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| **Section 1: Applicant Details** |
| First Name | Click or tap here to enter text. |
| Last Name | Click or tap here to enter text. |
| Faculty | Choose an item. |
| Department | Click or tap here to enter text. |
| Co-researcher Names (internal and external)Please include names, institutions and roles. If there are no co-researchers, please state N/A. | Click or tap here to enter text. |
| Is this application for a staff or a student? | Choose an item. |

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| **Section 1:1 UG and PGT Student Applications (only) See Section 1:2 for Doctoral Students**  |
| Student Course details  | Choose an item. |
| Name of Supervisor | Click or tap here to enter text. |
| 1. For UG and PGT students, the supervisor **must justify** why this is a high-risk project.

Failure to do so will result in the application being returned.1. Students **should only be undertaking high-risk research in exceptional circumstances**.

**The Supervisor should also consider:**Supervisors should ensure that all of the following are satisfied before the study begins:* The topic merits further research;
* The student has the skills to carry out the research;
* The participant information sheet is appropriate; and procedures for recruitment of research participants and obtained informed consent are appropriate.
1. The FREC/RESC can only consider an application from an undergraduate or postgraduate taught student if it is **justified as high risk.**

The supervisor **must add comments** to justify high risk in the text box below  |
| Click or tap here to enter text. |
| I confirm that I have assessed this project as high risk and requiring full ethical review | **Yes/No** |

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| **Section 1:2 Postgraduate Research - Doctoral students**  |

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| All doctoral student research involving human participants and human tissue requires ethical review.Evaluation studies with human subjects or research using identifiable personal data also require ethical review (even if they are exempt from review by an NHS Research Ethics Committee). **Director of Studies**Please insert your comments in support of this application. You do not need to justify if it is high/low risk.Click or tap here to enter text. |
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| **Section 2: Project**  |
| **Section 2:1 Project details** |
| Full Project Title |
| Click or tap here to enter text. |
| **Project Dates**These are the dates for the overall project, which may be different to the dates of the field work and/or empirical work involving human participants.   |
| Project Start Date | Click or tap to enter a date. |
| Project End Date | Click or tap to enter a date. |
| **Dates for work requiring ethical approval**You must allow **at least 6 weeks** for an initial decision, plus additional time for any changes to be made.  |
| Start date for work requiring ethical approval | Click or tap to enter a date. |
| End date for work requiring ethical approval | Click or tap to enter a date. |
| How is the project funded? (e.g. externally, internally, self-funded, not funded – including scholarly activity) Please provide details including the PIMS reference number where applicable.  |
| Click or tap here to enter text. |
| Is external ethics approval needed for this research?  | Choose an item. |
| If Yes please provide the following:For NHS Research please provide a copy of the letter from the HRA granting full approval for your project together with a copy of your IRAS form and supporting documentation, including reference numbers.Where review has taken place elsewhere (e.g. via another university or institution), please provide a copy of your ethics application, supporting documentation and evidence of approval by the appropriate ethics committee.  |
| Click or tap here to enter text. |
| **Section 2:2 Project summary** |
| Please provide a concise summary of the project, including its aims, objectives and background. (maximum 400 words)  Please describe in non-technical language what your research is about. Your summary should provide the committee with sufficient detail to understand the nature of the project, its rationale and ethical context.  |
| Click or tap here to enter text. |
| What are the research questions the project aims to answer? (maximum 200 words) |
| Click or tap here to enter text. |
| Please describe the research methodology for the project. (maximum 250 words) |
| Click or tap here to enter text. |

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| **Section 3: Human Participants** |
| Does the project involve human participants or their tissue or data?*If not, please proceed to Section 5: Data Collection, Storage and Disposal, you do not need to complete sections 3-4.* | Choose an item. |
| **Section 3.1: Participant Selection** |
| Who are your participants?  |
| Click or tap here to enter text. |
| Please explain how you will select your participant sample. |
| Click or tap here to enter text. |
| Please explain how you will determine the sample size.  |
| Click or tap here to enter text. |
| Please tell us if any of the participants in your sample are vulnerable, or are potentially vulnerable and explain why they need to be included in your sample. NB: Please do not feel that including vulnerable, or potentially vulnerable participants will be a bar to gaining ethical approval.  Although there may be some circumstances where it is inappropriate to include certain participants, there are many projects which need to include vulnerable or potentially vulnerable participants in order to gain valuable research information.  This particularly applies to projects where the aim of the research is to improve quality of life for people in these groups.Vulnerable or potentially vulnerable participants that you **must** tell us about: * Children under 18
* Adults who are unable to give informed consent
* Anyone who is seriously ill or has a terminal illness
* Anyone in an emergency or critical situation
* Anyone with a serious mental health issue that might impair their ability to consent, or cause the research to distress them
* Young offenders and prisoners
* Anyone with a relationship with the researcher(s)
* Frail elderly
 |
| Click or tap here to enter text. |
| **Section 3.2: Participant Recruitment and Inclusion** |
| How will you contact potential participants? Please select all that apply. |
| [ ]  Advertisement[ ]  Emails[ ]  Face-to-face approach[ ]  Post[ ]  Social media[ ]  Telephone calls[ ]  OtherIf Other, please specify: Click or tap here to enter text. |
| What recruitment information will you give potential participants?Please ensure that you include a copy of the initial information for participants with your application. |
| Click or tap here to enter text. |
| How will you gain informed consent from the participants?Please ensure that you include a copy of the participant information sheet and consent form with your application. Where written consent is not taken, please advise on how consent is obtained with a justification where appropriate. |
| Click or tap here to enter text. |
| What arrangements are in place for participants to withdraw from the study? |
| Click or tap here to enter text. |

