Academic Research & Innovation/Enterprise Ethics Framework Document

Cardiff School of Management

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PART A

1. Introduction

The purpose of this document is to establish an Ethical Framework for Cardiff School of Management that guides and supports staff and students towards ensuring that the School complies with the correct ethical practices as outlined under the University Ethics system. The Framework applies to all CSM programmes and students whether studying at home or internationally.

This framework aims to protect staff, students and participants who undertake research and/or innovation/enterprise projects where primary data is collected, used and subsequently analysed. This framework applies to all academic staff, postgraduate and undergraduate students when they plan to undertake internal or external research, innovation/enterprise projects, certain teaching exercises and/or innovation/enterprise work.

Issues of morality, safety and personal and institutional liability affect the University at many levels. As a public body and responsible employer, it must act, and be seen to be acting, with propriety and care for the welfare of staff, students and the wider public and has a duty to ensure that its graduates have been educated to uphold high standards of ethical conduct in research.

Research and innovation/enterprise projects can be defined as all research and consultancy proposals involving primary data gathering and analysis (including undergraduate dissertation proposals) and, as such, will include a section on ethical considerations of the methodology to be employed. Where research studies have included collection of empirical data prior to the proposal stage, a section outlining ethical considerations must be included and provided as an appendix with the research proposal. The School's Ethics Committee will address these factors and concerns.

In order to facilitate timely consideration of applications for ethics approval, CSM has two systems for reviewing applications. The first system applies to all taught programmes and utilises a devolved panel approach (see Appendix A). The second applies to all research based study and all staff research proposals (see Appendix B). In this instance all applications are reviewed by the School's Ethics Committee (SEC). The terms of reference defining SEC's role are given in a separate document and attached as an Appendix in this document (Appendix C). The operational context for the School's Ethics Committee is that it will act as a sub-committee of the University Ethics Committee and report to it as required.

Devolved Research Ethics Approval Panels (DEAP) are a sub-committee of SEC and have the responsibility for receiving research applications for their own modules and for determining whether approval can be given or referral to the SEC is required. The School Ethics Coordinator will be responsible, in collaboration with other members of staff for developing appropriate disciplinary and professional codes of ethical practice for DEAPs. Staff development for Link Tutors, academic and appropriate administrative staff is integral to the development of the research ethics process within CSM.

1.1 Responsibilities of persons submitting research proposals

It is the requirement of any person responsible for planning to undertake a research project, including bids for funding, within the School to consider possible ethical implications of that project. Typically, the projects that would require ethics approval would be:

a) All undergraduate and taught postgraduate dissertation/final project work
b) Postgraduate Research
c) Staff-led research
d) Innovation/Enterprise projects
e) Certain teaching activities where consent is required from companies with regards to specific company sensitive information etc.
f) All assessed work in which there is a requirement for primary data collection

All projects, including undergraduate proposals will need to be vetted at a subject level via the appropriate DEAP. It is the responsibility of the Module Leader and the other members of the Panel to identify any possible areas within their subject which may raise ethical issues. It will, therefore, be the responsibility of all persons to incorporate into research methods training at all levels an explicit consideration of the ethical codes which apply in their discipline, in order that students become explicitly aware of the need to be working within this code.

Proposals must, therefore, include a rationale for the methodology selected indicating that ethical practices will be adopted and how they will be assured. With regard to proposals arising from engagement with other Schools, the proposals should be viewed by the relevant School in which the ethical issue will arise. Responses to these may highlight a need to refer the proposal to the University Ethics Committee in accordance with the stepped approach below. A copy of the University's standard ethics form is included in Appendix D.

1.2. Researchers should therefore:

a) Satisfy the subject staff member responsible for vetting at a local level that all ethical considerations have been addressed for undergraduate and taught postgraduate proposals; **or**
b) Satisfy the School Ethics Committee that all ethical considerations have been addressed for all other proposals, including postgraduate research and staff projects; **or**
c) Obtain ethical approval for the research from the University's Ethics Committee for specific factors, such as use or involvement of deception or vulnerable participants.

All applications for funding from the University by postgraduate research students and staff, all submissions for external funding, and all submissions to School or University Research and Innovation Committees, should be accompanied by a statement of the relevant ethical considerations and implications. Where the SEC considers that the ethical implications of a research proposal require further investigation, the proposal will be submitted to the University's Ethics Committee for further consideration.

PART B

2. Procedures

i. The School Ethics Committee (SEC), when reviewing such proposals, will consider whether ethical issues have been appropriately addressed or resolved. If any proposals fail to meet guidelines, or are deemed to require expert input regarding ethical issues, the SEC will submit these research proposals to the University Ethics Committee.

ii. Confirmed approval from the Ethics Committee or gatekeeper, at Subject, School or University level must be received prior to the start of the research project. Chair's Action, where appropriate, after fulfilment of meeting additional requirements in the research proposal as outlined after initial submission, may be taken.

iii. Any changes to the specification of a project, which may raise additional ethical issues, are subject to further application to the Committee for renewed approval. This may be particularly relevant in relation to authoring texts where decisions to include an additional, or different, mode of data collection may be become necessary after the submission and approval of the original proposal.

iv. To ensure that no members of the Committee adjudicate on proposals in which they may be personally involved.

