Research Ethics Committee must be made to Senate Research Ethics Committee. An appellant whose appeal to the Senate Research Ethics Committee is not upheld may request an Institutional-level review.

A flowchart of the process is provided in Annex A.

Appeal procedure

1. Stage 1: Senate Research Ethics Committee Appeal

1.1 Grounds for appeal

- a) An applicant may appeal against a decision of any City Research Ethics Committee concerning their application, including:
 - Significant requested amendments/changes to the research protocol
 - Rejection of the application

- b) The appellant is required to state the grounds for the appeal and the impact of the decision in writing at the time of requesting a hearing. The appeal should be submitted to the Secretary of the Senate Research Ethics Committee within 20 working days of receiving the Committee's decision. The appellant is responsible for providing all documentation. The documentation should be collated into one document and have page number, and should include in chronological order:
 - the grounds for appeal;
 - the original unaltered application;
 - comments provided by the Committee in response to the application;
 - any correspondence regarding the application/appeal held with the Secretary, Chair and/or member/s of the Committee;
 - any other documents in support of the appeal.

1.2 Initial review

- a) The receipt of an appeal will normally be acknowledged within 5 working days.

- b) The appeal will be scrutinised independently by at least two members of Senate Research Ethics Committee. The members will be nominated by the Chair. They will not have been involved in the initial decision. If the appeal is against a the Senate Research Ethics Committee decision, the nominations will be made from among members who were not the lead or second reviewer of the application, and would normally be from a School other than that of the appellant. Their comments will be sent to the Secretary

within 5 working days of receipt by the Committee members. If the appellant is appealing a decision made by a local Research Ethics Committee, the Chair may consult with a representative from the local Research Ethics Committee that reviewed the original application.

- c) The purpose of the initial review is to determine whether valid grounds have been provided to merit consideration of an appeal hearing. If it is deemed that there are no valid grounds the appeal will be rejected.
- d) The appellant will be informed of the outcome of the initial review, normally within 15 working days of the acknowledgement being sent. Where an appeal is rejected reasons will be provided to the appellant. If the reviewers agree at this stage that there is a case for upholding the appeal, the Chair may agree to do so without requiring an appeal panel hearing. In cases where the reviewers recommend that the appeal merits further consideration, a hearing where the appellant will have an opportunity to state their case to an appeal panel will be arranged.
- e) The Secretary to the Senate Research Ethics Committee will confirm the time and place for the hearing at the time of informing the appellant of the outcome of the initial review.

1.3 Senate Research Ethics Committee appeal panel

- a) The appeal panel will normally be convened within 15 working days of the outcome of the initial review. It will comprise three members of the Senate Research Ethics Committee, including the Chair or Deputy Chair who will chair proceedings and two members from a School other than the appellant's, with the Secretary to the Committee in attendance.
- b) The appeal panel will discuss the issues raised with the appellant. The outcome of the hearing can include one of the following:
 - Agreement on required changes;
 - Upholding the appeal;
 - Rejecting the appeal.
- c) The outcome of the appeal panel hearing will be provided in writing, normally within 5 working days of the hearing.
- d) The outcome of the hearing will be reported to the local Research Ethics Committee and Senate Research Ethics Committee.
- e) An appellant whose appeal has not been upheld may request a Stage 2 Institutional-level review.

2. Stage 2: Institutional-level review

2.1 Grounds for review

- a) An applicant may request a review of the Senate Research Ethics Committee decision on one or both of the following grounds:

- Procedural error
 - Demonstrable evidence of prejudice, bias, or inadequate review
- b) The appellant is required to state the grounds for the review in writing at the time of requesting an institutional-level review. Note that dissatisfaction with the decision made by the Senate Research Ethics Committee hearing is not valid grounds for a Stage 2 review. The grounds should be submitted to the Secretary to the Senate Research Ethics Committee within 10 working days of receipt of written confirmation of Senate Research Ethics Committee's decision.

2.2 Initial review

- a) The receipt of the request for an institutional-level review will normally be acknowledged within 5 working days.
- b) The grounds for review of the Senate Research Ethics Committee decision will be scrutinised by the Vice-President (Research & Enterprise). The purpose of the review is to reach a view on whether sufficient grounds have been provided to merit consideration of a Stage 2 review. If there are insufficient grounds to merit consideration of the review, the review will be rejected.
- c) The outcome of the initial review will be reported to the Secretary to the Senate Research Ethics Committee. The appellant will be informed of the outcome of the initial review, normally within 15 working days of the acknowledgement being sent. Where a review is rejected reasons will be provided to the appellant.
- d) If the appeal is not rejected at this stage, the Secretary to the Senate Research Ethics Committee will confirm the time and place for the review hearing at the time the appellant is informed of the outcome of the initial review.
- e) The appellant is responsible for providing the review panel with all documentation at least 10 working days before the hearing. This includes the unaltered application, comments provided from the Committee in response to the application, correspondence regarding the application/appeal held with the SREC Secretary or member/s of the Committee, the grounds for the appeal and the correspondence/documentation from/with the appeal panel. The documentation should be collated and have page numbers. The documentation should be submitted to the SREC Secretary.

2.3 Institutional-level review

- a) The review panel will normally be convened within 15 working days of the outcome of the initial institutional-level review. It will comprise Vice-President (Research & Enterprise) who will Chair proceedings, an academic member of staff with domain expertise not on the original Research Ethics Committee or involved in the appeal, and a senior member of academic staff without domain expertise. The panel will not ordinarily include members of Senate Research Ethics Committee, but the with the Secretary to the Senate Research Ethics Committee will be in attendance.
- b) The appeal panel will discuss the issues raised with the appellant. The outcome of the hearing can include one of the following:

- Agreement on required changes; OR
 - Upholding the application; OR
 - Rejecting the appeal, accompanied by clear reasons that will be provided to the appellant.
- c) The outcome of the appeal panel hearing will be provided in writing, normally within 5 working days of the hearing.
- d) The outcome of the institutional review panel hearing will be reported to the Senate Research Ethics Committee and the Research Ethics Committee that reviewed the original application if not the same, and a record will be retained.

Research Office September 2011, Version 1
Research & Enterprise September 2017, Version 2
Research & Enterprise October 2018, Version 3

