CARDIFF METROPOLITAN UNIVERSITY

PDR ETHICS FRAMEWORK

1.0 Introduction

Cardiff Metropolitan University has the responsibility to ensure that all research carried out by its staff and students conform to the highest ethical standards. This document outlines PDR's Ethics Framework for the conduct of all research, enterprise and knowledge transfer activities involving human participants. This framework relates to the specific activities of PDR but is closely aligned with the institution-wide activities governed by the University Ethics Committee (UEC). UEC has the responsibility to ensure that the institution acts in an ethical manner at all times; routine scrutiny of applications for ethics approval has been delegated to School/Unit ethics committees which report directly to UEC.

This framework aims to protect the rights of participants, PDR staff and PDR students involved in a wide range of human-centred projects. In addition, the framework aims to protect the reputation of PDR as an international centre for high-quality design research.

The ethics policy set out here applies to all PDR staff and postgraduate students when they plan to undertake internal or external research, enterprise projects, knowledge transfer activity and certain teaching exercises. The purpose of the ethics framework is to ensure that projects undertaken by staff and students reflect consideration of the following ethical principles:

- Research should ***avoid harm*** to participants, researchers, institution and the environment.
- Research involving human participants ***should be beneficial*** to all parties involved; the dignity and autonomy of participants should be respected at all times.
- Research should be well planned, rigorous and unbiased, such that ethical considerations help to ***enable high-quality*** outputs, outcomes and impact.

2.0 PDR Ethics Committee

PDR is a stand-alone research unit within Cardiff Metropolitan University. With approximately 40 full-time staff and 15 PhD students, PDR undertakes research, enterprise and knowledge transfer projects across a number of research and practice groups. The PDR ethics committee is responsible for ensuring that all projects carried out by staff and students conform to the ethical standards set by PDR and approved by UEC.

User-centred design is a key activity across PDR; consequently, human participants can be at the heart of a number of research and enterprise projects. Internal PDR projects that rely on human participants can be typically classified as follows:

- The studies involve adults who can give informed consent – very few projects with children.
- No sensitive or highly-confidential information is recorded – the anonymity of participants can be easily maintained. Data tends to be based on participants' perception and experience of product/service design rather than personal data derived from laboratory tests involving participants.
- No samples are taken from participants, no substances administered to participants, no physiological or psychological stress induced, no prolonged testing regimes, and no covert research protocols.

Some partnered projects (such as enterprise life sciences projects) could involve sensitive information and/or invasive protocols. In these rare cases a collaborative approach to ethical considerations will be taken with input from Cardiff Met colleagues and NHS partners with the necessary expertise.

The membership and structure of the PDR ethics committee is given in Appendix I, and the formal UEC terms and conditions for the ethics committee are presented in Appendix II.

The ethics committee will undertake a planned programme of annual audits of projects; audit of approved projects will be an annual agenda item for the committee. Quality of panel decision-making will be assessed by consideration of the decisions made. Audits will also be used to improve the ethics process and to inform staff development activities.

3.0 Responsibilities of Researchers

All researchers have a responsibility and a duty of accountability to all relevant stakeholders, e.g. to their profession, to Cardiff Met and to the funders of the research. They have a duty to accept full responsibility for the professionalism and integrity of all aspects of the conduct and publication of their research, and for the activities of any staff or students under their direction. This extends to reporting conflicts of interest, actual or potential, or suspected misconduct, in the appropriate manner. Researchers must also accept accountability for taking steps to ensure the safety of those associated with the research, the probity of the financial management of the research project, and for seeking to provide optimum value for the public or private funds invested in the project. All legal and ethical requirements laid down by Cardiff Met or any other properly authorised bodies must be observed.

Studies may be required to comply with externally developed guidelines, such as projects funded by Research Councils, Professional Bodies, Charities or EU Framework programmes. Researchers are responsible for ensuring that their work meets the ethical requirements of external agencies (where necessary).

4.0 PDR Ethics Application and Decision Process

All activities involving human participants require an ethics application. A typical project within PDR would engage with singular or multiple participants (end-users, designers, purchasers, clients, etc.) through surveys, questionnaires, interviews and focus groups. The output from this work tends to be a qualitative measure of user needs and requirements. Generally no significant financial inducement is needed to engage with participants.

