These guidance notes are to assist staff and students completing an application for ethics approval.

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 he or she is 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.

Will the study involve NHS patients or staff?
Most studies involving NHS patients or staff will require approval from the NHS and will not require additional approval from Cardiff Met. If you are unsure if your project will require NHS approval, contact the Chair of your school research ethics committee.

If you are required to submit your application to the NHS, attach a copy to your Cardiff Met ethics approval form to be kept on record by the School research ethics committee. Your School committee will accept the completed NHS application and letter of approval in lieu of Cardiff Met approval.

In some instances, the NHS will not classify your project as research and will return your application. In this instance you must seek ethics approval from Cardiff Met via your School committee. Your School committee will require sight of the letter confirming exemption from NHS ethics processes.

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.

1B: Does your project fall entirely within one of the following categories?

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.

1C: Does your project fall entirely within one of the following categories: A project which is not compulsory in professional practice and has gained external ethics approval from a body other than the NHS
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.

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 data collected be subject to the data retention protocols of any of the external bodies listed?
If you answer Yes to this question, you are required to develop a data storage plan and submit it 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.

Part Two

A1 Will you be using an approved protocol in your project?
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.

A2 If yes, please state the name and code of the approved protocol to be used
Please ensure that the approved protocol is current at the time of application.

A3 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 including:

- Payment of expenses: The committee will normally agree to the reimbursement of reasonable expenses to cover travel and refreshments.
  NOTE: In order to pay expenses you will be required to follow standard Cardiff Met financial procedures. You should therefore ensure that participants complete all the required paperwork and that you keep a track of all agreements regarding the payment of expenses. Failure to comply with financial procedures could result in the Finance Department being unable to honour claims made.
- Recompense for time commitment: The committee will normally agree to this where time commitment is expected to be substantial. An appropriate rate would be the normal expected hourly rate of pay for the participant. Where the participant is not employed, payment equivalent to at least the standard national living wage would be expected.
- Financial incentives: The committee will closely scrutinise any financial incentives considered over and above recompense for the time commitment. This is to avoid situations where participants are

induced to undertake risks that might otherwise be against their better judgement.
NOTE: If you intend to offer payments of this kind you should normally offer vouchers rather than cash payments and you should carefully consider which vouchers will be offered. The University does not have an "approved list" of outlets for which it is acceptable to offer vouchers but panels will consider it good practice not to offer vouchers for goods and/or services which are linked to the project. For example, if your project involves research into products which would be of use to parents of young children, you would avoid offering vouchers for retailers or manufacturers of these types of products. You should never offer vouchers for goods or services provided by a partner in the project.
Alternatively, rather than offering an incentive to the participant, you could donate an agreed sum to a worthy cause.

Full details of any payments to be made must be included 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.

A4 Will the project involve deceptive or covert research?

and

A5 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.

A6 Will the project have security sensitive implications?

And

A7 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 Cardiff Met Prevent Policy which is available from the Cardiff Met Policy Hub.

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 research requires particular care to be taken to avoid any infringement of the law. Research material on such topics may be open to misinterpretation by the authorities and can put researchers in danger of prosecution under counterterrorism legislation. You are advised to refer to the UUK Guidance Oversight of Security-Sensitive Research Material in UK Universities and to seek guidance from the University's Prevent Co-ordinator to inform your project plan.

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.

B1 What previous experience of research involving human participants relevant to this project do you have

and

B2 What previous experience of research involving human participants relevant to this project 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.

C1 What potential risks do you foresee?
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)

Finally, you should consider any risks to the project itself.

C2 How will you deal with the potential risks?
Explain the methods you will use to reduce the risks detailed in C1 and measures that will be taken to ensure the safety of participants in the event that any identified risks eventuate

Gaining consent from participants

It is generally acknowledged that robust research ethics requires the voluntary consent of human participants. Potential participants in research projects must normally have the right to choose whether or not they will participate. Fully informed consent in this context means consent which is freely given with proper understanding of the nature and consequences of what is proposed and what is likely as a result.

