Guidance Notes for Ethical Approval

**Research ethics**

Research at YSJU is conducted according to the principles set out in the university research ethics policy. The policy applies to all staff and students of the university (including those with visiting or honorary contracts) and to third parties (e.g. staff from other institutions) who propose to undertake research with YSJU students. The policy states that all research must be conducted according to appropriate ethical, legal and professional frameworks, obligations and standards, and as a guide for staff and students, it specifies that the following types of research must undergo ethical scrutiny by the appropriate research ethics committee and obtain formal approval before it is undertaken:

* research involving living human participants, their tissue or their data;
* research with the potential for adverse environmental impact;
* research involving NHS patients, staff or resources;
* research involving animals;
* research into terrorism, extremism, radicalisation, and other areas under the counter-terrorism and security act (2015) and prevent duty for higher education (2015).

Other forms of research may also raise significant ethical issues, and this too should be subject to ethical review. if in doubt about whether research requires ethical review, advice should be sought from the chair of the university research committee which has oversight of research ethics at YSJU.

**Open Data & Data Management**

YSJU supports the principles set out in the UK Concordat on open research data, and supports the principle of open access for both research data and outputs, recognising the benefits to the public and wider academic community. These principles are set out in the YSJU Data Management Policy, and which outline that all researchers have a duty to:

* Take responsible ownership of all research data that they generate.
* Follow legal, regulatory and compliance needs.
* Ensure the maximum possible security and confidentiality of research data and that personal, confidential or sensitive data is not disclosed to unauthorised recipients.
* Ensure the integrity of research data.
* Ensure the appropriate availability of data.

Therefore, integrated into the research ethics form, is a section on data management, focusing on the storage, sharing and availability of your data. To find out more, please refer to:

* the YSJU open data policy
* the UK concordat on open data:

<https://www.ukri.org/files/legacy/documents/concordatonopenresearchdata-pdf/>

**GDPR**

The General Data Protection Regulation (GDPR) introduces a new requirement for organisations to carry out a data protection impact assessment (DPIA) prior to embarking on a project that involves the use of personal data. a DPIA enables you to

* identify and plan how to deal with the associated privacy risks
* ensure data protection compliance is built into the design of the project, demonstrate openness and transparency; and
* evidence compliance with your legal obligations.

The YSJU’s DPIA procedure must be followed when research involving the collection of individuals' personal data. The university secretary is the data protection officer and responsible for providing advice, ensuring the DPIA process is completed appropriately and monitoring its performance pursuant to GDPR article 35.

**GDPR Article 89 Research checklist**

If your research project involves the use of “special categories” of personal data you need to satisfy one of the conditions set out in the GDPR Article 9 (as well as an Article 6 condition) and the most appropriate will be:

(2) (j) *processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) based on Union or Member State law which shall be proportionate to the aim pursued, respect the essence of the right to data protection and provide for suitable and specific measures to safeguard the fundamental rights and the interests of the data subject*.

This means if you are using Article 9(2) (j) for your lawful basis you must meet the requirements set out in Article 89.

Article 89 of the GDPR allows controllers to process data for scientific or historical research purposes or statistical purposes **as long as appropriate safeguards are in place** (at YSJU this is the ethics approval process)**.**

Where possible, controllers are required to fulfil these purposes with data that does not permit, or no longer permits, the identification of data subjects using anonymisation or pseudonymisation techniques unless this would prejudice the purpose of the research or statistical process. If you are processing personal data for these purposes, you must ensure the following:

* Technical and organisational measures are in place to protect the data against risk of accidental or unlawful destruction, loss, alteration, unauthorised disclosure of or access to personal data;
* data is anonymised or pseudonymised so that it does not permit, or no longer permits, the identification of data subjects;
* A process is in place to justify and record any decision to retain identifiable data if anonymisation is not possible because this would prejudice the purpose of the research or statistical process.
* The minimum amount of personal data necessary for the purpose is used (data minimisation principle)
* The data is not used for the purposes of measures or decisions about an individual data subject,
* The processing of the data is not likely to cause substantial damage or substantial distress to an individual.
* The retention of special category data for research purposes has a public interest justification (UK Data Protection Act Schedule 1 Part 1(4)(c)).

