**APPLICATION FOR ETHICAL APPROVAL – INTRODUCTORY NOTES**

**In order for research to result in benefit and minimise risk of harm, it must be conducted ethically. A researcher may not be covered by the University’s insurance if ethical approval has not been obtained prior to commencement.**

The University follows the OECD Frascati manual definition of **research activity**:

“[C]reative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications”.

As such this covers activities undertaken by:

* Members of staff (academic staff or support staff);
* Individuals holding honorary title from the University;
* Postgraduate research students;

In all of these cases ethical review is required regardless of discipline.

The individual undertaking the research activity is known as the **lead researcher**.

Ethical approval is not required for routine audits, performance reviews, quality assurance studies, testing within normal educational requirements, and literary or artistic criticism.

For most projects you will only need to complete sections in the main part of the form. A few projects will need more detailed ethical consideration and will need you to fill in sections in an appendix. At some points in this form you will be asked questions about your research in the following way:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1 | Does your research involve <<something specific>>? | **YES** | **Click to continue to appendix <<N>>** | **NO** | **Continue to the next section** |
| 2 | Have you completed appendix <<N>>? | **YES** | ☐ | **NO** | ☐ |

Clicking in the appropriate box will take you to the appropriate location in the text. At the end of each appendix is a box. Clicking on this will return you to the question that originally took you to the appendix.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | **Return to the main form** |

NB These clickable links will only work if you are editing the document in the desktop version of Word, not the browser version. Please download and save the form before editing it.

Guidance notes are provided as comments or as text IN GREEN throughout this form. Please ensure that the comments are removed and that the green text is replaced by your own text or removed as appropriate BEFORE submitting this form.

Please ensure that you have read the UWTSD Research Ethics and Integrity Policy and the UWTSD Research Data Management Policy BEFORE submitting this form.

**APPLICATION FOR ETHICAL APPROVAL**

**SECTION A: About You (Lead Researcher)**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 | Full Name: | |  | | | | | |
| 2 | Tick all boxes that apply: | | Member of staff: | | ☐ | Honorary research fellow: | | ☐ |
| Undergraduate Student |  | Taught Postgraduate Student | |  | Postgraduate Research Student | |  |
| 3 | Institute/Academic Discipline/Centre: | |  | | | | | |
| 4 | Campus: | |  | | | | | |
| 5 | E-mail address: | |  | | | | | |
| 6 | Contact Telephone Number: | |  | | | | | |
| 7 | Project Title | |  | | | | | |
| 8 | Proposed Start Date | |  | Proposed End Date | | |  | |
| ***For students:*** | | | | | | | | |
| 9 | Student Number: | |  | | | | | |
| 10 | Programme of Study: | |  | | | | | |
| 11 | Director of Studies/Supervisor: | |  | | | | | |

**SECTION B: Grant or Contract Funding**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1 | Has your research been awarded, applied for, or intend to apply for external funding? | **YES** | [**Click to continue to appendix 1**](#APP_1) | **NO** | **Continue to the next section** |
| 2 | Have you completed appendix 1? | **YES** | ☐ | **NO** | ☐ |

**SECTION C: Internal and External Ethical Guidance Materials**

|  |  |  |
| --- | --- | --- |
| **Ethical Guidance Documents**  Please list the core ethical guidance documents that have been referred to during the completion of this form (including any discipline-specific codes of research ethics, location-specific codes of research ethics, and also any specific ethical guidance relating to the proposed methodology). Please tick to confirm that your research proposal adheres to these codes and guidelines. You may add rows to this table if needed. | | |
| 1 | UWTSD Research Ethics & Integrity Policy |  |
| 2 | UWTSD Research Data Management Policy |  |
| 3 | UWTSD Open Access Publications Policy |  |
| 4 | UWTSD Export Control Policy  *Required if Appendix 8 completed* |  |
| 5 | UWTSD Trusted Research and Innovation Policy  *Required if research is taking place outside the UK* |  |
| 6 | *[List any other relevant documents here]* |  |

**SECTION D: External Collaborative Research Activity**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1 | Does your research involve collaborating partners at another institution or organisation? | **YES** | [**Click to continue to appendix 2**](#APP_2) | **NO** | **Continue to the next section** |
| 2 | Have you completed appendix 2? | **YES** | ☐ | **NO** | ☐ |

**SECTION E: Details of Research Activity**

|  |  |
| --- | --- |
| **Aims, Vision and Approach of the Research (maximum 200 words per section)**  Please outline what are you hoping to achieve with your proposed work and how will you deliver it? | |
| 1 | **Research aims and objectives** |
| Briefly state your research:   * Aims (what the research is trying to achieve or advance) * Objectives (action or tasks required to do this)   (this box should expand as you type) | |
| 2 | **Vision** |
| Explain how your research:   * Is of importance within or beyond your area of research * Has the potential to advance current understanding, generates new knowledge, thinking or discovery within or beyond the field or area * Is timely given current trends, context and needs * Has the potential to generate impact in society, the economy or the environment   (this box should expand as you type) | |
| 3 | **Approach** |
| Explain your approach and how you have designed:   * Clearly describe both the methodological framework for data collection (if applicable) and any specific analysis methods proposed, making it clear what specific techniques may be used * Explain the reasons for their choice * Explain how these are feasible, effective and proportionate to achieve your objectives * Identify any risks to delivery and how they will be managed * Explain how your approach will maximise translation of outputs into outcomes and impacts   (this box should expand as you type) | |
| 4 | **Location of research activity**  Identify all locations where research activity will take place. |
| (this box should expand as you type) | |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 5 | Will any of your research be undertaken outside of the UK? | **YES** | [**Click to continue to appendix 3**](#APP_3) | **NO** | **Continue to the next section** |
| 6 | Have you completed any of appendix 3? | **YES** | ☐ | **NO** | ☐ |

