## Middlesex University Research Ethics Review Form A(v2) REC ref no:­\_\_\_\_\_\_\_\_\_

*Please read the* ***MU Code of Practice for Research: Principles and Procedures[[1]](#endnote-1)****. The purpose of this form is to help staff and students in their pursuit of ethical research methodologies and procedures. Students should complete this form in consultation with their supervisors. The* ***supervisor is responsible for submission[[2]](#endnote-2)*** *of this form and required accompanying documents[[3]](#endnote-3).* ***No fieldwork should begin until your Research Ethics Committee (REC) has given approval****.*

**Section 1: Applicant details**

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| **1.1 Details of Principal Investigator/Supervisor[[4]](#endnote-4)** |
| Name: | Email: | Department: |
|  | Tel: | Position: |
| **1.2 Details of Student Researcher** (if applicable) |
| Name: | Email: | Department: |
|  | Tel: | Position: |
| **1.3 Details of any co-investigators** (if applicable) |
| Name: | Email: | Organisation: |
| Name  | Email: | Organisation: |

**1.4 If this is a group student project please provide details of programme, module and student group:**

**Section 2: Details of proposed study**

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| **2.1 Title of study** |
| **2.2 Proposed start date**: |  |
| **2.3 Proposed end date:** |  |
| **2.4 Aims of the study** |
| **2.5 Please provide summary details of the research study and rationale (max 1,000 words). Include information, where relevant, about participants study design, data collection methods (e.g., interviews, questionnaire, observation etc) and/or secondary data sources (e.g., UK National Statistics) to be used in the research, data analysis and benefits of the research and citations.**  |

**Section 3. Initial checklist**

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| **3.1 Is this non-empirical research?** (i.e., does not involve data collection from human participants or animals or use of animal parts) | **Yes** | **No** |

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| **3.2.** **Does the research already have ethical approval from another UK Ethics Committee (e.g., a UK HEI or organisation e.g., NHS, IRAS)?**(Please submit evidence of ethical approval with your application) | **Yes** | **No** |
| 3.2.1 Is liability insurance provided by the other ethics committee body/institution? | **Yes** | **No** |
| 3.2.1 Does this research require approval from an external research ethics committee? (e.g., NHS or other organisations, agencies and local authorities)*If ‘Yes’ please provide further details of the external ethics committee below:* | **Yes** | **No** |

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| **3.3 Will you be utilizing Secondary Data in your research?** | **Yes** | **No** |
| 3.3.1 Does the research involve secondary data analysis using a government archive (e.g., UK Data Service / UK Data Archive), publication with ISBN or equivalent identifier?Please specify data set to be used and how it will be obtained.*You will need to submit evidence of approval to use the planned existing data.* | **Yes** | **No** |
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3.3.2 Do you need to contact the original researchers or data collectors to gain permission to use the data or inform them of the purpose of your secondary analysis? | **Yes** | **No** |

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| **3.4 Will the use of the data/outputs from the research (e.g., products, guidelines, publications etc) comply with UK legislation?***If ‘Yes’ please provide further details:* | **Yes** | **No** |

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| **3.5 Does your research fit into any of the following Security-Sensitive categories?** **If so, please indicate which:** | **Yes** | **No** |
| 1. Commissioned by the military
 | **Yes** | **No** |
| 1. Commissioned under an EU security call
 | **Yes** | **No** |
| 1. Involve the acquisition of security clearances
 | **Yes** | **No** |
| 1. Concerns terrorist or extreme groups
 | **Yes** | **No** |
| If you responded ‘Yes’ to any of the above, please complete the **Security-Sensitive questions sheet** which can be found on Unihub and the staff intranet sections for Research Ethics.  |

**If you responded “No” to all the questions in Section 3, please go to Section 7 and then complete the relevant declaration in Section 9. Otherwise, please complete the remainder of this form UNLESS your research involves Human Tissue (including blood)[[5]](#endnote-5) then please complete the Natural Sciences REC form[[6]](#endnote-6) or involves psychological research and requires approval from the Psychology REC and completion of the Psychology REC form.**

