Ethical Approval for Non-Clinical Research Involving Human Participants

FORM B: Application for ethical approval for medium/high risk projects

Name of Applicant	
School	
University e-mail Address	
Title of Project	
Co-Investigators (with internal School or external organisational affiliation)	
Projected Start Date	
Estimated End Date	
Funder (if applicable)	
Version of Application (1, 2, 3…)*	

* After revision, please update the version number before re-submission.

Students Only	
Level of Study (Undergraduate (UG); Taught Postgraduate (TPG); Research Postgraduate (RPG)	
Name of University of Dundee Supervisor	

Note: Students must copy in their supervisor when submitting the application for review.

1. Project Information

1a. Please provide, with reference to the relevant literature, an overview of the research project providing a short explanation maximum 400 words) of the research questions the project will address and why the study is justified. *Please write this section in a way that is accessible to a person who is not an expert in your field.*
1b.What are the aims and objectives of the project?

1c. Please describe the design of your study and the research methods including information about any tasks or measuring instruments (validated or otherwise) that you will be using. *If you are using non-validated instruments (e.g., surveys or questionnaires[1] you have designed, interview questions, observation protocols for ethnographic work or topic lists for unstructured data collection) please attach a copy to this ethics application.*

2. Participants

	YES	NO
2a. Will your research involve children under the age of 16[2]?*		
2b.Will your research involve the recruitment of vulnerable participants (for example, participants with learning difficulties, disabilities, members of marginalised communities, people involved in illegal activities such as drug abuse?*		
2c. Will your research involve participants with communication difficulties, including difficulties arising from limited facility with the English language?*		
2d. Will your research involve participants in unequal relationships with the researcher(s) (e.g., your own students)?		
2e. Will your research involve participants outside of the UK?		

* If you answered YES to question(s) 2a, 2b or 2c please attach a copy of your Protecting Vulnerable Groups (PVG) clearance from Disclosure Scotland (or the equivalent in other jurisdictions).

Please explain in detail how you intend to recruit your participants (including inclusion and exclusion criteria and the participant's location if outside the UK). Pay particular consideration to any issues arising from answering YES to any of these questions:

[1] Please provide details of any survey tools you intend to use. The University approved online survey tool is 'Online surveys' (formerly BOS). If you intend to use a different survey tool please indicate the reason.

[2] The legal age of capacity in Scotland is 16 under The Age of Legal Capacity (Scotland) Act 1991. The legal age of capacity in other jurisdictions should be checked if your research involves participants in other parts of the UK and/or internationally.

3. Informed consent

	YES	NO
3a. Will all participants be fully informed why the project is being conducted and what their participation will involve, and will this information be given before the project begins?		
3b. Will every participant be asked to give written consent to participation?		
3c. Will all participants be fully informed about what data will be collected, where and for how long it will be stored, and their rights under data protection legislation?		
3d. Will all participants be informed who has access to their data during the time it is stored?		
3e. If the project involves audio, video or photographic recording of participants will explicit consent be sought?[3]		
3f. Will every participant understand their right not to take part or to withdraw themselves and their data from the project without giving a reason and without penalty?		
3g. If the project involves deception or covert observation of participants will you debrief them at the earliest possible opportunity?		
3h. Will participants be fully informed about the potential reuse of their data by other researchers?		
3i. If required, will you obtain permission from relevant authorities (e.g. employers, third sector organisations, government institutions) as part of the recruitment process?		
3j. Are you satisfied that all participants have capacity to make their own decisions and understand the risks?		

If you answered YES to ALL of these questions please explain briefly how you will implement the informed consent scheme. *Please attach copies of the participant information sheet(s) and consent form to your application.*

[3] Where applicable, this should include consent for someone not on the direct research team to have access to the participant's data, e.g. for transcription.

If you answered NO to ANY of these questions, please provide an explanation. Please note that if written consent is not obtained, any other form of consent used must involve a deliberate action to opt-in (for example, in surveys or questionnaires).