PDR does not have direct undergraduate teaching responsibilities and there are a relatively small number of ethics applications compared with other Schools within Cardiff Metropolitan University.

The PDR ethics application process is summarised in Figure 1. There are three phases associated with the application process:

1. Applications are emailed to the three members of the PDR ethics panel.
2. The documentation is circulated electronically, reviewed, comments noted and the panel makes a decision. In some cases external ethical approval is required and/or the panel requests additional documentation.
3. The panel undertakes additional review and makes a decision. However, for some applications, such as incomplete external approval or complex ethics issues, then the documentation is forwarded to the full PDR ethics committee to make a decision.

The PDR ethics committee may also refer applications to UEC, for example undergraduate teaching activities or projects involving sensitive material. In these cases PDR staff may not have sufficient expertise to assess the risks; expertise from colleagues from across Cardiff Met will be used where appropriate.

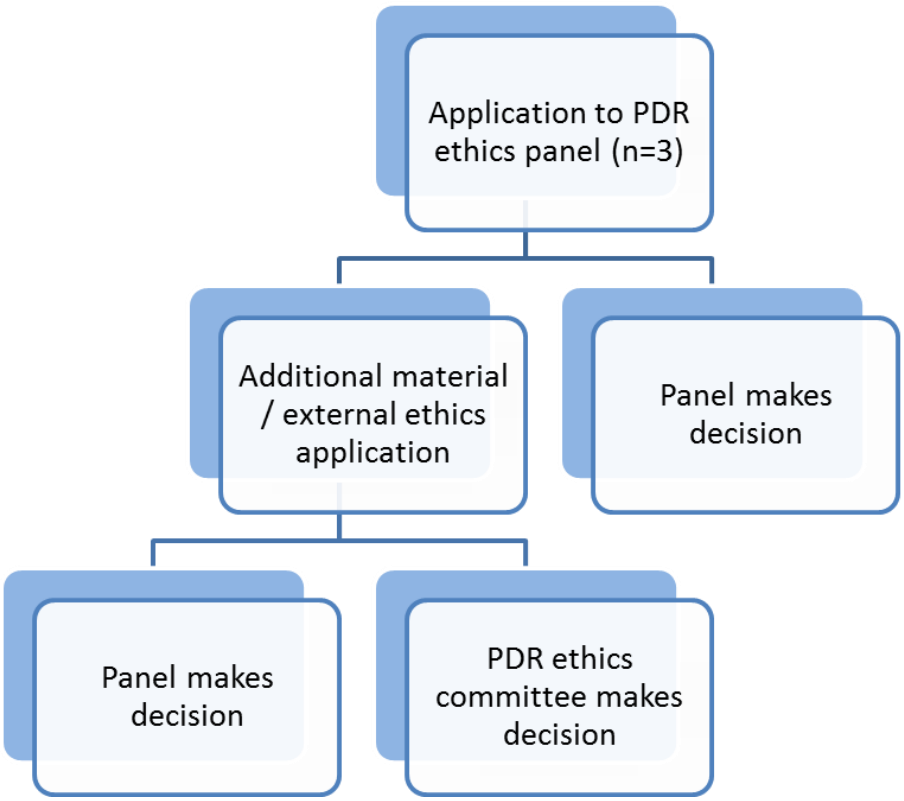

Figure 1: PDR Ethics Structure

The current forms for ethical applications are drafted for Cardiff Met institution-wide use and indicate in the decisions section that projects can be:

a) Approved
b) Approved in principle and deferred (where a minor revision is required)
c) Not approved (where the application is returned for major revision)
d) Reject (where the project is unethical)

Ethical approval, where granted, will normally be for a 12-month period from date of approval. 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 five years in circumstances where projects are designed to last longer or where their implementation depends on securing funding from recognised external organisations.

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 ethics committee reflects the expression of a favourable ethical opinion made on the basis of the information provided by the applicant. Staff and students in PDR should not proceed with projects if during the course of their activities 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 granted approval in the first instance for further guidance.

