

Low Risk Research Ethics Approval

Read this first

You should only use this checklist if you are carrying out a low risk research project through Coventry University: This normally applies to:

- Undergraduate students.
- Taught postgraduate students.
- Members of staff evaluating service-level quality e.g. reviewing course delivery.

The term "project" applies to **all** research projects within Coventry University.

Introduction to research ethics

Respect

One of the important qualities of a good researcher is to respect the people and their opinions that may form part of your research project. This is underlined by expectations from various bodies involved in monitoring higher education in the UK. It is also expected by the society in which we live. There have been a number of recent cases in the Press where confidential data, and indeed both personal financial and clinical data, have been "lost" or misused in some way. People who contribute their views to your research need to feel comfortable about what will happen to the information they give you, especially if your project is looking at an area which is confidential. As a general rule all research data should be treated confidentially and should not be discussed with colleagues, or participants referred to by name or in a demeaning manner.

Respect also implies that you have taken the time to think through the research, to ensure you have good internal and external validity for the questions, and that the information you ask for will fulfil your research objectives. Are you asking the right people the right questions? It is disrespectful to waste people's time with poorly planned research.

Risk

You need to consider your personal safety during the research project and the safety of any other people involved in it. The ethical approval process is intended to help you identify risks to you and to others. For example, would the research that you are carrying out:

- Endanger you by requiring data to be collected in unsafe places or by giving away personal data about yourself?
- Upset participants with research material that they may find distasteful or which may cause a violent reaction?
- Damage the participants' job prospects by confidential data about them becoming known to others because your research makes it easy for them to be identified or because you accidentally leaking information about them?
- Be reported and presented in a way that protects you and your participants from potential criminal or legal action?

Most risks can be minimised by taking sensible precautions. For example, if you are meeting people who you do not already know, you should always do so in a public place and let your Supervisor or a friend know who you are meeting, where you are and when you will return. Similarly, if you need to tell your participants how they can communicate with you, use your University email address, not your personal one. Is there a risk to the participant in taking part in the research? For example, are you distracting participants from doing their normal job, when their employer expects them to be doing something more important? You have to limit the risk for the participant, by making sure they will not experience any come back from their employer because they helped you with your project.

It is also not normal practice to post up a questionnaire on the Internet. One reason why this is not a good idea is the fact that you may not know who is replying to your questionnaire, or whether their responses are valid or reliable. Remember, you are **not allowed to send e-mail** requests to staff, students or other people to participate in your research unless they have made a specific request.

Rights

As researchers we need to let those involved in our research understand what is expected of them, their rights including the right to withdraw from the research, and our obligations towards them and towards the data we collect about them. The responsibility for acceptable behaviour in this area lies with you and not with the University. Indeed, it is a disciplinary offence to misuse research data or to fail to abide by the University's Ethics policy.