3. CSM Ethics Structure and Decision Process

The SEC will ensure that the formal UEC terms and conditions are correctly and robustly applied and the ethics management structure is followed as outlined in Appendix A for both taught and research based degree programmes.

4. Decisions Made by Panels and Committee

The current forms for ethical applications are drafted for institution-wide use and indicate that projects can be approved, approved in principle, deferred, not approved or rejected. Devolved ethics panels and SEC will make one of the following decisions for each considered application:

a. Approve
b. Approve in principle (subject to specific minor issues being addressed)
c. Defer (application is incomplete)
d. Not approved (where the application is returned for major revision)
e. Reject (where the project is unethical)

In addition a DEAP may also use the option "Defer to SEC" where it feels unable to form an opinion as to whether the application is (or can be made) ethically sound.

Ethical approval, where granted, will normally be for period specified on the application. It is the responsibility of the Principal Investigator to abide by the conditions of approval; this includes application for extension of approval. Approval may be granted for periods of up to 5 years in circumstances where projects are designed to last longer or where their

implementation depends on securing funding from recognised organisations such as Research Councils UK (RCUK)

It should be noted that although this document and the corresponding institutional forms for ethics application refer to ethical approval, the approval granted either by a panel or by SEC reflects the expression of a favourable ethical opinion made on the basis of the information provided by the applicant. Staff and students in the School should not proceed with projects if during the course of their conduct, they come across circumstances that may require further ethical consideration. If, after receiving approval, investigators become concerned about the ethics of their activities, they should contact the Chair of the Panel or Committee that approved in the first instance for further guidance.

5. Health, Safety and Risk Assessment

The Health and Safety aspects of activities requiring ethical consideration are covered by the School Health and Safety Policy. It is also a requirement for applicants to assess risk in the context of ethics and to complete relevant Risk Assessment documents. Consideration of risk must be undertaken in all applications, specifically via sections C1 and C2 of the Research Ethics form in Appendix D.

Further information on the School's Health & Safety Policy and Guidance on Risk Assessment can be found on the Staff Portal.

6. Security Sensitive Material

This is a mandatory process adopted by the University based on UUK's recommendation. Any staff or student wishing to undertake research into an extremism-related[1] field will be required to go through the normal ethical review process. Projects within this field will be referred to the Prevent Co-ordinator for risk assessment in line with the Prevent Policy. Ethics approval will only be granted once the Prevent Co-ordinator is content with the outcomes of that risk assessment. This includes projects which do not involve human participants. Applicants are required to provide this information in the ethics application form (see Appendix D, sections 1B and A6).

The purpose is not to police research but to record a subject title and researcher's name so that the University can assure any external inquiry of the validity of the research and ensure that ethical protocols are followed. Please contact the Prevent Coordinator (via safeguarding@cardiffmet.ac.uk) for advice on the process and applicability.

7. Research Requiring Third Party Research and Innovation/Enterprise Ethics Committee Approval

SEC will not endorse research or projects that require approval from a nationally recognised Research and Enterprise Ethics Committee (REEC) until such approval has been granted. In all cases a copy of the relevant REEG favourable ethical opinion must be submitted to the School for consideration. Where a Principal Investigator on the REEG-approved research is

[1] Section 12.1 of the Prevent Policy refers to security sensitive materials as extremism-related materials.

not from Cardiff Met, evidence supporting the role of Cardiff Met in the project must also be provided.

Where the research project is being undertaken in conjunction with another institution ethical approval can be obtained from any participating institution, usually that of the Principal Investigator. If the approval is not being sought via Cardiff Metropolitan University then the SEC must receive confirmation that ethical approval has been given before any research is undertaken.

In cases where research is undertaken within the NHS and that the appropriate NHS Unit has decided that proposed activities do not require REEG approval (e.g. service evaluations), a letter specifying exemption must be provided from the relevant unit (e.g. Research & Development Committee) together with the ethics application.

Other agencies may also have specific requirements for ethical approval (e.g. Police, Ministry of Defence, etc). In these instances applicants must notify the relevant devolved ethics panel with evidence of written permission.

Where the third party is a health care institution outside the UK, approval from a relevant recognised REEG in that country will be required.

8. Code of Practice – Informed Consent in research projects

8.1 An overarching principle of research ethics is respect for the autonomy of participants; this includes the protection of participants from harm whilst participating in a research study. Central to this is the concept of Informed Consent.

8.2 Informed Consent is the process by which a participant voluntarily confirms their willingness to participate in a study, having been informed of the full details of the project.

8.3 This Code of Practice details the process for obtaining informed consent from potential participants in research studies. It outlines the informed consent procedures for adults, for children and for individuals who may not be able to give fully informed consent, and the right of withdrawal of consent.

9. General principles for gaining informed consent

9.1 Potential participants in research studies must normally have the right to choose whether or not they will participate. Obtaining informed consent is therefore central to the ethical conduct of all research involving human participants. 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 may occur.

9.2 Written informed consent from participants will normally be required for all studies except those that are exclusively based on questionnaires and are not collecting sensitive data. There may however be instances where gaining written informed consent is deemed to be problematic; in such instances the researcher should fully explain the circumstances in their application for ethics approval. School research ethics Committees will assess such applications on a case-by-case basis.

9.3 Prior to embarking on the research study, ethics approval must be sought from the appropriate School Committee[2]. An application for ethics approval will include examples of the consent form and participant information sheets which must be approved by the Committee before the process of gaining informed consent commences.