5.0 External (Third Party) Ethics Approval

PDR will not endorse projects that require approval from a nationally recognised Research Ethics Committee (REC) until such approval has been granted. In these cases a copy of the relevant REC favourable ethical opinion must be submitted to the PDR panel/ethics committee for consideration.

For projects involving the NHS careful consideration is needed with regard to categorising the project activity. According to the Health Research Authority (HRA) ‘Research’ in the NHS is defined as:

“The attempt to derive generalisable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.”

HRA and the NHS R&D Forum have issued guidance on the categorising of research, clinical audit and evaluation. Whilst all three types of study require the permission of host Trusts and organisations, systems for permission for each type of study vary and only research requires Research Ethics Committee (REC) review. A well-used distinction is:

- **Research** – is designed and conducted to generate new knowledge and should follow the systems for approval of NHS Research
- **Audit** – is designed to answer the question "Does this service reach a pre-determined standard?"
- **Evaluation** – is designed to answer the question "What standard does this service achieve?"

For a number of PDR projects (e.g. Surgical and Prosthetic Design), the service interaction with the NHS is well established, the work is patient specific (i.e. not generalisable and no treatment allocation) and there is no study randomisation. Therefore an assessment of this type of PDR service with NHS staff (as opposed to direct contact with NHS patients) can be categorised as an audit or evaluation. Where proposed activities do not require REC approval, a letter/email specifying the exemption should be provided from the relevant unit or collaborating partner (e.g. Morriston Hospital / CARTIS) together with the ethics application.

Where the third party is a healthcare institution outside the UK, approval from a relevant recognised REC in that country will be required. Other agencies may also have specific requirements for ethical approval (e.g. Ministry of Defence or Ministry of Justice); if so, evidence of written permission should be obtained.

6.0 Ethical Approval and Human Participation

Prior to data collection on all postgraduate research and postdoctoral research projects involving human participants, an application for ethical approval must be submitted. An ethics application should be submitted for all PhD projects; paper-based and/or technology-based PhD projects not involving human participants require only a non-technical summary as part of the application.

For activities conducted externally by staff or students, the route to ethical approval depends upon the arrangements at the institution where the Principal Investigator (PI) resides (provided that these are at least equivalent to Cardiff Met arrangements). The collaborative work between PDR and the NHS may use Research Passports. The Research Passport is a system for issuing honorary research contracts (HRCs) or letters of access to HEI researchers who need to undertake their research within the NHS. The research passport provides evidence of the pre-engagement checks undertaken on the researcher in line with NHS Employment Check Standards.

If the PI is at Cardiff Met, they should apply through the internal PDR process. If the PI is at an external institution, they should gain formal ethics approval from that institution. Ethical approval from another institution does not remove the responsibility of researchers to comply with the policies laid down by UEC. The Cardiff Met collaborator should provide evidence that the project has received ethical scrutiny and approval for all work undertaken.

If data are to be collected in an organisation external to PDR, written evidence that the member of staff or student has sought such permission should be provided to PDR with the application for ethical approval.

Across the broad spectrum of research, enterprise and knowledge transfer projects, activities involving human participants are defined as those that:

a) Directly involve people through their physical participation. Physical participation may be invasive (e.g. taking samples of human origin) and/or non-invasive (e.g. laboratory-based experiments, interviews, questionnaires, surveys, observational, practical sessions) and may include the active or passive involvement of a person (passive refers to the use of secondary data about an individual).
b) Indirectly involve people in activities through their provision of, or access to, personal data or tissue of human origin.
c) Involve people acting on behalf of others (e.g. parents/legal guardians/carers of children and the psychologically and/or physically impaired, and supervisors of people in controlled environments, e.g. pupils, psychiatric patients, prisoners).

It must be noted that the procurement, storage, handling and disposal of samples of human origin must comply with Cardiff Met's policies and procedures as set out in the Research Governance Framework.

7.0 Health, Safety and Risk Assessment

The Health and Safety aspects of activities requiring ethical consideration are covered by PDR's Health and Safety Policy. It is also a requirement for applicants to assess risk in the context of ethics and to complete the relevant Risk Assessment documents. Risk assessments must be provided to the committee or panel on request but are not routinely required as accompanying documents for ethics applications. Information on PDR's Health and Safety Policy and Risk Assessment Procedures can be found on the PDR Teamsite.

