MVLS ethics applications

Video transcript

Introduction.

This short video will describe the University of Glasgow's MVLS ethical requirements for non-clinical research and the process of applying to the committee for ethical review of a study.

The University of Glasgow requires that all research involving human participants, their data or material is subject to formal ethical review, in order to protect the rights, safety, dignity and wellbeing of its participants. A College Ethics Officer and an Ethics Committee are in place to assess all non-clinical research projects. Firstly, it's important to establish if a project is categorised as Research, as defined by the UK Policy Framework for Health and Social Care Research, to determine which approval pathway must be followed. To establish this, access the online tool provided at the description.

Which ethics committee should I submit my application to?

To better understand which ethics committee should review your study, consider the following points:

- Clinical projects and those involving NHS patients or their carers or family members, along with any studies that involve human tissue, blood samples, or data from NHS patients should be submitted for ethical approval from an NHS Research Ethics Committee or REC for short.
- 2. This also applies to research studies wishing to recruit adults who are unable to give their own consent, even if they are taking place out with the NHS.
- 3. Studies involving 'medical devices' or any instrument, machine, in vitro diagnostic test or software app, that is being used for a medical purpose or to diagnose disease may be subject to additional regulations and require ethical approval from an NHS committee.
- 4. Most studies involving the NHS need NHS REC review, but a common exception is studies recruiting ONLY NHS staff as participants these should instead be submitted to the MVLS ethics committee for approval.
- 5. In most cases, an ethical opinion will be required from only one ethics committee. If, for example, a study involves NHS patients and healthy volunteers, the NHS REC will review the study in its entirety and MVLS ethical review will not be needed.
- 6. If NHS ethical approval is not applicable, then you should receive approval from the MVLS ethics committee, unless you are advised otherwise and retain evidence for future reference.

The remainder of this video will refer only to MVLS ethics committee procedures.

How do I complete a research approval application on the University's research ethics system?

You need a University of Glasgow email account to access the online system and submit a research ethics application. First, check which application form and supporting documents you need to provide by completing the Screening Form, found at the links in the description. Make sure that all attached supporting documentation are dated and version controlled to avoid delays with your review. If your study does not require a consent form or a participant information sheet, you should upload a Word document at the appropriate slot, stating that such documentation is not required and give the reason.

Some types of studies may require additional documents to be submitted:

- Studies recruiting University of Glasgow students should include documented 'permission to access students', along with permissions from the respective Head of School, College Dean or Clerk of Senate.
- Any clinical research involving participants outside Great Britain, Northern Ireland, the Channel Islands or the Isle of Man, any study involving pregnant participants, or more than 5000 participants, should contact the Research Regulation & Compliance Office to confirm adequate insurance coverage before submission. Students can upload all of the documents themselves, but their Academic Supervisor must submit the application.

For detailed guides on how to create, submit, amend, and withdraw applications, visit the link at the description.

What happens after I submit my application?

Applications may be submitted at any time. Following submission, the committee administrator will review your application within a week and assign it to a team of reviewers, that will assess it within 21 days. This timescale depends on the complexity of the project and the quality of the information provided. Details on the common types of decisions are outlined in the description.

When your application is approved, you will receive a letter containing the terms of the approval. Once you have obtained any additional necessary documents, such as management approval from the organisation hosting the research, you can begin your study.

What happens once my application has been approved?

Any changes to your project, must be submitted by email as AMENDMENTS for to the MVLS ethics committee. You must include the application reference number, justification for the changes and copies of any amended documents with tracked changes, along with new version numbers and dates.

If you wish to challenge the committee's decision, please contact the MLVS ethics committee administrator. If a satisfactory resolution cannot be reached, you can lodge an appeal with the University Ethics Committee.

What happens once my study has ended?

Your ethical end of study procedures will have been outlined in your approval letter. This generally includes the University's requirements for retention of research data, and the submission of a short End of Study report to the MVLS ethics committee within three months of study completion.

Closing.

The ethics application process is an important procedure but may be a bit daunting for first timers. For more information and further guidance, please visit the links at the description or get in touch with the <u>College Ethics Committee</u>.