**Section 4 Research data**

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| **4.1 Secondary data research** *(e.g., published data, archives, court reports, hospital records, case notes, internet site etc.)* Please **specify data set** to be used and **how it will be obtained** and whether appropriate or required **permission** will be obtained: | **N/A** |
| **4.2** **Primary data from** **human participants:** Please specify categories of human participants: *(e.g., students; those in an unequal relationship (e.g., your own students): general public; specific group(s) or team(s). (Note: NHS patients, and/or their relatives/carers, vulnerable adults unable to give informed consent must be reviewed by NHS NRES via the IRAS system. Collecting data from under-16yr olds and vulnerable adults will require DBS see 6.11)*i) **Categories and number** of participants: ii)How will participants be **recruited and approached?** (e.g., using email, social medie sites, posters, letters of introduction etc), what **contact/reply arrangements** will be made (e.g., mdx email or details a dedicated email account, or skype address for the research etc) or **accessed** gained to groups of participants (e.g., through gatekeepers, e.g., organisations, managers, parents, schools etc) *Please provide details:*iii) Details of **materials** to be used/**resources** required for this study: *(Please provide copies of questionnaires, indicative interview questions, topic guide/prompts, visual images etc. to be used in this research)* | **N/A** |
| **4.3** **Animals or the use of animal by-products***[[7]](#endnote-7)****:*** If the research involves the participation and/or observation of animalsor the use of animal by-products please refer to the *MU Statement on the Use of Animals in Research, Teaching and Practice* and provide the following details: 1. Type of animal/animal by-product
2. Justification for use of animal/animal by-products(s)
3. Where data collection is being undertaken
4. Where animals/animal by-products are kept and care/storage facilities/disposal[[8]](#endnote-8)
5. Evidence of relevant licence/permissions (where applicable)
 | **N/A** |
| **4.4** **Other data sources to be collected/used not categorised above** *e.g., flora/foliage, minerals, precious artefacts etc*.Please provide details: 1. Type of data
2. Justification for use
3. Where data collection is being undertaken
4. Where the data will be kept and care/storage facilities
5. Evidence of required licence/permissions (where applicable)
 | **N/A** |

**Section 5: Anonymity, confidentiality and consent**

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| **5.1**  Will the research involve collecting or analysing **personal data or sensitive personal data**? *(i.e.,* *personal data refers to information that may identify individuals e.g., name, address, date of birth, opinion, specifc event, set of characteristics that would clearly identify individuals or very small groups. Sensitive personal data refers to racial or ethnic origin, political opinion, religious beliefs, trade union membership, sexual life, physical or mental health, criminal matters.)****If ‘yes’****, consider irreversibly anonymising data, if possible, by removing names and other linked or identifying information which may still identify an individual without their name. Alternatively, if personal or sensitive personal data is required for the research, you* ***must comply with the Data Protection Act (DPA)(1998)*** *and understand your responsibiities under the DPA and have received* ***data protection training****. Please complete the* ***Data Protection Act Checklist for Researchers*** | **Yes** | **No** |
| **5.2** Will lists of identity numbers/codes or pseudonyms for individuals and/or organisations (i.e., **linking keys to personal identifiers**) be stored securely and separately from the research data and destroyed after the study to avoid any risk of confidentiality being compromised? *If ‘no’ please provide details:* | **Yes** | **No** |
| **5.3** Will you tell participants that their data will be treated **confidentially** and the **limits of anonymity** will be made clear in your **Participant Information Sheet\***? (e.g., their identities as participants will be concealed unless prior consent is given to include the name of the participant in any documents resulting from the research. Consider how participants’ narratives, quotes or involvement in specific events may make anonymity difficult to maintain.) *Please provide details how you will ensure this:*  | **Yes** | **No** |
| **5.4** Will you obtain **Written Informed Consent[[9]](#endnote-9)\*** directly from research participants (if applicable)? *If ‘no’ please provide details:**If ‘yes’ please specify how and when this will be achieved:* | **Yes** | **No** |
| **5.5** Will you obtain **Written Informed Consent\*** directly from gatekeepers (if applicable)? *If ‘no’ please provide details:**If ‘yes’ please specify how and when this will be achieved:* | **Yes** | **No** |
| **5.6** Will you inform participants that their participation is **voluntary** and that they have a **right to withdraw** from the research at any time **without penalty**? *If ‘no’ please provide details:* | **Yes** | **No** |
| **5.7** Will you have a process for managing **withdrawal of consent**? *Please provide details:*  | **Yes** | **No** |
| **5.8** Will it be necessary for **participants to take part in the study** **without their knowledge and consent** at the time, or by **deception** e.g., covert observation? *If ‘yes’, please provide justification and details of how this will be managed to respect the participants/third parties involved to respect their privacy, values and to minimise any risk of harmful consequences:* | **Yes** | **No** |
| **5.9** Will you provide a **Written Debriefing Sheet\***? (if applicable)  | **Yes** | **No** |
| **5.10** Will you need **consent from people** who appear **in visual data** (e.g., photos or films)? *If ‘yes’ please provide details:* | **Yes** | **No** |
| **5.11** Will you **audio or video record** interviews and/or observations? *If ‘yes’ please provide details on how* ***participants’ anonymity*** *will be maintained:*  | **Yes** | **No** |
| **5.12** Does the research involve **participants engaged in internet activity (eg., responding to internet** **surveys, emails, chatroom discussions, blogs, interactive games, social media and networking sites etc, and have** **i) gained their informed consent to be identified****ii) ensured anonymity**Explain how will you obtain permission from the website authors, or informed consent from participants, and ensure anonymity and protect confidentiality in an environment that generates significant amounts of background information e.g., data logs, IP addresses, cookies and caches and/or with low levels of system security? *Please provide details:*  | **Yes** | **No** |

