**APPLICATION FOR ETHICAL REVIEW OF RESEARCH INVOLVING HUMAN PARTICIPANTS**

This application form should be completed by members of staff and PhD/ Prof Doc students undertaking research which involves human participants. Undergraduate and Masters level students are required to complete this application form where their project has been referred for review by a supervisor to a Faculty Research Ethics Committee (FREC) in accordance with the policy at[**http://www1.uwe.ac.uk/research/researchethics**](http://www1.uwe.ac.uk/research/researchethics)**.** For research using human tissue, please see separate policy, procedures and guidance linked from [**http://www1.uwe.ac.uk/research/researchethics/policyandprocedures.aspx**](http://www1.uwe.ac.uk/research/researchethics/policyandprocedures.aspx)

Please note that the process takes **up to six weeks** from receipt of a valid application. **The research should not commence until written approval has been received from the University Research Ethics Committee (UREC) or Faculty Research Ethics Committee (FREC).** You should bear this in mind when setting a start date for the project.

**APPLICANT DETAILS**

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| --- | --- | --- | --- |
| Name of Applicant\* |  | | |
| Faculty |  | Department |  |
| Status: Staff/PG Student/ MSc Student/ Undergraduate |  | Email address |  |
| Contact postal address |  | | |
| Name of co-  researchers\* (where applicable) |  | | |

\*This form must include the name of the UWE Project Manager (normally the budget holder and PI)

**FOR STUDENT APPLICANTS ONLY**

|  |  |
| --- | --- |
| Name of Supervisor/Director of Studies |  |
| Detail of course/degree for which research is being undertaken |  |
| Supervisor’s/Director of Studies’ email address |  |
| Supervisor’s/  Director of Studies’ comments | ***Please note the supervisor must add comments here. Failure to do so will result in the application being returned.*** |
| **For student applications, 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; * The procedures for recruitment of research participants and obtained informed consent are appropriate. | |

**PROJECT DETAILS**

|  |  |  |  |
| --- | --- | --- | --- |
| Project title |  | | |
| Is this project externally funded? | Yes/No | | |
| If externally funded please give PASS reference |  | | |
| Proposed start date for the research |  | Anticipated project end date |  |

