University Teaching and Research Ethics Committee (UTREC)

Application Form – Cover Sheet

This first page is important -

UTREC reviews this and it may be subject to an FOI request.

Note: this page contains meta data about your research which is subject to audit and monitoring

This form requires use of Microsoft Word desktop version (available via IT Services)

Researcher Name			
Email	email@st-andrews.ac.uk	**Date Submitted**	Click or tap to enter a date.
School/Unit:		**Supervisor (if student):**	

Only tick one of these

Undergraduate	☐	Staff	☐
Postgraduate Research	☐	Postgraduate Taught	☐
Module Co-ordinator on taught module	☐	Module Code	

Project Title
(If your title is not immediately understandable to a lay audience, be sure it is clearly explained in the project description)

Check the title is understandable to a lay audience, if not then the project description must be clear and easily understandable.

Project description: Give a concise narrative description without technical terminology of what you are proposing to do; who your participants are (e.g. age, organisation) and how they will be approached/ recruited; where the research will take place (e.g. site, country); what methods you will use, (e.g. survey, interview). *(900 characters for database reasons)* (see exemplars).

The project description box should capture the key information (in the guidance text above) about the project and it's aims. Applicants shouldn't use these to create a bulleted list, it should be a narrative description. it is not acceptable to complete this with 'see form' or 'see question N'.

The information should be concise but sufficiently detailed to help someone with no familiarity with the project or discipline understand who the participants are, what will be asked of them and the research design.

These fields are reviewed by UTREC at their monthly meetings, so anything that raises questions, regardless of if they are answered later in the form, may be flagged up and queried with the School/researcher.

Ethical Considerations: Give an overview of both **the ethical issues raised** by your research and **how you will address** them (see exemplars). This could include: how you will ensure consent is voluntary and informed; confidentiality and how your data will be managed to protect this; potential risks to participants such as distress or reputational harm. NOTE: this should not substantially duplicate the response given in 'Project description' above**.** *(900 character max.)*

The ethical considerations box needs to be narrative overview of any ethical issues that may arise in the research (i.e. where there are 'NO' responses Q13-22 or 'YES' for Q23-26) and also how they will be addressed. A common mistake when completing this box is to detail ONLY the procedures that will be completed. It is very rare that there are 'no ethical considerations' and applications stating this will raise concerns at UTREC.

For example, someone may state 'I will collect written consent from participants'. This does not describe what issues there are around consent, only how it will be collected. A more appropriate response would be to describe the issue (i.e. there may a dependent relationship) and the way this will be tackled (i.e. reassuring participants that declining to participate will have no adverse impact on them, or having someone else recruit and consent them).

This should summarise roughly what is described in Q31 and should never simply be 'There are no ethical considerations'.

Has ethical approval for this research already been obtained from an external ethics committee? If YES, do not complete the rest of this form. Instead submit a copy of the external application paperwork and approval, and a copy of this page, to your School Ethics Committee.

In this form there are icons, links and guidance to assist you, hover over them for tips or ctrl+click to follow links:	
	This icon indicates that a supporting document may be required - see Appendix 1. DOCUMENT CHECKLIST
	This icon indicates that you may need to provide an explanation or more information in Q31
	This icon indicates there is guidance on how to answer (hover the pointer over the icon)
	This icon follows 'skip to question X' statements - Ctrl+Click the icon to skip to that part of the document
Link	**This formatting indicates a link to relevant documents or webpages**

RESEARCH INFORMATION		
	1. Estimated start date of research activities	This can vary depending on the research design but should normally be when the researcher starts research contact with participants – recruitment or consent can only start AFTER ethical approval has been granted
	LOCATION AND EXTERNAL APPROVALS	
	2. Location of the research	This should describe both the geographical location and the setting of the research – for example, the town and country and, if relevant, the organisation or place like a school, University, care home etc.
	3. If applicable, have you obtained permission to access the site of research? If YES please state agency/authority etc. and provide documentation If NO please indicate why in Q31	**Click to select** If the answer above includes an organisation or site where permission is needed, the applicant should attach something like a copy of emails, from a person in authority there, confirming the research is permitted
	FUNDING	
	4. Is this research funded by any external sponsor or agency?	**Click to select**
	If **YES**, please provide the name of the funder:	
	5. Does the funder appear on the automatically approved list of ethical funders? If NO, you must complete an ethical funder application and attach the approval to your application	**Click to select**
	COLLABORATION & ROLES	
	6. **a**. Does this research entail collaboration with researchers from other institutions and/or across other University Schools/Units? If YES state name and affiliations below:	**Click to select**

