Ethics main application

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Proposal

Code of Practice Governing the Ethical Conduct of Research

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Project title *

You should only submit an application if a supervisor has already been formally assigned to you.

Supervisor *

1.1 Please provide a description of the background with references to relevant literature (250 words) *

What is the background to your research? Where and when has work in this area been carried out? Include any key literature already produced in this area of research.

1.2 Please provide a brief description and the aims of your study (250 words) *

Briefly describe the project and the main aims of it. e.g. using x technique or questionnaire to investigate or identify x or y.

1.3 Please outline the design and methodology of your study and details of any invasive or intrusive procedures (400 words) *

Include details of the selection and recruitment of any participants. Invasive procedures could include taking of blood samples, inhalation or ingestion of food and/or non-food products (in abnormally higher or lower levels than normal or a different form).

1.4 Start date *

When the part of the proposal containing ethical implications, as within this application form, is due to commence.

Please note ethical approval is for a maximum of three years, therefore your start and end date should reflect that. Further your end date is the expiry date of the proposal's ethical approval period also.

1.5 End date of work *

The end date of the work with ethical implications and as contained within this application form.

Please note ethical approval is for a maximum of three years, therefore your start and end date should reflect that. Further your end date is the expiry date of the proposal's ethical approval period also.

External factors

2.1. Does your research include funding from an external organisation and/or involve external collaborator/s or co-Investigator/s? *

- ◯ Yes
- ◯ No

'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. The question 2.1. refers to whether your research or KE activity will involve any funding (including submitted awards not yet gained) and/or any external collaborations or co-investigators (with or without a financial agreement or other contract of agreement).

2.2 Are you seeking ethical approval from the Health Research Authority (HRA)? *

- ◯ Yes
- ◯ No

Approvals and amendments

2.2.1 Are you seeking University sponsorship (as defined by Health Research Authority)?

- ◯ Yes
- ◯ No

Roles and responsibilities

My research proposal includes an external organisation which may require external research approval or research ethics favourable opinion: *

- ☐ Ministry of Defence (MoD): United Kingdom
- ☐ His Majesty's Prisons and Probation Services (HMPPS)
- ☐ UK Health Security Agency (UKHSA)
- ☐ Any Other Organisation

2.3 Are you seeking ethical approval from any other external organisation (which is not the Health Research Authority)? *

- ◯ Yes
- ◯ No

E.g. are you seeking ethical approval from another regulatory authority or another university or charity etc. If so, you will still need to submit the application to the relevant internal REC for light-touch ethics review (and await an outcome decision) prior to submission to the external body for ethical review. If you are listed on the study team where the Principal Investigator is based at another institution and ethical approval has been gained from that institution, you will need to attach evidence of this to this VRE application in the form of an external research ethics application form and research ethics review

outcome letter, which will be noted by the internal REC, additional compliance conditions such as insurance cover or risk assessment may still be required).

2.3.1 Select one option:

- ◯ I have received external ethical approval
- ◯ I am still seeking external ethical approval

2.4 Have you been asked by an external organisation to produce evidence of ethical approval for your research? *

- ◯ Yes
- ◯ No

External organisations, including funding bodies may include within their terms a requirement to provide them evidence of ethical review from the research organisation (University).

Type of application

☐ I am submitting this application on behalf of a student.

Name of student (where the application is made on behalf of a student)

3.1. Is this an application by a member of staff for Generic (Block) approval of Class 1 research, for a cohort or part of a cohort of taught students? *

Note: this must be submitted to a CREC for review. Please do not check 'on behalf of a student' for block approval requests. Favourable Ethics Opinion will be for one Academic Year only.

- ◯ Yes
- ◯ No

New Guidance information: Generic or Block Approval refers to an ethics application made by a member of staff for a cohort or part of a cohort of taught students to conduct research following similar methodological parameters and potential risk of harm.guidance on what constitutes Generic and Pedagogic please refer to the Code. Aspects of the research with ethical implications should not commence prior to ethical approval.

For further guidance on what constitutes Generic and Pedagogic please refer to the Code. Aspects of the research with ethical implications should not commence prior to ethical approval.