**SECTION F: Research Methods**

|  |  |  |  |
| --- | --- | --- | --- |
| **Will the research activity include:** | | **YES** | **NO** |
| 1 | Use of a questionnaire or similar research instrument? |  |  |
| 2 | Use of interviews? |  |  |
| 3 | Use of focus groups? |  |  |
| 4 | Use of participant diaries? |  |  |
| 5 | Use of video or audio recording? |  |  |
| 6 | Use of computer-generated log files? |  |  |
| 7 | Participant observation with their knowledge? |  |  |
| 8 | Participant observation without their knowledge? |  |  |
| 9 | Access to personal or confidential information without the participants’ specific consent? |  |  |
| 10 | Administration of any questions, test stimuli, presentation that may be experienced as physically, mentally or emotionally harmful / offensive? |  |  |
| 11 | Performance of any acts which may cause embarrassment or affect self-esteem? |  |  |
| 12 | Investigation of participants involved in illegal activities? |  |  |
| 13 | Use of procedures that involve deception? |  |  |
| 14 | Administration of any substance, agent or placebo? |  |  |
| 15 | Working with live vertebrate animals? |  |  |
| 16 | Procedures that may have a negative impact on the environment? |  |  |
| 17 | Other primary data collection methods. Please indicate the type of data collection method(s) below. |  |  |
| Details of any other primary data collection method:  *(this box should expand as you type)* | |

**SECTION G: Research Participants**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Research participants include people who will be taking part in your research as providers of research data (e.g. being interviewed, answering questionnaires, or doing user testing of hardware or software). This includes animal participants. | | | | | |
| 1 | Does your research involve human or non-human participants? | **YES** | **Continue this section** | **NO** | [**Click to continue to section N**](#SEC_O) |

|  |  |  |
| --- | --- | --- |
| **Participant numbers and source**  How will you ensure an appropriately convened sample group in order to meet the aims of the research? Give details for subgroups separately, if appropriate. How will any potential pitfalls, for example dual roles or potential for coercion, be addressed? | | |
| 1 | How many participants will be recruited and how was the number decided upon? | *(this box should expand as you type)* |
| 2 | Who will the participants be? | *(this box should expand as you type)* |
| 3 | How will you identify the participants? | *(this box should expand as you type)* |
| 4 | Will you be excluding any groups of people, and if so what is the rationale for that? | *(this box should expand as you type)* |
| 5 | Will the research involve any element of deception? If yes, please describe why this is necessary and whether participants will be informed at the end of the study | *(this box should expand as you type)* |
| 6 | Describe whether participants will be able to withdraw from the study, and up to what point (eg if data is to be anonymised). If withdrawal is not possible, after a certain point, explain why not. | *(this box should expand as you type)* |
| 7 | How long will the participant have to decide whether to take part in the research? | *(this box should expand as you type)* |
| 8 | What arrangements have been made for participants who might have difficulties understanding verbal explanations or written information, or who have particular communication needs that should be taken into account to facilitate their involvement in the research? | *(this box should expand as you type)* |

**SECTION H: Research with Vulnerable People**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1 | Are your participants classed as vulnerable people? | **YES** | [**Click to continue to appendix 4**](#APP_4) | **NO** | **Continue to the next section** |
| 2 | Have you completed appendix 4? | **YES** | ☐ | **NO** | ☐ |

**SECTION I: Research Involving Animals**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1 | Are your participants non-human animals? | **YES** | [**Click to continue to appendix 5**](#APP_5) | **NO** | **Continue to the next section** |
| 2 | Have you completed appendix 5? | **YES** | ☐ | **NO** | ☐ |

**SECTION J: Research with the Prison Service or the Probation Service**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1 | Are your participants staff or offenders within the Prison Service or the Probation service? | **YES** | [**Click to continue to appendix 6**](#APP_6) | **NO** | **Continue to the next section** |
| 2 | Have you completed appendix 6? | **YES** | ☐ | **NO** | ☐ |

**SECTION K: Health and Social Care Research**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1 | Are your participants selected due to their health or social care needs? | **YES** | [**Click to continue to appendix 7**](#APP_7) | **NO** | **Continue to the next section** |
| 2 | Have you completed appendix 7? | **YES** | ☐ | **NO** | ☐ |

**SECTION L: Types of Personal Data**

|  |  |  |  |
| --- | --- | --- | --- |
| **Personal Data**  Does the research activity involve personal data (as defined by the General Data Protection Regulation 2016 and the Data Protection Act 2018)? | | **YES** | **NO** |
| 1 | Personal data means any information relating to an identified or identifiable natural person (‘data subject’). An identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person. Any video or audio recordings of participants and transcription of such are considered to be personal data. | ☐ | ☐ |
| **If you ticked YES, provide a description of the data and explain why this data needs to be collected:** |
| *(this box should expand as you type)* | | | |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Special Category Data**  Does the research involve the processing of special category data (as defined by the General Data Protection Regulation 2016 and the Data Protection Act 2018)? | | | **YES** | | **NO** | |
| 2 | Racial or ethnic origin | |  | |  | |
| 3 | Political opinions | |  | |  | |
| 4 | Religious or philosophical beliefs | |  | |  | |
| 5 | Genetic, biometric or health data | |  | |  | |
| 6 | Sex life or sexual orientation | |  | |  | |
| 7 | Trade union membership | |  | |  | |
| If you ticked **YES** to any of questions L2-L7, provide a description of the data and explain why this special category data needs to be collected to support the research and that it is in the public interest to do so: | | | | | | |
| 8 | *(this box should expand as you type)* | | | | | |
| 9 | Please describe how the research has been designed to gather the minimum amount of personal data necessary for the specified research purpose: | | | | | |
| *(this box should expand as you type)* | | | | | | |
| 10 | Demonstrate that the processing is not likely to cause substantial damage or distress to individuals and that their interests will be safeguarded: | | | | | |
| *(this box should expand as you type)* | | | | | | |
| 11 | Demonstrate that the data will not be used to take any action or make decisions in relation to the individuals concerned: | | | | | |
| *(this box should expand as you type)* | | | | | | |
| 12 | Data should be anonymised wherever possible, either at point of capture or once collated. If the data cannot be anonymised, and if pseudonymisation is not possible, demonstrate why the that is possible. If special category data cannot be anonymised, explicit consent to share that data must normally be obtained. | | | | | |
| *(this box should expand as you type)* | | | | | | |
| 13 | If special category data cannot be anonymised, will you obtain explicit consent to share that data? | **YES** | | **NO** | | **N/A** |
|  | |  | |  |

