



Title: Procedures for the Ethical Approval of Research / Innovation Projects
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# Procedures for the Ethical Approval of Research / Innovation Projects

## Outline of Process

1. Research projects or innovation activities whether undertaken as a group or by an individual must have a principal investigator who will take responsibility for compliance with the University Ethics Policy and these procedures.
2. All students (F/T, P/T and distance learners), staff and any limited companies set up under the auspices of Southampton Solent University and undertaking research or innovation activity, must give adequate consideration to any ethical matters which their proposal raises. Evidence will be required of such consideration.
3. Schools, hubs and services will ensure that the ethical proposal of research projects/innovation activities can be reviewed and a decision reached in a time scale that will not compromise business opportunities. As a result there must be a mechanism in place for reviewing routine, short-notice, and urgent cases.
4. The following projects do not need ethical approval:
  - a. Ad-hoc academic audit or service evaluation projects designed and conducted solely to produce information to inform the delivery of provision. These would usually involve analysis of existing data and may include minimal participation from staff or students;
  - b. literary or artistic criticism;
  - c. testing and review within normal education requirements, and
  - d. projects that draw on documentary material already in the public domain.
5. However, research/innovation activities involving focus groups will need to secure ethical clearance, either by way of an Ethics Release or a Full Ethical Review.
6. The Data Protection legislation must be observed in the storing, monitoring, recording and use of all data.

7. Ethical clearance may be obtained via two routes:
  - a. Fast tracking ethical approval, termed 'Ethics Release'
  - b. Full Ethical Review
8. The principal investigator must secure ethical clearance before any research project or innovation activity can commence and potential human participants can be approached.
9. Providing the research/innovation proposal meets the criteria for fast tracking (see below section on Ethics Release), an Ethics Release can be self-certificated by the principal investigator.
10. Where a proposal does not satisfy the criteria for an Ethics Release, the proposal must be submitted for a Full Ethical Review (see below section on Full Ethical Review).
11. The University Ethics Committee delegates Full Ethical Reviews and approval of research and innovation project proposals to its Ethics Standing/Specialist Panels.
12. For Full Ethical Review, and where a student is the principal investigator, it is the supervisor or director of studies (DoS)' responsibility to ensure that the student obtains ethical clearance.
13. It is the expectation that research projects or innovation activities undertaken as part of an undergraduate programme of study will not venture into areas requiring a Full Ethical Review.
14. Project proposals which are being submitted for funding from major funding bodies may also be subject to Full Ethical Review.
15. Any subsequent change in the proposal will require new ethical clearance.

## Exemptions

16. Areas with a robust ethical approval system already in place may apply to the University Ethics Committee for an exemption from following the ethical clearance process described herein. The University Ethics Committee will review and approve, where applicable, the applications for exemption on an annual basis.

## Staff

17. Where a project is undertaken collaboratively, a principal investigator will take responsibility for obtaining ethical clearance for the project on behalf of all the investigators:
  - a. The principal investigator will complete an Ethics Release Checklist [ERC].

See below section on Ethics Release for detailed process.

- b. If the proposal does not meet the criteria for an Ethics Release, the principal investigator will submit a Request for Ethical Approval Form along with the original ERC to the Chair of the relevant Ethics Standing/Specialist Panel (i.e. the one pertaining to the School/Hub/Service that employs the principal investigator).  
See below section on Full Ethical Review for detailed process

## Students

18. Students conducting a research project or taking part in an innovation activity will be under the active supervision of a member of staff known as the 'supervisor' and should always discuss their proposal in detail with their supervisor.
19. It is the responsibility of the principal investigator to submit their proposal for ethical consideration to their supervisor, in the first instance. The supervisor will give advice regarding the ethical issues involved with the proposed project. The supervisor will advise if an Ethics Release can be self-certificated or whether the proposal needs to be submitted for a Full Ethical Review.
20. The student(s) will complete an Ethics Release Checklist [ERC] and submit it to their supervisor for review. Where the information contained in the ERC satisfies all the criteria for fast tracking (see below paragraph 21), the ERC will be signed by the investigator(s) and the supervisor, forming part of the proposal and attached to the final work when submitted for marking. For group work there will be one completed and signed ERC for each project.
21. Where the information contained in the ERC does not satisfy the criteria for fast tracking, then the proposal will need to be submitted for a Full Ethical Review.

