

**St Mary’s University**

**Ethics Sub-Committee**

**Application for Ethical Approval (Research)**

This form must be completed by any undergraduate or postgraduate student, or member of staff at St Mary’s University, who is undertaking research involving contact with, or observation of, human participants.

You must complete the form in consultation with the “Guidelines for Completing an Ethics Application”.

Undergraduate and postgraduate students should have the form reviewed and signed by their supervisor, and forwarded to the Faculty/Institute Ethics Sub-Committee representative. Doctoral/MPhil applications must be reviewed and signed by an Ethics Representative. Staff applications should be forwarded directly to the Faculty/Institute Ethics Sub-Committee representative. All supporting documents should be merged into one document (in order of the checklist) and named in the following format: ‘**Full Name – Faculty – Supervisor’**

If the proposal has been submitted for approval to an external, properly constituted ethics committee (e.g. NHS Ethics), then submit a copy of the application and approval letter to the Secretary of the Ethics Sub-Committee. Please note that you will also be required to complete the St Mary’s Application for Ethical Approval.

Before completing this form refer to:

* the **University’s Ethical Guidelines**. As the researcher/ supervisor, you are responsible for exercising appropriate professional judgment in this review.
* the Ethical Application System (Three Tiers) information sheet.
* the Frequently Asked Questions (FAQs) and Commonly Made Mistakes sheet.

If you are conducting research with children or young people, ensure that you read the **Guidelines for Conducting Research with Children or Young People**, and answer the questions with reference to the guidelines.

Please note:

In line with University Academic Regulations the signed completed Ethics Form must be included as an appendix to the final research project.

If you have any queries when completing this document, please consult your supervisor (for students) or Faculty/Institute Ethics Sub-Committee representative (for staff).



**St Mary’s Ethics Application Checklist**

The checklist below will help you to ensure that all the supporting documents are submitted with your ethics application form. The supporting documents are necessary for the Ethics Sub-Committee to be able to review and approve your application*.* Please note, if the appropriate documents are not submitted with the application form then the application will be returned directly to the applicant and may need to be re-submitted at a later date.

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| **Document** | **Enclosed?\*** | **Version No** |
| 1. Application Form  | Mandatory |  |
| 2. Participant Invitation Letter | [ ]  Yes [ ]  No [ ]  Not applicable  |  |
| 3. Participant Information Sheet(s) | Mandatory |  |
| 4. Participant Consent Form(s) | Mandatory |  |
| 5. Parental Consent Form | [ ]  Yes [ ]  No [ ]  Not applicable |  |
| 6. Participant Recruitment Material - e.g. copies of posters, newspaper adverts, emails  | [ ]  Yes [ ]  No [ ]  Not applicable |  |
| 7. Written permission from host organisation (granting permission to conduct study on the premises) | [ ]  Yes [ ]  No [ ]  Not applicable |  |
| 8. Research instrument, e.g. validated questionnaire, survey, interview schedule | [ ]  Yes [ ]  No [ ]  Not applicable |  |
| 9. DBS certificate available (original to be presented separately from this application)\* | [ ]  Yes [ ]  No [ ]  Not applicable |  |
| 10. Other Research Ethics Committee application (e.g. NHS REC form) | [ ]  Yes [ ]  No [ ]  Not applicable |  |
| 11. Certificates of training (required if storing human tissue) | [ ]  Yes [ ]  No [ ]  Not applicable |  |
| 12. Data Management Plan | [ ]  Yes [ ]  No [ ]  Not applicable |  |

I can confirm that all relevant documents are included in order of the list and in one document (any DBS certificate to be sent separately) named in the following format:

**‘Full Name - Faculty – Supervisor’**

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| Signature of Proposer: |  | Date: |  |
| Signature of Supervisor (for student research projects): |  | Date: |  |



**Ethics Application Form**

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| **1. Name of proposer(s)** |  |
| **2. St Mary’s email address** |  |
| **3. Name of supervisor** |  |
| **4. Title of project** |  |

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| **5. School** | [ ]  Allied Health and Life Sciences☐ Business and Communications[ ]  Creative and Liberal Arts[ ]  Law & Society[ ]  Education[ ]  Sport, Exercise and Applied Science [ ]  Theology |
| **6. Programme**  | [ ]  UG [ ]  PG (taught) [ ]  PG (research)Name of course: |
| **7. Proposer status** | [ ]  Staff [ ]  UG student [ ]  PG student[ ]  Visiting [ ]  Associate  |

