PART ONE

1A: General Information

Project Title

This should capture the essence of the project for a non-specialist audience. Please remain consistent throughout. If you plan to use a shorter version of the title (for instance on the consent forms or information sheet) in addition to the full format title of the project, please include both in this box.

Expected Start Date

Participant recruitment and/or data collection must not start until ethics approval has been given and this should be reflected in the expected start date. Under exceptional circumstances it may be possible for a project to be given urgent consideration (ie to meet the deadline of a funding body). Any request for an urgent review should be submitted as a covering note to the application and should explain the reason for the request.

Funding Body

Provide details of any body from which you have received or will be receiving funding in relation to this project.

Other researcher(s) working on the project

All other collaborators / investigators should be listed.

If any collaborators are students provide details of the qualifications they are working towards.

If any collaborators are from other institutions please give details of their institution and explain their role in this project.

Note: Generally, where a project is conducted in collaboration with another university, ethics approval would normally be sought from the institution where the PI is located. If this is not Cardiff Met, you should inform Cardiff Met by submitting an application for ethics approval and attaching details of the approval gained elsewhere (see section 1G).

1B Will the project have security sensitive implications?

If yes, please explain what they are and the measures that are proposed to address them

If you think that your research may have security sensitive implications you should ensure that you familiarise yourself with and adhere to the <u>Cardiff Met Prevent Policy</u> which is available from the <u>Cardiff Met Policy Hub</u>.

You must provide details in this section of the process you intend to follow to ensure the security of your research material and steps you intend to take to ensure the safety and wellbeing of your participants and researchers.

Universities play an important role in undertaking research in areas related to security, terrorism and resilience, and the process of radicalisation. However, carrying out such

The Prevent Co-ordinator will keep a log of all security-sensitive research being undertaken by the University and may be required to disclose details as part of the provision of assurance of the University's compliance with the Prevent Duty or to assist the Police or other statutory authorities in the detection of crime.

1C Non-technical summary of the project

Provide the academic justification and background of the study and state the anticipated benefits of researching your chosen area. It may be helpful to refer to related studies.

1D: Data Collection and Storage

What types of data will you collect or create?

Provide details of the types and amount of data you will collect or create as part of the project. Provide some justification of why you have opted for particular formats.

How will you manage access to and security of the data?

In order to comply with UK GDPR and all relevant Data Protection laws, it is a Cardiff Met requirement that all non-anonymised data produced by students on taught courses is stored on their Cardiff Met student OneDrive account (the University's cloud based storage facility) and that all data held elsewhere is deleted, unless it is anonymised. It is good practice however for all researchers (students and staff) to store all data, including that which has been anonymised on OneDrive, as it is backed up regularly. You should never store your data solely on a laptop, computer hard drive or external storage device.

It is good practice to anonymise all data related to participants. You should confirm if you intend to do this and, if you do not intend to do so, give reasons why. Where participant data is not anonymised, guidance must be sought from the University's Data Protection Team to ensure compliance with Data Protection Law.

Provide details of how you intend to keep the data secure, including information on where you intend to store your data and indicate who will have access to it. If you are collecting data "in the field" you should detail how you will ensure its safe transfer into your main secured system.

Will the study involve human samples and/or human cell lines?

For research involving the use or storage of samples of human tissue or the use of stored samples of tissue, projects must comply with all codes of practice regarding the taking, use and storage of human tissue.

1F: Does your project involve the NHS?

If yes, has the NHS deemed that your project requires an IRAS application?

IF YES:

You will need to gain ethics approval via Cardiff Met before submitting an IRAS application. However, as most of the detail relating to your project will be contained within the IRAS documentation, the amount of detail required in the Cardiff Met application will be reduced and confined to Part A of the Cardiff Met form. It is important to submit the study protocol document, the completed IRAS form and any other documentation relevant to the IRAS application alongside your Cardiff Met ethics application. Failure to do this will result in your application being returned to you.

Full guidance on completing an IRAS application is available here.

IF NO:

In some instances, the NHS will not require an IRAS application to be completed. If this the case, you must seek ethics approval from Cardiff Met. Please attach the notification from the NHS confirming exemption from NHS ethics processes to your application.

1G: Has your project already received ethics approval from a body or organisation other than Cardiff Met?

Cardiff Met will accept ethics approval gained from another organisation if we are reasonably assured that the rigour and robustness of the process is at least equal to our own.

Generally, where a project is conducted in collaboration with another university, ethics approval would normally be sought from the institution where the PI is located.

If your project has been approved elsewhere, state which body has approved it in the non-technical summary and submit a copy of the approved ethics application with your form. If you are unable to supply a copy for any reason, eg the approval process was electronic only, explain this when you submit your form to the ethics panel.

Panel members may ask to see copies of other documentation linked to your project.

PART TWO

RESEARCH DESIGN

1 Will you be using an approved protocol in your project?

If yes, please state the name and code of the approved protocol to be used

Approved Protocol status may be awarded to certain standardised procedures to be used in research projects under the supervision of designated members of academic staff. Generally this simplifies the application process. A list of approved protocols and designated supervisors should be available via your School Ethics Coordinator. Students should liaise with their supervisor to decide if they are eligible to use an approved protocol in their study.

