1 INTRODUCTION

The University of Kent expects that all research, and the application of research, carried out at or on behalf of the University, by staff, including persons with honorary positions and collaborators, and students, is conducted to the highest level of ethical standards and in accordance with current legislation and policy requirements.

The purpose of this policy is to protect the dignity, rights, safety and well-being of research participants; the safety and reputation of researchers; the reputation of the University; to ensure research carried out in connection with the University is lawful; to manage and mitigate the risks arising from research; and to ensure ethical awareness is embedded across all faculties and schools.

The policy sets out the required standards of researcher integrity and requirements for ethical review of research projects that must be complied with for all projects undertaken by staff and students of the University of Kent. Researchers are also subject to the ethical guidelines and codes of practice relevant to their own subject areas.

Breaches of this Code should be considered as research misconduct and should be dealt with under the Code of Practice for the Investigation of Allegations of Misconduct in Research.

2 DEFINITIONS

For the purposes of this policy, research is defined as ‘the attempt to derive generalizable new knowledge by addressing clearly defined questions with systematic and rigorous methods’\(^1\) and ‘a process of investigation leading to new insights, effectively shared’\(^2\). The policy covers all areas and subjects of research including humans, animals, the environment and cultural objects, but it should also be applied more broadly, to activities such as enterprise and innovation, consultancy, the application of research, and service evaluation and audit where there are material ethical issues.

The policy applies to all studies carried out in connection with the University of Kent, by staff and students. For studies where external ethical approval has been secured, there is no need to duplicate this process. The relevant University Research Ethics Advisory Group (REAG) should be notified of the approval, and provided with a copy of the approval documentation in order that they can fulfil their reporting requirements to the University-level Research Ethics & Governance Committee. The REAG should be assured that the approving REC is constituted in accordance with recognised ethical standards and that the

\(^{1}\) Research Governance Framework for Health and Social Care (2nd edition), (DH, 2005)

\(^{2}\) REF2014 Assessment framework and guidance on submissions, (HEFCE, 2011)
http://www.ref.ac.uk/media/ref/content/pub/assessmentframeworkandguidanceonsubmissions/GOS%20incl uding%20addendum.pdf
approval is valid. Where it is suspected that this is not the case then a further review should be carried out by the REAG.

3 RESEARCH INTEGRITY

Researchers should ensure they carry out all their research activities in compliance with the following good practice principles, drawn from Universities UK’s Concordat to Support Research Integrity\(^3\) and the UK Research Integrity Office’s Code of Practice for Research\(^4\), which sets out the responsibilities and values relevant to research. Adherence to good research practice can help researchers avoid allegations of research misconduct.

- **Principles**

  **Excellence**: researchers should aim to conduct their research to the highest possible standards of research integrity in order to produce work of the highest quality.

  **Honesty**: in all aspects of research, including the presentation of research goals, intentions and findings; in reporting on research methods and procedures; in gathering data; in using and acknowledging the work of other researchers; and in conveying valid interpretations and making justifiable claims based on research findings.

  **Rigour**: in line with prevailing disciplinary norms and standards: in performing research and using appropriate methods; in adhering to an agreed protocol where appropriate; in drawing interpretations and conclusions from the research; and in communicating the results.

  **Integrity**: researchers should ensure they comply with all relevant legal and ethical requirements relating to their research area. They should be aware of and declare any potential or actual conflicts of interest relating to their research, and take steps to resolve them where necessary.

  **Cooperation**: researchers should promote the open exchange of ideas, research methods, data and results, and their discussion, scrutiny and debate, subject to any considerations of confidentiality.

  **Transparency and open communication**: in declaring conflicts of interest; in the reporting of research data collection methods; in the analysis and interpretation of data; in making research findings widely available, which includes sharing negative results as appropriate; and in presenting the work to other researchers and to the general public.

  **Accountability**: researchers should ensure that their research activities are compliant with any agreements, terms and conditions relating to the project, ensuring and cooperating with appropriate governance and transparency. Researchers should be aware of and compliant with requirements and guidance of any professional bodies in their field of research, and those who are members of a regulated profession must follow the requirements and guidance of the body regulating their profession. In and through their work researchers are ultimately accountable to the general public and should act accordingly.