**Fieldwork should not begin until ethics approval has been given**

**DETAILS OF THE PROPOSED WORK**

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| **Aims, objectives of and background to the research** |
| *This should provide the reviewer of the application with sufficient detail to allow them to understand the nature of the project and its rationale, and the ethical context, in terms which are clear to a lay reader. Do not assume that the reader knows you or your area of work. You may provide a copy of your research proposal in addition to completing this section. Please try to keep within 500 words.* |
|  |
| 1. **Research methodology to be used** |
| *You should explain how you plan to undertake your research. A copy of the interview schedule/ questionnaire/observation schedule/focus group topic guide should be attached where applicable.* |
|  |
| 1. **SELECTION OF PARTICIPANTS** |
| *You must indicate if any of the participants in your sample group are in the categories listed. Research involving adult participants who might not have the capacity to consent or who fall under the Mental Capacity Act must be reviewed either by an NHS Research Ethics Committee or the* [*National Social Care Research Ethics Committee*](http://www.hra.nhs.uk/resources/before-you-apply/non-nhs-recs/national-social-care-research-ethics-committee/)*.*  *If your proposed research involves contact with children or vulnerable adults, or others of the specified categories below, you may need to hold a valid DBS check. Evidence of a DBS check should take the form of an email from the relevant counter signatory confirming the researcher has a valid DBS check for working with children and/or vulnerable adults. It is the responsibility of the applicant to provide this confirmation.*  *Members of staff requiring DBS checks should contact Human Resources* [*hr@uwe.ac.uk*](mailto:hr@uwe.ac.uk)*. DBS checks for students are usually organised through the student's faculty, but students in faculties without a DBS counter signatory should contact* ***Marisa Downham*** *(Marisa.Downham@uwe.ac.uk).* |
| **Will the participants be from any of the following groups?** *( ‘x’ as appropriate)*  Children under 18\*  Adults who are unable to consent for themselves  Adults who are unconscious, very severely ill or have a terminal illness  Adults in emergency situations  Adults with mental illness (particularly if detained under Mental Health Legislation)  Prisoners  Young Offenders  Healthy Volunteers (where procedures may be adverse or invasive)  Those who could be considered to have a particularly dependent relationship with the investigator, e.g. those in care homes, medical students  Other vulnerable groups  None of the above  *\* If you are researching with children please provide details of completed relevant safeguarding training.*  **If any of the above applies, please justify their inclusion in this research.** |
| **Please explain how you will determine your sample size/recruitment strategy, and identify, approach and recruit your participants. Please explain arrangements made for participants who may not adequately understand verbal explanations or written information in English** |
| *In this section, you should explain the rationale for your sample size and describe how you will identify and approach potential participants and recruit them to your study.* |
|  |
| **What are your arrangements for obtaining informed consent whether written, verbal or other? (where applicable, copies of participant information sheets and consent forms should be provided)** |
| *Informed consent is an ethical requirement of most research. Applicants should demonstrate that they are conversant with and have given due consideration to the need for informed consent and that any consent forms prepared for the study ensure that potential research participants are given sufficient information about a study, in a format they understand, to enable them to exercise their right to make an informed decision whether or not to participate in a research study.*  *You should describe how you will obtain informed consent from the participants and, where this is written consent, include copies of participant information sheets and consent forms. Where other forms of consent are obtained (eg verbal, recorded) you should explain the processes you intend to use. If you do not intend to seek consent or are using covert methods, you need to explain and justify your approach. Please consider carefully whether or not you need to seek consent for archiving or re-use of data.* |
|  |
| **What arrangements are in place for participants to withdraw from the study?** |
| *Consent must be freely given with sufficient detail to indicate what participating in the study will involve and how they may withdraw. There should be no penalty for withdrawing and the participant is not required to provide any reason.*  *Please note:* *allowing participants to withdraw at any time could prejudice your ability to complete your research. It may be appropriate to set a fixed final withdrawal date.* |
|  |
| **If the research generates personal data, please describe the arrangements for maintaining anonymity and confidentiality (or the reasons for not doing so)** |