10. Responsibility for taking consent

10.1 It is ultimately the responsibility of the lead researcher to ensure that participants have fully understood what they are consenting to by agreeing to take part in the project. In the case of student led projects, this responsibility lies with the student's supervisor(s). Any individual who takes consent should meet the following criteria:

- Be qualified, through previous experience and appropriate training, for the process of gaining informed consent.
- Have a full understanding of the study, potential risks/benefits, and the associated research area in order that they are able to give appropriate information to participants.
- Be prepared to take on the additional responsibility and feel confident to seek informed consent.

10.2 Any individual undertaking the process of gaining informed consent in projects using human tissue samples must have attended the appropriate Cardiff Met training course[3] and must comply with the extant version of the Working with Human Samples Standard Operating Procedure HS 02 Consent.

11. The consent form

11.1 Participant information and consent forms to be used must have been approved by the appropriate ethics Committee prior to commencement of the project. This is also the case for any documents provided to participants in respect of the study.

11.2 In order to meet Cardiff Met requirements, the consent form should:

- Be produced on a headed paper
- Include the correct title and version number of the study (which should also be included on the participant information sheets)
- Include a statement that the participant has had the study explained to them and by whom and confirm that the risks and any benefits related to their participation have been discussed and all the participant's questions have been satisfactorily answered.
- Include a statement that participation is voluntary, that participants are free to withdraw at any time without penalty and give details of what withdrawal of consent will mean at any given stage of the project. (See Section 16 of this document for more details on withdrawal of consent)

[2] Details on the process of gaining ethics consent for your research can be found on the research pages of the Cardiff Met website.

[3] Details of the training course can be obtained from Research & Enterprise Services.

- Include a statement that confidentiality will be maintained throughout the study unless this cannot be guaranteed[4].

11.3 In order to meet these minimum standards, use of the Cardiff Met exemplar consent form is recommended.

12. Procedure for taking informed consent

12.1 In order to ensure fully informed consent has been obtained, researchers should follow the process below:

- Each participant should be given an oral explanation of what participation in the project will entail.
- Each participant should then be given an information sheet explaining in simple, non-technical terms, 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 cases where participants are either children or "vulnerable" adults, consent should normally be gained from a parent/guardian or legal proxy with the participant giving informed assent (see below for further details).
- Throughout the process there should be sufficient time allowed to answer any questions raised by the potential participant.
- Potential participants should not be coerced to participate.

12.2 When providing information to participants, either verbally or in writing, researchers should explain the following:

- The purpose of the study and any background information which might be relevant (including funding arrangements if appropriate).
- The reason that they have been approached to participate.
- That confidentiality will be maintained throughout the study, unless this cannot be guaranteed[4].
- The design of the study. Details such as the number and location of the study visits and the names of individuals who participants will meet should also be given.
- All procedures required as part of the study.
- The potential benefits and risks of participation in the study.
- That participation in the study is voluntary and that participants may withdraw at any time without penalty.

Details of any payments which will be made to participants (e.g. payment of expenses).

[4] Researchers are expected to respect participants' confidentiality at all times unless an issue arises, the disclosure of which is required by law. For further details refer to the Cardiff Met Guidelines for obtaining ethics approval.

- Their responsibility as a participant in the project. This is particularly important where the study duration is substantial.
- That, despite providing informed consent, they may not be engaged in the project should it be discovered that they do not meet the inclusion (or exclusion) criteria for the study.

Ideally, these points should be verbally discussed with the potential participant. They should then be provided with a written participant information sheet and separate consent form. Participants should be made aware that participant information sheets are available in a range of formats (e.g. large print, audio, Braille, other languages).

12.3 In order to meet these minimum standards, researchers are recommended to refer to the Cardiff Met Participant Information Sheet - Guidance for Researchers.

12.4 The consent form should be signed and dated by the potential participant and the person seeking consent. Each should also print their name next to their signature. A copy of the signed form should be given to the participant and the original retained for inclusion in the project file.

12.5 Contact details of the individual participants can contact for further information about the study should be provided. Cardiff Met contact details (eg Cardiff Met telephone number and / or email) rather than personal contact details should be provided.

12.6 It is important to note that the informed consent process does not end once the consent form has been signed. The practice of providing information about the study to participants should be an ongoing process performed by all members of the research team.

12.7 As the timing of the signing of the consent form relative to the commencement of the study may be subject to audit, it is important to record dates correctly on both the consent form and any associated documentation. The consent form must be signed by the participant prior to any aspect of their involvement in the study.

13. Projects involving participants under the age of 18

13.1 In essence, researchers carrying out studies involving participants under the age of 18 should follow the same process as outlined above. However, researchers should also ensure that their study meets the additional requirements outlined in this section.

13.2 It is essential that any study involving participants under the age of 18 either relates directly to this committee or can only be carried out on this committee.

13.3 The study should be designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the child's stage of development and continuous monitoring should take place throughout the study to ensure this remains so.

13.4 In studies involving children, generally Cardiff Met 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 and take account of their different roles and experiences within this process. Both should make clear that the participant may withdraw from the study at any time without penalty and give details of what withdrawal of consent will mean at any given stage of the project. (see Section 16 of this document for more details on withdrawal of consent).

