UNIVERSITY OF WESTMINSTER

University of Westminster Code of Practice Governing the Ethical Conduct of Research 2020/21

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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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, including working ethically for all types of research as outlined in the Universities UK 'Concordat to Support Research Integrity' (2019).

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 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 College 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 via the research ethics self-assessment form (Form Part A), prior to commencement, in line with good research practice. This allows the researcher to document that due consideration was given to ethical issues and a record is maintained of such consideration, even where risk issues are minimal or none (e.g. Class 1, see Section 2.1. for definition).

1.6 Where the self-assessment form upon completion shows the research as low risk, this does not require submission to a Research Ethics Committee, unless it is a requirement of a professional body, funder or regulatory authority. A record should be kept by the researcher or supervisor in the University's online ethics review system.

1.7 Where a self-assessment form requires the completion of a full research ethics application form (Form Part B), the researcher is required to submit this to the relevant Research Ethics Committee.

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.

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 review by a Research Ethics Committee 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 with the Research Ethics Committee .

1.8 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 16).

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 Health Research Authority (HRA) may classify a project as an audit or service evaluation whilst the University may still view the project as research. This may need to be considered when assessing what, if any, ethical review considerations and/or management permissions are required.

2.3. Classification of research ethics proposals are not exhaustive and research may involve a combination of these classifications with regards to ethical implications or risk levels (as below in Sections 2.4-3.14.) and therefore the highest Class numerically (Class 3 or 4) should normally be followed in terms of process for ethical review.

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

2.4. Class 1 research encompasses research which falls within the definition of this Code and which, after research ethics self-assessment has been found to have no or minimal potential ethical implications. In these circumstances ethical review by a Research Ethics Committee is not normally required unless this is required by a sponsor, funder, professional body, external organisation or regulatory authority (see Classes 2 and 3). The Part A research ethics application form 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.

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

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 review from a Research Ethics Committee, either at College 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). Some of this research will fall under regulatory and statutory requirements meaning it will need to be considered for research ethics review or permissions (or both, by an external research ethics review body and/or Research and Development (R&D) Office. Where this applies the examples below are highlighted in bold font and become by their nature Class 3:

Below are only a few examples of types of participants:

- 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

the research could also involve:

- the collection and use of human tissue as regulated by the Human Tissue Authority and as defined by the Human Tissue Act (2004) where Health Research Authority review is not required;
- **the administering of drugs, substance(s), or clinical intervention (the University does not carry out at its premises clinical trails involving medicinal products [CTIMPS])**
- 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, or adverse representation of individuals or groups of people

- personal or sensitive data including but not limited to:
- racial or ethnic origin;
  political opinions
- religious or philosophical beliefs
- trade union membership
- sex life data
- sexual orientation data
- gender reassignment data
- health data
- genetic or biometric data
- criminal convictions offences data
- 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-identification of personal or sensitive data following pseudonymisation; which is described by the General Data Protection Regulation as "…the processing of personal data in such a manner that the personal data can no longer be attributed to a specific data subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the personal data are not attributed to an identified or identifiable natural person."[2]

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

3. Class 3: research involving an external organisation's role and/or requirement

3.1. 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].

3.2. Class 3 is research with legal or regulatory requirements that falls outside the scope of the University and College Research Ethics Committees, and for which ethical review and/or R&D approval must be carried out or gained by the relevant agency or body e.g. social care research.

3.3. Examples of Class 3 include but are not limited to:

- research involving the Health Research Authority (Department for Health and Social Care), NHS patients, clinical trials, Her Majesty's Prisoners and Probation Services, Ministry of Defence, Human Tissue Act, and the Mental Capacity Act.

3.4. The research ethics application must be submitted to an external ethical review body (and/or R&D office), however the College Research Ethics Committee

must be informed of and support the initial application to the external body. The College Research Ethics Committee may wish to escalate an application to the University Research Ethics Committee. Where an application is made to the Health Research Authority, which requires University Sponsorship as defined by the 'UK Policy Framework for Health and Social Care' (Health Research Authority, 2017), a light touch ethical review must be undertaken by the University Research Ethics Committee in the first instance.

3.5. Where external ethical review or governance permissions have been gained, the researcher must submit a copy of the final ethics application (including all supporting or associated documents) and ethics approval letter to the College Research Ethics Committee. Research Ethics Applications associated with Health Research must be submitted to the University Research Ethics Committee in advance, as below.

3.6. Where the researcher requires University Sponsorship as defined by the Health Research Authority, the draft *Integrated Research Application System (IRAS) Form* must be submitted, along with Forms Part A and B, in the University's online research ethics system for a light-touch ethical review by the University Research Ethics Committee.

3.7. The compliance and governance issues involving University Sponsorship would be considered outside of the Research Ethics Committee structure, at University senior management level, but only post a successful ethical review by the University Research Ethics Committee. Further details on University Sponsorship can be gained by contacting the Research and Knowledge Exchange Office.

3.8. A researcher cannot submit an IRAS form to the Health Research Authority where the University is listed as Sponsor, without gaining the permission from the Sponsor in advance, as outlined in 3.6 and 3.7 above.

3.9. Where external favourable ethical opinion or approval has been gained, from any external organisation, the University may consider its own duty of care, as well as whether the research is in the interests of the University if such research is being primarily carried out under the aegis of the University.

