UNIVERSITY OF WESTMINSTER

University of Westminster Code of Practice Governing the Ethical Conduct of Research 2017/18

This Code should be read in conjunction with the *Code of Research Good Practice*. Doctoral researchers and their supervisors should also refer to the *Academic Regulations for Research Degrees.*

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C1 Operating Procedures

1. Guiding Principles

1.1 The University is guided by the fundamental principle that research involving humans and/or animals and/or the environment should involve no more than minimal risk of harm to physical or psychological well-being.

1.2 The University is concerned to protect the rights, dignity, health, safety and privacy of research participants, the welfare of animals and the integrity of the environment. The University is also concerned to protect the health, safety, rights and academic freedom of researchers and the reputation of the University as a centre for properly conducted, high quality research. This document is written to promote those ends, and to comply with the requirements of external research funding bodies and collaborating organisations. The University is committed to the Concordat to support research integrity and facilitates a research ethics process to ensure that its research is conducted according to appropriate ethical considerations, while also following standards of professional practice and wider legal obligations. Singly and together these principles provide safeguards for researchers, participants and others working on the research.

1.3 All research falling within the definition in paragraph 2.1 below, is subject to this Code of Practice Governing the Ethical Conduct of Research (hereafter referred to as the Code) and should take into consideration relevant University and national codes of practice and/or external guidelines for ethics in research and research good practice applicable to the discipline and subject area.

1.4 Where codes of professional ethics apply, a Faculty should decide how these are incorporated in considerations of research ethics. University staff and students are expected to refer to relevant professional codes of practice and comply with them.

1.5 Consideration of ethical implications is required for all research, prior to commencement, in line with University procedures.

1.6. Research Ethics is an ongoing consideration and needs to be considered, understood and applied by the researcher to the entire research life-cycle, revisited as appropriate and intermittently, including from inception, proposal, data collection, writing, publication and dissemination of results.

1.7 The Code ensures that research ethics policy and practice is not in conflict with teaching and learning policy and with the integration of teaching and research within the University.

1.8 Studies which are conducted by staff for purposes of enhancement of teaching quality, and which are consistent with the normal professional relationship between tutor and student, would represent normal pedagogic practice rather than research. These may not require research ethics approval if there is no likelihood of harm. Studies conducted for the purposes of research as defined at 2.1 would represent pedagogic research and be subject to ethics considerations as set out in this Code. Where the academic is uncertain whether their work is pedagogic research, or if it falls outside the normal original agreement between the student and teacher/institution they should consult appropriately.

1.9 Relevant Data Protection legislation and University guidance relating to data management and data security must be observed in the collection, use, storage, transport, back-up and the archiving and/or eventual destruction of all data (see Section 7).

2. Definition and Classification of Research

2.1 Research may be defined as "a process of investigation leading to new insights, effectively shared. It includes work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction"[1].

2.2. Where a project involves a collaborator or external organisation, their definition of research may vary from that of the University, for example, the National Health Service may classify a project as a clinical audit or service review while the University may still view the project as research. This may need to be considered when assessing what, if any, ethical and/or management approval is required.

2.3. Classification of research ethics proposals are not exhaustive and research may include a combination of these classes (as below) and therefore the highest class numerically (Class 3 or 4) should normally be followed in terms of process for approval.

2.4. Class 1: research with no or minimal ethical implications *(where risks will not exceed those experienced in normal day to day life).*

Class 1 research encompasses research which falls within the definition of this Code and which, after consideration has been found to have no or minimal ethical implications. In these circumstances ethical approval by a Research Ethics Committee is not normally required unless this is required by a sponsor, funder, professional body or other external organisation (see Classes 2 and 3). The Part A research ethics application form* and coversheet** should be completed by the applicant and signed by the supervisor (of taught course students and doctoral researchers) confirming that it has been accepted as Class 1.

Note that, all research undertaken in psychology, in accordance with the professional standards of the British Psychological Society, must be considered by a Research Ethics Committee regardless of Classification.

2.5. Class 2: research which has ethical implications *(the potential to cause a risk of harm)*

[1] Universities UK (2012), Concordat to Support Research Integrity

*, **; all documentation submitted should be in electronic form

Class 2 encompasses research which falls within the definition of this Code, has clear potential ethical implications and which may cause, or has the potential to

cause, harm in any form to participants, investigators, animals, the environment or others. Class 2 research must receive approval from a Research Ethics Committee, either at Departmental, Faculty or University level.

2.5.1 Examples of Class 2 may include, but are not limited to, any research which involves potentially vulnerable participants or those in Regulated Activity (adults) as defined by the Safeguarding Vulnerable Groups Act 2006 (and as amended by the Protection of Freedoms Act 2012), for example, those who:

- are under 18 years of age
- are included in the research by virtue of the fact that they are engaged in or under the care of the health and social care sectors;
- are sectioned under the Mental Health Act,
- are prisoners, arrestees, in detention, or ex-offenders with unspent convictions;
- refugees and asylum seekers;
- have a mental illness, learning difficulty or mental impairment, including, persons with a reduced level of consciousness, or unconscious, due to trauma or other agents; and
- are vulnerable due to their social and economic situations

or where the research will involve:

- the collection and use of human tissue where National Research Ethics Service (NRES) approval is not required;
- the administering of drugs, substance(s), or clinical intervention
- subjecting participants to environmental conditions outside of the norm, where these conditions create a potential for risk of harm;
- deception of participants;
- the procurement of data not already in the public domain that bears on issues of criminality;
- the internet for the procurement of sensitive data;
- invasion of privacy, harm to reputation, or adverse representation of individuals or classes of people and social groups;
    - personal or sensitive data (including but not limited to medical history);
- personal or sensitive data which may be directly or indirectly attributable to the participant or other identifiable individuals;
- personal or sensitive information which is recorded in audio/video or other forms of media
- Re-indentification of personal or sensitive date following pseudoanonymisation; which “is described by the NHS as “the technical process of replacing person identifiers in a dataset with other values (pseudonyms) available to the data user, from which the identities of individuals cannot be intrinsically inferred”[2] Such data should be treated sensitively and in the same manner as non-anonymised sensitive or personal data.

[2] JISC Digital Media, Storage, Access, Use and Onward Sharing (http://www.jiscdigitalmedia.ac.uk/storage-anonymisation.html)

2.5.2 These examples are not exhaustive and advice can be sought from the Faculty Research Ethics Committee or from the Secretary to the University Research Ethics Committee.

2.6. Class 3: research involving an external organisation

For the purposes of this Code 'external organisation' "refers to any bodies which: conduct, host, sponsor or fund research; employ, support or host researchers; teach research students; or allow research to be carried out under their auspices"[3].

Class 3 as defined by this Code includes two Routes: 3A and 3B. Class 3 encompasses research for which ethical approval from an external body may be required (Route **3A**), or where the University is required by an external body to confirm research ethics approval (Route **3B**).

2.6.1 Examples of Route 3A include but are not limited to, research involving the National Research Ethics Service, NHS patients, clinical trials, National Offenders Management Service, Social Care, Human Tissue Act, the Mental Capacity Act. A copy of the final ethics application (including supporting or associated documents) and ethics approval letter should be submitted to the University Research Ethics Committee, accompanied by a UREC Coversheet. The University may consider its own duty of care, as well as whether the research is in the interests of the University, where it is carried out under the aegis of the University.

2.6.2 An example of Route 3B is where an external body, e.g. Research Council, European Commission, Industrial collaborator, professional body or other external organisation requires evidence of research ethics consideration (and/or approval) by the University. With regard to research funded by an external body, evidence of institutional ethical consideration and/or approval may be required prior to submitting for an award or after an award has been made (in some cases the award is subject to institutional ethical, regulatory and good practice approval). When applying to the University Research Ethics Committee for approval of research within Route 3B, it is important that the Ethics application accurately reflects the protocol detailed in any external research proposal (regardless of whether it is funded research or not).

