Applying for ethical approval

Guidance for submitting an ethics application for approval

This guide has been created centrally, local processes may differ.

Ranked No.15 UK University
Guardian University Guide 2020

University of the Year for Student Experience
The Times and Sunday Times Good University Guide 2019

Queen's Award for Enterprise
International Trade 2015

Coventry University Research Ethics Statement

Coventry University requires all research to be submitted for ethical review and clearance as a matter of priority. All staff and students are required to obtain ethical approval before undertaking any research. Approval may also be required for other, non-research, activities involving human participants. Staff are responsible for following the internal process and supervisors of students are responsible for ensuring that their students do the same. The University Group Research Ethics Committee is responsible for ensuring that any research activity undertaken by staff or students meets the highest ethical standards and is in line with its policy on governance. These principles and standards apply to all research irrespective of whether it is unfunded, internally funded or externally funded through Research Councils, other public monies, or any other sources.

- Ethical approval is required before undertaking any:
- Research, design studies, product development, artistic studies or experiments
- Survey work, questionnaires, interviews, focus groups or case studies.

The university may require ethical approval for:

- Controversial or non-controversial literary or artistic works.
- Paid or un-paid internal or external consultancy work.

This is especially true if the activity requires or could involve:

- Active or unintentional participation by human participants.
- The use of tissue, cells, genetic material or body fluids from living or dead human participants (this is also covered under the Human Tissue Act 2007).
- Actual or potential disclosure and storage of personal or confidential information (this is also covered by the Data Protection Act 1998).
- An ethical, safety, moral or legal dilemma for the researcher and/or participants in allowing the activity to proceed.

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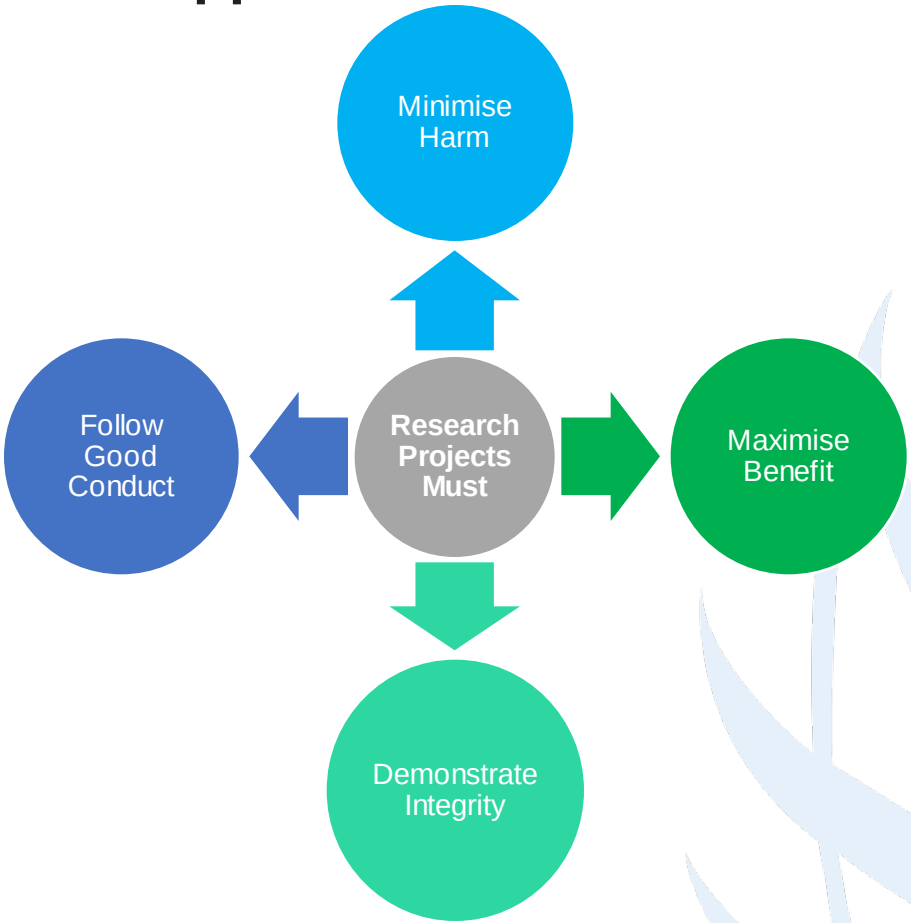


Research Design

Good research design is vital to ethical research practice.