## Ethics Release

22. An Ethics Release can be self-certificated for any research and innovation project that:
  - a. **Does not involve human participants** other than the investigator(s); However, for those projects that involve human participants, an Ethics Release can be used **if the project:**
    - o Does not involve vulnerable participants such as children, young people, disabled people, the elderly, people with declared mental health issues, prisoners, people in health or social care settings, addicts, or those with learning difficulties or cognitive impairment either contacted directly or via a gatekeeper (for example a professional who runs an organisation through which participants are accessed; a service provider; a care-giver; a relative or a guardian);
    - o Does not involve the use of control groups or the use of deception;

- Does not involve any risk to the participants' health (e.g. intrusive intervention such as the administration of drugs or other substances, or vigorous physical exercise), or involve psychological stress, anxiety, humiliation, physical pain or discomfort to the investigator and/or the participants;
  - Does not involve financial inducement offered to participants other than reasonable expenses and compensation for time;
  - Does not involve individuals unconnected with the University but who wish to use staff and/or students of the University as participants;
  - Does not involve the collection of participants' personal data other than gender, age and address; and that all reasonable steps are taken to safeguard the anonymity of the participants during and after completion of the project, with all personal data being destroyed in a timely manner; and
- b. **Does not involve sensitive materials** or topics that might be considered offensive, distressing, politically or socially sensitive, deeply personal or in breach of the law (for example criminal activities, sexual behaviour, ethnic status, personal appearance, experience of violence, addiction, religion, or financial circumstances);
- c. **Does not have a detrimental impact on the environment, habitat or species;**
- d. **Does not involve animal living subjects;** and
- e. **Does not involve the development for export of 'controlled' goods** regulated by the Export Control Organisation (ECO); *"This specifically means military goods, so called dual-use goods (which are civilian goods but with a potential military use or application), products used for torture and repression, radioactive sources."*<sup>1</sup>

## Full Ethical Review

23. When an Ethics Release cannot be self-certificated, the principal investigator or project supervisor/DoS (on behalf of the student) will complete a Request for Ethical Approval Form<sup>2</sup> to describe how the research project/innovation activity is to be conducted.
24. The Request for Ethical Approval Form along with the original ERC will be submitted to the Chair of the relevant Ethics Standing/Specialist Panel. Additional and relevant information may also be submitted, as appropriate, for example the proposed research questionnaire, information about informed

<sup>1</sup> For further information: <http://www.berr.gov.uk/whatwedo/europeandtrade/strategic-export-control/index.html>

<sup>2</sup> Already in operation in Faculties

- consent, written communication with the gatekeeper, etc.
25. Paperwork relating to a Full Ethical Review will be subject to regular audit as commissioned by the University Ethics Committee. Schools, Hubs and Services are required to retain paperwork relating to the Full Ethical Review for two years after completion of the project.
  26. The Chair of the relevant Ethics Standing/Specialist Panel will appoint two members of the Panel from the most appropriate discipline/service and together they will undertake the Full Ethical Review. The Chair should ensure that the two members, given their position, role or duty within the School/Hub/Service, have no interest which might affect, or be perceived as being capable of affecting, their judgement.
  27. The Chair may also appoint one additional member of staff outside of the Panel membership to undertake a Full Ethical Review when there is a requirement for specialist/expert knowledge not available to the panel membership. This would particularly apply to collaborative/cross-disciplinary projects. The appointment is valid for the duration of the said review only.
  28. The Full Ethical Review will use appropriate forms of discussion, which may take place virtually.
  29. When reviewing project proposals for full ethical approval, the Chair and the two appointed members of the panel should as a minimum consider:
    - the principle of 'doing good'
    - the principle of 'doing no harm'
    - assessment of hazard (source of potential harm)
    - analysis of risk (probability of such harm occurring)
    - confidentiality of information supplied by participants and their anonymity
    - recruitment process/coercion to participate
    - data protection issues
    - conflicts of interest or partiality
    - impact on the relationship (e.g. counsellor/client, student/tutor)
    - the nature of any trade secrets or commercially sensitive information
  30. The Full Ethics Review process leads to four kinds of decisions:
    1. **Approved** (ethically sound, permission to proceed);
    2. **Approved with condition** (e.g. results may not be published in the public domain);
    3. **Not approved**, right to re-submit (suitable changes required); or
    4. **Rejected** (not approved, no right to resubmit)

31. The Chair of the Panel will ensure that the decision is reported to the principal investigator, or supervisor/DoS in the case of a student's submission, normally within five working days of the proposal being submitted.

