# University Ethics Committee

# Guidelines for Ethical Practice in Research and Scholarship

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# Introduction

The UWS Code of Ethics establishes the University's approach to raising the ethical awareness of staff and students, and ensuring that all that we do is underpinned by global and future-focussed principles of fairness and opportunity. We have responsibilities as a University to maintain the highest ethical standards in research and scholarship: we are committed to ensuring a culture of honesty, rigour, transparency and respect. In this context research and scholarship are broadly defined as *systematic investigation to add to a body of knowledge or theory, and understanding*.

The purpose of these guidelines is to present the ethical framework and procedures for the conduct of all academic activity and to identify ethical considerations that should be addressed through the formal approval process. These guidelines sit alongside University Regulatory Framework, policies and statements.

# Our responsibilities

As a University it is our responsibility to maintain an environment that develops good practice in research and scholarship. In doing so we are required to ensure that every member of staff is aware of the policies and processes relating to ethical approval. Researchers and scholars have freedom in their academic choices, and so every member of staff has a personal responsibility to understand and maintain the highest standards of rigour and integrity, and to comply with ethical, legal and professional frameworks. We must therefore guide and support staff to reflect best practice in relation to these ethical, legal and professional requirements. Schools must ensure that all Programme teams are committed to raising awareness of the ethical implications of research and scholarship and demonstrate this within their programme.

The university is committed to implementing the following national frameworks:

- The Concordat to Support Research Integrity, Universities UK
- Code of Practice for Research, UK Research Integrity Office

# Principles for good practice

Confidence in research and scholarship requires that they be conducted according to core elements of research integrity.

- **Honesty** in the intentions of the work; in acknowledging the work of others; reporting all the findings; and in making valid interpretations and claims.
- **Rigour** in choosing and adhering to appropriate methods; in drawing conclusions; and in communicating the results.
- **Transparency** in declaring conflicts of interest; in reporting data collection methods; in the analysis and interpretation of data; and in making findings widely available, including to the general public.
- **Respect and care** for all participants in research and for the environment.

These principles apply to all discipline areas and to all aspects of research and scholarship including applications for funding and provision of peer review.

# Ethical principles guiding research with human participants

The cardinal ethical principle underlying research ethics is the respect for human dignity. This underpins a number of guiding moral principles that are taken into account during ethical review, in a participant-centred approach. These principles apply to all research and scholarship in all disciplines that involves human beings, including use of their tissues, data and records.

## Autonomy, veracity and informed consent

The principle of autonomy acknowledges the right of all individuals to determine their own course of action. It underlies the need for free and informed consent.

There are three elements to informed consent:

- The information provided by the researchers to the participant must be sufficiently detailed, relevant and accurate. The participant information sheet should outline clearly and honestly all aspects of the research that are relevant to a decision to consent.
- Consent must be freely given and may be withdrawn. There should be no undue influence or coercion e.g. by the offering of disproportionate reward or disincentives for not consenting.
- It is important to be sure that the potential participant understands the nature of the research and the procedures involved. Potential participants should be given sufficient time to consider the information and to make a decision regarding participation.

Failure to obtain informed consent in this way not only infringes the right to autonomy, but it compromises the validity of the research data. Consent should be sought from all participants in a manner appropriate to their age and level of competence. This is potentially particularly important in research involving vulnerable participants, including those where there is a potential power relationship e.g. school teachers serving as gatekeepers or recruiters for research. If there is a time limit on when data can be withdrawn and destroyed (e.g. when data is aggregated) this must be made clear to participants. There should be an auditable record of consent and, for long-term projects requiring substantial time commitment from participants it may be appropriate to seek renewed consent.

Participants may not see the benefits and harms of research in the same way as the researchers, who tend to over-rate the benefits and under-rate the risks; for this reason lay members are included on Ethics Committees.

