

Research ethics application form for Veterinary research

**Studies requiring ethics**.

Any studies involving human participants, personal data, or human tissue require research ethics approval. If you are unsure whether your study requires ethical approval, please use the [research ethics decision tool](https://app.onlinesurveys.jisc.ac.uk/s/liverpool/university-of-liverpool-do-i-need-research-ethics-approval).

All studies involving animals require ethical review. The nature of this review depends on context. Studies involving Routine Veterinary Practice, Clinical Veterinary Research or Routine Agricultural practice are reviewed by the IVES ethics committee.

Studies involving animals in other contexts come under the scope for review by Animal Welfare Ethical Review Board (or committees to which it delegates review).

**Projects will be reviewed by an appropriate ethics committee**

Studies from IVES researchers carrying minimal risk to humans and studies involving Routine Veterinary Practice, Clinical Veterinary Research or Routine Agricultural practice are reviewed by the IVES ethics committee.

**Studies involving more than minimal risk to humans** (where any question in section 3.1 yields a ‘Yes’ answer will be reviewed by a Central University Research Ethics committee with review of any animal elements by IVES ethics committee

**Studies requiring NHS research ethics committee approval**

Studies that require review by a [NHS Research Ethics Committee](http://www.hra-decisiontools.org.uk/ethics/) are outside the scope of a University Research Ethics Committee. Please apply for [Health Research Authority approval](https://www.hra.nhs.uk/approvals-amendments/what-approvals-do-i-need/hra-approval/).

**Studies outside the UK**.

For studies conducted outside the UK, local research ethics approval for each country should be sought wherever possible. Please see the [research ethics webpages](https://www.liverpool.ac.uk/research/research-environment/ethics/policies-and-guidance/international-research/) for guidance on identifying local ethics committees. Where attempts to identify an appropriate committee can be documented and such a committee is not available a University of Liverpool ethics committee will review these projects.

**Study permissions**.

If your study involves other organisations or research sites that require access permission, you will need to seek permission from the relevant organisations involved in the study in order for you to conduct your study. This process may take time so you must plan for this.

**Research ethics support**.

If you have any research ethics questions, please contact [ivesethics@liverpool.ac.uk](mailto:ivesethics@liverpool.ac.uk).

**Research governance requirements**.

* For any studies involving Sensitive IT Usage[[1]](#endnote-2), please contact the University Information Security Officer (IT Services) via the [IT Services self-service portal](https://servicedesk.liverpool.ac.uk) to discuss the requirements relating to the sensitive material aspects of your study.
* All non-desk based studies should be covered by a Health and Safety [risk assessment form](https://www.liverpool.ac.uk/intranet/safety/guidance/risk-assessment/) (contact [Steve Dunkley](mailto:sdunkley@liverpool.ac.uk?subject=Advice%20sought%20on%20the%20correct%20risk%20assessment%20form%20for%20research) for advice on the correct form).
* University Sponsorship is required for any studies that involve the NHS or healthcare patients overseas. Please visit the [Sponsorship webpages](https://www.liverpool.ac.uk/clinical-directorate/clinical-research/governance/), or contact [sponsor@liverpool.ac.uk](mailto:sponsor@liverpool.ac.uk) for advice on University Sponsorship.
* For any studies involving the collection of personal health data, please contact the Data Protection Officer, [Gaige Corvo](mailto:g.corvo@liverpool.ac.uk?subject=Research%20ethics%20personal%20health%20data%20query), for advice on compliance with the Caldicott Principles[[2]](#endnote-3).
* Studies involving any of the following require additional [insurance](https://www.liverpool.ac.uk/intranet/legal/insurance/) confirmation from [Mark Neill](mailto:Mark.Neill@liverpool.ac.uk?subject=Research%20ethics%20insurance%20query):
  + Recruitment of participants in the following groups into interventional studies or observational studies involving the taking of tissue samples (for research purposes)
    - Children under the age of 5
    - Pregnant women
    - Participants who lack the capacity to consent
  + First in Man Clinical Trials of Investigative Medicinal Products
  + Clinical Investigations of Medical Devices
  + Studies including medical intervention involving contraception
  + Human Health related based Studies taking place at international sites involving clinical or psychological intervention or clinical sampling
* Studies undertaken in the UK that involve either prison establishments, or the Ministry of Defence; will need approval from the [Ministry of Justice](https://www.gov.uk/government/organisations/her-majestys-prison-and-probation-service/about/research) or the [Ministry of Defence](https://www.gov.uk/government/groups/ministry-of-defence-research-ethics-committees#guidance-documents).
* For prospective studies involving animals please ensure appropriate professional indemnity insurance has been arranged.