**SECTION M: Participant Information and Consent**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Information for participants**  It is normally expected that those participating in research should do so having given their informed consent. If this is not appropriate or practical, explicit justification must be provided, in line with prevailing disciplinary conventions. Please note however, that informed consent to participate in the research is separate from consent to process (e.g. collect, analyse, store, reuse or share) personal data, as the University’s lawful basis for processing personal data in research activities is part of its ‘public task’. | | **YES** | | **NO** | | **N/A** | |
| 1 | Will you obtain written consent for participation? |  | |  | |  | |
| 2 | Will you describe the main research procedures to participants in advance, so that they are informed about what to expect? |  | |  | |  | |
| 3 | Will you tell participants that their participation is voluntary? |  | |  | |  | |
| 4 | Will you explain to participants that refusal to participate in the research will not affect their treatment or education (if relevant)? |  | |  | |  | |
| 5 | If the research is observational, will you ask participants for their consent to being observed? |  | |  | |  | |
| 6 | Will you tell participants that they may withdraw from the research at any time and for any reason? |  | |  | |  | |
| 7 | Will participants be made aware of how you will treat any information that may reasonably by considered as confidential? |  | |  | |  | |
| 8 | If your research requires your participants to sign up for a service provided by an external company or organisation will you inform them that their data may be stored and processed outside UWTSD? |  | |  | |  | |
| 9 | Will you give participants the UWTSD Privacy Notice for Research? |  | |  | |  | |
| If you have answered **NO** to any of questions M1-M8, please provide justification detailing why this is necessary for the research. | | | | | | | |
| 10 | *(this box should expand as you type)* | | | | | | |
| **Informed consent:** Describe the arrangements to inform potential participants, before providing consent, of what is involved in participating. Describe the arrangements for participants to provide full consent before the research begins. If gaining consent in this way is inappropriate, explain how consent will be obtained and recorded. | | | | | | | |
| 11 | *(this box should expand as you type)* | | | | | | |
| **Confidentiality:** Confidential information refers to information that can be related to an identifiable individual, whether living or deceased, which is not in the public domain and which is given with the expectation that it will be kept confidential. Under Common Law when an individual entrusts a researcher or research team with confidential information, the team must handle this in line with ‘reasonable expectations’. In other words, confidential information should only normally be shared when there would be ‘no surprises’ for the individuals concerned. Where participants would not expect the researcher to be sharing their confidential information with others, researchers can manage their expectations by informing them of their intentions (e.g. in the participant information sheet or during discussions about participation) and asking them if they are happy with these plans. They should understand what is being proposed and what this might mean for them, before they decide whether the researcher can share their confidential information with others. | | | | | | | |
| Please detail how you will treat confidential information: | | | | | | | |
| 12 | *(this box should expand as you type)* | | | | | | |
| Copies of any written consent form, written information and all other explanatory material should accompany this application. If you have included these then please list the documents included here. | | | | | | | |
| 13 | Sample information sheets and consent forms are available from the University ethical review intranet page at <https://intranet.uwtsd.ac.uk/research/research-integrity-and-ethics> | | | | | | |
| 14 | Consent form attached? | | **YES** | | **NO** | | **N/A** |

**SECTION N: Research with Potential Military Application**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1 | Does your research have any potential military application? | **YES** | [**Click to continue to appendix 8**](#APP_8) | **NO** | **Continue to the next section** |
| 2 | Have you completed appendix 8? | **YES** | ☐ | **NO** | ☐ |

**SECTION O: Use of Artificial Intelligence Tools**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Use of generative AI and other AI-based tools**  There are a number of ethical issues relating to the use of generative AI and other AI-based tools, including data security, output bias, and output errors. In general you should assume that any generative AI or other AI-based tool that you pay to use is more secure and accurate than one which is free to use.  Will the research use AI tools to do any of the following: | | **YES** | **NO** | **N/A** |
| 1 | Capture data? |  |  |  |
| 2 | Generate and/or edit text? |  |  |  |
| 3 | Generate graphics? |  |  |  |
| 4 | Generate video? |  |  |  |
| 5 | Generate sound/music? |  |  |  |
| 6 | Generate code? |  |  |  |
| 7 | Generate synthetic data? |  |  |  |
| 8 | Analyse data? |  |  |  |
| 9 | Analyse personal or sensitive data? |  |  |  |
| 10 | Classify data? |  |  |  |
| 11 | Do you intend to use the free version of any AI tools? |  |  |  |
| If you have answered **YES** to any of questions O1-O11, please provide justification detailing why this is necessary for the research. | | | | |
| 12 | *(this box should expand as you type)* | | | |

**Section P: Research Data Management Plan**

|  |  |
| --- | --- |
| 1 | **Data Summary** |
| * Briefly introduce the types of data the research will create or access. | |
| 2 | **Responsibilities** |
| * Who will be responsible for data management? * Outline responsibilities for data management within research teams at all partner institutions | |
| 3 | **Assessment of existing data** |
| * Provide an explanation of the existing data sources that will be used by the research project (if applicable). * Provide an analysis of the gaps identified between the currently available and required data for the research. | |
| 4 | **Management and curation of data** |
| * Outline your plans for preparing, organising and documenting data. | |
| 5 | **Quality assurance of data** |
| * Describe the procedures for quality assurance that will be carried out on the data collected at the time of data collection, data entry, digitisation and data checking. | |
| 6 | **Short-term data storage** |
| * How will the data be stored in the short term during the research. * Describe the data access, security and backup procedures you will adopt to ensure the data and metadata are securely stored during the lifetime of the project. | |
| 7 | **Long-term data storage and preservation** |
| * Which data are of long-term value and should be retained, shared, and/or preserved? * How the data will be stored in the long term? * Are the plans for preparing and documenting data for sharing and archiving with an external data repository (e.g. the UK Data Service) or the UWTSD data repository? * How long will it be stored for and why? | |
| 8 | **Documentation and metadata** |
| * What documentation and metadata will accompany the data? * How will the data be documented during research to provide high quality contextual information and/or structured metadata for secondary users? | |
| 9 | **Data sharing** |
| * If you plan to share your research data explain how it will be shared and the value it will have to others * If you are planning to share the data, please advise when you will be releasing it. * Are any restrictions on data sharing required? * Identify any potential obstacles to sharing your data, explain which and the possible measures you can apply to overcome these * If the data will have value to different audiences, how these groups will be informed? * Will the data need to be updated? Include future plans for updating if this is the case. * Will the data be open or will you charge for it? Justify if charging to access the data. | |
| 10 | **Copyright and intellectual property ownership** |
| * Who will own the copyright and Intellectual Property Rights (IPR) of any new data that you will generate? | |
| 11 | **Resources** |
| * What resources will you require to deliver your plan? * Costs of storage – why are these appropriate? * How will these be met? (costs related to long term storage will be normally permitted by funders providing these are fully justified and relate to the project) | |