See Code of ethics sections 4 1.7 3

Participants

4 Does this research proposal include: *

- ◯ Yes
- ◯ No

Participants are those who are human (live or deceased) or animal and are subject to the research, rather than others who help facilitate, support or collaborate in the research, or undertake the research. If a participant has more than one role, all roles should be indicated, including that of being a participant.

5 If your research fieldwork (virtual or in person) will not be carried out on University premises, please state the location of your research.

Location

Region

Country

Remove

Add another

This should include any locations including in the UK, if not on university premises. You may add multiple locations to this form, by selecting 'add another'.

Part A

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Risk of harm

Questions 6.1 - 6.6 have been hidden because you have stated you are not using participants

6.1 Will any pain or more than mild discomfort result from the study? *

- ◯ Yes
- ◯ No

Consider pain beyond the norm experienced in everyday life.

See Code of ethics sections 2.5 6.

6.2 Could the study induce any psychological stress or anxiety or cause harm or negative consequences beyond the risks encountered in normal life? *

- ◯ Yes
- ◯ No

Consider risks beyond the norm experienced in everyday life.

See Code of ethics sections 2.5 6.

6.3 Will the study involve prolonged or repetitive physical or psychological testing of human participants that may put someone at risk, e.g. use of treadmill? *

- ◯ Yes
- ◯ No

6.4 Will the study involve raising sensitive topics (e.g. sexual activity, drug use, revelation of medical history, bereavement, illegal activities, etc.)? *

- ◯ Yes
- ◯ No

See Code of ethics section 2.5.

6.5 Does your work involve relevant material, defined by the Human Tissue Act as material other than gametes, which consists of, or includes, human cells. In the Human Tissue Act, references to relevant material from a human body do not include: (a) embryos outside the human body, or (b) hair and nail from the body of a living person. *

Work falling under the Human Tissue Authority.

- ◯ Yes
- ◯ No

See Sections of the Code:

- Section 2.5. Class 2: research which has ethical implications (the potential to cause a risk of harm)
- Section 3.3. Examples of Class 3
- Section 10. Valid Consent and Participant Information (in particular 10.4.-10.9)
- Section 15 Location of the Investigation & Apparatus

Please refer to HTA Designated Individual for further details:

T.Madgwick@westminster.ac.uk

Also see https://www.hta.gov.uk.

6.6 Will DNA samples be taken from human participants? *

- ◯ Yes
- ◯ No

6.7 Does your study raise any issues of personal safety for you or other researchers or participants involved in the project (especially relevant if taking place outside working hours or off-site e.g. not on University premises)? *

- ◯ Yes
- ◯ No

For information on fieldwork research see Code of ethics sections:

- Section 6: Participants, Researchers and others involved in the Research
- Section 12: Insurance cover (including Fieldwork research in the UK and overseas)

Questions 6.8 - 6.9 have been hidden because you have stated you are not using participants

6.8 Does your study involve deliberately misleading the participants (e.g. deception, covert observation)? *

- ◯ Yes
- ◯ No

6.9 Does your work involve administration of a food or non-food substance of a different type from or in abnormally higher or lower amounts than normal or one that is known to cause allergic reaction(s) or potential psychological stress? *

- ◯ Yes
- ◯ No

See Code of ethics sections:

- Section 2.5. Class 2: research which has ethical implications (the potential to cause a risk of harm)
- Section 6. Participants, Researchers and others involved in the Research

6.10 Does your study involve issues relating to personal and/or sensitive data? *

- ◯ Yes
- ◯ No

See Section 2.5. and 11.4. for participant's data. See Section 16 for Research Data Protection and Security.

See Code of ethics sections 2.5 11.4 16

- 2.5. Class 2: research which has ethical implications (the potential to cause a risk of harm)
- 11.4. Managing health and safety aspects of a research study, should involve the following processes;
- 16. Research Data Protection and Security

6.11 Does your research involve any 'security sensitive material? *

- ◯ Yes
- ◯ No

See Universities UK Oversight of Security Sensitive Research Material (2019).