\(^3\) See: [http://www.universitiesuk.ac.uk/policy-and-analysis/reports/Pages/research-concordat.aspx](http://www.universitiesuk.ac.uk/policy-and-analysis/reports/Pages/research-concordat.aspx)

Training and skills: Researchers should ensure they have the necessary skills, training and resources to carry out research; they should take advantage of training opportunities provided by their host institution; and should identify, report and resolve any unmet training needs.

Safety: Researchers should ensure the dignity, rights, safety and wellbeing of all involved in research and avoid unreasonable risk or harm to research subjects, patients, participants, researchers and others. Research should be initiated and continued only where the anticipated benefits justify the risks involved. Any concerns relating to the dignity, rights, safety and wellbeing of those involved in research should be reported and resolved.

Care and respect: for all participants in and subjects of research, including humans, animals, the environment and cultural objects. Those engaged with research must also show care and respect for the stewardship of research and scholarship for future generations.

4 STRUCTURE

At the University of Kent, Research Ethics Advisory Groups exist at School- and/or Faculty-level, dependent on the volume of applications. There is no hierarchy and researchers should apply to their local REAG, whether that is at Faculty- or School-level. It is the aim that REAGs are convened in accordance with the Economic and Social Research Council (ESRC) Framework for Research Ethics (FRE), but not all REAGs are currently in compliance with all elements of the FRE, and so a separate ESRC Committee, which is fully compliant with the FRE, exists to review research funded by the ESRC, where there is not a policy or legislative requirement for review by an NHS REC. All research involving non-human subjects must be reviewed by the Kent Animal Welfare and Ethical Review Body which is convened on accordance with the Animals (Scientific Procedures) Act 1986.

There is a University-level Research Ethics and Governance Committee that sets policy and regulates and monitors the activities of the REAGs. Although this Committee does not review individual projects, it provides a forum in which the REAGs can share best practice, and can provide guidance to REAGs and reviewers where necessary. The Committee will also receive complaints and appeals against REAG decisions and will provide a final opinion in these cases. Committee membership includes all REAG chairs.

REAGs are required to report annually to the Research Ethics and Governance Committee, at the first meeting of the Spring Term, providing information on activity, the review process, training, problems and appeals, etc. in accordance with the published template.

5 RESEARCH REQUIRING ETHICAL REVIEW

All research, staff or student, funded or unfunded, that involves human participants, their tissue or data, or non-human subjects, or other material ethical issues, must undergo ethical review before initiation. This includes studies such as questionnaires and internet research where the researcher may not have direct contact with participants; and also studies involving combination of anonymous data where there is a possibility that individuals could be identified by combination of the data with another dataset or other information that is already in the public domain. Appropriate ethical approval must be in place before any contact with participants, their tissues or data, begins. Research not involving human
participants, but that raises other ethical issues, must also undergo ethical review before it starts. This could include research involving cultural objects or that has potential environmental implications for example.

- **Unfunded research**
  For unfunded research, appropriate ethical approval must be in place before any contact with participants, their tissue or data, or any research activities with material ethical issues, begins.

- **Funded research**
  For funded research it is generally accepted that ethical approval need not be sought until funding is confirmed, but it must be in place before any contact with participants, their tissues or data, or any research activities with material ethical issues begin. REAGs can advise on methodological ethical queries that arise on funding applications, before carrying out a full review, where necessary.

- **Overseas research**
  Researchers undertaking research activities overseas must ensure they are in compliance with legal and ethical requirements of the host country and must be able to demonstrate this with documentary evidence. Researchers intending to conduct research in which there is a possibility that legal requirements in the host country could be contravened must detail their plans in their application for research ethics review to a relevant UoK School or Faculty REAG in order that researcher and participant safety and risks to institutional reputation can be assessed alongside other ethical implications. All UoK research taking place overseas must first be approved by the appropriate UoK REAG and researchers should complete the ethical review process before travelling abroad. Assessment of researcher safety must be a key concern. Research activities involving human participants, their tissues or data, or other activities with material ethical issues, must only be initiated once final approval from a UoK REAG has been granted.

