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
2014

Contents

1. Introduction
2. Guiding principles
3. Basic principles
4. Professional standards
5. The University of West London Code of Practice for Dealing with Allegations of Misconduct in Research 2014

Sources of further guidance

Appendix 1: Extract from ESRC guidelines (accessible from www.esrc.ac.uk)

Appendix 2: Universal Ethical Code for Scientists

Appendix 3: NHS Health Research Authority: Defining Research
**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”.


We also understand research in terms of the straightforward definition developed for the Research Excellence Framework (REF) 2014:

“For the purposes of the REF, research is defined as a process of investigation leading to new insights, effectively shared.”

2. Guiding principles

The University of West London’s Code of Research Practice was 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 the 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).

### 3. Basic Principles

i. 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 parties involved.

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

iii. Explicit permission is given by participants demonstrating that they understand and accept the possibility of their person or interests being harmed;

iv. 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;

v. research must respect the autonomy, privacy and dignity of research participants;

vi. 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;

vii. 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;

viii. Any participation in a research project should normally take place in the context of a clear and unambiguous agreement between researcher(s) and participant(s). 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 risks;

ix. 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.

x. Researchers should allow sufficient time for participants to reflect on and consider information before they agree to participate in the study and any eventualities that may result from the investigation.
There may be exceptions to this principle in forms of research that requires 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, research on 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.

- Where participants are unable to give informed consent, the researcher 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).

- 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.

- Any research that 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.

- 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.

- 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.

- 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.

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

- 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

i. 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.

ii. The University expects researchers to observe openness in their research wherever possible, whilst recognising the requirement to protect aspects of research 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.

iii. All researchers conducting primary research are required to adequately document their procedures, data, and findings and to retain their records securely for at least five years from the date of any publication arising from the research. Data and records should be accurate, complete and in sufficient detail to enable verification of research results and to reflect what was communicated, decided or done. This will avoid any allegations of misconduct should any aspect of the research findings ever be put into question.

iv. 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.

v. **Authorship.** For a person to be recorded as an author of a publication requires that s/he is directly involved in the publication by –

- Conceiving it, analyzing and interpreting the data on which it is based;
- Writing or revising the intellectual content; and
- Giving final approval of the version to be published.

vi. 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 the entire contents of the output and be able to clearly identify their contribution made if the work is not of their sole authorship.

vii. All individuals who have contributed to a research work should be clearly and fairly cited in the list of authors. The right to authorship is not tied to position or profession; ghost, gift, or honorary authorship is unacceptable. Authorship should honestly reflect the contribution to
the work being published. Participation solely in the acquisition of funding or the collection of data is not sufficient for a person to be attributed as an author of a publication.

• No person who is an author, consistent with the definition above, may be excluded as an author without their permission in writing.

5. The University of West London Code of Practice for Dealing with Allegations of Misconduct in Research 2007/8

• The University of West London Code of Practice for Dealing with Allegations of Misconduct in Research 2007/8 is for the benefit of all the University’s 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@uwl.ac.uk).
Sources of further guidance

1. 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.shtml


   http://www.britisoc.co.uk/about/equality/statement-of-ethical-practice.aspx


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

6. Royal College of Nursing ~ research ethics guidance for nurses involved in research or any investigative project involving human subjects 2011.


Appendix 1

Extract from ESRC guidelines (updated 2015 accessible from www.esrc.ac.uk)

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

i. There are six key principles of ethical research that we expect to be addressed:

- Research participants should take part voluntarily, free from any coercion or undue influence, and their rights, dignity and (when possible) autonomy should be respected and appropriately protected.

- Research should be worthwhile and provide value that outweighs any risk or harm.

- Researchers should aim to maximise the benefit of the research and minimise potential risk of harm to participants and researchers. All potential risk and harm should be mitigated by robust precautions.

- Research staff and participants should be given appropriate information about the purpose, methods and intended uses of the research, what their participation in the research entails and what risks and benefits, if any, are involved.

