External organisations (the below sections should be read in conjunction with the full Code).

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.

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.