The following process is recommended to ensure that this is in place:

- Each participant should be given an oral explanation of what participation in the project will entail.
- Each participant would then be given an information sheet explaining in simple, non-technical terms, the background to the project, the procedures involved, any potential risks and hoped for benefits.
- The participant should be given reasonable time to consider this information and to consult others as necessary.
- Except in the case of questionnaire based studies, the participant should be asked to sign a consent form. In the cases where participants are either children or "vulnerable" adults, consent should normally be gained from a properly empowered proxy with the participant giving informed assent.

For research involving the use of samples of human tissue or the use of stored samples of tissue, you must refer to the University's guidance related to HTA procedures. For further details contact the University's HTA Designated Individual, Dr Claire Kelly.

Written consent from participants will normally be required for all studies except those that are exclusively based on questionnaires and are not collecting sensitive data. In these cases, submitting a completed questionnaire implies consent and this should be stated on the information sheet given to participants.

The standard position in the ethics advice of most learned societies is that informed consent should be obtained wherever possible. Your School may provide guidelines about research situations where the conventions of obtaining informed consent do not usually apply, or where a different approach to obtaining written consent is generally accepted.

If verbal consent, and not written consent, is to be obtained, please indicate this and complete the participant information sheet with the information that you intend giving to participants verbally.

If you do not intend obtaining consent at all you must provide a full justification for this. Please note, a strong justification is needed, either in terms of the benefits of the study, or of the research approach, before a school ethics committee will consider allowing a project to proceed without informed consent.

If it is proposed that research be conducted on adults who may not be able to give fully informed consent on their own behalf (eg people with dementia), justification for this must be clearly stated in your application for ethics approval.

Although consent cannot be given on behalf of another, it is important to inform and/or enlist the support of those involved in the care of vulnerable individuals.

Where appropriate, letters to parents, teachers and medical staff should be provided.

You should be mindful that consent become invalid under GDPR where any of the following apply:

- You have any doubts over whether someone has consented;
- The individual doesn't realise they have consented;
- You don't have clear records to demonstrate that consent was obtained;
- There was no genuine free choice over whether to opt in;
- The individual would be penalised for refusing consent;
- There is a clear imbalance of power between the researcher and the individual;
- Consent was a precondition of a service, but the processing is not necessary for that service;
- The consent was bundled up with other terms and conditions;
- The consent request was vague or unclear;
- You used pre-ticked opt-in boxes or other methods of default consent;
- The organisation carrying out the research was not specifically named;
- You did not tell participants about their right to withdraw consent;
- Participants cannot easily withdraw consent;
- Your purposes or activities have changed beyond the original consent.

Projects involving participants under the age of 18

Generally, the University requires that both the assent of the child and the consent of the parent or guardian are obtained prior to commencement of the project. Separate information sheets should be provided for parents and children to take account of their different cognitive abilities.

Child assent should be sought in a way which is appropriate to the age and ability of the child. For example, in the case of younger children, this may involve the use of pictures to signify how the child feels about participating the project

Projects involving very young children: Child assent is not needed in cases where the children involved are too young to understand a simple explanation of the research to be undertaken eg observational projects involving very young children of less than 18 months old. In such cases, the project may proceed with parental consent only.

Participants who are aged between 16 and 18 years old are minors but generally considered to be competent for the purposes of gaining consent. It may however be highly desirable to obtain parental consent for some projects involving participants in this age group. In other cases, the research involved may be clearly innocuous and not require parental consent. If your project involves participants in this age group and you do not intend requesting consent from parents, please justify this.

School / community based projects: Often, projects involving participants under the age of 18 will involve a group of pupils from a school or a group of attendees at, for example, a youth club. In such cases, consent should also be sought in writing from the head of the school or organisation from which the participants will be drawn. The letter requesting consent should include details of the project (including the questions which participants will be asked) and the involvement of the school / group. The committee will require sight of the written consent given by the head of the organisation before giving ethics approval to your project.