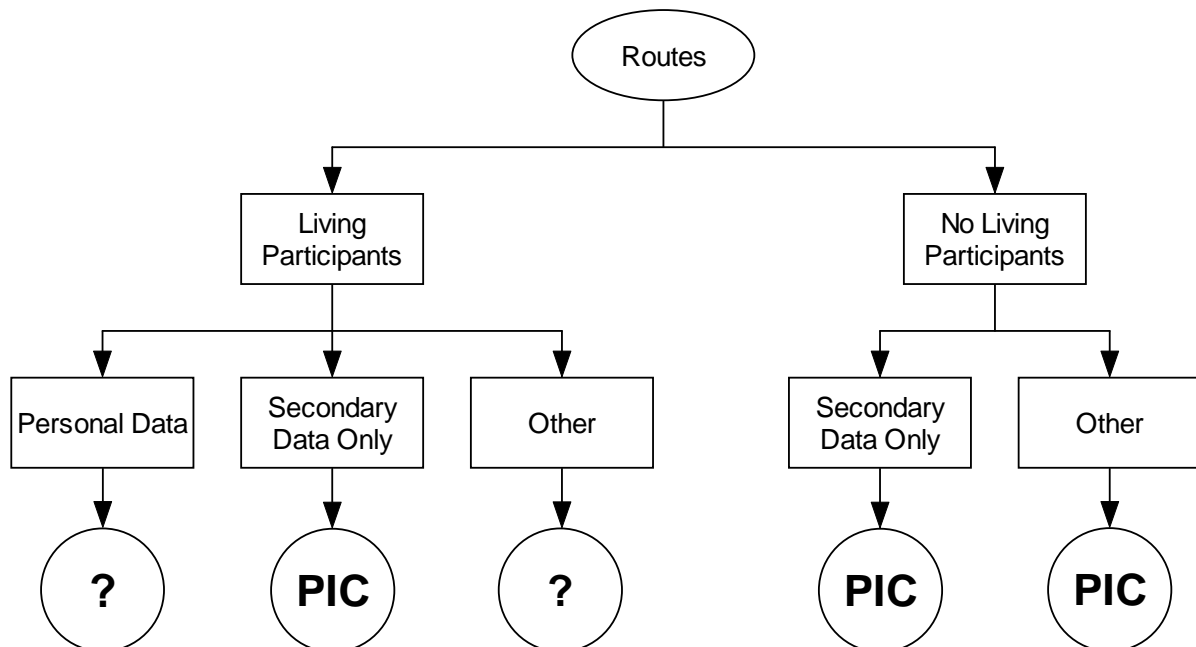
This means that you must have ethical approval **before** you start your research project. If you do not do this, there will be disciplinary consequences for you and the research will be declared invalid. Special additional conditions may also apply to research carried out in your Faculty so check that you have followed those too.

Routes

The questions in the following checklist offers a guided pathway through the various issues surrounding your research that need to be addressed and researcher behaviour that would be expected from all of our students and staff. You will need to complete the checklist and receive approval **before** you begin to collect any data. It is not acceptable to produce it after you have collected your data or finished your project and you will be penalised if this occurs.

No living participants

The following diagram gives an overview of the routes through ethical approval. If there are no living participants involved in the research, then you are likely to be able to complete the Low Risk Research Ethics Approval Checklist and use **Principal Investigator Certification (PIC)** to state that there is no need for ethical approval. You still need to go through the checklist and answer the questions but the likely outcome is you can use the PIC declaration.



Living participants

Most projects, especially at undergraduate level, will involve using data that has already been collected which is called secondary data. In these cases, completion of the questionnaire is very straightforward.

Some projects might use a survey to collect anonymous data, i.e. data that cannot be traced back to named or identified individuals either from other students or from other groups of people. In this case, a **participant information leaflet** about the project needs to be prepared and offered to all participants in the study even though you will not take their contact details. The participant information leaflet needs to be pre-approved by the research Supervisor or the Faculty Research Ethics Leader before any data is collected and will need to be included in the dissertation or report. The participant information leaflet should be attached to the low risk ethics checklist.

Some projects might ask individuals to be interviewed to provide data. In these cases, the interviewees will need to provide what is called "informed consent". The researcher will need to make sure that all interviewees have completed **informed consent forms** before being interviewed and they will also need to be given participant information leaflets at the time when informed consent is requested. The informed consent for should be attached to the low risk ethics checklist.

This means more work because these two leaflets have to be drafted and approved by research Supervisors or the Faculty Research Leader before any contact is made and therefore before any data is collected so this method of research requires a long development time and very good advance planning. Data collected in this way has to be stored securely. Again, a conversation with your Supervisor or the Faculty Research Leader may be necessary to cover this. It also needs to be destroyed after the research is completed and again this will need to be confirmed. You will need to convince interviewees that the information that they share with you will be treated confidentially and show to us that this is the case. Finally, the findings from research conducted in this way are normally shared with research participants in two ways:

- Interview transcripts may be sent to interviewees for confirmation.
- Summary findings of the research project should be offered to all participants.

Participant who can't give informed consent

It is not normal practice to collect data for undergraduate or master level research projects from children under 18 years of age, the mentally ill or participants under medical supervision. There are special regulations and legal requirements about these groups which must be followed. If you are planning to use any of these groups as a source of data in your research then this must be specially cleared with your Supervisor and with your Faculty as participants from these groups cannot themselves give informed consent.)