**SECTION Q: Risk Assessment**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Outline any anticipated risks that may adversely affect any of the participants, the researchers and/or the University, and the steps that will be taken to address them.  If you have completed a full risk assessment (for example as required by a laboratory, or external research collaborator) you may append that to this form. | | | | |
| 1 | Full risk assessment completed and appended? | | **YES** | **NO** |
|  |  |
| **Risks to participants, researchers, and the University** | | | | |
| 2 | **Social risks:** *disclosures that could affect participants standing in the community, in their family and their job.* | | **YES** | **NO** |
|  |  |
| *Risk:*  *(this box should expand as you type)* | | *How will you address any risks?* | | |
| 3 | **Legal risks:** *activities that could result in the participant, researchers and / or University committing an offence; activities that might lead to a participant disclosing criminal activity to a researcher which would necessitate reporting to enforcement authorities; activities that could result in a civil claim for compensation* | | **YES** | **NO** |
|  |  |
| *Risk:*  *(this box should expand as you type)* | | *How will you address any risks?* | | |
| 4 | **Economic harm:** *financial harm to participant, researcher and / or University through disclosure or other event.* | | **YES** | **NO** |
|  |  |
| *Risk:*  *(this box should expand as you type)* | | *How will you address any risks?* | | |
| 5 | **Reputational risk**: *damage to public perception of University or the University / researchers’ reputation in the eyes of funders, the research community and / or the general public.* | | **YES** | **NO** |
|  |  |
| *Risk:*  *(this box should expand as you type)* | | *How will you address any risks?* | | |
| 6 | **Safeguarding risks:**  *Risk to young people, vulnerable adults and / or researcher from improper behaviour, abuse or exploitation. Risk to researcher of being in a comprising situation, in which there might be accusations of improper behaviour.* | | **YES** | **NO** |
|  |  |
| *Risk:*  *(this box should expand as you type)* | | *How will you address any risks?* | | |
| 7 | **Sensitive, embarrassing or upsetting topics**. *If research activity may include sensitive, embarrassing or upsetting topics or issues likely to disclose information requiring further action (e.g. criminal activity), give details of the procedures to deal with these issues, including any support/advice (e.g. helpline numbers) to be offered to participants. Note that where applicable, consent procedures should make it clear that if something potentially or actually illegal is discovered in the course of a project, it may need to be disclosed to the proper authorities.* | | **YES** | **NO** |
|  |  |
| *(this box should expand as you type)* | | | | |
|  | **Health and safety risks** | | | |
| 8 | **Location hazards**: f*or example: fire; visiting or working in participant’s homes; working in remote locations and in high crime areas; overseas travel; hot, cold or extreme weather conditions; working on or by water. Also hazardous work locations, such as construction sites, confined spaces, roofs or laboratories. For overseas travel, researchers will need to check country / city specific information, travel health requirements and consider emergency arrangements as part of their research planning. In all cases the University’s International Travel Policy must be followed.* | | **YES** | **NO** |
|  |  |
| *Risk:*  *(this box should expand as you type)* | | *How will you address any risks?* | | |
| 9 | **Activity hazards:** *for example: potentially mentally harmful activities; distressing and stressful work and content; driving; tripping, or slipping; falling from height; physically demanding work; lifting, carrying, pushing and pulling loads; night time and weekend working.* | | **YES** | **NO** |
|  |  |
| *Risk:*  *(this box should expand as you type)* | | *How will you address any risks?* | | |
| 10 | **Machinery and equipment:** f*or example: ergonomic hazards, including computer workstations and equipment; contact with electricity; contact with moving, rotating, ejecting or cutting parts in machinery and instruments; accidental release of energy from machines and instruments.* | | **YES** | **NO** |
|  |  |
| *Risk:*  *(this box should expand as you type)* | | *How will you address any risks?* | | |
| 11 | **Chemicals and other hazardous substances**: t*he use, production, storage, waste, transportation and accidental release of chemicals and hazardous substances; flammable, dangerous and explosive substances; asphyxiating gases; allergens; biological agents, blood and blood products.* | | **YES** | **NO** |
|  |  |
| *Risk:*  *(this box should expand as you type)* | | *How will you address any risks?* | | |
| 12 | **Physical agents**: f*or example: excessive noise exposure, hand-arm vibration and whole body vibration; ionising radiation; lasers; artificial optical radiation and electromagnetic fields* | | **YES** | **NO** |
|  |  |
| *Risk:*  *(this box should expand as you type)* | | *How will you address any risks?* | | |
| 13 | **Environmental risks:** *for example: accidental spillage of pollutants, damage to local ecosystems* | | **YES** | **NO** |
|  |  |
| *Risk:*  *(this box should expand as you type)* | | *How will you address any risks?* | | |

