

University Teaching and Research Ethics Committee Frequently Asked Questions

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Do all University of St Andrews research projects involving human participants need ethical approval?

Yes. All projects involving human participants (people participating in a direct way by e.g. answering questions about themselves or their opinions, performing tasks, being observed, involving data about identified or identifiable people) must secure ethical approval from UTREC. All research and teaching activities of all staff and students in all Schools or Units of the University that involve data collection from, interviews of, interactive investigation of, experimentation upon or demonstrations involving living human subjects, tissues and / or other samples will require formal approval from UTREC.

Research brings researchers into contact with other people: people showing you how equipment works, providing information on matters connected with your research, and giving their views on your research do not count as human participants in the technical sense as they are not giving you information about themselves and the opinions offered are not the subject of the research. Ethical Approval is not required when your contact with people is confined to this sort of interaction.

Why do all research projects involving human participants need ethical approval?

To make sure that the participant's welfare, dignity and privacy are protected. Many funding bodies will not fund projects involving human participants unless they have been subject to ethical scrutiny and University approval procedures. The University itself seeks to ensure that its research does not expose participants, staff, or students to unnecessary or undue risk; that there is no morally inappropriate use of the outcomes of research involving human participants; that where potential conflicts of interest arise with research sponsorship, mechanisms are put in place to combat this.

Who gives ethical approval?

Ethical approval will normally be given by the SEC in the form of an approval letter after which the project can proceed. However in more complex research or where children are participants the SEC (with the exception of a select few Schools/Department) will pass the application to UTREC for its consideration and approval. Please note that the School Ethics Committee is a sub-section of UTREC

Even in cases where external permission is required, such as from an NHS Ethics Committee, the project must still be approved through the University procedures, as the University is legally responsible for all research undertaken by its staff.

UTREC meets monthly to monitor all applications approved by the SECs, and to take decisions on more complex applications.

Which School Ethics Committee (SEC) should I submit my form to?

If your School/Department has established a School Ethics Committee, the form should be submitted to the SEC secretary/administrator in the first instance, who will be able to offer advice. If you are doing a joint honours degree and your project could come under either School, submit it to the School to which your supervisor belongs. A list of SECs is available from the UTREC webpage. Where a project is being undertaken through or by a Unit, please submit the form directly to a UTREC secretary; unless it comes under ELT in which case submit it to an ELT secretary.

How soon will I hear whether my research project has approval?

You should submit your Ethical Application form to your School Ethics Committee (SEC) together with any supporting documentation indicated on the form, at least 30 days before you wish to start your research project. Normally you will receive a reply within two to four weeks, but extra time should be allowed in case the SEC officer needs additional information in order to be able to authorise research to start. Some SECs meet fortnightly, others monthly, others as and when required.

UTREC typically meets the third Wednesday of each month and papers are sent out to the committee a week in advance. A list of UTREC meeting dates is published on our webpage at <http://www.standrews.ac.uk/utrec/structure/procedures/>

When should we apply for approval?

You must secure approval for your project before you begin any part of your research which involves human participants, e.g. including pilot studies, gathering information of any kind, photographic material, interviews etc. You should do literature searches, gather information, read the UTREC guidelines, familiarise yourself with the UTREC website, familiarise yourself with your own discipline's ethical guidelines, discuss your plans with your supervisor or colleagues before you secure approval, and you need approval before carrying out a pilot study if that involves human participants. Grant awarding bodies may specify whether you should apply for ethical approval at the same time as you apply for financial support, or whether you need to secure approval before you apply for funding. UTREC has no view on this provided approval is secured before research starts. In general it may be sensible to wait until funding has been secured before submitting the paperwork but if time is likely to be of the essence once funding has been obtained, you should have the paperwork ready to submit as soon as possible.

Should I apply, or should someone else apply on my behalf?

The principal investigator of the research project, whether a member of staff, or the supervisor of the student carrying out the research, or the student researcher (under the guidance of the supervisor) is the formal applicant, though other researchers may prepare some parts of the application. If a student under a supervisor makes the application, the supervisor, if his/her research is wider than that applied for by his/her student, must make his/her own application. A staff member's research is not covered by an application made by a student.