5.1 **THE REVIEW PROCESS**

The ethical review process approved and recommended by the Research Ethics & Governance Committee involves two stages:

- The first stage is completion of a research ethics checklist. The checklist asks questions about the type of project to be undertaken and will identify, by a ‘yes’ response to any of the questions, those projects that require further, full review. This may be by a University REAG, or an external research ethics committee, such as an NHS REC, dependent on the nature of the research and its participants. The completed checklist must be countersigned by the relevant School ethics representative, and if all questions on the checklist are answered as ‘no’ then the form should be lodged with the relevant REAG, along with the project protocol and supporting documentation, and the researcher can continue with the project. For student research the checklist must also be countersigned by the supervisor who, by signing, is confirming that the checklist responses provided by the student are appropriate. For all studies below doctoral level, it is the ultimate responsibility of the
supervisor that ethical approval procedures are fully complied with. For doctoral level studies the ultimate responsibility lies with the student, with appropriate guidance from the supervisor.

- The second stage, full review for those projects that require it, involves completion of a more comprehensive application form, designed to gather all information about the study, relevant for a full review. The checklist and full application form, along with supporting documentation (consent forms; participant information sheets; research instruments; recruitment advertisements, etc. as appropriate) must be submitted to the relevant REAG, and the researcher must receive approval from the REAG before initiating the study.

6 RESEARCH REQUIRING REVIEW BY AN EXTERNAL COMMITTEE

Legislation and policy requires that certain types of research must gain approval from an external committee:

- NHS and Social Care
  Any research involving potential participants identified from, or because of, their past or present use of NHS and adult Social Care; their relatives or carers; their tissues or data; or any Social Care research funded by the Department of Health, must be submitted for approval to an NHS REC or the Social Care Research Ethics Committee.

  The HTA regulates ‘relevant material’: material which consists of or includes human cells. Where it is generally agreed that processed material is rendered acellular as a result of the process, the material will not fall within the Act. A Human Tissue Licence is required to store tissue for research purposes, except:
  - where it is stored for a specific research project which has ethical approval from a ‘recognised’ REC. For the purposes of the Act this must be a REC within the National Research Ethics Service, i.e. an NHS REC;
  - where it is received from a REC-approved tissue bank.

  The University does not hold a Human Tissue Licence and so where it is planned to store relevant material for the purposes of research, for any length of time, approval by an NHS REC must be sought. Once approval is in place, a copy of the approval document must be forwarded to the relevant REAG for their records.

- Mental Capacity Act (2005)
  The MCA covers ‘intrusive’ research, that is, any study that would normally require the consent of a person with capacity in order to be lawful. This type of research must be approved by an NHS REC before initiation.

  In order to legitimately involve those lacking capacity, the REC will assess whether the study is related to the ‘impairing condition’ or its treatment, and could not proceed as effectively with participants with capacity. In order to be approved, it must be evidenced that the study is likely to benefit the individual lacking capacity, or increase knowledge of the condition.
- **Health-related research involving prisoners**
  Approval is required from an NHS REC for health-related research conducted within prison settings and any prison research involving adults unable to consent for themselves.

- **Clinical investigations of medical devices**
  In compliance with the Medical Devices Regulations (2002) ethical approval must be sought from an NHS REC.

- **Clinical trials of investigational medicinal products**
  In compliance with the Medicines for Human Use (Clinical Trials) Regulations (2004) ethical approval must be sought from an NHS REC.

- **Non-human subjects**
  Research involving non-human subjects must be carried out in compliance with the Animals (Scientific Procedures) Act (1986). Three licences are required by the Act before testing on animals is permitted:
  - those carrying out procedures must hold a ‘personal licence’, which ensures that they are qualified and suitable;
  - the programme of work in which the procedures are carried out must be authorised in a ‘project licence’;
  - the place at which the work is carried out must hold an ‘establishment licence’.

  The University has a committee established to oversee and monitor research involving non-human participants and to ensure compliance with the legislation. Researchers intending to carry out work in this area must notify the Kent Animal Welfare and Ethical Review Body and adhere to its procedures.

For further information about legislative and policy requirements in research, researchers can contact the Research Ethics & Governance Officer who can offer guidance and assist with the application process.

7 **RESPONSIBILITIES**

- **Researchers**, that is, all those who carry out research at or on behalf of the University of Kent, including all staff, all students, persons with honorary positions, collaborators, are responsible for familiarising themselves with University requirements for ethical review and approval of research; assessing the appropriate route for ethical review for their project, with guidance as necessary; making the application and waiting until full approval has been granted before initiating the project. Researchers are responsible for conducting all research in compliance with good research practice, legal requirements and professional ethical standards relevant to the subject area.
Supervisors of student researchers are responsible for advising students on the ethical implications of their research, both prior to, and during the life of the project, including identifying the appropriate route for ethical approval, where necessary.