Application for ethical approval

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| **Section 1**: About you and the project | |
| Title of research: |  |
| Researcher: |  |
| Email address: |  |
| School: |  |
| Telephone number: |  |
| Status | Student: Undergraduate programme (e.g. BSc)  Student: Postgraduate taught programme (e.g. MSc)  Student: Postgraduate research programme (e.g. PhD)  Staff |
| Main supervisor:  (for student applications) |  |
| Are there any internal collaborators on the project? If so please list their names here: |  |
| Are there any external collaborators on the project? If so please list here their names and institutions: |  |
| Start date of project: |  |
| Expected duration of the project: |  |
| Has the project been externally funded? If yes please state the name of the funding organisation, and amount of award. |  |
| Additional notes | *Please include any additional information, for example will approval also be sought from the NHS, is this a group project, or a member of staff seeking approval for student group projects (block approval).* |

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| **Section 2:** Brief overview of the project | |
| Objectives of the investigation | |
| *Please provide a plain English summary of the investigation including an academic rationale and justification for the project. This should not exceed 500 words.* | |
| Will the project involve…. | |
| Human participants  Human tissue(s)  Documents (e.g. for the purposes of systematic review/ meta-analysis (*upon completion of section 2 please go to section 6*)  Other, please state below | |
| Will the research require the collection of primary source material that might possibly be seen as offensive or considered illegal to access or hold on a computer? (*e.g. studies related to state security, pornography, abuse, illegal behaviour or terrorism*). | Yes  No |
| Does your research concern groups which may be construed as terrorist or extremist?  (*If your answer to this question is “Yes”, you must complete and submit the supplementary form available as an appendix to your Research Ethics approval form).* | Yes  No |
| Will the research involve visual/vocal methods where participants may be identified? | Yes  No |
| Will the research involve the use of genetic data (inherited/acquired genetic characteristics resulting from the analysis of a biological sample e.g. chromosomal, DNA, RNA or other elements)? | Yes  No |

If you answer “yes” to any of the four questions above, your project involves the collection of sensitive data and as such your application **may** need to be reviewed by the university research ethics committee.

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| **Section 3:** Participants | |
| Will the research take place outside the UK? | Yes  No |
| If Yes will the research take place outside the EU? | Yes  No |
| Will the study require the co-operation of a gatekeeper to give access to, or to help recruit, participants?  *(e.g. head teachers giving access to schools, ministers giving access to congregations, group leaders publicising your research.)* | Yes  No |
| Will it be necessary for participants to take part in the study without their knowledge or consent at the time?  *(e.g. observations of group behaviour, or the use of data that was not intentionally collected for research.)* | Yes  No |
| Will the study involve recruitment of patients through the NHS? | Yes  No |
| Will inducements be offered to participants?  *(e.g. the offer of being entered in a prize draw, or, for students, the offer of course credit for participation.)* | Yes  No |
| Does the study involve participants who are particularly vulnerable or unable to give informed consent?  *(e.g. if any participants are under 18. Adults with learning disabilities, the frail elderly, or anyone who may be easily coerced due to lack of capacity. If you teach and you wish to research your own students, they should be classed as potentially vulnerable.)* | Yes  No |
| Is there a possibility that the safety of the researcher may be in question?  *(e.g. lone working)* | Yes  No |
| **Participant recruitment** | |
| Please detail the nature of the participants. | |
| *Detail should include the number and age range of participants. You should outline how the sample size has been determined, important characteristics, and any inclusion/ exclusion criteria.* | |
| Where will the research be conducted? | |
| *Please explain where your research will be collected, for example in a laboratory at the university, or in participants’ homes.* | |
| Describe the method of recruitment | |
| *Please explain how participants will be recruited, including detail on any gatekeeper approval you require, and information on any incentives (payments, expenses, prize draws etc.)* | |
| Participant consent | |
| *Please outline from whom consent/ assent will be sought. Detail should include how consent/ assent will be obtained, whether there will be a cooling off period, whether consent/ assent will be sought electronically or using paper forms. Copies of the participant information sheets and consent forms should be attached to this application form.* | |

