## R(D)SVS and Easter Bush Campus

## Human (Research) Ethical Review Committee (HERC) FORM

## Instructions

## This form is to be completed for all projects using human data as part of the methodology. This includes surveys, interviews, focus groups (even if the subject of these is the respondent’s pets or animals), and also human participants recruited as part of epidemiological or behaviour studies).

## PGT students should prepare this form in conjunction with their supervisor(s) and submit to HERC via the PGT coordinator for their course. Any queries relating to HERC should be asked via the PGT coordinator.

## PGR students should prepare this form in conjunction with their supervisor(s) and submit to HERC.vets@ed.ac.uk.

## Staff should send their completed form to HERC.vets@ed.ac.uk.

## All parts of the form must be completed and failure to do so will result in HERC approval being delayed. For sections that do not apply please put N/A.

## Section 1 Project Information

## Section 2 Personnel Information

## Section 3 Research

## Section 4 Recruitment

## Section 5 Mitigating Risk

## Section 6 Participant Consent

## Section 7 Legal, codes of conduct, and rights of human subjects

## Section 8 Data Management (including Data Protection Impact Assessment requirements)

## Appendix a Terrorism Act

Further information about HERC and research ethics can be found on the R(D)SVS intranet <http://edin.ac/2s8kwRU>, and the non-credit Research Methods and Statistics course (available to all staff and students at R(D)SVS).

**Checklist**

Please indicate what supporting documents you are including along with this HERC submission form.

|  |  |  |
| --- | --- | --- |
| **Relates to question(s) on the HERC form** | **Additional documentation** | **Included Y/N** |
| 3C | Measures to be used (e.g. questionnaires, surveys, interview/focus group topic guides/schedules/example questions, as appropriate). | Y/N |
| 3C | URLs of any videos being used/viewed by participants e.g. QBA welfare projects. | Y/N |
| Section 4 | Approach letters to ‘gatekeeper’ organisations e.g. for using data from an organisations’ database.  | Y/N |
| Section 4 | Recruitment documents (e.g. recruitment email, posters, flyers or advertisements). | Y/N |
| 6I | Information sheet | Y/N |
| Section 6 and 8 | Consent form/consent statement (this will be page 1 of a survey or an independent document for other activities). | Y/N |
| Section 6 | Copy of consent form, if data was collected as part of another project. | Y/N |
| Section 6 | Evidence of any other approvals or permissions e.g. permission/consent received from administrators to post on social media pages (print screen of permission is suffice). | Y/N |
|  | Appendices (where applicable) | Y/N |

**Section 1 - Project Information**

|  |  |
| --- | --- |
| **Title of research project** |  |
| **N.B. The dates relate to data collection/point of contact with humans, rather than the start/end of the project.** |
| **Start Date** (DD/MM/YYYY) |  |
| **End Date** (DD/MM/YYYY) |  |

**Section 2 - Personnel Information**

|  |  |
| --- | --- |
|  | Y/N |
|  | Staff | Student |
| Name of applicant: |  |  |
| Matriculation number (if a student): |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Y/N** |  | **Y/N** |
| SRC project |  | Taught Masters |  |
| Masters by research |  | PhD |  |
| Other (give details): |  |

List **all** study personnel and their contact details (indicate if supervisors).

* **State which UoE/SRUC staff member is taking overall responsibility** for the conduct of this research and is the guarantor of the accuracy of this application. Please provide the title, position, and email details for this individual. This individual cannot be a student and must be an academic member of staff.

|  |  |  |  |
| --- | --- | --- | --- |
|  |  |  | **Y/N** |
| Name | Email | Position | Applicant guarantor |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**Section 3 - Research**

1. Research Question, Research aims, and summary (500 words max)

|  |
| --- |
| Research question:  |
| Research aims and summary:  |

1. **Details of pilot studies and validation studies** (e.g. questionnaires)

