

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' – is it audit, research or service evaluation?
- '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. Definition of research?

Projects that are 'investigations undertaken in order to gain knowledge and understanding' are regarded as research projects by the University's Research Ethics Committee (UREC). This definition is deliberately broad in order to ensure that all supervised-student projects involving human participants, not all of which may be original and not all of which may be published, are included within the remit of the University's *Ethics Policy for Research Involving Human Participants, Data and Tissue*. Therefore, if an investigation undertaken in order to gain knowledge and understanding involves human participants then ethics approval must be obtained before the involvement of the human participants/prior to data gathering.

2. What types of research require ethics approval?

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

3. 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

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may be prudent to apply for ethics approval after you have received confirmation of the award.

4. 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:

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

5. 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 procedure.

6. If the only human participant(s) involved in the proposed research project will be the child(ren) of the researcher is ethics review required?

YES - particularly because it is their own child.

REAPPLYING FAQs:

7. 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 degree of potential risk to the participants might increase due to the changes (e.g. different method of interaction from that which was originally approved by the ethics reviewers).

8. 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.

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9. 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:

10. 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 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

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

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

12. 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.

13. 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).

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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).

- 14. My project involves videoing people interacting with a robotic device, without them being made aware first that the device is robotic, or that they are being filmed. I then hope to be able to identify people from the video recording so that I can contact them and interview them about the experience (at which point I will obtain consent). I have heard there may be some problems with this approach in relation to the Data Protection Act and the Regulation of Investigatory Powers Act?**

Under the Data Protection Act (Part IV), personal data obtained for research purposes is shown to be exempt from Part II Section 7 (which states that an individual has the right to be informed that data is being collected on them), providing the following conditions are met:

- a) That the data are not processed to support measures or decisions with respect to particular individuals;
- b) That the data are not processed in such a way that substantial damage or substantial distress is, or is likely to be, caused to any data subject;
- c) That the results of the research or any resulting statistics should not be made available in a form which identifies data subjects.

However, in order to be able to contact the research subjects for interview purposes the researcher will have to, at some stage, keep the material in such a way that individuals can be identified (ie 'in a form which identifies data subjects'). A possible solution to this problem would be if the researcher could speak to the research subjects immediately after they have been filmed with the robotic device, so they can at that point be asked for their consent prior to being interviewed.

With respect to the Investigatory Powers Act, there are conditions relating to 'surveillance' – although it does not define what 'surveillance' actually is at any point. However, it is clear from Schedule I, Parts I and II, that the Act covers official surveillance, not research, and it can therefore be considered not to apply in this situation.

- 15. My project involves taking photographs of people's houses from the street; will I need to obtain informed consent from the homeowners?**

Providing the research does not involve making potentially controversial remarks about the property or the community, there is no need to obtain informed consent for photography of the public exterior of a building, even if it is a private house. However, where there is obviously someone at the house being photographed, it may be polite to approach them to explain the reason for the photographs and ask for verbal consent before going ahead.

Another possibility is to put a letter through the door of every house photographed, explaining that the house has been photographed for research purposes and offering, on receipt of an e-mail, to send the owner/occupier a digital copy of the photograph (or photographs). Thus there is a quid pro quo for

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the homeowner, and anyone who wishes to register an objection can do so (without the need to go through the informed consent process).

The photographs should be taken ensuring that there are no identifiable individuals included in the image, otherwise informed consent would be required from those individuals.

PERSONAL DATA FAQs:

- 16. 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
- 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.

- 17. 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.

- 18. 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.

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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.

19. **A researcher wishes to analyse a sub set of data (which happen to be tape recordings) on a current research project that has been ethically approved, but wishes to use the data for a separate research project (i.e. analysis for secondary research). The data has not been transcribed. The original ethics approval stated "No other use will be made of the data from the research without the written permission of the human participants and no one outside the research project will be allowed access to the original recordings" Furthermore, it stated that only researchers who are members of the project team can have access to the data. Can the researcher be given access to the data sub set prior to the transcription of the data or after the transcription (i.e. once it has been anonymised)?**

The researcher cannot have access to the data sub set prior to the transcription because s/he is not a member of the research project team. However, s/he can access the data sub set in transcribed, anonymised form (see the answer to the above question on anonymised data).

