

Frequently Asked Questions

FAQs have been categorised as follows:

- 'General';
- 'Reapplying for ethics review';
- 'Informing & Consent';
- 'Personal Data';
- 'Retaining Data';
- 'Internet';
- 'Human Tissue';
- 'Indemnity Insurance';
- 'International Research';
- 'Undergraduate practicals involving learning about bacterial growth';
- 'Involvement of external organisations in carrying out research on behalf of University researchers';
- 'NHS – University boundary'
- 'The Mental Capacity Act'

The definitions of research, human participant, data' and tissue used are at: www.shef.ac.uk/researchoffice/gov_ethics_grp/ethics/er/ers.html

GENERAL FAQs:

1. What types of research require ethics approval via the University's Ethics Review System?

University members of staff and University registered students who plan to undertake research which involves human participants either directly (e.g. interviews, questionnaires) and/or indirectly (e.g. through provision of access to data or tissue) must ensure that their proposed research is ethically approved via the appropriate ethics review procedure, prior to commencing the research.

Guidance on each of the ethics review procedures (University, NHS, 'Alternative') is at: www.shef.ac.uk/researchoffice/gov_ethics_grp/ethics/er/ers.html

2. When should you apply for ethics approval?

Ethics approval is required prior to the involvement of human participants. Where scientific approval is also required it is a judgment call whether or not to apply for ethics approval prior to or following scientific approval. Several research funders (e.g. the ESRC) may make it a condition of release of funding that ethics approval is secured prior to the involvement of the human participants. If this is the case it may be prudent to apply for ethics approval after you have received confirmation of the award.

3. Does the University's ethics review procedure apply to course/curriculum evaluations?

YES. If the evaluation projects constitute research and do not involve the NHS (e.g. evaluations of innovative educational techniques). If a significant proportion of an academic department's research constitutes this type of educational research, and it is possible to describe the department's activities in this area in general terms, then that academic department can apply for that research to be ethically reviewed as a 'generic' project. The process for submitting 'generic' research ethics application is explained in a fact-sheet at:

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www.shef.ac.uk/researchoffice/gov_ethics_grp/ethics/er/ers.html

4. **If the research project does not involve human participants but the research funder that is funding the project requires the project to be subject to ethics review then is ethics review required?**

YES – the requirement of the research funder overrides the requirement of the University's ethics review system.

REAPPLYING FAQs:

5. **Will the applicant need to reapply for ethics approval if the nature of human participation changes during the research project's lifetime?**

YES. Ethics approval will need to be sought again if the project plans to involve participants in a different way (i.e. different involvement from that which was originally prescribed and approved by the ethics reviewers).

6. **Will a researcher need to reapply for ethics approval if s/he deviates significantly from or makes significant changes to the original documents approved by the ethics reviewers?**

If the researcher makes changes that s/he thinks are significant (i.e. because they may impact on the dignity, rights, safety and well-being of participants) and thus may require further ethics approval then, in the first instance, s/he should contact the Ethics Administrator for advice as regards whether or not new ethics approval is needed for the changes. The Ethics Administrator will then either directly give advice (e.g. requires the approval of the 'lead' ethics reviewer; requires submission of a new application; does not require further approval) or may contact the Chair of the department's Ethics Review Panel for advice. Issues will be handled on a case by case basis and, as case law develops (i.e. on cases where it was not clear-cut if further ethics approval was required) guidance will be added to the University's ethics website.

7. **Will a researcher need to reapply for ethics approval if s/he decides to use additional methods of contacting participants?**

A researcher who decides to use additional methods to contact participants (e.g. wishes to use a poster to boost the recruitment of volunteers), additional to the original methods approved by the ethics reviewers, then s/he should provide the Ethics Administrator with the additional information (e.g. the poster). The Ethics Administrator will then arrange for one of the original ethics reviewers (i.e. the ethics reviewer who was the 'lead' reviewer during the initial ethics review) to comment on it and, subsequently, will provide feedback to the applicant in the form of a revised ethics approval letter.

