APPLICANT’S ETHICS CHECKLIST

This checklist is designed to help you to decide whether or not ethics approval is required and, if required, to decide on the appropriate ethics review procedure.

**Who should use the checklist?** The Principal Investigator, or the Supervisor in the case of a supervised-student research project.

Guidance on the three different ethics review procedures that together make up the University’s ethics review system (i.e. ‘University’, ‘NHS’ and ‘Alternative’) is at:

<https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/index>

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**Research Project Title:** …

**Name of Principal Investigator / Supervisor:** …

**Name of Student (if applicable):** …

**Date:** …

|  |  |
| --- | --- |
| **The following 3 questions should be answered ‘Yes’ or ‘No’:** |  |

**Yes or No?**

|  |  |  |
| --- | --- | --- |
| **Q1.** | **Is the proposed project a research project?**  i.e. will it constitute an ‘investigation undertaken in order to gain knowledge and understanding’ (this includes work of educational value designed to improve understanding of the research process)? |  |
|  | **\*** If you answer ‘Yes’ to Q1 ethics review may be required.  If you answer ‘No’ to Q1 then ethics review is not required. | |
|  |  |  |
| **Q2.** | **Will the research project involve the NHS?** |  |
|  | **\*** If you answer ‘Yes’ to Q2 ethics review is required via the NHS. | |
|  |  |  |
| **Q3.** | **Will the research project involve human participants and/or human data and/or human tissue, but not the NHS?** |  |
|  | **\*** If you answer ‘Yes’ to Q1 and to Q3 then ethics review is required either via the University’s ethic review procedure or via an alternative ethics review procedure that is recognised by the University Research Ethics Committee.  If you answer ‘No’ to Q3 then ethics review is not required (see overleaf).   The definitions of ‘research’, ‘participant’, ‘data’ and ‘tissue’ are at:  <http://www.sheffield.ac.uk/ris/other/gov-ethics/ethicspolicy/policy-notes/participants-data-tissue> | |

*Continues overleafWhen is research ethics approval NOT required?*

Ethics approval is not required in the following situations:

* The project is not research, under the definition provided in the ‘[General Principles and Statements](https://www.sheffield.ac.uk/rs/ethicsandintegrity/ethicspolicy/general-principles/homepage)’ section of this Policy.
* The project does not involve human participants, either directly (e.g. through use of interviews, questionnaires) or indirectly (e.g. through provision of, or access to, a person’s data or tissue material).
* The project will only use publicly available anonymised data, such as census, population or other official statistical data.
* In the case of research funded by the Economic and Social Research Council (ESRC), the ESRC’s Framework for Research Ethics (FRE) states that ethics approval may not be required for data sets that exist in the public domain (e.g. data sets that are available from the Office for National Statistics, or from the United Kingdom’s Data Archive), so long as the appropriate permissions from individuals have already been obtained (through a process of informed consent) and it is not possible to identify individuals from the information provided. Data providers may, however, specify their own restrictions on the access to and use of their data and these restrictions must be complied with.
* In the case of research funded by the Economic and Social Research Council (ESRC), the ESRC’s Research Ethics Framework states that ethics approval may not be required for data sets that exist in the public domain (e.g. data sets that are available from the Office for National Statistics, or from the United Kingdom’s Data Archive), so long as the appropriate permissions from individuals have already been obtained (through a process of informed consent) and it is not possible to identify the individuals from the information provided. Data providers may, however, specify their own restrictions on the access to and use of their data and these restrictions must be complied with.
* A supervised undergraduate or postgraduate-taught student research project is deemed to be a minor variant of a ‘low risk’ research project that has been ethically approved via the University Procedure within the previous three academic years. If the student’s supervisor believes that a particular undergraduate or postgraduate-taught student research project is a minor variant of a research project that was classed as ‘low risk’ within the past three academic years inclusive then s/he should complete the [‘Minor Variant’ form](http://www.sheffield.ac.uk/polopoly_fs/1.89757!/file/Minor-Variant-Form.doc) in full, and provide an electronic and signed, dated paper copy of this form to the academic department’s Ethics Administrator. An explanation of what constitutes a minor variant and what constitutes ‘low risk’ is provided on the form.

Ethics approval *may* not be required for research projects using truly anonymised or aggregated human data that are not in the public domain, and were collected some time ago and which were, at the time, subject to appropriate ethics approval and consent. If this is believed to be the case, the researcher should communicate this in writing to the academic department´s Ethics Administrator, so that the Ethics Administrator has a record and can inform the Chair of the department´s Ethics Review Panel (or equivalent, i.e. whoever oversees the University Procedure within the department) that the researcher plans to go ahead without ethics approval. This written record should confirm that the research project does not require ethics approval because it only involves truly anonymised or aggregated data, which was collected in accordance with a research design that was appropriately ethically approved at the time, in which participants consented to the further future use of the data. The record should also briefly explain how the researcher now plans to use the data concerned. In other words, a decision not to seek ethics approval for this kind of research is not an appropriate default position: any such decision requires reflection and written justification, in the light of circumstances. There may, for example, be sensitivities among particular communities, groups or categories of people about research that concerns them, regardless of the age or anonymity of the data. Issues such as this should be taken into account, in a risk assessment, in any decision not to seek ethics approval.