In order to obtain ethical approval applications should:

- ✓ Explain the research methods
- ✓ Explain the intended outcomes (what will be produced)
- ✓ Identify potential ethical risks of the design e.g. working with vulnerable people
- ✓ Describe how risks will be managed and minimised

Secondary Research

- Secondary data is data that has already been collected by others
- Secondary research uses primary research sources as a source of data for analysis e.g. literature review, systematic review.
- Examples of secondary data include sourcing information from websites, library resources, published academic papers, historical documents in the public domain, publicly available data sets and private data sets with permission to use for research purposes.

Secondary Research – Public and Private Data

Public Data

- Research involving information freely available in the public domain
- e.g. newspapers, published biographies, published minutes of meetings, survey results published publically, publically available datasets

Private Data

- Research that is private or personal, and therefore not freely available and in the public domain requires consent or permission from the appropriate individual or organisation
- e.g. personal diaries, private correspondences, unpublished organisational reports or minutes of meetings, pre-existing interviews, questionnaires, census data that are not in the public domain

Primary Research

- Primary Research is collected by a researcher from first-hand sources, using methods like interviews, survey questionnaires, experiments or observations.
- Primary research requires significant information regarding:

❑ How consent will be obtained, the challenges involved in the consent process and how these will be minimised

❑ What are the potential physical and emotional risks to the researcher(s) and/or participant(s) and how will these be minimised

❑ How will data be gathered, stored, used and destroyed to ensure anonymity and confidentiality

Primary Research – Consent

- Research projects need to be explained clearly to participants and informed consent must be sought before any data is collected.

- Participants must be **fully informed** about the research project, including the purpose, methods, what data will be collected and why, what participation entails, what risks it might involved and how to withdraw if they change their mind about participating. Participant Information Sheet templates can be found here.

- Consent must be **freely** given. Participants must decide to take part freely without coercion.

- Consent is a **process**. It is not simply a signature, but an iterative process where information is shared and concerns addressed

Primary Research – Withdrawal

It should be made clear to participants that they have **the right to withdraw** their participation without giving any reasons, and without any repercussion.

- **Withdrawal of self:** Refusing to answer particular questions, refusing to participate in particular aspects of the study, ending all participation mid-way through the study

- **Withdrawal of data:** Participants should be able to withdraw their data up until the point where the researcher cannot reasonably exclude it. This moment will be different for each project.

- **Long-term use of data:** If data is to be archived and shared – and so potentially affecting withdrawal of data – specific consent must be obtained.

Primary Research – Online Surveys

- The university has approved the use of '**Online Surveys**' (formerly Bristol Online Surveys), contact ITS to request an account
- **'Qualtrics'** is also approved for PGR/Staff in some faculties/research centres, check with your local ethics administrator
- Survey software such as Survey Monkey is not permitted due to security risks. If you plan to use another survey collection software you will need to check it is approved by the university via the Information Governance Unit

Primary Research – Participants

- Application should include information on participant sample and recruitment.
- Consider potential conflicts of interest with sample can occur with peers, colleagues, students, and family/friends
- Working with children, young people or vulnerable participants normally requires additional training and DBS checks
  - To request a DBS check students contact faculty registry, staff contact People Team
- Consider if the participants have capacity to give consent
- Consider how information is presented in participant information sheets and how consent is being obtained
- If written consent can not be obtained, alternatives must be evidenced.

Research in Labs/Workshops

- All research involving work in a lab must have a risk assessment attached to the application
- Risk assessment should detail any risks associated with a procedure in the research project.
- COSHH information is needed for any substance (solid or liquid) that is not classed as food, drink or food supplements.
- Risk Assessment and COSHH form can be found here.