INFORMING & CONSENT FAQs:

8. **How should information on a proposed research project be communicated to prospective participants?**

The method of informing prospective participants about a research project (e.g. an information sheet, a covering letter or a script) is a less important consideration than considering what information should be communicated to the

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prospective participants. For further guidance see the guidance fact-sheet on completing the University's research ethics application form at: www.shef.ac.uk/researchoffice/gov_ethics_grp/ethics/form.html

9. When is the use of a consent form inappropriate/disproportionate?

Guidance is at: www.shef.ac.uk/researchoffice/gov_ethics_grp/ethics/form.html

10. Can consent be obtained via the use of electronic consent forms?

Wherever possible, and proportionate to the nature of the research activity, an individual's consent should be obtained in writing. Where this is not possible oral consent should be obtained, ideally in the presence of at least one witness (witnessed consent is required for particularly vulnerable participants who have intellectual or cultural difficulties in speech or understanding, but who are deemed capable of giving consent). However, bearing the above in mind, if a researcher wishes to use an electronic means of obtaining consent (i.e. an individual gives consent by electronically completing and returning an electronic consent form) then s/he should consider how abuse is to be avoided (e.g. identity theft). One solution might be to provide prospective participants with "unique logins and passwords" (e.g. sent by post) to enable them to access and complete an on-line consent form.

11. Is it ethically acceptable in research to publish photographs of people where clear consent for specific use has been secured?

Yes, this is acceptable so long as it has been made explicit to the human participants in writing, and perhaps also verbally, and the participants have given their consent in writing (or their implied consent – e.g. have returned a questionnaire).

Important Caveat:

The risk does remain, however, that the participant may choose to withdraw consent for the photographic data to be used (i.e. relying on purely photographic data may present a risk).

PERSONAL DATA FAQs:

12. My project will only involve anonymised or aggregated data which was collected some time ago and which was, at the time, subject to relevant ethics committee approval. Does my project need to be ethically reviewed again?

Ethics approval is not required if the data is truly anonymous (i.e. the individuals to whom the data relates cannot be identified because the project's researchers do not have access to any identifiable information (e.g. name, address, code identifying an individual). For example, truly anonymous data obtained from large national data sets (e.g. collected by the Office for National Statistics) does not require ethics approval.

Important Caveat:

Although ethics approval is not required if the data is 'truly' anonymous, the researcher should inform the department's Ethics Administrator (i.e. in an email):

- how the anonymised data was originally obtained from individuals (e.g. through use of a participant information sheet, by informed consent); and

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- how the research project plans to use the anonymised data.

The Ethics Administrator will then inform the Chair of the department's Ethics Review Panel or the 'lead' ethics reviewer, whoever is more appropriate.

13. Use of data in the public domain: My proposed project will only involve access to data stored on publicly available databases. Does my project need to be ethically reviewed again?

The answer given to question 13 above applies.

For ESRC funded research, the ESRC's Research Ethics Framework states that ethics review may not be required for data sets that exist in the public domain (e.g. datasets available through the Office for National Statistics or the ESRC Data Archive). However, this is on the provision that the individuals, to whom the data contained in the datasets relates, gave appropriate permission (e.g. informed consent) for the data to be included in the publicly available datasets and on the provision that it is not possible to identify the individuals from the data.

Data providers are, however, likely to specify their own restrictions on the access to and use of their data and these restrictions must be complied with.

14. The ethics of pooling/sharing data sets

Where two or more research teams collect data on different individuals, the datasets can be pooled/shared so long as the research projects were ethically approved and the data to be pooled and shared has first been anonymised. However, the anonymisation of the data has to be thoroughgoing and watertight. Furthermore, the research funder(s) involved that funded the data collection should be asked to approve the data pooling/sharing arrangement.

One precedent is the deposition of datasets with the ESRC Survey Archive at Essex; datasets which are used in secondary analysis by other researchers.

RETAINING DATA FAQs:

15. Should the content of interview tapes be erased once they have been transcribed?

Retention requirements for research data and records should be determined on a project by project basis taking account of:

- the legal and regulatory framework for particular types of research.
- the terms and conditions imposed by external research funders.
- the commercial, political or ethical sensitivity of particular types of research, or any research for particular external funders.

One of the Principles (no.5) in the Data Protection Act (1998) states that data should not be kept for longer than is necessary, but it is not inconsistent with the Data Protection Act to retain the actual interview tape recordings. Interview tape recordings constitute primary research data and the transcriptions form part of the research data record. Conversely, it may be more appropriate to dispose of interview tape recordings once they have been transcribed. But this can create difficulties if, for example, one were to be challenged on the veracity of the transcripts and one needed to refer back to the original tape recordings. It is

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important that an academic department takes a consistent approach on record retention with respect to particular types of research project.

