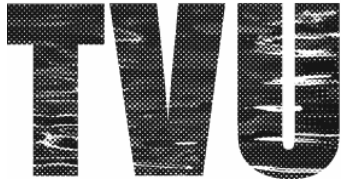


Thames Valley University



Thames Valley University
London Reading Slough

Research Office

Research Ethics Code of Practice

2007/8

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Please note

The information given in this publication is accurate at the time of going to press, but amendments may be made from time-to-time without notice, both in relation to individual research activities and the facilities or services available from or provided by the University.

**Research Ethics
Code of Practice
2007/8**

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Ethics of Research

1. Introduction

This Code of Practice provides guidance for staff and students engaged in or associated with research on the ethical issues that are likely to arise in the conduct, supervision, dissemination and use of research. It should be interpreted appropriately for different forms of research activity, and this is reflected in the information to follow. This code is advisory and should be read alongside the university's policies, procedures and advice relating to ethical review, health and safety, data protection, insurance cover and research contractual issues. Researchers should also follow the ethical codes of any professional association, educational institute or other external body with which they are associated, and abide by relevant legislation.

Our policies and code refer to the HEFCE definition of research as

"...activity which pushes forward the frontiers of knowledge...This will involve making new discoveries but, particularly in the humanities, it may involve reinterpreting and developing fresh insights from existing knowledge". - HEFCE's Review of Research (2000)

2. Guiding principles

The TVU Code of Research Practice follows has been drawn up in the context of the MRC/NHS governance frameworks and within a wider spectrum, the Statement on Safeguarding Good Scientific Practice issued by the BBSRC (2006) and the ESRC's Research Ethics Framework 2006. The Code also sits within the framework of national and international legislation and guidelines, in particular Human Rights Legislation and Declaration of Helsinki (World Medical Association 2000).

The Human Rights act of 1998 contains three articles explicit to safeguarding the rights of research participants, minimising risks, ensuring informed consent, privacy and confidentiality:

Article 3: No-one shall be subjected to torture or inhuman or degrading treatment.

Article 8: Everyone has the right to respect for his/her private and family life, his/her home and correspondence.

Article 9: Everyone has a right to freedom of thought, conscience and religion.

Research involving human subjects in any capacity is subject to a moral obligation through mutual respect and trust between participants and investigators in line with professional standards. Research conduct should always refer to the basic guiding principles of beneficence and non-maleficence (do no harm). Researchers should seek to protect the integrity, autonomy, privacy and dignity of research participants.

3. Basic Principles

3.1 All research should be undertaken under the basic principle that it does not cause harm, allow harm to be inflicted, or otherwise damage the interests of any involved parties.

3.2 Any exception to this overriding principle should be dependent on the following conditions:

- Explicit permission is given by participants demonstrating that they understand and accept the possibility of their person or interests being harmed.
- That any such risks are undertaken in order to bring about a greater benefit in terms of the acquisition of knowledge. Research should be carried out in the interests of the community, society and humanity as a whole. Any risks involved in a project must be balanced against the likely favourable outcomes of a successful investigation.

No project should be considered that runs a risk of causing harm to a person or persons who are unaware of such risks, or are incapable of evaluating the risks to themselves.

3.3 Researchers must be aware of, and respect, the rights of any who are directly or indirectly affected by their research. The physical, personal and psychological autonomy of participants must be respected.

3.4 Any participation in a research project should normally take place in the context of a clear and unambiguous agreement between researcher and participant. In projects which carry some risk for participants, this should normally take the form of written consent by the participant(s), with written information provided giving explicit details of any eventualities that may result from the investigation.

3.5 Participants should in most cases be given clear and unambiguous information relating to the activities in which they will be involved. Failure to fully inform participants of any known relevant factor may make consent invalid.

Researchers should allow sufficient time for participants to reflect on and consider information before they agree to participate in the study.

There may be exceptions to this principle in forms of research that require covert observation to be effective. Examples of such exceptions may include research involving groups with which open research access is particularly difficult or inappropriate to obtain for example illegal activities and research taking the form of general, unobtrusive community observation. In certain cases where prior information may invalidate the research by affecting participants' behaviour, as in certain forms of psychological research, it may be ethical to provide full information to participants following rather than prior to the research.