## Privacy and confidentiality

Every individual is entitled to privacy and confidentiality and applications for ethical review should demonstrate that these principles are upheld. Information obtained from and about a participant should remain confidential unless otherwise agreed in advance. In reporting data therefore, individual participants should not be personally identifiable except under exceptional circumstances and with clear informed consent. Confidentiality cannot be assured in focus groups, and this should be made clear in participant information sheets and consent forms. Where confidentiality may be overridden by a duty to protect

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individuals from harm that is identified at risk assessment, this should be specified in the protocol, along with the procedures that will be followed. Details of where data will be kept, how it will be secured, who will have access to it (named), how long it will be stored, anonymisation procedures, should be made clear in applications. The access, control and dissemination of data are also protected under the Data Protection Act 2018.

## Justice and inclusiveness

There should be fairness and equity for all research participants. There are particular obligations to those who are potentially vulnerable and this should be demonstrated where appropriate. Applications should describe clear plans to address particular participant needs that may arise during the course of research particularly where these may lie outside the researcher's expertise.

The ethics review process itself should also be fair and transparent.

## Benefits and harms

The balance between benefits and risks is central in the review of applications. In this context risk is defined as potential harm, discomfort or stress generated by the research. There is therefore an ethical obligation, not only to minimise risk in the design and conduct of research, but since research is intended to contribute to knowledge, to also ensure the scientific validity of a project and therefore whether participant time is warranted. In some circumstances an Ethics Committee may therefore request a more detailed literature review to ensure the study is indeed novel and that the methods are appropriate. This judgement is context specific – the status and experience of the researcher (e.g. student or experienced researcher) should be taken into account, as well as the social context. If a piece of research is primarily of educational value this should be made clear both to the students performing the research and to the research participants.

The interests and integrity of the participants should be protected from physical, psychological and cultural harm. Minimising harm (non-maleficence) also involves using the smallest number of participants and tests that will ensure scientific validity. Where the giving of advice (e.g. medical, psychological) to a participant is an intrinsic part of the research, this should be agreed with the participant in advance, and should have been subject to ethics review. If problems are detected and the investigator is not competent to offer assistance, the appropriate source of professional advice should be recommended. Provision for emergency situations and participant distress should be made clear in the application. Maximising benefit (beneficence) imposes a duty on researchers to advance knowledge that will help individuals and society. One of the first codes of practice for ethical research, the World Medical Association Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects differentiated between therapeutic and non-therapeutic research. Therapeutic research involves offering of a treatment that may have beneficial effects for the participants whereas the results of non-therapeutic research may benefit others but is unlikely to benefit the research participants themselves.

# University ethics review procedure

## Scope and purpose

All research and scholarship involving animals, human participants, personal data or risk to the investigator, not adequately mitigated by proper application of the University [Health and Safety Policies and Procedures](#), requires independent ethical scrutiny. This requirement applies to all staff employed by the University, both academic and administrative, as well as to students, and to all research taking place within the University or under the auspices of the University; and must take place *before* data gathering takes place. The purpose of this scrutiny is to protect the dignity, rights, welfare and safety of all participants, including the researcher, and to consider the legitimate interests of other individuals, bodies and communities associated with the research. The impact on the reputation of the University of the research carried out under its sponsorship is therefore also important. Ethical review will furthermore ensure that there is informed judgement of the scientific merit of the proposal and may make recommendations to the researcher. The ethics review procedure is therefore also an opportunity for peer review of research.

Since each research project is seeking to make unique contributions, the ethical principles described in the preceding section cannot be applied in a formulaic fashion. Complex projects take time to assess, and researchers should be prepared for this by considering issues early in the research planning process. The onus is on the researcher to demonstrate application of these principles within the design and conduct of the study and to justify any exception to a principle that is deemed appropriate. An example of this is where deception may be deemed necessary to the methodology. In this case the dignity and autonomy of participants should always be protected and it is usually important to provide an appropriate debriefing.