INTERNET FAQs:

16. Do I need ethics approval to access data available on the internet (e.g. in chat rooms, blogs, forums)?

The main determinant is whether or not the websites that the researchers wish to access data from are in the public domain.

If one has to go through a process in order to 'join' a website in order to access the data (e.g. by registering, being invited to join) then the site is not in the public domain and concerns for anonymity, confidentiality, data protection and privacy will apply. In the case of such websites (a) ethics approval is required, (b) the permission of the website administrator/controller/moderator to carry out the research should be obtained and (c) the informed consent should be obtained from the users of the website in order to be able to use data that they have created (e.g. conversations). It is also good practice to ask prospective human participants if they would prefer to be referred to by their internet name or by their real name.

If, on the other hand, you can simply access the data without going through a process in order to join the website, then the data should be considered as being in the public domain. Accordingly, consent and ethics approval is not required.

However, there are grey areas here (if in doubt a belt and braces approach is probably worth while – i.e. ethics approval and consent). Furthermore, it is worth reading the following guidance fact-sheet:

www.shef.ac.uk/researchoffice/gov_ethics_grp/ethics/er/guidance.html

HUMAN TISSUE FAQs:

17. What is meant by human tissue?

The UK Human Tissue Authority defines human tissue as:

'Relevant material that has come from a human body and consists of, or includes, human cells'

For further guidance please see the fact-sheet on human tissue at:

www.shef.ac.uk/researchoffice/gov_ethics_grp/ethics/er/guidance.html

18. I plan to undertake research that involves human tissue (tissue as defined by the UK Human Tissue Authority). How do I obtain ethics approval for the research?

Ethics approval is always required for research that involves human tissue.

There are two potential routes for applying for ethics approval:

- 1) You can use tissue from a UK Human Tissue Authority-recognised bank that is housing tissue for unspecified research (the research purpose to be specified prior to the use of the tissue) and which has received generic ethics approval from an NHS Research Ethics Committee. There are two such banks within the University: one in the School of Medicine and one in the

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Kroto Institute. In order to access and use the tissue from such a bank you will need to comply with the bank's standard operating procedures. For example, the tissue should be anonymised at the point of release for the research and the release of the tissue should comply with the terms of the donor's original consent.

- 2) You can use apply for ethics approval from an NHS Research Ethics Committee

Note on Secondary Use of Human Tissue:

If you originally obtained the human tissue following ethics approval from an NHS Research Ethics Committee, at the time of applying to the NHS Research Ethics Committee you could have specified your intention to deposit the human tissue, at the end of the project's lifetime, in a UK Human Tissue Authority-recognised bank that is housing tissue for unspecified research, stating the intention to use the tissue again on a future as yet unspecified research project (i.e. to enable secondary use of the tissue).

When applying to an NHS REC in order to undertake a specific research project that will involve removing tissue from human participants (subject to and following their informed consent), it is good practice to ask the participants' permission for their tissue sample(s) to be used for future research (subject to the sample(s) either being stored in an HTA-licensed bank housing tissue for unspecified research (research purposes to be specified prior to the use of the tissue) or being used on a subsequent specified NHS REC-approved research project).

19. My research involves using human tissue. What should I do with the human tissue at the end of the research?

There are three potential options:

- 1) Destroy the human tissue; or
- 2) Deposit the human tissue in a UK Human Tissue Authority-recognised bank that is housing tissue for unspecified research; or
- 3) Apply to an NHS Research Ethics Committee in order to use the human tissue on a new research project.

20. If I wish to use blood samples held by the National Blood Service will I need to apply for ethics review via the NHS ethics review procedure?

YES – and following confirmation of ethics approval from an NHS Research Ethics Committee the applicant will need to inform the National Blood Service. However, the National Blood Service is very happy to support researchers by providing them with necessary, relevant information for inputting into their NHS research ethics application forms (e.g. information concerning the terms of the consent given by people who have donated blood to the National Blood Service).

INDEMNITY INSURANCE FAQs:

21. Is the University's current indemnity provision sufficiently adequate to cover research projects that involve human participants which are undertaken by University-registered distance learning students overseas?

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YES

INTERNATIONAL RESEARCH FAQs:

22. Does research by students registered with the University but undertaking their research outside the UK or based outside the UK require ethics approval?