## Section 1: Project information

### 1.1 Title of the research:

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### 1.2 What type of approval you are seeking? Choose an item.

*(Please note projects using only an approved* [*series of studies methodology*](https://www.liverpool.ac.uk/media/intranet/research-support-office/ethics/Research,Ethics,Handbook,%5bMASTER%5d.pdf#page=376) *can be approved using a shortened route via Chairs Action)*

### 1.3 Principal Investigator or Supervisor(s) details:

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| --- | --- |
| Principal Investigator(s) or Supervisor(s) name: |  |
| Principal Investigator(s) or Supervisor(s) email address: |  |

### 1.4 Student investigator details:

|  |  |
| --- | --- |
| Student name: |  |
| Student programme of study: |  |
| Student telephone number: |  |
| Student email address: |  |

### 1.5 Are there any other Investigators involved in the study? Choose an item.

| Investigator name: | Investigator role in the study: | Investigator telephone number: | Investigator email address: |
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### 1.6 Approximate study dates:

Proposed start date: Click or tap to enter a date.

Proposed end date: Click or tap to enter a date.

### 1.7 Please list all the locations where the research will take place[[3]](#endnote-4):

| Research site: | Individual responsible: | Contact details: |
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### 1.8 Has the study received any external funding? Choose an item.

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| --- | --- |
| Funding body: |  |
| Amount: |  |
| Duration: |  |
| Funding reference number: |  |

### 1.9 Has the study received peer review? Choose an item.

(*If ‘No’, please explain whether there are any plans for the study to undergo peer review*)

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## Section 2: Research outside the UK

Research outside the UK should follow the [University’s procedure for research undertaken outside the UK](https://www.liverpool.ac.uk/intranet/media/livacuk/researchethics/reviewprocedures/Research,outside,the,UK,application,procedure.pdf). Resources on research at international sites can be found on the [research ethics webpages](https://www.liverpool.ac.uk/research/research-environment/ethics/policies-and-guidance/international-research/).

### 2.1 Will the research take place at a site outside the UK[[4]](#endnote-5)? No

*(If the research will not take place outside the UK, please go to question 3.1)*

### 2.2 Is it possible to obtain approval from a local Research Ethics Committee? Choose an item.

If it *is* possible to obtain approval from a local Research Ethics Committee, then you should consider whether to apply to a University of Liverpool Research Ethics Committee in the first instance using this form; or whether to apply to a local research ethics committee first, and then apply to the University of Liverpool using the ‘Recognition of external approval’ application form (this form can be requested from [ethics@liverpool.ac.uk](mailto:ethics@liverpool.ac.uk)).

If it is not possible to obtain approval from a local Research Ethics Committee, please answer the questions below.

### 2.3 Please explain what efforts have been made to identify a local research ethics committee[[5]](#endnote-6):

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### 2.4 Please explain whether permission is required from any local organisations or institutions in order to carry out the research?