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| **8. Confidentiality** |
| Will all information remain confidential in line with the Data Protection Act 2018?  | [ ]  Yes [ ]  No |
| **9. Consent** |
| Will written informed consent be obtained from all participants/participants’ representatives? | [ ]  Yes [ ]  No [ ]  Not applicable |
| **10.** **Pre-approved Protocol** |
| Has the protocol been approved by the Ethics Sub-Committee under a generic application? | [ ]  Yes [ ]  No [ ]  Not applicableDate of approval: |
| **11.** **Approval from another Ethics Committee** |
| Will the research require approval by an ethics committee external to St Mary’s University? | [ ]  Yes [ ]  No  |

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| **12.** **Identifiable risks** |
| 1. Is there potential for physical or psychological discomfort, harm, stress or burden to participants?
 | [ ] Yes [ ]  No |
| 1. Will your research involve persons under 18 years of age or vulnerable adults?
 | [ ]  Yes [ ]  No  |
| 1. Do participants have limited ability to give voluntary consent? This could include cognitively impaired persons, prisoners, persons with a chronic physical or mental condition, or those who live in or are connected to an institutional environment.
 | [ ] Yes [ ]  No |
| 1. Are any invasive techniques involved? And/or the collection of body fluids or tissue?
 | [ ] Yes [ ]  No |
| 1. Is an extensive degree of exercise or physical exertion involved?
 | [ ] Yes [ ]  No |
| 1. Is there manipulation of cognitive or affective human responses which could cause stress or anxiety?
 | [ ] Yes [ ]  No |
| 1. Are drugs or other substances (including liquid and food additives) to be administered?
 | [ ] Yes [ ]  No |
| 1. Will deception of participants be used in a way which might cause distress, or might reasonably affect their willingness to participate in the research? For example, misleading participants on the purpose of the research, by giving them false information.
 | [ ] Yes [ ]  No  |
| 1. Will highly personal, intimate or other private and confidential information be sought? For example sexual preferences.
 | [ ] Yes [ ]  No |
| 1. Will payment be made to participants? This can include costs for expenses or time.
 | [ ] Yes [ ]  NoIf yes, provide details:  |
| 1. Could the relationship between the researcher/ supervisor and the participant be such that a participant might feel pressurised to take part? If ‘Yes’ please state where this issue is addressed in the application.
 | [ ] Yes [ ]  No |
| 1. Are you working under the remit of the Human Tissue Act 2004?
 | [ ] Yes [ ]  No |
| 1. Do you have an approved risk assessment form relating to this research?
 | [ ] Yes [ ]  No |

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| **13. Proposed start and completion date** |
| Indicate as precisely as possible: * When the study is due to commence.
* What data will be collected, how and when.
* The expected date of completion of the study.

Ensure that your start date is at least five weeks after the submission deadline for the Ethics Sub-Committee meeting.  |
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| **14. Sponsors/collaborators**  |
| 1. Give names and details of sponsors or collaborators on the project. This does not include your supervisor(s) or St Mary’s University.
* Sponsor: An individual or organisation who provides financial resources or some other support for a project.
* Collaborator: An individual or organisation who works on the project as a recognised contributor by providing advice, data or another form of support.
1. Explain their roles in the research.
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| **15. Other Research Ethics Committee Approval**  |
| Please indicate whether:* additional approval is required or has already been obtained (e.g. an NHS Research Ethics Committee).
* approval has previously been given for any element of this research by the University Ethics Sub-Committee.