6.12. Does your research ethics proposal include off-site (i.e. not on University premises) research fieldwork and travel involving face to face interactions? *

- ◯ Yes
- ◯ No

6.12.1. In the UK?

◯ Yes

◯ No

Please list locations proposed to be visited:

6.12.2. In an overseas territory (i.e. outside of the U.K)?

◯ Yes

◯ No

Please select the country you propose to travel to (you can select more than one):

-- select --

Remove

Add another

6.12.3. Are you already based overseas?

◯ Yes

◯ No

6.12.4. Please list which country you are based in:

-- select --

Remove

Add another

Does your research include historically and culturally significant sites or objects? *

◯ Yes ◯ No

Does your proposal include research travel or research fieldwork which is under current Foreign and Commonwealth and Development Office (FCDO) travel advisory? *

◯ Yes ◯ No

Potential risk of harm to the environment or significant natural habitats *

◯ Yes ◯ No

Sections 7 and 8 have been hidden because you have stated you are not using participants

Participants

Does your work involve any of the following:

7.1 Human participants in Health and Social Care settings? *

◯ Yes

◯ No

Health settings refers to private or public hospitals, clinics, walk-in health centres etc. both in the UK and overseas. The involvement of these participants and their settings could be for selection, advertisement, recruitment or actual research.

See Code of ethics section 2.5.1 (examples of Class 2)

7.2 Human participants who may be deemed vulnerable due to their setting(s)? *

◯ Yes

◯ No

See 2.5.1 for examples. See also Regulated Activity information from the Department of Health (2012 guidance) as defined by the Safeguarding Vulnerable Groups Act 2006 here.

See Code of ethics section 2.5.1 (Examples of Class 2)

7.3 Expectant or new mothers? *

- ◯ Yes
- ◯ No

7.4 Refugees or asylum seekers or recent migrants? *

- ◯ Yes
- ◯ No

7.5 Minors (under the age of 18 years old)? *

- ◯ Yes
- ◯ No

7.6 Participants in custody (e.g. prisoners or arrestees)? *

- ◯ Yes
- ◯ No

For more information on Research in Her Majesty's Prison and Probation Services Click here.

See Code of ethics section 2.5.1 (examples of class 2)

7.7 Participants who may potentially fall under the remit of the Mental Capacity Act *

https://www.nhs.uk/conditions/social-care-and-support-guide/making-decisions-for-someone-else/mental-capacity-act/

- ◯ Yes
- ◯ No

See Code of ethics section 2.5.1. (examples of class 1)

Research under the Mental Capacity Act needs to be reviewed by the Social Care Research Ethics Committee.

A VRE ethics application should be submitted to UREC for a light touch review prior to submission of an HRA application.

7.8 Animals (or animal tissue)? *

- ◯ Yes
- ◯ No

If you're not sure whether your research constitutes animal research please contact the UREC by email research-ethics@westminster.ac.uk . The University does not hold any of the three licences under the Animals (Scientific Procedures) Act 1986 (ASPA), if you are considering such research please contact your Supervisor and UREC.

Information to participants

8.1 Will you provide participants with a Participant Information Sheet prior to obtaining informed consent ? *

- ◯ Yes
- ◯ No

See section 10. Valid Consent and Participant Information

8.2 Will you describe the procedures to participants in advance, so that they are informed about what to expect? *

- ◯ Yes
- ◯ No

See section 10. Valid Consent and Participant Information

8.3 Will you obtain informed consent for participation (normally written)? *

◯ Yes
◯ No

See section 10.	Valid Consent and Participant Information

8.4 Will you tell participants that they may withdraw from the research at any time and for any reason? *

◯ Yes
◯ No

See section 10.	Valid Consent and Participant Information

8.5 Will you give participants the option of omitting questions they do not want to answer? *

◯ Yes
◯ No

See section 10.	Valid Consent and Participant Information

8.6 Will you tell participants that their data will be treated as confidential and that, if published, it will not be identifiable as theirs? *