Record keeping

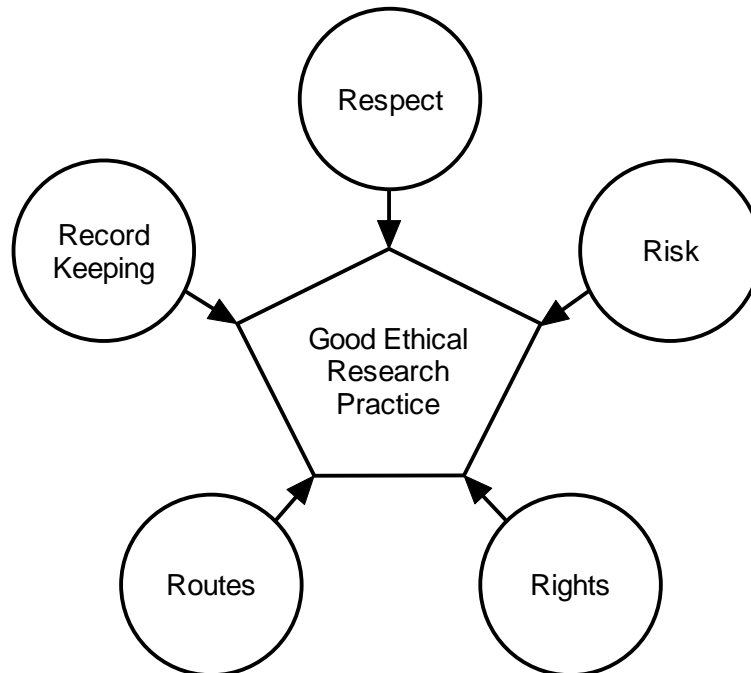
It is also not acceptable to record interviews without getting prior permission or consent from the interviewees (so this might form part of your informed consent form). You also need to provide details of how the information collected, whether it is confidential or not, how it will be used, stored and the disposal method. It is not a good idea to interview without seeking the prior informed consent of participants and having evidence of that consent, nor is it good practice to collect data and not "verify" by sending back transcripts of interviews to participants. Finally, the issue about the destruction of the data once the project is completed needs to be clarified.

All of this is intended to protect you. For example, if someone later says that they did not agree to being recorded or suggests that you have leaked confidential information about them. You need to be able to show that you have protected yourself and looked after any material very carefully.

In all cases the survey that will be used and the interview questionnaire or protocol needs to be signed off by Supervisors before they are used. It is also good practice to test them, not least to find out where the problems might be. In addition, when you write up your research, you can talk about the testing process as a demonstration of good practice, which for students may count towards your marks.

There are examples of informed consent leaflets and information leaflets on the Registry Research Unit Intranet.

Remember



Frequently Asked Questions

Can I begin work before the project is ethically approved?

No. Primary data collection cannot begin until you have established that your project does not need ethical approval using this checklist or you have received written approval from your Faculty Research Ethics Leader, Chair of the Research Degrees Sub-Committee or University Applied Research Committee.

What will happen if I proceed without approval or falsely self-certify research ethics approval?

Collecting primary data in the absence of ethical approval or falsely self-certifying the level of risk associated with a project will constitute a **disciplinary offence**.

- For **Students** – this means disciplinary action resulting in immediate failure in any module or project associated with the research and potentially dismissal from the University.
- For **Staff** – This means disciplinary action, which may potentially lead to dismissal.

If you do not have ethical approval, the University's insurers will not cover you for legal action or claims for injury. In addition, you may be debarred from membership of some professional or statutory bodies and excluded from applying for some types of employment or research funding opportunities.

What happens if the project changes after approval?

If after receiving ethical approval your project changes such that the information provided in this checklist is no longer accurate, then the ethical approval is automatically suspended. You must re-apply for ethical approval immediately and stop research based on the suspended ethical approval.

What about multi-stage projects?

If you are working on a project which involves multi-stage research, such as a focus group that informs the design of a questionnaire, you need to describe the process and focus on

what you know and the most risky elements. If the focus group radically changes the method you are using then you need to re-apply for the ethical approval.

Is there any help available to complete this checklist?

Guidance can be found in the ethics section of the Registry Research Unit Intranet. You will find documents dealing with specific issues in research ethics and examples of participant information leaflet and informed consent forms.