Risk of Harm

- Consider risk of harm to the researcher(s) and participant(s)
- Highlight the risk and describe how you will minimise/manage it
- Harm can be low impact but very likely, but it can also be less likely and high impact
- Different types of harm
  - Personal and physical safety e.g. location of fieldwork
  - Psychological and emotional e.g. topic of discussion
- What are the areas of risk of harm in the research? E.g. laboratory procedures, handling and storage of materials, travel and remote working, personal data collection and storage

Anonymity and confidentiality

Anonymity

- Making data 'anonymous‘ by removing the contributor's name and other possible identifiers.

Confidentiality

- Relates to the protection of the data collected during the research project and after
- Ensuring that those who have access to data maintain confidentiality (not discussing issues which might identify an individual; not disclosing what an individual has said)
- If there is a likelihood confidentiality may have to be broken this must be explained to participants prior to any data collection (e.g. in the Participant Information Sheet).

Data Management

- Before applying for ethical approval, consider data management during and after data collection, be mindful of the data policies for retention and describe your data management and storage protocol in your application

- Consider where the data will be stored and who will have access to it
  - Electronic data - University OneDrive account (UG/PGT), Sharepoint for Research (PGR/Staff)
  - Paper data - consider security and storage availability on campus

- If you are planning to share data with others this needs to be clear in the ethics application and in any participant facing documents e.g. Participant Information Sheet

- Consent forms must be held securely and separately from research data
- See the university's RDM policy here.

Travel

- Researchers travelling overseas should check the travel advice and ‘risk level’ for the country/city they are intending to visit as part of their research using World Aware

- All high risk travel should contain a separate High Risk Travel Assessment Form uploaded to the application.

- Further information on travel for research can be found here
  - Students: https://share.coventry.ac.uk/students/SafetyOffice/Pages/TravelRA.aspx
  - Staff: https://share.coventry.ac.uk/staff/ps/estates/Pages/travel%20safety.aspx
  - Contact Safetyoffice.est@coventry.ac.uk

Levels of Risk – Low Risk

Examples	Review Process
• Often *secondary research* • For example analysis of published data • Literature based reviews, systematic reviews, critical and service evaluations • Desk-based research where critical analysis is the principal mode of research • Projects using publicly available statistics • E.g. Notational analysis and performance analysis in sport using publically available material	Students – Reviewed by Supervisor Staff – Reviewed by Faculty/ Peer Reviewer/ Ethics Lead

Levels of Risk – Medium Risk

Examples	Review Process
• Often *primary research* • Collecting data from human participants via surveys, interviews, observations, focus groups etc. • Travel off home campus to conduct research • e.g. Healthy participants engaging in physical activity similar to levels they perform in every day life • e.g. Administration of substances classified as food and drink or food supplements to healthy volunteers • e.g. Arts research using secondary data for exhibition, publication, and sharing where there is a potential harm to audiences as participants (e.g. through issues represented)	Students – Reviewed by Supervisor and Reviewer/ Module Leader/ School Ethics Leader Staff - Reviewed by Ethics Lead/ Peer Reviewer

Levels of Risk – High Risk

Examples	Review Process
• Often primary research • Research with a high impact of risk • Sensitive research (primary or secondary) • Submitting for ethical approval outside of the university e.g. Health Research Authority (HRA) for research with the NHS e.g. clinical trials. HMPSS for research in prisons • Working with vulnerable samples with additional risks involved • e.g. Physical activity in participants with clinical conditions or high physical risk activity (e.g. with extreme environmental conditions), administration of any substances classified as drugs • High jeopardy e.g. flight trials	Medium Risk review process, followed by referral to the University Research Ethics Committee (REC) for final approval (for both staff and students)

Common errors in ethics applications

- × Lack of detailed explanation of how the researcher will address the ethical issues the research presents
- × Lack of information regarding risk assessments and health and safety
- × Missing documentation, e.g. questionnaires, interview guides, participant information sheet and consent forms, risk assessment, gatekeeper template
- × Incomplete application or missing relevant sections
- × Inconsistent information in application and supporting documents
- × Incorrect module code