My research has started and I forgot to apply for approval, what should I do?

You must apply for approval immediately, even if it is retrospective. It is possible that if the judgement is made by a SEC or UTREC that your failure to apply for approval constitutes a serious breach of procedure, you may not be able to use the information gained in your fieldwork in your dissertation/thesis.

What steps must we go through to gain ethical approval?

Some Schools (Computer Science, Geography/Geoscience, International Relations) have a checklist, which is their first stage of ethical approval and is designed to separate projects which don't need ethical approval (for example those which are audit, not research) from those that do.

If your project needs ethical approval, fill in the Ethical Approval Application Form and prepare supporting documents i.e. Participant Information Sheet, Consent Forms, Questionnaires, Debriefing etc. In the interest of continuity in good research all researchers must use the template documents provided on the UTREC website, adapting to your specific research requirement if necessary. Applications should be submitted to the relevant SEC for approval.

My checklist showed that my project needed further scrutiny: what should I do? [For Schools which have a checklist (Geography & Geosciences, Computer Science, International Relations)].

Complete a full application form (available on UTREC website) and submit it to the appropriate SEC officer electronically and with a signed paper version. If the application is approved you may start your research: if it is not, you must change your research procedures to meet the committee's concerns and resubmit your proposal. Be aware that your study may be audited (see FAQ??) later for its compliance with research ethics procedures.

The checklist showed that my research project needs no further University scrutiny. What now? [For Schools which have a checklist (Geography & Geosciences, Computer Science, International Relations)]

Send your checklist to the appropriate SEC Chair electronically and also a signed paper version. He or she will review the checklist and then write to you to confirm the outcome of that review, normally approving the start of the research project. In some cases, however, the SEC officer may request further information. If your research project is approved, you can proceed with your study with no further reference to UTREC, unless the nature of your study changes (see FAQ??).

You should submit your checklist/Ethical Application Form to the relevant SEC at least 30 days before you wish to start your research project. The SEC officer will need sufficient information in order to be able to authorise research to start; if the officer has to request additional information, this may cause a delay.

The checklist showed that my research project needs to be scrutinised by the NHS. What now?

Start NHS ethical review procedures (<http://www.nres.npsa.nhs.uk/>). Once you have received NHS approval, send a copy of the NHS documentation approving your project to the SEC secretary or convener so that the University has full details of all approved research involving human participants, and also fill in the first page of the UTREC Ethical Application Form (the research is then entered on to the UTREC database). The SEC convener looks over the project and NHS approval letter and if he/she has concerns takes the project to the SEC. Final approval can only be given by the SEC or UTREC, not by the NHS, as the University is legally responsible for all research carried out by its staff or students.

There are terms in the checklist/application form/on this website that I don't understand. What do I do?

Use the [UTREC glossary and guidance](#).

I already have NHS REC approval do I still need to go through the University UTREC process?

Yes, you must complete and submit the UTREC Ethical application form and copy of the approval letter to the relevant School Ethics Committee or UTREC.

What is meant by Collaboration in the Ethical Application Form?

'Research collaboration' is defined as occurring when more than one person works on a particular piece of research. All School/Department/Unit researchers, assistants, including students, involved in the project should be detailed in the "Researchers name(s)" box on Page 1 of the application Form.

- Question 4, in the Ethical Application form, "Does this research entail collaboration with other Researchers?" is aimed at capturing information regarding researchers across other University Schools/ Departments/Units or from other institutions. Therefore this box should be ticked YES if anyone involved in the project is not based within your own School/Department/Unit or indeed this University.
- Question 5, in the Ethical Application form "If the research is collaborative has a framework been devised to ensure that all collaborators are given appropriate recognition in any outputs?" includes University Staff, Students, and External Researchers to ensure appropriate recognition is given to everyone involved in the research.

I am involved in collaborative research and ethical approval has already been obtained from the other University. Do I still need to go through the University UTREC process?

Yes, however we are happy for you to complete the first page and signature page of the UTREC Ethical Application form and submit along with a copy of the approved application and approval letter. So that the SEC Convenor and members can satisfy themselves that the other University have reviewed and approved to an equivalent standard.