3.10. Where an external body, e.g. Research Council, European Commission, industrial collaborator, professional body or other external organisation requires evidence of research ethics review by the University an application using the University's online research ethics review system should be made to the College Research Ethics Committee of the Principal Investigator (for Class 1 and 2 research).

3.11. Class 3 applications must be submitted to the College Research Ethics Committee for review. It is important that the Research Ethics application accurately reflects the protocol detailed in any external research proposal (regardless of whether it was funded research or not).

3.12. The College Research Ethics Committee may escalate an application to the University Research Ethics Committee.

Class 4 is 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**

3.13. Class 4 research encompasses the definition within this code, which includes, but is not limited to research that may involve higher risks to researchers, 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 Researchers should seek advice on a case by case basis from the Chair and Secretary of the University Research Ethics Committee. Class 4 may involve, but is **not limited** to:

- security sensitive research
- research which has the potential for serious risk of harm or adverse events
- research which poses a risk of potential reputational damage to the University

3.14. The University may consider any classification of research to be defined as Class 4 under its own discretion. An application which is considered Class 4 would be escalated to the University Research Ethics Committee for research ethics review, which in turn may be required to consult with other bodies within the University governance structure.

4. Pedagogic Practice and Pedagogic Research

4.1. Pedagogic research is distinct from the acquisition of data for normal educational development and quality assurance purposes. Examples of the latter i.e. 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 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 research ethics review.

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

4.6. 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.

4.7. Data acquisition or investigations conducted as part of regular pedagogic or professional activities may require ethics consideration or review 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 there is a student/teacher or similar relationship, care must be taken by the researcher to avoid any circumstances where the student may feel obliged to participate and explain that non-participation (without reasons being given) would have no adverse effect on the outcome of the student's studies.

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

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

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

4.8. 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.

4.9. A record of all pedagogic research which is Class 1 should be kept by the Principal Investigator via the University's online 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 College Research Ethics Committee for their information. Class 2 and 3 pedagogic research would be submitted for review to the College Research Ethics Committee (unless external review was required).

5. **Generic Approval**

5.1. Generic approval may be granted to research staff by the College 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.

5.2. A module leader may apply for generic approval for a cohort of UG or taught PG students conducting Class 1 or Class 2 research <u>where ethical implications do not differ in the course of the research studies</u>.

5.3. The module leader 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], in class or as part of their coursework outside of the University's online research ethics management system.

5.4. Where generic approval is granted, it will be granted for one academic year, in the first instance. It will be the Principal Investigator's responsibility to inform the College Research Ethics Committee of any changes to the project within that period.

5.5. Generic approval may not be applied for any research with legal or regulatory requirements to conduct ethical review outside the University's ethical review structures, by the relevant agency or body. An example only is research regulated by the Health Research Authority.

5.6. 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 College Research Ethics Committee which had previously considered and approved the generic application, unless the proposed changes escalate the classification of the research (this *may* cause the research to no longer be applicable to generic approval).

6. Participants, Researchers and others involved in the Research

6.1. Safeguarding of Participants

6.2. All reasonable measures must be taken to safeguard the participants' health, to protect their psychological wellbeing, and to respect their privacy, data, tissue or other human material. The researcher is also viewed as a participant in the research and should take steps to protect his/her own health and wellbeing at all stages of the research.

6.3. 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.

6.4. Where research 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 review by a research ethics body prior to commencement of fieldwork research, the PI should provide the full contact details and background to the nominated Fieldwork Team leader.

6.5. 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 the participation as a matter of course, and the Research Ethics Committee would expect that this provision be designed into the investigative procedure.

6.6. 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 Sheet (or similar) 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.

7. Adverse events and Incident Reporting

7.1. An adverse event, incident or near-miss of a safety, health and well-being nature, relating to **any research discipline** must be reported by the Principal Investigator

using the University's Safety, Health and Wellbeing online 'incident or accident reporting system' for all University related activity on University premises or University organised off-site activities e.g. research fieldtrips: https://westminsterhealthandsafety.co.uk/Home/home.aspx.

7.2. An **adverse event** (AE) is any event that: caused harm or had the potential to cause harm to staff, students or visitors; led to or had the potential to lead to a breach of security of the premises and the contents contained therein; caused harm or had the potential to cause harm to stored human tissue (including loss); gave rise to an internal inquiry[6].

7.3. A data breach is an adverse event. However, it cannot be reported using the University's Safety, Health and Wellbeing online 'incident or accident reporting system'. It must be reported to the University's Data Compliance Team within 72 hours of having occurred by the Principal Investigator via email to dpa@westminster.ac.uk

7.4. An **incident** can be considered an untoward event or sequence of events that has caused or has the potential to cause damage; harm; or a direct negative impact to an organisation's business, security, reputation, facilities, personnel, students, safety, health, environment; an event where an important policy, procedure, or practice was not followed by staff leading to detriment or the potential detriment of the above.[7]

7.4.1. Complaints shall be treated as an "incident". However, any research participant complaint relating to Human Tissue Authority research must follow the Standard Operating Procedure (SOP) for **HTA Managing Participant Complaints** (UoW Ref. No. HTA SOP-011).

