Research Office

Research Ethics
Governance Policy
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2016

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Research Governance

1. Introduction:

Research Governance ensures that all research activity within the University of West London meets the highest attainable standards of practice and procedure. Such standards conform to principles laid down by:

- Disciplinary bodies;
- International frameworks of law and human rights;
- Protocols of Government agencies and Research Councils
- Other statutory requirements.

Institutions in receipt of funding from the Research Councils or Government agencies are specifically required to maintain and ensure:

- clear Research Governance policies;
- procedures ensuring ethical conduct of all research.

This Research Ethics Governance Policy has been developed to serve the interests of all academic members of staff and all students at the University. Its objectives are:

- to ensure that all research activities are performed to the highest standards, and
- to establish the University of West London as a centre of excellence within the HE sector of the UK.

For these purposes, Research may be defined as the attempt to engender and further new knowledge through academic investigation, be it creative/practice-based, critical/analytical, empirical/statistical, theoretical or of any other appropriate nature. Such activity will address clearly defined questions through a systematic, articulate and rigorous methodology. This requirement is fundamental to the ethos and practice of the University of West London and of any other University.

Through its research activity, the University seeks to promote:

- Generation, advancement, preservation and dissemination of knowledge;
- the highest the attainable quality in the education of undergraduate and graduate students, and of postdoctoral fellows;
- advancement of the public interest.
This document describes the University’s Research Ethics Governance Policy and procedures. It should be read in conjunction with the Research Ethics Code of Practice, by which all research activity within the University is guided.

2. Definition of Research to which this Policy should apply:

The University's Policies and its Code of Practice acknowledge specifically the definition of research laid down by the Higher Education Funding Council of England [HEFCE]:

“…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 recognise the straightforward definition of research 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”.

Members of academic staff at the University of West London are expected to refer to these definitions when determining whether – for ethical and governance-related purposes - a project should be defined as Research. In some cases the work will conform neither to the HEFCE or REF research definition above nor to the ethical spectrum addressed by this document. Examples include:

- undergraduate research projects when they do not involve human participants or the use of personal data;
- certain postgraduate projects, such as literature reviews.

The University’s procedures for ethical approval apply to every aspect of human participation in research, whether direct or indirect or where the researcher or others may be exposed to harm. They do not replace procedures and advice relating to:

- Health and Safety;
- Insurance cover;
- Contract authorisation by Government, funding bodies and the University’s associated establishments;
- Wider legal frameworks.
Research collaborations and sources of funding may raise ethical concerns regardless of whether or not the research in question involves human subjects. Therefore all researchers should refer as a matter of course to this Research Ethics Governance Policy and to the University’s Research Ethics Code of Practice.

In addition to internal ethical endorsement by the University, ethical approval for any research proposal must always be obtained from the relevant quarter if any collaborating institution requires such approval.

In addition, external ethical clearances are essential wherever there is an intention to conduct random controlled clinical trials, or a need for access to patients’ medical records.

The University currently has no direct research interests involving animals on any of its premises. In the event that such a research activity were encouraged within the University research portfolio, Governance for such research would be maintained and monitored by the law, and also by the Home Office, under the Animals Scientific Procedures Act (1986).

3. Policy

The University attaches crucial importance to supporting, promoting and developing research that aspires to the highest standards of ethical and academic conduct. The University of West London acknowledges its responsibility to ensure an environment in which all research meets such standards.

Ethical policies and procedures are vital for the following purposes:

- To safeguard, promote and enhance the quality of research;
- To protect the rights and wellbeing of research participants or subjects;
- To protect the right of academic researchers to carry out legitimate investigation and to ensure their wellbeing when conducting research;
- To uphold, safeguard and enhance the reputation of the University for the research which it conducts and sponsors;
- To guarantee appropriate indemnity, keeping to an absolute minimum the incidence of claims for negligence and/or misconduct against University staff members and students or against their external collaborators in research.
4. Procedures for Ethical Approval of Research Activity:

4.1. School Research Ethics Panels, and The University Research + Ethics Committee:

Overall responsibility for the University’s research policy and conduct rests with the University Research, Scholarship and Enterprise Committee (URSEC). This functions as a sub-committee of the University’s Academic Board. In each School, a School Research Ethics Panel (SREP) oversees Research Ethics. Each of these has representation at, and reports to, the central University Research Ethics Committee (UREC) that, in turn, reports to the University Research, Scholarship and Enterprise Committee.

