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POLICY ON THE ETHICAL CONDUCT OF STUDIES INVOLVING HUMAN PARTICIPANTS

Policy Statement

The University of Southampton is committed to protecting the rights, welfare, and dignity of all those involved in research, (whether they are participants, researchers, collaborators, sponsors or other third parties) and to promoting high quality ethical studies. The purpose of this Policy is to:

1. Set out the principles applicable to all studies involving human participants conducted at, by or in the name of the University of Southampton;
2. Provide members of the University with a clear understanding of the ethical review regime operated by the University of Southampton; and
3. Support a culture of academic freedom and excellence by providing the framework for a review process which subjects research proposals and other studies to a level of scrutiny that is in proportion to the risk of harm or adverse effect to participants, the University and to society as a whole.

Scope

This Policy applies to all staff and students of the University engaged in studies or research involving human participants, as well as to visitors, individuals, collaborators, or agents conducting research or other studies involving human participants in the name of or at the University and/or engaged to conduct research by the University.

Principles of Ethical Research

1. Studies and research should be designed, reviewed and undertaken to ensure integrity, quality and transparency.
2. Participants must be informed fully about the purpose, methods, and intended possible uses of the findings, what their participation in the research/study entails and what risks, if any, are involved.
3. The confidentiality of information supplied by participants and the anonymity of respondents must be respected. All personal data must be processed strictly in accordance with the requirements of the Data Protection Act 1998.
4. Participants must take part voluntarily and free from any coercion.
5. Harm to participants must be avoided or minimised in all instances, and the benefits of research/study must always outweigh any potential harm to the individuals participating.
6. The independence of the research/study must be clear, and any conflicts of interest or partiality must be explicit.

7. The same high ethical standards shall apply wherever in the world the study/research is undertaken.

The University meets these principles by communicating its standards and policies to staff through education and training, publication of this and related policies, and through its Ethics Framework, this policy and the process for the ethical review of all research/studies involving human participants.

Ethical Review Process

The University of Southampton is committed to providing a competent, rigorous and independent process of ethical review for all studies and research involving human participants that is proportionate to the risk involved.

Ethical Review at the University is the responsibility of the University Ethics Committee (UEC), whilst the task of conducting ethical reviews falls to the Faculty Ethics Committees. It is anticipated that each of the University's 8 Faculties will have its own Ethics Committee. However, the Faculty Ethics Committees (FECs) have the freedom to operate combined ethics committees where the workload makes that an appropriate course of action. Similarly each FEC may, if needed, operate one or more sub-committees. Further all Professional Services Departments in the University should have in place arrangements with an appropriate FEC for any study they/their staff may undertake which involves human participants.

All studies involving human participants must be registered on the University's electronic document management system, Ethics and Research Governance Online (ERGO), which is accessible at: <https://www.ergo.soton.ac.uk>

The ERGO system will prompt researchers to provide information about their study, which will determine the level of risk involved in the study and the level of scrutiny which that study will receive. ERGO also identifies which FEC has responsibility to review the researcher's study in order to provide the formal approval before the research can be started. ERGO submission also ensures higher risk studies are forwarded to the University's Research Governance Office (RGO), to arrange for University sponsorship and insurance.

There are 3 levels of review and approval dependent on the category of the study:

- Category A studies will require review and approval of the Research Governance and Insurance Offices before they can start¹ in addition to that of the FEC.
- Category B studies only require approval from the FEC before they can start.
- Category C studies still require registering on ERGO and the oversight of an FEC but can be approved by a single member of their FEC, or such other suitably qualified individual

¹ These are the type of studies that are required by our insurers to have this additional approval level or that the University Ethics Committee considers are of a nature that this additional review is necessary before the research/study can start.

designated by them to do so (but not the researcher or supervisor for their own study). The FEC is required to monitor studies approved in this fashion and will report annually to UEC.

UEC will keep under review these Categories and may change the criteria as it considers appropriate subject to sufficient notice given to FECs and the research community.

