

Research Ethics Sub-Committee

Policy for applying for retrospective ethical approval

It is not expected that applications will be received for retrospective approval, save in exceptional circumstances.

Where an exceptional circumstance exists, a two-stage process is followed:

- Step 1: The applicant must satisfy the Research Ethics Sub Committee (RESC) that there are exceptional circumstances for their failure before starting their research to obtain ethical approval; and
- Step 2: The full RESC on a majority vote must agree that the application could be approved *without conditions**

Applications must therefore be made to RESC with a full explanation of the reasons why ethical approval was not sought and obtained before the research was carried out. Any supporting evidence must also be provided.

The full RESC will consider the reasons and decide whether they consider the circumstances to be exceptional. A record will be kept of decided cases by the RESC.

If the reasons are considered exceptional, the full RESC will vote on whether the application as submitted to RESC could have been approved without conditions.

If both conditions are satisfied, the RESC may exercise its discretion to grant approval for the research. (Note: when the full committee agrees that the conditions for approval can be met this decision may be approved by email)

* Given that approval is often conditional, the Committee agreed that in such cases, provided general ethical principles have been followed, and the conditions would have constituted points for clarification or minor issues such as corrections of typos, then the research could be considered as having been capable of approval.

Retrospective Approval Policy and Procedure

1. The diagram at **Appendix 1** demonstrates how the Procedure may operate in practice. For all applicants:
 - i) At Stage 1, a case must be made why the circumstances are genuinely exceptional. It is the intention that there should never be retrospective approval, as approval must be in advance. The Procedure is therefore not a 'catch all' for those who forgot, or failed to properly understand their ethical obligations. This first Stage is therefore a necessary pre-requisite for any consideration of the substantive application.
 - ii) If the Stage 1 justification is accepted by the Committee, then the Committee will move on to assess whether it would have given unconditional approval. If so, then a favourable opinion may be granted. If, however, unconditional approval would not have been given, then it cannot retrospectively be given, as, de facto, research would have taken place which the Committee considered did not meet acceptable standards. This would then be rejected, and the matter would need to be referred for appropriate management action, including potentially, a referral to the Research Misconduct Procedures (as the research would have taken place without the necessary ethical review).
 - iii) The Procedure allows for referral for consideration of research misconduct/for management action. In this regard, the Committee could and should highlight within that any immediate ethical concerns particularly in relation to any ongoing concerns regarding the welfare of human participants.
 - iv) The decision as to whether there needs to be a full Committee discussion of a case, or whether the matter can be dealt with by Committee correspondence, will rest with the Chair.

1. There may be an 'innocent party' involved. Students will generally be considered to be an 'innocent party', as they are under Supervision and the UWE Project Manager is the DOS/Supervisor. However, this will not in every case apply, for example if the student has failed to act on the instruction of the supervisor. As an exemplar, if there is ethical review, but the student has then done something other than or additional to what is covered, without the Supervisor's knowledge or against their advice, then the student is not clearly an entirely 'innocent party'. Equally, external collaborators would usually be entitled to rely upon the UWE collaborator having obtained ethical review where that had been agreed, but it might reasonably be expected that there would be some evidence that they had taken steps to agree who was responsible for the ethical review. It may be necessary to obtain further detail on this point to enable the Committee to take a decision about whether the matter should pass to the next stage for review of the application. Such issues can be tricky to unpick, and the Research Governance Manager will advise the Committee as appropriate. Where, **and only where**, there is an 'innocent party' who may be unfairly disadvantaged by a refusal to grant a retrospective favourable opinion, the proposed operation of the procedure **also** allows for the following:
 - i. Even where there is no adequate case made for exceptional circumstances (such as where the Supervisor has simply failed to ensure that the application was made), where there is an 'innocent party', the retrospective application can proceed to Stage 2.

- ii. If it is clear that the application would have been granted unconditional approval, then it can be approved, in line with Stage 2 of the Policy. This does not, however, prevent the Committee from making a referral for management action, including to the appropriate Research Misconduct Procedures (e.g. a referral of the Supervisor whose failure it was that the application was not made properly in advance) or Conduct Procedures (in relation to non-research activities) or other appropriate management action. But it does mean the innocent party, where the research, as conducted, was entirely ethical, is not unfairly penalised.
- iii. If it is clear that unconditional approval would **not** have been granted, the application will be rejected. The provisions relating to the 'innocent party' are intended to permit an application to proceed to step 2 even if there is no good exceptional circumstances case. **It is never intended that research which has taken place and which the Committee considers not to meet appropriate ethical standards should receive retrospective approval.**
- iv. If it is not clear whether the research would have been approved unconditionally, for example if the application is not well put together, the Committee may choose to iterate to establish the facts. If, following iteration about what actually took place in the research, the Committee is satisfied, a favourable opinion can be given, if not, the application will be rejected.

Appendix 1 (RESC Retrospective Approval Policy and Procedure) Flow Diagram