**SECTION R: Disclosure and Barring Service**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Disclosure and Barring Service** | | | | |
| 1 | If the research activity involves children or vulnerable adults, a Disclosure and Barring Service (DBS) certificate must be obtained before any contact with such participants. | **YES** | **NO** | **N/A** |
|  | Does your research require you to hold a current DBS Certificate? |  |  |  |
| 2 | If YES, please give the certificate number. If the certificate number is not available please write “Pending”; in this case any ethical approval will be subject to providing the appropriate certificate number. |  | | |

**SECTION S: Declaration**

|  |  |  |
| --- | --- | --- |
| The information which I have provided is correct and complete to the best of my knowledge. I have attempted to identify any risks and issues related to the research activity and acknowledge my obligations and the rights of the participants**.**  In submitting this application I hereby confirm that I undertake to ensure that the above named research activity will meet the University’s Research Ethics and Integrity Policy which is published on the website: <https://www.uwtsd.ac.uk/research/research-ethics/> | | |
| 1 | **Name of applicant** |  |
| 2 | **Electronic or written signature of applicant**: |  |
| 3 | **Date** |  |
| 4 | **Name of Director of Studies** |  |
| 5 | **Electronic or written signature of Director of Studies**: |  |
| 6 | **Date** |  |

**Checklist:** Please complete the checklist below to ensure that you have completed the form according to the guidelines and attached any required documentation:

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 |  | I have read the guidance notes supplied before completing the form. | | | | | | | | |
| 2 |  | I have completed all relevant sections of the form in full. | | | | | | | | |
| 3 |  | I have attached a copy of the Participant Information Sheet (PIS) or Consent Form | | | | | | | | |
| 4 |  | I have attached a completed copy of the Trusted Research and Innovation Checklist (where applicable) | | | | | | | | |
| 5 |  | I have attached a full risk assessment (where appropriate) | | | | | | | | |
| 6 |  | I understand that it is my responsibility to ensure that the above named research activity will meet the University’s Research Ethics and Integrity Code of Practice | | | | | | | | |
| 7 |  | I understand that it is my responsibility to ensure that the above named research activity will meet the University’s Research Data Management Policy | | | | | | | | |
| 8 |  | I understand that it is my responsibility to ensure that the above named research activity will meet the University’s Research Export Control Policy | | | | | | | | |
| 9 |  | I understand that it is my responsibility to ensure that the above named research activity will meet the University’s Open Access Research Policy | | | | | | | | |
| 10 | I have completed the following appendices: | | 1 |  | 2 |  | 3 |  | 4 |  |
| 5 |  | 6 |  | 7 |  | 8 |  |

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| --- |
| All communications relating to this application during its processing must be in writing and emailed to [pgresearch@uwtsd.ac.uk](mailto:pgresearch@uwtsd.ac.uk) , with the title ‘Ethical Approval’ followed by your name. |

**APPENDIX 1 – Grant or Contract Funding**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| A1.1 | Has your research been awarded external funding? | **YES** |  | **NO** |  |
| A1.2 | Have you applied for funding / awaiting decision? | **YES** |  | **NO** |  |
| A1.3 | Are you intending to apply for funding? | **YES** |  | **NO** |  |
| A1.4 | Funding Body |  | | | |
| A1.5 | Lead institution (grant holder) |  | | | |
| A1.6 | If awarded, grant reference |  | | | |
| A1.7 | If awarded, grant value |  | | | |
| A1.8 | If awarded, start date and duration |  | | | |

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**APPENDIX 2: External Collaborative Research Activity**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **INSTITUTION 1** | | | | | |
| A2.1 | Name |  | | | |
| A2.2 | Researcher name and position |  | | | |
| A2.3 | Role in project (e.g. co-investigator) |  | | | |
| A2.4 | Contact e-mail address |  | | | |
| A2.5 | **External Ethical Approval**  *Please detail the ethical approval required and arrangements for this partner.* *See Section 14 of the UWTSD Research Ethics and Integrity Policy. If approved, please supply confirmation.* | **Obtained?** | **YES** | **NO** | **PENDING** |
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| --- | --- | --- | --- | --- | --- |
| **INSTITUTION 2** | | | | | |
| A2.6 | Name |  | | | |
| A2.7 | Researcher name and position |  | | | |
| A2.8 | Role in project (e.g. co-investigator) |  | | | |
| A2.9 | Contact e-mail address |  | | | |
| A2.10 | **External Ethical Approval**  *Please detail the ethical approval required and arrangements for this partner.* *See Section 14 of the UWTSD Research Ethics and Integrity Policy. If approved, please supply confirmation.* | **Obtained?** | **YES** | **NO** | **PENDING** |
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| --- | --- | --- | --- | --- | --- |
| **INSTITUTION 3** | | | | | |
| A2.11 | Name |  | | | |
| A2.12 | Researcher name and position |  | | | |
| A2.13 | Role in project (e.g. co-investigator) |  | | | |
| A2.14 | Contact e-mail address |  | | | |
| A2.15 | **External Ethical Approval**  *Please detail the ethical approval required and arrangements for this partner.* *See Section 14 of the UWTSD Research Ethics and Integrity Policy. If approved, please supply confirmation.* | **Obtained?** | **YES** | **NO** | **PENDING** |
|  |  |  |
|  | | | |

*Add additional collaborators as needed*

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**APPENDIX 3: Research Undertaken Outside of the UK**

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| A3.1 | **Research activity outside of the UK**  If research activity will take place overseas, you are responsible for ensuring that local ethical considerations are complied with and that the relevant permissions are sought. Specify any local guidelines (e.g. from local professional associations/learned societies/universities) that exist and whether these involve any ethical stipulations beyond those usual in the UK (provide details of any licenses or permissions required). Also specify whether there are any specific ethical issues raised by the local context in which the research activity is taking place, for example, particular cultural and/or legal sensitivities or vulnerabilities of participants. Describe the measures you have taken to comply with these and provide evidence of approvals etc. If you live in the country where you will do the research then please state this. If you have a local research supervisor or research advisor then please give their contact details here. | |
| *(this box should expand as you type)* | | |
| A3.2 | **Responsible Research and Innovation**  If research is taking place overseas please refer to the UWTSD Trusted Research and Innovation Policy and complete the Trusted Research and Innovation Checklist and submit it with this form. | |
| A3.3 | Confirm that you have read the Trusted Research and Innovation Policy |  |