## University and School Ethics Committees

Schools are responsible for reviewing and making decisions on ALL applications for ethical approval.

Each School therefore has a responsibility to make sure that local and University ethical guidelines are available to every member of their staff and students. School Ethics Committees are required to be formed according to University Regulations and guidelines, including the minimum requirements outlined later in this document. School Ethics Committees are required, for example, to demonstrate to the University Ethics Committee that they are independent and multidisciplinary, and have appropriate operating procedures in place. All applications for ethical scrutiny by staff and students should be submitted to one of these School Ethics Committees using the forms prescribed by the University Ethics Committee.

For applicants who are not based in a School including individuals from outwith the University, applications for ethical approval should be submitted via one of the School Ethics Committees. The choice of School Ethics Committee will be determined on the nature and subject of the proposed research. The Chair of the University Ethics Committee may advise further.

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Applications for research involving human participants will be fully scrutinised at School level. Mitigation of risk must be detailed in the application. Other applications will be dealt with in the following ways:

- Research that may require approval of an NHS Research Ethics Committee e.g. work involving NHS patients and carers, access to data, organs or other bodily material of past and present NHS patients, health-related research involving prisoners, should be submitted through IRAS[2] and a copy of this application should also be submitted to the School Ethics Committee;
- Research for which the funding body requires lay input into the ethics review process <u>may also be forwarded</u> to the University Ethics Committee for advice, depending on the composition of the School Ethics Committee, noting that the UEC does not make decisions on applications for ethical review;
- Research involving animals regulated by the [Animals (Scientific Procedures) Act](#) should be submitted directly to Animal Welfare Ethical Review Body; Non-regulated procedures on captive or temporarily-captive living vertebrates and cephalopods should be submitted to the School Health & Life Sciences Ethics Committee

## Classification of risk

Activities that involve potentially vulnerable participants or highly sensitive topics are more likely to be of higher risk and applicants must satisfactorily demonstrate to the School Ethics Committees that these are mitigated. All research and scholarship should apply the following risk framework.

| Class | Risk Characteristics | Risk response |
|-------|---------------------|---------------|
| 1 | Project exhibits none of the characteristics that indicate the need for independent ethical scrutiny. | Documented and registered self-assessment, reviewed and approved by supervisor/director of studies for student applications |
| 2 | Exhibits one or more characteristics indicating a need for independent ethical scrutiny but none of the risk factors indicating potentially higher risk. | Assessment/approval by the relevant School Ethics Committee. |
| 3a | Exhibits one or more factors considered to be indicators of higher risk.<br><br>Demonstrates that the risk factors have been adequately addressed through the use of standard protocols and established methodologies for potentially higher risk situations. | Assessment/approval by the relevant School Ethics Committee following scrutiny of the adequacy of the proposed risk mitigation. |

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| Class | Risk Characteristics | Risk response |
|---|---|---|
| 3b | Exhibits one or more factors considered to be indicators of higher risk.<br><br>Proposed risk mitigation and/or research methodology involves novel approaches, heightened residual risk etc. | Assessment by the relevant School Ethics Committee. SEC may seek advice from the University Ethics Committee prior to final decision. |

Topics/methods which are very familiar to the School or in which the applicant has great expertise may well fall into Category 3a whereas the same topic in a different School or less experienced researcher may be categorised as 3b.

Research involving the following groups/situations are likely to be considered "higher risk". It is particularly important in these circumstances to be "risk aware" and to reflect on potential vulnerabilities and demonstrate approaches to minimising their impact.