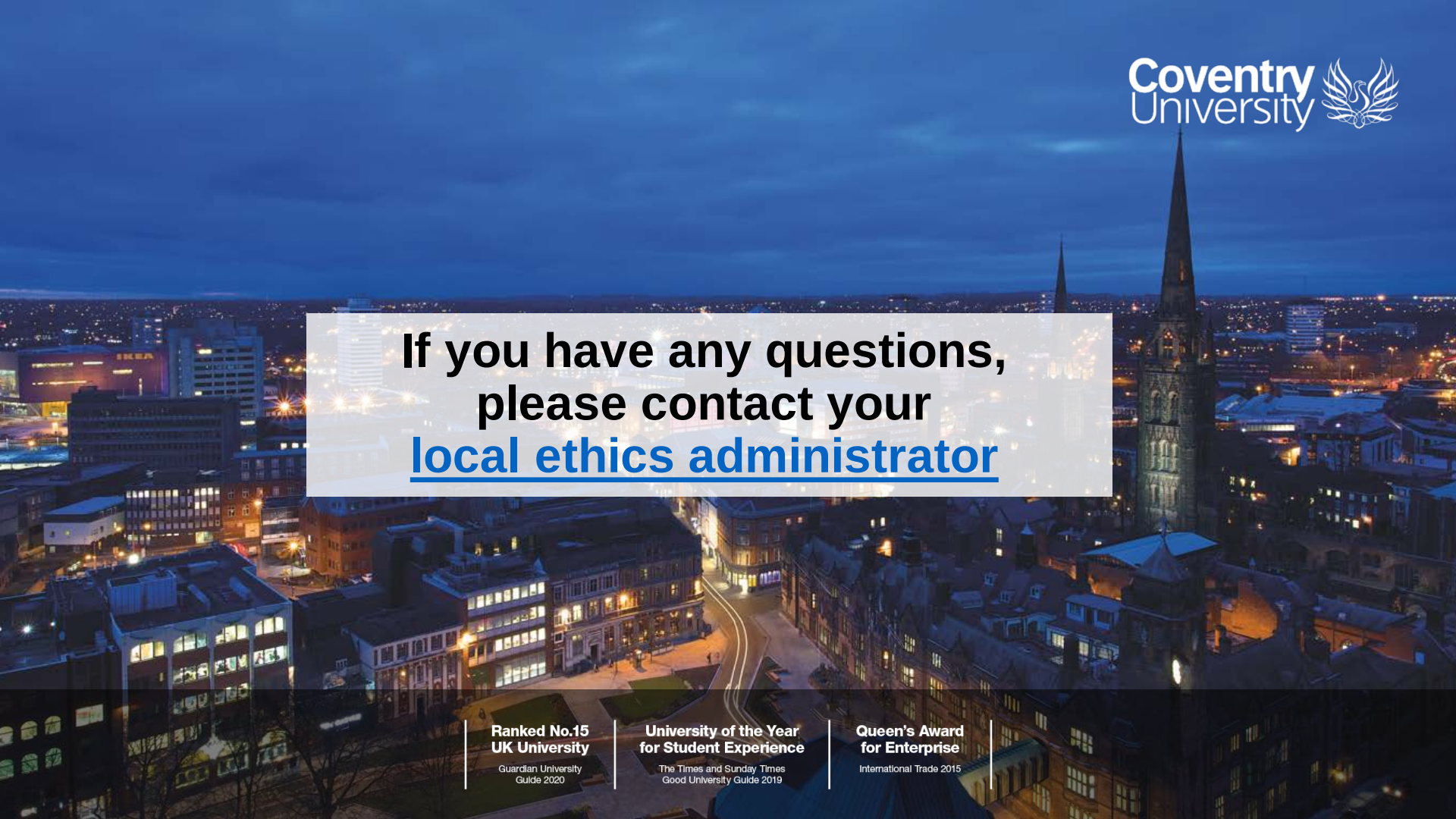
After ethical approval

- ✓ Follow the procedures outlined in your ethics application
- ✓ Use the documents you have approval for and are included in your application e.g. participant information sheet, consent forms, gatekeeper letter, risk assessment etc.
- ✓ Follow the data management plan

Failure to comply will be subject to ethical misconduct.

Ethics Amendment

- An amendment must be submitted if a research project develops beyond the scope of the original approved application
- An amendment must be in place and approved before any changes are made
- Applicants should check with their local ethics administrator for local amendment processes as these can vary across the university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