Further advice is also available from:

- Supervisor (Students)
- Faculty Research Ethics Leader (Staff)

What is Principal Investigator Certification (PIC)?

If you answer **No** to **all** the questions in the low risk ethical approval checklist then it is likely that your project has a low ethical risk. You may sign the Principal Investigator Certification part of the checklist and proceed with your project using good ethical practices. If you are a student, your Supervisor needs to countersign to show they agree with your judgment. They may require some restrictions or changes to your project to reduce the ethical or other risks, which would be recorded on the PIC declaration.

What do I do with the completed checklist?

Students should discuss the checklist as it relates to the project with your Supervisor. Once s/he countersigns the PIC declaration at the end to say that this is a low risk project then you may begin your project. However, you must keep hold of the checklist and associated documents, as you need to bind it in to your final project report.

Staff should complete the checklist. If all your questions have “No” responses, then you need to sign the PIC declaration and you can proceed with your project. If you were unable to answer all the questions with a No, then you need to talk to your Faculty Research Ethics Leader. This may result in changes to your project or research design to maintain it as low risk. If this is not the case then you may have to complete either seek approval through the Medium-High or NHS-Medical ethical approval routes before begin your project.

If you have any questions about the checklist or the questions on it, please consult your:

- Research Supervisor (Students)
- Faculty Research Ethics Leader (Staff).

Who are the Faculty Research Ethics Leaders?

Check the Registry Research Unit Intranet site for the most up to date list of Faculty Research Ethics Leaders.

Low Risk Research Ethics Approval Checklist

Applicant Details

Name	E-mail
Department	Date
Course	Title of Project

Project Details

Summary of the project in jargon-free language and in not more than 120 words:

- Research Objectives
- Research Design (e.g. Experimental, Desk-based, Theoretical etc)
- Methods of Data Collection

Participants in your research

1. Will the project involve human participants?	Yes	No
---	-----	----

If you answered **Yes** to this questions, this may **not** be a low risk project.

- If you are a student, please discuss your project with your Supervisor.
- If you are a member of staff, please discuss your project with your Faculty Research Ethics Leader or use the Medium to High Risk Ethical Approval or NHS or Medical Approval Routes.

Risk to Participants

2. Will the project involve human patients/clients, health professionals, and/or patient (client) data and/or health professional data?	Yes	No
3. Will any invasive physical procedure, including collecting tissue or other samples, be used in the research?	Yes	No
4. Is there a risk of physical discomfort to those taking part?	Yes	No
5. Is there a risk of psychological or emotional distress to those taking part?	Yes	No
6. Is there a risk of challenging the deeply held beliefs of those taking part?	Yes	No
7. Is there a risk that previous, current or proposed criminal or illegal acts will be revealed by those taking part?	Yes	No
8. Will the project involve giving any form of professional, medical or legal advice, either directly or indirectly to those taking part?	Yes	No

If you answered **Yes** to **any** of these questions, this may **not** be a low risk project.

- If you are a student, please discuss your project with your Supervisor.
- If you are a member of staff, please discuss your project with your Faculty Research Ethics Leader or use the Medium to High Risk Ethical Approval or NHS or Medical Approval Routes.

Risk to Researcher

9. Will this project put you or others at risk of physical harm, injury or death?	Yes	No
10. Will project put you or others at risk of abduction, physical, mental or sexual abuse?	Yes	No
11. Will this project involve participating in acts that may cause psychological or emotional distress to you or to others?	Yes	No
12. Will this project involve observing acts which may cause psychological or emotional distress to you or to others?	Yes	No
13. Will this project involve reading about, listening to or viewing materials that may cause psychological or emotional distress to you or to others?	Yes	No
14. Will this project involve you disclosing personal data to the participants other than your name and the University as your contact and e-mail address?	Yes	No
15. Will this project involve you in unsupervised private discussion with people who are not already known to you?	Yes	No
16. Will this project potentially place you in the situation where you may receive unwelcome media attention?	Yes	No
17. Could the topic or results of this project be seen as illegal or attract the attention of the security services or other agencies?	Yes	No
18. Could the topic or results of this project be viewed as controversial by anyone?	Yes	No

If you answered **Yes** to **any** of these questions, this is **not** a low risk project. Please:

- If you are a student, discuss your project with your Supervisor.
- If you are a member of staff, discuss your project with your Faculty Research Ethics Leader or use the Medium to High Risk Ethical Approval route.