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| **Section 4: Human Tissue** |
| **Does the project involve human tissue?**For further information, see <https://www1.uwe.ac.uk/research/researchgovernance/resourcesforresearchers/humantissue.aspx>  |  |
| *If you answer ‘No’ to the above question, please go to Section 5* |
| I confirm that I have read the [UWE Human Tissue Quality Management System](https://www2.uwe.ac.uk/internal/Human-Tissue-Research/1-HT-Research-QMS-v1.2_final.pdf) | Choose an item. |
| Institution acting as Sponsor for the Project: |
| Click or tap here to enter text. |
| Please summarise the human tissue aspects of your proposed research here. This should include a summary of what tissue you will be using, how you will acquire it, why it is required, what you will do with it and how you will store it, ,what information you and the research team will have access to about the participants/donors, whether it will be rendered acellular and at what stage of the research and what will happen to any remaining tissue at the end of the project |
| Click or tap here to enter text. |
| **Relevant Material** |
| Is the tissue considered to be ‘Relevant Material’ under the HT Act[[1]](#footnote-1) for the purposes of this research project? | Choose an item. |
| Is the proposed use considered to be a ‘Scheduled Purpose’ under the HT Act1 for the purposes of this research project? [[2]](#footnote-2) | Choose an item. |
| Have you included with this application a copy of the project specific NHS REC Application Form and Approval Letter | Choose an item. |
| If the tissue is being provided by a Tissue Bank Application have you included the Form and Approval Letter with this application? | Choose an item. |
| Have you included the research protocol with this application? | Choose an item. |
| Is it necessary to have one or agreements relating to the transfer of human tissue for your project? This might for example include agreements relating to the sharing of tissue with collaborators, as well as with the supplier of the material to you. | Choose an item. |
| If any or all such agreements are in place, have you included them with this application? | Choose an item. |
| If not all necessary agreements relating the transfer of human tissue are currently in place, please explain what action you have taken. |  |
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| For projects involving ‘Relevant Material’ and / or the NHS please provide: the NHS REC Reference Number: | Click or tap here to enter text. |
| **Non-relevant Material and/or use not for a scheduled purpose but which involves NHS Patients)** |
| Has a copy of the project specific NHS REC Application Form and Approval Letter been included with this application?  | Choose an item. |

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| **Section 5: Data Collection, Storage and Disposal** |
| Research undertaken at UWE by staff and students must be GDPR compliant. For further guidance see [Research and GDPR compliance](https://www.uwe.ac.uk/research/policies-and-standards/research-ethics/policies-procedures-and-guidance)[ ] Please confirm that you have included the UWE Privacy Notice with the Participant Information Sheet and Consent Form [ ] By ticking this box, I confirm that I have read the [Data Protection Research Standard](https://www2.uwe.ac.uk/services/Marketing/about-us/pdf/Policies/GDPR-Research-Governance-Standard.pdf), understand my responsibilities as a researcher and that my project has been designed in accordance with the Standard. |
| **Section 5.1 Data Collection and Analysis** |
| Which of these data collection methods will you be using? Please select all that apply.  |
| [ ]  Interviews[ ]  Questionnaires/surveys[ ]  Focus groups[ ]  Observation[ ]  Secondary sources[ ]  Clinical measurement[ ]  Digital media[ ]  Sample collection[ ]  Other If Other, please specify: Click or tap here to enter text.Please note that online surveys must only be administered via [Qualtrics](https://www.qualtrics.com/uk/) Please ensure that you include a copy of the questionnaire/survey with your application. |
| What type of data will you be collecting?  |
| [ ]  Quantitative data[ ]  Qualitative data |
| How will you record your data and transfer it to secure storage? |
| Click or tap here to enter text. |
| Please describe the data analysis and data anonymisation methods. |
| Click or tap here to enter text. |
| **Section 5.2 Data Storage, Access and Security** |
| Where will you store the data? Please select all that apply. |
| [ ]  H:\ drive on UWE network[ ]  Restricted folder on S:\ drive[ ]  Restricted folder on UWE OneDrive[ ]  Other (including secure physical storage)If Other, please specify: Click or tap here to enter text. |
| Please explain who will have access to the data. |
| Click or tap here to enter text. |
| Please describe how you will maintain the security of the data and, where applicable, how you will transfer data between co-researchers. |
| Click or tap here to enter text. |
| **Section 5.3 Data Disposal** |
| Please explain when and how you will destroy personal data. |
| Click or tap here to enter text. |