Name	Affiliation

	b. If the research is collaborative, has a framework been devised to ensure that all collaborators, are given appropriate recognition in any outputs?	**Click to select**
	7. Where projects raise ethical considerations to do with roles in research, intellectual property, publication strategies/authorship, responsibilities to funders, research with policy or other implications etc., have you taken appropriate steps to address these issues?	**Click to select**

RESEARCH PARTICIPANTS

8. Are you using **only** library or archival sources; media publications; secondary data (with appropriate licenses and permissions) or data in the public domain?

If **YES**, but the project has other ethical considerations, skip to Q31 and detail these

If **YES,** and the project has no other ethical considerations, skip to 'Declara

If **NO**, continue with the rest of the form

Click to select

What is and isn't 'public domain' can be a thorny issue. There are particular considerations when using identifiable data from social media or data archives containing sensitive information such as health data.

Data that should likely have further explanation in Q31 and may also require the completion of the data management section: using identifiable data from private individuals, projects processing personal and/or special category data or where the data source requires data protection assurances

9. Who are your participants?

This section should describe the defining characteristics of the participants – their age group, whether they will be a specific gender, ethnic group, religion, political interest, job type.

Be conscious that there may be ethical issues if the participants are from a vulnerable group or in any way at risk because of their characteristics (for example, being a minority religion in a religiously strict country)

10. Describe below how you will identify, approach and recruit participants

In this box there should be explanation of how participants will be recruited. This should be: fair, free from bias, not unduly pressure participants to participate, not put participants at risk by exposing them as having certain characteristics, ensuring participants understand what is being asked of them.

Consider the response to the previous question – are there special considerations for this particular population?

This links into issues around informed consent, dependent relationships, deception and good research practice.

11. Estimated duration of participant involvement

Here reviewers will assess if what is being asked of participants is reasonable, achievable and justifiable.

Consider the aims and potential benefits of the research versus the burden on participants, plus the time available for the project and researchers experience – what might be reasonable within a Staff or PGR project may be unreasonable (and unrealistic) for an UG or PGT.

12. Do participants fall into any of the following vulnerable groups? (Check all that apply)

Children (under the age of 16 in Scotland or 18 in England and Wales)	☐
Protected adult, receiving care or welfare services	☐
People with learning or communication difficulties	
Residents/Carers in a specific location e.g. Care Home	
NHS patients or staff	
People in custody	
People engaged in illegal activities (e.g. drug taking)	

If participants are in any of these groups there are additional ethical considerations, a need for additional documents or both.

Ethical issues should be described in Q31 and may include:

- Issues around capacity, understanding and informed consent
- Dependent relationships or pressure to participate, depending on how they are recruited
- Managing sensitive information or disclosures including risk of distress or legal problems

In many cases a PVG or DBS clearance will be needed and in some (the NHS) external ethical approval is needed BEFORE University approval. Permission to access the site/population should also be considered.

Reconsider Q10 & 11 – are they still appropriate?