 Where applicable all questionnaires should be piloted prior to submission to the HERC Committee. This should be carried out with volunteers, who are colleagues or friends – not the public. **If you wish to pilot with the public or potential research participants, HERC approval should be sought for the pilot.**

|  |
| --- |
|  |

1. **Methods/research protocol**

Please provide details of the proposed methods including the name of any tools used (e.g. **Jisc Online Survey (formerly Bristol Online Surveys – BoS) for surveys).** Please include copies of any questionnaires that are being used as an attachment or appendix. If the questionnaire is not yet completed HERC can provide approval subject to seeing it at a later date. However, if this is needed for a **grant application**, please acknowledge this below and this will be taken into consideration in the review. If checklists are being used in interviews, please provide them. Include details of all demographic details that will be recorded about subjects and any other information that might be considered highly personal. Expand this section as necessary.

|  |
| --- |
|  |

**Section 4 - Recruitment**

|  |  |  |
| --- | --- | --- |
| A | How many participants do you hope to include in the research |  |
| B | Who are the participants you hope to recruit e.g. students, members of the public? |  |
| C | What criteria, if any, will be used in deciding on the inclusion and exclusion of participants in the study? |  |
| **N.B.** Please note if you are recruiting the following type of participant, this is how you are to contact them:* **Undergraduates or staff:** this requires approval via HERC. Please email herc.vets@ed.ac.uk
* **Postgraduates:** this needs to be in consultation with the PGT Coordinator e.g. including if you want agreement to disseminate via the programme social media or the programme Base course,
 |
| D | **Describe how subjects will be recruited**. Please provide copies of any advertising material, posters, emails etc. If slides are to be used, please provide copies (attach as necessary). |  |
| E  | **Where will you be recruiting participants from?** Give details of any organisations or groups through which you will recruit participants. Please **provide evidence that these organisations or groups have been approached and agreed to your recruiting through them** (this can be an email exchange or letter). You must also check whether they have any specific requirements for how you can use their information or contact their members and/or if they have their own ethical approval processes that you need to adhere to in addition to the UoE. |  |
|  |  | Yes | No |
| F | Are you recruiting via social media? |  |  |
| G | If yes, please provide details e.g. which platforms and whether permission has been required (please provide evidence of permissions along with your HERC application e.g. screen shot of the email) |  |

**Section 5 - Mitigating risk**

|  |  |  |  |
| --- | --- | --- | --- |
| **Potential harm, discomfort or stress for living human subjects** | yes | no | N/A |
| A | Is there significant foreseeable potential for psychological harm or stress for those involved in your research (including the research team)? |  |  |  |
| B | Is there significant foreseeable potential for physical harm or discomfort for those involved in your research (including the research team)? |  |  |  |
| C | Is there significant foreseeable potential for violation of cultural or social norms/practices? |  |  |  |
| D | Is there significant foreseeable potential for conflict or discomfort for any humans your research will impact on? |  |  |  |
| E  | If YES to any of the above, explain and describe the measures that will be used to protect and/or inform participants. |  |

|  |  |  |
| --- | --- | --- |
| **Are any of the intended participants likely to be** | yes | no |
| 1 | Under 16 years of age? |  |  |
| 2 | Children in the care of a Local Authority?  |  |  |
| 3 | Known to have special educational needs, physically or mentally ill? |  |  |
| 4 | Adults lacking capacity? |  |  |
| 5 | Vulnerable in other ways |  |  |
| 6 | Members of a vulnerable or stigmatized minority?  |  |  |
| 7 | Unlikely to be proficient in English? |  |  |
| 8 | In a client or professional relationship with the researchers? |  |  |
| 9 | In a student-teacher relationship with the researchers? |  |  |
| 10 | In any other dependent relationship with the researchers?  |  |  |
| 11 | Have difficulty in reading and/or comprehending any printed material distributed as part of the study?  |  |  |
|  |  |  |  |
| If YES to any of the above, explain and describe the measures that will be used to protect and/or inform participants. |

**Section 6 - Participant Consent**

**Informed consent is where research participants can make an informed, educated decision, based on the information provided to them, as to whether or not they wish to participate in the research.**

