

The process for obtaining ethical approval for Programmes of Work

What are Programmes of Work?

University researchers may apply for ethical approval for a Programme of Work if they are undertaking a number of linked studies with common research objectives and methodology. Programme Applications are intended to allow investigators to gain 'umbrella' ethical approval for interlinked studies without needing to submit a Full Application for ethical review to the Committee for each individual study.

Programme Applications must define the research methodology and the characteristics of the participant cohort(s) to be used very clearly. Each individual study which then wishes to use this 'umbrella' approval must then apply independently to use it. It is envisaged that this process will take less time and require less information than is necessary when submitting an ethics application for a new, standalone project.

Revised process for obtaining ethical approval for Programmes of Work

- Applicants considering applying for ethics approval for a Programme of Work are encouraged to discuss this with the Ethics Team at the earliest stages, to establish whether this would be appropriate and to obtain help and guidance
- Applicants should complete and submit a Programme Application to the Ethics Team, at least six weeks before any work under the Programme is due to start. The application should include sample participant documentation (which can then be adapted for individual studies as required) and copies of all research measures/ instruments (e.g. standard questionnaires) which may be used.
- The application will be reviewed by the relevant University Ethics Committee as appropriate. The reference assigned to Programme applications will have a 'P' suffix (e.g. ERN_12-0124P).
- If approval is granted, the conditions of approval will include the requirement to complete and submit a document (a 'proforma') highlighting the main ethical issues and parameters of the approved Programme. This will then be used by the ethics team as the basis for a dedicated application form which must be submitted for all future applications to use the approved Programme.
- In the majority of cases, a meeting will be held with the PI prior to final approval in order to discuss the Programme and its future use.
- An appropriate 'Programme Lead' (see below) must be identified, and this will usually be the PI.

The responsibilities of the 'Programme Lead'

The Programme Lead, who will usually be the PI of the original Programme application, is responsible for:

- Holding the approved Programme, and the application form required in order to carry out future work as part of the Programme.
- Triaging, and submitting to the relevant Ethics Committee, all subsequent applications to carry out work under that Programme. Researchers wishing to use an approved Programme should submit their application to the Programme Lead, who should then pass this on to the relevant Ethics Committee once he/she is satisfied that the application is appropriate and of a sufficient standard for review.
- Keeping a record and maintaining oversight of all work being conducted under the approved Programme.
- Providing an annual update to the relevant Ethics Committee about the Programme and the individual studies using it.

Applications to use an approved Programme of Work

- Researchers wishing to apply to carry out work under an approved Programme should complete the revised application form for applying to use an approved Programme. The application form includes a table detailing the main features of the approved Programme, and the applicant should consider each of these and indicate how the proposed work fits within the approved Programme. Copies of the study-specific participant documentation (based upon the approved sample documentation) and any additional materials specific to the study should also be submitted with the application. The reference assigned to applications to use/amend a Programme will have a 'PA' suffix (e.g. ERN_12-0124PA1).
- In the first instance, the applicant should discuss their application with the Programme Lead. Once the Programme Lead is satisfied that the application is appropriate and of a sufficient standard for review, the Programme Lead should submit the application to use the Programme to the relevant Ethics Committee.
- The application will be reviewed by the relevant University Ethics Committee as appropriate.
- Note that significant changes to research methodology or the participant populations that raise additional ethical issues are likely to require a new application.