ETHICAL RISK CHECKLIST		
	If you answer 'NO' to any of the following please provide a full explanation in Q31	
	13. Will you tell participants that their participation is voluntary and that they can decline to participate with no disbenefit?	
	14. Will you describe the main project/experimental procedures to participants in advance so th they can make an informed decision about whether or not to participate?	
	15. Will you tell participants that they may withdraw from the research within the time specifie the PIS and for any reason, without having to give an explanation, and with no disbenefit?	
	16. Will you obtain appropriate consent from participants?	
	17. If the research is photographed or videoed or taped or observational, will you ask participant their consent to being photographed, videoed, taped or observed?	
	18. Will participants be free to continue in the study if they reject the use of intrusive research methods such as audio-visual recorders and photography?	
	19. Will you tell participants that their data will be treated with full confidentiality and that if published or shared, it will not be identifiable as theirs? (see DATA MANAGEMENT Q30)	
	20. Will participants be clearly informed of how the data will be stored, who will have access to it and when the data will be destroyed? (see DATA MANAGEMENT Q30)	
	21. Will you give participants a debrief explanation in writing of the study after participant involvement explaining where participants can find out about the results of the project and access sources of support, if appropriate?	
	22. With questionnaires and/or interviews, will you give participants the option of omitting ques they do not want to answer?	
	If you answer YES to any of the following please provide a full explanation in Q31	
	23. Is there any significant risk (inc. physical/psychological harm or distress) to the researcher and / or any participants, field assistants, students, collaborators involved in the project?	**Click to select**
	24. Will your project involve deliberately misleading participants in any way?	
	25. Will any financial inducement, other than expenses, be offered to participants?	
	26. Are any of the participants in a dependent relationship with the investigator? i.e. fa members, patients, students	

These questions relate mainly to 'informed consent' – any NO response to these means that participants' consent is not given freely (or at all), or it is not fully informed.

This raises serious ethical concerns and there only limited research scenarios where this would be justifiable.

Q18 and 22 – a NO response to these questions may be less 'high risk' as the research aim or design may justifiably require that all data be collected. However, participants should still be given an appropriate period to withdraw their data.

Audio-visual data is normally identifiable and requires careful management.

A 'YES' to any of these questions indicates there are significant risks to participants or ethical issues around freely given informed consent.

Applicants must explain, mitigate and/or justify these in Q31, to the extent that they will satisfy the concerns of reviewers.

RISK ASSESSMENTS & INSURANCE		
	27. Does your research require a risk assessment as per University policy ? (if YES, include this with your application, or if it is still being processed, indicate this in Q31)	**Click to select**
	28. For fieldwork and travel abroad, have you checked that you are covered by University travel insurance ?	**Click to select**

The SEC will want to know the applicant has considered whether they need these documents – it shows they have thought about all the risks involved in their research. However, they are largely the remit of Health and Safety and the Insurance Office.

DATA MANAGEMENT

Collection, storage and destruction of data should be undertaken in accordance with University guidance and policies plus data protection law. For queries on data protection, contact dataprot@st-andrews.ac.uk ; on research data management, contact research-data@st-andrews.ac.uk. Additional training is available.

In this section, the following definitions are used:

- **Personal data -** information relating to natural persons who: can be identified directly from the information in question; or who can be indirectly identified from that information in combination with other information. NOTE: consent forms are not considered personal data (copies must be securely retained for the lifetime of the research)
- **Special category data** - personal data relating to race, ethnic origin, politics, religion, trade union membership, genetics, biometrics (where used for ID purposes), health, sex life, or sexual orientation
- **Fully identifiable data** - personal data that can be directly linked to an individual
- **Pseudonymised data** - personal data that can be indirectly linked to an individual using a 'key'
- **Anonymised data -** data that cannot be linked to an individual using any reasonable means, is NOT personal data.

29. Given the definitions above - at the point of collection, will data collected by your research include:	
a. personal data?	**Click to select**
b. special category data?	**Click to select**

30. Data Lifecycle

Describe how you will ensure the confidentiality of personal data over the full lifecycle (see exemplars).

You should include in each of these sections:

- What form the data will take, particularly if and how it will be anonymised or pseudonymised or if it will remain identifiable
- Who will have access to the data, e.g. John Doe and Professor X or me and my supervisor/co-researcher(s)
- Secure locations where data is stored, e.g. encrypted file on secure University Server, locked filing cabinet
- Consideration of the requirements of data protection law and Open Access requirements of funders

The information you provide in these sections should reflect the contents of your participant documents

a. Collection and Transfer

Describe what data you will be collecting (ensuring it is the minimum amount necessary for your purposes), including how/when you will collect it, and how you will ensure its safe transfer into storage

Research data collected should be in line with the aims and methods of the project and minimise the amount of data collected where possible. Collecting excessive data can burden participants, discouraging them from participating in this or future research. It can also create risk to confidentiality by collecting personal data which is not useful for analysis or which, when combined with other data, could be used to identify participants.

