

RESEARCH ETHICS COMMITTEE APPLICATION AND ASSESSMENT PROCESS

October 2020

The following process is followed for the submission, assessment and approval of applications.

1. Application submission and distribution to committee members

- 1.1 Applicants submit the signed application to the committee secretary by the submission deadline.
- 1.2 The committee secretary checks that the forms have been signed by the researcher and supervisor and that all relevant materials are enclosed. If the form is incomplete, the committee secretary sends back the application with a request for it to be returned complete within 48 hours.
- 1.3 The committee secretary distributes every application to all committee members.
- 1.4 All members read all applications.

2. Research ethics committee meeting

- 2.1 About 2 weeks after the deadline, committee meets and considers each application.
- 2.2 If a committee member is named on an application as researcher, supervisor, line manager or head of department, they will leave the room for the discussion.
- 2.3 Committee members bring with them their assessments and recommended decisions for each application (Decision options are summarised below). If members are unable to attend, they send their assessments and recommended decisions 3 days in advance of the meeting to the committee secretary who brings them to the meeting.
- 2.4 The decision is made in the meeting and the committee secretary records the decisions and any recommended revisions.

3. Returning applications

- 3.1 The committee secretary communicates the initial decision and any recommendations to the applicants within 1 week of the meeting. Applicants should respond to recommendations and minor revisions within 1 week of hearing form the committee secretary. Subsequently, applicants should be responded to within 2 weeks of returning modifications to the application.

4. Decision options

Accept

Committee secretary issues a certificate and the study can begin.

Accept with recommendations

Applicants are invited to consider recommendations. They are not required to do them, but they are required to send back a final version of all the documents.

- Committee secretary sends the decision and recommendations to the applicant.
- Once all documents have been returned to the committee secretary, the committee secretary issues a certificate and the study can begin.

Minor revisions

Required revisions are requested.

- Committee secretary sends the decision and requests for revisions to the applicant.
- Once all documents have been returned to the committee secretary, they are sent to the chair and/or deputy chair who can sign them off by chair's action or can defer to other members of the committee.
- If all amendments have been made, the committee secretary issues a certificate and the study can begin. If not, remaining modifications are requested and – on resubmission to the committee secretary – go to the chair and/or deputy chair. If revisions reveal the need for major revisions, the chair and/or deputy chair can request (1) major revisions to be submitted for consideration by a sub-committee or the full committee or (2) resubmission to the full committee.

Major revisions

Major revisions are needed that require the consideration of a subcommittee or the full committee over email.

- Committee secretary sends required revisions to the applicant.
- Once all documents have been returned to the committee secretary, they are sent to the sub-committee or full committee over email. Committee members must send their approval or further comments to the chair within 1 week over email. The Chair collates responses.
- If all amendments have been made, the committee secretary issues a certificate and the study can begin. If not, remaining modifications are requested and – on resubmission to the committee secretary – go to the chair and/or deputy chair.
- If revisions at any stage reveal the need further revisions, the chair and/or deputy chair can request (1) major revisions to be submitted for consideration by a sub-committee or the full committee or (2) resubmission to the full committee.

Resubmission to the full committee

The revisions needed require the consideration of the full committee in person.

- Committee secretary sends required revisions and provides deadline for next committee meeting where the revision will be discussed.

Rejection

- The application is not within the remit of the RCM REC and will not be considered. Committee secretary sends rejection to the applicant with explanation.

Amendments after approval has been granted

5.1 *Minor amendments*: Changes are considered minor if no new unaddressed ethical issues arise. Examples include changes that arise from unforeseen logistical issues that require changes in, for example, data collection location (e.g. a survey will be sent to a different university or focus group needs to be replaced with separate interviews).

5.2 *Major amendments*: Changes are considered major if the changes lead to new ethical issues not previously dealt with in the application. For example, the age range of participants now covers infants or children under the age of 18, or questions are added that explore mental health issues in a project that did not touch on this area before.

5.3 Applicants inform the Committee about minor or major amendments using the RCM Research Ethics Amendments Form. In both cases, they describe the change and tick the relevant box and send the form to the committee secretary who logs the amendment form and sends it on to the chair and/or deputy chair.

5.4 For minor amendments, if the chair agrees that this is a minor amendment, the material is logged for information and reported at the next RCM Research Ethics Committee meeting. If the chair needs more information, the committee secretary asks for clarification of the changes with the applicant and either the application is logged as expected or the category is changed to a major amendment.

5.5 For major amendments, the application is considered by the full committee at the next meetings and follows the same route as full applications.

6. Existing applications

6.1 RCM researchers whose research already has ethical approval from another institution must provide the application and certificate of approval to the RCM Research Ethics Committee. In some cases, that institution's committee will be the committee of record (e.g. the NHS). In cases where the process of gaining ethical approval does not match the standards of the RCM Research Ethics Committee a new application to the RCM Research Ethics Committee will be requested. In order to assess whether a new application is needed, the chair will arrange for the review of the existing approval process. The chair will either table the approval for record at the next committee