There are several phases to my research. Should I gain ethical approval for all of them now?

UTREC has no view on this beyond the practical one that it cannot approve research unless it has enough information to make an appropriate assessment. Your funding body may have a view. There is no point in applying for future research phases if there is a strong chance that your design may change between application and starting research.

If your application is one with several phases, you may prefer to make separate application for each one, so that if one fails or needs resubmission, the others may be given the go ahead. Submitting everyone at once can run the risk of the project being turned down as it stands and so is delayed.

My project involves St Andrews students: do I need to take any special steps?

Yes. It will be important to ensure that any invitation to any students of this University to participate in a research project makes it clear that the participation or non-participation in the project will not affect the student's academic assessment in any way. The participant information

should also make it clear that no information arising from the research will be disclosed to the student's school, department or faculty. Similar statements should be made in relation to their employment if the participants in the research are employees of this University.

My project is just an undergraduate dissertation. Surely I don't need to get ethical approval for it?

ALL research in the University which involves human participants needs ethical approval, no matter who is doing it. The Extract from the Undergraduate and Postgraduate Student Handbook 2009-2010 says 'It is a requirement that any Honours or Masters dissertation or PhD thesis that required ethical approval from UTREC [SEC], should have the letter or email of ethical approval bound into the appendix before submission'. Approval for research involving human participants, not involving a dissertation, is given through an email from the SEC.

I'm using data about people but the people aren't identifiable: do I need to get ethical approval?

If all the data about people to be used in your study are previously collected anonymised data which neither you nor anyone else involved in your study can trace back to individuals who provided them (e.g. census data, administrative data, secondary analysis), then generally you need not get ethical approval. If however the data are anonymised but if anyone, including the researcher, on the project can, by using a key, ascribe the data to individuals then the project must get ethical approval. In addition even if individuals cannot be identified, any research that may have potential adverse consequences for human welfare and wellbeing, must obtain ethical approval. If you are unsure please consult your SEC convener or UTREC.

I'm just observing people: do I still need ethical approval?

Yes. Observation can seem more intrusive to the people being observed than to the observer. Sometimes observation can pose serious ethical questions, for example if the people observed are in embarrassing situations.

All the people in my study are dead: do I need to get ethical approval?

Not normally. Make sure all the people really are dead (do not just assume they are) and think if the information provided by those people contains sensitive information about the living. If the latter then ethical approval is needed. If in doubt consult the [relevant SEC or UTREC convener](#).

My proposed research involves interaction with children / vulnerable adults. Will I need (Enhanced Disclosure) Protection of Vulnerable Adults approval?

Effective February 2011 Disclosure Scotland applications will be known as and made through the Protection of Vulnerable Groups Scheme (PVGS), which remain administered by Disclosure Scotland. This Scheme will replace the standard disclosure and enhanced disclosure application process.

This will depend on the nature of the contact involved. If the intention is to have one-to-one contact (in the UK or Abroad), without supervision then PVG will be required. If your interaction will be supervised by a member of PVG approved staff at all times there may not be a need for you to obtain PVG approval. You MUST however contact Ailsa Richie, Student Services to discuss your application and confirm this will indeed be the case – please do not assume.

Expanded information regarding the PV Scheme and flowchart to guide you through the UTREC ethical approval process, when working with Children or Vulnerable Adult, is available at <https://www.st-andrews.ac.uk/utrec/EthicalApplication/children/>

What is Anonymous Data, Coded Data and Identifiable /attributable Data?

Anonymous Data - The term Anonymous Data refers to data collected by a researcher that has no identifier markers so that even the researcher cannot identify any participant. Consent is still required by the researcher, however no link between the participant's signed consent and the data collected can be made. It is not sufficient to just remove the participant's name as there can still be a risk that data could be linked by the participant's age, postcode or medical condition depending to the location and size of the data set collected. Although the participant provides his/her name on the consent form, there is no identifiable link between the participant's signed consent and the data collected.

Generally anonymous data may be collected to maintain confidentiality and trust between the participant(s) and researcher(s). When data is collected anonymously individuals feel encouraged to share information without being linked to it at a later date. Whenever possible researchers should use only truly anonymous data, unlinked, and the sharing of data should be limited to only those directed linked to the research.