(*If so, please describe your plans to obtain this approval and provide an indicative timeline for obtaining the approval*)

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### 2.5 Please provide guidance on the local legislative and regulatory environment relevant to research in this setting[[6]](#endnote-7):

(*Please provide links to relevant online resources and information. Guidance on potentially relevant legislation in different countries can be found in the* [International Compilation of Human Research Standards](https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html) document)

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### 2.6 Please describe the local cultural practices that are relevant to the conduct of research in this setting[[7]](#endnote-8):

(*Please ensure you outline the ways in which your research will address and accommodate these practices*)

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### 2.7 Please provide details of the arrangements to ensure the safety of the researcher[[8]](#endnote-9):

(*This should include the safety measures in place to protect participants, as well as other stakeholders who may be involved in the research*)

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## Section 3: Ethics review routes

### 3.1 Will the study involve any of the following?

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| --- | --- |
| Potentially vulnerable people[[9]](#endnote-10), or potentially vulnerable individuals in a dependent or unequal relationship | Choose an item. |
| Children; or adults who may lack the capacity to consent | Choose an item. |
| Obtaining consent from a gatekeeper  (*For example: a parent, carer, workplace supervisor etc*) | Choose an item. |
| The collection of data without written consent from participants | Choose an item. |
| Secondary analysis of confidential or sensitive datasets | Choose an item. |
| Potentially sensitive topics that may cause distress or embarrassment | Choose an item. |
| Topics that raise may require the disclosure of confidential information (criminal activity, child protection etc.) | Choose an item. |
| Deception, or misleading participants | Choose an item. |
| A physical intervention (exercise, physical contact with people etc.) | Choose an item. |
| The administration of substances (food, drink, medication etc.) | Choose an item. |
| Human tissue or stem cells | Choose an item. |
| Physical risks to the safety of the researcher or the participants | Choose an item. |
| Methods where written consent will not be obtained | Choose an item. |
| Access to restricted or private data gathered through the internet | Choose an item. |

If you your study involves any of the above categories, then you are likely to require review from a Central University Research Ethics Committee. You will need to described the associated risks, and how these risks will be managed in section 6 of this form.

## Section 4: Description of the research

### 4.1 Please select which of the following methods/procedures will be used in the study:

|  |  |
| --- | --- |
| Routine Veterinary Practice / Clinical Veterinary Research |  |
| Routine Agricultural Practice |  |
| Veterinary clinical trials requiring an Animal Test Certificate |  |
| Archival research (primary source data held in public or private archives) |  |
| Autoethnography |  |
| Clinical audit |  |
| Focus groups |  |
| Internet-mediated research  (data collected via social media, online chat rooms, private websites etc.) |  |
| Interviews |  |
|  |  |
| Non-invasive experiments on human participants  (for example: classroom tests; the administration of tasks to participants etc.) |  |
| Observations of humans or animals |  |
| Surveys (including questionnaires) |  |
| Other |  |

If ‘Other’ has been selected, please describe the method that will used:

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### 4.2 Please describe the research aims and rationale[[10]](#endnote-11):

(*This will be based upon your research proposal*):

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### 4.3 Please describe the research design in language suitable for your participant audience[[11]](#endnote-12):

(*This will include the full methodology as outlined in your research proposal*):

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4.4 Please provide a one paragraph project description in lay language

(Lay language is non-technical language understandable to a person with average reading ability)

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## Section 5: Veterinary considerations

### 5.1 Does the study involve animal subjects, their tissues or data about them? Choose an item.

*(If ‘No’, please go to question 6.1)*

### 5.2 Is this work Routine Veterinary Practice (RVP)/Clinical Veterinary Research (CVR) or research of Routine Agricultural Practice (RAP)? Choose an item.

(*If ‘Yes’, please explain how the research meets the criteria for Clinical Veterinary Research:*)

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### 5.3 If your project is not RVP/CVR/RAP, please justify why your research falls outside of the remit of the Animals (Scientific Procedures) Act 1986, i.e. why a Home Office License is not required:

(*Please read the* [*UK Government Website on Animal testing and research*](https://www.gov.uk/guidance/research-and-testing-using-animals)):

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### 5.4 Is an [Animal Test Certificate](https://www.gov.uk/guidance/animal-test-certificates) required for this project? (Please see the [Veterinary Medicines Directorate website](https://www.gov.uk/government/organisations/veterinary-medicines-directorate) for further information)? Choose an item.

(*If ‘Yes’, please include the approval letter in your application*)

### 5.5 Will ‘additional’ bodily fluids[[12]](#endnote-13) (blood, urine, cerebrospinal fluid) be collected from a single clinically indicated needle stick event for research purposes only? Choose an item.