2.6.3. Where Route 3B applies, a local or Faculty Research Ethics Committee may not approve the research but must provide this to the University Research Ethics Committee for consideration, the latter may take advice from the local or Faculty Committee.

2.7. **Class 4** research which has significant ethical implications or the potential to cause a significant risk of harm, including research where there may be an institutional and/or reputational risk.

Class 4 research encompasses the definition within this code, which includes, but is not limited to research that may involve higher risks to researchers,

[3] UK Research Integrity Office (UKRIO) (2009) Code of Practice for Research: Promoting good practice and preventing misconduct, page 5 (http://www.ukrio.org/publications/code-of-practice-for-research/)

participants, animals, the environment and/or the University or others involved with the research. The University may consider a wide range of research activity falling within this category, and advice may be sought on a case by case basis by the Secretary of the University Research Ethics Committee or Chair.

3. Pedagogic Practice and Pedagogic Research

3.1 Pedagogic research is distinct from the acquisition of data for normal educational, development and quality assurance purposes. Examples of the latter e.g. of pedagogic practice, include obtaining data for the purposes of offering advice to students, and standard practices within the profession such as observation, assessment, intervention, evaluation and monitoring. This could include study or evaluation of the staff and student experience, curriculum content, teaching and learning methods, learning resources, course management, and teaching and learning facilities. Such activities would not normally be regarded as pedagogic research or require ethics scrutiny.

3.2 Acquisition of such data for the purposes of research, as defined at 2.1, would be defined as pedagogic research and require ethics scrutiny in the same way as research in any other discipline.

3.3 Where data originally acquired for non-research or pedagogic practice purposes is subsequently used for the purpose of research as defined at 2.1, ethics considerations and the processes outlined in this Code would apply.

3.4 Data acquisition or investigations conducted as part of regular pedagogic / professional activities may require ethics consideration in circumstances:

i. where the staff member is unsure whether the activity represents pedagogic research according to the current professional and institutional understanding.

ii. where the staff member is not normally the teacher of the group

iii. where the staff member does not normally have access to the information

iv. where the outcome of the study may be published or disseminated externally

v. where the study is being conducted by a student or external academic[4]

3.5 A record of all pedagogic research should be kept by the Principal Investigator via the University's online research (including research ethics) management system. A record should include a brief description of the research, the date of the research and which class/module or course it relates to (if relevant). This record would be accessible to the Faculty Research Ethics Committee for their information.

[4] Liverpool John Moores University (1 May 2010) University Staff Code of Ethical Practice and Pedagogic Research

3.6. The relationship of the students or participants to the academic staff member should be a consideration in good research practice, and should be taken into account when designing and proposing pedagogic research.

4. Generic Approval

4.1 Generic approval may be granted to research staff by the Faculty Research Ethics Committee for research which is conducted on a regular basis either as part of an ongoing research project, or as part of module delivery within a course, and which does not vary substantially from an approved protocol in the subsequent research study or raise new ethical implications.

4.2 Where generic approval is granted, it will be granted until such time when a relevant programme of study, protocol or legal requirement is due for review. It will be the Principal Investigator's responsibility to inform the Faculty Research Ethics Committee of any such changes.

4.3 Generic approval may not be applied for if National Research Ethics Service approval or R&D permission are required.

4.4 A record of any generic research must be kept on an ongoing basis by the Principal Investigator and any change in protocol must be notified to the Faculty Research Ethics Committee which had previously considered and approved the generic application.

4.5 A member of staff who is the tutor of a course may apply for generic approval for a cohort of UG or PG taught students conducting Class 1 research that is similar in methodology or where ethical implications do not differ in the course of the research studies. These research studies are training exercises for the cohort.

4.6 If the UG or PG taught students are undertaking individual projects, in order for generic approval to be appropriate, the projects should remain a low risk and Class 1 in definition, and follow similar parameters for topic, questions, aims, objectives, type and number of participants, Participant Information and Consent sheet format etc.

4.7 The member of staff will remain responsible for research ethics issues and applications for approval where necessary, however students may be asked to complete application forms or draft these as a form of training exercise within ethical good practice locally.[5]

5. Participants, Researchers and others involved in the Research

5.1 Safeguarding of Participants

5.1.1 All reasonable measures must be taken to safeguard the participants' health, to protect their psychological wellbeing, and to respect their privacy. The researcher is also viewed as a participant in the research and should take

[5] University of Sussex (January 2013) Guidelines for Completing an Application for Ethical Review – Generic Approval

steps to protect his/her own health and wellbeing at all stages of the research.

5.1.2 The Principal Investigator (PI) is responsible for the wellbeing of others involved in the research. The Principal Investigator should take sufficient steps to minimise and avoid any possible or potential risk of harm through continuous review and assessment of the study and its benefits or risks.

5.1.3 Where fieldwork is involved, the Principal Investigator may be the Fieldwork Team leader or nominate and agree with another researcher to be the Fieldwork Team leader. Where research with ethical implications exists which requires approval by an ethical approval body prior to commencement of fieldwork research, the PI should provide the full contact details and background to the nominated Fieldwork Team leader.

5.1.4 Any deception considered necessary should not involve the participant in any unjustifiable risk, such as unexpected anxiety or distress, lowering of self-esteem, or any form of psychological or physical harm. Where deception is used, revelation should normally follow participation as a matter of course, and the Research Ethics Committee will expect that this provision be designed into the investigative procedure.

5.1.5 Principal investigators shall encourage participants to report any unusual or unexpected effects during or after the investigation, demonstration, research or experiment to the Principal Investigator. The Participant Information Form must be explicit enough to encourage participants to report any such effects and give information about the support available both during and after the research.

5.1.6 Any serious event affecting a participant or Investigator, or other persons, during or after a research project must be reported without exception or delay to the relevant Research Ethics Committee by the Principal Investigator. The research must be halted immediately.

5.1.7 Participants should be informed of their right to appropriate support were there to be a subsequent adverse effect. The Dean of Faculty's contact details can be provided to the Participant.

5.1.8 Changes from an approved protocol may be allowed if there is danger or risk to the participant or Investigator, or other persons. Subsequently such changes to the process must be reported to the Research Ethics Committee for approval. The research shall be halted immediately and until such approval is received. The researcher should attempt to contact the Chair or Secretary of the approval body immediately upon halting research where there has been a potential increased danger or risk.

5.2 Selection and Recruitment of Participants and Declaration of Incentives

5.2.1. "It is the duty of the researcher to protect the life, health, privacy and dignity of the human research participant"[6]

[6] Brunel University (14 May 2013, revised 17 February 2014) Code of Research Ethics, page 5

5.2.2. Researchers should limit the use of human or animal participants and explain the benefits and risks involved in undertaking such research when drafting a proposal.

5.2.3. The proposed method of selection and recruitment and intended numbers of participants in research should be clearly explained in the research protocol, together with a rationale.

5.2.4 Researchers should carry out literature reviews and provide a brief summary with their proposal in order to inform an ethics approval body of details of similar research already undertaken.

5.2.5 Any proposed financial incentive to participate, other fee, or expense reimbursement made to volunteers and/or participants should be declared and will be subject to the approval of a Research Ethics Committee.

5.2.6 Any proposed financial or other incentive to participate to staff or Departments should be declared in the research protocol and to participants.

5.2.7 Care should be taken in the selection of participants to ensure that the proposed research does not expose them to potential harm because of an existing medical or psychological condition. Consideration of suitability of participants, exclusion criteria and medical advice should be carried out here.

5.2.8 Researchers and Principal Investigators should ensure that a professional relationship is maintained with participants at all times.

