Depending on your research study, you may need to include supporting documentary evidence as part of this form. Please refer to the University Research Ethics and Governance handbook, or those provided by your Faculty or Service Department for information about the type of evidence you need to provide.

|  |  |
| --- | --- |
| **Project title:** |  |

|  |  |
| --- | --- |
| **Submitter Name:** |  |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Status:** |  | Staff |  | PG research |  | PG taught |  | Undergraduate |

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| --- | --- |
| **Faculty:** |  |
| **Department:** |  |
| **Email:** |  |
| **Principal Supervisor (if relevant):** |  |
| **Please list your co-investigators (if relevant):** |  |

**Data Source**

Tick all relevant boxes that apply to your proposed research and then make sure that you also complete **all** of the relevant sections.

|  |  |
| --- | --- |
| **1. People and/or personal data of a living individual** |  |

Participants are defined as including living human beings; also included are human beings who have recently died, embryos and foetuses, human tissue and bodily fluids, where the remains/body parts etc are still held on NHS premises and require specific permission from the NHS to access. This also includes human data and records (such as but not restricted to medical, genetic, financial, personnel, criminal or administrative records including scholastic achievements). Personal data is defined as any identifiable information that affects a person's privacy such as information which is biographical in a significant sense or has the relevant individual as its focus rather than some other person or some transaction or event. This includes video/audio and photographic materials.

**PLEASE COMPLETE SECTIONS: 1, 5, 6, 7, 8, 9**

|  |  |
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| **2. Human Tissue** |  |

Any material that has come from a human body that consists of, or includes human cells, with the exception of hair and nails from living people, and live gametes and embryos created outside the human body.

**Please Complete SectionS: 2, 5, 6, 7, 8, 9**

|  |  |
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| **3. Animal Subjects** |  |

Any living vertebrate, other than man, and any living cephalopod*.*

**Please Complete SectionS: 3, 5, 7, 8, 9**

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| **4. Hazardous Materials** |  |

Does your Research involve work with, transport of or disposal of any of the following:?

* Chemicals/gases
* Biological agents
* Genetically modified organisms
* Nanotechnology
* Radioactive materials

**Please Complete SectionS: 4, 5, 7, 8, 9**

**1. PEOPLE AND/OR PERSONAL DATA**

If you are involving human participants, or are gathering personal data about a living individual then please complete all of the sub-sections in section 1.

**A: RESEARCH AIMS**

State your research aims/questions (maximum 500 words). This should provide the theoretical context within which the work is placed, and should include an evidence-based background, justification for the research, and clearly stated hypotheses (if appropriate):

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**B: Study design and data analysis**

Please provide a description of the study design, methodology (e.g. quantitative, qualitative), the sampling strategy, methods of data collection (e.g. survey, interview, experiment, observation), and analysis

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**Ci SAMPLE**

Provide details of the sample groups that will be involved in the study and include details of their location (whether recruited in the UK or from abroad) and any organizational affiliation. For most research studies, this will cover: the number of sample groups; the size of each sample group; the criteria that will be used to select the sample group(s) (e.g. gender, age, sexuality, health conditions).If the sample will include NHS staff or patients please state this clearly. If this is a pilot study and the composition of the sample has not yet been confirmed, please provide as many details as possible.

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Will your study involve vulnerable people? Refer to the University ‘Policy on Research Involving Children and Vulnerable Adults’ for definitions and examples of “vulnerable”.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**If yes:** Describe what role, if any, parents/carers/consultees will take in the study:

|  |
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|  |

**Cii** If you will be including personal data of living individuals, please specify the nature of this data, and (if appropriate) include details of the relevant individuals who have provided permission to utilise this data, upload evidence of these permissions in the supporting documentation section.

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**ciii. RecruitMENT**

Describe the step by step process of how you will contact and recruit your research sample and name any organisations or groups that will be approached. Your recruitment strategy must be appropriate to the research study and the sensitivity of the subject area. You must have received written permission from any organizations or groups before you begin recruiting participants. Copies of draft requests for organizational consent must be included in the ‘Supporting Documentary Evidence’. You must also provide copies of any recruitment emails/posters that will be used in your study.