|  |  |
| --- | --- |
| **If you are a postgraduate research student working with a research supervisor or research advisor at your local university then you do not need to fill in any more sections of this appendix.**  **If you are working in a research collaboration with an overseas partner please complete the remaining sections of this appendix.** | [**Return to the main form**](#SEC_F) |

|  |  |
| --- | --- |
| **Organisational Details** | |
| A3.4 | Name of Organisation |
|  | |
| A3.5 | Country where organisation is based: |
|  | |
| A3.6 | Registration number and name of registration body (examples of relevant registration bodies are government, tax, corporation, charity, educational authority): |
| *(this box should expand as you type)* | |
| A3.7 | What is the legal status of the organisation? (for example: public university, private university, charity, private company, non-profit making company, government research organisation, independent research organisation) Please include the date of foundation. Note: We may be required to ask for evidence of this at a later stage. |
| *(this box should expand as you type)* | |
| A3.8 | Is your organisation affiliated to any other organisation? (i.e. is the organisation legally part of a larger organisation or a group of larger organisations). |
| *(this box should expand as you type)* | |
| A3.9 | Name(s) of investigators in the organisation who will be responsible for the collaborative research and innovation |
| *(this box should expand as you type)* | |

|  |  |
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| **About New Partners** | |
| A3.10 | Why does a partner want to work with you? |
| *(this box should expand as you type)* | |
| A3.11 | What are they expecting in return for their financial support or involvement? |
| *(this box should expand as you type)* | |

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| A3.12 | Is the organisation associated with a country which may be viewed as hostile to the UK or one which has different democratic and ethical values from our own? If you have ticked YES, please briefly describe below how you will maintain the UK’s democratic and ethical values within the research. | **YES** | **NO** |
|  |  |
| *(this box should expand as you type)* | | | |
| A3.13 | Has due diligence into the partner identified any involvement in research on behalf of the military or police with links to a hostile state? If you have ticked YES, please summarise below how you will prevent information from this research from being released to these organisations. | **YES** | **NO** |
|  |  |
| *(this box should expand as you type)* | | | |
| A3.14 | Set within the context of any information gained from due diligence, could your research be misused or have unintended applications which would be negative? If you have ticked YES, please summarise below how this might occur. | **YES** | **NO** |
|  |  |
| *(this box should expand as you type)* | | | |
| A3.15 | Are there any legal, regulatory or university policy constraints on undertaking your research with this partner? If you have ticked YES, please summarise these below. | **YES** | **NO** |
|  |  |
| *(this box should expand as you type)* | | | |
| A3.16 | Having considered the answers to questions A3.10-A3.15, are there potential reputational or ethical risks to you or the university? If you have ticked YES, please summarise these risks below. | **YES** | **NO** |
|  |  |
| *(this box should expand as you type)* | | | |

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| --- | --- | --- | --- |
| **About Research Relationships** | | **YES** | **NO** |
| A3.17 | Are the terms of any proposed Memorandum of Understanding (MoU) in keeping with the expectations of your department and university? |  |  |
| A3.18 | Are you providing existing intellectual property (IP), research data, confidential or personally identifiable data to the project? If so, how is this going to be protected? |  |  |

|  |  |
| --- | --- |
| *(this box should expand as you type)* | |
| A3.19 | Who will own any IP that is generated? |
| *(this box should expand as you type)* | |
| A3.20 | What plans do you have in place for protecting the resulting IP? |
| *(this box should expand as you type)* | |
| A3.21 | What contractual requirements are you able to put in place to protect the interests of your academic institutions? |
| *(this box should expand as you type)* | |
| A3.22 | What access will the research partner have to your IT network? If they do have access, what broader visibility might this provide? |
| *(this box should expand as you type)* | |
| A3.23 | Is there any physical separation or protection required between research in similar fields? |
| *(this box should expand as you type)* | |

|  |  |  |  |
| --- | --- | --- | --- |
| **About Existing Partners** | | | |
| A3.24 | Would proceeding with the research raise potential conflicts of interest with existing research partners? If you have ticked YES, please explain these conflicts below. | **YES** | **NO** |
|  |  |
| *(this box should expand as you type)* | | | |
| A3.25 | Have you spoken with your existing partners about any potential conflict of interest? If you have ticked YES, please briefly summarise their response(s) below. | **YES** | **NO** |
|  |  |
| *(this box should expand as you type)* | | | |
| A3.26 | Does any non-disclosure agreement for this project include an expectation that you will need to provide visibility to existing partners? If you have ticked YES, please explain below how this will be managed. | **YES** | **NO** |
|  |  |
| *(this box should expand as you type)* | | | |
| A3.27 | Will this research breach any existing contractual agreements that you, your department or university already have? If you have ticked YES, please explain below how this will be managed. | **YES** | **NO** |
|  |  |

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| *(this box should expand as you type)* |

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**APPENDIX 4: Research with Vulnerable People**

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| **Will the research involve data processing involving the following data subjects:** | | | | | **YES** | | **NO** |
| A4.1 | Children under 16 | | | |  | |  |
| A4.2 | Adults with learning disabilities | | | |  | |  |
| A4.3 | Adults with other forms of mental incapacity or mental illness | | | |  | |  |
| A4.4 | Adults in emergency situations | | | |  | |  |
| A4.5 | Prisoners or young offenders | | | |  | |  |
| A4.6 | Those who could be considered to have a particularly dependent relationship with the investigator, e.g. members of staff, students | | | |  | |  |
| A4.7 | People who have not given their explicit consent to participate in the project | | | |  | |  |
| A4.8 | People engaged in illegal activities | | | |  | |  |
| A4.9 | Any other people who can be considered vulnerable in the context of this project | | | |  | |  |
| Please justify the inclusion of the above people (if applicable), explaining why the research cannot be conducted on non-vulnerable people. | | | | | | | |
| A4.10 | *(this box should expand as you type)* | | | | | | |
| Please give details of extra steps taken to assure the protection of vulnerable people participating in the research. You should describe any arrangements to be made for obtaining consent from a legal representative. | | | | | | | |
| A4.11 | *(this box should expand as you type)* | | | | | | |
| It is the researcher’s responsibility to check whether a DBS check (or equivalent) is required and to obtain one if it is needed. Please confirm: | | | | | | | |
| A4.12 | DBS Check required? | **YES** | | **NO** | | | |
|  | |  | | | |
| A4.13 | DBS certificate obtained? | **YES** | **NO** | | | **N/A** | |
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**APPENDIX 5: Research Involving Animals**

