

Ethics self-certification form

If you have completed the University of Birmingham's ethics review preparation training in the last 3 years, and are conducting research that involves minimal risk to the subjects, participants, researchers and the university, then you have the option of self-certifying concerning the ethical issues in your project by completing the form below.

Once you have completed and submitted this form, if you have answered 'No' to all the questions in part B, you will be able to start your research project.

Forms should be submitted to aer-ethics@contacts.bham.ac.uk.

These forms will still be reviewed centrally by the University's research ethics committees, and a small proportion of them will, as a matter of routine, be followed up.

If you answer yes to any of the questions in part B, you should complete and submit a full application for ethics review (<https://intranet.birmingham.ac.uk/finance/documents/public/aer.doc>), and must obtain full ethics approval prior to commencing your research.

Please also note that this form should **not** be used for the following categories of project, and a full application for ethics review should be submitted instead:

- Postgraduate research student projects
- Projects requiring sponsorship in line with the Department of Health's Research Governance Framework (this includes projects involving the NHS, Social Care, and participants lacking capacity to consent)
- Projects led by researchers who have not undergone training within the last 3 years to use the self-certification system

Please note by not moving to further review you are self-certifying that you do not think there are ethically risky or controversial issues in your research. If it should transpire that this is not the case, and it was unreasonable for you to make this judgement, then you will be regarded as having failed in your responsibilities as a researcher and appropriate action will be taken. Ethical review focuses on three key groups the **participants**, the **researcher** and the **institution**. When considering your research please consider the **likely, potential** and **possible harms** to each of these three stakeholders. If you are in doubt please seek advice from the ethics team.

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Part A:

Name of researcher	ERN reference number

Title of project

Start date	End date

Please submit a summary of the research question(s) <i>This can be copied from and pasted from elsewhere</i>

Please tick which of the following methodologies will be used in this research:

- | | |
|--|--|
| <input type="checkbox"/> Interview | <input type="checkbox"/> Controlled Trial/Other Interventional Study |
| <input type="checkbox"/> Focus Group | <input type="checkbox"/> Use of Personal Records |
| <input type="checkbox"/> Questionnaires | <input type="checkbox"/> Systematic Review |
| <input type="checkbox"/> Action Research | <input type="checkbox"/> Secondary Data Analysis |
| <input type="checkbox"/> Observation | <input type="checkbox"/> Literature Review |
| <input type="checkbox"/> Other (please give details below) | |

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Section B:

Harms and Risks to Participants:

Design risks

Does your study include any of the following?

	Yes	No
Are drugs, placebos or other substances to be administered to the study participants, or will the study involve invasive, intrusive or potentially harmful procedures of any kind E.g. administration of food substances or supplements, exercise testing or other physiological monitoring.		
Will human tissue (as defined at http://www.hta.gov.uk/db/documents/Supplementary_list_of_materials_2008_11252407.pdf) including blood, saliva, urine or faeces be collected or used in the project?		
Will gametes (i.e. sperm or eggs) be collected or used in the study?		
Is pain or discomfort likely to result from the study?		
Could the study induce psychological stress or anxiety, or cause harm or negative consequences beyond the risks encountered in normal life?		
Will the study involve prolonged or repetitive testing?		
Will financial inducements (other than reasonable expenses and compensation for time) be offered to participants?		

Data risks and harms

Does your research include any of the below?

	Yes	No
Will the research involve administrative or secure data that requires permission from the appropriate authorities before use?		
Will the study require the co-operation or approval of a gatekeeper for initial access to the groups or individuals to be recruited? E.g. staff of other organisations (such as the NHS or a Council), students at school, members of self-help groups, or residents of a nursing home.		
Will it be necessary for participants to take part in the study without their knowledge and/or consent at the time? E.g. covert observation of people in non-public places.		
Will the research involve data collection/recruitment via the internet?		
Will the research involve visual/vocal recording methods which may allow respondents to be identified?		

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If you have answered Yes to any of these you should complete a full ethics approval form, unless the vulnerability is ethically unproblematic. If this is the case please give details:

Vulnerable participants

Does your research involve research on any of the below?

	Yes	No
Children		
Participants with cognitive impairment		
Participants which come from groups which are vulnerable for identity or stigma reasons (for instance, sexuality, gender or race)		
Participants which might be personally vulnerable (for instance, if the research is about their personal lives rather than their professional role)		
Participants in unequal power relations (for instance, groups you teach or work with where refusal to participate or withdrawal might be difficult)		
Participants who may become vulnerable because of what is revealed in the study. For instance, if the study reveals instances of criminality or behaviour which is cultural or socially questionable		
Participants who might experience emotional or psychological trauma. For instance if the study raises sensitive issues, such as sexual activity, drug use, financial impropriety or questions about identity		
Participants who are likely to suffer negative consequences if identified. For instance, professional censure, exposure to stigma or abuse, damage to social standing.		

If you have answered Yes to any of these you should complete a full ethics approval form, unless the vulnerability is ethically unproblematic. If this is the case please give details:

Harms and Risks to Researchers:

Does your research present any of the following risks to researchers?

	Yes	No
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Is there a possibility that the researcher could be placed in a vulnerable situation either emotionally or physically? For instance, by being alone with vulnerable or potentially aggressive participants or by entering an unsafe environment.		
Is the topic of the research sensitive or controversial such that the researcher could be compromised? For instance, by creating obligations of relationship from disclosures made.		
Is the researcher at risk of being compromised? For instance, because of long-standing relationships with partner institutions which might result in institutional capture.		
Will the research take place outside the UK? If so is there a possibility that the safety of the researcher may be in question? For instance, travel to countries in political unrest or where violence or illness is likely.		
If you have answered Yes to any of these you should complete a full ethics approval form, unless the vulnerability is ethically unproblematic. If this is the case please give details:		

Harms and Risks to the Reputation of the Institution

Does your research present any of the following risks to the University?

	Yes	No
Will the study involve discussion of sensitive or controversial topics which might (if they came to light) create negative press cover? For instance, sexual activity, drug use, financial impropriety.		
Could any aspects of the research mean that the University has failed in its duty to care either for researchers or for participants? For instance, by not doing a full ethics review or because the researcher is unnecessarily placed in a risky situation.		
Could the research result in the damage of any relationships with partner institutions? For instance, have all relevant partner institutions been appropriately consulted and informed and relevant permissions sought?		
Might there be any reputational risk concerning the source of your funding and have you been fully transparent regarding your funding sources?		
Could any aspect of the research bring the university into disrepute in any other way?		

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If you have answered Yes to any of these you should complete a full ethics approval form, unless the vulnerability is ethically unproblematic. If this is the case please give details:

If you have answered yes to any of the questions above, self-certification may not be appropriate for your study. If you go ahead and submit this form having ticked yes to one of the questions above, you will be contacted by the Ethics Team for further information.

Please also be aware that a proportion of applications completing this form will be contacted for monitoring and evaluation purposes.

Declaration:

By submitting this form, I declare that the questions above have been answered truthfully and to the best of my knowledge and belief, and that I take full responsibility for these responses. I undertake to observe ethical principles throughout the research project and to report any changes that affect the ethics of the project to the University Ethical Review Committee for review. I have read and undertake to abide by the University's Code of Practice for Research
(<http://www.birmingham.ac.uk/Documents/university/legal/research.pdf>)