In the case of school or community based projects, the University will normally expect you to gain informed parental consent in addition to the consent of the head of the organisation. However, it is recognised that, in some cases, this could represent a large administrative burden and often leads to difficulties for the

school. Thus, in projects dealing with issues which could be considered "public" eg discussions about views on music or sport, consent may be gained solely from the head of the organisation acting in loco parentis. For projects dealing with issues focussed on the personal or family life of participants, due to the nature of the subject matter, parental consent must be sought. In all cases, the assent of the participants themselves must be obtained.

For further information on research projects involving children, please refer to the guidance for researchers produced by the National Children's Bureau available from the "research" section of the NCB website, www.ncb.org.uk .

An exemplar consent form is available from the Cardiff Met website.

Participant Information Sheet

A copy of the participant information sheet you will use must be submitted with your application form. These are vital and must be completed carefully.

The information sheet should be written clearly using simple words, sentences and paragraphs. The use of jargon and acronyms should be avoided and any which are used should be accompanied by a clear explanation. As a guide, you should expect a ten year old to be able to read and understand the information. You should make the information as personal as possible using words such as we, you and your child rather than using impersonal terms such as participant or student.

It is good practice to offer to provide the information sheet and the consent form in other formats eg large print, Braille, audio, and in languages other than English.

The information sheet should contain:

Study Title (and Reference Number if applicable)

Invitation paragraph
Include the following introductory paragraph:
We would like to invite you to take part in the above named research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please therefore take time to read the following information carefully.

What is the purpose of the study?
Give a brief background of the project and state the aim of the project. Include details of the start date, the length of the project and outline the overall design of the project.

Why have I been invited to participate?
Explain how the individual was chosen to take part in the project and how many other people will be asked to take part.

If there are any exclusions to participation, you should outline them here so that potential participants are aware of any reasons that they should not participate, or will be exempted from participation.

Do I have to take part?
Explain that taking part in the project is entirely voluntary and that participants will be asked to complete and sign a Participant Consent Form prior to their involvement.

Explain that they have a right to withdraw from the project at any time and explain what action you will take if they do withdraw. When doing so, be aware that the timing of their request will have a bearing on what action you are able to take, for example, once you have anonymised and analysed data it is often not possible to extract a specific participant's data. If possible, include on the information sheet details of when you intend to begin anonymisation and analysis.

Let them know that a Participant Withdrawal Form is available and includes more details of what actions the University will take following a request to withdraw.

What will participation involve?
Explain what the individual will be asked to do, it may be helpful to contextualise this by explaining your methods of data collection but keep in mind that the information should be easily understood by a lay person.

Give details of how much time will be involved and indicate where the activities will be undertaken.
Give sufficient information about any research interviews, focus groups or questionnaires to ensure participants are fully aware of what they will be asked to do.
Ensure that you let participants know if interviews or focus groups are to be recorded.

Are there any risks associated with taking part?
Describe any risks involved in participation in the project using language which the participant will easily understand.
Include details of the likelihood that risks will arise and the measures you have put in place to manage the risks.
State that the Principal Investigator will be happy to answer any queries about what the study involves. (full contact details of the PI should be provided at the end of the Information Sheet)

Are there any benefits associated with taking part?
Describe the direct benefits to the participant as well as wider benefits (eg furthering understanding of the topic being researched).

In most cases, the University would not expect any reward to be offered to participants but, if you do intend to offer compensation or reward for participation you should give details of this here. Note however that details of any compensation or reward must have been included in your ethics application and approved by the ethics panel.

It must be made clear that any compensation or reward will not be lost if the participant decides to withdraw from the project.

What will happen to the results of the research project?
Indicate how the results of the research will be used eg journal article, report for the project funder, will form part of a dissertation etc.