13.5 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 in the project.

13.6 For projects involving very young children, eg those who are too young to understand a simple explanation of the research to be undertaken, the project may proceed with parental consent only.

13.7 Further guidance on projects involving participants under the age of 18 can be found in the Cardiff Met Ethics application guidance notes.

14. Projects involving participants who are unable to give informed consent

14.1 Researchers who intend to conduct research involving adults who may not be able to give fully informed consent on their own behalf must give a clear justification for this when applying for ethics approval of their project. It will be expected that the study will produce benefits to the participants and that there will be no risk associated with participation. Continuous monitoring must take place throughout the project in order to ensure that risks to the participant are minimised at all times.

14.2 The legal representative of a potential participant must be provided with full information about the project and the likely involvement of the participant. This should include an assurance that the participant may withdraw from the study at any time without penalty. The representative should also be given sufficient time to ask questions during the consent process.

14.3 The participant must be given information about the study according to their level of understanding. In cases where the potential participant is able to form an opinion based on the information provided, their wish to participate or not must be respected by the person seeking consent.

14.4 No incentives or financial rewards must be used to influence either the potential participant or their representative.

15. Projects without informed consent

15.1 Notwithstanding the detail provided in previous sections, there may be instances where obtaining informed consent is problematic (e.g. ecological validity, averting alarm, implacability).

15.2 In such instances, the researcher must apply for ethics approval to proceed without gaining informed consent and make explicit within the application:

i) why the research is important, and
ii) that there is no alternative approach through which informed consent could be secured satisfactorily.

16. Withdrawal of consent

16.1 An important part of gaining informed consent is ensuring that participants are aware of their right to withdraw their consent at any time, without prejudice. It is true however that the timing of a request to withdraw consent will have a bearing on the type of action the University is reasonably able to take.

16.2 Where a request to withdraw from the study is received either before or during the data collection phase of the project, a participant can expect that any data collected to that point will be withdrawn and not used in the data analysis phase of the project, or included in any publication of project outcomes.

16.3 Once data analysis has started, it is much more difficult to remove an individual's data from the dataset due to the likelihood that it will have been anonymised. Therefore, where a request to withdraw from the study is received after data analysis has started, or has been completed, a participant can expect that any data from which they can be identified will be removed.

16.4 GDPR includes "right to erasure" or the "right to be forgotten". This typically applies after studies have been completed and the results produced and is different to the right to withdraw during a research project. GDPR Article 17 states that research studies are exempt from the right to erasure, where erasure is "likely to render impossible or seriously impair the achievement of the objectives of that processing" ie if the erasure of the person's data would harm the research outcomes, over and above simply having less participants. In cases where a participant requests the right to be forgotten, the PI should consult the Chair of UEC and Cardiff Met's Data Protection Team for advice on how to proceed.

16.5 In order to ensure that participants are fully informed about what will happen in the event that they withdraw their consent, it is good practice to include on the Participant Information Sheet and Consent Form details of when both the data collection and data analysis phases of the project will begin and end and to explain what this will mean in terms of withdrawal of their data. Providing more information at the start of the project will be helpful to both participant and researcher should a withdrawal request arise.

16.6 In order to meet the requirements laid out above, use of the Cardiff Met consent form and reference to the Cardiff Met Participant Information Sheet Guidance for Researchers is recommended to researchers.

17. Deceptive and Covert Research

17.1 While it is recognised that there is a continuum of covert-overt research (and therefore difficulty in defining research simply as entirely covert or overt). Researchers should endeavour, wherever possible and practicable, to avoid the use of deception in their

research methods, as this violates the principle of informed consent and may invade the privacy of those under study, particularly in non-public spaces.

17.2 Any researcher considering deceptive methods in research must seek approval from the UEC (University Ethics Committee). The burden of proof will rest on the investigator to show that no alternative methods are possible, and that the data sought are of sufficient value to over-ride the issues of free and informed consent. Where approval has been given, the potential implications arising from publication must be fully considered.

17.3 Covert research in non-public spaces (that is, where persons would not normally expect to be under observation), or experimental manipulation of research participants without their knowledge should be a last resort when it is impossible to use other methods to obtain the required data. It is particularly important in such cases to safeguard the anonymity of participants.

17.4 If covert methods are approved and employed, and informed consent has not been obtained prior to the research, every attempt should be made to obtain this post hoc.

18. Confidentiality and Anonymity

18.1 The anonymity and privacy of research participants should be respected and personal information relating to participants should be kept confidential and secure. Researchers must comply with the provisions of the Data Protection Act and should consider whether it is proper or appropriate even to record certain kinds of sensitive information.

18.2 Where possible, threats to the confidentiality and anonymity of research data should be anticipated by researchers and normally the identities and research records of participants should be kept confidential, whether or not an explicit pledge of confidentiality has been given.

18.3 Whilst the researcher should take every practicable measure to ensure the confidentiality and anonymity of research participants, s/he should also take care not to give unrealistic assurances or guarantees of confidentiality. Research participants with easily identifiable characteristics or positions within an organisation should be reminded that it may be difficult to disguise their identity totally without distorting the data. Researchers should be mindful that it is sometimes necessary to sacrifice data if there is no means of securing anonymity.