◯ Yes
◯ No

See section 2.5.1.	Examples of class 2
See section 10.	Valid Consent and Participant Information
See section 16	Research Data Protection and Security

8.7 Will you offer feedback to participants at the end of their participation, upon request (e.g. give them a brief explanation of the study and its outcomes)? *

◯ Yes
◯ No

See section 10.	Valid Consent and Participant Information

The proposal includes politically sensitive work which may lead to a potential higher risk of harms or reputational risk *

Psychology

Who will be your participants? (age, gender, etc.) *

How do you intend to recruit your participants? *

What will the participant be asked to do? *

Risk Assessment and Hazard Analysis

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9.1 Describe any potential hazards which may cause harm or distress to the participants and investigators, psychologically or physically, in the study and/or any potential harm to the community, environment etc: *

- Section 2.5. Class 2: research which has ethical implications (the potential to cause a risk of harm).
- Section 3. 13. 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.

9.2 Give details of any measures taken to reduce the risk of such harm or distress to the participants and investigators, psychologically or physically, in the study (e.g. risk assessment). *

See the following Sections of the Code:

- Section 6: Participants, Researchers and others involved in the Research
- Section 12: Insurance cover (including Fieldwork research in the UK and overseas)
- Section 11: Health and Safety (including Health and Safety Risk Assessment
- Section 16: Research Data Protection and Security

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9.3 Outline the extent to which these risks are balanced against the potential benefits to education and/or the contribution to scientific knowledge. *

See the following Sections of the Code:

- Section 6: Participants, Researchers and others involved in the Research.

9.4 What criteria will be employed for deciding the end point at which the study will stop because of unjustifiable further risk of harm or distress, psychologically or physically, to the participants or others or risk of harm to the environment? *

See the following Sections of the Code:

- Section 6: Participants, Researchers and others involved in the Research.
- Addendum A3: Life Cycle of Research and Research Ethics Approval limitations.

Questions 9.5 has been hidden because you have stated that you are not using participants.

9.5 What monitoring mechanisms will be in place to decide when some or all participants should be withdrawn from the study i.e. explain what your procedures and criteria for detecting and addressing these issues are? *

Informed consent of participants and recruitment of participants

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10.1 Will you obtain valid consent (written, verbal or via other mediums)? *

- ◯ Yes
- ◯ No

See Section 10. of the Code 'Valid Consent and Participant Information'.

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

Please explain further if consent will not be sought (in any format):

10.1.1 will you be obtaining written consent?

- ◯ Yes
- ◯ No

Section 10: Valid Consent and Participant Information

Please explain further if consent will not be sought in writing:

Please see the Code Section 5.3.2. for further information, some examples where written consent may not apply (subject to Committee approval) could be for elite interviews, investigator safety, cultural norms, illiteracy of participants, etc. e.g. or a transcript of any oral consent to be provided.

See Code of ethics section 5.3.2

10.1.2 Please upload the draft consent form or an outline of the method used to gain consent, if not using a form

- ☐ Consent form uploaded

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10.2 Will you be providing Participant's Information about this research (this could be written or in other formats)? *

- ◯ Yes
- ◯ No

10.2.1 Please explain whether Participant Information will be provided in writing, verbally, by video or other means:

10.2.2. Please upload the Participant Information Sheet or outline the information which will be provided to participants if not in the form of a sheet

- ☐ Participant Information Sheet uploaded

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10.3 Who are the participants and how many participants will you recruit? How and where will you make contact with the participant(s) in order to recruit them? *

- Section 6: Participants, Researchers and others involved in the Research.
- Section 10: Valid Consent and Participant Information.

10.4 How will consent be obtained, stored and ultimately destroyed?

Section 16: Research Data Protection and Security.

10.5 Is parent/guardian consent required for any participants under 18 years of age? *

- ◯ Yes
- ◯ No
- ◯ N/A

N/A should only be used as an answer if participants are over the age of 18 years.

How will this be obtained?

- Section 6: Participants, Researchers and others involved in the Research
- Section 10: Valid Consent and Participant Information.