For more information on these categories please see [Category Guidelines](#). Please note that although Studies normally will be allocated automatically to a Category via the ERGO system FECs may, at their discretion, elevate a study to a higher category where they consider it appropriate.

Studies which may not need additional ethical review by the FEC:

- Where a study has been or is required to obtain ethical approval from an external body such as the National Research Ethics Service (NRES) the UEC does not require additional scrutiny by the FEC.
- Where a study is being undertaken in collaboration with other universities or institutions and the lead institution has undertaken ethical review the UEC does not require additional FEC review save where the standards of review do not meet the high ethical standards we expect.

These matters still require registering on ERGO, should be monitored by the FEC and if a Category A study will require Research Governance and Insurance Office approval.

Roles and Responsibilities

University Ethics Committee

The University Ethics Committee is chaired by the Pro Vice-Chancellor (Research), and is responsible for developing, keeping under review and monitoring the implementation of the University Ethics Policy, and for sustaining a University-wide awareness of research governance, ethical and related issues. UEC is also responsible for developing guidance in these areas, for receiving reports from the Faculty Ethics Committees and for ensuring that the members of Ethics Committees at the University receive appropriate training in ethical issues.

[link to TOR & Membership]

Faculty Ethics Committees

Each Faculty will normally be expected to have an Ethics Committee but, with the agreement of the Chair of UEC, Deans may agree to establish joint Ethics Committees across faculties, or to operate one or more sub-committees.

The role of the FECs is to review and consider the ethical implications of all studies involving human participants (save where an ethics applications is being considered by an appropriate external ethics committee), and to ensure that all such projects adhere to applicable Faculty and University policies, legislation, professional guidelines and best practice.

FECs must include a minimum of 6 staff members and one student representative from the relevant Faculty (with one senior member of the Faculty management committee or appropriate nominee to act as Chair), and one independent member from outside the University. Ethics Committees must meet face to face at least once in every semester but otherwise may conduct meetings via email or other electronic media and record decisions via ERGO.

In order to manage workloads and ensure the timely ethical review of studies FECs may also develop delegation strategies for the appropriate review of studies registered on ERGO including by sub-committee(s), a subset of FEC members, single sign off in the case of Category C studies and/or for expedited review. Any matter delegated may be elevated for full FEC review should any of the reviewers consider it appropriate. UEC expects all FECs to report annually on any strategies adopted and to regularly monitor these approvals to ensure the quality of the ethical review undertaken. Issues with/arising from reviews should be discussed at FEC so that training needs can be identified and recommended.

[link to TOR & Membership]

Research Governance Office

The primary function of the Research Governance Office (RGO) is to review all the applicable elements of good research governance for higher risk studies involving human participants; and to arrange University sponsorship and insurance for eligible research studies. All researchers conducting Category A studies must insure that they have both “sponsorship” and insurance in place prior to starting their research or any study, (in addition to any external approvals that may be required), and this is applied for by submitting details of the proposed research/study to the RGO through the ERGO system.

The RGO is also responsible for monitoring the University’s Ethical review system on behalf of UEC and ensuring that high ethical standards are maintained across the University. In the event that the RGO discovers any failure to comply with this policy or to attain the high ethical standards required by the University in the course of its monitoring, it will refer its concerns to the appropriate FEC, and report on the action it has taken to UEC. The RGO will only directly intervene on a project that has already commenced where it is a Category A study which it has not approval for or in all other cases where it perceives an immediate risk to the health or well being of researchers or participants, or to the integrity of the University.

In addition to its regulatory and monitoring role, the RGO provides guidance and training to FECs as well as researchers, and provides researchers with a source of support and advice when they are submitting research for external ethical review.

The RGO Website <http://www.soton.ac.uk/corporateservices/rgo/index.html>

Researchers

The University expects all researchers (whether staff, visiting scientists or students) to take personal responsibility for familiarising themselves with this policy and with the procedures they need to follow to obtain sponsorship and insurance for their research or studies they undertake.