RETAINING DATA FAQs:

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

INTERNET FAQs:

21. **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.

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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:

For guidance specific to research involving human tissue please see the factsheet on human tissue at:

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

22. What is meant by human tissue?

Human tissue is defined as:

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

Relevant materials is defined on the Human Tissue Authority website at:

www.hta.gov.uk/legislationpoliciesandcodesofpractice/definitionofrelevantmaterial.cfm

List of what constitutes relevant material:

www.shef.ac.uk/content/1/c6/07/21/15/Supplementary_list_of_materials_200811252407.pdf

23. 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?

Human tissue samples can be obtained for research in 3 ways:

1. Obtain the human tissue sample(s) from an HTA-licensed bank housing tissue for unspecified research (the research purpose(s) must be specified prior to the use of the tissue) and comply with the HTA-licensed bank's conditions, which will include the need to:
 - provide evidence of independent scientific approval; and
 - comply with the terms of the donor's consent; and
 - ensure that the sample(s) are anonymised at the point of release; and
 - abide by a supply agreement.

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2. Submit an application for a specific research project to an NHS Research Ethics Committee (NHS REC). All NHS RECs can ethically review research which plans to use human tissue. The NHS National Research Ethics Service (NRES) governs NHS RECs: www.nres.npsa.nhs.uk/. NHS research ethics applications are submitted via IRAS – www.myresearchproject.org.uk/;
The NHS REC will give authority to store the human tissue sample(s) for the duration of the research project.
3. If collecting (i.e. removing) human tissue sample(s) from healthy volunteers (e.g. taking blood from students) then submit an application for a specific research project via the University's research ethics review procedure. The human tissue sample(s) can only be collected subject to and after informed consent has been obtained from the healthy volunteers and the human tissue sample(s) cannot be stored – the human tissue sample(s) must be processed within 48 hours from the sample(s) having been collected.

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).

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

25. Is consent always legally required to store and use tissue for research?

No.

There are a number of exceptions under the Human Tissue Act. The most important of these are:

- Tissue which is an 'existing holding' – i.e. it was already held before 1 September 2006;

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- Tissue which has been taken from a living person and the researcher is not able to identify the person and the research is ethically approved by a research ethics committee;
- Imported tissue.

26. Should consent to use tissue be obtained if it is not legally required?

Applicants should consider whether it is ethically appropriate to obtain may be sought from ethics committees. In the case of *existing holdings*, the HTA's Code of Practice on Consent includes specific guidance on whether consent should be sought to use of tissue in research (see paragraphs 114-115). Considerations include whether other sources of tissue are available, the feasibility of tracing and contacting donors, the potential for the research to discover information of clinical significance for donors, or to cause them unnecessary further distress.

In the case of new tissue from the living, it is good practice to obtain prospective consent to use the tissue in research where practicable.

27. Is consent always required to remove tissue for research?

Appropriate consent is always required under the Human Tissue Act to remove tissue from the deceased for research purposes.

Consent is always required under the common law to remove tissue from the living. However, consent from the living may be given for diagnostic or therapeutic purposes. If it is also intended to store and use part of the tissue for research, it is good practice to seek specific consent for research at the same time but this is not a legal requirement. Tissue from the living may be stored and used for research without consent provided the research is ethically approved and the researcher cannot identify the donors.

28. DNA analysis – is ethical approval required?

Under the Human Tissue Act, the only circumstances where ethical approval is legally required in relation to DNA research is where cellular material from the living (e.g. blood) is stored with the intention of conducting DNA analysis without consent from the person whose body manufactured the DNA. In these circumstances ethical approval from an NHS REC is required under Schedule 4 Paragraph 1-0 of the Human Tissue Act. The material must be non-identifiable to the researcher. Where consent is in place for DNA analysis, no requirement for ethical approval would arise. In some cases consent is only given to analyse the DNA for the specific study – in these circumstances, further ethical approval would need to be sought to analyse DNA in further projects. Researchers may anticipate this by seeking broad consent at the outset.