19. Audit of Approved Projects

SEC will undertake a planned programme of annual audits of projects. Audit of approved projects from Devolved Ethics panels will be an annual agenda item for SEC. Quality of panel decision making will be assessed by consideration of the decisions made. Audits will be used to improve the ethics process and to inform staff development activities.

In maintaining the highest standards of ethics governance we comply with the statement of the UK research integrity office by providing the “summary details of all research projects reviewed by the CSM ethics committee together with evidence of the ethics review and outcomes should be recorded and made available for institutional reporting and audit.”

20. Composition of Devolved Ethics Approval Panels and role of Supervisors

A typical devolved ethics panel would comprise the research project supervisor and two other persons, typically the module leader and a member of the CSM Ethics Committee. All three will have received Cardiff Metropolitan University or CSM ethics training. The role of the supervisor in the DEAP process is presented in Appendix E.

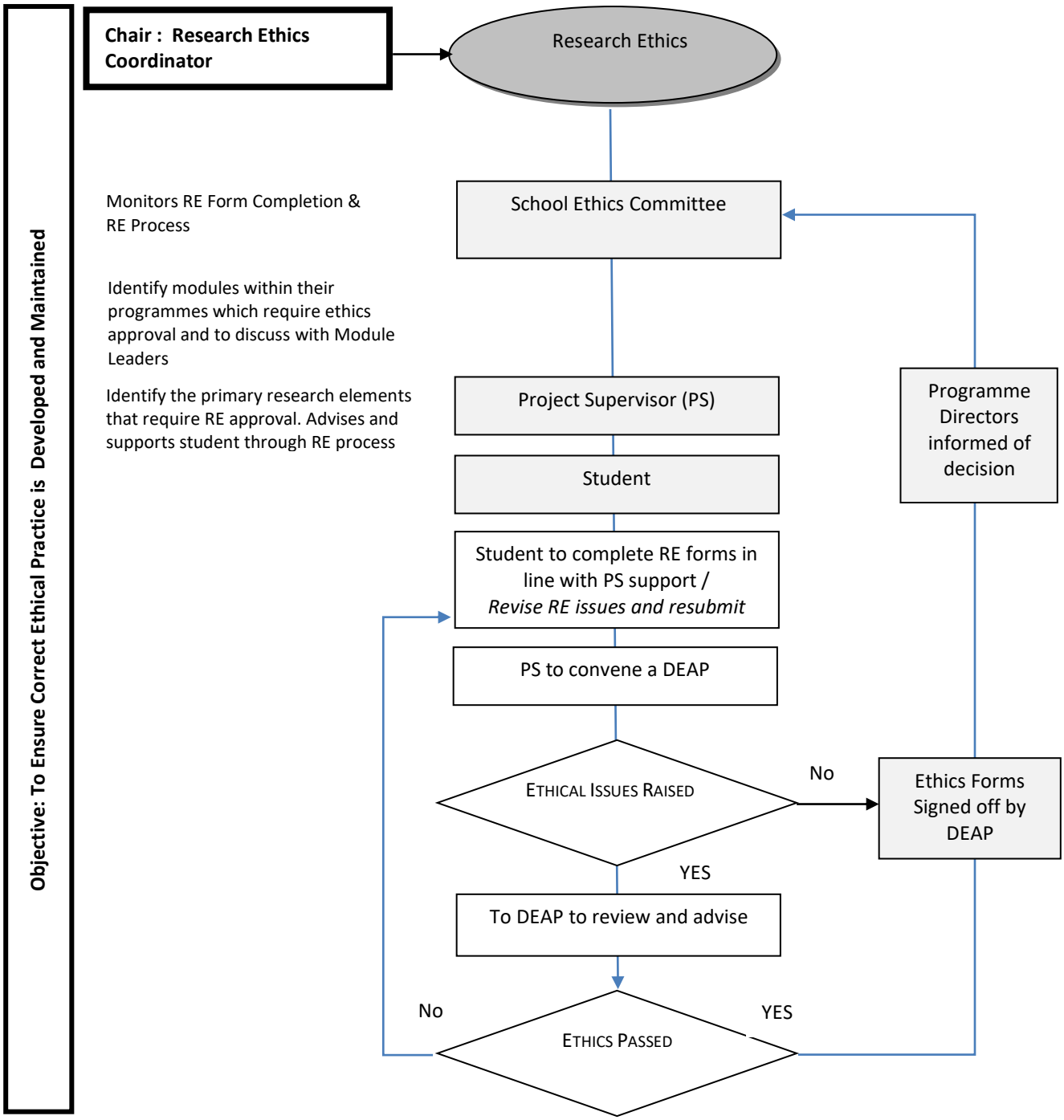
DEAP procedures for UK collaborative partners are detailed in *Appendix F*
DEAP procedures for Overseas collaborative partners are detailed in *Appendix G*

21. Appeals and Complaints Procedure

Applicants to SEC and Devolved Ethics Panels have the right of appeal against a decision. The process for such appeals and any complaints can be found in Appendix E.

