

**UNDERSTANDING ETHICS PROCEDURES**

**Formal Ethics Assessment**

Please ensure you complete your "Ethics Pre-screening Form" prior to completing your "Formal Ethics Assessment”.

All Undergraduate (UG) and Postgraduate (PG) submissions will be reviewed by the tutor responsible for that student.

**Section 1: Personal and Project Details (For the completion of the student)**

|  |  |  |
| --- | --- | --- |
| **Student Details** | | |
| Student Name | Click or tap here to enter text. | |
| Student Number | Click or tap here to enter text. | |
|  | | |
| **Study Level (Please indicate with a tick)** | | |
| Undergraduate (BA, BSc) | |  |
| Postgraduate (MA, MSc) | |  |
|  | | |
| Course Title: | Click or tap here to enter text. | |
| Module Title: | Click or tap here to enter text. | |
|  | | |
| **Project Information** | | |
| Project Title: | Click or tap here to enter text. | |

|  |  |
| --- | --- |
| **Formal Ethics Assessment (for the completion of the student’s tutor)** | |
| Tutor Name: | Click or tap here to enter text. |
| Date Application Received: | Click or tap to enter a date. |

**Section 2: Research Methodology (For the completion of the student)**

Please provide a summary of the research methodology using the table below. For each method, please describe how it has been selected and how the data will be analysed.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Method** | **Why was the method selected?** | | | | |
|  |  | | | | |
| **Description of Participants** | **Data Analysis** | | | | |
|  |  | | | | |
|  | |  | | | |
| Where will the project be undertaken |  | | | | |
| Please describe details of any permissions required to use the location(s) specified |  | | | | |
| **Section 3: Risk to Researchers (For the completion of the student)** | | | | | |
| **Answer following questions, if you respond yes to a given question, please answer the subsequent follow up questions.** | | **Yes** | | **No** | |
| Will the research involve international travel and/or travel to a potentially risky environment? | |  | |  | |
| **If yes.** | | | | | |
| Please describe the risk to researchers | |  | | | |
| Please provide details of the actions to be taken to reduce risks to researchers and procedures to deal with potential problems | |  | | | |
|  | | | | | |
| **Answer following questions, if you respond yes to a given question, please answer the subsequent follow up questions.** | | **Yes** | | **No** | |
| Will the research involve the use of hazardous or controlled substances? | |  | |  | |
| **If yes,** | |  | | | |
| Please describe the risk to researchers | |  | | | |
| Please provide details of the actions to be taken to reduce risks to researchers and procedures to deal with potential problems | |  | | | |
|  | |  | | | |
| **Answer following questions, if you respond yes to a given question, please answer the subsequent follow up questions.** | | **Yes** | | **No** | |
| Does the research have potential to cause distress, discomfort or personal injury to any member of the research team? | |  | |  | |
| **If yes,** | | | | | |
| Please describe the risk to researchers | |  | | | |
| Please provide details of the actions to be taken to reduce risks and procedures to deal with potential problems | |  | | | |
|  | |  | | | |
| **Answer following questions, if you respond yes to a given question, please answer the subsequent follow up questions.** | | **Yes** | | **No** | |
| Does the research involve lone working? | |  | |  | |
| **If yes,** | | | | | |
| Please describe the risk to researchers | |  | | | |
| Please provide details of the actions to be taken to reduce risks to researchers and procedures to deal with potential problems | |  | | | |
|  | |  | | | |
| **Answer following questions, if you respond yes to a given question, please answer the subsequent follow up questions.** | | **Yes** | | **No** | |
| Does the research involve visiting participants in their home or other non-public space? | |  | |  | |
| **If yes,** | | | | | |
| Please describe the risk to researchers | |  | | | |
| Please provide details of the actions to be taken to reduce risks to researchers and procedures to deal with potential problems | |  | | | |
| Please describe the training that will be provided to researchers in relation to the risks identified above | |  | | | |
|  | |  | | | |
| **Answer following questions, if you respond yes to a given question, please answer the subsequent follow up questions.** | | **Yes** | | **No** | |
| Does the research involve the use of genetically modified organisms? | |  | |  | |
| **If yes,** | | | | | |
| Please describe the use of GMOs in the research | |  | | | |
|  | | | | | |
| **Note:** Do you need to support this section with any of the following?   * Health and Safety Risk Assessment * COSHH Risk Assessment Form | | | | | |
|  | | | | | |
| **Section 3: Human Participants (For the completion of the student)** | | | | | |
| **Answer following questions, if you respond yes to a given question, please answer the subsequent follow up questions.** | | **Yes** | | **No** | |
| Does the research involve human participants? | |  | |  | |
| **If yes,** | |  | |  | |
| How will human participants be identified? | |  | | | |
| Please list any inclusion criteria to be used | |  | | | |