Coded Data - The term 'Coded Data' refers to when data collected by the researcher is identifiable as belonging to a particular participant but is kept with personal identifiers removed. The researcher(s) retain a 'key' to the coded data which allows individual participants to be re-connected with their data at a later date. The un-coded data is kept confidential to the researcher(s) (and Supervisors). If consent is given to archive data (see consent section of form) the participant may be contacted in the future by the original researcher(s) or other researcher(s). Coded data is not anonymised data and should not be referred to as such.

Identifiable/Attributable Data – 'Identifiable/Attributable data' is data where the participant is identified, such as when a public figure gives an interview, or where consent is given by a participant for their name (including perhaps gender and address) to be used in the research outputs. The raw

data will be held confidentially by the researcher(s) (and supervisors). The published research will clearly identify and attribute data collected to the participant.

FOR A MORE IN-DEPTH EXPLANATION PLEASE SEE DATA PROTECTION ACT DOCUMENT
[HTTP://WWW.ICO.GOV.UK/UPLOAD/DOCUMENTS/LIBRARY/DATA_PROTECTION/DETAILED_SPECI
ALIST_GUIDES/160408_V1.0_DETERMINING_WHAT_IS_PERSONAL_DATA -
_QUICK_REFERENCE_GUIDE.PDF](http://www.ico.gov.uk/upload/documents/library/data_protection/detailed_speci_alist_guides/160408_v1.0_determining_what_is_personal_data_-_quick_reference_guide.pdf) ALSO SEE THEIR WEBSITE FOR MORE INFORMATION ON DATA
PROTECTION PRINCIPLES
[HTTP://WWW.ICO.GOV.UK/FOR_ORGANISATIONS/DATA_PROTECTION/THE_GUIDE/THE_PRINCIPL
ES.ASPX](http://www.ico.gov.uk/for_organisations/data_protection/the_guide/the_principles.aspx)

The people in my study live thousands of miles away: there is no way they can be affected by my research, by my dissertation, or by publication of my study: do I still need ethical approval?

Yes. All people deserve consideration of their dignity and in fact there are special considerations surrounding research in different cultures.

My project involves the use of Tissue

Studies requiring human tissue samples including blood and cell lines require submission to the appropriate SEC. This tissue including blood and cell lines which are derived from people/patients need to be exerted to ethical scrutiny of their origin.

For cell lines, normally, obtaining ethical approval is not a significant issue as the provenance is clear. This requires checking by the SEC. There have however been instances where lines have been derived from laboratory workers, or from primary cells, where there is a clear need to establish the ethical background of their origin. For example, where primary cells are derived from tissue obtained surgically, NHS approval is required. Where primary cells are purchased commercially, the ethical background needs to be established through the company.

For how long is approval granted?

The approval will remain in force for three years from the date that approval was granted, assuming that there are no changes to the research project (see [question??](#) above).

Do I need to include in my dissertation/thesis proof that I have obtained ethical approval?

Yes. The Student Handbook 2009-10 states that for all projects that require ethical approval, the approval email (in the case of undergraduates) or the approval letter (in the case of postgraduates) must be bound into the appendix of your submission. This regulation was introduced 2009-10 so while it cannot be insisted on for submission of doctoral theses in 2009-10, it is nevertheless good practice to include it. Though this regulation was introduced in 2009-10, the requirement for research involving living humans has been in existence for several years and in such cases approval must have been obtained.

I think my study is an 'audit' or an 'evaluation' but is not research. Do I need ethical approval?

Generally if you can answer 'Yes' to any of these three questions (a) Does your study primarily aim to monitor and/or improve and/or test the performance of a particular service provider or colleague?, (b) Will your conclusions be applicable wholly or primarily to that service provider or colleague?, (c) Are you conducting your study on behalf or at the request of a service provider or colleague?, then it is likely that your study is an 'audit', not 'research'. Further, if you are merely seeking an evaluation of a module through a series of questions at the end of a module, this does not count as 'research' – approval for the questions are likely to have been given by SALTIRE. If you believe your study is an 'audit' or an 'evaluation', and not research, seek the confirmation of the SEC secretary or convener. He/she will write to you confirming this, normally approving the start of the research project. If your research project is approved, you can proceed with your study with no further reference to the SEC, unless the nature of your study changes and comes under UTREC's remit.