5.2.9 The Principal Investigator should maintain the wellbeing of participants and others involved in the research, including other researchers. Risks or burdens should be highlighted after consideration by the Principal Investigator, these should be assessed and reviewed by the Principal Investigator on an ongoing basis and not only prior to designing and drafting the protocol.

5.2.10 Any recruitment materials should include the ethics application reference number and Research Ethics Committee or ethics approval body name which provided research ethics approval, as well as the contact details, of the Dean of Faculty, in the case of complaints.

5.3 Informed Consent and the Participant Information Sheet

5.3.1 Explicit informed consent should be obtained orally or in writing and must be documented before any research can begin. If oral consent is being sought, this must be documented by the Principal Investigator and a reason for not gaining written consent should be provided to a Research Ethics Committee as appropriate. For research involving techniques such as internet surveys, journalistic interviews or market research, for example, other approaches to documenting consent may be used.

5.3.2 Consent may not be required in some circumstances such as, but not exclusive to, observational research where obtaining informed consent may not be seen as feasible, however ethical scrutiny and/or consideration would still be required

here. Reasons for not gaining consent need to be clearly articulated to an ethical review body.

5.3.3 Informed consent in this Code of Practice is defined as: participant's consent given freely and independently, in the absence of coercion, in light of information provided on the participant information sheet. Principal Investigators are required to inform participants about anything that would affect their decision to take part. Informed consent may need to be an ongoing process for participants of a study.

5.3.4 The Participant Information Sheet should inform the participant of the following in plain, jargon-free language:

- the aims of the research and why it is being undertaken
- whether the research is part of a student project and/or the University of Westminster affiliation
- what the participant is required to do
- whether there is an inclusion or exclusion criteria
- why they have been chosen as a potential participant
- any harm which might occur as a result of participating
- the right to complain, and to whom, in the event of a problem in the research
- the right to withdraw, or withdraw their data, from the investigation
- arrangements ensuring the confidentiality and privacy of the participant and protection of the data
- technical protection of the data
- what will happen to their data after the research, e.g. destruction, archiving, etc. and the relevant timescales involved taking account of any requirements to retain data for formal audit purposes
- contact details of the Principal Investigator/Supervisor
- the requirement to report any symptoms which may occur
- how the participant will be informed of the results of the research if applicable
- the intended use(s) of the results of the research
- how the research will be published or disseminated.

5.3.5 A copy of the Participant Information Sheet must be retained together with the signed Consent Form and stored suitably in the records of the investigation. A copy of the Participation Information Sheet should also be made available for the participant to take away.

5.3.6 Some participants may lack the ability to give their informed consent to participate in research, for example:

- Children: If school children are asked to be participants in a school-based environment, the Principal Investigator shall inform the Head Teacher of the school of what is proposed and obtain their permission for pupils to take part. The parent(s) or guardian(s) consent should also be sought. Such permission is in addition to, not instead of, individual consent previously described. Minors must be informed that they have the same rights as an adult.
- Those who lack competence for other reasons: In situations where participants are unable to give consent due to legal reasons, or are not

able to understand fully the nature and consequences of what is proposed, written permission to participate must be obtained from the parent, guardian, person in authority, or person with legal responsibility for the participant. Such participants should be allowed to participate only on grounds of minimal hazard, absence of alternatives and sufficient potential social or medical benefit. Psychological illness or brain damage may or may not be sufficient to render the participant incompetent to give consent.

- The Mental Capacity Act and Social Care Ethics Committee may need to be considered in such circumstances.

5.3.7 Where the participant is vulnerable (medically, socially and/or psychologically), greater care needs to be taken in obtaining consent. Legal constraints need to be checked before a third person can give any consent.

5.3.8 In cases where participants have limited command of written English the information and consent form, and any other explanatory materials must be translated into their main language. When participants have limited command of written texts in their own language, oral versions of these documents must be accessible and subsequently documented in written form.

5.3.9 Participants may also withdraw their data from the investigation as far as it is possible. In the case of a participant leaving the investigation, any comments made, or explanations given, should be recorded and kept by the investigator.

5.3.10 Deception should only be used if there is strong scientific justification, whether it is in terms of the research or as a public interest justification. Where deception is to be used it will normally be considered as Class 2 as a minimum.

5.3.11 Where appropriate, potential participants should be allowed sufficient time to reflect on the decision to participate and to seek advice from individuals with appropriate expertise as necessary. There should be sufficient time for reflection between giving consent and participation and consent and participant information should be seen as an ongoing process by the researcher and explained as such to any participants or others involved in the research, including other researchers.

5.4. Health and Safety (including Health and Safety Risk Assessment)[7]

5.4.1 “Principal Investigators have a responsibility to manage the health, safety and well-being aspects for those involved in the research, including themselves and other researchers and to ensure they have identified reasonably foreseeable risks (including through the completion and approval of a risk assessment document, with control measures in place as a result, where appropriate).

[7] Institute of Occupational Safety and Health (October 2012) Responsible Research; Managing Health and Safety in Research: guidance for the not-for-profit sector (http://www.iosh.co.uk/~/media/Documents/Books%20and%20resources/Guidance%20and%20tools/capPOL0686%20%20USHA%20Health_%20Safety%20Report%20v3.ashx)

A reasonably foreseeable risk is one that, if realised, could result in injury or damage, and which could be predicted by a reasonable person with the necessary skills and knowledge"

5.4.2 "Post-doctoral researchers and research supervisors should be competent in the research area and aware of the risks inherent in the techniques, equipment and methods they use."

5.4.3 Managing health and safety aspects of a research study, should involve the following processes;

- Planning the health and safety arrangements for the activity *(including risk assessment, hazard identification, security issues, preparedness and response etc.).* Also where legally required, evidence of Disclosure and Barring Service (previously Criminal Records Bureau) clearance must be provided.
- Implementing the planned health and safety controls and carrying out the activity
- Checking that the arrangements and controls put in place to stop injury, damage and ill health are working as planned
- Reviewing the activity to ensure that the health and safety arrangements were adequate and proportionate and then feeding any changes into the next research activity

5.4.4 **Planning for Research**

5.4.5 **"**All research tasks and projects should be evaluated for foreseeable health and safety risks before the work starts. The employer must then ensure that significant risks are recorded and that reasonably practicable risk control measures have been put in place. These control measures should be built into systems of work and research protocols."

5.4.6 "PIs and supervisors need to take responsibility for all assessments associated with their projects, but they may occasionally need to ask research workers to risk-assess some aspects of the work. The research supervisor or PI should check that the researchers doing this have been trained in risk assessment practice and that the assessments have been done to a satisfactory standard."

5.4.7 "In some fast-changing research environments, dynamic risk assessment and risk control solutions may be required. Dynamic risk assessment is a continuous process of identifying hazards and evaluating risks as they come up, taking appropriate actions to eliminate or reduce the risk. The researcher continually monitors and reviews the changing circumstances in the research environment. The actions taken should be documented to improve overall knowledge of risk and risk controls in similar projects."

5.5 Insurance cover (including Fieldwork research in the UK and overseas)

5.5.1 All participants in an investigation must be covered by insurance.

[7] Institute of Occupational Safety and Health (October 2012) Responsible Research; Managing Health and Safety in Research: guidance for the not-for-profit sector (http://www.iosh.co.uk/~/media/Documents/Books%20and%20resources/Guidance%20and%20tools/capPOL0686%20%20USHA%20Health_%20Safety%20Report%20v3.ashx)

5.5.2 The University of Westminster maintains in force a Public Liability Policy and Employers' Liability Policy, which indemnifies it against legal liability for accidental injury to persons (other than its employees) and for accidental damage to the property of others. The University holds a range of insurance cover. This insurance cover relates to claims arising within normal activities of the University.