7.5. A **'near-miss'** is where an incident could have happened if intervention had not been made.

7.6. Any adverse event, incident or near-miss affecting a participant or Investigator, a deceased donor's tissue, or other persons, during or after a research project must be reported without exception or delay (within 24 hours) to the relevant Research Ethics Committee (where ethical approval is in place) by the Principal Investigator, **AND** logged on the University's Safety, Health and Wellbeing online 'incident or accident' reporting system (other than the exceptions above in sections 7.3. and 7.4.1. which cannot be logged on the 'incident and accident' reporting system): https://westminsterhealthandsafety.co.uk/Home/home.aspx . The research must be halted immediately.

7.7. Any adverse event, incident or 'near-miss' affecting a participant or deceased donor's human tissue (as regulated by the Human Tissue Authority) **must** be reported to the Safety Health and Wellbeing Team (as above) and the University Research Ethics Committee in line with the Standard Operating Procedure (SOP) for **HTA Adverse Events and Incident Reporting** (UoW Ref. No. HTA SOP-010). Mitigating actions to address the adverse event would need to be taken immediately by the Principal Investigator with advice from the University's Human Tissue Authority (HTA) Designated Individual.

7.8. Participants must be informed of their right to appropriate support were there to

be a subsequent adverse effect. Where the research involved human tissue, the Human Tissue Authority's codes of practice[8] would need to be referred to and adhered to by the Principal Investigator with regards to support for participants or donor's representatives. The Head of College's contact details should be provided to the Participant.

7.9. Researchers should be familiar with any legal or regulatory requirement for them to report Adverse Events to an external organisation where one exists.

8. Urgent safety measures (all studies)

8.1. Where research was internally reviewed for research ethics implications, 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 immediately for further review. The research shall be halted immediately and until such subsequent approval is received (if appropriate). The researcher should attempt to contact the Chair or Secretary of the research ethics review body immediately upon halting research where there has been a potential increased danger or risk.

8.2. "Health Research Authority allows for urgent safety measures to be taken by the Sponsor or investigator where they "may take appropriate urgent safety measures in order to protect research participants against any immediate hazard to their health or safety, without prior authorisation from a regulatory body.

The main REC (and the MHRA for CTIMPs) must be notified immediately and in any event within three days, in the form of a substantial amendment, that such measures have been taken and the reasons why.

Copies of the information should be provided to the REC that approved the study using the appropriate REC safety reporting cover sheet."[9]

9. Selection and Recruitment of Participants and Declaration of Incentives

9.1. 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.

9.2. 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.

9.3. Researchers must carry out literature reviews and provide a brief summary of these with their proposal in order to inform a research ethics review body of details of similar research already undertaken.

9.4. 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.

9.5. Any proposed financial or other incentive to participate to staff or Schools should be declared in the research protocol and to participants and will be subject to the approval of a Research Ethics Committee.

9.6. 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.

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

9.8. The Principal Investigator must 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.

9.9. Any recruitment materials should include the ethics application reference number and Research Ethics Committee, or other research ethics review body name, which provided the research ethics approval.

9.10. In case of complaints, the contact details, of the Head of School should be provided to participants. Where the Head of School is directly involved in the research, the contact details of the Head of College should be listed for participants. Complaints should not be handled by the research team or supervisors of student researchers. Complaints must be treated as an incident and reported to the relevant Research Ethics Committee (See Adverse Events section).

10. Valid Consent and Participant Information

10.1. Valid and appropriate consent should be obtained orally or in writing and must be documented before any research can begin. If oral consent is being sought, the Principal Investigator must ensure it is documented and a reason for not gaining written consent must 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, in consultation with relevant professional codes e.g. Code of Conduct of the Market Research Society.

10.2. 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 consideration and review would still be required. Reasons for not gaining consent should be clearly articulated to an ethical review body.

10.3. Valid and appropriate consent in this Code of Practice is defined as: participant's consent (or the Representative of a deceased donor) given freely and independently, in the absence of coercion, in light of information provided to the participant. Principal Investigators are required to inform participants or the Representative of a deceased donor about anything that could affect their decision

to take part. Consent may need to be an ongoing process for participants of a study.

10.4. Staff working under the University's Human Tissue licence must follow the University's Standard Operating Procedure (SOP) **HTA Seeking Consent** f**or the removal**, **storage and use of relevant material for the purpose of research** (UoW ref. SOP HTA-009).

10.5. The Human Tissue Authority allows for a small number of consent exceptions, details of which can be found in the Human Tissue Authority's Code E Research, of the Code of Practice and Standards. However, where the Consent 'exceptions' are being proposed for Human Tissue related research, a University Ethics Committee (REC) is not able to approve such research as it does not fall within the definition of a 'recognised REC'.