(*If ‘Yes’, please indicate the volume and explain why this volume will not be of harm to the subject animals:*)

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### 5.7 Please state species of animal subjects, source of animals and the nature of their involvement:

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### 5.8 In relation to the animal subjects what is the study design?

(*For example, retrospective study of clinical data, prospective observational study, prospective interventional study such as a clinical trial*):

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### 5.9 How many animal subjects will be recruited?

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### 5.10 How was the number of animal subjects decided upon?

(*If a sample size calculation was performed, please include details of type of sample size calculation (e.g. end points considered), assumptions. If a convenience sample, please state how numbers were decided upon.*):

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|  |

### 5.11 Explain how you will recruit the number of animal subjects listed above:

(*For example, based on historic caseloads or number and size of farms to be enrolled.*):

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### 5.12 What are the inclusion criteria for the animal subjects?

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### 5.13 What are the exclusion criteria for the animal subjects?

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### 5.14 If this is a prospective project, are these animals subjects involved in any other research projects?

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### 5.15 Are there any definite or potential benefits for the animal subjects (or their group) of being involved in this study?

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### 5.16 If this is a prospective interventional study, describe any planned deviations from Routine Veterinary Practice:

(*For example, randomisation, blinding, placebos, non-prescription of standard of care therapies.*):

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### 5.17 If this is a prospective study, what steps are in place to deal with any unintended outcomes or welfare issues?

(*For example, rescue protocols.*):

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### 5.18 What are the risks of harm to animals that could arise during the study and how will these be addressed?

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### 5.19 How do the benefits outweigh the risks for the animal subjects involved in this study or other members of their group?

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## Section 6: Recruitment and consent

### 6.1 Please describe the human participant group (e.g. animal owners, Vets, students etc.) that you intend to recruit:

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### 6.2 How many human participants do you expect to recruit?

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### 6.3 How was the number of human participants decided upon?

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### 6.4 Are there any specific human participant groups which you aim to include in your sample?

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### 6.5 Are any human participant groups to be excluded from this study? Choose an item.

(If so, please list the groups who will be excluded and explain why they cannot take part in the study)

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### 6.6 Describe how potential human participants in the study will be identified, approached and recruited:

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### 6.7 Please describe the arrangements for obtaining informed consent from the human participants:

(*Where written consent will be obtained, a copy of your consent form must be included in your submission*)

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### 6.8 Please describe any reimbursements for time and inconvenience, or other forms of compensation that the human participants may receive[[13]](#endnote-14):

(*Please include a copy of the advertisement material with your submission*):

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Where written consent will be obtained, please ensure that you use the [University’s template participant consent form and participant information sheet](https://www.liverpool.ac.uk/research/research-environment/ethics/policies-and-guidance/templates/).

## Section 7: Risk management

In this section, you should reflect on the risks involved in the project.

Please do not write “No risk” or “Not applicable” in the answers below. Applications which do not adequately discuss the risks involved, will be returned to applicants.

While the intention is not to fabricate or overstate potential risks, it should be recognised that all research involving human participants or personal data carries some risk, and applications should contain a constructive reflection on the likelihood and magnitude of risks.

### 7.1 Please describe the risks to the researcher[[14]](#endnote-15):

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### 7.2 Please describe the risks to the participants[[15]](#endnote-16):

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### 7.3 Please describe how the risks will be managed:

(*Please attach a* [*health and safety risk assessment*](https://www.liverpool.ac.uk/intranet/safety/guidance/risk-assessment/) *if required for any non desk-based research*)

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## Section 8: Research data management

Support for your research data management is available from the following sources:

* [Research data management team](https://www.liverpool.ac.uk/library/research-data-management/) ([rdm@liverpool.ac.uk](mailto:rdm@liverpool.ac.uk))
* [Information security team](https://www.liverpool.ac.uk/csd/security/information-security/) ([C.J.Price@liverpool.ac.uk](mailto:C.J.Price@liverpool.ac.uk))
* [Data protection team](https://www.liverpool.ac.uk/legal/data_protection/) ([legal@liverpool.ac.uk](mailto:legal@liverpool.ac.uk))
* [Records management team](https://www.liverpool.ac.uk/csd/records-management/) ([recman@liverpool.ac.uk](mailto:recman@liverpool.ac.uk))