5.5.3 The Research Ethics Committee may require, as part of the Research Ethics Application, either written confirmation that the University of Westminster insurers are content for their policy to apply, or that appropriate additional insurance cover has been arranged. It is the responsibility of the Dean of Faculty to ensure, through the Head of Procurement, that appropriate insurance cover is arranged if the investigation falls outside the scope of the University's insurance policies; details of such cover should be attached with the application form.

5.5.4 Participants must be clearly informed that insurance policies cover is in place in the event of accident, injury, or ill health arising as a result of taking part in the research.

5.5.5 Other researchers working on the study must be clearly informed before the investigation of their rights to insurance cover in the event of accident, injury, or ill health arising as a result of taking part in the research.

5.5.6 Before considering research ethics approval the Research Ethics Committee may require evidence of how researchers will be covered by the University's insurance policies, this will include, if appropriate, insurance cover for travel and actual research work (including Fieldwork).

5.5.7 Where fieldwork may take place, a Fieldwork Team Leader must be identified and agreed upon amongst the research team, the Principal Investigator should take responsibility for finalising this matter.

5.5.8 It is the Principal Investigator's responsibility, to keep abreast of current developments regarding the location and environment of research, including concern for the safety of all involved. The University requires that guidance is referred to on the Foreign and Commonwealth Office travel website and relevant and current advice regarding insurance arrangements for research and research fieldwork should be sought from the University's Procurement Team.

5.5.9. All insurance cover (travel, fieldwork, research) should be sought prior to applying for ethical approval or evidence of steps taken towards gaining appropriate cover should be shown when applying for ethical approval to any ethical approval body.

5.5.10 As with all aspects of research ethics, the Principal Investigator should keep under review any potential change in protocol. Steps must be taken, with advice from the University's Procurement Team, to ensure appropriate cover is in place prior to carrying out changes in protocol (even if these have been approved by an ethical approval body).

5.5.11 For purposes of research including human participants, conducted by doctoral researchers, the Supervisor should act as Chief Investigator and the doctoral researcher as Principal Investigator.

6. Location and environment of the Research

6.1 Joint Research Activities

6.1.1 Staff or students who wish to carry out research on human participants or animals outside University premises must obtain written permission from any collaborating organisation as well as from the University of Westminster.

6.1.2 Principal Investigators who are not University employees or University enrolled students, and who wish to carry out research on University premises, must conform to the University's *Code of Practice for Research Ethics*.

6.1.3 Principal Investigators who are not students or employees of the University shall state this on their Application for Research Ethics Committee approval.

6.1.4 In the case of collaborative investigations or investigations involving non-employees of the University, a Research Ethics Committee will focus on Section 6 (Insurance), and Section 8 of the application form (External Approval), before considering the proposed investigation further. In the case of collaborative projects, the Research Ethics Committee may agree either to accept ethical approval granted elsewhere or to require that University approval be granted before the project may commence, if this is within the University's remit.

6.1.5 Research Ethics approval should normally be sought as locally to the site of the actual research as possible, including where University employees or students are proposing to conduct research or part of a research study, elsewhere, and not within the University's premises.

6.2. Research Conducted Abroad

6.2.1 The Principal Investigator and/or supervisor must consider ethical implications of research conducted outside the UK.

6.2.2 The Principal Investigator and/or supervisor is advised to make a reasonable attempt to gain ethical approval from a relevant independent body abroad, where applicable, in addition to any ethical approval sought at the University. If the majority of the work with ethical implications is to be carried out overseas, then the local approval should be sought first, however no work with ethical implications should be carried out in advance of University or Faculty consideration (including consideration of any conditions or approvals set elsewhere).

6.2.3 The local review and ethical approval of research carried out abroad is a necessity because the ethical acceptability of the research must be in accordance with local legislation, regulations, best practice, customs, traditions and beliefs. Local ethical standards and practices need to be taken into account and a statement on how they will be accommodated by the research team should

be provided to any ethical approval body, both at the University and overseas. Where local research ethics consideration is not possible or practical, an explanation of why this is the case should be provided as part of the University research ethics application or proposal.

6.2.4 University members must ensure the University insurance will cover them for any research conducted abroad and must obtain a letter from the Procurement Team to this effect from the University before they travel. See Section 5.

6.2.5 Researchers should refer to the guidelines produced by Universities, Colleges and Employer's Association (UCEA) regarding Travel (within and outside the UK), Fieldwork, Risk Assessment and Safety, Health and Wellbeing guidance for researchers.

6.3 Location of the Investigation & Apparatus

6.3.1 The Principal Investigator and/or supervisor will ensure that any specific locations proposed for research are appropriate to the type of study and the risk involved.

6.3.2 An inspection of the proposed premises or location may be carried out by a University Research Ethics Committee at its discretion.

6.3.3 A Research Ethics Committee will need to be satisfied by the Principal Investigator that all equipment and apparatus intended to be used will be safe and properly maintained in accordance with the standards and procedures referred to in the University Health, Safety and Wellbeing Guidelines.

7. Research Data Protection and Security

7.1 Data Security and Confidentiality

7.1.1 Relevant Data Protection legislation and University guidance in data security must be observed in the collection, use, storage, back-up and eventual destruction of all data.

7.1.2 The Principal investigator shall be responsible for safeguarding the confidentiality of participant data.

7.1. 3 The recording of investigations and handling of all personal data must comply with the Data Protection Act 1998. A copy of the Act and additional advice is available from the Secretary to the Research Ethics Committee.

7.1.4 Information about named participants shall be communicated only to clinicians involved with their care (in the case of medical studies) or to researchers involved in the research. In all other cases the identity of participants must be protected.

7.1.5 With respect to digitisation of participant data, proposals for investigations involving storage of participants' names and other personal data should indicate reasons for holding such data, and the intended maximum period of retention with details of the steps proposed to minimise the risk of a breach of

confidentiality. All participant data must be handled in accordance with the Data Protection Act 1998.

7.1.6 The following guidelines on security arrangements for any recorded information should be adhered to:

- The Data Protection Act 1998 requires that the participant's informed consent be sought where personal information is to be used and that those who have access to the information, or receive copies of it, are clearly identified
- Systems used for the storage of data should ideally be located on University Information Services' secure network infrastructure within the firewall so that access control measures and auditing policies can be enforced.
- Desktop/laptops used by researchers should always be fully patched and ideally, regularly scanned for software vulnerabilities.
- All the data held on recordable media (e.g. discs, tapes, films or USB storage devices) should be password protected as a minimum security measure, to protect the contents if they are lost.
- Any recordable media containing identifiable personal data should be stored securely when not in use.
- Knowledge of procedures and passwords to access any medical or research data of named individuals should be held securely and be made available only to those authorised.
- File protection (Encryption) should be in operation on computer systems used to hold named individual data.
- Transmission of identifiable personal data across public communication lines (e.g. Email, DropBox etc.) should be avoided at all times. Where this is absolutely necessary, the prior approval of a Research Ethics Committee is required.
- Access to the data should be directly supervised by a designated system manager and permitted only to those authorised by the Dean of Faculty.

7.1.7 Once the research project is complete and following expiry of Research Council; professional or research body; or legal requirements for retention, consideration must be given to the secure disposal and destruction of any data that is either, provided at the outset or gathered during the project. Where personal information is involved, then specific measures to ensure the data is securely 'deleted' must be implemented.

8. Responsibilities

8.1 There is an onus on the University to provide transparent procedures for approval and scrutiny to ensure that checks and balances are in place so that research associated with the University, adheres to acceptable ethical standards.