8.0 Research Involving Children

For projects involving participants under the age of 18, 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 to take account if necessary 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 in the project.

Participants who are 16 and 17 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.

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. The distinction between consent and assent is as follows:

- **Consent** is the legal process of a person with "capacity" granting permission for, in this instance, participation in research.

- **Assent** is defined as the child or young person's permission or affirmative agreement to participate in research. Unlike consent, assent is not a legally mandated process and has no legal authority. Assent is an opportunity given to children to express their opinions and concerns surrounding participation in research, providing them with a formal means to be included or excluded.

Both assent and consent should be both ***voluntary*** and ***fully informed***.

9.0 Data Storage, Confidentiality and Anonymity

The retention of data and the storage of documents associated with approved projects should comply with Cardiff Met's Data Storage Policy (RES Sharepoint). In addition, the research, enterprise and knowledge transfer activities across PDR may have distinct local arrangements for the management and storage of documentation. In the case of commercial projects, PDR has a documentation system compliant with ISO 9001 procedures.

Project documentation should reflect the distinction between confidentiality and anonymity:

- **Confidentiality** is concerned with who has the right of access to the data provided by the participants.

- **Anonymity** refers to concealing the identities of participants in all documents resulting from the research.

Staff and students owe an ethical and legal obligation to respect the confidences of research participants and this obligation extends to all personal information. If researchers plan to share data with another party, this must be highlighted and permission obtained if confidential information is to be used in a manner which will identify the research participant.

The information sheet or consent form should state clearly if participant details are to be passed to any other individuals or organisations. In this context, researchers should aspire to confidentiality rather than promise it.

10.0 Appeals and Complaints Procedure

Applicants to the PDR ethics panel/committee have the right of appeal against a decision. The process for such appeals and any complaints can be found in Appendix III.

Contact:

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Appendix I

PDR Ethics Committee Membership: May 2015

Ethics Co-ordinator (Chair):	Huw Millward[1]
Head of Unit:	Gavin Cawood
Director of Research:	Andy Walters[1]
Commercial Director:	Jarred Evans
Head of SPD:	Dominic Eggbeer[1]
External Member:	Andrew Thomas (CSM)

[1]**PDR Ethics Panel**: the primary review team for ethics applications.

Appendix II

PDR Ethics Committee: Terms of Reference

The PDR 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 PDR, within Cardiff Met or at other locations, conforms to the highest ethical standards. Reporting to the UEC, and the PDR Board as necessary, the PDR Ethics Committee will:

1. Establish, implement, and keep under review procedures and guidelines for the consideration, approval, and monitoring of research projects involving human participants which are undertaken by members of staff and/or student members of PDR.

2. Ensure that ethical principles are clearly laid down and are disseminated to staff and students of PDR, and that ethical practices are adhered to.

3. Ensure that appropriate training in ethics is put in place for members of PDR undertaking or supervising research involving human participants.

4. Keep PDR's Ethics Framework under annual review.

5. Report annually to UEC on the numbers and types of projects considered by the committee, together with details of any policy or procedural changes recommended by the committee.

Appendix III

Appeals Procedure

1) Appeals against Panel Decisions

Where an application has been rejected by the Panel, the applicant (or supervisor) has the right to request that the decision is reconsidered by the Panel. Appeals should be made to the Chair of the Panel in the first instance, 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 Panel revokes its original decision, the appeal can be upheld without a hearing.

If the Panel affirms its original decision, the applicant has the right to appeal to the PDR Ethics Committee. The Ethics Committee 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 hearing. After the hearing, the Ethics Committee 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.

2) Appeals against PDR Ethics Committee Decisions

Where an application has been rejected by PDR Ethics Committee, the applicant (or supervisor) has the right to request that the decision is reconsidered by the Committee. Appeals should be made to the Chair of the Ethics Committee, 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 Ethics Committee revokes its original decision, the appeal can be upheld without a hearing.

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

3) Complaints

Complaints against the PDR Panel or Ethics Committee should be made following the University published complaints procedure.