***\*****Please* ***submit copies of these forms*** *with this application*

**Section 6: Avoiding harm: risk assessment and management, safety and legal issues**

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| **6.1** Will you use an **experimental research design** (ie.,implement a specific plan for assigning participants to conditions and noting consequent changes) involving either i) drugs, placebos or other substances (e.g., food substances, vitamins) to be administered to the participants, or ii) invasive, intrusive or potentially harmful procedures or any kind? *If ‘yes’, please provide details of treatment/intervention (and specify is these are intrusive interventions e.g., hypnosis or physical exercise, or include the use of drugs, placebos or other substances e.g., vitamins, food substances etc.) and provide details of required resources for this study:*  | **Yes** | **No** |
| **6.2** Will the research cover **sensitive topics**? (e.g., sexual activity, drug use etc) *If ‘yes’ please provide details of how possible adverse reactions will be avoided and what support will be in place to manage any adverse consequences:*  | **Yes** | **No** |
| **6.3** Is **pain or more than mild discomfort** likely to result from the study? *If ‘yes’ please provide details:*  | **Yes** | **No** |
| **6.4** Could the study induce **psychological stress or anxiety** or **cause harm or negative consequences** beyond the risks encountered in normal life? *If ‘yes’ please provide details and state how participants will be supported:*  | **Yes** | **No** |
| **6.5** **Will the study involve prolonged and repetitive testing?** *If ‘yes’ please provide details, justification and state how participants will be supported and length of each* ***data collection session****, number of sessions and location of data collection:* | **Yes** | **No** |
| **6.6** Will this research be conducted **off-site** (i.e., not on MU premises) AND the Risk Assessment Form does not indicate low risk? *If ‘yes’, - the research is off-site - please provide details of other locations and complete a Risk Assessment Form for Fieldwork[[10]](#endnote-10) to be submitted with this form.* *If the research is not off-site, a risk assessment form will need to be completed if the research involves groups of participants and there is a need to control space risks or to comply with relevant licence(s).* | **Yes** | **No** |
| **6.7** Will **being alone** with individual participants or group of participants place you at risk?*If ‘yes’ please state how this can be avoided or managed?*  | **Yes** | **No** |
| **6.8** Are there any **adverse risks** or **safety issues** (e.g., from **potential hazards)** that your methodology raises for you and/or for your participants or others? *If ‘yes’,* *please specify* *and provide details of mitigating actions that will be taken* (e.g., travelling alone, working in hazardous conditions, discussing illegal activities on-line etc*.)* *and how you, and your participants/third parties will be supported?* | **Yes** | **No** |
| **6.9** Is the research or outputs from the research **likely to cause harm** to others (e.g., to their physical well-being, mental health, dignity or personal values) to an extent greater than that encountered in ordinary life? *Please provide details; e.g., dissemination plans and how an increased risk of harm will be avoided.* | **Yes** | **No** |
| **6.10** Is this research likely to have a **damaging effect on the environment e.g., damage to habitats, plants**, or **sites** of **archaeological** or **geological** or **cultural** significance? Or a **negative impact on people living/working in** the **immediate locality** of the study? *If ‘yes’ please provide details and state how damage will be minimised:* | **Yes** | **No** |
| **6.11** Will this research require a current **Disclosure and Barring Service** (DBS) Certificate\*? *\*Needed when working with under-16yr olds and/or vulnerable adults for example, in education or healthcare contexts.* *If ‘Yes’, please provide details of DBS number and date of issue:*  | **Yes** | **No** |