Expenses and conflict of interest

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11.1 Will expenses be paid to participants? *

- ◯ Yes
- ◯ No

If you have chosen 'yes' and anticipate paying expenses to participants, please elaborate in the section of the form below how much this will be and what the expenses are planned to cover, e.g. travel distance, lunch etc.

- Section 6: Participants, Researchers and others involved in the Research
- Section 10: Valid Consent and Participant Information

If yes, how much?

Please state how much the expenses payment will be and what is it designed to cover.

11.2 Will a reward separate from expenses be made to participants? *

- ◯ Yes
- ◯ No

- Section 6: Participants, Researchers and others involved in the Research.
- Section 10: Valid Consent and Participant Information

If yes, how much?

Please state how much the reward payment will be and what is it designed to cover.

11.3 Will any of the participants be known to you? *

- ◯ Yes
- ◯ No

If you have chosen 'Yes' please explain in the section below your relationship with the participants you know, e.g. you are their tutor.

If yes, please provide details regarding your relationship with the participants you know.

Confidentiality of Information, Data Protection and Freedom of Information

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12.1 Will the study include: *

- ◯ Named participants
- ◯ Participants whose names have been separately coded
- ◯ Anonymous participants
- ◯ Other/multiple categories (please provide details)

If 'other' such as pseudoanonymisation for example, please provide more details.

- Section 16: Research Data Protection and Security

If you selected Other or multiple categories category, please provide further details.

If you selected Other, please provide further details.

Advice can also be sought from the University's Information Compliance Team by contacting DPA@westminster.ac.uk.

See Section 16.1. Data Security and Confidentiality

12.2 Who will you be providing access to identifiable information? *

- ◯ No others will be provided access to identifiable information
- ◯ Others working on the project/research team (staff and students of the University)
- ◯ External collaborators (as named and specified in this research proposal)
- ◯ Commercial organisations and funding bodies

- ◯ Participants
- ◯ Charities
- ◯ Sponsors
- ◯ Other Higher Education Institute
- ◯ Other/multiple categories (please provide details)

Section 16: Research Data Protection and Security

Further details

12.3 How will you store and make secure the data and/or material of human origin collected in the study? *

- Section 16: Research Data Protection and Security
- Section 10: Valid Consent and Participant Information (in particular see 10.4-10.9)
- Section 2.5. Class 2: Research which has ethical implications (the potential to cause a risk of harm)
- Section 3.3. Examples of Class 3
- Section 15: Location of the Investigation & Apparatus

12.4 If the investigation involves storage of computerised data or other personal and sensitive data which might enable a participant to be identified, please name the person in charge of computer system security for the study.

Section 16: Research Data Protection and Security

12.5.1 Does the study include use of, or planned publication of, photographs or videos relating to: *

-- select --

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

12.5.2 If the study includes use of, or planned publication of, photographs or videos relating to individuals, please provide details e.g. whether individuals will be identifiable.

12.5.3 If the study includes use of, or planned publication of, photographs or videos relating to individuals, please upload a photographic/video consent form.

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Please attach a consent form which is designed specifically for the purposes of photographs or videos relating to individuals and/or human material. This is in addition to a consent form regarding participation in the wider research.

Funding and links with external organisations

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13.1 If your work involves research which includes working with or being facilitated by those external to the University, please provide details of any organisations/individuals involved. *

Contact name

Organisation

Address

Telephone

Email

Add another

‘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.

The contact details should relate to an individual who has the authority to represent the external organisation e.g. headteacher of a School.

13.2 Please upload any agreement letters/emails from the External Organisation which are ready for consideration by the Research Ethics Committee, or indicate if these will be provided later. *

- ◯ Agreement letters/emails uploaded
- ◯ Agreement letters/emails will be provided later

Agreement letters; e.g. be permission letters, management approval letters, memoranda of understanding, formal collaboration letters etc. to host, conduct or facilitate researchers/research fieldwork, provide access to resources/participants etc. Sometimes these are not ready at the outset of the design phase, and therefore not available for a REC to consider. Where this is the case, the REC will include the provision of such letters to the REC as an ongoing condition. No research (involving ethical implications) with an external organisation may be carried out without the submission (and subsequent approval) of such an agreement letter/permission letter to a REC.