All research/studies involving human participants conducted under the auspices of the University of Southampton must be submitted for ethical review through the ERGO system. This includes, but is not limited to, all staff, visiting researchers, those with honorary post and registered students. It is the responsibility of the Chief or Principal Investigator for any research/study to ensure that all their colleagues involved in that research/study are aware of and comply with the policies of the University. Any changes to the study design and consents must be also notified using ERGO and receive approval.

Notwithstanding any ethical approval that may be obtained, researchers are still required to ensure that their research or other studies are conducted in accordance with the ethical requirements of their funding body and/or any professional bodies or associations relevant to their discipline as well as comply with health and safety requirements.

Professional Service Departments

The University expects all Professional Service Department to have arrangements with an appropriate FEC to ensure any research/study they or their staff undertake involving human participants receive ethical review. All such research/study shall be registered on and administered through ERGO.

Research & Innovation Services teams based in the Faculties shall have responsibility for supporting FECs and administer the use ERGO. Find your [R&IS Contact](#)

Appeals

Where a researcher has a concern about the decision of a FEC to withhold, suspend or withdraw ethical approval of research/study involving human participants, they should attempt to resolve the matter with their FEC. In the first instance they should contact the Chair who may decide to convene a different panel from its FEC members to review the application, seek guidance from another FEC, invite the researcher to resubmit his/her application or confirm the original decision.

In the event that their concerns cannot be resolved at FEC level, researchers may appeal the decision of an FEC to the University Ethics Committee by contacting the Head of the Research Governance Office at rgoinfo@soton.ac.uk . Appeals will only permitted on one of 2 grounds:

1. That the researcher possesses new evidence that was not available at the time the FEC made its decision and it has subsequently refused to consider such evidence; or

2. That there had been a significant failure in the application of procedures which had affected the decision of the FEC.

Researchers may not question the judgement of the FEC. Upon receiving an appeal the Head of the RGO will refer the appeal to the Chair of UEC, who may remit the appeal to a differently constituted FEC or reserve it for the decision of UEC.

Sanctions

Any breach of this policy will be taken extremely seriously, and may result in disciplinary action including for gross misconduct where the breach is committed by a member of staff, or formal Disciplinary proceedings under the relevant University procedures where it is committed by a student.

Other Policies that may apply to your research

- [Research Integrity and Academic Conduct](#)
- [Research involving animals](#)
- Research Governance webpages within SUSSED
- [Conflicts of Interest Policy](#)
- [Data Protection](#)
- Health and Safety - See HR website in SUSSED
- [Guidance on Bribery Act 2010](#)
- [Anti-Corruption, Fraud and Bribery Policy](#)

NB The following wording does not form the Policy as such but will be included in the web pages hosting the policy and/or in ERGO as appropriate. FAQs will be further developed in conjunction with FECs and the Ethics Forum however we will avoid duplication & conflicting guidance on different locations.

Frequently Asked Questions

1. Do all University of Southampton studies involving human participants need to be registered on ERGO and obtain ethical approval?

Yes. All studies which involve human participants must obtain ethical approval from the appropriate body.

There are different levels of review required and a “light touch” oversight enabled through the ERGO system for low risk studies.

2. Why do all studies involving human participants need ethical approval?

To ensure that participants health, safety and dignity are protected, to minimise the risk to them and to ensure that the benefit deriving from the research outweighs any potential harm to people and to the environment.

3. My Study involves Students and/or Staff of the University of Southampton: do I need to take any special steps?

Yes. You will need to make sure that both staff and students are informed that participation or non-participation in the research will have no impact on their programme of studies or employment.

4. What steps do I need to take to obtain ethical approval?

You will need to register details of your study on the ERGO system, which will categorise it according to risk, and ask for additional information where appropriate. The level of risk will determine the degree of scrutiny applied to your proposal, which will also affect the amount of time it takes to obtain ethical approval.