Please attach a copy of the participant information sheet and consent form (where applicable) to your application.

4a. Data Management: Lawful Processing of Data

1) Data protection legislation[4] requires participants to be informed of the lawful basis for processing their personal data. At the University of Dundee, the normal basis for the lawful processing of personal data in research is that 'processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller'. If you intend to use another lawful basis you must contact the University's Data Protection Officer (DPO) for advice and insert the lawful basis agreed with the DPO below.

2) In addition to the lawful basis above, where the research involves the processing of special category[5] (sensitive personal) data, participants must be informed of the specific condition under which this processing will be performed. At the University of Dundee, the specific condition for the lawful processing of special categories of personal data in research is normally that 'processing is necessary for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes'. If you will be processing special category data and intend to use another condition you must contact the University's Data Protection Officer (DPO) for advice and insert the condition agreed with the DPO below.

4b. Data Management: Planning

4 The General Data Protection Regulation ((EU) 2016/679) and the UK Data Protection Act (2018). Further information can be obtained from the University of Dundee data protection website and the website of the Information Commissioner's Office.

5 Special category data is sensitive personal data belonging to the following categories: racial or ethnic origin; political opinions; religious or philosophical beliefs; trade union membership; genetics, biometrics; health; sex life; or sexual orientation.

	YES	NO
4a. Are there any reasons why you cannot guarantee the full security and confidentiality of any personal or confidential data collected for the project?		
4b. Is there a possibility that any of your participants, organisations they are affiliated with, or people associated with them, could be directly or indirectly identified in the outputs from this project?		
4c. Will any personal or confidential data be retained at the end of the project other than in fully anonymised form?		
4d. Will it be possible to link information or data back to individual participants in any way (include consideration of the use of secondary data)?		

If you have answered YES to ANY of these questions, please explain why it is necessary to breach normal ethical procedures regarding confidentiality, security and/or retention of research data.

Irrespective of your answers to questions 4a to 4d, please describe your plan for managing the data[6] you will collect during your project and how it complies with data protection legislation. Include information on: i) The type and volume of data[7]; ii) Where and for how long will the data be stored and what measures will be in place to ensure secure storage[8]; iii) Whether the data will be anonymised or pseudonymised[9]; iv) How secure access will be provided to data for collaborators; v) Whether and how data will be shared for reuse by other researchers beyond the project (including details on any access restrictions); vi) Processes in place to erase and/or stop processing an individual participant's data (except where this would render impossible or seriously impair the research objectives)[10]; vii) Processes in place for individuals to have inaccurate personal data

[6] Note that staff and postgraduate research students are required to complete a research data management plan under the University of Dundee's Policy to Govern the Management of Research Data. However, providing you have included the information requested above, it is not necessary to attach a formal data management plan to this application.

[7] If your research involves high-risk or high-volume *processing* of personal data you will be required to complete a Data Protection Impact Assessment for your project. Please consult the University's data protection pages and Data Protection Officer for advice.

[8] Please consult the Information Security Classification Scheme on the University's data protection pages for guidance.

[9] (Article 4(5) of the General Data Protection Regulation describes pseudonymisation as: "The processing of personal data in such a way that the data can no longer be attributed to a specific data subject without the use of additional information". An example would be where a coded reference or pseudonym is substituted for personally identifiable data.

[10] The right to erasure under the General Data Protection Regulation does not apply if erasing the data would prejudice scientific or historical research, or archiving that is in the public interest.

rectified, or completed if it is incomplete; viii) Who has overall responsibility for data management for the research project; ix) Arrangements for collection and transfer of data outside the UK.