Responsibility for ethical scrutiny and clearance of research is delegated to the SREPs, which scrutinise proposals at their regular meetings.

Details of how research projects are addressed may be read below. In all cases staff and students should complete the online Research Ethics Risk Assessment Form at https://uwloffice365live.sharepoint.com/Pages/Research.aspx for consideration by their SREP. Those unsure how the procedures may apply to their project should contact the Secretary to their SREP.

Staff members and students should remain aware of the necessity to allow time in their project planning for submission of a proposal to ethical review. They should contact the Secretary to their SREP for information on forthcoming meeting dates and deadlines, and should take account of the possibility that formal queries may be raised by the SREP following an initial application.

SREPs will record all decisions made in respect of ethical review, reporting those data to UREC to allow for consideration of a ‘whole University’ picture.

4.2. Types of Project:

All research proposals – whether for a Student or Staff project - are assigned to one of two categories for purposes of ethical approval. This classification takes place at School level. This classification is determined by the nature of the research, not the level of study at which the research is conducted. Those unsure which category applies to their (or their student’s) project should contact the Secretary to the relevant SREP or the University Research Office for advice.

Student Research Projects:

Explicit and relevant advice on ethical considerations will be provided for students in all applicable Module Study Guides and Course handbooks. Where relevant (for example, in postgraduate research-based dissertations), ethical research conduct should be embedded within the Learning Outcomes and Marking Criteria for research projects. A student’s research supervisor or
tutor should advise on the procedure for ethical clearance for the project, and monitor adherence to ethical standards as the project is being carried out.

**Category 1: Work that has minimal ethical implications (i.e. work that does not involve participants or the use of data/materials that are not already in the public domain or that does not have potential for harm to the researcher)**

This includes literature-based work, secondary analysis of data in the public domain, creation of artefacts, experimental laboratory-based work not involving human tissues and other forms of creative/artistic activity.

Such work requires only that the researcher(s) complete the Research Ethics Risk Assessment Form to indicate that this is the case and in order that the University can maintain a record of all research conducted. However, it should be noted that the usual University policies and over-reaching legal frameworks apply to all research. These include Health & Safety, Data Protection, Intellectual Property and Copyright Law.

**Category 2: Work that has ethical implications and must be considered by the relevant SREP:**

This embraces all projects directly involving human participants (including human tissues) and those projects where the researcher may be exposed to harm.

The category includes all projects being planned or conducted by students, as well as any projects by members of staff, which directly involve the University's students, and/or staff as participants; or any human participant outside of the University. It also includes projects where security sensitive material may be accessed by the researcher, including materials that may be otherwise prohibited or access to people or places where there is potential for harm.

SREPs will consider all applications based on their completion, in full, of the Research Ethics Risk Assessment Form.

Staff and students conducting research in certain discipline areas are formally required to obtain clearance from an external ethical committee (for example, The Law Society or NHS Research Ethics Committee.). In the case of students, external application to such professional bodies should proceed only once the relevant SREP has given them permission to proceed. Where projects are sponsored by external sponsors, researchers should ensure that their signature is obtained following ethics approval, and returned to the Research Office.

The main category of research currently requiring external approval is that involving NHS and Social Care work, and the current relevant guidance on categories requiring application, and the procedures, should be followed.
4.3. Procedure for ‘High-Risk’ Projects:

Work in either category 1 or 2 above but which also carries particular risks may require clearance by the University Directorate/Finance Office – please see Appendix 3 for further information.

5. University Research and Enterprise Operations Unit

The University Research Office forms part of the Research and Enterprise Operations unit. Its objective is to support funded research activity. It can provide advice and signposting on policies and procedures, insurance, indemnity cover, contract advice, legal advice, etc., as needed. In all cases where there is a lack of clarity regarding interpretation of policies, procedures and codes of practice, researchers should contact the Research Office for advice.

All University research projects should be logged with the Research Office and basic details of the project provided for the University’s research database.