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| A | Do you think there is a possibility that a reasonable person might judge that participants may feel pressured into taking part?  |  |  |
| B  | Is it clear that a participant’s decision whether to take part or not is private (that is that other participants cannot work out whether another participant has declined to volunteer)? |  |  |
| C | If the answer to the above question is no, please justify what you propose to mitigate this situation. |  |
| D | Will participants receive any financial or other material benefits because of participation? (please note monetary incentives are generally discouraged) |  |  |
| E | If YES, what benefits will be offered to participants and why is this essential? |  |

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Yes | No |
| F | Will the research require the collection of personal or identifiable information e.g. name, email address, IP address (from survey data collection) |  |  |
| G | Will the research require the collection of personal information from e.g. universities, schools, employers, or other agencies about individuals without their direct consent?  |  |  |
| H | If yes, please provide further information |  |
| I | For projects where participants are being directly recruited. Is there a copy of the **information sheet and consent form** or **consent statement** (if an online questionnaire) attached to your HERC submission  |  |  |
| J | Are you using deception as part of your research project? |  |  |
| K | If yes, please provide further information |  |
| L  | If informed consent is not considered necessary (in surveys, interviews, focus groups or any other means for collecting data), please explain why you believe this approach is appropriate to your study |  |

**Section 7 - Legal, codes of conduct, and rights of human subjects**

Further information from the University of Edinburgh about:

* Research and data protection: <http://edin.ac/2s8LZ5W>
* Research integrity <http://edin.ac/2trntkj>

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | yes | no |
| A | In relation to the country in which you are **collecting the data** - Are you collecting data relating to activities that are illegal? |  |  |
| B | In relation to the country where you are **storing the data** - Are you collecting data relating to activities that are illegal? |  |  |
| C | In relation to the country in which you are **collecting the data** - Are you collecting data relating to activities that may call into question a subject’s fitness to practice; or information that might call into question the fitness to practice of others?  |  |  |
| D | In relation to the country where you are **storing the data -** Are you collecting data relating to activities that may call into question a subject’s fitness to practice; or information that might call into question the fitness to practice of others?  |  |  |
| E | If the answer is ‘yes’ to question A-D, we would expect a detailed justification, including details of how you intend to deal with these issues. Based on previous examples of such research we would likely need to take expert legal advice from the UoE. Review of such projects is likely to take longer than one month. We would expect that you have discussed these issues with senior academic staff prior to submission. |
| F | How will you deal with disclosures of harm to self, others, or animals by participants? Remember as a researcher you must stay within the law of whatever country you are working in. Think carefully about when you would and should share such disclosures with relevant authorities; again as above further legal advice may be necessary on this issue. |
| G | Are there any conflicts of interest between the researchers, funding bodies, the institution, and/or research subjects? |  |  |
| H | Will participants be informed of your responsibilities to report any evidence of abuse or criminal activity? (if yes, this should be included on the consent form) |  |  |
| I | If the research is to take place outside the UK, will the research be, or has the research been, reviewed in the host country? |  |  |
| J | Does your research concern groups which may be construed as terrorist or extremist?\*If your answer to this question is “Yes”, please complete and submit with this completed questionnaire the supplementary form available as an **appendix** to this.\*The University is required to comply with the duty to prevent people being drawn into terrorism (“the Prevent duty”. Section 26 (1) of the Counter-Terrorism and Security Act 2015 imposes a duty on ‘specified authorities’ to have due regard to the need to prevent people from being drawn into terrorism. Government guidance¹ for HEIs on implementation of this duty includes the statement that “We (the UK government) would expect to see clear policies and procedures for students and staff working on sensitive or extremism-related research.” (para 25) |  |  |
| K | Does your research involve a **conflict of interest** as outlined below? The University has a draft ‘Policy on the Conflict of Interest’ (copies available from the Research Support Office). Regarding research the draft states that a conflict of interest would arise in cases where an employee of the University might be “compromising research objectivity or independence in return for financial or non-financial benefit for him/herself or for a relative or friend.” The draft policy also states that the responsibility for avoiding a conflict of interest, in the first instance, lies with the individual, but that potential conflicts of interest should always be disclosed, normally to the line manager or Head of Department. Failure to disclose a conflict of interest or to cease involvement until the conflict has been resolved may result in disciplinary action and in serious cases could result in dismissal.  |  |  |
| L | If yes, please provide details: |  |
|

