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**Form RE1**

**Research Ethics Checklist**

August 2021

**Note:** *undergraduate and taught postgraduate students must use this form where human participants, human tissues or data, potentially sensitive material or a potential reputational risk forms part of their project. Research students, staff and external researchers must use the online EFIT system.*

This checklist should be completed for every research project. It is used to identify whether a full application for ethics approval needs to be submitted.

**Before completing this form,** please refer to the University **‘Code of Practice on Ethical Standards for Research Involving Human Participants’** and the **‘Scope of the Code of Practice’** document. The student’s supervisor is responsible for exercising appropriate professional judgment in this review.

***This checklist must be completed before potential participants are approached to take part in any research.***

**Section 1: Applicant Details**

|  |  |
| --- | --- |
| 1. Name of Researcher (applicant): |  |
| 2. Status (please click to select): | Choose an item. |
| 3. Email Address: |  |
| 4a. Contact Address: |  |
| 4b. Telephone Number: |  |
| 5. Project Title: |  |
| 6. Course title/module name/number  School/Centre: |  |
| 7. Supervisor’s or module leader’s name: |  |
| 8. Supervisor’s Email address: |  |
| 9. Supervisor’s Telephone number: |  |
| **Comments from Researcher, and/or from Supervisor:** |

***Declaration by Researcher*** *(Please check the appropriate boxes)*

|  |  |
| --- | --- |
| [ ]  | I have read the University’s Code of Practice |
|[ ]  The topic merits further research |
|[ ]  I have the skills to carry out the research |
|[ ]  The participant information sheet, if needed, is appropriate |
|[ ]  The procedures for recruitment and obtaining informed consent, if needed, are appropriate |
|[ ]  The research is exempt from further ethics review according to current University guidelines |
|[ ]  Where relevant, I have read the ethical guidelines of the regulatory body that is relevant to my discipline and verify that the research adheres to these guidelines |

**Section 2: Research Checklist** (*Please answer each question by selecting the appropriate response)*

|  |  |
| --- | --- |
|  | **YES/NO** |
| 1. Will the study involve participants who are particularly vulnerable or who may be unable to give informed consent (e.g. children, people with learning disabilities, emotional difficulties, problems with understanding and/or communication, your own students)? | Choose an item. |
| 2. Will the study require the co-operation of a gatekeeper for initial access to the groups or individuals to be recruited (e.g. students at school, members of self-help group, residents of nursing home)? | Choose an item. |
| 3. Will deception be necessary, i.e. will participants take part without knowing the true purpose of the study or without their knowledge/consent at the time (e.g. covert observation of people in non-public places)? | Choose an item. |
| 4. Will the study involve discussion of topics which the participants (or readers of the research) may find sensitive or disturbing (e.g. sexual activity, drug use, controversial/extreme texts)? | Choose an item. |
| 5. Will drugs, placebos or other substances (e.g. food substances, alcohol, nicotine, vitamins) be administered to or ingested by participants or will the study involve invasive, intrusive or potentially harmful procedures of any kind? | Choose an item. |
| 6. Will human blood or tissue samples be obtained for use in the research? | Choose an item. |
| 7. Will pain or more than mild discomfort be likely to result from the study? | Choose an item. |
| 8. Could the study induce psychological stress or anxiety or cause harm or negative consequences beyond the risks encountered in normal life? | Choose an item. |
| 9. Will the study involve prolonged or repetitive testing? | Choose an item. |
| 10. Will financial inducements (other than reasonable expenses and compensation for time) be offered to participants? | Choose an item. |
| 11. Will participants’ right to withdraw from the study at any time be withheld or not made explicit? | Choose an item. |
| 12. Will participants’ anonymity be compromised or their right to anonymity be withheld or information they give be identifiable as theirs? | Choose an item. |
| 13. Might permission for the study need to be sought from the researcher’s or from participants’ employer?  | Choose an item. |
| 14. Will the study involve recruitment of patients or staff through the NHS? | Choose an item. |
| 15. Does the research have any potential implications for the reputation of the University? | Choose an item. |
| 16. Does the research involve socially or politically sensitive (actual of potential) topics? | Choose an item. |
| 17. Will the research have the potential to uncover or highlight illegal or potentially harmful activities?” | Choose an item. |

If ALL items in the Declaration are checked and all items in the Section 2 checklist have been answered NO; **send the completed and signed Form RE1 to your School/Centre Research Ethics Officer (REO)** for information. You should receive a signed copy in return from your REO. You may proceed with the research but should follow any subsequent guidance or requests from the School/Centre Research Ethics Officer or your supervisor/module leader where appropriate.