Under NHS research governance systems, ethical approval is not required for research involving anonymised extracted DNA, as the research involves neither tissue (i.e. cellular material) nor data of NHS patients. Ethical approval would only be required where identifying data is held with the DNA sample. However, it would be open to researchers using anonymised DNA to seek ethical review on a voluntary basis (e.g. if required by the research funder or if the project raises unusual issues on which they needed ethical advice).

29. Cell lines – is ethical approval required?

Cell lines are not relevant material under the Human Tissue Act.(although primary cell cultures are). Research using cell lines does not required ethical approval under the Human Tissue Act.

The Human Tissue Act relates to cells directly produced by a human body. Cell lines are considered to be created outside the human body (viewed as manufactured products) and therefore do not come under the Human Tissue Act and laboratory based research only using cell lines does not require ethical review.

30. Exporting human tissue samples for research overseas – is ethical approval required?

There is no legal requirement for ethical approval. However, applications may be made voluntarily to a NHS REC. The NHS REC will confine its review to the activities to be conducted in the UK, in particular the arrangements for informed

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consent. It will not undertake detailed scrutiny of overseas research projects. Where appropriate these should be ethically reviewed in the host country.

When seeking consent from donors it is good practice to inform them of plans to export their tissue outside the UK for use in research by overseas collaborators.

31. 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:

32. 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?

YES

INTERNATIONAL RESEARCH FAQs:

33. 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

34. 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 Minute Secretary, Ms Lindsay Cooper – l.v.cooper@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

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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 Minute 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.

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 Minute Secretary with a translated copy of the ethics approval letter from the German research ethics committee. The U-REC's Minute Secretary will then write a letter to the research funder confirming that ethics approval has been obtained.

35. 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).

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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.

SIMPLE STUDENT PRACTICALS CONCERNING LEARNING ABOUT BACTERIUM FAQS:

36. 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

37. 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

38. Is the project audit, research or service evaluation?

Projects that are 'investigations undertaken in order to gain knowledge and understanding' are regarded as research projects by the University's Research Ethics Committee (UREC). This definition is deliberately broad in order to ensure that all supervised-student projects involving human participants, not all of which may be original and not all of which may be published, are included within the remit of the University's *Ethics Policy for Research Involving Human Participants, Data and Tissue*. Therefore, if an investigation undertaken in order to gain knowledge and understanding involves human participants then ethics approval must be obtained before the involvement of the human participants/prior to data gathering.

The NHS ethics review system (i.e. the National Research Ethics Service – NRES) distinguishes research from audit and service evaluation in a guidance factsheet: <http://www.nres.npsa.nhs.uk/search/?q=audit+service+>

However, **if a University of Sheffield researcher is in doubt as to whether a project is or is not research then s/he should follow the UREC's broad definition of research – i.e. research is an investigation undertaken in order to gain knowledge and understanding.**

39. 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).

40. 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.

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41. 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 & 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 to gain knowledge & understanding') then it will require ethics review via the University's ethics review procedure.

42. For my proposed research project I plan to interview people who use the public service 'Books on Prescription' (the service is run by Primary Care Trusts and by library authorities throughout the UK and involves a library holding a collection of recommended self-help books that can be either taken out by library users independently of the NHS, or prescribed by GPs for people with conditions like depression & anxiety - Do I require ethics approval from the NHS or from the University?

Ethics approval from the NHS is not required if the researcher is not recruiting the users of the service by virtue of their past or present treatment by, or use of, the NHS. If the researcher is recruiting prospective participants solely in their capacity as users of library services (i.e. & not in their capacity as people who have been prescribed access to the service by their GPs) then the research require ethics approval via the University's ethics review procedure.

THE MENTAL CAPACITY ACT

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

43. 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 should accept any applications submitted under the Mental Capacity Act, whether

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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/