3.6 Where participants are unable to give informed consent, researchers

should consult a professional body to determine an ethical course of action. Any project involving children or mentally incapacitated persons falls under this category. Specific guidelines in this respect have been developed by a number of professional bodies, including BERA (British Educational Research Association).

3.7 Privacy and confidentiality of participants must be maintained unless there is clear agreement by participants that this is not needed. Full and explicit permission should be obtained to use personal details, images or similar data of participants. Such permission should also be sought for such data to be put into the public domain, for example in an exhibition or recording.

3.8 Any research which takes place in the public domain, or results in outcomes disseminated in the public domain, should respect cultural sensitivities and abide by decency and obscenity laws.

3.9 Researchers are expected to be aware of any legal requirements that may apply to their work. Legal acts that may apply to research projects include, but are not limited to, the Equal Opportunities Act, the Data Protection Act, the Computer Misuse Act, the Race Discrimination Act, the Human Rights Act and the Obscene Publications Act.

3.10 Researchers should respect the rights of individuals to decline participation in a study or to withdraw at any time, without penalty, irrespective of any financial agreement(s) or incentives, and they may require destruction of their personal data.

3.11 Researchers should be aware that coercion might be introduced inadvertently. Such instances could include the recruitment of students known in a professional capacity to academic staff and/or the use of financial inducements, although participants' personal costs for participating in research should normally be reimbursed.

3.12 Researchers have a duty to care for participants and may be held liable where this duty is breached and harm is incurred.

3.13 Researchers should, where possible and appropriate, communicate with participants at the conclusion of a study or following the completion of data collection. This is to provide information, clarify any issues or misconceptions and monitor any unforeseen negative effects requiring intervention.

4. Professional standards

4.1 All researchers should be honest in respect of their actions. Research design, collection and analysis of data, publication of research findings and acknowledgment of the contribution(s) of colleagues, collaborators and affiliated individuals should all be referred to with honesty.

4.2 The University expects researchers to observe openness in their research wherever possible, whilst recognising the requirement to protect aspects of research interests preventing breaches of any copyrights, patents or

confidentiality agreements. The University encourages researchers, wherever appropriate, to discuss their work with other researchers in the field, but also with the general community at large.

4.3 All researchers conducting primary research are advised to adequately document their procedures and findings and to retain their records securely for an appropriate length of time. This will avoid any allegations of misconduct should any aspect of the research findings ever be put into question.

4.4 It is the responsibility of the Principal Investigator(s) to ensure that appropriate direction of research and supervision and support of researchers and research students is provided. Principal investigators carry the primary responsibility for ensuring that research governance principles and contractual obligations are maintained. Supervisors should refer to the university's Code of Practice for Research Supervisors and Students for guidance on good practice in supervision of research students.

4.5 All named researchers on a publication or research output (such as exhibition or performance) should give explicit permission for their authorship. Authors should accept personal responsibility for ensuring they are familiar with their contribution to, as well as entire contents of the output and be able to clearly identify their contribution made if the work is not of their sole authorship.

4.6 All individuals who have contributed to a research work should be clearly and fairly cited in the list of authors. 'Honorary authorship' is unacceptable, especially where an individual has made no contribution to the work. If that individual has contributed informed discussion of the research, due acknowledgement by agreement and with their permission is, however, acceptable and good practice.

5. TVU Code of Practice for Dealing with Allegations of Misconduct in Research 2007/8

5.1 The TVU Code of Practice for Dealing with Allegations of Misconduct in Research 2007/8 is for the benefit of all TVU researchers and their collaborators who are conducting research on university premises or using university facilities in the pursuit of the highest standards of research.

Staff should familiarise themselves with this Code which can be obtained from the Research Office (research@tvu.ac.uk) or the TVU website.