10.6. "A university ethics committee is not, for the purpose of the (Human Tissue Authority) consent exception, considered to be a recognised REC. Therefore, consent is still required for tissue to be used in a research project approved by a university ethics committee, even if it uses tissue from the living and the researcher is not in possession, and not likely to come into possession, of information identifying the participant."[10]

10.7. "For the purposes of the HT Act, recognised RECs include all RECs within the Research Ethics Service of the four UK countries (although the HTA does not license storage of tissue for research in Scotland)."[11]

10.8. "Recognised RECs can consider all applications relating to research involving the use of human tissue, even where this is conducted outside the NHS."[12]

10.9. The Participant Information Sheet (or similar participant facing material) should inform the participant of the following in plain, jargon-free language:

- why they have been chosen as a potential participant
- 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 (applies to staff as well as students)
- exactly what the participant is required to do, how often and for how long
- whether there is an inclusion or exclusion criteria and what this is
- any harm which might occur as a result of participation
- the right to complain, and to whom, in the event of a problem or perceived issue in the research study or with the research team
- the right to withdraw, or withdraw their data, from the investigation as practicable
- 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 for further questions and to report adverse or serious events
- 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.
- any limitations of confidentiality
- consent for future research

10.11. A copy of the Participant Information Sheet must be retained together with the signed Consent Form (where these exist), 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.

10.12. Some participants may lack the ability to give their consent to participate in research, for example, including but not limited to:

- 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.

- For any other situation where potential participants may lack the ability to consent, the Mental Capacity Act must be referred to and an application provided to the Social Care Research Ethics Committee (https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/search-research-ethics-committees/social-care-research-ethics-committee/).

10.13. Where the participant is vulnerable (medically, socially and/or psychologically), greater care needs to be taken in obtaining consent.

10.14. In cases where participants have limited command of written English the information and consent, 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.

10.15. Participants may also withdraw their data, without providing a reason, from the investigation as far as it is possible. In the case of a participant leaving the investigation, and providing a reason, any comments made, or explanations given, should be recorded and kept by the researcher.

10.16. 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.

10.17. 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.

11. Health and Safety (including Health and Safety Risk Assessment)[13]

11.1. "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).

11.2. 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"

11.3. "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."

11.4. 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

11.5. Planning for Research

11.5.1. **"**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."

11.5.2. "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."

11.5.3. "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."

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

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

12.2. 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.

12.3. 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 Head of College 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.

12.4. 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.

12.5. 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.

12.6. 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).

12.7. 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.

12.8. 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.

12.9. 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.

12.10. 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).

12.11. 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.

13. Location and environment of the Research

13.1. Joint Research Activities

13.1.1. 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.

13.1.2. 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 Governing the Ethical Conduct of Research*.

13.1.3. In the case of collaborative research or research involving non- employees of the University, a Research Ethics Committee will focus on Section 12 (Insurance), and Section 8 of the application form (External Approval), before considering the proposed research 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 ethical approval be granted before

*the University of Westminster does **not** hold a Home Office licence under the Animals (Scientific Procedures) Act 1986 (ASPA)

the project may commence, if this is within the University's remit, for example if there are no legal or regulatory requirements for ethical review outside of the University's ethical review structures.

13.1.4. Research Ethics approval must 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.

14. Research Conducted Abroad

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

14.2. 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 College Research Ethics consideration (including consideration of any conditions or approvals set elsewhere).

14.3. 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.

14.4. 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 12.

14.5. 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[14].

15. Location of the Investigation & Apparatus

15.1. 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.

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

15.3. 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 (and for Human Tissue Authority related work, in accordance with the standards and procedures of the Human Tissue Authority's Codes and the University's own Human Tissue Authority Quality Manual and Quality Management System, including associated Standard Operating Procedures (SOPs).

15.4. Where there has been a failure of equipment or apparatus this would be regarded as an adverse event or incident.

15.5. Storage of relevant material under the University's Human Tissue Authority Licence must only be conducted at the licensed premises of 115 New Cavendish Street.

16. Research Data Protection and Security

16.1. Data Security and Confidentiality

16.1.1. 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.

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

16.1.3. The handling of all personal data, including recordings and images, must comply with the General Data Protection Regulation (GDPR) and the Data Protection Act (2018).

16.1.4. 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.

16.1.5. With respect to digitisation of participant data, proposals for research 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 General Data Protection Regulation (GDPR) and the Data Protection Act (2018).

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

- The General Data Protection Regulation (GDPR) Article 4 (11) and the The Data Protection Act (2018) defined consent as "any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of personal data relating to him or her"[15]. Consent to the proposed research must be recorded and accompanied by a clear indication, at the time of collection, as to how the personal data will be processed, shared and managed.
- Research activities should follow University guidance on where to store documents and data, and if appropriate, use specialist research infrastructure and data storage as advised, to ensure security and access control and all relevant policies and procedures are adhered to. 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.
- File protection (Encryption) **must** be in operation on desktop and laptop computers used for research that holds research related named individual data.
- 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.
- 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 Head of College.

16.1.7. Research records, including research data, must be managed in line with the University's Records Management Policy and the University's Research Data Management Policy. Records should be securely disposed of in line with any legal, regulatory, best practice and research funding requirements. If personal information has been collected, then specific measures to ensure that information is securely disposed of must be implemented.

17. Responsibilities

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

17.2. 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 review 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.

17.3. 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) and for meeting any external obligations, in order to proceed with their research. For insurance purposes a supervisor of a doctoral researcher would act as a Chief Investigator.

17.4. The Code requires that the University or College Research Ethics Committees and Research Ethics Representatives 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).

17.5. Heads of College and Heads of School 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 College or School complies with the Code.

17.6. A named College Research Ethics Co-ordinator is to be designated to take responsibility for all aspects of research ethics within the College and 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.