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| **Section 4**: Methodology | |
| Will the study require participants to commit extensive time to the study?  *(e.g. Single-session interviews or completing questionnaires once or twice would not be considered excessive, but long-term studies with multiple sampling, intensive data gathering over a day or more, or long interviews and questionnaires that take some hours to complete might fall into this category.)* | Yes  No |
| Are drugs, placebos or any other substances to be administered to participants, or will the study involve invasive, intrusive or potentially harmful procedures of any kind?  *(Even simple procedures such as tasting sessions might be dangerous if participants have allergies, so tick yes if the research involves any substance trials.)* | Yes  No |
| If there are experimental and control groups, will being in one group disadvantage participants?  *(e.g. testing new teaching methods where pupils without the trial procedure may be disadvantaged, or trying a new procedure where the outcomes are uncertain.)* | Yes  No |
| Is an extensive degree of exercise or physical exertion involved? | Yes  No |
| Will blood or tissue samples be obtained from participants? | Yes  No |
| Could the study induce psychological stress or anxiety or cause harm or negative consequences beyond the risks encountered in normal life?  *(This might be because the subject area is sensitive, the nature of task (e.g. decision-making under pressure), or the participants are particularly vulnerable to stress or anxiety (e.g. those with a history of poor mental health).)* | Yes  No |
| Please describe the research methodology and procedure. | |
| *Describe the research methodology and procedure, providing a timeline of activities where possible. Please use plain English.* | |
| Please provide details concerning what your participants will be required to do. | |
| *Please describe the specific techniques that will be used, and outline exactly what will be asked of participants. This could include a description of the experimental methods to be used, or a description of the questionnaire or interview schedule. It may be helpful to provide reference to supporting material supporting the use of such techniques with your sample. Please attach a copy of any scales or measures, or focus group/ interview schedules to this application.* | |

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| **Section 5**: Ethical Issues |
| *Please describe the main ethical issues and how you propose to address them.*  *If you answered yes to any of the questions in section 3 and 4, further detail can be provided here. You should also ensure that you have discussed any risk associated with your project and how this will be managed, and how participants will be provided with the right to withdraw.* |

**Section 6**: Data management plan & data protection impact assessment

These questions are intended to help you decide whether a DPIA is necessary. Answering ‘yes’ to any of these questions is an indication that a DPIA is required.

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| **Screening question** | **Yes** | **No** |
| 1. Will the project involve the collection of information about individuals? |  |  |
| 1. Will the project require individuals to provide information about themselves? |  |  |
| 1. Will you be using information about individuals for a purpose that it? is not currently used for, or in a way it is not currently used? |  |  |
| 1. Does the project introduce new or significantly change the way in which personal data about a large number of individuals is handled? |  |  |
| 1. Does the project introduce new or additional information technologies that can reveal an individual’s identity and has the potential to affect that person’s privacy? |  |  |
| 1. Does the project involve the use of systematic and extensive profiling or automated decision making to make significant decisions about people? |  |  |
| 1. Will you be processing special category data or criminal offence data on a large scale? |  |  |
| 1. Will you be systematically monitoring a publicly accessible place on a large scale? |  |  |
| 1. Does the project involve the use of new technologies? |  |  |
| 1. Does the project involve profiling, automated decision-making or special category data to help make decisions on someone’s access to a service, opportunity or benefit? |  |  |
| 1. Do you intend to carry out profiling on a large scale? |  |  |
| 1. Will you be processing biometric or genetic data? |  |  |
| 1. Does the project involve combining, comparing or matching data from multiple sources? |  |  |
| 1. Do you plan to process personal data without providing a privacy notice directly to the individual? |  |  |
| 1. Do you plan to process personal data in a way which involves tracking individuals’ online or offline location or behaviour? |  |  |
| 1. Do you plan to process children’s personal data for profiling or automated decision-making or for marketing purposes, or offer online services directly to them? |  |  |
| 1. Do you plan to process personal data which could result in a risk of physical harm in the event of a security breach? |  |  |
| 1. Do you plan to carry out any other:  * Evaluation or scoring; * Automated decision-making with significant effects; * Systematic monitoring; * Processing of sensitive data or data of a highly personal nature; Processing on a large scale; Processing of data concerning vulnerable data subjects; * Innovative technological or organisational solutions; * Processing involving preventing data subjects from exercising a right or using a service or contract. |  |  |
| 1. Will the personal data be processed out of the EU? |  |  |

