

Frequently Asked Questions

1. Do all research projects involving human participants need ethical approval?

Yes. All projects which involve human participants must secure ethical approval. Ethical approval is required to ensure that participants' dignity and privacy is protected, and to minimize the risk to participants. Additionally, the University itself seeks to ensure that its research does not expose participants, staff or students to unnecessary risk.

2. Who gives ethical approval?

The University has an Ethics Sub-Committee which makes recommendations on policy, and approves Level 3 research and teaching ethics applications. Each Faculty has representatives on the Ethics Sub-Committee, who are listed on the SIMMSpace and StaffNet ethics pages. Only level 3 applications will be submitted to the Ethics Sub-Committee for review. Level 1 and 2 applications will be signed off at Faculty level. Please refer to the 'Ethical Application System (Three Tiers)' document for further guidance.

You may also require approval from an external ethics committee, for example if you are working in an NHS or social care setting. If this applies to your work seek advice from your supervisor.

Where staff are undertaking courses (such as MSc) externally but wish to carry out their research at St Mary's University, the ethics sub-committee must be informed and see the ethics approval of the external institution in advance.

3. I am an undergraduate. Surely I don't need to get ethical approval for my project?

All research which involves human participants needs ethical approval.

4. The application looks long and complicated. Do I have to apply for ethics approval?

Yes. By not complying you may expose your participants to harm. You may also exposure the University and yourself to harm or litigation. Finally, the University may take disciplinary measures against you.

5. Who should submit an application for ethical approval?

Students (and staff who are also students) should submit their completed ethics application form to their supervisor for initial review. Staff should submit their completed ethics application form to their Faculty ethics representative. Please ask your Faculty ethics representative if in doubt.

6. When should I apply for approval?

You must secure approval for your project before you begin any part of your research (including a pilot study) which involves human participants. Please note that approval cannot be given retrospectively. Ethics review takes time. Please try to ensure your start date is at least 6 weeks after the deadline of the Ethics Sub-Committee meeting you are submitting to, preferably longer.

The Ethics Sub-Committee meets monthly; applications should be submitted by the deadline for each meeting. The deadlines are advertised on the SIMMSpace and StaffNet ethics pages.

7. What steps must I go through?

First you will need to fill in an ethics application form. You must complete the one which is relevant to your project (a research or teaching application). <u>Please ensure you are using the latest version of the application form downloaded from SIMMSpace or StaffNet, as these are updated regularly</u>. Failure to do so may result in your application being rejected. Once this is completed you will then need to sit down with you supervisor for review. A decision will then be made in as to whether it can be signed off, or needs to be sent to the Faculty ethics representative. The Faculty ethics representative may refer the application to the Ethics Sub-Committee.

8. Some of the questions on the full application are irrelevant to my research. What should I do?

Please complete all sections of the application. If a question is irrelevant please state why.

9. I need approval in a hurry. What can I do?

Submit your form to your supervisor (if a student) or Faculty ethics representative (if a member of staff) as soon as possible, making sure that you have completed all the sections and supplied all the necessary documents (on the application checklist) so that there is no delay. If in doubt contact the Ethics Sub-Committee secretary.

10. My research was approved by the Ethics Sub-Committee but my plans have changed. What should I do?

If your plans have changed significantly so that it amounts to a different project then start the approval process again. Please consult your supervisor (if a student) or your Faculty ethics representative (if staff).

If you modify your original proposal (for example from working with children to working with adults, or vice versa) or supporting documents please notify your supervisor (for students) or Faculty ethics representative initially. Please note your supervisor may refer your amendments to the Faculty ethics representative or Ethics Sub-Committee.

If more than six months has elapsed since you submitted your ethics application, but approval was not granted because you became ill and could not carry out amendments, you will need to resubmit a new application.

11. My proposed research involves interaction with children. Will I need Disclosure and Barring Service (DBS) certificate?

This will depend on the nature of the contact involved. For research involving one-to-one contact with children or vulnerable adults, or storage of images/videos/personal details of children, it should be assumed that an enhanced DBS check (undertaken within the last 3 years) will be required unless external guidance to the contrary can be produced. You can apply via Registry Services. Detailed guidance can be found on the DBS website on the procedures involved in obtaining clearance and from your supervisor if you are a student undertaking a research project. Please also refer to the 'Ethical Application System (Three Tiers)' document for guidance.