- Potentially vulnerable participants are those who may not be in a position to give competent or unfettered informed consent. Examples include:
  - Children under 16
  - Adults with learning disabilities
  - Adults with severe or terminal illness
  - Adults with mental illness
  - Adults in care homes
  - Those with a dependent relationship with the investigator e.g. students, relatives and friends
  - Those who may have perceived and/or real benefit from participation to which they otherwise would not have access
- Potentially highly sensitive topics. Examples include:
  - "race" or ethnicity
  - spiritual beliefs
  - sexuality
  - abuse and personal violence
  - criminal activities
- Where there is a significant element of deception
- Procedures, treatments, therapeutic techniques, psychosocial or other interventions. Examples include:
  - collection of body tissues or fluids e.g. venepuncture
  - administration of any substance or agent
  - counselling sessions
- Where there is significant risk to the researcher

## Process of ethics review

It is required that all applications be submitted by the Principal Investigator to a School Ethics Committee. In the case of student research the application must also be reviewed and signed by the Supervisor. In some cases a Supervisor may submit a single application to the Committee for a research project involving several students. In this case, in order for students to have an

authentic research experience, they may complete their own ethics application for review by the Supervisor only.

The School Ethics Committee will distribute received applications to independent reviewers. The number of reviewers will depend on the level of risk and extent of preceding peer review. "Lower risk" research, from supervised undergraduate or postgraduate students for example, may require only one reviewer and should therefore go through a "fast-track" route. Most other types of applications will be reviewed by at least two independent assessors. "High risk" research will be reviewed by at least two assessors for the School Ethics Committee and advice may be sought from the University Ethics Committee prior to decision, a process that may take a total of 4-6 weeks. It is recommended that, where possible, decision-making take place by face-to-face meeting, rather than by email, to allow full discussion of ethical issues and to facilitate consensus.

The time taken for ethical review will depend on the number of assessors but should not exceed six weeks and should be considerably shorter for "lower risk" research. *Retrospective ethics review i.e. request to approve research that has been commenced or completed, is not permitted. This is considered to be a breach of ethics – see below.*

Ethics reviewers will recommend one of the following outcomes:

- **Approved**: the project can proceed;
- **Approved with conditions**: the project can proceed provided the compulsory changes are made or requirements met;
- **Not approved**: the project cannot proceed for the reasons clearly specified; and
- **No decision**: the project requires further clarification or further review

Reviewers may also make suggestions that are intended to improve the project. This is not reflected in the decision but may be included in a comments section within the report.


The University Ethics Committee oversees the [Ethics Appeals procedure.](#)


## Ethics approved research

Approved projects are required to be carried out in accordance with the original application and the conditions. If changes are made to the project whether these have an ethics impact or not e.g. engagement of different groups of participants, different recruiting methods, a different approach to obtaining consent, different experimental procedures, then the School Ethics Committee must be informed immediately. The proposed changes will be considered, usually by the original team of reviewers, and a recommendation will be made. In the case where the research is not completed and participants have already been approached, endeavours should be made to notify the participants that the study has been discontinued and thank the participants for their interest.


The Principal Investigator is required to provide a written report of activities to the School Ethics Committee one year after the date of approval, or at the end of the research project, whichever is the sooner. In the case of projects running

for more than one year a report should be submitted to the School Ethics Committee on each anniversary of approval. In the case of undergraduate projects, the Supervisor should provide a summary report. Principal Investigators and Supervisors should not have reports of activities that are outstanding, when making new applications for ethical approval.

Where the School Ethics Committee has concerns about the ethical conduct of the study a full ethics review should take place, and the University Ethics Committee should be kept informed. If an ongoing research project is considered unethical, then the research should be discontinued while subject to investigation (see following paragraph).

### Research that does not have ethics approval (Breach of Ethics)
Should there be concerns that research is taking place that does not comply with ethical guidelines or is without ethical approval the Chair of the University Ethics Committee should be informed. The Chair of the University Ethics Committee should contact the Dean of the School and request that the research is suspended to allow investigation. The consequences of breaches of ethics should be made clear to students and staff as part of awareness raising activities overseen by School Ethics Committees. The investigation should be carried out by the University Ethics Committee and the School, collaboratively. In the event there is a complaint or the applicant is dissatisfied with the handling of the investigation, a request for a review may be submitted and will be conducted by the University Secretary.