8.2. Research projects being undertaken by taught UG and PG students as part of their degree should be discussed in detail between the student and the supervisor. For these research projects the supervisor will act as the Principal Investigator and will be responsible for ensuring ethical standards are met and for ensuring ethical approval and/or management approval(s) are sought by the

student researcher where appropriate. Supervisors are responsible for ensuring good research practice is both taught and followed. Taught UG and PG students should not normally be permitted to undertake any research that is higher risk, recognising that these researchers are typically the least experienced researchers of the University.

8.3. In all other research, e.g. doctoral research and staff research, the applicant is responsible for ensuring they meet the required ethical and research practice standards appropriate for their research, and obtaining necessary management approval(s) to proceed with their research. For insurance purposes a supervisor of a doctoral researcher would act as a Chief Investigator.

8.4 The Code requires that the University or Faculty Research Ethics Committees or Ethics Advisors demonstrate that they have given consideration to ethical implications of research, to approval processes and to the implementation of the Code in the relevant discipline(s).

8.5 Deans of Faculty and Heads of Department hold management responsibility for notification to all staff of their individual responsibilities under this Code, and for ensuring that all research with ethical implications undertaken in their Faculty or Department complies with the Code.

8.6 A named Faculty Research Ethics Co-ordinator is to be designated to take responsibility for all aspects of research ethics within the Faculty or associated Research Centres, to include knowledge of relevant ethics codes of practice for research, and to record research ethics applications for annual and ad-hoc audit and monitoring.

8.7 Where taught UG or PG students are undertaking research as part of the learning activities of a taught course, they shall be under the active responsible supervision of a member of staff known as the 'supervisor' who will ensure that the student complies with this Code.

8.8 All research whether undertaken by a group or by individuals must have a single named Principal Investigator who shall take responsibility for compliance with this Code.

8.9 Supervisors are responsible for the classification of taught UG and PG research and for ensuring that the students they supervise comply with the requirements of this Code and any other relevant codes and professional guidelines, both internal and external to the University. Where it is not clear which class the proposed research falls into, advice should be sought from the Faculty Research Ethics Chair, or from the Secretary to the University Research Ethics Committee. If it is not clear whether the research falls under Class 1, it should be forwarded to an appropriate Research Ethics Committee for review.

8.10 Individual staff members and students are required to comply with this Code.

8.11 For cross-Faculty projects, or where there is collaboration with an external organisation, responsibility shall lie with one named Principal Investigator.

8.12 The University Research Ethics Committee will seek expert guidance or advice as required through the co-opted membership policy; any external advisor will abide by the Committee's confidentiality requirements.

8.13 The University Research Ethics Committee shall report to the University Research Committee.

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[4] Liverpool John Moores University (1 May 2010), University Staff Code of Ethical Practice for Pedagogic Research

[5] University of Sussex (January 2013), Guidelines for Completing an Application for Ethical Review – Generic Approval

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[7] Institution of Occupational Safety and Health (October 2012), Responsible Research; Managing Health and Safety in Research: guidance for the not-for-profit sector (http://www.iosh.co.uk/~/media/Documents/Books%20and%20resources/Guidance%20and%20tools/capPOL0686%20%20USHA%20Health_%20Safety%20Report%20v3.ashx)

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Addendum A

Research Ethics consideration and approval process information

A1 Research ethics consideration and approval process

A.1.1 The process of obtaining ethical consideration and approval may require consideration of ethical implications by academic supervisors, PhD Coordinators, University, Faculty or Departmental Research Ethics Committee, or a designated external ethical approval body.

A.1.2 A completed application which has been subject to peer review and academic methodology consideration should be provided to an ethical approval body.

A.1.3 Staff, doctoral researchers and postgraduate taught students and undergraduate Psychology students, should complete applications for ethical approval using the using the University's online application system. All other undergraduate students requiring ethical approval can complete the application forms which are available on the University website http://www.westminster.ac.uk/research-framework.

A.1.4 Where an application for ethical consideration or approval needs to be provided to an external ethical approval body, and the University does not have the remit to provide its own approval, a researcher may not proceed until external approval has been gained and this approval has been confirmed by the University.

A.1.5 When providing evidence of external ethical approval to the University, copies of the completed final ethics application form and any supporting documentation and conditions and/or approval letters received by the researcher should be provided to the University Research Ethics Committee.

A.1.6 Where the external organisation is outside the UK and ethical approval or conditions have already been received, the original documentation should be submitted to the University Research Ethics Committee for consideration.

A.1.7 Additional permissions may be required for compliance purposes such as organisational permission to conduct research on external premises, use participants or data belonging to an external organisation etc.

A2. Procedure

A.2.1 The University aims to promote good academic practice in research by asking individual researchers to complete and retain an initial assessment document to demonstrate that ethical implications have been considered – this will be the Part A Research Ethics application form or a local Part A equivalent form (approved by the University Research Ethics Committee) and a Cover-sheet. Where there are ethical implications, an application for ethical approval must be made and submitted to an appropriate Research Ethics Committee or ethical approval body. Staff, doctoral researchers or postgraduate taught course students applying to a Research Ethics Committee at the University, should make their application via the online application system. Undergraduate taught course students applying to a Research Ethics Committee should complete an application form and submit it to an appropriate committee via their supervisor who fulfils the role of Principal Investigator and is responsible for ensuring the

application meets required standards in terms of research design and the identification of ethical issues.

A.2.2 All doctoral researchers must complete Annual Progress Review 1 (APR 1) which is scrutinised and signed off by a supervisor, the Faculty Research Director and the Graduate School Board. Completion of this process provides evidence that research design and a provisional assessment of ethical implications has been considered. The process includes research ethics consideration as good academic practice.

A.2.3 Research ethics implications should be considered at the design phase of all taught UG and PG student research project preparations when proposals are scrutinised by a supervisor. A checklist is available to support applicants and initial reviewers. The checklist focuses on the identification of ethical issues and the reasoning behind such identifications, as well as the purpose of carrying out research with ethical implications in the broader sense of research good practice.

A.2.4 Applications for research ethics approval are dealt with at respectively Departmental, Faculty, or University level (University Research Ethics Committee).

A.2.5. All proposals for conducting field work (research activity) in the UK or overseas require consideration and completion of a risk assessment in line with University Safety, Health and Wellbeing requirements: https://myintranet.westminster.ac.uk/my-journey/health-and-wellbeing/travel-overseas

A.2.6. All staff and students submitting proposals for conducting fieldwork (research activity) in the UK or overseas will be required to follow protocol in line with this Code of Practice in order to avoid invalidating insurance cover.

A.2.7. All proposals for conducting fieldwork (research activity) and/or for travel in the for purposes of University research, require travel insurance cover in line with the University Procurement requirements: https://myintranet.westminster.ac.uk/my-tools/bookings/travel/overseas-travel

A.2.7 Ethical approval shall be obtained before the commencement of any research which has ethical implications. A Research Ethics Committee may allow part of the research to commence, prior to full approval being granted, for those aspects of the research which do not relate to the ethical implications but which are intended to contribute to the final piece of research.

A.2.8 A Faculty Research Director, Supervisor or other designated named person/Research Ethics Committee Chair/Secretary will be available to give advice concerning the ethical implications of an application, if required.

A.2.9 A Research Ethics Committee reserves the right to request modifications or clarifications of any applications/proposals.

A.2.10 A Research Ethics Committee should review proposals in terms of ethical issues they raise, not the scholarly or scientific merits of the research. The scholarly or scientific standards of the proposal should be considered prior to its submission. By signing the application, the applicant confirms this has been done within the norms of regular professional practice. Such practice may include supervisory discussion or peer review, as appropriate to the application.