## Appeals

32. Where a decision has gone against a proposal or has required significant revisions to the project/activity, the principal investigator or the supervisor or the DoS on behalf of the student has the right to appeal to the University Ethics Committee which will review the reasonableness and fairness of the decision made by the Ethics Standing/Specialist Panel Chair and members.

## Misconduct

33. In the context of research and innovation, the University defines misconduct to include the following, whether deliberate, reckless or negligent:
- Failure to obtain appropriate ethical approval before the commencement of the project;
  - Deception in relation to the proposal submitted; and
  - Supervisor's negligence in providing appropriate ethical advice when fast tracking ethical approval for a student's project.
34. Any individual who believes that an act of misconduct relating to the ethical approval of research or innovation has occurred or is occurring should notify the Chair of the University Ethics Committee, detailing the precise nature of the allegation and whom this concerns. The Chair of the University Ethics Committee will liaise with the School/Hub/Service concerned. An appropriate internal process will need to be in place to investigate any suspected case of misconduct.

## Complaints

35. Expressions of concern about the ethical approval or the conduct of research or innovation activity carried out under the auspices of the University should be made in the first instance to the Chair of the University Ethics Committee. The Chair will liaise with the investigator, where applicable their supervisor, and a relevant Dean/Director/Head in recommending further action, which may invoke the University disciplinary and/or complaints procedures.

## **Staff Development**

36. The Research and Innovation Office is responsible for monitoring the work of the Standing/Specialist Panels, continuing the work of ethics training and awareness, in association with Deans/Directors/Heads, and submitting written reports to the University Ethics Committee three times a year.

## **Ethics Standing/Specialist Panels**

37. There will be ethics standing/specialist panels involving Schools / Hubs / Services.

## **Terms of Reference**

38. The Ethics Standing/Specialist Panels shall:
  - a. Scrutinise all proposals for full ethical consideration submitted to their Chair; and
  - b. Share good practice.
39. In addition, the Chair of each Ethics Standing/Specialist Panel will confirm the Panel's current membership to the University Ethics Committee (UEC), at the beginning of each academic year.
40. The Chair of each Ethics Standing/Specialist Panel should ensure timely dissemination of relevant information from the University Ethics Committee to all members of the panel, and report to the University Ethics Committee on ethical issues, including processes and practices in relation to ethical approval of proposals.
41. Where an Ethics Standing/Specialist Panel is unable to resolve a particular issue, including any concerns of an ethical or related nature raised by the investigator(s) or participant(s) in a project, the Chair will relay all relevant details to the University Ethics Committee which will consider such matters and deliver judgment on the issue which has been raised.
42. Members of Ethics Standing/Specialist Panels cannot be involved in discussion and decision about their own proposal or proposal of individuals they are related to.

### KEY TERMS

A project is defined as an activity that involves the collection of primary data.

An investigator is defined as a student or staff member undertaking research or innovation activity.

A principal investigator is defined as a student or staff member taking responsibility for leading a research/innovation project.

- The responsibility lies with the principal investigator (student or staff member) to self-certify an Ethics Release. In the case of a student's project, the supervisor/DoS will need to sign off the Ethics Release.
- For a Full Ethical Review, the responsibility lies with the staff member or the supervisor/DoS (on behalf of the student) to submit the proposal to the Chair of the relevant Ethics Standing/Specialist Panel.

Human participants are defined as including living human beings, and human data and records (such as, but not restricted to medical, genetic, financial, personnel, criminal or administrative records and test results including scholastic achievements).

Documentary material already in the public domain include, for example, published biographies, newspaper accounts of an individual's activities, published minutes of a meeting, interviews broadcast on radio, television or online, diaries or letters in the public domain, and historical records authorised for public access by record offices.

Academic audit is a process 'to investigate the effectiveness of academic policies, procedures or practice (...) to protect University standards, or enhance the student learning experience, or improve the quality of course provision and/or operational effectiveness.'<sup>3</sup>

A gatekeeper is a professional who runs an organisation through which participants are accessed, as well as a service provider, a care-giver, a relative or a guardian.

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<sup>3</sup> Programme monitoring, periodic academic review and academic audit (2E), Academic audit, Southampton Solent University Academic Handbook

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