Can I submit a teaching module to UTREC, where students will be doing various kinds of low risk research?

Yes. Some modules (for example, Modern Languages) require students when overseas to conduct low-risk interviews with public figures, persons of note within the community where they are based. The module co-ordinator should explain precisely in the UTREC application form what the students will be required to do, what paperwork will be used, what consent is obtained, etc. Some questions in the UTREC form may not seem wholly appropriate, but please fill it in as best as you can.

How do I submit a teaching module for UTREC approval?

If your module describes a general project under which several sub-projects will be conducted, submit a completed application form, making clear in question 1 that yours is a module application. Complete the form such that all anticipated sub-projects are covered. If possible complete the application form for the module at the same time as seeking approval for a specific project which will fall under the module but which is presented in full detail. It can be hard for the committee to take a view on generic elements without any concrete example and approval might be delayed.

If your module covers a research practice normal in your discipline (e.g. gaining consent by only verbal means, asking people to opt out rather than opt in to research) but does not at this stage refer to a particular sequence of intended sub-projects, submit a statement identifying the ethically contentious aspects of methodology, why the method should be used despite its being contentious, and what safeguards must be put in place to ensure that this departure from ethical norms should not pose a risk to participants. If the method outlined conforms with a code of practice of a scholarly or professional association, append details of that code of practice.

Note that approval of modules, like individual projects, is valid only for a certain period (maximum three years). After this period it lapses and you must resubmit your module. This ensures that modules reflect the most recent ethical views and current research practice.

Is my project fully covered by a Teaching module?

Sometimes the answer to this will be clear, for example if your supervisor/project leader completed the module application with your project and others in mind. Sometimes you may find that an existing module application appears to cover your module fully, even though it was written for another set of projects. It is up to you to ensure that the module you cite covers the whole duration of your project and all its ethically sensitive aspects. Remember your project may be audited to check that this is the case. If in doubt discuss this with your supervisor, colleagues, or SEC or UTREC officers.

My research project needs full scrutiny but I need approval in a hurry: what should I do?

Submit your form as soon as possible, making sure that you have completed all the sections and supplied all the documents so that there is no delay whilst these are chased up. Tell the SEC that you need urgent approval and the committee may do its best to get a decision as soon as possible. Please do not ask for urgent approval unless you really need it, as it will cause delays for those who do.

The questions on UTREC forms seem to be completely irrelevant to my research: what should I do?

Do your best to complete the forms so as not to delay the start of your project. Send suggestions for improvements of the forms to [UTREC](#) so that they can be adapted better to suit researchers' needs. UTREC forms are scrutinised annually and changes are made annually. Please note that the UTREC forms fit the topic of 'research' better than 'teaching', but even when used for 'teaching', please fill in the form as best as you can.

My research was approved by SEC/UTREC but my plans have changed. What should I do?

If your plans have changed so much that you are planning what amounts to a different project then start the approval process again.

If you have modified (rather than abandoned) your original proposal, bringing in new elements, review the answers you gave on the form. If there is only minor adjustment, and if none of your planned changes would alter any of the responses that you made on the form in any significant way, submit an Ethical Amendment Application form. .

If you have modified (rather than abandoned) your original proposal bringing in substantial new elements review the answers that you gave on the forms. If any of your planned changes would alter any of the responses you originally made significantly or if your planned changes would increase the risks that you expose any participant to then an Ethical Amendment Application form with the changes highlighted must be submitted. Do not start your modified research until you have secured SEC approval for any amendments to your research. If your changes reduce risk to participants or have no bearing on risk you need not tell SEC of them.

If the principal researcher/supervisor of the project changes you must always tell your SEC but you need not wait for approval of the change.

This all looks a bit complicated: do I really need to bother?