A.2.11 Exceptionally, where a Research Ethics Committee has concerns that the methodology described in an application may unnecessarily increase the likelihood of harm, then it may return the application for further clarification proportionate to the risks involved. Where a Research Ethics Committee needs to appraise the value of a project in order to make a judgment about ethics issues arising from potentially methodologically unsound research, the advice of an experienced researcher independent to the project and the Research Ethics Committee, who has experience in the proposal's methodology and paradigm, should be sought.

A.2.12 A Principal Investigator or researcher cannot attend any discussion at a Local, Faculty or University Research Ethics Committee involving their own research proposal even if they are members of the relevant committee, unless invited. Members must also declare any special interest including personal, Faculty, departmental or financial etc. If the Committee Chair is involved in any such conflict of interest(s) then the vice-Chair or nominee will take over until the discussion is concluded. A conflict of interest register should be maintained by the Committee Secretary.

A.2.13 Dates of University Research Ethics Committee meetings will normally be published in the University Calendar. Applications for University Research Ethics Committee consideration and/or approval, via the appropriate method, should reach the Secretary no later than ten working days before the meeting at which they are to be considered.

A.3 Life Cycle of Research and Research Ethics Approval limitations

A.3.1 A research ethics proposal should clearly state the proposed date when the research will start and end, and any ethics approval would be related to this specific time frame.

A.3.2 The Code contains further details regarding ongoing ethics consideration of a research study, including the need to re-visit consent and participant information where new data or new participants may be used for which previous research ethics approval was not gained.

A.3.3 Secondary uses of research data which did not receive ethics approval previously must be submitted to an ethics approval body, where ethical implications exist and where the data is not currently in the public domain.

A.3.4 Similarly other changes in the protocol which are significant and/or raise ethical implications, which did not exist or where not known previously when consideration was given by an ethics approval body, should be submitted for

consideration as a 'significant change/amendment to protocol' using the same application reference number.

A4. Pre and post award research good practice and research ethics

A.4.1 Applicants to external funding bodies or organisations should consider the external organisations Codes for research good practice and research ethics and take these into account, along with the University Research Governance Framework prior to applying for funding.

A.4.2 Some external funding bodies will require full ethical consideration or expedited ethical consideration by the University to be carried out prior to the award of the grant, and in some cases they require this to be carried out when making the grant application itself. Please check the guidance of the funding body.

A.4.3. As well as evidence of ethics consideration the funding body will require the organisation to confirm the research good practice and training requirements they may have as a condition of the grant, this may involve training to carry out the research ethically, as well as insurance and other liabilities.

A5. Decisions

A.5.1 Following consideration of each Application for Ethics Approval, a Research Ethics Committee decision shall be either:

- to approve the application;
- to approve the application subject to conditions or modifications;
- not to approve the application but invite the applicant to resubmit a revised or new application after addressing the concerns/conditions of the committee; or
- not to approve the application.

A.5.2 The applicant(s) shall be notified of the Committee's decision within ten working days of the meeting at which the application was considered.

A.5.3 Any application which has been approved subject to modifications should be submitted with revisions as required to the Committee Secretary within 10 working days of the response from the Committee having been provided to the applicant (and supervisor). The research should not normally begin until such modifications have been provided and approved by the Committee or separately by Chair's action.

A.5.4 If a proposal has been rejected and new information becomes available, a revised application may be submitted.

A.5.5 A Research Ethics Committee may require that changes are made to a research protocol for health, safety and wellbeing reasons. Please see Section 5 of the Code.

A.5.6 Ethical approval, in exceptional circumstances may be granted, with the Committee's approval, outside the Committee meetings (virtual or in person), advice must be sought from the Committee Secretary regarding this.

A.5.7 Approval shall normally be for the duration of the research project, which should be stated in the application form.

A.6. Appeals

A.6.1 An appeal against a decision by a Departmental or a Faculty Ethics Committee may be made to the University Research Ethics Committee only on the grounds that there has been demonstrable material irregularity in the conduct of the Committee's procedures. The decision of University Research Ethics Committee will be final.

A.6.2 The appellant shall submit his/her appeal in writing to the University Research Ethics Committee no later than 10 working days after the receipt of the relevant Committee's decision.

A.6.3 An appeal against a decision with reference to an application considered by the University Research Ethics Committee may be made to the Academic Registrar or nominee only on the grounds that there has been demonstrable material irregularity in the conduct of the University Research Ethics Committee procedure.

A.6.4 The appellant shall submit in writing his/her appeal to the Academic Registrar or nominee no later than 10 working days after the receipt of the University Research Ethics Committee's decision.

A.6.5 The conclusion of an appeal may determine:

- That the appeal is upheld and refer it back to the University Research Ethics Committee for review; or
- That the original decision of the University Research Ethics Committee is upheld and that no further action be taken.

A.6.6 The result of an appeal will be notified in writing to the appellant within 10 working days of the decision being reached.

Addendum B

University of Westminster Research Ethics Committees and guidance on which Committee to apply to

B1. Operation of devolved Research Ethics Committees in the Faculties and Departments

Introduction

1. The University's Code of Practice Governing the Ethical Conduct of Research (the Code) requires Schools to establish effective systems for implementing the Code, for considering research ethics and for providing approval routes for ethically challenging work. This will normally be through Departmental or Faculty Research Ethics Committees (D/FREC) which may be at the Faculty or Department level.

2. A Departmental or Faculty Research Ethics Committee is responsible for operating the ethical approval system for investigations, demonstrations, research and experiments within the Faculty or Department and for providing reports on ethics approval activities to the University Research Ethics Committee (UREC). The Faculty Research Director (or a Research Ethics Co-ordinator or Advisor) will usually act as Chair of the local committee.

3. The Faculty Ethics Advisor or Chair and/or Faculty Research Director will act as a focus for ethics issues within the Faculty and as a liaison with the UREC, which will be responsible for consideration and approval for specific classes of work.

4. For purposes of ethical approval the University's Ethics Code has established the following classes of research:

   Class 1: Work which after due consideration by the Principal Investigator has been found to have no or minimal ethical implications.

   Class 2: Work which has clear ethical implications and which may cause, or has the potential to cause, harm in any form to participants, investigator, animals or to the environment.

   Class 3a: Work for which the approval of an external ethics body is required.

   Class 3b: Work which due to external requirements (for example those of funders) requires institutional confirmation of ethics consideration and/or approval (through UREC)

   Class 4: Work which has significant ethical implications or the potential to cause a significant risk of harm, including research where there may be an institutional/reputational risk (consideration through UREC)

Delegated Authority

5. D/FRECS may consider and approve applications in all of the above classes. However D/FRECs should be aware that Class 3 and Class 4 work will always need institutional confirmation of consideration or approval even where it has already been considered by an D/FREC. Class 3 and Class 4 work may not commence until approval for the work has been obtained either from the UREC or from a relevant external approving body.