17.7. 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.

17.8. 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.

17.9. 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 College Research Ethics Chair, or from the Secretary to the University Research Ethics Committee. If it is not clear whether the research falls within Class 1, it should be forwarded to an appropriate Research Ethics Committee for review.

17.10. Individual staff members and students are required to comply with this Code. For cross-College projects, or where there is collaboration with an external organisation, responsibility shall lie with one named Principal Investigator.

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

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

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[3] UK Research Integrity Office (UKRIO) (2009) Code of Practice for Research: Promoting good practice and preventing misconduct, page 5 https://ukrio.org/wp-content/uploads/UKRIO-Code-of-Practice-for-Research.pdf

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[7] See citation 6 above.

[8] Human Tissue Authority, Codes of Practice and Standards https://www.hta.gov.uk/hta-codes-practice-and-standards-0

[9] Health Research Authority, Safety Reporting https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/safety-reporting/

[10] Human Tissue Authority, Code of Practice and Standards; Code E Research, pages 16-18 https://www.hta.gov.uk/sites/default/files/Code%20E%20-%20Research%20Final.pdf

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Addendum A

Research Ethics review and approval process information

A1 Research ethics review and approval process

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

A.1.2 A completed Research Ethics 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 review using the using the University's online research ethics system. All other undergraduate students requiring ethical review (Class 2 or above only) would require their Supervisor to complete the Research Ethics Application in collaboration with them, via the University's online research ethics system.

A.1.4 Where a Research Ethics Application for ethical review must be provided to an external ethical review body, and the University does not have the remit to provide its own review and approval, a researcher may not proceed until external approval or favourable opinion has been gained and this approval or favourable opinion has been confirmed by the University.

A.1.5 When providing evidence of external ethical approval or favourable opinion to the University, copies of the completed and final external research ethics application form and any supporting documentation and conditions and/or approval/favourable opinion letters received by the researcher, must be provided to the relevant University or College 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. The University may consider the ethical review is sufficient depending on the standards followed by the external organisation, or may choose to conduct its own review and/or set additional research ethics related conditions. The University retains its right to request any additional compliance or governance conditions.

A.1.7 Additional external 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.

A2. Procedure

A.2.1. The University aims to promote good academic practice in research by asking individual researchers to complete and retain a research ethics self-assessment form to demonstrate that research ethics implications have been considered – this will be the Part A Research Ethics Application Form. . Where there are potential research ethics implications, an application for ethical review must be completed and submitted to an appropriate Research Ethics Committee or research ethics review body.

Supervisors for taught students are responsible that the Research Ethics

Application meets required standards in terms of research design , methodology and the identification of ethical issues.

A.2.2. All doctoral researchers must complete the Annual Progress Review 1 (APR 1) which is scrutinised and signed off by the Director of Studies, an assessor independent of the supervisory team, the School Doctoral Coordinator and the Graduate School Board. Completion of this process provides evidence that research design and a provisional assessment of ethical implications have 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 initially scrutinised by a supervisor.

A.2.4 Applicants and Supervisors are encouraged to consult the Research Integrity Office (UKRIO) researcher check-list available at https://ukrio.org/publications/checklist-for-researchers/

A.2.5. Applications for research ethics review are dealt with at respectively College or University level (University or College Research Ethics Committee).

A.2.6. All proposals for conducting research field work (off-site research) in the UK or overseas requires consideration and completion of a risk assessment in line with University Safety, Health and Wellbeing requirements.

A.2.7. All staff and students submitting proposals for conducting research fieldwork in the UK or overseas will be required to follow the protocol as approved by the relevant Research Ethics Committee, in line with this Code of Practice, in order to avoid invalidating insurance cover. Any proposed changes to protocol would require re-consideration by the appropriate ethics review body and a new insurance cover note where needed, prior to commencement. Urgent Safety Measures are detailed earlier in this Code.

A.2.8. All proposals for conducting research fieldwork and/or for travel for purposes of University research, require travel insurance cover in line with the University Procurement policy requirements.

A.2.7 Ethical approval shall be obtained before the commencement of any research which has the potential for 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 College Research Director, Supervisor or other designated named person e.g. Research Ethics Committee Chair or 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 and proposals received for review.

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 to an ethics review body. By signing the application, the applicant confirms this has been carried out 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 risk 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 research 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 College 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, School, College or financial.. 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 must be recorded in the Minutes 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 review , should reach the Secretary no later than ten working days before the meeting at which they are to be reviewed.

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 only.

A.3.2 This Code contains further details regarding ongoing ethics consideration of a research study by the Principal Investigator, including the need to re-visit consent and participant information where new data or new participants or donors 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 review body, where potential ethical implications exist and where the data is not currently in the public domain. Similarly other changes in the protocol which are significant and/or raise potential ethical implications, which did not exist or were not known previously when review or consideration was given by an ethics approval body or in a research ethics self-assessment respectively, should be submitted for review as a ‘significant amendment to protocol’ in the University’s research ethics online system .

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 Codes and Policies prior to applying for funding.

A.4.2 Researchers proposing to undertake contract research or consultancy should consult and consider the good practice and ethics guidance within the contract or Company Corporate Social Responsibility Statements (or similar professional good practice guidance).

