

## UREC-SOP-007 Service delivery levels for Research and Knowledge Exchange Ethics Committees (RECs)

### Background

The University's RECs are committed to progressing formal ethics review efficiently and rapidly within defined timeframes, with appropriate analysis of risk and the associated proportionality of review, with mechanisms for 'expedited' review in exceptional and well-justified situations.

### Purpose and Scope

To provide RECs and applicants of research and KE ethics review a standard delivery service level employed consistent across the University.

### Process

1. **Receipt of an application via the VRE:** This cannot be acknowledged by colleagues due to the high volume of applications however the VRE will keep you abreast of the status via your VRE application homepage.
2. **Scheduling:** The Secretary will schedule an application for review within 15 working days of receipt or 15 working days in advance of the next 'scheduled meeting'. If there are too many applications scheduled for a 'scheduled meeting' then an 'additional meeting will be held' (depending on the appropriate 'system for review' **UREC SOP-002**).
3. **Requesting exceptional 'expedited review':** a request for fast tracking an application (whilst maintaining the standard rigour of review) is made against clear criteria contained within the **UREC SOP-005 Expedited Review**. In the instances that a request for expedited review is made, the Chair or Secretary will aim to respond to the applicant within 5 working days to inform them of whether the request can be met as stated in **UREC SOP-005**.
4. **Pre-meeting planning:** it is not often possible for applications to receive an initial filter for completeness or standards prior to scheduling to reviewers. However, if it is possible, then it may be that your application is '**returned for more information**' i.e. clarification or missing information which is needed for an informed ethics review.
5. **First Review meeting and Initial Outcome:**

the outcome of a review meeting or Chair's Action will be provided to the applicant (Principal Investigator) within 15 working days of the date of the meeting or Chair's Action;

- to provide favourable ethical opinion of the proposal;
- to provide provisional favourable ethical opinion of the proposal subject to conditions or clarifications;
- not to approve the application.

if an application is incomplete and/or isn't methodologically sound and of an appropriate standard then it could be '**returned for more information**', and none of the above decisions will be made at this stage (this is because an ethics review body requires a methodologically

sound and preferably peer reviewed research proposal to reach them, so they can carry out an accurate ethics review, as well as needing all information in the proposal in summary lay-person terms to understand the areas of the work which may include ethics implications, and the context in which they are being undertaken).

## 6. Response to Conditions or Providing More Information:

An applicant (the Principal Investigator) shall submit their Response to Conditions usually within 15 working days of receipt of the VRE outcome/notification request for more information. If an applicant requires further time to respond, they can request this from the Secretary or Chair.

For work requiring external processes to be undertaken a longer deadline (usually 30 working days) will be provided in the VRE. However often external process time-lines are not often predictable by the University and so there is flexibility for requesting an extension to the University Secretary or Chair.

It is expected that most Conditions or Requests for More information will expire if not completed within 3 months of the date of the **Condition Letter** or **Request for More Information**.

7. **Receipt by REC via the VRE:** The Secretary will schedule an application for review within 15 working days of receipt or 15 working days in advance of the next 'scheduled meeting'. If there are too many applications scheduled for a 'scheduled meeting' then an 'additional meeting will be held' (depending on the appropriate 'system for review' **UREC SOP-002**).
8. **Pre-meeting planning:** it is not often possible for applications to receive an initial filter for completeness or standards prior to scheduling to reviewers. However, if it is possible, then it may be that your application is '**returned for more information**' i.e. clarification or missing information which is needed for an informed ethics review and was previously requested. It is also possible that if an initial filter has occurred, that the REC Representative informs you that the '**Conditions have not been met**' without providing it to the reviewing meeting again where this is obvious to the REC Representative. This helps the researcher without waiting for a scheduled meeting to inform them of this.
9. **Second and upwards Review meeting and Initial Outcome or Decision:**

The outcome of a review meeting or Chair's Action will be provided to the applicant (Principal Investigator) within 15 working days of the date of the meeting or Chair's Action;

- to provide favourable ethical opinion of the proposal;
- to provide provisional favourable ethical opinion of the proposal subject to conditions or clarifications;
- not to approve the application.

Unless new information has come to light, during a '**request more information**' or '**conditional/provisional favourable ethical opinion**', then the reviewers should not include new conditions/clarifications, which did not get set earlier.

Where reviewers note that they should have **requested more information** or set **conditions/clarifications** but did not during the first review, then they should set this aside as a lesson learned exercise for ensuring consideration is given by reviewers for future reviews.

## Standard Operating Procedure (SOP)

### Service delivery levels for RECs

Where a proposal has been escalated for **potential higher risk (Class 4)**, there is a possibility that in order to protect the researcher, participants, institution, environment or significant historic or cultural sites and objects, that an applicant may be provided additional conditions, which were not considered earlier, prior to the request for escalation was made by a governance colleague of the University or a REC.

#### **10. Appeals of an Initial Outcome or Decision:**

See the [REC Appeals Procedure](#).