6. Faculty Research Ethics Committees may approve applications for generic approval.

7. Table 1 below sets out the consideration and approval routes for each of these classes of work:

Table 1

Class	Definition	Who can approve?	Best Practice	Which Form/s?
Class 1	Research which falls within the definition of the Code and which, after due consideration has been found to have no or minimal ethical implications	Approval not usually required	Consider and complete Form Part A (UREC) and retain for your own or Faculty record	Form Part A or similar local diagnostic tool
Class 2	Research which falls within the definition of the Code, has clear ethical implications and which may cause, or has the potential to cause, harm in any form to participants, investigator, animals or the environment	D/FREC (can escalate to UREC where necessary)	Submit Application for Ethical Approval to relevant ethical approval body in line with the Code and any professional codes of ethics and best practice	Consider and complete Form Part A and Form Part B (UREC) or local relevant form/s
Class 3A	Research for which ethics approval from an external body may be required	The relevant external ethical approval body in line with the Code, national legislation and governance frameworks (e.g. NHS Research Ethics Committees or Medicines and Healthcare products Regulatory Agency {MHRA})	Class 3A lies outside the remit of UREC or D/FRECs, and therefore timely approval, in line with research governance must be sought; See UoW NHS governance guidance. Copy of original documentation to be provided to UREC	Consider and complete Ethical Approval Application Form/s for the appropriate external ethics body and provide these to UREC following final outcome.
Class 3B	Where the University is required by an external body to confirm research ethics approval	UREC	advice and consideration may be given by an D/FREC or advisor but final ethical consideration and/or approval can only be obtained at institutional level (UREC), where a confirmation sign-off can occur	Consider and complete Ethical Approval Application Form/s if research falls into Class 2. If no ethical implications but institutional confirmation is still required by the external body complete Form Part A and submit to the UREC for sign-off
Class 4	Research which is considered to have a significant high risk of harm	UREC	advice and consideration may be given by an D/FREC or advisor but final ethical	Part A and Part B to be submitted to UREC for consideration

			consideration and/or approval can only be obtained at institutional level (UREC), where a confirmation sign-off can occur	

8. D/FRECs may consider applications from all staff within their designated area, whether this be by Department, Faculty or Research Group. For work which crosses Faculty boundaries, D/FRECs should ensure appropriate communication with the counterpart local committee. In the case of collaborative work, consideration and approval should normally be undertaken by the host Faculty of the named Principal Investigator.

9. D/FRECs may develop their own documentation and procedures for local use that may be over and above those currently set out in the Code or detailed in this guidance document.

Terms of Reference and Composition of the University Research Ethics Committee (2016/17)

The Research Ethics Committee is sub-committee of the Research Committee. Its primary focus is to consider general ethical issues concerning activities of research undertaken by University staff and students or other individuals working with the University, in accordance with the Code of Practice Governing the Ethical Conduct of Research (the Code).

Specifically, the Research Ethics Committee is required to:

1. Consider and approve, where appropriate, applications for Ethical Approval by the University staff and students or other individuals working with the University; in accordance with the Code and university guidance;
2. Keep under review the Code of Practice Governing the Ethical Conduct of Research, with particular regard to external developments;
3. Develop, monitor and audit the operation of the University's framework for research ethics, including Faculty ethical approval bodies, decisions and systems, in accordance with the Code;
4. Have oversight of the provision, institutionally, of ethics guidance, development and training for staff, including Faculty Ethics Co-ordinators and Advisors;
5. Consider, where relevant, the impact of the research on the environment from a sustainability perspective;
6. Report to the Research Committee on research ethics matters, including through the Annual Activity Report.
7. Faculty Research Ethics Committees report to Faculty Research Committee and University Research Ethics Committee.

Membership

Chair, nominated by the Chair, Research Committee (1)

Ex-officio
Faculty Research Ethics Committee
Chairs (5)
Polyclinic Manager (1)
University Human Tissue Authority Officer (HTA Designated Individual) (1)
Director, Governance Security and Risk (1) {–currently, nominee: Head of Information Security & Compliance (1)}
Research Development Team Manager (1)

Research Quality & Standards Manager (1)

Nomination/Elected
Doctoral Researchers – one from a STEM area and one from a non- STEM area (2) External Lay Members nominated by the Committee (2-4)

Co-opted, by invitation
Information Compliance Manager (1)

Secretariat
Nomination of the Associate Director, Academic Quality & Standards

A quorum of the Research Ethics Committee shall comprise a minimum of 40% of the members, including the Chair or her/his nominee.

Nominated/elected members shall serve a term of office not exceeding three years commencing 1 August in the year of appointment. Members may serve a maximum of two terms of office.

Declarations of interest shall be considered by the Committee and recorded in the minutes. If it is decided and agreed upon that a Conflict of Interest is deemed to exist, the Committee shall exercise its right to exclude that member from participation in the decision-making (vote), however the member may still participate in a discussion. A Conflict of Interest should be recorded in the Minutes.

Meetings

The Research Ethics Committee shall normally meet 7 times a year where there is business to consider. Also additional meetings may be called by the Chair as deemed necessary to execute the business of the Committee.

Terms of Reference and Composition of the Faculty Research Ethics Committee (2016/17)

The Faculty Research Ethics Committee is sub-committee of the University Research Ethics Committee. Its primary focus is to consider ethical issues concerning activities of research undertaken by Faculty staff and students or other individuals working with the Faculty, in accordance with the Code of Practice Governing the Ethical Conduct of Research (the Code).

The Faculty Research Ethics Committee cannot approve Class 3 or 4 research.

Terms of Reference

Specifically, the Faculty Research Ethics Committee is required to:

1. Support and promote engagement and compliance with the *University of Westminster Code of Practice Governing the Ethical Conduct of Research*
2. Consider applications for approval of work and to approve or not approve, or require modifications to, such proposals;
3. Protect the rights and interests of investigators, human participants, animals, the environment and reputation of the University;
4. Avoid the use of animals for research projects where possible;
5. Assess whether the work proposed is in line with relevant professional codes;
6. Consider the environmental and sustainability impact of the work proposed;

7. Consider whether the work proposed complies with data protection legislation as well as other relevant legislation;
8. Refer individuals for further advice as well as advise staff and students in their locale
9. Maintain records of applications and documentation (i.e. letters, Agendas, Minutes etc.);
10. Promote a culture of ethical research and provide advice to the University Research Ethics Committee;
11. Report to University Research Ethics Committee and Faculty Research Committee on research ethics matters, including through the Annual Activity Report.

Membership

Ex-officio
Faculty Ethics Co-ordinator (Chair) (1)
Faculty Director of Research (1)
Doctoral Programme Co-ordinators (all)
Faculty-specific staff associated with research infrastructure and delivery (e.g. Polyclinic Manager) (all)
University Human Tissue Authority Officer (HTA Designated Individual) (1) (where appropriate)
Research Development Manager (1)

Nominated/Elected
Research Centre Directors associated with the Faculty and/or Departmental nominees, nominated by Heads of Department (up to a maximum of 3)
Faculty Doctoral Researcher (1)
External advisor/lay member, nominated by the Committee (1)

Co-opted, by invitation
Information Compliance Manager (1)

Secretariat
Nomination of the Faculty Registrar

A quorum of the Faculty Research Ethics Committee shall comprise a minimum of 40% of the members, including the Chair or her/his nominee.

Nominated/elected members shall serve a term of office not exceeding three years commencing 1 August in the year of appointment. Members may serve a maximum of two terms of office.

Declarations of Interest shall be considered by the Committee and recorded in the Minutes. If it is decided and agreed upon that a Conflict of Interest is deemed to exist, the Committee shall exercise its right to exclude that member from participation in the decision-making (vote), however the member may still participate in a discussion. A Conflict of Interest must be recorded in the Minutes.

Meetings

The Faculty Research Ethics Committee shall meet a minimum of 3 times a year. Additional meetings may be called by the Chair as deemed necessary to execute the business of the Committee.

Operations

10. D/FRECs should publish a calendar of meeting dates each year but should also make provision for the consideration and approval of applications by Chair's Action between calendared meetings.

11. D/FRECs should ensure the necessary administrative systems are in place for the

maintenance of records, monitoring and reporting and should appoint a Secretary to maintain formal records of applications, meetings and provision of reports and monitoring responses.

12. The D/FRECS should not normally consider applications unless at least 40% of the Committee are able to consider the applications, excluding the Secretary. However, provision may be made to approve applications by Chair's Action or through a smaller panel where business cannot be postponed until the next calendared meeting. In this case, Chair's Action or panel consideration and decisions should be recorded and reported at the next opportunity to the D/FREC.