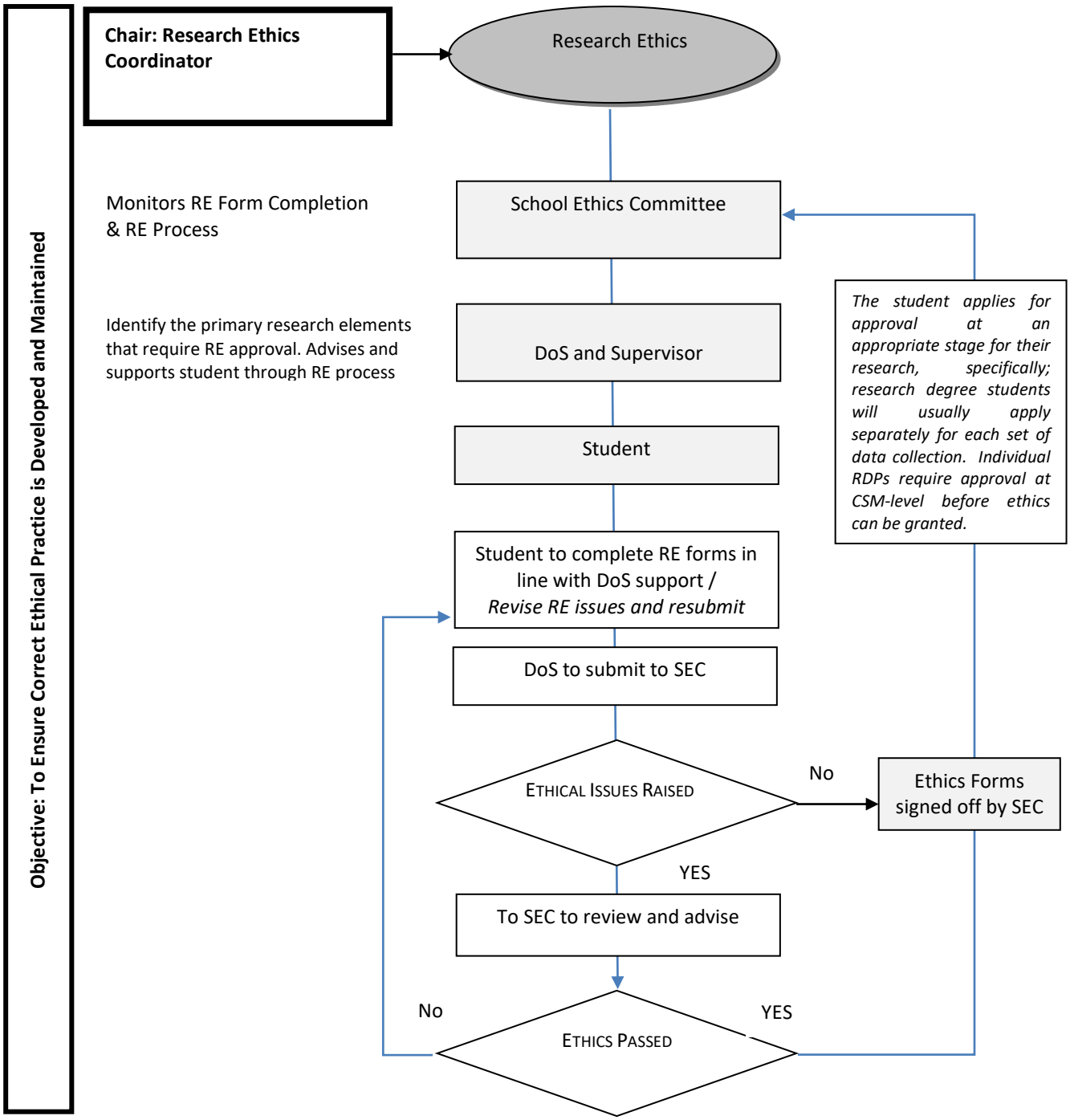
Appendix A

RESEARCH ETHICS PROCESS (TAUGHT PROGRAMMES BA, MBA, MSc)



APPENDIX B

RESEARCH ETHICS PROCESS (RESEARCH DEGREES AND ALL STAFF RESEARCH)



APPENDIX C

Terms of reference for CSM SEC

The School Ethics Committee has responsibility for upholding the general principles laid down in Cardiff Met's Ethics Framework and for ensuring that all research involving human participants carried out by staff and students of the School, within Cardiff Met or at other locations, conforms to the highest ethical standards. Reporting to the University Ethics Committee, and the School SMPT and School Research & Innovation Committee as necessary, it:

1. Ensures that Cardiff Met's Ethics Framework is disseminated to staff and student members.
2. The membership of the committee may include members external to the University.
3. Considers the compliance of the School with the sections of the Ethics Framework relevant to its Research, Enterprise and Learning & Teaching activities.
4. Advises the School Management and Planning Team about actions needed to comply with Cardiff Met's Ethics framework;
5. Establishes, implements and keeps under review codes of practice, procedures and guidelines for the consideration, approval and monitoring of research projects involving human participants which are undertaken by members of staff and/or students;
6. Makes decisions on ethical matters pertaining to the conduct of research, both individual and collaborative;
7. Establishes procedures for appeals against decisions made by the Ethics Committee;
8. Puts in place training for those involved in considering applications under this machinery and, as and when appropriate, for those undertaking research involving human participants;
9. Reports annually to the University Ethics Committee.