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Will you make any payment or remuneration to participants or their carers/consultees?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**If yes:** Please provide details/justifications. Note that your Faculty may have specific guidelines on participant payments/payment rates etc and you should consult these where appropriate:

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**Civ. Research team – DBS clearance**

If you, or any members of the research team, will have regular contact on an individual basis with children or vulnerable adults as part of this research study, the relevant DBS (Disclosure and Barring Service) clearance may have to be obtained in advance. Check at the DBS website https://www.gov.uk/disclosure-barring-service-check/overview and then complete the sections below

Will you, or any member of your research team, require DBS clearance?

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| --- | --- | --- | --- |
|  | Yes |  | No |

**If yes:** Provide details of the DBS clearance that has been obtained

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Type of DBS clearance**  **(State: standard, enhanced, enhanced with lists)** | **Reference** | **Date of DBS check** |
|  |  |  | Click here to enter a date. |
|  |  |  | Click here to enter a date. |
|  |  |  | Click here to enter a date. |
|  |  |  | Click here to enter a date. |

**D. CONSENT**

Please indicate the type of consent that will be used in this study:

|  |  |
| --- | --- |
|  | **Informed consent** |

Please include copies of information sheets and consent forms in the ‘Supporting Documentary Evidence’. If you are using alternative formats to provide information and /or record consent (e.g. images, video or audio recording), provide brief details and outline the justification for this approach and the uses to which it will be put:

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|  | **Informed consent in line with sections 30-33 of the Mental Capacity Act** |

If the study involves participants who lack capacity to consent, procedures in line with sections 30-33 of the Mental Capacity Act will need to be put in place. Please outline the intended process for seeking consent and include copies of information and consent forms in the ‘Supporting Documentary Evidence’. If you are using alternative formats to provide information and /or record consent (e.g. video or audio recording), provide brief details:

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|  | **If using an alternative consent model (e.g. for ethnographic research)** |

Provide a rationale that explains why informed consent is not appropriate for this research study and detail the alternative consent arrangements that will be put in place. Add any relevant supporting documentation to the ‘Supporting Documentary Evidence’ section.

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**F. Tasks and activities for research participants**

1. Provide a detailed description of what the participants will be asked to do for the research study, including details about the process of data collection (e.g. completing how many interviews / assessments, when, for how long, with whom). Add any relevant documentation to the ‘Supporting Documentary Evidence’ section of this form.

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1. Provide full details of all materials that will be used (including consent documentation). If you are using newly developed or unpublished materials these must be provided as Supporting Documentary Evidence

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1. If the task could cause any discomfort or distress to participants (physical, psychological or emotional) describe the measures that will be put in place to reduce any distress or discomfort. Please give details of the support that will be available for any participants who become distressed during their involvement with the study.

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1. If the research involves the use of pharmacologically active substances, list these substances here, and state how they will be administered

|  |  |
| --- | --- |
| Substance | Administration method |
|  |  |
|  |  |
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**2. HUMAN TISSUE**

If your research study uses human tissue, all of the questions in this section must be completed.

**A. Samples**

Provide details of the type of human tissue samples (e.g. blood, oral fluids, urine, saliva) and the number of samples the research study will collect and/or examine.

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Will this research study use samples that have been collected by another organisation or institution?

|  |  |  |  |
| --- | --- | --- | --- |
|  | Yes |  | No |

**If yes:** Where applicable ( e.g. commercially available cell lines)provide details of the supplier (company or institution name, address and telephone number). Appropriate letters of permission should be included as supplementary evidence. Describe any measures that will be put in place to meet the supplier’s terms and conditions. (Note: arrangements about anonymising data, data storage and security should be provided in section 6). N.B. Primary cell lines and stem cells require consent documentation and compliance with HTA regulations.

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Describe how the sample will be taken or collected and provide the names and university/company affiliation of the researchers or technicians involved in taking or collecting samples. If your study involves blood samples, name the trained phlebotomist who will be taking the blood samples.