It is usually expected that where research projects are undertaken by a student in fulfilment of educational qualifications below doctoral level, the academic supervisor will take ultimate responsibility for the ethical conduct of the research.

It is normally expected that a doctoral student undertaking a research project will take ultimate responsibility for the ethical conduct of the research.

8 REFERENCES AND ADDITIONAL GUIDANCE

Researchers must be aware of and comply with all relevant research integrity guidance and policy, including University guidance and requirements, their relevant professional guidelines, and codes of practice relevant to their own subject areas. An inexhaustive list of research integrity and good practice guidance documents is included below.

General good research practice guidance

UK Research Integrity Office Code of Practice for Research: http://www.ukrio.org/publications/code-of-practice-for-research/

Research Councils UK Policy and Guidelines on the Governance Of Good Research Conduct: http://www.rcuk.ac.uk/funding/researchintegrity/

Universities UK Concordat to Support Research Integrity: http://www.universitiesuk.ac.uk/highereducation/Pages/Theconcordattosupportresearchintegrity.aspx

Professional codes of practice


British Sociological Association Statement of Ethical Practice: http://www.britsoc.co.uk/the-bsa/equality/statement-of-ethical-practice.aspx


British Educational Research Association Ethical Guidelines: https://www.bera.ac.uk/researchers-resources/resources-for-researchers


European Commission RESPECT project (Professional and Ethical Codes for Technology-related Socio-Economic Research): http://www.respectproject.org/ethics/

Academy of Social Sciences research ethics: https://www.acss.org.uk/developing-generic-ethics-principles-social-science/

**Medical research**


Health Research Authority: http://www.hra.nhs.uk/research-community/


**Research Councils**


Economic and Social Research Council: http://www.esrc.ac.uk/funding/guidance-for-applicants/research-ethics/

Medical Research Council: http://www.mrc.ac.uk/research/research-policy-ethics/

Natural Environment Research Council: http://www.nerc.ac.uk/about/policy/policies/

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APPENDIX
The UK Research Integrity Office’s Recommended Checklist for Researchers can help researchers to consider good research practice and should be referenced at an early stage of the design of a research project.5

Before conducting your research, and bearing in mind that, subject to legal and ethical requirements, roles and contributions may change during the time span of the research:
1. Does the proposed research address pertinent question(s) and is it designed either to add to existing knowledge about the subject in question or to develop methods for research into it?
2. Is your research design appropriate for the question(s) being asked?
3. Will you have access to all necessary skills and resources to conduct the research?
4. Have you conducted a risk assessment to determine:
   a) whether there are any ethical issues and whether ethics review is required;
   b) the potential for risks to the organisation, the research, or the health, safety and well-being of researchers and research participants; and
   c) what legal requirements govern the research?
5. Will your research comply with all legal and ethical requirements and other applicable guidelines, including those from other organisations and/or countries if relevant?
6. Will your research comply with all requirements of legislation and good practice relating to health and safety?
7. Has your research undergone any necessary ethics review (see 4(a) above), especially if it involves animals, human participants, human material or personal data?
8. Will your research comply with any monitoring and audit requirements?
9. Are you in compliance with any contracts and financial guidelines relating to the project?
10. Have you reached an agreement relating to intellectual property, publication and authorship?
11. Have you reached an agreement relating to collaborative working, if applicable?
12. Have you agreed the roles of researchers and responsibilities for management and supervision?
13. Have all conflicts of interest relating to your research been identified, declared and addressed?
14. Are you aware of the guidance from all applicable organisations on misconduct in research?

When conducting your research:
1. Are you following the agreed research design for the project?
2. Have any changes to the agreed research design been reviewed and approved if applicable?
3. Are you following best practice for the collection, storage and management of data?
4. Are agreed roles and responsibilities for management and supervision being fulfilled?
5. Is your research complying with any monitoring and audit requirements?

When finishing your research:
1. Will your research and its findings be reported accurately, honestly and within a reasonable time frame?
2. Will all contributors to the research be acknowledged?
3. Are agreements relating to intellectual property, publication and authorship being complied with?
4. Will research data be retained in a secure and accessible form and for the required duration?
5. Will your research comply with all legal, ethical and contractual requirements?

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5 From: UKRIO Code of Practice from Research, 2009 (http://www.ukrio.org/publications/code-of-practice-for-research/)