Mae’r ddogfen hon hefyd ar gael yn Gymraeg / This document is also available in Welsh

When undertaking a research or innovation project, Cardiff Met staff and students are obliged to complete this form in order that the ethics implications of that project may be considered.

The document ***Ethics application guidance notes*** will help you complete this form and is available from the Ethics Governance Section of the Cardiff Met website. The School or Unit in which you are based may also have produced some guidance documents which you can access via your supervisor or School Ethics Coordinator.

**PLEASE NOTE:
Participant recruitment or data collection MUST NOT commence until ethics approval has been obtained.**

**Completion of all sections of Part One and the Declaration is compulsory in all cases.
Forms which have been modified to delete or edit any of the questions will be returned to the applicant without being considered.**

**PART ONE**

|  |
| --- |
| **1A GENERAL INFORMATION** |
| Name of applicant: |  |
| Supervisor (if student project): |  |
| School / Unit: |  |
| Student number (if applicable): |  |
| Programme enrolled on (if applicable): |  |
| Project Title:If using a working title, it should convey what the project is about |  |
| Expected start date of data collection: |  |
| Approximate duration of data collection: |  |
| Funding Body (if applicable): |  |
| Other researcher(s) working on the project:If your collaborators are external to Cardiff Met, include details of the organisation they represent |  |
|  |  |
| **1B SECURITY SENSITIVITY** |
| Will the project have security sensitive implications?NB: Any project which falls under this definition will be referred to the Prevent Co-ordinator by the Committee which is considering the application so it can be risk assessed in line with the [Prevent Policy](https://www.cardiffmet.ac.uk/about/policyhub/Pages/default.aspx). Ethics approval will only be granted once the Prevent Co-ordinator is content with the outcomes of that risk assessment | Yes / No |
| If yes, please explain what they are and the measures that are proposed to address them. (500 words max) |
|  |
|  |
| **1C NON-TECHNICAL SUMMARY** |
| Please provide a non-technical summary of the project below (max 250 words) |
|  |
|  |
| **1D DATA COLLECTION AND STORAGE** |
| What types of data will be collected or created as part of the project? (max 250 words) |
|  |
| How will you manage access to and security of the data? (max 500 words) |
|  |
| Will the project involve human samples and/or human cell lines? | Yes / No |
| Will the data collected be subject to the data retention protocols of either:* Human Tissue Authority (HTA)
* The Health Research Authority - Health and Care Research Wales (HRA-HCRW)
 |
| Yes [ ] For any project which is subject to the data retention protocols of either the HTA or HRA-HCRW, you are required to develop a data storage plan to be submitted alongside your ethics application. The plan should expand on the answers you have provided to the preceding two questions and should show how it will meet the expectations of the external body involved. |
| No [ ] Please confirm that the data collected will be stored in a manner which complies with Cardiff Met requirements via one of the following statements. |
| **STATEMENT 1: FOR STUDENTS ON TAUGHT COURSES**I confirm that any non-anonymised data related to research participants will only be stored on OneDrive, or by agreement with supervising staff, on Figshare, and that all data held elsewhere will be deleted, unless it is anonymised. | [ ]  |
| **STATEMENT 2: FOR STAFF APPLYING ON BEHALF OF STUDENTS ON TAUGHT COURSES**I confirm that all students covered by this application are aware of their obligation to ensure that non-anonymised data related to research participants must only be stored on their Cardiff Met student OneDrive account and that all data held elsewhere must be deleted, unless it is anonymised. | [ ]  |
| **STATEMENT 3: FOR RESEARCH STUDENTS AND STAFF**I confirm that any non-anonymised data related to research participants will be stored in a secure manner (using a platform such as OneDrive or FigShare) and that all data held elsewhere will be deleted unless it is anonymised. | [ ]  |
|  |
| **1E PROJECT CATEGORIES** |
| From the options provided, select the category which best describes your project, bearing in mind that “desk based” can encompass any non-practice based project which takes place primarily outside of a laboratory. | Desk based [ ] Laboratory based [ ] Practice based [ ]  |
| Do any of the following statements describe your project?:* Desk based involving only documents and ***NOT*** involving the collection of data from participantsOR
* Laboratory based ***NOT*** involving human participants, human samples, animals or animal derived materialOR
* Practice based (eg curatorial, practice audit) ***NOT*** involving human participants
 | Yes / No |
| Answering **YES** indicates that the project does not include any participants and you will not therefore be collecting participant data. If this is the case, complete the Declaration at the bottom of the form and forward this form to your School Ethics Committee (or equivalent). No further information regarding your project is required and you do not need to complete any more sections of this form.If you have answered **NO**, please proceed to the next question. |
|  |
| **1F NHS** |
| **Does your project involve the NHS?**If no, proceed to 1G | Yes / No |
| **If yes, has the NHS deemed that your project requires an IRAS application?** |
| Yes [ ] For a project which requires an IRAS application, you must submit the following alongside your ethics application.* The study protocol document
* The completed IRAS form
* Any other documents relevant to the IRAS application