Sources of further guidance

Association of Social Anthropologists-Ethical guidelines ~ interesting discussion on ethics from the ASA's Chair, plus Position Paper, ASA guidelines and other material.
<http://www.theasa.org/ethics.htm>

Ethical Guidelines for Educational Research (2004) from BERA (British Educational Research Association).
<http://www.york.ac.uk/res/ref/kb.htm>

British Sociological Association: Statement of Ethical Practice ~ ethics codes produced by the BSA, March 2002.
<http://www.britisoc.co.uk/equality/63.htm>

British Psychological Society: Code of Conduct ~ Code of Conduct, Ethical Principles & Guidelines, published 2000.
<http://www.bps.org.uk/the-society/ethics-rules-charter-code-of-conduct>

Nuffield Council on Bioethics ~ leading UK body examining bioethics across a range of contemporary issues.
<http://www.nuffieldbioethics.org>

Royal College of Nursing ~ research ethics guidance for nurses involved in research or any investigative project involving human subjects.
<http://www.rcn.org.uk/publications/pdf/researchethics.pdf>

Social Research Association (SRA) Code of Ethics ~ leading UK social research organisation.
<http://www.the-sra.org.uk>

UK Market Research Society: Code of Conduct
<http://www.marketresearch.org.uk>

Appendix 1

Extract from ESRC guidelines 2006 (accessible from www.esrc.ac.uk)

Note: All staff and students at TVU engaged in social science research are strongly recommended to obtain a full copy of the ESRC ethical guidelines for reference and to ensure that their research complied with these.

There are six key principles of ethical research that the ESRC expects to be addressed, whenever applicable:

- Research should be designed, reviewed and undertaken to ensure integrity and quality
- Research staff and subjects must be informed fully about the purpose, methods and intended possible uses of the research, what their participation in the research entails and what risks, if any, are involved. Some variation is allowed in very specific and exceptional research contexts for which detailed guidance is provided in the policy Guidelines
- The confidentiality of information supplied by research subjects and the anonymity of respondents must be respected
- Research participants must participate in a voluntary way, free from any coercion
- Harm to research participants must be avoided
- The independence of research must be clear, and any conflicts of interest or partiality must be explicit

To implement these principles:

- The responsibility for conduct of the research in line with relevant principles rests with the principal investigator.
- The responsibility for ensuring that research is subject to appropriate ethical review, approval and monitoring lies with the institution seeking or holding an award with the ESRC and which employs the researchers performing it, or some of the researchers when it is acting as the co-ordinator for collaborative research involving more than one organisation. Institutions should have clear, transparent, appropriate and effective procedures in place for ethical approval whenever it is necessary.
- Ethical review should always be proportionate to the potential risk, whether this involves primary or secondary data. Whilst the secondary use of some datasets may be relatively uncontroversial, and require only expedited ethical review, novel use of existing data and especially data linkage may, in some contexts, raise ethical issues. Research involving primary data collection will always raise ethical issues that must be addressed.
- Breaches of good ethical practice in ESRC – funded research will be treated as a very serious matter by the Council. They could result in the immediate suspension of the individual project and other projects based at or under the coordination of the contracting institution, and a halt to the consideration of further applications from that institution.

Appendix 2

Rigour, respect and responsibility: A universal ethical code for scientists

This is a public statement of the values and responsibilities of scientists. They are intended to include anyone whose work uses scientific methods, including social, natural, medical and veterinary sciences, engineering and mathematics. It aims to foster ethical research, to encourage active reflection among scientists on the wider implications and impacts of their work, and to support constructive communication between scientists and the public on complex and challenging issues.

Individuals and institutions are encouraged to adopt and promote these guidelines. It is meant to capture a small number of broad principles that are shared across disciplinary and institutional boundaries. They are not intended to replace codes of conduct or ethics relating to specific professions or areas of research.

Rigour, respect and responsibility: A universal ethical code for scientists

Rigour, honesty and integrity

Act with skill and care in all scientific work. Maintain up to date skills and assist their development in others.

Take steps to prevent corrupt practices and professional misconduct.
Declare conflicts of interest.

Be alert to the ways in which research derives from and affects the work of other people, and respect the rights and reputations of others.

Respect for life, the law and the public good

Ensure that your work is lawful and justified.