YES. In the first instance the student should apply for ethics review via the ethics review procedure in the relevant organisation in the particular country, if such a procedure exists. For guidance on the 'Alternative' ethics review procedure (i.e. alternative to the University's or NHS's ethics review procedure) see the fact-sheet at: www.shef.ac.uk/researchoffice/gov_ethics_grp/ethics/er/ers.html

23. What are the requirements for international research?

University members of staff and University registered students are expected to conduct research in other countries in accordance with the University's 'Good Research Practice Standards' and 'Ethics Policy':

www.shef.ac.uk/researchoffice/gov_ethics_grp/grpstandards.html

Firstly, if a researcher is undertaking research outside the UK that requires ethics approval (i.e. because it involves human participants, data or tissue), in the first place s/he is expected to obtain ethics approval via that country's own ethics review system. If that country does not have a sufficiently robust system (the researcher needs to provide the U-REC's Secretary, Mr Richard Hudson - r.j.hudson@sheffield.ac.uk, with information – see the examples below) the ethics review will be required via the University's ethics review procedure.

A University researcher is also expected to comply with the research ethics arrangements of the country in which s/he is operating. For most of the developed world this may involve different methods of seeking approval, but there is a common basis of international guidelines. For the developing world a review of how local approval is obtained would be an essential part of the ethical process here. Each case would be dealt with on its merits but there are many considerations to take into account, such as the **effectiveness of local ethical approval** (sometimes it is just the signature of a local official, which raises concerns), the **balance between** 'official' approval and the interests of the individuals or community involved, the **balance between** individual and community consent (especially in parts of the world where the concept of individual consent is different) and the **different value of 'rewards'** which might be offered.

Example 1 A PhD student from Chad is investigating population histories of Chad using forensic DNA profiling techniques. The PhD student has shown the Supervisor a copy of a letter from the local University Hospital ethics committee in Chad approving her information sheet and consent form and approving the project on ethics grounds.

The PhD student/Supervisor should provide the U-REC's Secretary with a translated copy of the ethics approval letter and with a brief statement (in an email) explaining the ethics review procedure in place in Chad, specifying if possible what information the Chad ethics committee expects to receive from an applicant in order to effectively ethically scrutinise an application.

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Example 2 A researcher plans to study the DNA of German patients, whose blood has been originally obtained for genetic studies following receipt of ethics approval from a German research ethics committee. The researcher is applying for external funding and the particular research funder has requested evidence of ethics approval.

If this is the case the researcher should provide the U-REC's Secretary with a translated copy of the ethics approval letter from the German research ethics committee. The U-REC's Secretary will then write a letter to the research funder confirming that ethics approval has been obtained.

24. How can I receive 'generic' ethics approval?

The process for submitting 'generic' research ethics application is explained in a fact-sheet at: www.shef.ac.uk/researchoffice/gov_ethics_grp/ethics/er/ers.html

Example 1 - student questionnaire study:

Each year a cohort of 30 undergraduate students undertake short research projects to find out about eating preferences and about the relationship between smoking and health. However, 3 of the students within the cohort plan to include in their line of questioning, questions that are of a 'sensitive' nature which therefore have the potential to cause distress (e.g. concern illegal activity, stigma, discrimination, cultural, ethnic, racial, political, religious or sexual issues/preferences).

Whilst the majority of the cohort of planned projects would fit under a 'generic' project, each of the 3 projects asking sensitive questions would need to submit individual University research ethics applications for separate ethics approval (or one application between the 3 of them if there was little difference between them).

Example 2 - student fieldwork:

All the modules for 1st, 2nd and 3rd year undergraduates, within a particular department, require students to collect data from participants about their language use and how this relates to their social identity. The students produce presentations and projects based upon their fieldwork. All the students' projects are similar.

Example 3 – interaction with schools in Science Week:

Year on year a researcher visits schools during Science Week to give demonstrations that are all performed on school children (e.g. measuring blood pressure, heart rate and taking ECGs). As this is not strictly research it would not require ethics approval. However, for good practice, the researcher might actively choose to seek ethics approval to demonstrate that ethical issues have been considered.

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SIMPLE STUDENT PRACTICALS CONCERNING LEARNING ABOUT BACTERIUM FAQS:

25. Undergraduate practicals involving learning about bacterial growth

Undergraduate practicals that involve students learning about bacterial growth (for example in the biologies departments) do not require ethics approval when the practicals simply involve the following exercise:

- Students are asked to determine if they are carriers of a particular bacterium (e.g. *staphylococcus aureus*). This is determined by students wiping the inside of their own noses with a cotton bud and spreading it on an agar plate. The plates are then incubated and the students see if anything has grown (without even opening the plates).