Failure to do this will result in your application being returned to you. |
| No [ ] Proceed to Part Two (below) |
|  |
| **1G ETHICS APPROVAL OBTAINED ELSEWHERE** |
| Has your project already received ethics approval from a body or organisation other than Cardiff Met? |
| Yes [ ] No further information regarding your project is required. Complete the Declaration at the bottom of this form and submit it to your School Ethics Committee (or equivalent) alongside the following documents:* Copy of the externally approved ethics application and any associated documents.
* Copy of the approval letter from the external organisation.
 |
| No [ ] Proceed to Part Two (below) |

**PART TWO**

|  |
| --- |
| **RESEARCH DESIGN** |
| 1 Will you be using an approved protocol in your project?(An approved protocol is one which has been approved by Cardiff Met to be used under supervision of designated members of staff. For details of protocols in use in your School or Unit, contact your Ethics Coordinator) | Yes / No |
| If yes, please state the name and code of the approved protocol to be used |
|  |
| 2 Describe the research design to be used in your project by giving details under the following four headings. If your project involves the use of an approved protocol, much less detail will be required but you should indicate which areas of the project are covered by the protocol* The research method(s) to be used;
* Sample and sampling;
* The proposed participant group, including recruitment methods, activities to be undertaken, the expected time commitment and details of any proposed payments;
* Analytical techniques to be used.

(max 1000 words) |
|  |
| 3 Will the project involve deceptive or covert research? | Yes / No |
| If yes, give a rationale for the use of deceptive or covert research (max 500 words) |
|  |

|  |
| --- |
| **PREVIOUS EXPERIENCE** |
| 1 What previous experience of research involving human participants, relevant to this project, do you have? (max 500 words) |
| Click here to enter text. |
| 2. **Student projects only**What previous experience of research involving human participants, relevant to this project, does your supervisor have? (max 500 words) |
| Click here to enter text. |

|  |
| --- |
| **POTENTIAL RISKS** |
| Provide details of any risks you foresee related to the project and, for each risk, explain the methods you will use to reduce them. Ensure that you include details of measures that will be taken to ensure the safety of participants in the event that any identified risks arise.Include details of risks to the participants, the researcher and the project as a whole.***NB: You must provide detail related to all risks identified in the previous question. Failure to do so could result in your application being returned to you.***(max 1000 words) |
|  |

When submitting your application, you **MUST** attach a copy of all information sheets, the consent/assent form(s) and the withdrawal of consent form.

An exemplar information sheet, exemplar participant consent form and exemplar participant withdrawal form are available via the research section of the Cardiff Met website (see section on Ethics Governance). These are based on good practice and will be useful in the majority of cases. However, it is recognised that in some cases a project will be subject to requirements from an external body. Use of these exemplars is therefore not obligatory.

**DECLARATION**

|  |
| --- |
| **I confirm that this project conforms with the** [**Cardiff Met Research Integrity & Governance Framework**](http://www.cardiffmet.ac.uk/research/Pages/Research-Integrity-and-Governance.aspx)**I confirm that I will abide by the Cardiff Met requirements regarding confidentiality and anonymity when conducting this project.****STUDENTS: I confirm that I will not disclose any information about this project without the prior approval of my supervisor.** |
| Signature of the applicant: | Date:  |
| **FOR STUDENT PROJECTS ONLY** |
| Name of supervisor:  | Date:  |
| Signature of supervisor: |

|  |
| --- |
| **Research Ethics Committee use only** |
| Decision reached: Click here to enter text. |
| Project reference number: Click here to enter text. |
| Name: Click here to enter text. | Date: Click here to enter a date. |
| Details of any conditions upon which approval is dependant:Click here to enter text. |