Supervisor Responsibilities

13. Supervisors are responsible under the Code for:

- The classification of taught UG and PG student research under the Ethics Code and for obtaining advice from the D/FREC Chair, Ethics Advisor or from the Secretary to the UREC where necessary, including in regard to whether consideration and approval by an appropriate ethics body is needed.
- Ensuring that ethical implications are considered during the design phase of all taught UG and PG student research projects, providing advice to students and maintaining records of such consideration.
- Ensuring applications requiring ethics approval are submitted to the UREC or a relevant external ethics approval body
- Where undergraduate or postgraduate students are undertaking research as part of the learning activities of a taught course, they shall be under the active responsible supervision of a member of staff known as the 'supervisor' who will ensure that they comply with this Code.
- Staff applications must be signed by the Dean of Faculty, or Faculty Research Director or their nominee, as appropriate.

Student Responsibilities

14. Students on taught courses are responsible under the Ethics Code for:

- considering the ethical implications of their work from the outset, regardless of whether actual ethical approval is required.
- keep their supervisor informed of any changes to the ethical nature or dimensions in their work, ensuring that any emerging ethical issues are discussed without delay and where relevant for not commencing the work until approval is granted
- To obtain the approval and signature of their supervisor before submitting an application to an ethics approval body

Doctoral Researchers have the status of Principal Investigators for the purposes of an Ethics application, and for insurance cover purposes, the Supervisor will act as Chief Investigator and the doctoral researcher as Principal Investigator.

Addendum C
University Research Ethics Committee Operating Procedure

Section	Title
C.1.1	Operating Procedures
C.1.2	Guiding Principles in Summary
C.1.3	Classification of Research
C.1.4	Committee
C.1.4.8	Procedure

C1. Operating Procedures:

C.1.1 The University Research Ethics Committee is primarily responsible for an ethical approval system for research. In addition to considering submissions for approval and monitoring the work of Departmental or Faculty Research Ethics Committees, the Committee has a duty under the University's *Ethical Policy Framework* to discharge the University's responsibility "to ... protect the rights and interests of human subjects involved in research projects and to protect them from harm"[1]. It is also responsible for upholding the University's position on avoidance of the use of animals in research. The Committee will also be responsible for a Generic Approval system through the Faculty Research Ethics Committees.

C.1.2. Guiding Principles in Summary:

- The University is guided by the fundamental principle that research involving humans and/or animals and/or the environment should involve no more than minimal risk to physical or psychological well-being.
- The University is concerned to protect the rights, dignity, health, safety and privacy of research participants, the welfare of animals and the integrity of the environment.
- The University is also concerned to protect the health, safety, rights and academic freedom of researchers and the reputation of the University as a centre for properly conducted, high quality research.

C.1.3. Classification of Research:

- Research may be defined as "a process of investigation leading to new insights, effectively shared. It includes work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction"[2].

C.1.4. Committee:

1.4.1. **Quorum[3]**

- The quorum for any meeting is 40% of the members with voting rights.

- A meeting must achieve a quorum before it may formally proceed. If the meeting is not quorate at the due time for the meeting to start, the Chair will allow fifteen minutes for latecomers to arrive, after which, if the meeting has still failed to achieve a quorum, it will be adjourned.

[1]University of Westminster Ethical Policy Framework
[2]Universities UK (2012) Concordat to Support Research Integrity
[3]University of Westminster Academic Council Operating Procedures

- If, during the meeting, a member claims that the meeting no longer has a quorum, account of members will be taken. If a quorum no longer exists, the
- Chair will declare the meeting adjourned. Such declaration does not invalidate decisions taken before the question was raised.

1.4.2. Conflict of Interest

- Conflict of interest by members will be declared in advance of the Committee meeting and they will not be able to vote, but may be able to remain present or participate in a discussion if invited by the Committee.
- A conflict of interest register should be maintained per meeting.

C.1.4.3. Decisions:

The Committee shall consider each Application for Ethics Approval, and the decision of the Committee shall be;

- to approve the application;
- to approve the application subject to conditions or modifications;
- not to approve the application but invite the applicant to resubmit a revised or new application after addressing the concerns/conditions of the committee; or
- not to approve the application.

The Committee will refer individual proposals or Applications for Ethics Approval for external consideration and/or approval as necessary.

The applicant shall be notified of the Committee's decision within ten working days of the meeting at which the application was considered.

C.1.4.4. Approval subject to conditions or modifications;

An application which has been approved subject to conditions and/or modifications should be submitted with revisions as required to the Committee Secretary within 10 working days of the response from the Committee having been provided to the applicant (and Supervisor where relevant).

Approval shall normally be for the duration of the research project which should be stated in the application form.

The Committee may require as part of the Application for Approval, either written confirmation that the University of Westminster Insurers are content for their policy to apply, or that appropriate additional insurance cover has been arranged.

C.1.4.5. Full Approval;

Please refer to the terms and conditions of your Final (full) Approval letter.

Relevant legislation and professional guidance should be applied to all research work as well as the University Research Governance Framework.

C.1.4.6 **Not to approve the application (with or without an invitation to submit a revised or new application);**

The Committee may request you submit a new application, with or without advice to you (and your Supervisor where relevant). The new application will receive a new Ethics Application Number and will be considered by the Committee at another meeting.

The Committee may not request you submit a new application. Further advice may be sought by an Ethics Advisor, Supervisor, Faculty Research Director or the Committee directly.

If a proposal has been rejected and new information becomes available, a revised application may be submitted.

C.1.4.7. **Chair's Action:**

In exceptional cases, Chair's Action can be applied in between scheduled meetings, but the use of this will be avoided where a decision by the Committee can be made by correspondence instead. Where Chair's Action has taken place it will be reported and ratified at the next scheduled meeting.

Where the Committee has set conditions, and it agrees that these conditions can be reviewed and considered as having been met by the Secretary, this can occur outside of scheduled meetings.

A sub-panel of the Committee would usually consist of three members (including one Chair) and excluding the Secretary, one member to be external to the applicant's Faculty.

Applications reviewed by correspondence or other virtual means, will be sent to the entire Committee for consideration, the Secretary will request that as many members as possible consider this. Normally the considerations of at least 40% of the members should be conveyed back to the applicant in the form of a Conditions Letter.

C.1.4.8 Procedure:

The University aims to promote good academic practice in research by asking individual researchers to complete and retain an initial assessment document (Ethics Application form Part A for example), to demonstrate that ethical implications have been considered. Where there are ethical implications, an Ethics Approval form must be completed and submitted to the appropriate Research Ethics Committee.

1. All applications for research ethics approval to the University Research Ethics Committee should be submitted using the research ethics approval application forms.
2. Applications must be prepared in accordance with the format approved by the University Research Ethics Committee.
3. Applications from Students must be checked and signed by the Supervisor.
4. Staff applications must be signed by the Dean of Faculty, or Faculty Research Director or their nominee, as appropriate.
5. Ethical approval shall be obtained before the commencement of any research which has ethical implications. The University Research Ethics Committee may allow part of the research to commence, prior to full approval being granted for those aspects of the research which do not relate to the ethical implications but which are intended to contribute to the final piece of research.
6. The University Research Ethics Committee reserves the right to request modifications or clarifications of any applications/proposals.
7. A Principal Investigator or researcher cannot attend any discussion involving their own research proposal even if they are members of the Committee (except by invitation).
8. Members must declare any special interest including personal, faculty or departmental or financial etc.
9. If the Chair is involved in any such conflict of interest(s) then the vice-chair or nominee will take over until the discussion is concluded.
10. The University Research Ethics Committee will seek expert guidance or advice as required through the co-opted membership policy.
11. Applications for University Research Ethics Committee approval should reach the Secretary no later than ten working days before the meeting at which they are to be considered.
12. Committee meeting dates are published in advance of the Academic Year start, in the University Calendar.