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13.3 Is this study initiated/sponsored by the external organisation? *

- ◯ Yes
- ◯ No

‘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. In some cases the study may have no ethical implications (Class 1), but the sponsor may require review or noting of this study by UREC or another ethical approval body, or general management permission.

13.3.1 If yes, give the name of the organisation/individual who is initiating and/or sponsoring the study:

13.4 Is this research funded by an external organisation? *

- ◯ Yes
- ◯ No

‘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.

Also see Section 3 of the Code:

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

13.4.1 Please state the name of the funding body/organisation.

13.5 What benefits will you receive, if any, for conducting this research by the organisation or individual named above?

13.6 Do you have any relationship with the organisation/individual? *

- ◯ Yes
- ◯ No

13.6.1 If yes, please provide further details:

Insurance

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14.1 Are all of the investigators/researchers either employees or students of the University of Westminster? *

- ◯ Yes
- ◯ No

If uncertain about answering any questions in this section, please contact the University's Insurance Officer; Procurement, Finance Department procurement@westminster.ac.uk.

For any research undertaken away from the University it is the responsibility of the Principal Investigator and Researchers to ensure that adequate insurance cover is in place before the commencement.

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.

See Code of ethics section 5

14.2 If no, please provide evidence of external insurance cover for all investigators/researchers who are not either employees or students of the university.

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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.

Security sensitive research

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Does your research fit into any of the following security-sensitive categories?

Please refer to the Universities UK Guidance:

Oversight of security-sensitive research material in UK universities (2019)

No work with ethical implications, including security sensitive work can commence prior to consideration and approval by a REC.

15.1.1 Commissioned by the military? *

- ◯ Yes
- ◯ No

If you are uncertain please contact your College Research Ethics Committee (CREC) Chair.

You can also contact UREC via research-ethics@westminster.ac.uk for advice.

15.1.2 Commissioned under an EU security call? *

- ◯ Yes
- ◯ No

If you are uncertain please contact your College Research Ethics Committee (CREC) Chair.

You can also contact UREC via research-ethics@westminster.ac.uk for advice.

15.1.3 Involve the acquisition of security clearances? *

- ◯ Yes
- ◯ No

If you are uncertain please contact your College Research Ethics Committee (CREC) Chair.

You can also contact UREC via research-ethics@westminster.ac.uk for advice.

15.1.4 Does your research concern terrorist or extreme groups? *

- ◯ Yes
- ◯ No

If you are uncertain please contact your College Research Ethics Committee (CREC) Chair.

You can also contact UREC via research-ethics@westminster.ac.uk for advice.

15.2 Does your research involve the storage on a computer of any such records, statements or other documents?

- ◯ Yes
- ◯ No

If you are uncertain please contact your College Research Ethics Committee (CREC) Chair.

You can also contact UREC via research-ethics@westminster.ac.uk for advice.

Contact your College & Institute Research Director or the UREC for further advice at research-ethics@westminster.ac.uk.

15.3 Might your research involve the electronic transmission (e.g. as an email attachment) of such records or statements?

- ◯ Yes
- ◯ No

Contact your College & Institute Research Director or the UREC for further advice at research-ethics@westminster.ac.uk.

15.4 If you answered 'Yes' to questions 15.2 or 15.3, do you agree to store all documents relevant to questions 15.2 and 15.3 on the University's file store?

- ◯ Yes
- ◯ No

If you are uncertain please contact your College Research Ethics Committee (CREC) Chair.

You can also contact UREC via research-ethics@westminster.ac.uk for advice.

Contact your College & Institute Research Director or the UREC for further advice at research-ethics@westminster.ac.uk.

15.5 Do you agree not to transmit electronically to any third party documents in the document store?

- ◯ Yes
- ◯ No

If you are uncertain please contact your College Research Ethics Committee (CREC) Chair.

You can also contact UREC via research-ethics@westminster.ac.uk for advice.