12. Do I need ethical approval if I am just observing people?

Yes. Observation may seem more intrusive to the people being observed than to the observer. Studies which involve observation normally need Level 1 approval but sometimes observation can pose serious ethical questions, for example if the people observed are in embarrassing situations.

13. Something has gone wrong during my research and a participant has been harmed. What procedure should I follow?

You should try to pre-empt harm as much as possible prior to conducting your research. However, if something has gone wrong please consult your supervisor or a suitable member of staff.

When there is immediate physical harm your first priority will be the participant's welfare. If the event takes place within the University you will need to follow normal safety procedures such as completing an accident report form and if necessary alerting the University safety officer. Serious adverse events must be reported to the Ethics Sub-Committee secretary as soon as possible.

14. I have received a lot of amendments to my research project from the Ethics Sub-Committee. I won't be able to submit a revised application in time for the deadline. What should I do?

Please let the Ethics Sub-Committee secretary know as soon as possible.

The Ethics Sub-Committee will tell you why your project was not approved. The Committee's comments will help you revise your research procedures and you may then be able to resubmit your application form, highlighting the elements you have changed to address the concerns of the sub-committee.

Commonly Made Mistakes

There are a number of mistakes that may delay the approval of your application. Some of these mistakes can result in your application not being put forward to the Ethics Sub-Committee in time or approval not being given until a later date.

All attachments should be included in one document and clearly labelled in the following order: full name, Faculty, supervisor and submission date, and merged in order of the checklist (on the research application form).

It is the proposer's responsibility to ensure that this has been passed on with the correct information. Please liaise with the Faculty ethics representative (if you are staff) or your supervisor (if you are a student) to ensure that this has been done.

Below are examples of commonly made mistakes which will help you to prepare your application and avoid delaying the start of your project.

1. You have not used the current version of the application form/templates.

You must download current forms and templates from the ethics pages on SIMMSpace or StaffNet, as these are regularly updated. Failure to do so may result in your application being rejected.

2. Sections of the application form have not been completed.

Please make sure that you complete every question on the form. If a section is not applicable, please state this and why.

3. The start date of the research project is too soon.

Ethical approval must be obtained before any research is undertaken. The research start date on the application form should be at least 6 weeks after the submission deadline of the Research Ethics Sub-Committee meeting you are submitting to, preferably longer. This is to allow time to make amendments or address any other issues the Ethics Sub-Committee wants you to respond to.

4. Potential risks have not been addressed.

You should acknowledge potential risks, however small, and state how you will mitigate such risks, for example, you may decide to have a first aider present. Researchers should take particular care when working with vulnerable people (for example, children or very elderly people). For research using supplements, the intended brand and dosage of the supplement should be stated, backed up by reliable sources that have identified safe limits and / or previous research that has administered a similar supplement/dosage. Please do not buy supplements yourself – you will be referred to a nutrition technician to do this. You should acknowledge any possible side effects on the application form and participant information sheet.

5. The application/information sheet and/or consent form is not in lay language.

The application form should be written in language that a lay person (an ordinary member of the public) can understand, and the participant information sheet, consent form (and all documents going to participants) should be written in a style that the participants can understand. If a person does not understand the purpose of the research study then informed consent cannot be given. Applications may be returned without review if the application form includes technical language without explanation, or if the application is poorly constructed grammatically so that it is unclear. In some cases, for example if you are intending to work with children of different ages, you may need several versions of both the information sheet and consent form to ensure that the language is targeted at the right level. Templates are available on SIMMSpace and StaffNet.

6. Relevant correspondence has not been included in the application

Correspondence with external organizations must be attached to your application. If you do not include the documents, the approval of your applications will be delayed.

If you have stated you will be working under supervision, for example under the supervision of a teacher, a letter will be needed from the organization confirming this.

7. Personal email addresses/phone numbers have been used.

You should avoid using personal contact details. Your St Mary's email address should be the primary contact email address. If you are a student your supervisor's telephone number should be used for contact purposes (with their permission).

8. You do not have a Disclosure and Barring Service Certificate

If your research includes children and vulnerable persons then you may be required to produce an enhanced DBS certificate obtained within the last 3 years before you can begin the research (please refer to the 'Ethical Application System (Three Tiers)' document for further guidance). You can apply for one via Registry Services. You are advised to apply for this, if necessary, well in advance of the start date for your research as a DBS check takes approximately 4-6 weeks. If a DBS certificate is required for your research, you will not be given approval until it has been seen by a member of the Ethics Sub-Committee.