Frequency of meetings: Monthly

Membership

Ethics Co-ordinator (Chair)*	1
Associate Dean (Research)	1
Deputy Dean (Learning and Teaching)	1
Associate Dean (Enterprise)	1
Associate Dean (Partnership)	1
Dean of School (Ex officio)	1
1 Academic Associate (approved by the Chair)	1
Ethics Co-ordinator (Chair)*	1
Module Leaders with DEAP applications approved	All
Up to 4 co-opted members (approved by the Chair)	4
A member external to the University	1

Additional membership for consideration of Research Ethics:

Member of an alternative school ethics committee or UEC

*If the School does not have an Ethics Co-ordinator, the Associate Dean (Research) shall act as Chair

Organisation

The School may organise meetings of the School Ethics Committee considering applications for ethical approval to take place at a different time from its meetings to consider other aspects of the School Ethics Committee's work, and may co-opt additional members from the School for these meetings. The School may also authorise (subject to UEC approval) substructures, panels or sub- committees to carry out some or all of the reviews, and approve applications.

Appendix D - Copy of Research Ethics Form (v9 February 2020)

APPLICATION FOR ETHICS APPROVAL

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.

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	
Will the study involve NHS patients or staff? If yes, attach a copy of your NHS application to this form	
Will the study involve human samples and/or human cell lines?	

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

Desk based, involving only documents and not involving the collection of data from participants	Yes / No
Laboratory based, not involving human participants, human samples, animals or animal derived material	Yes / No
Practice based not involving human participants (eg curatorial, practice audit)	Yes / No
Answering **YES** to any of these questions indicates that the project does not include any participants and you will not therefore be collecting participant data. If this is the case, please provide a short (150 words) non-technical summary of the project, 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. The only exception to this is in relation to projects which include security sensitive research – see below for further details. If you have answered **NO** to all of these questions, please proceed to 1C.	
Provide a non-technical summary of the project below. NB: Any project which includes security sensitive research will be referred to the Prevent Co-ordinator so it can be risk assessed in line with the Prevent Policy. Ethics approval will only be granted once the Prevent Co-ordinator is content with the outcomes of that risk assessment.	

1C: Does your project fall entirely within one of the following categories:	
Compulsory projects in professional practice (eg Initial Teacher Education)	Yes / No
A project for which NHS approval has been obtained NB If this is the case, please ensure that you submit copies of the following with this form: • any questionnaires to be used • participant consent / asset form and withdrawal form • participant information sheets	Yes / No
A project which is not compulsory in professional practice and has gained external ethics approval from a body other than the NHS. NB If this is the case, please ensure that you submit a copy of the approved ethics application with this form.	Yes/ No
If you have answered **YES** to any of these questions, please provide a short (150 words) non-technical summary of the project and **complete the rest of Part One of this form**. You do not need to complete Part Two. Forward your completed form, along with any additional documents required (as indicated above) to your School Ethics Committee (or equivalent). If you have answered **NO** to all of these questions, please complete the rest of this form including Part Two.	
Provide a non-technical summary of the project below:	

1D: DATA COLLECTION AND STORAGE
What types of data will you collect or create?
How will you manage access to and security of the data?
Will the data collected be subject to the data retention protocols of any of the following bodies? • Human Tissue Authority (HTA)

• Health and Care Research Wales (HCRW) • Applications involving the NHS which will be submitted via IRAS
Yes ☐ For any project which is subject to the data retention protocols of an external body listed, you must develop a data storage plan to be submitted alongside this document for consideration by your School or Unit Ethics Panel.
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.	☐

DECLARATION: **I confirm that this project conforms with the Cardiff Met Research Integrity & Governance Framework** **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.	

PART TWO

If you haven't already done so elsewhere on this form, in the box below, provide a short (150 words), non-technical summary of the project.	
A RESEARCH DESIGN	
A1 Will you be using an approved protocol in your project?	Yes / No
A2 If yes, please state the name and code of the approved protocol to be used[5]	
A3 Describe the research design to be used in your project In this section, include details (as appropriate) of: • Research method(s); • Sample and sampling; • Participants including recruitment methods, activities to be undertaken, time commitment, details of any proposed payments; • Analytical techniques If your project does involve the use of an approved protocol, much less details will be required but you should indicate which areas of the project are covered by the protocol.	
A4 Will the project involve deceptive or covert research?	Yes / No
A5 If yes, give a rationale for the use of deceptive or covert research	
A6 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. Ethics approval will only be granted once the Prevent Co-ordinator is content with the outcomes of that risk assessment.	Yes / No
A7 If yes, please explain what they are and the measures that are proposed to address them	

B PREVIOUS EXPERIENCE
B1 What previous experience of research involving human participants relevant to this project do you have?
Click here to enter text.
B2 **Student project only** What previous experience of research involving human participants relevant to this project does your supervisor have?
Click here to enter text.

[5] 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

C POTENTIAL RISKS
C1 What potential risks do you foresee?
Include details of risks to the participants, the researcher and the project as a whole.
C2 How will you deal with the potential risks?
Click here to enter text.

When submitting your application you **MUST** attach a copy of the following:

- All information sheets
- Consent/assent form(s)
- 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.

Appendix E

Appeals Procedure

1. Appeals against Devolved Ethics Approval Panel Decisions

Where an application has been rejected by a Panel, the applicant has the right to request that the decision is reconsidered by the relevant Devolved Ethics Panel. Appeals should be made via the CSM Ethics Coordinator setting out the causes for concern. This communication should contain sufficient information to allow the grounds for appeal to be clearly understood. If the Devolved Ethics Panel revokes its original decision, the appeal can be upheld without a hearing.