Undergraduate and taught postgraduate students should retain a copy of this form and submit the REO signed version with their research report or dissertation.

If Question 6 in the Section 2 checklist has been answered YES; the University of Bolton does not hold a Human Tissue Authority (HTA) licence. Therefore, no researcher at University premises can store human tissue (which may be body parts, organs, tissue, cells, bodily waste products, including blood, serum, plasma, etc.), unless an exemption applies. Refer to the document [Registration and Storage of Human Tissue](https://www.bolton.ac.uk/assets/Registration-and-Storage-of-Human-Tissue-for-the-Purpose-of-Research-Nov-2017.pdf) for guidance and refer to your Research Coordinator, REO or Designated HTA Officer. **You cannot proceed with your research at this stage.**

If Question 14 in the Section 2 checklist has been answered YES; you will have to submit an application to the appropriate external NHS ethics committee for approval. After you have received approval from the NHS you should then submit an RE2(U) form together with a copy of the NHS approval to the School/Centre Research Ethics Officer who will arrange for UREC to consider your request. **You cannot proceed with your research at this stage.**

If Question 15 and/or Q17 in the Section 2 checklist has been answered YES; you will need to complete an RE2(U) form and send it together with this RE1 form to the School/Centre Research Ethics Officer who will arrange for UREC to consider your request. **You cannot proceed with your research at this stage.**

If ANY of the items in the Declaration are not ticked AND / OR if you have answered YES to questions in Section 2 (apart from Q6, Q14, Q15, or Q17); you will need to describe more fully in Section 3 of this form how you plan to deal with the ethical issues raised by your research. **This does not mean that you cannot do the research, only that your proposal will need to be approved by the School/Centre Research Ethics Officer or DREC/UREC**. You will be guided on completion of form RE2(D) or RE2(U).

**Section 3: Addressing Ethical Problems**

If you have answered YES to any of questions in Section 2 (apart from Q6, Q14, Q15, or Q17) please complete below and submit the form to your School/Centre Research Ethics Officer.

|  |
| --- |
| **Project Title** |
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| --- |
| **Principal Investigator/Student** |
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| --- |
| **Supervisor** |
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| **Summary of issues and action to be taken to address the ethics problem(s)** |
|  |

Please note that it is your responsibility to follow the University’s’ Code of Practice on Ethical Standards’ and ‘Scope of the Code of Practice’ alongside any relevant academic or professional guidelines in the conduct of your study. **This includes providing appropriate information sheets and consent forms, and ensuring confidentiality in the storage and use of data**.

You may only conduct your research in line with the ethical approval received. Any significant change to the design or conduct of the research should be notified to the School/Centre Research Ethics Officer using form RE7 and may require a new application for ethics approval. You must stop your research until this variation is approved.

Signed: Principal Investigator/Student

Approved: Supervisor/Module Leader (for UGT & PGT)

Date:

**For use by School/Centre Research Ethics Officer (REO):**

|  |  |
| --- | --- |
|  | **Tick all that apply** |
| No ethical problems are raised by this proposed study |  |
| Appropriate action taken to maintain ethical standards |  |
| The research protocol should be revised to eliminate the ethical concerns or reduce them to an acceptable level, using the attached suggestions  |  |
| Please submit School/Centre Application for Ethics Approval (Form RE2(D)) |  |
| Please submit University Application for Ethics Approval (Form RE2(U)) |  |

**Note to REO:** ensure this form contains all appropriate signatures and is completed fully. Retain a copy on your file and send a copy to the applicant and their supervisors.

REO name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signed:

Date: