**This guidance should be read in conjunction with**

[**Northumbria University’s Research Ethics and Governance Handbook**](https://www.northumbria.ac.uk/research/ethics-and-governance/)

**WHEN DO I NEED ETHICAL APPROVAL?**

All research activity conducted by staff, researchers and students within the University must be subject to appropriate ethical scrutiny and review, proportionate to the potential ethical ‘risks’ of the research. In order to avoid disproportionate review, or to ensure that ethical consideration is not bypassed, it is important that all ‘researchers’ understand what is meant by the term ‘research’, and follow the correct steps to ensure that appropriate procedures are followed.

**WHAT IS ‘RESEARCH’?**

There are numerous definitions of research, for example:

“…. *original investigation undertaken in order to gain knowledge and understanding*”

(UKRIO Code of Practice for Research, 2009)

 “… *any form of disciplined inquiry that aims to contribute to a body of knowledge or theory*”.

(ESRC Research Ethics Framework)

*“…a process of investigation leading to new insights, effectively shared…. work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction.”  (REF 2014)*

It is recognised that within the University there are different types of ‘research’ activity, and not all may require ethical scrutiny. These are as follows:

1. Funded ‘formal’ research projects (Research Councils, EU, Charity funded projects etc).
2. Unfunded ‘formal’ research projects (research conducted by staff, researchers).
3. Project/dissertation work conducted by undergraduate and postgraduate students.
4. Postgraduate research projects (PhD, MPhil, Prof. Doc etc).
5. Small-scale exploratory (‘pilot’) work within a research team to inform a methodology or research question.
6. Audits and survey evaluations that gather large quantities of data but which are primarily designed to measure existing standards and practices (Service Departments).

Only the first 4 categories listed above would usually require scrutiny by an Ethics Committee, however; it must be noted that all of the activities should only be undertaken after appropriate Health & Safety and other relevant guidelines have been consulted (e.g. CoSHH, Data Protection Act, Official Secrets Act etc).

**ETHICAL RISK LEVELS**

Research activity which falls under cases 1-4 can then be further defined in accordance to its perceived level of ethical risk. Northumbria University seeks to ensure that ethical standards are maintained in research by and throughout the University. Faculties, on behalf of the University, are responsible for ensuring all students and staff conducting research, and all research conducted on University staff, students, and premises is in accordance with the University’s ethical standards.

In order to help you determine the level of ethical risk for your research projects, the research ethics submission form should be completed and submitted for approval.

There are 3 levels of ethical risk:

* **High**
* **Medium**
* **Low**

**High ethical risks**

Does your research involve one or more of the following?

* Medicinal products
* Clinical trial
* Pharmacologically active substances
* Animals, or material derived from animals
* Children or vulnerable adults
* NHS staff, patients, premises or equipment
* Human tissue (e.g. blood or saliva samples)
* Significant concerns around personal safety or physical discomfort beyond normal experience, for the participants or researchers
* Sensitive topics such as trauma, bereavement, drug-use etc.
* Data which comes under the Official Secrets Act

If **YES**, then your project has **High** ethical risks

Your research project will be reviewed by two independent reviewers. There may also be legislative requirements to comply with e.g. [MHRA](http://www.mhra.gov.uk/Howweregulate/index.htm), [NHS REC](http://www.nres.nhs.uk/), [Human Tissue Act](http://www.legislation.gov.uk/title/human%20tissue) and [EudraCT](https://eudract.ema.europa.eu/). Indemnity arrangements may also need to be reviewed in light of the additional risk involved. Health & Safety implications will need to be addressed and any necessary HSE approvals or licence sought.

**Medium ethical risks**

Does your research involve any one or more of the following?

* Non-vulnerable adults
* Personal data referring to a living individual
* Secondary data not in the public domain
* Environmental issues
* Commercially sensitive information

If **YES**, then your project has **Medium** ethical risks

Your research proposal will be reviewed by one independent reviewer. Some factors to be considered include considering obtaining informed consent forms from organisations or people involved, permission to use data from the Data Controller, as well as confidentiality/anonymity issues.

**Low ethical risks**

Does your research involve any of the following?

* the analysis of secondary data which has been previously published
* desk or lab-based research which does not involve collecting data from people (other than pilot data collected solely within the research team).

Your research project needs to be added to the ethics and governance approval system however; it will not require independent review. You need to be ethically aware and ensure that you have not breached plagiarism or copyright regulations and have adequately referenced your material.