5. Risk of harm to researchers and participants

	YES	NO
5a. Is there a risk that the project may lead to physical discomfort or pain for the participants?		
5b. Is there a risk of emotional or psychological distress to participants?		
5c. Will your research involve the use of tissue samples (including blood and biopsies from healthy volunteers) excluding use for genetic analysis only or tissues obtained from a tissue bank?		
5d. Will the research involve psychological intervention?		
5e. Will the research involve working with any substances and/or equipment which may be considered hazardous?		
5f. Will the study involve discussion of sensitive or potentially sensitive topics (e.g., sexual activity, drug use, personal lives)?		
5g. Is there a risk that the safety of the researcher may be compromised (e.g., lone working, working in potentially dangerous environments), i.e. does the research incur a risk of injury or ill-health above the level of risk prevalent in daily living?		
5h. Does the research involve fieldwork outside the UK?		

If you answered YES to ANY of these questions, please explain the nature of the risks involved, why it is necessary to expose the participant or researcher to such risks, how you propose to assess, manage and mitigate the identified risks and how you plan to communicate the risks and your plans for mitigation to the participants. Please also explain the arrangements you will make to refer participants or researchers to sources of help or advice if they are distressed or harmed as a result of taking part in the project. *Where the research incurs a risk of injury or ill-health above the level of risk prevalent in daily living the relevant risk assessment form(s) (general risk assessment form and/or the risk assessment for Travelling on University Work Overseas) should be submitted with this application.*

6. Risk of disclosure of harm/potential harm or of criminal offences

	YES	NO
6a. Is there a risk that the study will lead participants to disclose evidence of previous criminal offences, or their intention to commit criminal offences?		
6b. Is there a risk that the project will lead participants to disclose evidence that children or vulnerable adults are being, or have been, harmed, or are at risk of harm?		
6c. Is there a risk that the study will lead participants to disclose evidence of serious risk of other types of harm?		

If you have answered YES to ANY of these questions please explain why it is necessary to take the risk of potential or actual disclosure and what actions you would take if such disclosures were to occur. Please explain what advice you would take from whom before taking these actions and what information you will give participants about the possible consequences of disclosing such information.

7. Payment of participants*

	YES	NO
7a. Do you intend to offer participants cash payments or any other kind of inducements for taking part in your project?		
7b. Is there a possibility that such inducements will cause participants to consent to risks that they might not otherwise find acceptable?		
7c. Is there any risk that the prospect of payment or other rewards will systematically skew the data?		
7d. Will you inform participants that accepting compensation or inducements does not negate their right to withdraw from the study?		

* Typically small sums or vouchers to compensate participants for out of pocket expenses such as travel and subsistence and for time spent/inconvenience.

If you have answered YES to ANY of these questions, please explain the nature of the inducement or amount of payment you will offer and the reason why it is necessary to offer inducements. You

should also explain why you consider it ethically and methodologically acceptable in the context of this study to offer such payments or other inducements.

8. Voluntary participation

	YES	NO
8a. Will you recruit students or employees of the University of Dundee or of organisations that are formally collaborators in the study and who will be in an unequal relationship with you or the researchers affiliated with the project?		
8b. Will you recruit participants who are employees recruited through other businesses, voluntary or public sector organisations?		
8c. Will you recruit participants who are pupils or students recruited through educational institutions?		
8d. Will you recruit participants who are clients recruited through voluntary or public services?		
8e. Will you recruit participants who live in residential communities or institutions?		
8f. Will you recruit participants who may not feel empowered to refuse to participate in the research?		

If you have answered YES to ANY of these questions please explain how your participants will be recruited and what steps you will take to ensure that participation in this project is genuinely voluntary.

9. Any Other Ethical Considerations

Are there any other ethical considerations relating to your project which have not been covered above? If so, please explain.

10. Documentation

Please list all attached documentation, ensuring that each item has a date and version number.

11. Declaration

By signing below I declare that I have read the University Code of Practice for Non-Clinical Research Ethics on Human Participants and that my research abides by these guidelines. I understand that this application and associated documents will be retained by the University.

Principal Investigator or Student

Name: Date:

Signature:

Supervisor (for applications from students)

Name: Date:

Signature: