

Guideline:
Amendment and Extension Requests

Researchers who have received ethical approval, whether for a low risk study or full review, may submit for either an amendment or extension a limited number of times throughout the lifespan of the ethics approval.

Researchers intending to request an amendment or extension post approval should do so by completing the correct version of the [Request to Amend/Extend Form \(HR4\)](#).

Requests to amend or extend (including the addition of new researchers) are only granted where the proposed amendment and/or extension does not alter the study in any way and does not negate the original ethics approval. There is a provision in the form to note any unexpected adverse event but such an event should also be presented in more detail using the [HREC Unexpected Adverse Event Form \(HR5\)](#).

Amendment & Extension Approvals

Approval for a request to amend or extend is communicated via email to the researcher. The email will provide a listing of how many requests have been made and the dates for each approval.

Please note the following:

- There is a limit of five requests for each approved study unless that study was approved for more than three years.
- Only straightforward cases will be dealt with by the Chair and Vice Chair and notified to the committee at its next meeting.
- A case is straightforward if it refers to issues to do with timing of research, increases in sample size, or where the procedure remains the same and where there is no threat to consent, confidentiality and anonymity of participants, or no increased risk over and above that identified in the original application.
- All other cases not satisfying these conditions will be tabled and reviewed by the Committee in the usual way.

- The Committee will review all cases where an adverse event has been reported.
- Extension requests (without any amendments being made) on studies that were approved three years or more prior to the date of submitting the request will be reviewed by the Chair in the usual way. Requests to extend for studies that were approved less than three years will be approved by the Office of Research Ethics.
- Amendments or extension requests that are received after the submission of an **End of Study Report (HR6)** cannot be processed.

For further instructions on the Post Approval Reporting Process and for all current versions of the post approval forms, please see the 'How to Apply' on the UCD Research Ethics Website: www.ucd.ie/researchethics/howtoapply.