Consider whether appropriate safeguards are in place for the collection and transport of data –
Will it be in electronic or paper form? Will it be physically or electronically secured via a locked container or encrypted device? Will it be in the researchers possession at all times? Will it be in transit directly to secure storage (i.e. the University) or will it need to be kept in the field for some time? How long will it be in transit for?

Worse case scenarios – is there a risk of identifiable or confidential information being left somewhere public.

b. Storage, Backup and Access

Describe how the data will be securely stored, backed up and accessed

Much as with the previous section, the key is that:
Data is stored securely – physically under lock and key or electronically through encryption
Data is backed up securely – this means that participants data is not wasted or lost if anything happens
Data is securely accessed – ensuring only the appropriate people can access the data (i.e. researchers/supervisors)

The University recommends that research data be backed up on the University servers (i.e. via the Home Drive). If data must be stored on a removable drive, this should be encrypted and ideally also under physical security. Researchers should not use cloud storage for personal or identifiable data, although OneDrive is acceptable when using your @st-andrews.ac.uk account.

Physical data (i.e. paper forms) should be input as soon as possible and then follow the advice above. If physical copies need to be retained, they should be kept secure – ideally in a locked cabinet within the School.

Access to data should be limited to only authorised users – this might be controlled via password protection and avoiding download and storage of local copies.

c. Sharing and Publication

Describe if, where and in what form the data will be shared. Researchers should consider institutional, funder and publisher policies before deciding on their approach to sharing data arising from their study. It is crucial that researchers anticipate their potential future data sharing and/or publication requirements.

Some example of sharing data include:

- depositing the data (raw or edited) in a research data repository
- including data files with a publication, dissertation or other research output
- including excerpts of data like tables, figures or quotes in a publication, dissertation or other research output

If your data will be shared or published in an IDENTIFIABLE form, provide a rationale and further explanation in Q31

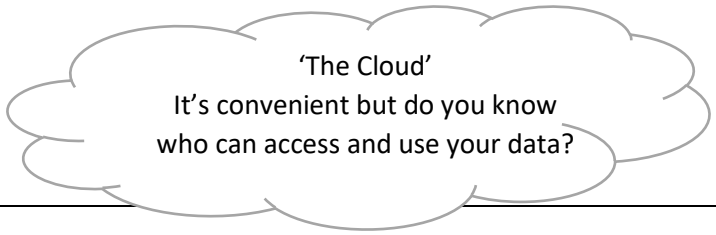
Finding the balance between protecting anonymity and confidentiality and the requirements of research funders and the 'open access' agenda can be tricky.

Sharing of data can maximise the value of participants contributions by allowing it to be re-used – as long as researchers have fully informed participants, have processed the data appropriately (i.e. anonymised), and understand the access rights, users and protections offered by a repository/resource.

Almost all research data will be published in some way – even if it is in an undergraduate dissertation or a conference poster, this counts as publication.

The main consideration is that researchers are completely transparent about what will happen to participants data. What is written here must be consistent with and clear in the PIS.

Researchers and reviewers should be vigilant for personal or special category data – this may require additional safeguards or care when it comes to sharing and publication.



d. Retention and Destruction

Describe how long the data will be retained for and if or when the data will be destroyed (see University guidance).
This may be a fixed date, relative to an event such as study completion, or could be indefinite.
Include here if and how the data will change form (i.e. pseudonymised data becoming anonymised for long term retention).

The University's recommended periods vary between UG and PGR/Staff:

- UG data – this should be destroyed once the project is complete (i.e. a grade awarded), including any assessment and appeal periods. There may be exceptions should there be intent to publish in an academic journal or use the data as part of a larger project, however this is rare.
- PGR/Staff data – this should be destroyed 10 years after the date it was last accessed.

When a student leaves the University, any research data that needs to be retained should be passed into the care of their supervisor.

Retained data should be stored on University servers or in recognised research data repositories.

It is inadvisable to store research data in cloud storage. It is unacceptable to store personal or identifiable data in cloud storage.