Minimise and justify any adverse effect your work may have on people, animals and the natural environment.

Responsible communication: listening and informing

Seek to discuss the issues that science raises for society. Listen to the aspirations and concerns of others.

Do not knowingly mislead, or allow others to be misled, about scientific matters. Present and review scientific evidence, theory or interpretation honestly and accurately.

Commentary

There are already powerful incentives for individuals and for institutions to

adhere to the principles set out in these guidelines. These include: the high professional and ethical standards upheld by the scientific community; structures put in place by employers, professional bodies and funders to enforce these standards; and national and international conventions, treaties and laws.

Scientists and institutions are encouraged to reflect on and debate how these guidelines may relate to their own work. For example, acting with rigour, honesty and integrity may include: not committing plagiarism or condoning acts of plagiarism by others; ensuring that work is peer reviewed before it is disseminated; reviewing the work of others fairly; ensuring that primary data that may be needed to allow others to audit, repeat or build on work, are secured and stored. Similarly, in communicating responsibly, scientists need to make clear the assumptions, qualifications or caveats underpinning their arguments.



National Patient Safety Agency

National Research Ethics Service

Useful references

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www.nres.npsa.nhs.uk

Defining
research

Issue 3

Patients expect healthcare professionals to undertake audit and service evaluation as part of quality assurance. These have no, or less than minimal, risk that can also be regulated in ways other than Research Ethics Committee (REC) review.

Research may carry greater risk to good clinical practice and it may generate conflicts of interest for the healthcare professional.

Hence our different approach to the review. Audit and service evaluation do not warrant mandated REC review. Research does.

The table in this leaflet differentiates research, audit and service evaluation, but we recognise that judgement, on occasions, will be needed.

If required, the National Research Ethics Service (NRES) can provide further help: queries@nationalres.org.uk

To help, key discriminants are:

1 INTENT

The primary aim of research is to derive new knowledge; audit and service evaluation measure level of care. Research is to find out what we should be doing; audit is to find out if we are doing.

Nevertheless, a project may have more than one intent; in such a case, a judgement is needed as to what the primary aim is.

2 TREATMENT

Neither audit nor service evaluation uses a treatment without a firm basis of support in the clinical community.

3 ALLOCATION

Neither audit nor service evaluation allocate treatment by protocol. It is by decision of clinician and patient.

4 RANDOMISATION

If randomisation is used, it is research.

Differentiating audit, service evaluation and research

Research	Clinical audit	Service evaluation
The attempt to derive generalisable new knowledge, including studies that aim to generate hypotheses, as well as studies that aim to test them.	Designed and conducted to produce information to inform delivery of best care.	Designed and conducted solely to define or judge current care.
Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology.	Designed to answer the question: "Does this service reach a predetermined standard?"	Designed to answer the question: "What standard does this service achieve?"
Addresses clearly defined questions, aims and objectives.	Measures against a standard.	Measures current service without reference to a standard.
Quantitative research – may involve evaluating or comparing interventions, particularly new ones. Qualitative research – usually involves studying how interventions and relationships are experienced.	Involves an intervention in use ONLY (the choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference).	Involves an intervention in use ONLY (the choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference).
Usually involves collecting data that are additional to those for routine care, but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.	Usually involves analysis of existing data, but may include administration of simple interview or questionnaire.	Usually involves analysis of existing data, but may include administration of simple interview or questionnaire.
Quantitative research – study design may involve allocating patients to intervention groups. Qualitative research uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications.	No allocation to intervention groups: the healthcare professional and patient have chosen intervention before clinical audit.	No allocation to intervention groups: the healthcare professional and patient have chosen intervention before service evaluation.
May involve randomisation.	No randomisation.	No randomisation.
ALTHOUGH ANY OF THESE THREE MAY RAISE ETHICAL ISSUES, UNDER CURRENT GUIDANCE:-		
RESEARCH REQUIRES REC REVIEW	AUDIT DOES NOT REQUIRE REC REVIEW	SERVICE EVALUATION DOES NOT REQUIRE REC REVIEW