| Please list any exclusion criteria to be used | |  | | | |
| Please specify if you are using any of the protected characteristics as defined in the Equality Act 2010 as an exclusion criteria | |  | | | |
| Please specify how potential participants, records or samples will be identified and by whom | |  | | | |
|  | |  | | | |
| **Answer following question, if you respond yes to a given question, please answer the subsequent follow up question.** | | **Yes** | | **No** | |
| Does your research involve participants who are in a potentially vulnerable situation? This could include any children or vulnerable adults. | |  | |  | |
| **If yes,** | |  | |  | |
| Please describe why the participants may be in a potentially vulnerable situation | |  | | | |
| Please describe how the participants will be protected | |  | | | |
|  | |  | | | |
| **Answer following question, if you respond yes to a given question, please answer the subsequent follow up question.** | | **Yes** | | **No** | |
| Does your research involve community-based participatory research. | |  | |  | |
| **If yes,** | |  | | | |
| Please refer to the guidance on community-based participatory research and describe how needs and expectations will be managed to ensure ethical practice is encouraged and enforced. | |  | | | |
|  | |  | | | |
| **Approaching Participants** | |  | | | |
| If applicable, describe any existing relationship between the investigator(s) and participant(s) (e.g. teacher-student or employer-employee). Please explain how this will be managed to reduce the risk to participants | |  | | | |
|  | |  | | | |
| **Recruiting participants** | |  | | | |
| Please describe how long you will allow participants to decide whether to take part | |  | | | |
|  | |  | | | |
| **Answer following question. Check “Yes” or “No”.** | | **Yes** | | **No** | |
| Will informed consent be obtained from the research participants? | |  | |  | |
| How will feedback be provided to participants either during or at the end of the project? | |  | |  | |
|  | |  | | | |
| **Withdrawal of Participants** | |  | | | |
| Please describe the arrangements that will be made for participants to withdraw their participation and data (either in part or in full) both during and after the research project | |  | | | |
| Please explain any consequences for the participant of withdrawing from the study and indicate what will be done with the participant’s data if they withdraw | |  | | | |
| Please describe whether and how participants will be able to withdraw their data after the results have been published | |  | | | |
|  | |  | | | |
| **Answer following questions. Check “Yes” or “No”.** | | **Yes** | | **No** | |
| Will the research involve actively deceiving participants? | |  | |  | |
| Does the project involve study or participation in social media activity? | |  | |  | |
| Will the research involve discussion or collection of information on potentially sensitive, embarrassing or distressing topics? | |  | |  | |
| Does the research involve investigation or possible disclosure of illegal activities or behaviours? | |  | |  | |
| Is it possible that this research will lead to awareness or the disclosure of actual or intended harm to a participant or other individual? | |  | |  | |
|  | |
| **Answer following questions, if you respond yes to a given question, please answer the subsequent follow up question.** | | **Yes** | | **No** | |
| Is there a risk of physical harm, psychological harm or discomfort for participants, or prolonged or repetitive testing which may be a burden to participants? | |  | |  | |
| **If yes,** | |  | |  | |
| Please describe each potential risk and the likelihood of the risk occurring | |  | | | |
| Please describe how each potential risk will be monitored and mitigated | |  | | | |
|  | |  | |  | |
| **Answer following questions, if you respond yes to a given question, please answer the subsequent follow up question.** | | **Yes** | | **No** | |
| Does the research involve invasive or potentially intrusive procedures? | |  | |  | |
| **If yes,** | |  | | | |
| Procedure | |  | | | |
| Description of Participants | |  | | | |
| Location | |  | | | |
| Number of occasions estimated completion time | |  | | | |
| Frequency and Duration | |  | | | |
| Researcher(s) carrying out procedure | |  | | | |
|  | |  | | | |
| **Answer following questions, if you respond yes to a given question, please answer the subsequent follow up question.** | | **Yes** | | **No** | |
| Does the research involve the administration of substances? | |  | |  | |
| **If yes,** | |  | | | |
| Substance and Method of Administration | |  | | | |
| Description of Participants | |  | | | |
| Location | |  | | | |
| Number of occasions estimated completion time | |  | | | |
| Frequency and Duration | |  | | | |
| Researcher(s) administering substance | |  | | | |
|  | |
| **Answer following questions, if you respond yes to a given question, please answer the subsequent follow up question.** | | **Yes** | | **No** | |
| Will your research involve collecting, storing or processing human tissue samples? | |  | | | |
| **If yes,** | |  | | | |
| What types of human tissue samples are involved? | |  | | | |
| Please describe how each type of sample will be collected | |  | | | |
| Please describe how each type of sample will be processed | |  | | | |