For all risk levels, itis recommended that you refer to [Northumbria University Research Ethics and Governance Handbook.](https://www.northumbria.ac.uk/research/ethics-and-governance/)

**SOME EXAMPLES**

1. **Our research team is conducting some pilot work. We are exploring reaction times to computer generated visual and verbal stimuli but are not sure exactly which stimuli will work best, or how best to present and record it. We are thus trying out different ways of displaying and recording the stimuli using the members of our team, so that we can refine our research question and methodology. Do we need ethical approval?**

Not normally! If pilot research of this kind is being conducted solely within a research team, then ethical approval is not required. However, if the pilot entails ‘high’ ethical risks however, then ethical approval may be required. Of course, as soon as participants external to the research team are recruited, then appropriate ethical approval must be sought.

1. **Our Service Department is conducting a user-satisfaction survey of our current facilities and provisions. We will be circulating a questionnaire to all of our Service users to enable us to improve our future provision, do we need ethical approval?**

No! A service evaluation would not normally require ethical approval, though your methodology should conform to relevant guidelines (e.g. the ‘Data Protection Act’ the ‘Freedom of Information Act’ etc). However, if the survey is being conducted by a student as part of their final year dissertation, then ethical approval must be obtained).

1. **Our Service Department conducted a recent survey concerning customer satisfaction. The results of this survey were somewhat surprising and we would like to present our data at a National Conference of Service providers. Can we do this?**

No! The dissemination of such data is classed as ‘research’ and in order to be able to present your data you would need to have obtained ethical approval of the original survey, you would have to have obtained the informed consent of all of the participants and debriefed them afterwards about the aims and outcomes of your project. Retrospective ethical approval for projects that have been completed is not possible.

1. **I am an academic, and am currently working on a new mathematical theorem that could overturn an existing paradigm, I hope to be able to publish my new theorem in a peer-reviewed journal. Do I need ethical approval?**

No! This is research but this does not entail collecting data from / about other individuals, or using secondary data not in the public domain, and so does not require approval by an Ethics Committee beforehand.

1. **I am a member of staff and am conducting some research as part of a module that I am currently delivering– do I need ethical approval?**

This depends on what the data is being used for. It is common for academics to conduct data collection within a teaching session in order to generate some ‘real’ data that can then be used to illustrate methodological/practical/statistical issues. This data is only ever being used within such sessions and will not be disseminated. Such data collection falls under the remit of ‘Health & Safety’ and should of course conform to the ‘Data Protection Act’ etc. In some instances, however the academic might consider disseminating this data, e.g. at a conference, at a workshop, in a journal publication, in a report etc. If you think that the data collection exercise you plan to conduct as part of a taught session might in the future be disseminated/published etc, then you must obtain ethical approval for your research, you can then disseminate/publish your findings.

1. **I am conducting some research with colleagues in other institutions and they have received ethical approval from their institution – do I need to obtain ethical approval as well?**

If you can provide the original ethics application prepared by your collaborators - this must

include mention of the collaboration, along with the signed letter of ethical approval from their institution, then you will not need to obtain additional ethical approval. As levels of ethical scrutiny may differ slightly between institutions, then your ethics coordinator will review the submission and discuss any issues with you as necessary.

**g) My dissertation student is undertaking secondary data collection only – does this need ethical approval?**

Yes! All student dissertations require ethical approval.  The approval process differs according to the level of ethical risk involved in the research project. All dissertation work conducted by U/G and PGT students must have received ethical consideration. The use of secondary data can fall under the ‘low’ or ‘medium categories (depending upon whether or not it is in the public domain), and will have different requirements for review.

**h) My dissertation student will analyse secondary data. The data will be obtained from Freedom of Information (FOI) requests. Is this low ethical risk?**

If the data has already been obtained via Freedom of Information requests, that data is now classed as being ‘in the public domain’, therefore it is low risk. Similarly, if the data is held within an FOI publication scheme, this is a prescribed list of data that an organisation does/will make available to the public, therefore this data is public domain.

If the data isn’t on a publication scheme, and you need to make an FOI to request the data, this means the data is not currently in the public domain; permissions are required to access it and therefore it is medium risk and will require ethical review.

1. **I am a member of staff conducting some research using analysis of secondary data which is currently in the public domain, do I need ethical approval?**

In this case your project is ‘low risk’ but you still need to register your project with your Department Ethics Lead. However, if the secondary data is not currently in the public domain, you will need permission from the Data Controller to access and use this data, and your ethical risk will be ‘medium’.