It is generally inadvisable to keep data 'indefinitely' and reviewers should question whether this is truly necessary.

If the data is to be shared in a repository with no destruction date, this should be described in the above field and this field should be completed to describe the destruction of any local copies.

Data protection guidance is often changing – reviewers and applicants should regularly check the guidance pages.

ETHICAL ISSUES

31. Please provide a clear, concise description of your research design and methodology, the ethical issues raised and how you will address them (see exemplars). You should also include:

- Details of how you will obtain consent
- Description and rationale for adjustments made to the template participant documents
- Detailed responses for questions marked ✎, if required.

Use sub-headings for structure where appropriate. If necessary, continue on a separate sheet.

[If you answered questions:
3. If applicable, have you obtained permission to access the site of research?

If YES please state agency/authority etc. and provide documentation.
If NO please indicate why in Q31
8. Are you using only library or archival sources; media publications; secondary data (with appropriate licenses and permissions) or data in the public domain?
If YES, but the project has other ethical considerations, skip to Q31 and detail these ⏭
If YES, AND the project has no other ethical considerations, skip to 'Declarations' ⏭
If **NO**, continue with the rest of the form13-22. If you answer 'NO' to any of the following please provide a full **explanation**
23-26. If you answer YES to any of the following please provide a full **explanation**
30c. If your data will be shared or published in an IDENTIFIABLE form, provide a rationale and further explanation
Appendix 1. DOCUMENT CHECKLISTif your application is made prior to obtaining any required external approvals or documents, describe how you will ensure that these are in place before your research commences
TIP: You can Ctrl+Click on the question text above to go to that question] Delete/overtype this guidance as required.

This box is where you would expect to see more detailed descriptions about the project, ethical issues and any steps the researcher would take to mitigate or minimise issues or justify any residual risk. The response should ideally be structured into multiple paragraphs or sections. If there are topics you are unsure about or where you need to check University policy, first check the guidance pages or pages on applying for ethical approval.

The issues and procedures should match up with what has been completed in earlier parts of the form and procedures should be reflected in the PIS and consent forms.

The dignity, safety and wellbeing of participants should always be a priority.

Consider the following principles:

Fair recruitment and consent

Identification of participants is fair and free from bias
Consent is fully informed, accounting for individual autonomy or lack of
Be free from coercion to participate or continue participation
Ensure that by choosing not to participate individuals are not disadvantaged or treated less favourably
Minimise power imbalances

The risk-benefit balance - maximise potential benefits and minimise potential risks

Prioritise participant wellbeing above all else
Maximise benefits: is the research well planned, will it be shared or published?
Minimise risks: is there any risk of harm, distress or disbenefit to participants, how will this be mitigated?

Respect the confidentiality of participants

Observe common law duty
Comply with Data Protection laws (see the section on Data Protection)

DECLARATIONS	
○ I am aware of, understand and will enact my responsibilities as a researcher as detailed in: ○ The University's Principles of Good Research Conduct policy and ethical guidelines ○ Any relevant professional guidelines (e.g. BPS, MRC, ASA) ○ The University's Policy and guidance on Data Management and Protection	☐ ☐ ☐
○ I am aware of the conditions of any funding associated with my work and will ensure that information given to my research participants is in line with those conditions.	☐
○ I understand that I must store the final completed copy of this form as part of my research project paperwork.	☐

Researcher signature		**Date**	Click or tap to enter a date.

ADDITIONAL SECTION FOR STUDENT RESEARCHERS

Student researchers must not submit an ethical amendment application without first discussing it with their Supervisor, and the Supervisor reading and signing this form. Applications submitted without the below section completed by the Supervisor will be returned to the applicant.

Supervisor Comment	
I confirm that I have discussed the ethical implications of this project with the student applicant, that I have read this application, and that I approve its submission to the ethics committee for consideration	
Supervisor signature	

Supervisors must support their students to do good, ethical research.

SECs can refer supervisors for training if applications regularly fall short of expectations.