A.4.3 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 review and consideration the funding body may require the University to confirm the research good practice and training requirements 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 and review of each Research Ethics Application, 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.

A.5.2 On occasion a Research Ethics Committee may not be able to reach any of the decisions outlined above, without a request for further information from the Principal Investigator or to invite the Principal Investigator to a meeting of the Committee to discuss the proposal further.

A.5.3 In any case, the Principal Investigator shall be notified of the Committee's decision or request for further information, within ten working days of the meeting at which the application was considered.

A.5.4 Any application which has been approved subject to conditions and/or clarifications should be submitted with revisions or response to clarifications as required, to the Committee Secretary within 10 working days of the response from the Committee having been provided to the Principal Investigator. The research should not begin until a response to conditions has been provided and approved by the Committee, or by Chair's action.

A.5.5 If a proposal has been rejected (not approved) and new information becomes available, a revised application may be submitted by the Principal Investigator.

A.5.6 A Research Ethics Committee may require that changes are made to a research protocol for health, safety and wellbeing reasons. Please see Section 12 of the Code.

A.5.7 Research ethics approval, in exceptional circumstances may be granted, with the Committee's approval, outside the Committee meetings (e-meeting or in person). Advice should be sought from the Committee Secretary regarding this.

A.5.8 Approval shall normally be for the duration of the research project, which should be stated in the Research Ethics Application form.

A.6. Appeals

A.6.1 An appeal against a decision by a College Research 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 the University Research Ethics Committee will be final.

A.6.2 The appellant shall submit his or 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 Research Committee 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 or her appeal to the Research Committee 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 referred 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 for research ethics review

B1. Operation of devolved Research Ethics Committees in the Colleges

Introduction

1. The University's Code of Practice Governing the Ethical Conduct of Research (the Code) requires Colleges to establish effective systems for implementing the Code, for considering research ethics and for providing approval routes for ethically challenging work. This will be carried out through College Research Ethics Committees (CRECs).

2. A College Research Ethics Committee is responsible for operating the ethical approval system for research including contract or consultancy research, within the College and for providing reports on ethics review and approval activities to the University Research Ethics Committee (UREC). The College Research Director (or the Research Ethics Coordinator) will usually act as Chair of the College committee.

3. The College Research Ethics Coordinator or Chair or College Research Director will act as a focus for research ethics issues within the College and as a liaison with the UREC.

4. For purposes of ethical consideration, review and 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 potential ethical implications and which may cause, or has the potential to cause, risk of harm in any form to participants, donors, the investigators, animals, the environment or others.

   Class 3: Work for which the approval of an external ethics review body and/or R&D office is required.

   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 and/or reputational risk (consideration through UREC).

Delegated Authority

5. CRECs may consider and approve applications in all of the above classes. However CRECs should be aware that Class 3 where University Health Research Authority Sponsorship is requested and Class 4 research will always need institutional confirmation of review and approval even where it has already been considered initially by a CREC. Class 3 where University Health Research Authority Sponsorship is requested and Class 4 research may not commence until approval for the work has been obtained either from the UREC or from a relevant external review body.

6. College Research Ethics Committees may approve applications for generic approval which fit the criteria of generic research within this Code.

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

Table 1

Class	Definition	Who can approve?	Procedure	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 (unless it is a requirement of an external body)	Consider and complete Form Part A (University's online research ethics system) and retain for your own and College record Where there is an external requirement for ethical review, even for low or no risk research, the Form Part A (University's online research ethics system) should be submitted to CREC.	Form Part A (research ethics self-assessment form) or similar local diagnostic tool
Class 2	Research which falls within the definition of the Code, has clear potential ethical implications and which may cause, or has the potential to cause, harm in any form to participants, donors, investigator, animals, the environment or others.	CREC (can escalate to UREC where necessary)	Submit a Research Ethics Application 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 (University's online research ethics system).
Class 3:	Research for which ethics approval from an external body is 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 3 lies outside the remit of UREC or CRECs, and therefore timely submission, in line with research governance requirements is necessary. An initial light-touch research ethics review is carried out by CREC, except in the case of requests from University staff and students for Health Research Authority defined Sponsorship whereby the light-touch ethics review would be conducted by UREC.	Consider and complete Research Ethics Application Forms and provide a draft of the external ethics application form For an initial light touch review to CREC or UREC as appropriate.

				Sponsorship requests are considered by the University following a successful internal light-touch research ethics review. Contact the Research Office for guidance.
Class 4	Research which is considered to have a significant high potential risk of harm including to the University or the University's reputation	UREC	advice and consideration may be given by an CREC but final ethical consideration and approval can only be obtained at institutional level (UREC), where a confirmation sign-off can occur, on occasion in liaison with other bodies at the University, including senior management.	Consider and complete the Research Ethics Application Form (Part A and Part B) to be submitted to UREC for consideration . Class 4 may be applied as a research classification by a College or University Research Ethics Committee at its discretion.

8. CRECs may consider applications from all staff within their designated areas in the College for example all Research Groups, Schools or centres. For research which crosses College boundaries, CRECs should ensure appropriate communication with the counterpart local committee. In the case of collaborative research, consideration and approval should normally be undertaken by the host College of the named Principal Investigator.