### 8.1 Please tick the types of data that will be processed during the study, and describe how any data analysis will be carried out:

|  |  |
| --- | --- |
| Audio data |  |
| Data associated with human material |  |
| Documents and scripts |  |
| Geospatial data |  |
| Imaging data |  |
| Interview transcripts |  |
| Online responses |  |
| Physiological / biochemical data |  |
| Video recordings |  |
| Veterinary clinical records |  |
| Other data type |  |

If ‘Other data type’ has been selected, please describe the data type that will be processed during the study:

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### 8.2 Please select where the data will be stored during the research project: Choose an item.

8.3 *Please describe how the data will be stored securely:*

*(Please include details of what the data security arrangements will be):*

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### 8.4 During the analysis, the data will be: Choose an item.

(*For guidance on anonymisation, please see the* [*UK Data Service webpages*](https://www.ukdataservice.ac.uk/manage-data/legal-ethical/anonymisation.aspx))

### 8.5 Please describe who will have access to this data: Choose an item.

If individuals external to the research team will have access to the data, please describe how this will be managed:

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### 8.6 How will the data be shared with your Research Team or Supervisor? Choose an item.

If ‘Other’, please describe how the data will be shared with your Research Team or Supervisor:

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### 8.7 In the written findings for the research, the data will be: Choose an item.

If the data are to be anonymised, please describe the anonymisation process:

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If the data are to be identifiable, you must ensure that the consent form and participant information sheets explicitly reference the use of identifiable data:

I agree to ensure that the consent form and information sheet explicitly reference the use of identifiable data

### 8.8 Please select how long the data will be stored for following completion of the study: Choose an item.

Please describe the plans for the destruction or long-term storage of the data:

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|  |

### 8.9: Please describe how the consent forms will be managed: Choose an item.

If ‘Other’, please describe how the consent forms will be managed:

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### 8.10 Up to what point will human participants be able to withdraw their data: Choose an item.

If ‘Other’, please describe the point up to which participants will be able to withdraw their data:

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### 8.11 Will any of the following categories of data be collected during the study:

|  |  |
| --- | --- |
| Racial origin |  |
| Political opinions |  |
| Ethnic origin |  |
| Religious beliefs |  |
| Philosophical beliefs |  |
| Trade union membership |  |
| Genetic data |  |
| Biometric data for the purpose of uniquely identifying a person |  |
| Data concerning health |  |
| Data concerning a person's sex life |  |
| Data concerning a person's sexual orientation |  |
| Data relating to criminal convictions and offences, or related security measures |  |

If any of the above categories of data will be collected during the study and participants could be identified from this data, then a [data protection impact assessment](https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/accountability-and-governance/guide-to-accountability-and-governance/data-protection-impact-assessments/) must be completed.

### 8.12 Will feedback of the findings be given to participants at the participants' request[[16]](#endnote-17)? Choose an item.

If feedback of the findings will be given to participants, please describe the process for feeding back the results to participants:

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### 8.13 Please select how the findings of the research will be disseminated:

|  |  |
| --- | --- |
| Dissertation thesis |  |
| Internal report |  |
| Conference presentation |  |
| Peer reviewed journal |  |
| Other |  |

Please describe any ethical issues that arise from this dissemination:

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### 8.14: Are there any factors which may compromise the duty of confidentiality towards participants? Choose an item.

If so, please describe the strategy to manage the factors which could compromise the duty of confidentiality:

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### 8.15 Will personal data be transferred from inside the UK or inside the EU, to a location outside the EU? Choose an item.