Yes. If you do not you may expose participants to serious risk, the University and yourself to litigation, and yourself to disciplinary measures. You may not be allowed to use in your dissertation/thesis any material for which you have not received ethical approval. In addition, your dissertation/thesis could be failed if you have not adhered to the ethical procedures and not included an email/letter of approval in the appendix of your dissertation or thesis.

My project was not approved: what do I do now?

The SEC or UTREC will tell you why your project was not approved. Sometimes this will be for reasons over which the committee has no discretion, for example if you are failing to comply with the provisions of the Data Protection Act. Sometimes it will be for reasons over which the committee is required to exercise its judgement, for example it may judge that the project entails risks out of proportion to the benefits it may bring. The SECs/UTRECs comments will help you revise your research procedures and you may then resubmit your application form, highlighting the elements you have changed to address the concerns of the committee. If the SEC fails your application again you may submit it to UTREC for a final decision only if you dispute the SEC's judgement in matters where it can exercise discretion and not, for example, if you are failing to comply with statutory requirements.

When I was in the field for reasons outside my control I had to alter my plans in a way which increased/altered the risk to participants without first securing permission. What should I do?

Retrospective scrutiny of research projects is not acceptable except in exceptional cases. If it is at all possible you should inform SEC/UTREC of your new plans before undertaking them. If you are in a very remote area this may not be possible. Do your best to ensure that your revised project and any documents you will give to participants meet UTREC's standards, which you will be familiar with from your initial application. Submit your project to UTREC approval procedures as soon as you can, even if this is after the research is completed.

Something has gone wrong in my project and a participant has been harmed. What should I do?

Your first priority will be the welfare of the person who has been harmed. If the event takes place within the University you will need to follow normal safety procedures such as making a report in the accident book and if necessary alerting the School or Department safety officer. Serious adverse events must be reported to the SEC which approved your application within seven days. Before continuing with your research think whether changes to your method or equipment or personnel are necessary to prevent further adverse events. Remember to treat emotional distress seriously, as well as physical harm, especially where participants are vulnerable.

My research project has been chosen for audit by UTREC. What does this mean?

A sample of projects will be audited each year by UTREC. They are chosen at random, not because they are suspect. You need not stop research but UTREC will ask the SEC for information which will enable them to learn more about the ethical aspects of your research. UTREC is not auditing your rate of progress or on the scholarly or scientific aspects of your work but just the ethical

aspects. Audited project leaders will be asked for information about their project to substantiate the information they gave on the checklist and application form and to show how the project was in fact carried out. The process will not be overly intrusive but is necessary to ensure that the forms are responsibly filled in and that UTREC has a clear understanding of research in the University and to see if the University's approval and monitoring procedures need to be changed to encourage good practice and/or make researchers' lives easier. UTREC welcomes constructive criticism during audit or any other time

I am away from St Andrews and cannot access the forms and protocols on the UTREC website.

Please contact the [UTREC secretary](#) who will email you the forms.

How do I find out whether the organisation funding my research requires any form of monitoring of my project?

The terms and conditions of the research funding will indicate whether any form of monitoring is required, to ensure that standards of ethical conduct are maintained after the study has received initial approval.

However, the two main funders which attach conditions relating to monitoring are:

- the Economic and Social Research Council (see the [Research Ethics Framework](#)) and
- the [US National Institutes of Health](#) which stipulate that projects which require ethical approval must be reapproved for every year of the research funding. (Note: applications for ethical approval of research with US federal government funding, including from the NIH, are handled by [UTREC](#)).

Do I need ethical approval of my funder(s)?

Yes. A list of automatically approved funders is on the UTREC website, and if your funder is there you do not need ethical approval. If your funder is not listed, please submit the Funders and Funding Application form on the UTREC website to your Head of School. He/she, after discussion within the School, will submit it with comments to a sub-committee of UTREC who will add their own comments, returning the form to the Head of School, who will then inform the applicant. It may be that the funder will subsequently be added to the automatically approved funders list. Some funders will only be approved on a project by project basis.

I need a letter for my funding body to show the University has approved my research: what should I do?

When you complete a checklist or an application form or submit a module application you will always receive a letter from the SEC (or UTREC, as appropriate) telling you of the outcome of the scrutiny procedure.