Submission guidance:

To submit your application, it must be sent to your School Ethics contact:

- Electronic form (.doc, .docx, .pdf) is the preferred submission format for Ethics Applications, as it allows for easy transferral of text to the database
- If you submit a scanned copy of a handwritten or typed form, or a hardcopy, please email your School Ethics contact an electronic form version of the Cover Sheet (first page).

Signing the form:

- Creating an electronic signature is straightforward – sign a piece of blank paper, take a photo i.e. with a smartphone, copy and paste the image into the signature box and resize it as necessary
- If you or your supervisor wish to physically sign a hardcopy, please follow the guidance above on submission requirements
- If you/your supervisor choose to type a signature:
  - staff: email the form to your School Ethics administrator from your @st-andrews.ac.uk email address to confirm your identity.
  - students - email the form to your supervisor from your @st-andrews.ac.uk email address.
    - supervisor: add your name/ signature to the form and then forward it to the School Ethics administrator from your @st-andrews.ac.uk email address

Under **no circumstances** should this form, or supplementary documents, contain identifiable information about your participants i.e. completed consent forms.

Application forms and documents can be made available to third parties via Freedom of Information requests. Attaching identifiable information may mean that data protection law is breached.

APPENDIX 1. DOCUMENT CHECKLIST

Please ensure **all relevant documents** are attached to your application.

You should indicate in Q31 if your research will require any additional documents/approvals. If you have approvals in hand when submitting this form, you should append these to the application and indicate this below. Some School Ethics Committees may require all documents/approvals to be fully obtained before you seek ethical approval.

For online research, such as surveys, you may include relevant screenshots or excerpts of text instead of forms.

Templates are available for some documents, follow the links. Preferably, template participant documents should be used as given. You may adjust the content to suit your project, but you MUST document a rationale for the changes in Q31 of the application form

Application document(s)	**Attached?**	**When to include this**	
Participant Information Sheet	Click to select	Research involves human participants	
Participant Consent Form	Click to select	Research involves human participants	ℹ
Participant Debrief	Click to select	Research involves human participants	ℹ
All advertisements	Click to select	Participants will be recruited using adverts	ℹ
Questionnaire / Online Survey Screenshots	Click to select	Research includes questionnaires or surveys	ℹ
Interview questions/Focus Group guide	Click to select	Research includes interviews or focus groups	
Copies of letters to parents/ guardians/children	Click to select	Research involves children or educational establishments	ℹ
External approvals/documents	**Attached?**	**When to include this**	
Data Management Plan (DMP)	Click to select	ONLY if you already have a DMP (e.g. due to funder requirements). If YES, also email a copy to research-data@st-andrews.ac.uk.	ℹ
Ethical funder approval lette	elect	The research is funded by an organisation not on the approved funders list	ℹ
Risk assessment	elect	Research involves fieldwork risk, such as travel abroad or lone working	ℹ
Insurance documents	elect	May be required for fieldwork or travel abroad	ℹ
DBS / PVG documents	elect	Research involves vulnerable participants: • Children (under 16 in Scotland/18 in England) • Vulnerable adults	ℹ
External permission forms / emails	Click to select	Research requires permission for access to sites, data, participants or other aspects.	ℹ
Security sensitive research declaration	Click to select	Research involves contact with individuals, data or material linked to terrorist or extremist activity	ℹ
External ethical application/approval documents	**Attached?**	**When to include this**	
NHS ethical approval documents - in full	Click to select	Research involves: • NHS data, patients, sites or staff • Participants who are in custody Participants who are in care	ℹ
Ethical approval documents (in full) from an external review body	Click to select	Your research has already been reviewed and approved by another institution or organisation	ℹ

These are documents that you would expect, at a minimum, for research with direct human contact

These are documents that are project-specific and may or may not be included. The SECs role is to check the researcher has or will obtain them if needed – not to review and approve.

Please list ... other documents that are included in your application:

Normally these will accompany a 'cover sheet only' application

These should be checked over to ensure they meet the same standard of review as at this University. If so, the approval can be ratified. This is normally true of approvals from other UK institutions and the NHS and its associated review bodies.

If there are doubts, the applicant can be asked to submit a full application.

Other documents might include things like data sharing agreements, research protocols, terms of a data repository or tissue bank, continuation of Q31…