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| The use of animals in research is tightly governed and monitored by law and by the Home Office, specifically under the Animals (Scientific Procedures) Act 1986 and its accompanying codes of practice and processes. The Act regulates procedures that are carried out on protected animals for scientific or educational purposes that may cause pain, suffering, distress or lasting harm. Under the Act, a protected animal is ‘any living vertebrate, other than man, and any living cephalopod’. The University does not hold a Home Office issued Establishment Licence and therefore researchers must ensure that any proposed work involving animals is either exempt from the Act or falls outside of its scope. Exempted research, for example involving routine veterinary practice or clinical veterinary research, may still require external ethical approval from the Royal Society of Veterinary Surgeons. When undertaking collaborative research involving animals, the UWTSD Research Ethics Committee must be assured that the partner institution(s) conform to the appropriate regulatory framework or legislation, and have approval from their local Research Ethics Committee. Any such work must follow the guidance of the National Centre for the Replacement, Reduction and Refinement of Animals in Research, known as the 3Rs. In all cases, advise must be sought from INSPIRE for any proposed research involving animals, either at UWTSD, or by research collaborators in partnership with UWTSD. This should be at the very early stages of research design, so that an appropriate due diligence exercise can be undertaken. | | | |
| **Will the research involve any work with any of the following animals (including observation in their natural habitat)** | | **YES** | **NO** |
| A5.1 | Any living vertebrates, other than humans? |  |  |
| A5.2 | Any living cephalopods? |  |  |
| A5.3 | Has INSPIRE undertaken an initial due diligence exercise? |  |  |
| A5.4 | Due diligence assessment appended to this application? |  |  |
| Please provide a summary of the due diligence exercise, noting arrangements for compliance with the necessary regulatory frameworks and legislation. Please append the full due diligence assessment from INSPIRE. | | | |
| A5.5 | *(this box should expand as you type)* | | |

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**APPENDIX 6: Research with Staff or Offenders in Prison Establishments and Probation Services**

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| Research with staff and/or offenders in prison establishments, the Probation Service or within His Majesty’s Prison and Probation Services requires additional approvals. | | | |
| **Will the research involve any of the following?** | | **YES** | **NO** |
| A6.1 | Staff in prison establishments |  |  |
| A6.2 | Offenders in prison establishments |  |  |
| A6.3 | The Probation Service |  |  |
| A6.4 | His Majesty’s Prison and Probation Services |  |  |
| All researchers wanting to conduct research with staff and/or offenders in prison establishments, the Probation Service regions or within HM Prison and Probation Service (HMPPS) Headquarters are required to formally apply for research approval to the HMPPS National Research Committee (NRC). Before doing so, INSPIRE must undertake an initial due diligence exercise. If you have not contacted INSPIRE, please do so immediately. If YES to any of the above, please confirm: | | | |
| A6.5 | Has INSPIRE undertaken an initial due diligence exercise? |  |  |
| A6.6 | Have you applied to the HMPPS National Research Committee (NRC)? |  |  |
| A6.7 | Has HMPPS National Research Committee approval been granted? If yes, please append to this application. |  |  |
| A6.8 | Due diligence assessment appended to this application? |  |  |
| Please provide a summary of the due diligence exercise, noting arrangements for compliance with the necessary regulatory frameworks and legislation. Please append the full due diligence assessment from INSPIRE. | | | |
| A6.9 | *(this box should expand as you type)* | | |

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**APPENDIX 7: Health and Social Care Research**

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| All health and social care research must have a sponsor as defined by the Health Research Authority UK Policy Framework for Health & Social Care. The University will under no circumstances act as the sponsor of health and social care research (i.e. that which requires approval by a NHS Research Ethics Committee). In all cases, therefore, an appropriate collaborating partner must lead the research. Any health and social care research therefore requires an initial due diligence exercise, which will be undertaken by INSPIRE. The purpose of the due diligence exercise is to ensure that the University has the capability to undertake the research, either independently or in collaboration with research partners. This will include advice on suitable collaborative arrangements and the appropriate involvement of UWTSD researchers in the proposed research study. This is likely to apply to the following areas: | | | | | | | |
| **Will the data processing involve:** | | | | **YES** | | | **NO** |
| A7.1 | Participants who have been recruited on the basis of medical and health conditions, life stage or other physical or mental attribute. | | |  | | |  |
| A7.2 | Participants who will engage in physical exercise, activity or exertion of any kind, or who use exercise equipment, assistive devices or other apparatus for the purposes of the research study. This includes interventions that are minimally invasive. | | |  | | |  |
| A7.3 | Patients and users of the NHS (including NHS patients treated in the private sector). | | |  | | |  |
| A7.4 | Individuals identified as potential participants because of their status as relatives or carers of patients and users of the NHS. | | |  | | |  |
| A7.5 | Patients who are cared for in private and voluntary sector nursing homes. | | |  | | |  |
| A7.6 | Confidential patient information. | | |  | | |  |
| A7.7 | Clinical trial of a medicinal product or medical device. | | |  | | |  |
| A7.8 | Access to organs or other bodily material of past and present NHS patients, or any material consisting of or containing human cells. | | |  | | |  |
| A7.9 | Use of human tissue (including non-NHS sources) where the collection is not covered by a Human Tissue Authority licence. | | |  | | |  |
| A7.10 | Foetal material and IVF involving NHS patients. | | |  | | |  |
| A7.11 | The recently deceased under NHS care. | | |  | | |  |
| A7.12 | NHS staff or premises. | | |  | | |  |
| A7.13 | Practising midwives conducting a clinical trial. | | |  | | |  |
| A7.14 | Investigational medicinal product. | | |  | | |  |
| A7.15 | Medical devices that are not CE-marked or CE-marked medical devices that have been modified or are being used for a new purpose. | | |  | | |  |
| A7.16 | Exposure to ionising radiation. | | |  | | |  |
| A7.17 | Other health and social care related research. | | |  | | |  |
| *Please specify*  *(this box should expand as you type)* | | | |
| Researchers proposing to work on projects involving health and social care research must check whether their study meets the HRA definition of research and whether it should undergo ethics review by a NHS Research Ethics Committee. If you have answered **YES** to any of questions A7.1-A7.17 then this is likely to be the case and sponsorship by a third party will be required. This can be checked via the Health Research Authority’s Decision Tool : <https://www.hra-decisiontools.org.uk/research/> | | | | | | | |
| A7.18 | Does the research meet the HRA definition of research? | **YES** | **NO** | | | **N/A** | |
|  |  | | |  | |
| A7.19 | Is the Research being sponsored by a collaborating partner? | **YES** | **NO** | | | **N/A** | |
|  |  | | |  | |
| A7.20 | Has NHS ethics approval been granted? | **YES** | **NO** | | | **N/A** | |
|  |  | | |  | |
| A7.21 | Has INSPIRE undertaken an initial due diligence exercise? | **YES** | | | **NO** | | |
|  | | |  | | |
| Please provide a summary of the due diligence exercise, noting arrangements for compliance with the necessary regulatory frameworks and legislation. Please append the full due diligence assessment from INSPIRE. If you have not contacted INSPIRE, please do immediately. | | | | | | | |
| A7.22 | *(this box should expand as you type)* | | | | | | |