Please also note which code of practice / professional body you have consulted for your project.  |
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| **16. Purpose of the study** |
| In lay language, provide a brief introduction to the background and rationale for your study. Ensure you cite sources/previous research for any assertions that you make, where necessary *[150 word limit]* |
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| **17. Study design/methodology** |
|  In lay language, provide details of:1. The design of the study (qualitative/quantitative questionnaires etc.)
2. The proposed methods of data collection (what you will do, when you will do this, how you will do this and the nature of tests).
3. The requirement of the participant i.e. the extent of their commitment and how much of their time will need to be given to data collection. Consider using charts or diagrams/illustrations to aid clarity.
4. Details of where the research/testing will take place, including country.
5. State whether the materials/procedures you are using are original, or the intellectual property of a third party. If the materials/procedures are original, describe any pre-testing you have done or will do to ensure that they are effective. Provide any surveys or interview questions and name the platform you will use for any online questions e.g. Jisc Online Surveys.
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| **18.** **Participants** |
| Please mention:1. The number of participants you are recruiting and their specific age or sex. Justify your sample size.
2. How they will be recruited and chosen.
3. The inclusion criteria
4. The exclusion criteria.
5. For internet studies, clarify how you will verify the age of the participants.
6. If the research is taking place in a school or organisation then include (or forward later) their written agreement for the research to be undertaken.
7. State any connection you may have with any organisation you are recruiting from, for example, employment.
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| **19.** **Consent** |
| If you have any exclusion criteria, ensure that your Consent Form and Participant Information Sheet clearly makes participants aware that their data may or may not be used.1. Are there any incentives/pressures which may make it difficult for participants to refuse to take part? If so, explain and clarify why this needs to be done.
2. Will any of the participants be from any of the following groups?
* Children under 18
* Participants with learning disabilities
* Participants suffering from dementia
* Other vulnerable groups.
1. If any of the above apply, state whether the researcher/investigator holds a current DBS certificate (undertaken within the last 3 years). A copy of the DBS must be supplied **separately from** the application.
2. Provide details on how consent will be obtained (e.g. written, online) and how long participants will have to read the Information Sheet before consenting. This includes consent from all necessary persons e.g. participants, guardians etc.
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| **20.** **Risks and benefits of research/activity** |
| 1. Are there any potential risks or adverse effects (e.g. injury, pain, discomfort, distress, changes to lifestyle) associated with this study? If so provide details, including information on how these will be minimised. Consider any risk there may be to the researcher as well as the participants.
2. Identify any risks / effects which will be difficult to completely eliminate or minimise.
3. Does the study involve any invasive procedures? If so, confirm that the researchers or collaborators have appropriate training and are competent to deliver these procedures. Please note that invasive procedures also include the use of deceptive procedures in order to obtain information.
4. Will individual/group interviews/questionnaires include anything that may be sensitive or upsetting? If so, clarify why this information is necessary (and if applicable, any prior use of the questionnaire/interview).
5. Describe how you would deal with any adverse reactions participants might experience. Discuss any adverse reaction that might occur and the actions that will be taken in response by you, your supervisor or some third party (explain why a third party is being used for this purpose).
6. Are there any benefits to the participant or for the organisation taking part in the research?
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| **21.** **Confidentiality, privacy and data protection** |
| 1. What steps will be taken to ensure participants’ confidentiality?
2. How will data, particularly personal information, will be stored e.g. using MS Teams or One Drive (please state that all electronic data will be stored on St Mary’s University servers).
3. If there is a possibility of publication, state that you will keep the data for a period of 10 years.
4. How you will identify participants who request their data be withdrawn, such that you can still maintain the confidentiality of theirs and others’ data?
5. Do you have a data management plan? If so, please attach.
6. How do you plan to store the data once the project has ended (for example, transferring it to your supervisor’s One Drive)?
7. State that data will be stored and handled in accordance with the General Data Protection Regulations brought in under the Data Protection Act 2018.
8. Who will have access to the data (normally yourself and your supervisor)?
9. Will the published results (e.g. in a dissertation, thesis, journal article or conference presentation) include information which may identify people or places?
10. If so, how will the persons or places (e.g. organisations) be made aware of this in advance?
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| **22. Feedback to participants** |
| Please give details of how feedback will be given to participants: 1. As a minimum, it would normally be expected for feedback to be offered to participants in an acceptable format, e.g. a summary of findings appropriately written.
2. Do you intend to provide feedback to any other individual(s) or organisation(s)? If so, what form this would take.
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The proposer recognises their responsibility in carrying out the project in accordance with the University’s Ethical Guidelines and will ensure that any person(s) assisting in the research/ teaching is/are also bound by these. The Ethics Sub-Committee must be notified of, and approve, any deviation from the information provided on this form.

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| Name of Proposer: |  |  |  |
| Signature of Proposer: |  | Date: |  |
| Name of Supervisor (for student research projects): |  |  |  |
| Signature of Supervisor: |  | Date: |  |



**Approval Sheet**

(This sheet must be signed at all relevant boxes)

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| Name of proposer(s) |  |
| Name of supervisor(s) |  |
| Programme of study |  |
| Title of project |  |

Supervisors, please complete section 1. If approved at level 1, forward a copy of this Approval Sheet to the Faculty Ethics Representative for their records.

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| **SECTION 1:** To be completed by supervisor.(for student research projects). Doctoral/MPhil applications must be referred to and reviewed by an Ethics Representative at Section 2 below. |
| [ ]  Approved at Level 1.[ ]  Refer to Ethics Representative for consideration. |
| Name of Supervisor: |  |  |  |
| Signature of Supervisor: |  | Date: |  |

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| **SECTION 2:** To be completed by Ethics Representative.  |
| [ ]  Approved at Level 1[ ]  Approved at Level 2[ ]  Level 3 consideration is required by Ethics Sub-Committee. |
| Name of Faculty Ethics Representative: |  |  |  |
| Signature of Faculty Ethics Representative: |  | Date: |  |