9. CRECs 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 with prior approval from UREC and within the limitations of the University's online research ethics system.

Terms of Reference and Composition of the University Research Ethics Committee (2020/21)

The Research Ethics Committee is a 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 Consideration 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 College ethical review 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 College Research Ethics Co-ordinators and Advisors;
5. Consider major gift acceptance which may require ethical scrutiny, separate from research ethics scrutiny, in liaison with the relevant teams
6. Consider, where relevant, the impact of the research on the environment from a sustainability perspective;
7. Directly report to the Research Committee on research ethics matters, including through the Annual Activity Report.
8. Have overview of College Research Ethics Committees which report to College Research Committee and University Research Ethics Committee.
8.9. Manage and monitor the Human Tissue Licence and the Human Tissue Steering Group.

Membership

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

Ex-officio
- College Research Ethics Committee Chairs (3)
- Polyclinic Manager (1)
- University Human Tissue Authority Officer (HTA Designated Individual) (1)
- Head of Research Office (1)

Nomination/Elected
- Doctoral Researchers (2)
- External Lay Members nominated by the Committee (2)

Co-opted, by invitation
- College Research Ethics Committee (academic) representatives (3)
- Information Compliance Manager (1)
- Data Security Manager (1)
- Contracts Partner (1)
- Research Development and Awards Team Manager (1)
- Research Environment and Scholarly Communications Lead (for Research Data Management) (1)
- Research Fellow (for Health Research Authority {NHS} Advice) (1)

Secretariat
Nomination of the Head of Research Office

Terms of Reference and Composition of the College Research Ethics Committee (2020/21)

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

The College Research Ethics Committee cannot approve 4 research.
Terms of Reference
Specifically, the College 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 Ethical Consideration by the University staff and students or other individuals working with the University, in accordance with the Code and University guidance
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 Assess whether the work proposed is in line with relevant professional codes;
5. Consider the environmental and sustainability impact of the work proposed;
6. Consider whether the work proposed complies with data protection legislation as well as other relevant legislation;
7. Refer individuals for further advice as well as advise staff and students in their locale
8. Maintain records of applications and documentation (i.e. letters, Agendas, Minutes etc.);
9. Promote a culture of ethical research and provide advice to the University Research Ethics Committee
10. Report to University Research Ethics Committee and College Research Committee on research ethics matters, including through the Annual Activity Report.

Membership

Ex-officio
College Research Ethics Co-Coordinator (Chair) (1)
College Research Director (1)
College PhD Co-Coordinator (1)

Additional Ex-officio for College of Liberal Arts and Sciences REC:

- Polyclinic Manager (1)
- University Human Tissue Authority Designated Individual (1)

Nominated/Elected
College Doctoral Researcher (1)
External lay-member nominated by the Committee (1)
One representative from each academic School (4)

Co-opted, by invitation
Data Security Manager (1)
Information Compliance Manager (1)
Research Institute Representatives (where required)

Secretariat
Nomination of the Director of College Operations

A quorum of the College 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, and 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 College 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.

A College Research Ethics Committee may hold sub-panels (by e-meeting or in person) where proposals need to be expedited, a sub-panel will constitute a minimum of 3 members, inclusive of Chair.

Operations

10. CRECs 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, as well as e-meetings (via the University's online research ethics system).

11. CRECs should ensure the necessary administrative systems are in place for the maintenance of records, retention of records in line with the University Records Management Policy, monitoring and reporting and should appoint a Secretary to maintain formal records of applications, deliberations and outcomes of meetings (including e-meetings and Chair's Action).

12. The CRECs should not normally consider applications unless at least 40% of the ex-officio and nominated Committee members 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 sub-panel where business cannot be postponed until the next calendared meeting or the business is low risk with regard to considering common response to conditions issues. In this case, Chair's Action or sub-panel consideration and decisions should be recorded and reported at the next opportunity to the full CREC meeting.

- Sub-panels must consist of at least three Committee members, including the Chair (or nominated Acting Chair). The three members of the sub-panel, including the Chair (or nominated Acting Chair) must not have a conflict of interest with any of the applications or proposals to be reviewed. Where this is the case an additional member must be appointed to the sub-panel.
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- The sub-panel must include at least one member from outside of each of the applicant's own host School.
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- Each sub-panel requires a Secretary to be present, who does not count towards the membership.

Supervisor Responsibilities

13. Supervisors are responsible under the Code for:

    - The classification of UG and taught PG student research as defined by the Ethics Code, and for obtaining advice from the CREC Chair, School Research Ethics Representative, Human Tissue Authority Designated Individual or from the Chair or Secretary to the UREC where necessary, including in regard to whether review 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 considerations.
    - Ensuring applications requiring ethics approval are submitted to the College or University Research Ethics Committee or a relevant external ethics approval body or R&D office.
    - Where UG or taught 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 they comply with this Code.
    - For Health Research Authority research by a doctoral researcher, the Supervisor will normally act as Chief Investigator responsible for supervision and research ethics advice, including advice on matters around compliance and governance, and the student will act as the Principal Investigator.
    - For all research subjects, the doctoral researchers have the status of Principal Investigators for the purposes of a Research Ethics application. For insurance cover purposes; the Supervisor will act as Chief Investigator and the doctoral researcher as

Principal Investigator.

