**Purpose**

**SOP No.16**

**Research Ethics Committee (REC)**

This procedure outlines the role of the Research Ethics Committee (REC) and the Research Ethics Committee Convenor of the two Research Ethics Committees (1) Human Research Ethics Committee (HREC) & (2) Animal Research Ethics Committee (AREC).

**Scope**

Research Ethics Committee Convenor, Research Ethics Chair, Research Ethics Committee, Office of Research & Innovation

**Procedure**

**16.1 How to prepare for a REC meeting**

**1. Introduction**

The RCSI Research Ethics Committees, HREC & AREC, are in place to ensure that all research involving human participants, animals or tissue samples is conducted within Irish & EU law and legislation as well as within the best practice guidelines laid out by the Irish Council for Bio-ethics in Ireland. The role of REC Convenor is to ensure that all applications for ethical approval are reviewed properly, that the requested clarifications and revisions are implemented within the application, that the applicant understands what is being requested of them by the committee and that the final decision of approval/rejection is made in as timely a manner as possible.

**Briefly:**

The AREC & HREC committees have a 2-month cycle, with a break in July. For each committee the deadline for applicants is 12 noon on the last Friday of the month, the AREC and HREC meets and discusses the applications on the last Tuesday and Wednesday respectively of the second month commencing at 12pm. After the new application submission deadline, applications are assigned to reviewers, who review and submit their comments prior to the committee meetings, these are discussed at the meeting and letters for applicants are sent after the meeting based on these discussions. Applicants can then submit their revised applications at any time post this first letter. The Convenor reviews each application to ensure that the clarifications and revisions have been made, this may need further letters requesting revisions and clarifications and only once satisfied that they have all been met issues a letter of approval. The Convenor needs to be the primary point of contact for all REC enquiries, this aids in protecting the REC members from potential pressure, it also means that there is one source of information. At all times the Convenor relies on the individual HREC or AREC members for assistance in matters outside of his/her area of expertise, e.g. the Convenor may ask that the HREC statistician assess a particularly difficult statistical method etc. A special separate meeting outside of the two monthly cycle is held for Masters student project applications, usually the deadline is mid-November and the meeting early December (note this is the only HREC in December).

**Amendments: – These are alterations to previously approved applications.**

**Fast-track applications**: – It is at the discretion of the Chair and Convenor if a suitable case has been made to fast-track an application e.g., the applicant has a deadline for receiving approval that does not fit with the REC calendar (not all applicants are forward thinking!); or a funding award is dependent upon institutional ethical approval. A fast-track policy can be found on <https://www.rcsi.com/dublin/research-and-innovation/research/resources-and-facilities/research-ethics/review-process>

**2. Deadline preparation**

a. Submission dates for new applications and corresponding meeting dates are found on <https://www.rcsi.com/dublin/research-and-innovation/research/resources-and-facilities/research-ethics/review-process>

b. RCSI staff and students have automatic access to the online application portal <https://rcsi.academic.ie/live/w_rms_security.login?p_url=!W_VA_ETHICS.SHOW> once they have an active RIMS account.

c. Once an application has been submitted on-line the PI receives an automated email stating an application has been submitted. This application is then locked and set to “pending” automatically once submitted.

**3. Meeting preparation:**

After the deadline once all applications have been submitted and locked the Convenor must:

A Check all necessary documentation is uploaded and assign reviewers.

B For **HREC** applications **three reviewers** are assigned to each application plus the **legal advisor** and where possible at least one reviewer with an area of expertise in that of the application needs to be assigned. **AREC applications are assigned to the DV, ACWO and Information Officer of the relevant facility, a scientist, and a lay person, as a minimum**. Recently, it was agreed all AREC members would be reviewing all applications to properly discuss them

C The applications where possible, should be divided up evenly among the reviewers so that no one reviewer is overloaded compared to the rest. If there are very few applications then committee members with general areas of expertise that would be applied to all applications can be asked to check those specific bits in all cases e.g. statistics, ethics etc. they usually do without asking, or their opinion can be sought in the REC meeting if not beforehand. The Convenor also acts as a reviewer.

D Applications involving staff and or students need approval from the QEO and or the students Union. This is done automatically within the online system as representatives from both the QEO and SU are assigned reviewers where relevant (this information is also included here: <https://www.rcsi.com/dublin/research-and-innovation/research/resources-and-facilities/research-ethics> ).

E Reviewers of the applications are automatically notified by email that they have been assigned to the applications. Reminders are sent in advance of the meeting for committee members to submit their comments/review.

