

Requirements for establishing and operating Faculty Research Ethics Committees

1. Requirements for Faculty RECs

Developing a system of tiered review requires creating Research Ethics Committees in each of the five Faculties. Currently local review (all at School level, with the exception of IoE in which review occurs at Faculty level) covers UG and PGT only. All other applications, including those from research masters and other PGR students as well as staff, are reviewed by the DCU REC. The below list provides information on the minimum requirements that must be fulfilled prior to the inception of FRECs in order for DCU to meet its various legal and ethical obligations. (Note that the University's insurers confirmed that the current insurance policy can provide an indemnity to FRECs once the institution is satisfied that relevant assurances on set-up and governance/controls are in place.)

a) Agreement on determination of risk level

When institutions of higher education consider establishing a system of tiered review to be conducted by Schools or Faculties, this must be done within the hierarchy of risk (UK Research Integrity Office, 2020); to this end it has been confirmed with the DCU Chief Operating Officer (COO) that only 'low risk' research should be initially considered at Faculty level upon devolvement. Determining the specifics of risk thresholds for FRECs will therefore need to be developed in consultation with Faculties, the Office of the COO, the Data Protection Unit and DCU's legal advisors.

b) Reporting mechanism to DCU REC

The Chairs of FRECs will be required to attend and report to the DCU REC on a bi-monthly basis.

c) Committee composition

i. FREC membership should include the ethics expertise covering the range of research that it scrutinises. Requirements as follows:

- A chairperson who is trained or has practical experience in the area of research ethics
- One GDPR advocate as designated by the faculty
- Members from within / outside of the university who are competent in the specialist areas in the Faculty and who have practical experience in the area of research ethics. The proportion of Faculty to external members should be approximately 3:1.
- Administrative support adequate to the requirements of each FREC, at both governance and research ethics review level, must be appropriately resourced for good practice to be sustained (UK Research Integrity Office 2020, World Health Organisation 2011). Recommendation 4 of the 2019 Review of DCU REC noted that REC should have a dedicated part-time

secretariat to support REC activity, including but not limited to *“advising researchers on the research ethics review process, queries regarding how best to handle ethical challenges arising from research proposals, prep for REC meetings – triaging applications in line with risk, minuting REC meetings, communication and follow up on REC decisions”*

A similar position would be required to support the work of FRECs.

- ii. The process for appointment of FREC members (Dean/Research Committee) will need to be determined.
- iii. FRECs also require access to the University’s legal advisors and a process for accessing this will need to be determined.

d) Committee documentation

A range of documentation will need to be developed by FRECs. These include:

i. Terms of Reference (ToR)

These should be developed in line with the DCU REC ToR and should reflect the specific remit of FREC’s, addressing the following aspects:

- Evaluation of (low – risk) ethics applications – apply the principles of the Satori Framework to facilitate ethical review, and mandate processes for forwarding of applications to DCU REC that are deemed beyond this level or risk or beyond their expertise.
- Development of policies and procedures to promote research ethics at faculty level
- Implementation of policies and procedures
- Evaluation of policies and procedures
- Reporting

ii. Appeal documentation

In the event that an applicant is dissatisfied with the outcome of a research ethics application, an appeal of a FREC decision must be referred to the chair of the relevant FREC and each FREC must develop a process to support an appeal system.

iii. Process to amend applications.

iv. Each FREC will need to develop a process to allow the FREC oversight of locally-devolved/School-level ethics procedures, processes and policies in operation throughout the Faculty.

e) Training for members

Appropriate training for all FREC members will need to be provided.

2. Other considerations for Faculty RECs

a) Transition period

There will be a transition period (suggested duration of 12 months) during which the FREC Chairs will attend the monthly meetings of DCU REC. This will enable the Chairs to build collaborative relationships with colleagues involved in research ethics and obtain informal training. During this period the DCU REC agenda will include items to allow the FREC Chairs to:

- Raise queries and discuss challenges arising from FREC set-up
- Seek assistance regarding specific ethical queries.

b) Consistency with the operational features of the DCU REC re. Review System

A critical feature of locally devolved FRECs is that they operate within the structures used in the University for the review of ethics applications (World Health Organisation 2011; UK Research Integrity Office 2020; Satori framework). FRECs, therefore will be required to utilise an IT system suitable for the digital management of ethics applications and review.