## School Ethics Committees: minimum requirements

There are four principles that should underlie the governance of ethics in research and scholarship: independence, competence, facilitation and openness. These are described in [Research Ethics Support and Review in Research Organisations](). School Ethics Committees are required to adhere to the University ethics review procedure described above, and also to demonstrate to the University Ethics Committee how the principles detailed below are incorporated. Schools that do not meet these criteria must refer applications from their staff and students to another School Ethics Committee.

### Independence
Conflicts of interest should be mitigated by sufficient impartial scrutiny. In order to demonstrate independence Schools are required to have a School Ethics Committee that:

- Has a minimum of 6 members, at least two of whom are from outside the School
- Is multidisciplinary and represents a broad range of methodological expertise
- Complies with the University [Policies and Procedures]()
- If possible, includes at least one "lay" member
- Ensures that the ethics review process is independent of the research itself i.e. is constituted to avoid conflicts of interest

- Provides a report of activity of the School Ethics Committee to the University Ethics Committee on an annual basis

## Competence

Applications for ethical review must be scrutinised by individuals with relevant expertise and decision-making must be consistent and coherent.  In order to demonstrate competence Schools are required to:

- Demonstrate a comprehensive standard operating procedure for the School Ethics Committee so that ethics opinions are reached consistently and fairly
- Identify and describe how they comply with relevant discipline-specific Codes of Professional Practice and expectations of funding bodies and other stakeholders
- Use the application forms and ethical review procedures prescribed by the University Ethics Committee and ensure details are sufficient to make sound and coherent decisions
- Support and authenticate the contribution of members of School and University Ethics Committees in the School context
- Ensure every member and assessor of the School Ethics Committee receives systematic training in ethics

## Facilitation

In addition to protecting research participants School Ethics Committees have an additional role in facilitating good research and scholarship. In order to demonstrate facilitation Schools should:

- Demonstrate that applications to the School Ethics Committee receive timely and proportionate review, with arrangements for expedited review of lower risk applications
- Ensure that researchers are informed and supported in the development of their research by making informed judgements of the scientific merits of proposals and making informed recommendations to the researcher if the proposal is found wanting in some respect
- Consider the safety of the researcher
- Ensure every member of staff has opportunity to receive training in ethics

## Openness

The decisions of Ethics Committees should be transparent and accountable within the University governance structure. In order to demonstrate openness Schools are required to:

- Make the composition of the School Ethics Committee and the processes for ethical review available to all staff;
- Give applicants an opportunity to respond to any review without prejudice and have a clear appeals procedure;
- Monitor the outcomes of research, proportionate to the nature and degree of risk;

- Provide a report of activity of the School Ethics Committee to the University Ethics Committee on an annual basis and regular reports of key issues to each meeting of the University Ethics Committee;
- Review the composition and the standard operating procedures of the School Ethics Committee on a regular basis
- Recognise the dual responsibility of the administrator to the School Ethics Committee (to protect its independence) and to their line manager
- Recognise the dual responsibility of the Chair of the School Ethics Committee (to protect its independence) and to their line manager

## Embedding a culture of ethics in research and scholarship

In seeking to develop a research environment that is characterised by a culture of integrity that nurtures good practice in research and scholarship, the University will implement the [Concordat to Support Research Integrity](#). Ethical frameworks are constantly evolving within a social and legal context. In addition to having clear policies, practices and procedures and a management system for their implementation, the University is committed to ensuring that researchers have the opportunity to contribute to the development of these frameworks and to refresh and develop their expertise in ethics. Members of the School and University Ethics Committee play a central role and should have ongoing training in ethics and are expected to participate in providing training and mentorship for other members of staff. All members of staff should take a proactive role in their development and also be supported to make time available to reflect on practice, and seek assistance if needed either within, or outside of the PDR process.