Please ensure that the any approved protocol you refer to is current at the time of application.

2 Describe the research design to be used in your project

Describe your project's overall design and the method of data collection which will be used.

The nature of your project may mean that changes in the approach or direction may be necessary as the research develops. Please indicate if this is the case and describe the start out approach and direction as fully as possible.

Provide a brief summary of the nature of the participants' involvement in order for the committee to understand exactly what will happen to the participant.

The following points should also be clarified:

- Why is it necessary
- Where the interaction will take place
- How long each session will take
- How many sessions participants will have to attend
- How long the interval between sessions will be

Provide full details of any payments that are to be offered to participants taking full account of the University Research Participant Payment Policy (available from the Policy Hub) which states the following:

Where individuals are engaged as Research Volunteers, they will not normally be offered payment above and beyond the compensation of any expenses incurred, and it is the responsibility of the PI to ensure this is made clear to potential Research Volunteers before they consent to participate. The following exceptions will apply:

- Offering a nominal payment as thanks in the form of a voucher
 Close scrutiny will be paid to any such proposed payments as part of the ethics approval process, in order to avoid situations where participants are induced to undertake risks that might otherwise be against their better judgement. Ethics panels will consider it good practice not to offer vouchers for goods and/or services which are linked to the project. Vouchers for goods or services provided by a partner in the project must not be offered.
- Participation which is likely to involve a significant time commitment
 In such instances, PIs should refer to the payment threshold referred to 4.2 of the
 Research participant Payment Policy and ensure any proposed payments are fully
 detailed in the Participant Information Sheet.

If your data collection will involve the use of a questionnaire you should provide a copy of the questionnaire with your application. In cases where the questionnaire has not yet been finalised you should give examples of the kinds of questions which participants will be answering. Similarly, if your data collection will involve the use of focus groups, you should provide details of the topics which will be discussed.

Describe the methods and techniques which will be used in the analysis of the results.

Generally, the University expects researchers to take an inclusive approach to recruitment of participants. It would be helpful therefore to give details of any limitations on which groups can participate in the project and include reasons for adopting these limits.

In the case of projects involving groups, please give details of what will happen to excluded participants.

For quantitative research projects, state and give full justification for the number of participants you plan to recruit.

3 Will the project involve deceptive or covert research?

and

If yes, give a rationale for the use of deceptive or covert research

Deceptive and covert research is generally undesirable because it violates the principle of voluntary informed consent, and in some circumstances may be illegal. However, it may be the only practical way to gather important information; for example, where awareness of being observed would alter the behaviour of subjects sufficiently to invalidate the research. In order to be approved, projects must fully meet the following conditions:

- 1. There is a strong case that the research is worth doing.
- 2. There is a strong case that covert research is essential to gain the required information (ie that there are no alternative methods available that are not deceptive or covert).
- 3. Once the period of covert observation has been completed, the agreement of each participant will be required before any data relating to the individual can be included in the research analysis. This will only not apply in cases where this is impractical (for example, where a public place has been observed with transient subjects being impossible to trace) and data gathered cannot be related to any individual observed.
- 4. No permanent record will be kept of any personal information which could possibly lead to the identification of a participant, unless the individual has been told that the information has been acquired during the course of the research and has agreed to its retention.

PREVIOUS EXPERIENCE

1 What previous experience of research involving human participants relevant to this project do you have

and

<u>2 What previous experience of research involving human participants relevant to this project</u> does your supervisor have?

It is vital that you give details of previous experience of research involving human participants relevant to the proposed project. In the case of a student project, this information should be provided in respect of the supervisor.

Members of the ethics committee will refer to this information to ensure that the PI (and/or the supervisor in the case of student projects) has sufficient relevant experience of the type of project to be carried out. Information should therefore be provided illustrating previous experience which is relevant to this application. This should include specific details of previous use of the same project design, particularly where the project has resulted in published outputs. For supervisors, specific details of supervision of previous similar projects would be helpful.

POTENTIAL RISKS

Provide details of any risks you foresee relate 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.

Describe the potential hazards, risks and adverse effects for participants in the research, specifying the probability and seriousness in each case. For research involving interviews and questionnaires, any risk of psychological or social ill effects should be considered.

If the study design has been informed by statistical power calculations an indication as to the basis on which this was done should be provided.

If possible, you should complete a standard Cardiff Met Risk Analysis for the project. This should however **be in addition to** the provision of a full response to this question.

If your project will involve invasive procedures, please provide details such as:

- where the procedure will take place;
- what facilities are available;
- what size of sample will be taken (eg amount of blood taken, size of dose administered);
- where will samples be stored and how will they be identified;
- who will have access to the samples.

Also consider any potential risks you may be exposed to. These should include risks due to any procedures being carried out (eg collection of blood samples, use of equipment) or to the environment in which you will be working (eg field work situations)

Consider any risks to the project itself.

In all cases, explain the methods you will use to reduce the risks detailed and measures that will be taken to ensure the safety of participants in the event that any identified risks eventuate.