15.6 Will your research involve visits to websites that might be associated with extreme, or terrorist, organisations?

- ◯ Yes
- ◯ No

If you are uncertain please contact your College Research Ethics Committee (CREC) Chair.

You can also contact UREC via research-ethics@westminster.ac.uk for advice.

15.7 Do you accept oversight by the Ethics Officer to the titles of documents stored?

- ◯ Yes
- ◯ No

If you are uncertain please contact your College Research Ethics Committee (CREC) Chair.

You can also contact UREC via research-ethics@westminster.ac.uk for advice.

15.8 Do you agree to sign the register of Security-Sensitive Research?

- ◯ Yes
- ◯ No

If you are uncertain please contact your College Research Ethics Committee (CREC) Chair.

You can also contact UREC via research-ethics@westminster.ac.uk for advice.

Contact

Your preferred contact email address *

For University staff and students this should be your UoW (University of Westminster) email address

Your preferred telephone number *

Attachments

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Please attach the documents you have submitted to an external ethical approval body including but not limited to the following:

1. **The final Ethics Application Form or Proposal as provided to the external ethical approval body.**
2. **Supporting documents e.g. Participant Information Sheet, Consent Form, sample questions/questionnaire, risk assessment, insurance, permission letters etc. as provided to the external ethical approval body.**
3. **Any internal compliance documents which you have received from the university whilst preparing the external application/proposal but which were not provided to the external approval body e.g. Insurance or Risk Assessment or Lab Safety Forms.**

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If you have received ethical approval from an external ethical approval body, please attach the Outcome letter. The Outcome letter could be conditional or full approval or not approved.

If you have been provided with an R&D approval, please attach it here.

You will not be able to submit an application for the University Research Ethics Committee to note an external approval, until the Outcome letter is provided.

If you would like to discuss further please email research-ethics@westminster.ac.uk

Drag files here or choose file...

Upload any additional files to support your application which have not already been uploaded within your application. For instance, Participant information sheet, Consent form, Photographic/video consent form, Indicative questions sheet, Insurance cover, Security sensitive research assessment, Health and Safety Risk Assessments, COSHH, Ionising Radiation, Display screens etc.

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Adverse event or untoward incident

Custom information rendering
The information here cannot be previewed in the form editor.

What kind of event or incident would you like to report (see guidance 'i.' button for more info)? *

- ☐ Adverse events (all disciplines, except work falling under the Human Tissue Act)
- ☐ Adverse events (for work falling under the Human Tissue Act)
- ☐ Adverse event (Data Breach with regard to confidential, personal and sensitive data (as defined by the GDPR guidelines)
- ☐ Incident (all)
- ☐ Incident (participant complaint)

If your project has ethical approval, an adverse event or incident must be reported in the VRE by submitting information via the 'report an adverse event' button to the relevant Research Ethics Committee. Depending on the nature of the adverse event or incident, Principal Investigators also have a responsibility to report the adverse event or incident via the University's Safety, Health and Well-being incident reporting tool (OSHENS). See further information below, including information for research falling under the Human Tissue Act. For urgent safety measures and external reporting requirements please see Section 8 of the Code.

Following reporting in the VRE of an adverse event or incident, the REC will temporarily suspend the research approval. A Principal Investigator must then respond with any mitigating and corrective actions taken or planned to address the event/incident and prevent it from occurring again. The REC will review the response and liaise with relevant colleagues as needed (e.g. Head of College, SHW Team, HTA Designated Individual etc.).

See Section 7. of the Code: 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.

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.

7.4.1. 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 practice8 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.

When / where did the event take place? *

What happened? *

What actions have been taken? *

Has the study been stopped? *

- ◯ Yes
- ◯ No

Are there any potential implications for research participants as a result of terminating / halting the study prematurely?

- ◯ Yes
- ◯ No

Describe the steps taken to address the implications.

Provide the justification for temporarily halting / not halting the study, including details of when / if you expect the study to re-start. *

Any other information?

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☐ I certify that to the best of my knowledge the information given above, together with any accompanying information is complete and correct and I take full responsibility for it.