Informed Consent of the Participant

19. Are any of the participants under the age of 18?	Yes	No
20. Are any of the participants unable mentally or physically to give consent?	Yes	No
21. Do you intend to observe the activities of individuals or groups without their knowledge and/or informed consent from each participant (or from his or her parent or guardian)?	Yes	No

If you answered **Yes** to **any** of these questions, this may **not** be a low risk project. Please:

- If you are a student, discuss your project with your Supervisor.
- If you are a member of staff, discuss your project with your Faculty Research Ethics Leader or use the Medium to High Risk Ethical Approval route.

Participant Confidentiality and Data Protection

22. Will the project involve collecting data and information from human participants who will be identifiable in the final report?	Yes	No
23. Will information not already in the public domain about specific individuals or institutions be identifiable through data published or otherwise made available?	Yes	No
24. Do you intend to record, photograph or film individuals or groups without their knowledge or informed consent?	Yes	No
25. Do you intend to use the confidential information, knowledge or trade secrets gathered for any purpose other than this research project?	Yes	No

If you answered **Yes** to **any** of these questions, this may **not** be a low risk project:

- If you are a student, discuss your project with your Supervisor.
- If you are a member of staff, discuss your project with your Faculty Research Ethics Leader or use the Medium to High Risk Ethical Approval or NHS or Medical Approval routes.

Gatekeeper Risk

26. Will this project involve collecting data outside University buildings?	Yes	No
27. Do you intend to collect data in shopping centres or other public places?	Yes	No
28. Do you intend to gather data within nurseries, schools or colleges?	Yes	No
29. Do you intend to gather data within National Health Service premises?	Yes	No

If you answered **Yes** to **any** of these questions, this is **not** a low risk project. Please:

- If you are a student, discuss your project with your Supervisor.
- If you are a member of staff, discuss your project with your Faculty Research Ethics Leader or use the Medium to High Risk Ethical Approval or NHS or Medical Approval routes.

Other Ethical Issues

30. Is there any other risk or issue not covered above that may pose a risk to you or any of the participants?	Yes	No
31. Will any activity associated with this project put you or the participants at an ethical, moral or legal risk?	Yes	No

If you answered **Yes** to these questions, this may **not** be a low risk project. Please:

- If you are a student, discuss your project with your Supervisor.
- If you are a member of staff, discuss your project with your Faculty Research Ethics Leader.

Principal Investigator Certification

If you answered **No** to **all** of the above questions, then you have described a low risk project. Please complete the following declaration to certify your project and keep a copy for your record as you may be asked for this at any time.

Agreed restrictions to project to allow Principal Investigator Certification

Please identify any restrictions to the project, agreed with your Supervisor or Faculty Research Ethics Leader to allow you to sign the Principal Investigator Certification declaration.

Participant Information Leaflet attached.

Informed Consent Forms attached.

Risk Assessment Form attached.

Principal Investigator's Declaration

Please ensure that you:

- Tick all the boxes below and sign this checklist.
- Students must get their Supervisor to countersign this declaration.

I believe that this project does not require research ethics approval . I have completed the checklist and kept a copy for my own records. I realise I may be asked to provide a copy of this checklist at any time.	
I confirm that I have answered all relevant questions in this checklist honestly.	
I confirm that I will carry out the project in the ways described in this checklist. I will immediately suspend research and request a new ethical approval if the project subsequently changes the information I have given in this checklist.	

Signatures

If you or your supervisor do not have electronic signatures, please type your name in the signature space. An email sent from the Supervisor's University inbox will be accepted as having been signed electronically.

Principal Investigator

Signed (Principal Investigator or Student)

Date.....

Students storing this checklist electronically must append to it an email from your Supervisor confirming that they are prepared to make the declaration above and to countersign this checklist. This-email will be taken as an electronic countersignature.

Student's Supervisor

Countersigned (Supervisor)

Date.....

I have read this checklist and confirm that it covers all the ethical issues raised by this project fully and frankly. I also confirm that these issues have been discussed with the student and will continue to be reviewed in the course of supervision.