**Section 7: Research funding, sponsorship and collaboration**

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| --- | --- | --- |
| **7.1** Does the research have **external funding**? *Îf ‘Yes’, please provide further details:* | **Yes** | **No** |
| **7.2** Does the research have a **sponsor** (i.e., any person or organisation who provides support for the research in the form of income, use of data, facilities, materials, assistance with data collection etc) that may have **ethical implications for the research**? *If ‘yes’ please provide details of the role of the funder and issues:**If ‘yes’, what ethical review procedures must this research comply with for that country, and what steps have been taken to comply with these:* | **Yes** | **No** |
| **7.3** Does the research involve an **international collaborator** or research conducted **overseas**? *If ‘yes’, what ethical review procedures must this research comply with for that country, and what steps have been taken to comply with these: (e.g., Do you need local permission/approval? Are there any country specific cultural social or legal considerations that need to be taken into account? Who will be collecting the data overseas? Have you considered intellectual property issues?)* | **Yes** | **No** |
| **7.4** Will this research or part of it be conducted in a language **other than English**? *If ‘yes’, full translations of all non-English materials will need to be submitted.*  | **Yes** | **No** |

**Section 8: Other issues - to be completed by ALL applicants**

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| **8.1** Does the research involve any **ethical and/or legal issues** **not already covered** that should be taken into consideration? *If ‘yes’ please give details:* | **Yes** | **No** |
| **8.2** Do you or your researchers require training on the requirements of the **Data Protection Act for researchers**? | **Yes** | **No** |
| **8.3** Does the research raise **any other risks to safety for you or others** that would be greater than in normal life?*If ‘yes’ please complete the MU Risk Assessment Form for submission to the REC with this form.* | **Yes** | **No** |
| **8.4** Will participants receive any **financial inducements/reimbursements** (other than reasonable expenses and compensation for time) will be offered to participants? *If ‘yes’ please provide details and justification:*  | **Yes** | **No** |
| **8.5**Are there any **conflicts of interests** **to be declared** in relation to this research? |  |  |

**Section 9: Declaration – to be completed by ALL applicants**

**As principal investigator/student researcher I confirm that:**

1. I have read and agree to abide by the relevant Code(s) of Ethics appropriate to my research field and topic.
2. I have reviewed all the information submitted with this research ethics application and believe that it accurately represents the proposed research.
3. I have read and agree to abide by the University’s *Code of Practice for Research: Principles and Procedures.*
4. I agree to inform my Supervisor/Research Ethics Committee of any adverse effects or changes to the research procedures.
5. I understand that the research/research data may be subject to inspection for audit purposes and I agree to participate in any audit procedures required by the Research Ethics Committee (REC) if requested.
6. I understand that personal data about me contained in this form will be managed in accordance with the Data Protection Act.
7. I have completed and signed a risk assessment for this research study (if applicable).

**Principal Investigator Name……………………………Signature:……………………….….Date:…………….**

**Student Name……………………………………………..Signature:……………………….….Date:…………….**

**As supervisor I confirm that:**

1. I have reviewed all the information submitted with this research ethics application and believe that it accurately represents the proposed research.
2. I accept responsibility for guiding the applicant so as to ensure compliance with the terms of the protocol with any applicable Code(s) of Ethics.
3. I understand that research/data may be subject to inspection for audit purposes and I agree to participate in any audit procedures required by the Research Ethics Committee (REC) if required.
4. I confirm that it is my responsibility to ensure that students under my supervision undertake a risk assessment to ensure that health and safety of themselves, participants and others is not jeopardised during the course of this research.
5. I understand that personal data about me contained in this form will be managed in accordance with the Data Protection Act.
6. I have seen and signed a risk assessment for this research study (if applicable).