5. I am using data about people but they are not identifiable. Do I need ethical approval?

If a key is held by anyone on or involved with the study that can be used to identify data subjects from otherwise seemingly anonymised data then ethical approval must be obtained at a Category B level or higher. If none of the data subjects can be identified then the study may fall within the Category C review criteria. Please register the study on ERGO or seek guidance directly from your FEC.

6. Who should apply for Ethical approval?

It is the responsibility of the Chief/Principal Investigator of the study to apply for approval. Where a study is to be carried out by a student, the application should be made by the student under the guidance of the supervisor.

7. I am having difficulty in understanding some of the terminology used by the ERGO system and am not sure what it is asking me: what do I do next?

Contact the Research Governance Office by telephone on [number] or by email at [address], and they will help you with your query.

8. My study will be conducted overseas: do I still need to obtain ethical approval from the University?

All research carried out under the auspices of the University of Southampton must meet the same high ethical standards, and participants have a right to be treated with the same level of respect and professionalism no matter where the study is carried out. Research to be carried out in other countries must comply with local ethical requirements, and this information supplied to the FEC through the ERGO system. If it has been reviewed by another institution's ethical committee then it is for the Chair of the relevant FEC to decide whether additional scrutiny is required.

9. There has been an Adverse Event affecting the well being of either a participant or researcher involved in my study: what should I do?

Your first priority must be the welfare of the individual in question, and you should ensure that you follow the University's normal procedures for reporting and dealing with injury or accident. Serious Adverse Events should also be reported within 7 days to the relevant FEC and the RGO.

10. In the course of my role at the University I have access to Personal Data which I would like to use in my research. If I already have that data to hand can I use it in my research without seeking consent?

No. You may only use individual's personal data for the purposes for which that data was made available in the first place. In order to use that data in research you will need to obtain the individual's consent to do and submit your proposal for ethical review using the ERGO system.

11. My research involves the development of a platform/web tool to enable others, including those external to the University of Southampton to conduct research involving human participants. Do I need to get ethical approval for my research? Also does any study utilizing the platform/web tool require ethical approval from the University of Southampton?

Your research project probably does not require ethical approval unless during the development you carry out research involving human participants. The University of Southampton would expect you to put in place appropriate terms and conditions that users of the platform/web tool should sign up to. These should include the requirement that appropriate ethical approval is obtained from their own institution and enable the University of Southampton to take down any study at its sole discretion particularly where it considers the University of Southampton's high ethical standards are not being met. We recommend you contact the Research & Innovation Services who will be able to guide you on this.

12. I am a visiting researcher conducting research elsewhere do I need ethical approval from the University of Southampton?

If you are undertaking research in the name of or in connection with the University of Southampton then it should be registered on ERGO so that ethical approval can be obtained if necessary. Where approval has been obtained from another organisation's ethics committee then additional approval may not be required but this still needs registering on ERGO. If in doubt seek guidance from the FEC of the Faculty that is hosting you.

NB these are indicative at this stage and will be developed further with input from FECs and RGO

Further Information and Guidance

The following is a list of useful links

Internal

Research Governance Office

Health & Safety

Professional Associations

British Psychological Society Code of Ethics and Conduct

General Medical Council Guidance on Good Practice

Nursing and Midwifery Council Standards of conduct, performance and ethics

Research Councils & Charities

Medical Research Council: ethics and research guidance

Economic and Social Research Council: Research Ethics Framework

Wellcome Trust

NHS Resources

Department of Health Research Governance Framework

NRES Guidance for Applicants

Standard Operating Procedures for Research Ethics Committees in the UK

Legislation

The Medicines for Human Use (Clinical Trials) Regulations 2004

The Human Tissue Act 2004

The Data Protection Act 1998

Mental Capacity Act 2005

Health & Safety at Work Act 1974 and all related amendments.