| *You should explain what measures you plan to take to ensure that the information provided by research participants is anonymised/pseudonymised (where appropriate) and how it will be kept confidential. In the event that the data are not to be anonymised/pseudonymised, please provide a justification.*  ***IMPORTANT:*** *Please refer to* [*Research and GDPR compliance*](https://intranet.uwe.ac.uk/whats-happening/sites/gdpr/updates/pages/research-and-gdpr-compliance-update-08-may-2019.aspx) ***20May 2019***  [*Research Template Privacy Notice*](https://docs.uwe.ac.uk/ou/Communications/_layouts/15/download.aspx?SourceUrl=https://docs.uwe.ac.uk/ou/Communications/Documents/GDPR/guidance_on_research_participant_privacy_notice%20FINAL.docx)  [Research Template Consent form](https://docs.uwe.ac.uk/ou/Communications/_layouts/15/download.aspx?SourceUrl=https://docs.uwe.ac.uk/ou/Communications/Documents/GDPR/GDPR%20consent%20form%20FINAL.docx)  [Research Template Information Sheet](https://docs.uwe.ac.uk/ou/Communications/_layouts/15/download.aspx?SourceUrl=https://docs.uwe.ac.uk/ou/Communications/Documents/GDPR/guidance_on_participant_information_sheets%20FINAL.docx)  Please confirm that you have included the UWE Privacy Notice with the Participant Information Sheet and Consent Form |
|  |
| **Please describe how you will store data collected in the course of your research and maintain data Security and protection.** |
| *Describe how you will store the data, who will have access to it, and what happens to it at the end of the project, including any arrangements for long-term storage of data and potential re-use. If your research is externally funded, the research sponsors may have specific requirements for retention of records. You should consult the terms and conditions of grant awards for details.*  ***It may be appropriate for the research data to be offered to a data archive for re-use. If this is the case, it is important that consent for this is included in the participant consent form****.*  *UWE IT Services provides data protection and encryption facilities - see* [*http://www.uwe.ac.uk/its-staff/corporate/ourpolicies/intranet/encryption\_facilities\_provided\_by\_uwe\_itservices.shtml*](http://www.uwe.ac.uk/its-staff/corporate/ourpolicies/intranet/encryption_facilities_provided_by_uwe_itservices.shtml) |
|  |
| **What risks (eg physical, psychological, social, legal or economic), if any, do the participants face in taking part in this research and how will you AddRESS these risks?** |
| *Describe ethical issues related to the physical, psychological and emotional wellbeing of the participants, and what you will do to protect their wellbeing. If you do not envisage there being any risks to the participants, please make it clear that you have considered the possibility and justify your approach.* |
|  |
| **Are there any potential risks to researchers and any other people impacted by this study as a consequence of undertaking this Research that are greater than those encountered in normal day to day life?** |
| *Describe any health and safety issues including risks and dangers for both the participants and yourself (if appropriate) and what you will do about them. This might include, for instance, arrangements to ensure that a supervisor or co-researcher has details of your whereabouts and a means of contacting you when you conduct interviews away from your base; or ensuring that a ‘chaperone’ is available if necessary for one-to-one interviews.*  *Please check to confirm you have carried out a risk assessment for your research* |
|  |
| **How will the results of the research be reported and disseminated?** |
| *Please indicate in which forms and formats the results of the research will be communicated.* |
| **(Select all that apply)**  Peer reviewed journal  Conference presentation  Internal report  Dissertation/Thesis  Other publication  Written feedback to research participants  Presentation to participants or relevant community groups  Digital Media  Other (Please specify below) |
| **12. WILL YOUR RESEARCH BE TAKING PLACE OVERSEAS?** |
| *If you intend to undertake research overseas, please provide details of additional issues which this may raise, and describe how you will address these. Eg language, culture, legal framework, insurance, data protection, political climate, health and safety. Please also clarify whether or not ethics approval will be sought locally in another country.* |
|  |
| **13. Are there any other ethical issues that have not been addressed which you would wish to bring to the attention of the Faculty and/or University Research Ethics Committee?** |
| *This gives the researcher the opportunity to raise any other ethical issues considered in planning the research or which the researcher feels need raising with the Committee.* |
|  |

**CHECKLIST**

**Please complete before submitting the form**

**Please note: supporting documentation should include version numbers and dates**

|  |  |
| --- | --- |
|  | **Yes/No** |
| Is a copy of the research proposal attached? |  |
| Have you explained how you will select the participants? |  |
| Is a participant information sheet attached? |  |
| Is a participant consent form attached? |  |
| Is a copy of your questionnaire/topic guide attached? |  |
| Have you described the ethical issues related to the well-being of participants? |  |
| Have you described fully how you will maintain confidentiality? |  |
| Have you included details of data protection including data storage? |  |
| Where applicable, is evidence of a current DBS (formerly CRB) check attached? |  |
| Have you considered health and safety issues for the participants and researchers? |  |

**DECLARATION**

**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.**

|  |  |
| --- | --- |
| **Principal Investigator name** |  |
| **Signature** |  |
| **Date** |  |
| **Supervisor or module leader name (where**  **appropriate)** |  |
| **Signature** |  |
| **Date** |  |

**The signed form should be submitted electronically to Committee Services:** [**researchethics@uwe.ac.uk**](mailto: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).**

**For student applications where an electronic signature is not available from the Supervisor we will require an email from the Supervisor confirming support.**

**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)**