**6b**. Why is a DPIA needed?

N/A a DPIA is not needed. Please go to question 6d.

*With reference to the checklist, briefly explain why a DPIA is needed*

**6c**. The nature of your research data

1. Are you collecting any of the following personal data as part of your research project?

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| --- | --- | --- |
| **Type of data\*** | **Yes** | **No** |
| Race |  |  |
| Ethnicity |  |  |
| Political Opinions |  |  |
| Religious or philosophical beliefs |  |  |
| Trade union membership |  |  |
| Genetic data |  |  |
| Biometric data (where this is used for identification purposes) |  |  |
| Health data |  |  |
| Sex life |  |  |
| Sexual orientation |  |  |
| Criminal convictions and offences |  |  |
| Other |  |  |

\* These categories are taken from the information Commissioners Office (ICO) categories of personal data, see: <https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/what-is-personal-data/what-is-personal-data/>

1. Describe the scope of the processing: what is the nature of the data? There are three categories of data with regard to anonymisation:

* **Anonymised data** are data in a form that does not identify individuals and where identification through its combination with other data is not likely to take place is anonymised data and out of the scope of data protection legislation.
* **Pseudoanonymised data** are data where no personal information is included through the consent process, instead participant codes are used. Researchers/ participants generate a code (e.g. date of birthday and last three digits of postcode); this is then entered on the participant information sheet (so participants have a record), on the consent form as evidence of consent and on the data (e.g. on the questionnaire).
* Data where anonymisation is not possible, for example video recordings of interviews, personal information that has to be collected for safeguarding purposes.

What is the nature of your data?

Anonymised

Pseudoanonymised

Data where anonymisation is not possible

1. Additional data on the anonymisation process

*Please outline here, how your research data will be anonymised/ pseudoanonymised, explaining the process through which this will be achieved. If anonymisation is not possible, please explain why here.*

**6d. Research Data Flow**

1. What data will be collected?

*For example: What physical data will you study? (e.g. artefacts, samples, paper archives, questionnaire scores etc.). What digital data will you generate? (e.g. field-notes, images, spreadsheets, audio interviews, survey data, annotated bibliography, etc.)*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Please use the table below to document all the research data you will collect or generate as part of the project. An example has been provided in red. | | | | | | |
| Data type | Original format | Preservation format | Estimated volume | IPR Owner | Active storage location | Completed storage location |
| Questionnaire data | SPSS file | SPSS file/ .dat | ~400mb | Name here | YSJU One:drive account | RAY, OSF |
| Interview notes | .xlsx, .docx | .csv, .rtf | <10MB | Name here | Password protected U:Drive account | U:Drive, RAY |

Plans for data sharing and access in the short and long term

1. Will anyone other than the named applicants have access to the data?

☐Yes

☐No*If yes, please list their names and institutions and explain the reason for access here.*

1. Will your data be made openly available upon completion of your project?

☐Yes

☐No

If no, please explain why you will not make your data openly available *and then go to question 6d.7.*

1. What repository will you use? *E.g. RAY, PURE, OSF*
2. Can your data be released immediately, or should you embargo (delay access to) the data?
3. If your research involves people, have you obtained appropriate consent for data sharing?