F Draft an agenda for the meeting, this should include the following: meeting time, date & location, apologies. Items always on the agenda are **minutes of the last meeting**, **matters arising**, **list of new applications (table)**, **AOB**, **date of next meeting**. Any correspondence should be included here too.

**4. At the meeting**

Note any matters arising that require follow-up. For each application (fast-tracks usually only get an update on the status not a full discussion), including amended applications, the chair will ask each reviewer to take them through the application, highlighting any potential ethical issues. Notes of all comments are made. Also, if there is any other business make a short note of it for the minutes.

**16.2 How to follow-up REC applications**

**5. Meeting follow-ups**

a. After the meeting – revision letters are created for each application summarizing the committees’ comments

b. This letter is uploaded within the attachment section of the application (along with other associated documentation relevant to the application).

c. If the application is to be approved simply click approve. If there are conditions for the approval these should be outlined in the letter to the applicant, for example, an application that was being conducted on multiple sites and they only supplied letters of permission from a few of them.

d. Ensure the REC Calendar is up to date as the automated dates rely on this (such as ethics expiry dates)

e. The status of the application will be “pending” (this is before review or before approval) and “draft” (this is when the applicant is editing the application post review) or “approved” final version of the application.

**6. Masters’ student’s applications**

* Preparation for this should be done in September: The Masters student projects normally require discussion to set a deadline that gives both (a) the students enough time to draft project proposal and therefore also the ethics application and (b) sufficient time for the ethical approval process to be completed by February. This usually means setting a deadline in mid-November for the applications to be in by and a REC meeting (or two meetings depending on the numbers of applications) to discuss the application reviews in early December.
* This can involve a lot of applications – up to 12 at any one time. It is important to spread the workload so that the REC committee members are not swamped with applications.
* After this, just follow the same format as before. There is no special form for either undergraduate or Masters students they all use either the animal or human forms.

**16.3 How to Fast-Track Applications**

 **7. Fast-track applications:**

Fast-Track applications can occur at any time. Fast-track applications require 4 reviewers who submit their comments as above. These comments are summarized and returned to the applicant as outlined above. This process generally takes 1 week to 10 working days to complete.

**16.4 How to Amend Applications**

 **8. Amendment applications**

It is simplest where possible to assign the reviewers that originally reviewed the original application if not assign new reviewers based on their areas of expertise. Depending on the amendment the work load for these can be light or heavy. If you judge it to be too different from the original application you can ask the applicant to submit a brand new application instead. Also, if the amendment is minor ie time extension or name change the convenor can independently approve.

**16.5 How to Access the RIMS system**

 **9.** The link to the RIMS is: <https://rcsi.academic.ie/live/w_rms_security.login?p_url=!W_VA_ETHICS.SHOW>

The REC Convenor is set up as an administrator for this system and using this system is able to:

1. Assign users

2. Set the Calendar

3. Assign Reviewers

4. Read reviews

5. Submit a review

6. Submit letters to summarise committees’ comments or other relevant documents.

**Templates**

[Sample: Information leaflet DOC | 119 KB](https://www.rcsi.com/dublin/-/media/feature/media/download-document/dublin/research-and-innovation/research/ethics/templates/sample-information-leaflet.doc)

[Sample: Research participant consent form DOC | 83 KB](https://www.rcsi.com/dublin/-/media/feature/media/download-document/dublin/research-and-innovation/research/ethics/templates/sample-research-participant-consent-form.doc)

[Sample: Retention of tissue patient consent form DOC | 91.5 KB](https://www.rcsi.com/dublin/-/media/feature/media/download-document/dublin/research-and-innovation/research/ethics/templates/sample-retention-of-tissue-patient-consent-form.doc)

[Sample: Retention of tissue patient consent form (genetics) DOC | 89.5 KB](https://www.rcsi.com/dublin/-/media/feature/media/download-document/dublin/research-and-innovation/research/ethics/templates/sample-retention-of-tissue-patient-consent-form-genetics.doc)

[RCSI Data Protection Impact Assessment Template PDF | 554.8 KB](https://www.rcsi.com/dublin/-/media/feature/media/download-document/dublin/research-and-innovation/research/ethics/templates/rcsi-data-protection-impact-assessment-template.pdf)

[Instructions on how to complete each question in the standard application form DOC | 459.5 KB](https://www.rcsi.com/dublin/-/media/feature/media/download-document/dublin/research-and-innovation/research/ethics/human-projects/instructions-on-how-to-complete-each-question-in-the-standard-application-form.doc)