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| **Section 6: Other Ethical Issues** |
| What risks, if any, do the participants (or donors, if your project involves human tissue) face in taking part in the project and how will you address these risks? |
| Click or tap here to enter text. |
| Are there any potential risks to researchers and any other people as a consequence of undertaking this project that are greater than those encountered in normal day-to-day life? For further information, see [guidance on safety of social researchers](https://docs.uwe.ac.uk/sites/health-and-safety/_layouts/15/download.aspx?SourceUrl=https://docs.uwe.ac.uk/sites/health-and-safety/Documents/G017_Social_Researchers.docx). |
| Click or tap here to enter text. |
| How will the results of the project be reported and disseminated? Please select all that apply. |
| [ ]  Peer reviewed journal[ ]  Conference presentation[ ]  Internal report[ ]  Dissertation/thesis[ ]  Written feedback to participants[ ]  Presentation to participants[ ]  Report to funders[ ]  Digital media[ ]  OtherIf Other, please specify: Click or tap here to enter text. |
| Does the project involve research that may be considered to be security sensitive?For further information, see [RESC guidance for security sensitive research](https://www.uwe.ac.uk/-/media/uwe/documents/research/guidance-on-security-sensitive-research.pdf). | Choose an item. |
| Please provide details of the research that may be considered to be security sensitive. |
| Click or tap here to enter text. |
| Does the project involve conducting research overseas? | Choose an item. |
| Have you received approval from your Head of Department/Associate Dean (RKE) and is there sufficient insurance in place for your research overseas? | Choose an item. |
| Please provide details of any ethical issues which may arise from conducting research overseas and how you will address these. |
| Click or tap here to enter text. |

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| **Section 7: Supporting Documentation** |
| Please ensure that you provide copies of all relevant documentation, otherwise the review of your application will be delayed. Relevant documentation should include a copy of: • The research proposal or project design.• The participant information sheet and consent form, including a UWE privacy notice (see links below). • The questionnaire/survey.• External ethics approval and any supporting documentation. For further guidance concerning Participant Information Sheet, Consent form and Research Privacy Notice please visit [Research Ethics policies, procedures and guidance](https://www.uwe.ac.uk/research/policies-and-standards/research-ethics/policies-procedures-and-guidance) Please note, the Privacy Notice must be tailored to each specific research project. If the Privacy Notice is not provided alongside the PIS and consent form you may make this available to participants electronically by using a dedicated folder on OneDrive. Please clearly label each document - ensure you include the applicant's name, document type and version/date (e.g. Joe Bloggs - Questionnaire v1.5 191018).  |

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| **Section 8: Declaration** |
|  [ ]  By ticking this box, I confirm that the information contained in this application, including any accompanying information is, to the best of my knowledge, complete and correct. I have attempted to identify all risks related to the research that may arise in conducting this research and acknowledge my obligations and the right of the participants.Name: Click or tap here to enter text.Date: Click or tap to enter a date. |

**This form should be submitted electronically to the Research Ethics Admin Team:** **researchethics@uwe.ac.uk** **and email copied to the Supervisor/Director of Studies where applicable, together with all supporting documentation (research proposal, participant information sheet, consent form etc).**

**Please provide all the information requested and justify where appropriate.**

**For further guidance, please see** [**http://www1.uwe.ac.uk/research/researchethics**](http://www1.uwe.ac.uk/research/researchethics) **(applicants’ information)**

1. Further details of the Human Tissue Act (2004) and the list of materials considered to be ‘relevant materials’ under the Act can be found at: <https://www.hta.gov.uk/policies/list-materials-considered-be-%E2%80%98relevant-material%E2%80%99-under-human-tissue-act-2004>.
 [↑](#footnote-ref-1)
2. Please note: if you are using relevant material and it is for a ‘scheduled purpose’ you will need HRA approval. [↑](#footnote-ref-2)