|  |
| --- |
| **Section 8 - Data Management (including Data Protection Impact Assessment requirements for UK GDPR)****Rights of Humans Subjects**The **UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018** protect the rights of individuals when you process personal data about them, including obtaining, holding and destroying it. |
| For any **identifiable data**,which is data that can be used to identify an individual, such as name, email address, demographic information, IP address, medical details etc. (whether in paper documents, data files or recordings): |
|  | Yes | No |
| A | Is the research compliant with the **UK** **General Data Protection** Regulation (**UK** **GDPR**) and the **Data Protection Act 2018** protect the rights of individuals when you process personal data about them, including obtaining, holding and destroying it; and the University of Edinburgh Data Protection procedures? (please see <http://www.ed.ac.uk/records-management/data-protection>)  |  |  |
| B | Will any of the personal data be processed under a duty of confidentiality? (which means protecting data subjects’ right to privacy) If yes, how is that confidentiality being maintained? |  |  |
| C | Will you ensure anonymity of individuals? |  |  |
| D | Are the research participants capable of understanding their rights and providing informed consent? |  |  |
| E | Will participants be informed about your obligations under **UK** **General Data Protection** Regulation (**UK** **GDPR**) and the **Data Protection Act 2018** <https://www.ed.ac.uk/records-management/policy/data-protection>  |  |  |
| F | Does the project involve the use of existing personal data for new purposes? E.g. a supervisor or colleague provides you with an existing data set? |  |  |
| G | If yes (question F), did the previous consent state that the data could be used in future research projects? |  |  |
| H | On the consent form, are individuals being made aware of how their personal data will be used? |  |  |
| I | Will you collect or use National Health Service (NHS) or human medical data?Please note: If you are collecting or using NHS data you may require sponsorship and/or Caldicott Approval.Please refer to the ACCORD (Academic and Clinical Central Office for Research and Development) website for more information.  |  |  |
| J | Will you be collecting information which is defined as special categories of personal data (health data, data relating to race or ethnicity, to political opinions or religious beliefs, trade union membership, criminal convictions, sexual orientations, genetic data and biometric data)?**If you are using collecting information which is defined as a ‘special category’, then you must ensure that the UK GDPR Article 9(2)(j) legal basis you have for collecting this data is “necessary for research purposes”. Please ensure that there is a clear rationale for collecting this ‘special category’ data.**  |  |  |
| K | If you answered ‘Yes’ above (J), please answer this question:Explain what safeguards e.g. technical or organisational you have in place, such as: * Compliance with the minimisation principle: provide assurances you are only collecting the absolute minimum of personal data required for your purpose (not ‘just in case’ you need it)
* How will you anonymise data?
* If you cannot anonymise, how you will pseudonymise i.e. using ‘participant numbers/ID’s’?
 |
| L | **Student Projects:**How long is the raw data being kept for? (This should generally be time-limited for student projects). |
| M | **Staff projects:** Research data can be stored indefinitely as long as it is stored securely (however, where possible, it is recommend that there is a time-limit).For storage guidance please refer to LINK TO DATAVAULT/UNIVERITY STORAGE INFORMATIONHow long is the raw data being kept for? |
|  |  | Yes | No |
| N | **This question is applicable to UoE/SRUC staff only** Have you completed the mandatory data protection training on the self-enrolment page on Learn? (Please note, you are required to complete this training - <https://www.ed.ac.uk/records-management/training/data-protection>)  |  |  |