- Individual research participant and group preferences regarding anonymity should be respected and participant requirements concerning the confidential nature of information and personal data should be respected.

- Research should be designed, reviewed and undertaken to ensure recognised standards of integrity are met, and quality and transparency are assured.

- The independence of research should be clear, and any conflicts of interest or partiality should be explicit.

ii. To implement these principles:

- Responsibility for the conduct of ESRC-funded research by all staff, in line with relevant ethics principles, rests with the principal investigator and the administering RO. However all researchers are expected to take personal responsibility for undertaking research to the highest ethical standards.

- Responsibility for determining the appropriate ethics review required lies with the principal investigator and the research team. Ensuring that
research is subject to appropriate ethics review and monitoring lies with the RO seeking or administering an ESRC grant. A single review process should be agreed in collaborative research involving more than one organisation or multi-discipline research. The applicant should ensure that participating organisations and collaborative researchers are satisfied that the research proposal has received adequate ethics review, and that regular monitoring of the conduct of the research takes place and is promptly reported to all organisations or multi-discipline researchers involved.

- ROs should have clear, transparent and effective procedures for ethics review and governance and appropriate mechanisms for monitoring.

- Research should be designed in such a way that the dignity and (when possible) the autonomy of research participants is respected and appropriately protected.

- Ethics review should always be proportionate to the potential risk. Where possible, risks should be minimised; for example, whether the research involves primary data collection or the re-use of existing data.

- Research involving primary data collection will always raise issues of ethics that must be addressed. Whilst the re-use of some datasets may be relatively uncontroversial and require only light-touch ethics review, novel use of existing data and especially data linkage, as well as some uses of administrative, internet-mediated data and controlled data, will raise ethics issues.

iii. Breach of compliance with the ESRC Framework of Research Ethics and RCUK Policy and Guidelines on Governance of Good Research Conduct (http://www.rcuk.ac.uk/publications/researchers/grc/) in ESRC-funded research will be treated as a serious matter. Where this occurs, the RO, principal investigator and researchers will be called to account by the ESRC and sanctions may apply depending on the severity of the breach. These could result in the immediate suspension of the individual project and other projects based at or under the co-ordination of the administering RO and a halt to the consideration of further proposal submissions from that RO.
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.
Appendix 3: NHS Health Research Authority: Defining Research

This is an extract from guidance taken from the NHS Health Research Authority: http://www.hra.nhs.uk/documents/2013/09/defining-research.pdf. The purpose of the guidance is to help you decide if a project is research, which will normally require review by a Research Ethics Committee (REC), or whether it is some other activity such as audit, service evaluation or public health surveillance.

National Research Ethics Service

The National Research Ethics Service (NRES) reviews research proposals to protect the rights and safety of research participants and enables ethical research which is of potential benefit to science and society.

Defining research – guidance from NRES

Patients expect health professionals to undertake audit and service evaluation as part of quality assurance. These involve minimal additional risk, burden or intrusion for participants, and are regulated outside of NRES.

Research may involve greater risk, burden or intrusion for participants than standard clinical practice. It may generate conflicts of interest for the researcher, which will require review by an ethics committee. With some exceptions, research requires review by a REC.

The table in this leaflet helps to confirm if your activity is research, audit, service evaluation or public health surveillance.

When is an NHS REC review required?

Review by an NHS REC is required for research within the scope of the UK Health Departments’ Governance Arrangements for Research Ethics Committees.

In addition, some legislation, such as the Clinical Trials Regulations, Human Tissue Act and Mental Capacity Act, requires ethical approval from an appropriately recognised REC whether or not the research takes place within the NHS.

Guidance on whether research requires ethical review under either the law or the policy of the UK Health Departments’ can be found on the NRES website at www.nres.nhs.uk/applications/.