INVOLVEMENT OF EXTERNAL ORGANISATIONS IN CARRYING OUT RESEARCH ON BEHALF OF UNIVERSITY RESEARCHERS

26. For my proposed University research project I would like to use the services of a market research company in order to contact prospective human participants. However, how can I be confident that the company involved can be relied upon to undertake the research in a manner that will satisfy the University's research ethics requirements?

Firstly, the researcher should make it a requirement on the company (e.g. by including a specific clause in a contract/agreement) that the company must comply with the University's 'Ethics Policy for Research Involving Human Participants, Data and Tissue' in addition to complying with its own appropriate governing code (e.g. Market Research Society code of conduct).

Secondly, in terms of being able to ensure that the company will in practice comply with the University's Ethics Policy and Market Research Society code this is actually a matter of 'research governance' rather than research ethics. If it remains a concern, despite a contract being in place, then it may be a matter of altering the research design.

NHS – UNIVERSITY BOUNDARY

27. Does a research project which involves the NHS and also non-NHS participants need to be ethically reviewed by both the NHS ethics review procedure and the University ethics review procedure?

NO – so long as the approach used to recruit and inform NHS participants is broadly similar to the approach used to recruit and inform non-NHS participants. However, if the recruitment procedures, information sheet and/or consent form to be used for NHS staff/patients are significantly different to the recruitment procedures, information sheet and/or consent form to be used for non-NHS participants then separate ethics review, via the University ethics review procedure, would be recommended in respect of the non-NHS participants (i.e. in addition to the NHS ethics review in respect of the NHS participants).

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- 28. For my proposed University research project I plan to ask staff based in University medical schools across the UK to complete a questionnaire about their experience of medical education/training. I will not be gathering personal data. Do I require ethics approval and, if so, from the University or from the NHS?**

This issue is not whether you will be collecting personal data but whether the prospective human participants (the people completing the questionnaire) are NHS staff. If they are NHS staff then ethics approval from the NHS ethics review procedure is required. If they are not NHS staff then ethics approval from the University ethics review procedure is required.

If staff are University staff but some of them hold honorary contracts with the NHS then the researcher should make it very clear that they are being contacted in their capacity as University staff.

- 29. For my proposed University project I plan to investigate the NHS's IT policy and procedures?**

If the project is a 'research' project (i.e. not classed by the NHS as another type of project – e.g. 'audit' or 'service evaluation') and is going to involve any of the following then it will require NHS ethics approval:

- i. Patients and users of the NHS;
- ii. Individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS, as defined above;
- iii. Access to data, organs or other bodily material of past and present NHS patients;
- iv. Foetal material and IVF involving NHS patients;
- v. The recently dead in NHS premises;
- vi. The use of, or potential access to, NHS premises or facilities;
- vii. NHS staff – recruited as research participants by virtue of professional role;
- viii. Phase 1 studies involving healthy volunteers.

On the other hand, if the project involves human participants but is not classed by the NHS Research Ethics Committee as research, but is classed as research by the University (i.e. is an 'investigation in order to gain knowledge and understanding') then it will require ethics review via the University's ethics review procedure.

THE MENTAL CAPACITY ACT

Web link to the Act: www.dca.gov.uk/menincap/legis.htm

- 30. Can University Research Ethics Committees/Universities' Ethics Review Panels ethically review research that falls under the Mental Capacity Act?**

NO.

On 19.03.08 Mr David Neal (Head of Policy and Deputy Director, NHS National Research Ethics Service) confirmed the following:

"The Department of Health has no plans to recognise ethics committees for the purpose of giving approval for research under the Mental Capacity Act, other than those established under its Governance Arrangements for NHS Research Ethics Committees (GAfREC). There seems no prospect of universities gaining such recognition. However, we have given explicit instructions to NHS RECs that they

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should accept any applications submitted under the Mental Capacity Act, whether or not the research is to take place in the NHS. We have "flagged" a number of NHS RECs to review Mental Capacity Act applications - around 30 in total throughout England and Wales - and have run a number of in-depth training workshops for their members at which we discuss the possibility of applications in research settings outside the NHS, including social care. We have also introduced arrangements for all Mental Capacity Act applications to be booked through our Central Allocation System (CAS – 0845 270 4400), which is well aware of the procedures and will advise on a suitable flagged NHS REC to which the application can be allocated.

Further information about booking procedures can be found at:
www.nres.npsa.nhs.uk/applicants/apply/applying-for-ethical-review/