If that Panel affirms its original decision, the applicant has the right to appeal to SEC in which case the appeal will be received by SEC as written. SEC will then convene a hearing and invite the applicant to meet with them. If additional expertise is required, the Chair may invite up to two members of staff with relevant expertise but who have not been involved in the initial decision to join the Panel. After the hearing, SEC will determine whether the applicant is successful. It is the duty of the Ethics Appeal Panel to provide clear justification for its decision regarding whether an appeal has been successful or unsuccessful.

The Panel must consider any written appeal within 10 working days and SEC within 20 working days. All appeals must be made within 2 months of the original decision being relayed to the applicant /supervisor.

2. Appeals against SEC Decisions

Where an application has been rejected by SEC, the applicant (or supervisor if the applicant is a student) has the right to request that the decision is reconsidered by the Committee. Appeals should be made to the Chair of SEC via the University's Ethics Coordinator, setting out the cause(s) for concern. This communication should contain sufficient information to allow the grounds for appeal to be clearly understood. If the SEC revokes its original decision, the appeal can be upheld without a hearing.

If SEC affirms its original decision, the applicant has the right to appeal to UEC in which case the appeal will be forwarded by SEC to the Chair of UEC with the justification for its decision.

SEC must consider any written appeal within 20 working days. Appeals must be made within 2 months of the original decision being relayed to the applicant.

3. Complaints

Complaints against the SEC Panel should be made following the University published complaints procedure

Appendix F

Responsibility of Supervisors of undergraduate and taught postgraduate student research projects which will be reviewed via CSM Devolved Ethics Approval Panels (DEAP).

Prior to a devolved ethics panel meeting it is the responsibility of the research project supervisor to instruct their supervisees in completing the Application for Ethics Approval correctly. The research project supervisor is responsible for;

1. endorsing their supervisee's ethics application by the inclusion of a Devolved Ethical Approval Panel (DEAP) Application Summary (attached) ,
2. initiating the convention of an appropriate devolved ethics panel to consider the application,
3. ensuring that the application for Ethical Approval is considered and returned in a timely fashion, normally within two weeks of submission (teaching period).

Following a DEAP meeting it is the responsibility of the research project supervisor to relay any comments made by the Panel to the supervisee and to provide guidance and support to address those comments. The supervisor should retain an electronic copy of the final approved application.

Devolved Ethical Approval Panel (DEAP): Application Summary

Student Name: _____ Student Number: _____

Module Name: _____ Module Number: _____

Programme Name: _____ Supervisor Name: _____

Accompanying Documents Checklist

Questionnaires: Ethics Application + Questionnaire + Participant Withdrawal Form
Interviews and Focus Groups: Ethics Application + Participant Information Sheet + Participant Consent Form + Participant Withdrawal Form + Interview/Focus Group questions

To be completed by student and supervisor before submission to Ethics Approval Panel	Student Signature;		Supervisor Signature;	
	Yes	N/A	Yes	N/A
Application for ethics approval	[ ]	-	[ ]	-
Participant information sheet	[ ]	[ ]	[ ]	[ ]
Participant consent form	[ ]	[ ]	[ ]	[ ]
Pilot interview/s	[ ]	[ ]	[ ]	[ ]
Pilot questionnaire/s with cover note	[ ]	[ ]	[ ]	[ ]
Letter/s to participating organisation/s	[ ]	[ ]	[ ]	[ ]
Confirmation of interviewee participation	[ ]	[ ]	[ ]	[ ]
Participant withdrawal form	[ ]	[ ]	[ ]	[ ]

First Submission [ ] Resubmission [ ]

Date: _____

For use by the devolved ethics approval panel:

Panel Members Name Signature

Module leader, Chair:

_____ _____

Supervisor: _____ _____

CSM Ethics Committee Representative:

_____ _____

Date: _____ Date of Reassessment: _____

Application Form completed to an appropriate standard Y[ ] N[ ]

throughout

Signed correctly in all sections	Yes [ ]	No [ ]
All accompanying documentation submitted	Yes [ ]	No [ ]
Accompanying documentation appropriate and relevant	Yes [ ]	No [ ]
Professional, grammatically correct presentation	Yes [ ]	No [ ]

Overall comments by the devolved ethics approval panel to the applicant

*The original to be retained by the supervisor and a copy given to the student and module leader. In the case of a resubmission being required this **original form** should be submitted with the resubmission.*

Outcome:

Project Approved	[ ] | Reference number:_____
Project Approved in Principle	[ ]
Decision deferred (application not ready/incomplete)	[ ]
Project Not Approved (major revisions)	[ ]
Project Rejected	[ ]

Appendix G

Composition of a Devolved Ethics Approval Panel (DEAP) in Collaborative Partner Institutions.

A typical DEAP in a CPI would comprise the research project supervisor and two other persons typically the module leader and a third person whose role is to ensure that CSM's ethics procedures are complied with and that parity in decision making is maintained across all CSM DEAPs in their institution. This person may be a member of academic or administrative staff and will have been identified by the CPI in conjunction with their CSM link tutor. The CSM link tutor will ensure that this person is kept up to date with all of Cardiff Metropolitan University and CSM's ethical procedures. All members of the Panel will have received Cardiff Metropolitan University or CSM's ethics training.