| Please describe how each type of sample will be stored | |  | | | |
| Please describe what will happen to the samples at the end of the study, including how they will be destroyed, transferred or retained | |  | | | |
| Please advise the latest sample storage end-date. | |  | | | |
| If the samples are to be retained for use in your future research or by other researchers, please describe the process that will be followed to store the samples and to provide access to them at a later date | |  | | | |
|  | |
| **Answer following question. Check “Yes” or “No”.** | | **Yes** | | **No** | |
| Does your research require you to have a DBS check? | |  | |  | |
|  | |  | | | |
| **Answer following questions, if you respond yes to a given question, please answer the subsequent follow up question.** | | **Yes** | | **No** | |
| Will the participants receive financial compensation or other rewards? | |  | |  | |
| **If yes,** | |  | | | |
| Please describe the financial compensation or other rewards | |  | | | |
| Please describe how you will deal with compensation if participants choose to withdraw | |  | | | |
|  | |  | |  | |
| **Note:** Do you need to support this section with any of the following?   * Participant Information Sheet * Participant Consent Form * Parent/Guardian Consent Form * Health and Safety Risk Assessment | | | | | |
|  | | | | | |
| **Section 5: Involvement of Animals (For the completion of the student)** | | | | | |
| **Answer following questions, if you respond yes to a given question, please answer the subsequent follow up question.** | | **Yes** | | **No** | |
| Does your research involve live animals? | | ☐ | |  | |
| **If yes,** | |  | | | |
| Species | |  | | | |
| Number | |  | | | |
| Life Stage | |  | | | |
| How many live animals will be used? | |  | | | |
| How and where will the animals be sourced? | |  | | | |
| Indicate if the source is within the UK, within EU/EEA, or in the rest of world. | |  | | | |
| Please include information on how and where you will obtain the animals, including any suppliers involved and how you are assured that the suppliers are meeting appropriate welfare standards | |  | | | |
|  | |
| **Answer following questions, if you respond yes to a given question, please answer the subsequent follow up question.** | | **Yes** | | **No** | |
| Are wild animals involved? | | ☐ | |  | |
| **If yes,** | |
| Indicate where these are obtained, if they are captured for this project and if so, how they are captured | |  | | | |
| Please explain how each capture method is the most refined for the species and purpose of the study. Include details on the positioning of traps, frequency of checking and the potential for non-target species to be captured | |  | | | |
| How will you examine and assess any animals that are found to be ill or injured at the time of capture? | |  | | | |
| How will you ensure the competence of the person responsible for making this assessment? | |  | | | |
| If sick or injured animals are to be treated, how will you transport them for treatment? | |  | | | |
| If sick or injured animals are to be humanely killed, which methods will you use? | |  | | | |
| If animals are to be transported, please describe how, by whom and how welfare standards will be maintained during transport (e.g. environmental conditions, frequency of checking) | |  | | | |
|  | |
| **Answer following questions, if you respond yes to a given question, please answer the subsequent follow up question.** | | **Yes** | | **No** | |
| Does your research involve tissues obtained from animals? | | ☐ | |  | |
| **If yes,** | |
| What type of samples? | |  | | | |
| How many samples? | |  | | | |
| How and where will the samples be sourced? Please describe the sources of the animal tissue. Describe any permissions and transfer agreements which may be required | |  | | | |
| Please indicate if the source is within the UK, within EU/EEA, or in the rest of world | |  | | | |
| Please include information on how and where you will obtain the tissue samples, including details of any suppliers involved and how you are assured that the suppliers meet appropriate animal welfare standards | |  | | | |
| If tissue samples are to be transported, please describe how and by whom. Describe how the sample integrity will be maintained | |  | | | |
| Explain why you need to use animals and/or animal tissue in this project | |  | | | |
|  | |
| **Explain how you have considered the principles of the 3Rs (Replacement, Reduction, Refinement)** | | | | | |
| **Replacement** - Avoiding or replacing animal use entirely throughout your research | |  | | | |
| **Reduction** - Where animal use is essential, keeping numbers to the minimum | |  | | | |
| **Refinement** - Where animal use is essential, refining research activities to ensure no pain, suffering or distress is inflicted on the animals e.g., ensuring they are able to perfume their natural behaviours | |  | | | |
|  | |  | | | |
| **Answer following questions, Check “Yes” or “No”.** | | **Yes** | | **No** | |
| Does your project involve observation without intervention? | | ☐ | | ☐ | |
| Does your project involve any interventions or invasive procedures? | | ☐ | | ☐ | |
| Is the research regulated under the Animals Scientific Procedures Act 1986 (ASPA)? | | ☐ | | ☐ | |