☐Yes

☐No

1. How will data be documented and described?

*Will others understand your data? Will you write documentation such as variable lists, syntax files etc..Will you make sure table and spreadsheet values are clearly labelled?*

*What information about data collection methodology will be recorded?*

*Is it important for the research to be reproducible? Why/why not? If so, what additional documentation or pointers will be required?*

*Will you write software? Where will this be documented and stored for future use?*

1. How will data be structured and stored?

*Estimate how much data you will produce over time – do you have enough storage?*

*Are you making full use of University provided, fully backed-up storage? How will data generated in the field be saved to safe University storage? Do you have a logical file naming convention and directory structure? How will you use versioning so you can identify the current version of documents / data?*

1. Are there any ‘special’ requirements for your data? *Does your research funder have specific data management and sharing requirements?*

*Should some data be destroyed? When and how?*

**Identify the privacy and related risks**

N/A a DPIA is not needed. Please go to section 7.

Identify the key privacy risks and the associated compliance and corporate risks. Larger-scale PIAs might record this information on a more formal risk register.

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| --- | --- | --- | --- | --- |
| Describe the source of the risk and nature of the potential impact in individuals. Include associated compliance and corporate risks | Risk to individuals | Likelihood of harm (remote, possible or probable) | Compliance risk | Associated organisation / corporate risk |
|  |  |  |  |  |

**Identify measures to reduce risks**

Describe the actions you could take to reduce or eliminate the risks identified, and any future steps which would be necessary (e.g. the production of new guidance or future security testing for systems).

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| --- | --- | --- | --- |
| **Risk** | **Solution(s)** | **Result:** is the risk eliminated, reduced, or accepted? | **Evaluation:** is the final impact on individuals after implementing each solution a justified, compliant and proportionate response to the aims of the project? |
|  |  |  |  |

**Sign off and record the DPIA outcomes**

Who has approved the privacy risks involved in the project? What solutions need to be implemented?

|  |  |  |
| --- | --- | --- |
| Risk | Approved solution | Approved by |
|  |  |  |
|  |  |  |

**Integrate the PIA outcomes back into the project plan**

Who is responsible for integrating the DPIA outcomes back into the project plan and updating any project management paperwork? Who is responsible for implementing the solutions that have been approved? Who is the contact for any privacy concerns that may arise in the future?

|  |  |  |
| --- | --- | --- |
| Action to be taken | Date for completion of actions | Responsibility for action |
|  |  |  |
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**Contact point**

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| --- |
| Contact point for future privacy concerns (if this is a student project, this should be your supervisor). |
|  |

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| **Section 7**: Declaration | |
| Declaration – I have read the ethics policy and guidance and the general data protection regulation information alongside abiding by the practice in place within my research discipline. The information supplied here is accurate to the best of my knowledge. | |
| Staff Signature (principal investigator) |  |
| Name |  |
| Date |  |
|  |  |
| Student Signature(s) (if applicable) |  |
| Name |  |
| Date |  |

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| **Appended material** | | |
| List here the material you have appended to the end of this form. This should include letters to gatekeepers, examples of informed consent sheets, copies of questionnaires, interview schedules, participant screening tools etc.). If you cannot easily append this material, email it as an attachment. | | |
| **Checklist** | **Attached** | **N/A** |
| Participant Information Sheet(s) |  |  |
| Consent Form(s) |  |  |
| Sample questionnaire(s) |  |  |
| Sample interview format(s) |  |  |
| Sample advertisement(s) |  |  |
| Security-sensitive material |  |  |
|  |  |  |
| Any other documents (please specify below) |  |  |