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 sought and granted
- To obtain advice, approval and the signature of their supervisor before submitting an application to an ethics review body

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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 review and approval system for research. In addition to considering submissions for research ethics review and monitoring the work of College 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 College Research Ethics Committees.

C1.2. The Committee is responsible for keeping under review the Code of Practice Governing the Ethical Conduct of Research, with particular regard to external developments.

C1.3. The Committee holds governance responsibility to Manage and monitor the University's Human Tissue Authority Licence and the Human Tissue Act Steering Group.

C1.4. This Code refers individuals listed as working under the University's Human Tissue Authority Licence to the relevant University Human Tissue Authority Standard Operating Procedures, including for Consent, and all other aspects of ethical and legal compliance with the Human Tissue Authority's Code of Practice.

C.1.5. Guiding Principles in Summary:

- The University is guided by the fundamental principle that research involving humans, animals, and/or the environment should involve no more than minimal risk to physical or psychological well-being or risk to the sustainability of the environment.
- The University is concerned to protect the rights, dignity, health, safety and privacy of research participants, research donors, 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.1.6. 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.1.3. Committee:

1.4.1. **Quorum**[3]

- The quorum for any meeting is 40% of the members with voting rights (ex-officio and nominated members only).

- 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.

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[1]University of Westminster Ethical Policy Framework
[2]Universities UK (2019) Concordat to Support Research Integrity
[3]University of Westminster (2019) Academic Council Standing Orders

- 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.

- Where a meeting has failed to achieve its quorum, substantive items for approval may be discussed but not approved.

- Where a meeting has failed to achieve its quorum, and applications are due for review, the Committee Chair may choose to hold a sub-panel, with minimum three members, meeting the sub-panel criteria outlined earlier in this Code.

1.4.2. Conflict of Interest

- Conflict of interest by members will be declared in advance of the Committee meeting and the member with the declared interest 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 were perceived by the Committee or declared by the researcher should be recorded in the Minutes of each meeting.

C.1.4.3. Decisions:

The Committee shall consider each Research Ethics Application, 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.

The Committee will refer individual proposals for external research ethics review and/or R&D 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 only for the duration of the research project which should be stated in the application form.

The 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.

C.1.4.5. Full Approval;

The University Approval includes a number of terms and conditions. Similarly external ethical review bodies will have their own conditions which the Principal Investigator is responsible for abiding by. The University Research Ethics Committee's Terms and Conditions are as follows:

- *Your responsibility to notify the Research Ethics Committee immediately of any information received by you, or of which you become aware, which would cast doubt upon, or alter, any information contained in the original application, or a later amendment, submitted to the Research Ethics Committee and/or which would raise questions about the safety and/or continued conduct of the research.*
- *The need to comply with the Data Protection Act 2018 and General Data Protection Regulation (GDPR) 2018.*
- *The need to comply, throughout the conduct of the study, with good research practice standards.*
- *The need to refer proposed amendments to the protocol to the Research Ethics Committee for further review and to obtain Research Ethics Committee approval thereto prior to implementation (except only in cases of emergency when the welfare of the subject is paramount).*
- *The desirability of including full details of the consent form in an appendix to your research, and of addressing specifically ethical issues in your methodological discussion.*
- *You are authorised to present this University of Westminster Ethics Committee letter of approval to outside bodies, e.g. NHS Research Ethics Committees, in support of any application for further research clearance.*
- *The requirement to furnish the Research Ethics Committee with details of the conclusion and outcome of the project, and to inform the Research Ethics Committee should the research be discontinued. The Committee would prefer a concise summary of the conclusion and outcome of the project, which would fit no more than one side of A4 paper, please.*

Relevant legislation and professional guidance should be applied to all research work as well as the University's *Code of Research Good Practice*.

C.1.4.6 Not to approve the application

If a proposal has been rejected and new information becomes available, a revised application may be submitted, which will receive a new application number and can be considered by a Research Ethics Committee.

There is an appeals procedure found at the end of this Code for those who wish to appeal a decision of an internal Research Ethics Committee.

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 or e-meeting 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 in advance of receipt of these conditions that they can be reviewed and considered as having been met by the Secretary, this can occur outside of scheduled meetings.

C.1.4.8 Procedure:

The University aims to promote good academic practice in research by asking individual researchers to complete and retain a research ethics self-assessment form to demonstrate that ethical implications have been considered. Where there are potential ethical implications, a Research Ethics Application 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 application forms in the University's online research ethics system.
2. Applications must be prepared in accordance with the format required by the University Research Ethics Committee and the University's online research ethics system.
3. Applications from Students must be checked for potential ethical implications and signed by the Supervisor.
4. Ethical approval shall be obtained before the commencement of any research which has potential ethical implications. The College or 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.
5. The University Research Ethics Committee reserves the right to request modifications or clarifications of any applications/proposals.
6. 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).
7. Members must declare any special interest including personal, disciplinary or financial etc.
8. If the Chair is involved in any such conflict of interest(s) then the nominated vice-chair will take over until the discussion is concluded.
9. The University Research Ethics Committee will seek expert guidance or advice as required through the co-opted membership.
10. Applications for College or 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.
11. Committee meeting dates are published in advance of the Academic Year start, in the University Calendar.