|  | |
| **Answer following questions, if you respond yes to a given question, please answer the subsequent follow up question.** | | **Yes** | | **No** | |
| Is the animal research to be conducted outside the UK? | | ☐ | | ☐ | |
| **If yes,** | |
| **Answer following questions, Check “Yes” or “No” or where appropriate provide a full answer.** | | **Yes** | | **No** | |
| Would the research be regulated under the Animals (Scientific Procedures) Act 1986 as if it were to be conducted in the UK? | | ☐ | | ☐ | |
| Does this research require another licence or site permissions for conducting the research or for transporting animals or samples? | | ☐ | | ☐ | |
|  | |  | | | |
| What arrangements are in place to protect the welfare of the animals concerned | |  | | | |
| Describe any potential harms or adverse effects that will be experienced by the animals | |  | | | |
| Describe how the potential harms and adverse effects will be monitored and mitigated | |  | | | |
| How long will the animals be kept? | |  | | | |
| What will happen to the animals at the end of the research? | |  | | | |
| What training will be provided for the research team? | |  | | | |
|  | |  | |  | |
| **Section 6: Data Management (For the completion of the student)** | | | | | |  |
| What data will be collected and used during the project? | |  | | | |
| Where and how will data be stored during the project? | |  | | | |
| How long will the data be retained after the project is complete? | |  | | | |
| How will data be destroyed when it is no longer needed? | |  | | | |
| How will access to the data be controlled? | |  | | | |
|  | |  | | | |
| **Answer following question, if you respond yes to a given question, please answer the subsequent follow up question.** | | **Yes** | | **No** | |
| Will the research or its results involve the use of any sensitive or restricted materials? | | ☐ | | ☐ | |
| **If yes,** | |  | | | |
| Describe the use of sensitive or restricted materials | |  | | | |
| Please describe any associated risks and how they will be mitigated | |  | | | |
|  | |  | | | |
| **Answer following question, if you respond yes to a given question, please answer the subsequent follow up question.** | | **Yes** | | **No** | |
| Will the research or its results pose any potential environmental impact? | | ☐ | | ☐ | |
| **If yes,** | |  | | | |
| Describe any potential environmental impact of the research or its results | |  | | | |
| Please describe how any potential impacts will be monitored and minimised | |  | | | |
|  | |
| **Answer following questions, Check “Yes” or “No”.** | | **Yes** | | **No** | |
| Is there an access control process or a gatekeeper for access to data e.g secondary data? | | ☐ | | ☐ | |
| Will any of the data be used in future research and/or made available to other research projects? | | ☐ | | ☐ | |  |
| Will your project involve processing confidential data belonging to organisations? | | ☐ | | ☐ | |  |
| Will your project involve collecting new personal data from participants? | | ☐ | | ☐ | |  |
| Does the research involve photographs, videos or audio recordings of research participants? | | ☐ | | ☐ | |
| Will participant data be treated as confidential? | |  | |  | |
| Will participant data be anonymous? | | ☐ | | ☐ | |
| Will participant data be pseudonymised or link-anonymised? | | ☐ | | ☐ | |  |
| **Section 7: Student Declaration (For the completion of the student)** | | | | | |
| **Declaration** | | **Yes** | | **No** | |
| I agree to take full responsibility for the information provided in this form. | |  | |  | |
| I confirm that I will not commence with my research until my Ethics Application has been granted full ethics approval. | |  | |  | |
|  | |
| **Name:** | |  | | | |
| **Date:** | |  | | | |
|  | | | | | |
| **Section 8: Tutor Decision and Declaration (For the completion of the tutor)** | | | | | |
| **Risk (Please refer to the “Framework for Identifying Ethical Risk for UG and PG Students”)** | | **Low** | **Medium** | | **High** |
| Risk | |  |  | |  |
|  | |  | |  | |
| **Decision** | | | | | |
| Decision Made | | Choose an item. | | | |
| Decision Date | | Click or tap to enter a date. | | | |
| Approval End Date | | Click or tap to enter a date. | | | |
|  | |  | | | |
| **Conditional Approval** | | | | | |
| **Answer following question, if you respond yes to a given question, please answer the subsequent follow up question.** | | **Yes** | | **No** | |
| Has the application been conditionally approved? | |  | |  | |
| **If yes,** | | | | | |
| What is the condition? | |  | | | |
|  | | | | | |
| **Escalation** | | | | | |
| **Answer following question, if you respond yes to a given question, please answer the subsequent follow up question.** | | **Yes** | | **No** | |
| Escalation Required? | |  | |  | |
| Reviewer’s Name: | |  | | | |
|  | |  | | | |
| **Comments** | | | | | |
| The nature of the application, reason for escalation? | | | | | |
|  | | | | | |
| **Declaration (for the completion of the applicant’s tutor)** | | | | | |
| As the applicant’s tutor, I agree with the information provided in this form and I will monitor this student’s research as it progresses and will reassess the need for an ethics application periodically. | |  | | | |
|  | |  | | | |
| Name: | |  | | | |
| Date: | |  | | | |