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Provide a schedule that shows the type of sample(s) (e.g. blood, oral fluids, urine, saliva) and the number of samples that will be taken from participants over your chosen period of time.

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If the task could cause discomfort or distress to participants (physical, psychological or emotional) describe the measures that will be put in place to reduce any distress or discomfort.

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Explain how the samples will be disposed of, or transferred to another facility after your research has ended.

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**3. ANIMAL SUBJECTS**

If your research study uses animal subjects or biological material from animals, all of the questions in this section must be completed. If the study has the potential to cause distress or harm to animals, you must consider the 3 Rs (replacement, refinement and reduction) and apply these principles to the study.

**A. Sample**

Describe how animals, or biological material from animals, will be used in this study. Your description should include: the species; the number of animals or the number of samples that will be used in the study; and if the study will take place in the natural environment or in research premises.

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**B. Source of sample**

Provide the contact details (company or organisation name, address and telephone number) of the supplier who is providing the animals or animal tissue. If it is a commercial supplier, include a copy of the letter or email confirming the supplier’s Schedule One status under ‘Supporting Documentary Evidence’. If the supplier is a University, include a letter or email confirming that the animal was culled under Schedule One conditions under ‘Supporting Documentary Evidence’.

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**C. Licenses**

Does your work require licensing under the Animals (Scientific Procedures) Act 1986?

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| --- | --- | --- | --- |
|  | Yes |  | No |

**If yes:** Provide details of the licences that you currently hold or will be applying for:

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**4. HAZARDOUS MATERIALS**

Depending on your activity a COSHH, BioCOSHH or general risk assessment is required by law for the possession or use of hazardous chemicals, substances or agents. The possession or use or biological agents, infected materials and certain toxins is controlled by Health and Safety law and some require operating licences from the Enforcement Authorities.  These materials must be registered with the Central Health & Safety Section *before* they are brought into the University. A risk assessment must be completed and approved before work begins, and before chemicals/substances/samples are brought into the University.

List all the hazardous materials to be used in your study, their use, and transportation/disposal

|  |  |  |  |
| --- | --- | --- | --- |
| Material | Use | Transport | Disposal |
|  |  |  |  |
|  |  |  |  |
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**5**. **RISK**

For RED projects a risk assessment must be completed and approved before work begins, and before chemicals/substances/samples are brought into the University. Please refer to any Risk Assessments (RA) you have consulted and the risk level associated with each; also indicate who has signed off these assessments.

|  |  |  |
| --- | --- | --- |
| Risk Assessment Code | Risk level | Signed off by? |
|  |  |  |
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|  |  |  |
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I have generated new risk assessment(s) – see attached documents

**6. Data security and storage**

1. **ANONYMISING DATA**

Describe the arrangements for anonymising data and if not appropriate explain why this is and how it is covered in the informed consent obtained.

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1. **STORAGE**

Describe the arrangements for the secure transport and storage of data collected and used during the study. This should include reference to ‘clouds’, USB sticks.

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**C. RETENTION AND DISPOSAL**

Describe the arrangements for the secure retention and disposal of data when the research study is complete.

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**7. Intellectual property**

Please provide details of any Intellectual Property issues or commercial implications arising from the proposed study. Please describe the agreements that are in place to protect / exploit the Intellectual Property.

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**8. Timescale**

Proposed start date of data collection: Click here to enter a date.

Proposed end date of data collection: Click here to enter a date.

**9. Supplementary information**

Please tick the boxes that relate to the supplementary documentation that you will attach as part of your submission:

|  |  |
| --- | --- |
|  | Participant information sheet |
|  |  |
|  | Consent form(s) |
|  |  |
|  | Debrief sheet |
|  |  |
|  | Participant recruitment email/poster |
|  |  |
|  | Unpublished (in-house) questionnaire(s) |
|  |  |
|  | Interview / observation / focus group schedules |
|  |  |
|  | Risk Assessments / Standard Operating procedures |
|  |  |
|  | Permission letters (e.g. from school, organization, team etc) |
|  |  |
|  | Other documents. Please specify below: |

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