**j) I am being employed as a consultant by a company who have asked me to conduct some research with their employees, do I need ethical approval?**

This depends on what the data is being used for. Normally, consultancy work is not classed as ‘research’ (even though various research methods might be used to obtain the data required by the organization) and so does not require ethical approval. However, as in case e) if you wanted to publish your findings then the consultancy is classed as ’research’ and you must obtain ethical approval – this can be complicated as data sharing agreements need to be put into place and clear understanding between the researcher and organization in terms of what can and cannot be published etc.

**k) I am a member of staff conducting an evaluation of service delivery within a local authority. I will be interviewing vulnerable people, carers and service providers. Do I need ethical approval?**

Normally evaluation work is not classed as research (even though various research methods might be used to obtain the data) and so does not require ethical approval. However, as in case e), if you wanted to publish your findings then the evaluation is classed as research and you must obtain ethical approval. Whether or not you require ethics approval, you must ensure you adhere to all relevant University policies including Health and Safety and Safeguarding. You must ensure that all relevant permissions are sought within the organisation in which you are conducting the evaluation, for example from the Research and Development Department.

**l) A student/member of staff is interested in photographing people sitting on public seating with the intention of selecting some images for showing in a public exhibition. Does this need ethical approval?**

Yes, but...

*Openly* taking *panoramic* photographs when both the photographer and the subject are in “public spaces” and where there can be a presumption that images will be taken (eg visible CCTV cameras and warning notices) is usually acceptable. However, train stations, shopping malls, pavements with identified ownership, university campuses, etc are not public areas and approval must be obtained from the designated authority before starting to take pictures. Furthermore, there are some premises, criminal courts, police stations, military installations, the airside of airports, etc that if photographed might attract unwished for attention. For simplicity, it is best to avoid sites of “strategic importance” and to be prepared, if requested to do so by a police officer, to immediately delete these images.

There are some other spaces where photography is constrained by law. For example, if using a tripod, without paying a “fee” in Paris or on Hampstead Heath. If general “panoramic” images are not sufficient and *close-ups* are sought, then the student/member of staff must obtain informed consent from those people included in the image. However, as asking for such permission might change behaviour it might be acceptable to ask for permission retrospectively; irrevocably deleting immediately, and in the present of the people concerned, those images for which approval was not obtained. This protocol would need specific approval from the Ethics Committee which would expect contact details and the intentions for publication to be left with those in the photograph together with a reminder that, if they so wish, they can withdraw their consent later. If children or other vulnerable people are to be knowingly included in the images, then the application will also need additional scrutiny before approval may be given.

**m): I am conducting some research in which I would like to include some reflections and insights from personal experiences (or from experiences of family and friends). Do I need to obtain ethical approval?**

This will depend on the level of personal disclosure, the people that this disclosure may directly or indirectly affect, and the nature of the information shared. If the personal elements of the research project relate to people other than the researcher (e.g. members of the family or named professionals or organisations), then you need ethical approval. If the shared information only relates to you (the researcher), you need ethical approval if the disclosure puts the researcher or other people or organisations in a vulnerable position or “at risk”, e.g. by disclosing activity that may be considered unlawful, such as drug-taking, or by sharing information that is likely to cause undue distress or harm.

**n): As part of their taught sessions, students are encouraged to collect some ‘real data’ for analysis and interpretation. Does this require ethical approval?**

As part of their coursework, students may often be required to collect some data for analysis and interpretation within a class. Such data is collected solely for teaching purposes and will not be disseminated. This data is not normally classed as ‘research’ and so does not require ethical approval. However, in such cases it is important that the data is only collected from Northumbria students, and that these participants are made fully aware that the data they are providing is a) anonymous, and b) is only being used for teaching purposes. If data is being sought from non-Northumbria students, then ethical approval must be obtained in advance

**Note that it is the professional responsibility of the individual to make a decision as to whether or not their planned activity falls under the 1- 4 category. If an activity is undertaken which does fall under 1-4 and is not submitted for ethical consideration, or the appropriate Health & Safety guidelines not be consulted, then the individual will not be covered by the University insurance policy should any adverse events occur. In addition, the individual could also find themselves facing disciplinary action on grounds of academic misconduct. If in any doubt contact your Department Ethics Lead or Faculty Ethics Director for advice before proceeding.**