**Section 8 (O) – Risk Table**It is expected that you will have consulted with collaborators to enable you to answer the following questions: It is essential that you identify and list all risks to the privacy of research participants. You will then need to consider the likelihood of the risks actually manifesting and the severity of harm if the risks actually manifest.**You must consider all risks and add these to the table.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Risk number | Risk |  | **Likelihood of risk manifesting** | **Severity of harm** |
| N/A | Low | **Medium** | **High** | Low | **Medium** | **High** |
| 1 | Identifiable due to data linkage |  | □ | □ | □ | □ | □ | □ |
| 2 | Identifiable due to low participant numbers |  | □ | □ | □ | □ | □ | □ |
| 3 | Identifiable due to geographical location |  | □ | □ | □ | □ | □ | □ |
| 4 | Identifiable due to transfer of data |  | □ | □ | □ | □ | □ | □ |
| 5 | Identifiable due to access of data |  | □ | □ | □ | □ | □ | □ |
| 6 | *Using an external transcription company* |  | □ | □ | □ | □ | □ | □ |
| 7 | *Other risk* |  | □ | □ | □ | □ | □ | □ |
| 8 | *Other risk* |  | □ | □ | □ | □ | □ | □ |

 |
|  | Yes | No |
| P | Please identify measures you could take to reduce or eliminate risks identified as **medium and high (likelihood) and also medium and high (severity).** |
|  |
|  | Yes | No |
| Q | Does your research include the use of video or audio recordings |  |  |
| Q-1 | If yes are codes used for participants to anonymise them? How is the issue of withdrawal of consent in group videos being dealt with? |
|  | Yes | No | N/A |
| R | Will identifying data be kept secure (paper, recordings, electronic data)? |  |  |  |
| R-1 | Describe how identifying data is being kept secure, and access controlled (including paper, recordings, electronic data, and surveys)? This includes technical and organisational security measures that will be in place to prevent any unauthorised or unlawful processing of the data. |
| S | Will the anonymous datasets be made available to other researchers in a form that is usable to them?  |  |  |
| T | Will information containing **personal, identifiable data** be transferred to, shared with, supported by, or otherwise available to third parties outside the University? |  |  |
| U | If yes (T), Please explain why this is necessary and how the transfer of the information will be made secure. Since the European Court of Justice decision in **July 2020**, a special risk assessment is required for transfer of personal data in particular to the **US** but also to **other non-EEA countries**. Please assess how likely this is and please obtain guidance from the HERC herc.vets@ed.ac.uk  |
| U-1 | If yes (S), what if any conditions will you attach for its use? |
| V | Other than the use by third parties, will the data be used, accessed or stored away from University premises, University servers and storage? |  |  |
| W | Describe the arrangements you have put in place to safeguard the data from accidental or deliberate access, amendment or deletion when it is not on University premises, including when it is in transit, and (where applicable) it is transferred outside the EEA. |
| X | Are you required to inform participants of the results of the study? |  |  |
| X-1 | If yes, how will this be done and who is taking responsibility for this? |

**Appendix A (ONLY COMPLETE, if you answered ‘yes’ to Section 7J)**

**The Terrorism Act (2006)** outlaws the dissemination of records, statements and other documents that can be interpreted as promoting or endorsing terrorist acts.

|  |  |  |
| --- | --- | --- |
|  | Yes | No |
| A | Does your research involve the storage on a computer of any such records, statements or other documents? |  |  |
| B | Might your research involve the electronic transmission (e.g. as an email attachment) of such records or statements? |  |  |
| C | If you answered ‘Yes’ to questions A or B, you are advised to store the relevant records or statements electronically on a secure university file store. The same applies to paper documents with the same sort of content. These should be scanned and uploaded. Access to this file store will be protected by a password unique to you and your School Research Ethics Officer. Please indicate that you agree to store all documents relevant to questions 1 and 2 on that file store: |  |  |
| D | Please indicate that you agree not to transmit electronically to any third party documents in the file store by checking the Yes box. |  |  |
| E | Will your research involve visits to websites that might be associated with extreme, or terrorist, organisations? |  |  |
| F | If you answer ‘Yes’ to question E, you are advised that such sites may be subject to surveillance by the police. Accessing those sites from university IP addresses might lead to police enquiries. Please acknowledge that you understand this risk by checking the Yes box. |  |  |
| G | By submitting to the ethics process, you accept that your School Research Ethics Officer and the convenor of the University’s Compliance Group will have access to a list of titles of documents (but not the contents of documents) in your document store. Please acknowledge that you accept this by checking the Yes box. |  |  |