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| A7.23 | Have you been granted NHS ethical approval? | **YES** | [**Click to continue to Section R**](#SEX_S) | **NO** | [**Return to the main form**](#SEC_L) |

**APPENDIX 8: Export Control for Research with Potential Military End Uses**

|  |  |  |  |
| --- | --- | --- | --- |
| Export controls apply to the physical, electronic or oral transmission outside the UK of applied research, sensitive technology, software and equipment that could potentially be misused, either directly or indirectly, for military purposes. These legal controls are a serious obligation and UWTSD researchers must actively manage the risks of these being misused to fuel conflict, threaten national security, support terrorism and crime, violate human rights or proliferate Weapons of Mass Destruction. UWTSD’s Export Control Policy provides a clear six step process to determine if your research is covered by export controls. Please complete the following screening to judge if you need to compete a full export control assessment. If you are in any doubt, then please contact INSPIRE. Any research in UWTSD involving the following high-risk areas must be screened.  **Will the research involve:** | | | |
| **Defence** | | **YES** | **NO** |
| A8.1 | Military equipment and munitions |  |  |
| A8.2 | Defence equipment, including satellites |  |  |
| A8.3 | Technical data, including some border and port information |  |  |
| A8.4 | Dual use research |  |  |
| **Materials and Technologies** | | **YES** | **NO** |
| A8.5 | Nuclear materials, facilities and equipment |  |  |
| A8.6 | Chemicals, microorganisms and toxins |  |  |
| A8.7 | Electronics design, development and production |  |  |
| A8.8 | Computers |  |  |
| A8.9 | Telecommunications |  |  |
| A8.10 | Sensors and lasers |  |  |
| A8.11 | Navigation and avionics |  |  |
| A8.12 | Marine technology |  |  |
| A8.13 | Composite materials |  |  |
| A8.14 | Aerospace and propulsion |  |  |
| **Sensitive Information** | | **YES** | **NO** |
| A8.15 | Cryptology |  |  |
| A8.16 | Counterterrorism |  |  |
| A8.17 | Counternarcotics |  |  |
| A8.18 | Cyber-related |  |  |
| A8.19 | Non-proliferation |  |  |
| A8.20 | Transnational criminal organisations |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Genetic Resources** | | **YES** | **NO** |
| A8.21 | Genetic material of actual or potential value |  |  |
| A8.22 | Organisms, or parts thereof |  |  |
| A8.23 | Populations (or organisms) |  |  |
| A8.24 | Other biotic components of ecosystems |  |  |
| A8.25 | Domesticated or cultivated species in which the evolutionary process has been influenced by humans |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Will you be exporting military or dual-use technology, now or possibly in the future? This information may take many forms, including:** | | **YES** | **NO** |
| A8.26 | Physical transfer of goods, technologies, material or equipment |  |  |
| A8.27 | Blueprints |  |  |
| A8.28 | Plans |  |  |
| A8.29 | Diagrams |  |  |
| A8.30 | Models |  |  |
| A8.31 | Formulae |  |  |
| A8.32 | Tables |  |  |
| A8.33 | Engineering designs and specifications |  |  |
| A8.34 | Manuals and instructions |  |  |
| A8.35 | Software |  |  |
| A8.36 | Know-how |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Will your project transfer technology using any of the following physical methods?** | | **YES** | **NO** |
| A8.37 | USB flash drives |  |  |
| A8.38 | Portable hard drives |  |  |
| A8.39 | Laptops |  |  |
| A8.40 | Tablets |  |  |
| A8.41 | Intangible forms by using electronic media, such as email, phone storage and cloud file sharing |  |  |
| A8.42 | Physical exports |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Will your project involve any of the following?** | | **YES** | **NO** |
| A8.43 | Oral transfer by phone or videoconferencing or presentations |  |  |
| A8.44 | Travelling overseas for any purpose, while unintendingly carrying any of the above. |  |  |
| A8.45 | Will you be hosting foreign visitors? |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **If you answer YES to any of questions A8,1-A8.45 then you should complete a full export control assessment and append that to this application. Before doing this please contact INSPIRE who will advise further.** | | **YES** | **NO** |
| A8.46 | Full export control assessment required? |  |  |
| A8.47 | Full export control assessment completed? |  |  |
| A8.48 | Full export control assessment appended? |  |  |

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|  |  |  |  |  | [**Return to the main form**](#SEC_O) |