If ‘Yes’, and personal data will be collected inside the UK or inside the EU[[17]](#endnote-18), and then transferred outside the EU, you will need to gain explicit consent through the participant consent form:

I understand and agree to obtain explicit consent prior to the transfer personal data outside the EU

### 8.16 It is understood that the Principal Investigator or Supervisor should act as the primary custodian for the data generated by the study:

## Section 9: Application sign off declarations

### 9.1 Are there any [declarations of interest](https://www.liverpool.ac.uk/legal/policies/) to disclose in relation to this study? Choose an item.

If ‘Yes’, please describe the potential conflict of interest, and how this will be managed:

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### 9.2 Please confirm that you have read and understood the [University’s Policy on adverse events in research](https://www.liverpool.ac.uk/media/intranet/research-support-office/ethics/Research,Ethics,Handbook,%5bMASTER%5d.pdf#page=309):

### 9.3 Please confirm that you have read and understood the [University’s Research ethics policy](https://www.liverpool.ac.uk/media/intranet/research-support-office/ethics/Research,Ethics,Handbook,%5bMASTER%5d.pdf#page=6):

### 9.4 Please describe the training in research ethics and research integrity that the Principal Investigator or Supervisor and the Student investigator have undertaken:

(*This should include reference to the* [*University’s training in research ethics and research integrity*](https://www.liverpool.ac.uk/research/research-environment/ethics/ethics-training/)*, as well as any relevant training that is specific to the study*)

|  |  |
| --- | --- |
| Principal Investigator or Supervisor training: |  |
| Student investigator training: |  |

### 9.5 Checklist of enclosures:

(Have you included the following documents in your submission?)

|  |  |
| --- | --- |
| Participant information sheets: | Choose an item. |
| Participant consent forms: | Choose an item. |
| Recruitment advertisement: | Choose an item. |
| Survey or questionnaire: | Choose an item. |
| Interview schedule: | Choose an item. |
| Debriefing material: | Choose an item. |
| A protocol for managing distress | Choose an item. |
| Study plan or study protocol: | Choose an item. |
| Evidence of external permissions: | Choose an item. |
| Research data management plan: | Choose an item. |
| Health and safety risk assessment: | Choose an item. |
| Data protection risk assessment: | Choose an item. |
| Other research tools that will be given to participants: | Choose an item. |
| Animal Test Certificate: | Choose an item. |
| Academic honesty declaration: |  |

# Appendix 1: Literature and guidance notes

* [University research ethics webpages](https://www.liverpool.ac.uk/intranet/research-support-office/research-ethics/international-research/)

1. Security Sensitive research includes, but is not limited to the commissioning, acquisitioning and communication with various groups, searching and downloading texts, videos and images that relate to:

   * Terrorism and Counter Terrorism
   * Extremism e.g. Al Qaeda, Jihadist, ISIS
   * Religious
   * Political
   * UK Government/ Ministry of defence (MOD)
   * Military/Weaponry/Explosives
   * Nuclear

   For more information please refer to the [Oversight of security sensitive research materials](https://www.universitiesuk.ac.uk/policy-and-analysis/reports/Pages/security-sensitive-research-material-UK-universities-guidance.aspx). [↑](#endnote-ref-2)
2. Please visit the [UK Caldicott Guardian Council website](https://www.ukcgc.uk/manual/principles) for information on the Caldicott principles [↑](#endnote-ref-3)
3. Please list all countries and research sites involved in the research. [↑](#endnote-ref-4)
4. This includes any research which targets data collection from participants outside the UK, for example:

   All fieldwork conducted overseas (observations, interviews, surveys etc.)

   Any health-related research conducted overseas (clinical trials, human tissue collection, interventions, health-related surveys etc.)

   Online data collection (such as questionnaires, video interviews, chat room data etc.) that is specifically targeted at an overseas population [↑](#endnote-ref-5)
5. Resources on the various overseas research ethics committees can be found on the [research ethics webpages](https://www.liverpool.ac.uk/research/research-environment/ethics/policies-and-guidance/international-research/). [↑](#endnote-ref-6)
6. For example - are the data protection laws similar to those in the UK, or are there important differences? Guidance on potentially relevant legislation in different countries can be found in the [International Compilation of Human Research Standards](https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html). [↑](#endnote-ref-7)
7. For example: Are there any specific considerations with regard to approaching individuals? What are the normal practices for obtaining informed consent in this setting? [↑](#endnote-ref-8)
8. Please explain here the safety considerations outlined in your risk assessment, including:

   what training and support you received in order to carry out your research project overseas;

   whether advice from the [Safety Office](https://www.liverpool.ac.uk/safety/contactus/) has been sought;

   what arrangements are in place to ensure that you will be receiving on-going supervision and oversight throughout your research project. [↑](#endnote-ref-9)
9. Vulnerability is a fluid and contested term as there are many reasons why research participants may be disadvantaged. Vulnerability may result from factors such as the participants’ sexual behaviour; their legal or political behaviour; their experience of violence; their gender or ethnic status; their age (e.g. children aged under 16); or their status in a dependent or unequal relationship. People may be vulnerable in different ways, and to different degrees at different points in their lives due to the circumstances in which they find themselves at a particular time. Vulnerability should not be seen as a characteristic of individuals or categories of people. It is important to recognise that prospective participants may be vulnerable, but not to assume they are vulnerable. Researchers should assess potential vulnerability within the context of the research. [↑](#endnote-ref-10)
10. The research aims should include: the background to your research; the research questions; any relevant existing literature. [↑](#endnote-ref-11)
11. This section should include details of: your methodology; the identification and recruitment of participants; details of how the data will be collected; how the data will be analysed. [↑](#endnote-ref-12)
12. Residual bodily fluids are the bodily fluids left over after clinical use of a clinically indicated sample e.g. in a syringe or vacutainer.Additional bodily fluids are collected when more bodily fluid than is clinically required is collected deliberately with the intent of using the additional sample for research purposes [↑](#endnote-ref-13)
13. A reimbursement can be given to participants that acknowledges the time and effort they have provided in participating in the research or reflects any expenses that may occur I.e.- transport, parking, child care. [↑](#endnote-ref-14)
14. Please do not write “No risk” or “Not applicable”. Applications which do not adequately discuss the risks involved, will be returned to applicants. While the intention is not to fabricate or overstate potential risks, it should be recognised that all research involving human participants or personal data carries some risk, and applications should contain a constructive reflection on the likelihood and magnitude of risks. Potential risk to researchers may include:

    risk of physical threat or abuse

    risk of psychological trauma, as a result of actual or threatened violence or the nature of what is disclosed during the interaction

    risk of being in a comprising situation, in which there might be accusations of improper behaviour

    increased exposure to risks of everyday life and social interaction, such as road accidents and infectious illness [↑](#endnote-ref-15)
15. Please do not write “No risk” or “Not applicable”. Applications which do not adequately discuss the risks involved, will be returned to applicants. While the intention is not to fabricate or overstate potential risks, it should be recognised that all research involving human participants or personal data carries some risk, and applications should contain a constructive reflection on the likelihood and magnitude of risks. Potential risk to researchers may include:

    Research topic: Is the topic of the study contentious and sensitive. How will you deal with this issue in your research project?

    Participants: Will the study will involve vulnerable people who might not be able to provide informed consent? What arrangements have you put in place to ensure that your participants fully understand the project and there is no coercion to participate?

    Recruitment of participants: Will participants in the study be approached in a public space? What matters arise from this research decision relating to the voluntary participation of people in the study and how have you addressed them?

    Confidentiality: Will you be able to offer confidentiality and anonymity to all your participants? What if they disclose illegal or potentially harmful information? Are they well known in their community? what if the answers they provide make them identifiable to other? [↑](#endnote-ref-16)
16. It is good practice for researchers to provide feedback of the findings to research participants at the end of the study. The feedback usually covers:

    what participants can expect to happen to them at the end of a study;

    how those that have participated in the research can access the study results;

    how those who would rather not see the findings can opt out of the process, if this has not been covered already;

    who to contact if participants have any further questions;

    an acknowledgement of the contribution they have made to research. [↑](#endnote-ref-17)
17. For the purposes of data protection, the UK is classed as “adequate” and is free to transfer data within the EU with no additional obligations [↑](#endnote-ref-18)