

# DUBLIN CITY UNIVERSITY

## Research Ethics Committee Standard Operating Procedures

### RULES FOR THE RESEARCH ETHICS COMMITTEE

1. The name of the committee is the DCU Research Ethics Committee (REC).
2. It is a condition of employment in DCU that research into human or animal subjects must only be conducted in accordance with the law, and also according to acceptable ethical standards. In order to obtain approval that a proposed course of research or other related activity is of an acceptable ethical standard, submission may be made to the REC for approval. The REC is precluded from supervising the execution of research, or giving any assurances other than those relating to whether or not a proposed course of research or related activity meets acceptable ethical standards.
3. The REC shall operate in accordance with the Terms of Reference determined by the University for the primary functions and responsibilities of the DCU Research Ethics Committee. Specifically, the REC :-
  - (a) Shall establish procedures and sub-groups to consider, approve or reject proposed projects involving research by any member of staff or any student of DCU which involves either experimenting upon any human or animal matter or activity including systematic questioning of human subjects;
  - (b) Shall provide opinions or papers on matters relating to research or research ethics;
  - (c) May issue guidelines, frameworks for local review, Standard Operating Procedures or directions, or publish papers relating to research or research ethics, and;
  - (d) May collaborate with other committees, bodies or persons both inside DCU and outside in relation to research ethics, research, teaching or scholarly activity generally.
4. The REC shall consist of a Chairperson, a Secretary, administrative support as assigned by the Vice-President for Research and Innovation and usually not more than 16 other members whose appointments shall be approved by the DCU Research Committee.
5. Members shall normally hold office for a term of three years. The REC may approve renewal of a person's membership for a maximum one further term of three years. A derogation to this rule exists where the Chair or Vice-Chair is appointed from the existing committee membership. In exceptional circumstances, with the approval of the Vice-President for Research and Innovation, the term of membership may be extended further.
6. A member of the REC who fails to attend three successive ordinary meetings of the REC shall be deemed to have resigned and a replacement shall thereafter be co-opted by the chair in consultation with the Research Committee.
7. The REC may co-opt to membership any person approved by the Research Committee and may similarly fill casual vacancies by retirement, resignation or otherwise.
8. The REC shall meet:
  - (a) For ordinary meetings, at least once every two months at the dates and times fixed in advance each year

- (b) Virtual meetings will take place in the interim period between ordinary meetings. Only expedited and notification level applications will be considered at virtual meetings.
9. The secretary shall organise for each member of the REC to receive the Agenda for the meeting together with a copy of all papers necessary for an informed and responsible consideration of the matters on the Agenda. The secretary shall ensure that members receive the documents at least four working days before an ordinary meeting.
  10. REC members are obliged to declare any potential for conflict of interest, so as to ensure an absence of bias in REC decision-making. No REC member will participate in the review for ethical approval of a research project or proposal in which they have an interest and will be asked to step out of any discussion of the research proposal at issue.
  11. At REC meetings no resolution may be passed unless a quorum of 50% of the members is present.
  12. The Chairperson shall preside at every REC meeting, and if the chairperson cannot attend, or is not present within 15 minutes for the time appointed for the meeting, the Vice-Chairperson shall act as chair. Where there is an equality of votes, the Chair of the meeting shall have a second or casting vote.
  13. The REC shall only consider proposals for research projects submitted under the conditions and in the format set out in Appendix 1; and each such proposal shall be sent to the appropriate number of members of the REC for review of the ethics of the proposal in question. These reviewers may consult among themselves and if they agree that the proposal conforms to acceptable ethical standards shall inform the REC Administrator before the next REC meeting of their view. At this next meeting of the REC the reviewers shall each inform the REC of their views, in order to ascertain what if any matters should be put to the proposer or his or her nominee.
  14. The REC may opt to hear the proposer or the proposer's nominee on the proposed research project. The proposer or nominee shall answer questions put to him or her about the project. The proposer or nominee shall have sufficient authority to agree to necessary modifications of the project.
  15. The REC shall discuss and approve or reject research projects in the absence of all persons interested in or associated with the proposal.
  16. The REC shall allow for a process of expedited review, carried out by three members of the committee, nominated by the REC Administrator. Standard operating procedures for expedited review have been developed and agreed by the committee, and will be updated as required.
  17. The REC shall allow for a process of notification to the committee of low risk research projects, in which personal information that is deemed not sensitive is being collected by interview, questionnaire or other means. Standard operating procedures for the notification procedure have been developed and agreed by the committee, and will be updated as required.
  18. The REC may attach conditions to a research project. The Chairperson may appoint one or more of the REC members to act as agent(s) for the purpose of detailing these conditions. The agent(s) shall notify the proposer of these conditions, which shall be noted by the subsequent meeting of the REC so far as practicable, without comment or discussion.