If your project will be taking place within the NHS, your local research and development (R&D) office will be able to advise on whether the project is research and requires management within the Research Governance Framework for Health and Social Care. They will also confirm if ethical review by a REC is required, and advise on local governance procedures for other types of project such as audit or service evaluation.
If you remain uncertain after reading this leaflet, you should approach your R&D office for advice in the first instance. If further clarification is then required, the R&D office can obtain this from the chair of a REC or the NRES queries line nres.queries@nhs.net.

**Key discriminants are:**

1. **Intent**

The primary aim of research is to derive generalizable new knowledge, whereas the aim of audit and service evaluation projects is to measure standards of care. Research is to find out what you should be doing; audit is to find out if you are doing planned activity and assesses whether it is working.

Some projects may have more than one intent, in which case a judgement will need to be made on the primary aim of the project.

2. **Treatment/service**

Neither audit nor service evaluation uses an intervention without a firm basis of support in the clinical or health community.

3. **Allocation**

Neither audit nor service evaluation allocate treatment or service by protocol. It is a joint decision by the clinician and patient.

4. **Randomisation**

If randomisation is used, it is research.
Differentiating clinical audit, service evaluation, research and usual practice/surveillance work in public health

<table>
<thead>
<tr>
<th><strong>RESEARCH</strong></th>
<th><strong>SERVICE EVALUATION</strong></th>
<th><strong>CLINICAL AUDIT</strong></th>
<th><strong>SURVEILLANCE</strong></th>
<th><strong>USUAL PRACTICE (in public health)</strong></th>
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<tbody>
<tr>
<td>The attempt to derive generalizable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.</td>
<td>Designed and conducted solely to define or judge current care.</td>
<td>Designed and conducted to produce information to inform delivery of best care.</td>
<td>Designed to manage outbreak and help the public by identifying and understanding risks associated.</td>
<td>Designed to investigate outbreak or incident to help in disease control and prevention.</td>
</tr>
<tr>
<td>Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology.</td>
<td>Designed to answer: “What standard does this service achieve?”</td>
<td>Designed to answer: “Does this service reach a predetermined standard?”</td>
<td>Designed to answer: “What is the cause of this outbreak?”</td>
<td>Designed to answer: “What is the cause of this outbreak?” and treat.</td>
</tr>
<tr>
<td>Addresses clearly defined questions, aims and objectives.</td>
<td>Measures current service without reference to a standard.</td>
<td>Measures against a standard.</td>
<td>Systematic, statistical methods to allow timely public health action.</td>
<td>Systematic, statistical methods may be used.</td>
</tr>
<tr>
<td>Quantitative research – may involve evaluating or comparing interventions, particularly new ones. Qualitative research – usually involves studying how interventions and relationships are experienced.</td>
<td>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.</td>
<td>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.</td>
<td>May involve collecting personal data and samples with the intent to manage the incident.</td>
<td>Any choice of treatment is based on clinical best evidence or professional consensus.</td>
</tr>
<tr>
<td>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.</td>
<td>Usually involves analysis of existing data but may include administration of interview or questionnaire.</td>
<td>Usually involves analysis of existing data but may include administration of simple interview or questionnaire.</td>
<td>May involve analysis of existing data or administration of interview or questionnaire to those exposed.</td>
<td>May involve administration of interview or questionnaire to those exposed.</td>
</tr>
<tr>
<td>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.</td>
<td>No allocation to intervention: the health professional and patient have chosen intervention before service evaluation.</td>
<td>No allocation to intervention: the health professional and patient have chosen intervention before audit.</td>
<td>Does not involve an intervention.</td>
<td>May involve allocation to control group to assess risk and identify source of incident but treatment unaffected.</td>
</tr>
<tr>
<td>Normally requires REC review.</td>
<td>Does not require REC review.</td>
<td>Does not require REC review.</td>
<td>Does not require REC review.</td>
<td>Does not require REC review.</td>
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*Service development and quality improvement may fall into this category.*