**Supervisor’s Name………………………………………Signature:…………………………….Date:………….**

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| **Supervisor’s recommendation**  |  |  |
| This is a low risk project (i.e., none of the response given are in the shaded box/column) and all ethical, legal and safety issues have been sufficiently addressed | Yes | No |
| I approve the project as supervisor (Please submit to the relevant REC administrator). | Yes | No |
| This project will be submitted to the relevant REC for further consideration | Yes | No |

**If submitting to your Research Ethics Committee please use the documents checklist below:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Please check and attach the following documents where applicable:** |  |  |  |
| 1. Evidence of external approval – from external ethics body
 | Yes | No | NA |
| 1. Evidence of external approval – from external ethics body
 | Yes | No | NA |
| 1. Letter of permission (if required from organisation(s) where research is to be conducted)
 | Yes | No | NA |
| 1. Participant information sheet
 | Yes | No | NA |
| 1. Written informed consent sheet
 | Yes | No | NA |
| 1. Written debriefing sheet
 | Yes | No | NA |
| 1. Completed risk assessment form
 | Yes | No | NA |
| 1. Copy of materials – questionnaires, interview guide, visual images etc.
 | Yes | No | NA |
| 1. Disclosure of conflict of interests (if applicable)
 | Yes | No | NA |
| 1. Evidence of relevant licence for research with animals/animal by products
 | Yes | No | NA |

**Templates for Participant Information Sheets, Consent Forms and Debriefing Sheets can be found on the MU Ethics intranet site and Unihub.**

***FOR RESEARCH ETHICS COMMITTEE USE ONLY***

**REC NO:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_DATE:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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| --- |
| Name of Principal Investigator or Student:  |
| Name of Supervisor (if applicable):  |
| Project Title: |

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| --- | --- | --- |
| First Reviewer’s decision: (Please avoid revealing the reviewer’s identity) |  |  |
| 1. Approved | Yes | No |
| 2. Approved subject to the following minor amendments: | Yes | No |
| 3. Resubmission required and further information is needed on the following: | Yes | No |
| 4. Not approved for the following reasons: | Yes | No |

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| --- | --- | --- |
| Second Reviewer’s decision: (Please avoid revealing the reviewer’s identity) |  |  |
| 1. Approved
 | Yes | No |
| 1. Approved subject to the following minor amendments:
 | Yes | No |
| 1. Resubmission required and further information is needed on the following:
 | Yes | No |
| 1. Not approved for the following reasons:
 | Yes | No |

**Name of REC …………………………………………Chair of REC Name: ……………………………………….**

**Signature:……………………….……………………………………….Date:………………………………………..**

1. ***MU Code of Practice for Research: Principles and Procedures*** *is available on the MU intranet and internet* [↑](#endnote-ref-1)
2. *See list of* ***Research Ethics Committee Contacts List*** *on the intranet and internet for submission process details* [↑](#endnote-ref-2)
3. ***Required accompanying documents*** *include the following:*

*Participant information sheet*

*Informed consent sheet*

*Debriefing information*

*Risk assessment form (required if research is to be conducted away from MU property. Institutions/locations listed for data collection must match original letters of acceptance.)* [↑](#endnote-ref-3)
4. *Please note that a student (UG, PG taught or research) cannot be the Principal Investigator for ethics purposes* [↑](#endnote-ref-4)
5. ***Human Tissue*** *(under the Human Tissue Act, 2004) refers to ‘relevant material’ that contains at least a single cell from a human body, e.g., organs, blood, bodily waste products, cell deposits or tissue sections. (It does not include embryos outside the human body or hair and nail from the body of a living person.) Please refer to the HTA list of relevant materials at* [*http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial/listofmaterialsconsideredtoberelevantmaterialunderthehumantissueact2004.cfm*](http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial/listofmaterialsconsideredtoberelevantmaterialunderthehumantissueact2004.cfm) [↑](#endnote-ref-5)
6. *For research involving* ***Human Tissue (including blood etc.)*** *please use the form and process for the Natural Sciences Department. For* ***psychological research*** *please use the forms and process for the Psychology Department.* [↑](#endnote-ref-6)
7. *The* ***Middlesex University Statement on Using Animals*** *is available on the intranet and internet* [↑](#endnote-ref-7)
8. *For more information on risk assessment and disposal of* ***animal by-products*** *refer to* [*https://www.gov.uk/dealing-with-animal-by-products*](https://www.gov.uk/dealing-with-animal-by-products) [↑](#endnote-ref-8)
9. *Researchers that intend to obtain* ***consent from participants to use human tissue*** *must attend a consent training course at MU as part of the HTA requirements. See the Natural Science REC info for further details.* [↑](#endnote-ref-9)
10. *The* ***Middlesex University Risk Assessment Form*** *is available on the intranet and internet* [↑](#endnote-ref-10)