How will my data and my privacy be protected?
State that confidentiality will be maintained throughout the study, unless this cannot be guaranteed.
Where confidentiality cannot be guaranteed, explain the reason why.
Give details of how and where participant data will be stored and who will have access to it. Be mindful of the Cardiff Met requirement that any non-anonymised data generated by undergraduate students must be stored on the relevant student's Cardiff Met student OneDrive account.
You should only collect data which is required for completion of the study and you should make it clear here that this is the case.
Give details of how and when the data will be anonymised.
Include details of the length of time that the data will be held (this is normally two years after graduation for undergraduate projects where the data has been stored in OneDrive).
If your project is subject to data retention requirements of an external body, ensure you indicate that you have complied with these requirements.

Who is involved in the project?
Explain that you are conducting the research as either a student or member of staff at Cardiff Met.

State the names and affiliations of the research team members.

Give details of any funders of the project.

State that the project has been approved by [insert name of the Ethics Committee which gave approval.

If I have any questions, who should I contact for further information?
Provide the name and Cardiff Met email address for the PI.

Thank you
Remember to thank the individual for taking time to read the information sheet.

If you are intending to collect information classified as sensitive personal data which is identifiable or could potentially be traced back to an individual, you must inform participants of this and gain specific written consent from them.

If your study is questionnaire based, consent to participate will be implied by completion of the questionnaire, a separate consent form is therefore not required. If you are not collecting sensitive personal data you should state on the Information Sheet that submission of a completed questionnaire implies consent to participate in the project. However, if your questionnaire will require the disclosure of this type of information, you should include the following statement in the body of your questionnaire:

Any information you provide will be treated in accordance with data protection principles for the purposes specified within the Participant Information Sheet. Cardiff Metropolitan University will process your personal data in line with Article 6(1)(a) and Article 9(2)(a) of the General Data Protection Regulation 2018 which specifies that your personal data can only be processed with your explicit consent. By signing this form and answering the questions contained within it you are confirming that you have understood the reasons for obtaining your data and you are happy for the study to proceed. Please note that you have the right to withdraw consent at any point. Should you wish to invoke that right please contact [insert contact details of relevant individual]

Provide the name and contact details of the person participants should contact in an emergency and who they should contact to obtain further details about the project. You should provide your contact details at the University and NOT your personal email address or mobile phone number. Students are advised to include University contact details for their supervisor.

Guidelines for the production of posters, leaflets and emails for participant recruitment

Recruitment of participants should be undertaken in such a way that participation is truly voluntary and there is no coercion, either explicit or implicit.

The committee prefers the use of indirect approaches rather than face to face individual requests to potential volunteers. Ideally individuals should be able to take a positive step to participate rather than have the discomfort of declining a direct approach.

Posters and leaflets may be used to recruit participants. The material can fall into several categories:

- Posters displayed within the University
- Posters displayed in other institutions (although recruitment on NHS premises would require NRES or MREC approval)
- Leaflets
- Advertisements in newspapers, magazines etc

Care should be taken when writing copy to consider the nature of the target group, ensuring that appropriate terminology is used. This is especially important for material likely to be seen by vulnerable groups, and especially for advertisements that are to be published in large circulation magazines etc.

A good poster/leaflet or advert should have the following characteristics:

- The material should be visually attractive with a short clear heading in the form of an invitation and may include illustrations
- Sufficient information should be given for potential participants to know roughly what is involved
- Adequate information for making contact should be given

The committee requires that all posters/leaflet:

- Carry identification to allow reference to the records held by the committee
  The minimum requirement is the project reference number.
- A copy of the poster must be sent to the committee to be deposited with the application papers, for review by the committee and must be approved before use.
- Posters to be displayed in other institutions outside the University must be sent, with a covering letter, to the administrative officers of that institution for information

Recruitment emails should meet with the requirements outlined above and should not be overly long.

Proposed emails should be provided to your School committee for approval along with a justification for using this means of participant recruitment and the proposed target mail lists. An email must be approved before it can be circulated.