19. The REC shall communicate decisions in writing to applicants within 14 days of the REC committee meeting at which the decision was taken, in the following manner:
  - (a) **Approved**
  - (b) **Provisionally approved**, subject to recommended revisions to the proposal or answers to questions posed to the applicant.
  - (c) **Application declined**, with detailed reasons for the decision forwarded to the applicant, with or without an invitation to resubmit a substantially altered proposal for reconsideration.
  
20. Neither the Chairperson nor the Secretary shall be empowered to give sole approval on behalf of the REC to any proposal considered at an extraordinary meeting of the REC.
  
21. The discussions of the REC shall remain confidential. The Minutes, Reports and decisions of the REC shall, however, be publicly available on the DCU website to as great an extent as possible. The names and identifying details of research projects and proposals may be deleted from the public record of REC decisions if deemed necessary by the REC. The REC Administrator is responsible for maintaining the REC records.
  
22. These rules and the schedules thereto may be amended if a majority of more than three quarters of the REC members present and voting so resolve, which ruling must be communicated by the REC Chairperson to the Secretary of the Research Committee, for consideration at its next meeting.
  
23. The REC shall report annually to the Research Committee. In its report, it shall specify the members of the REC, shall indicate in general terms the matters that have come before it, shall indicate which issues have appeared to the REC to be important, and shall indicate in general what approach the REC has taken to these.

## Appendix 1

### Research Ethics Committee Review Process - Overview

#### Background

Responsibility for conducting ethical review is as follows:

- The Research Ethics Committee reviews all proposals for DCU research masters, PhD's and academic/research staff.
- All DCU undergraduate and taught masters proposals are reviewed at local level, under procedures which have been reviewed and approved by the Research Ethics Committee.

The Research Ethics Committee works together with the Research Ethics Advisers/ Researchers/ Heads of School/ Faculty Associate Deans for Research to highlight the need for vigilance to ensure all research activities on campus get ethical approval where appropriate.

The following review routes relate to proposals submitted for Research Ethics Committee review.

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#### Route 1: (a) No ethical risk research (b) Low risk research – ‘notification review’

##### (a) No ethical risk research

**It may not be necessary to obtain ethical approval for a research project in which none of the following procedures are being used:** observational clinical research; clinical trials; research on human tissues/biological fluids; physiological studies; gathering personal information through questionnaires or interviews; research on animal subjects. Where there is any doubt, the opinion of the REC should be sought about the applicability of this guidance to a particular research project

##### (b) Low risk research – ‘notification review’

In many cases, the research proposal may involve low risk research – e.g. where personal information that is deemed not sensitive is being collected by interview, questionnaire, or other means. In these cases, notification review will apply.

The researcher is required to complete the appropriate form and attach the relevant documentation (e.g. plain language statement, informed consent form, questionnaire etc.) **The review is carried out by one member of the committee, nominated by the REC Administrator.**

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#### Route 2: Moderate risk research – ‘expedited review’.

Where the researcher has acknowledged that there is some ethical risk with the proposal, then the proposal may be eligible for expedited review. This normally applies in cases where the risks to subjects and/or researchers associated with the project are not greater than those encountered in everyday life. The researcher is required to complete the appropriate form and attach the relevant documentation. **The process of expedited review is carried out by three members of the committee, nominated by the REC Administrator.**

Further to the expedited review process, the reviewers may decide to refer the proposal for full committee review, and the proposal will then be considered at the next scheduled ordinary meeting.

### **Route 3: Moderate to high ethical risk research – “full committee review”**

This normally applies in cases where the risks to subjects and/or researchers associated with the project are greater than those encountered in everyday life. The researcher is required to complete the appropriate form and attach the relevant documentation. **The process of full committee review is carried out by all REC members at the ordinary meeting.**

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Research proposals must be submitted a minimum of 10 working days in advance of the next Research Ethics Committee for inclusion in the review list for the meeting. A full list of the Research Ethics Committee meeting dates is available at [https://www.dcu.ie/researchsupport/rec\\_application\\_process.shtml](https://www.dcu.ie/researchsupport/rec_application_process.shtml)

In some cases, the researcher(s) concerned may be invited to attend the meeting to clarify issues relating to their proposed research. In all cases, the decision of the committee will be communicated to the Principal Investigator via e-mail.