6. Related policies

This policy document should be used with reference to the following University policies and statements:

i. Intellectual Property Policy (under review)
ii. Data Protection Policy
iii. Health and Safety Policy
iv. Equality and Diversity Statement
v. Statement on Corporate Social Responsibility

Researchers should also refer to and be guided by:

- The University’s Research Ethics Code of Practice;
- codes of practice laid down within the applicable discipline, profession or subject area;
- all relevant external legislation

7. Guidance for academic staff supervising student research

Members of academic staff are not responsible for the conduct and activities of students undertaking their own research. However, they do have a
responsibility to provide appropriate advice and guidance, to highlight the need
for students to read and follow relevant policies and codes of conduct, and to
monitor the conduct of the research.

Written guidance to students on research assignments, proposals and
dissertations should explicitly mention ethical conduct of research, as
applicable to the subject or discipline. Students should demonstrate in their
written assignments how they have attempted to anticipate and address
research ethics appropriate to their discipline, and thereby to ensure proper
ethical conduct in any projects they undertake.

8. Contacts and further information

1) Research and Enterprise Operations
PE.GF.007
University of West London
St. Mary’s Road
London W5 5AF

You can contact Research and Enterprise Operations staff by email:
research@uwl.ac.uk

Or by telephone: 020 8231 2255

2) NHS Health Research Authority

The HRA was established in December 2011 to protect and promote the
interests of patients and the public in health research, and to streamline the
regulation of research.

See more at: http://www.hra.nhs.uk/

Appendix 1: ESRC Ethical Guidelines 2015 (accessible from
www.esrc.ac.uk)

http://www.esrc.ac.uk/files/funding/guidance-for-applicants/esrc-framework-for-
research-ethics-2015/

Appendix 2: Extract from the Joint Research Councils Terms and
Conditions of Research Council Grants

GC 2 Research Governance

It is the responsibility of the Research Organisation to ensure that the research is
organised and undertaken within a framework of best practice that recognises
the various factors that may influence or impact on a research project. Particular
requirements are to ensure that all necessary permissions are obtained before
the research begins, and that there is clarity of role and responsibility among the
research team and with any collaborators. The Research Councils expect research to be conducted in accordance with the highest standards of research integrity and research methodology.

**Research Ethics**

The Research Organisation is responsible for ensuring that ethical issues relating to the research project are identified and brought to the attention of the relevant approval or regulatory body. Approval to undertake the research must be granted before any work requiring approval begins. Ethical issues should be interpreted broadly and may encompass, among other things, relevant codes of practice, the involvement of human participants, tissue or data in research, the use of animals, research that may result in damage to the environment and the use of sensitive economic, social or personal data.

**Use of Animals in Research**

Wherever possible, researchers must adopt procedures and techniques that avoid the use of animals. Where this is not possible, the research should be designed so that:

- The least sentient species with the appropriate physiology is used.
- The number of animals used is the minimum sufficient to provide adequate statistical power to answer the questions posed.
- The severity of procedures performed on animals is kept to a minimum. Experiments should be kept as short as possible. Appropriate anesthesia, analgesia and humane end points should be used to minimise any pain and suffering.

The provisions of the Animals (Scientific Procedures) Act 1986, and any amendments, must be observed and all necessary licences must have been received before any work requiring approval takes place.

**Medical and Health Research**

The Research Organisation is responsible for managing and monitoring the conduct of medical and health research in a manner consistent with the Department of Health’s Research Governance Framework for Health and Social Care (or equivalent). There must be effective and verifiable systems in place for managing research quality, progress and the safety and well-being of patients and other research participants. These systems must promote and maintain the relevant codes of practice and all relevant statutory review, authorisation and reporting requirements.

Research involving human participants or data within the social sciences that falls outside the Department of Health’s Research Governance Framework must meet the provisions and guidelines of the ESRC’s Research Ethics Framework. While this research may involve patients, NHS staff or organisations, it is defined as research that poses no clinical risk or harm to those who are the subjects of research. Research Organisations must ensure that appropriate arrangements are in place for independent ethics review of social science research that meets local research ethics committee standards.
Significant developments must be assessed as the research proceeds, especially those that affect safety and well-being, which should be reported to the appropriate authorities and to the Research Council. The Research Organisation must take appropriate and timely action when significant problems are identified. This may include temporarily suspending or terminating the research.

The Research Organisation is responsible for managing and monitoring statutory requirements for which it accepts responsibility, for example, in relation to legislation on clinical trials, use of human organs, tissues and data.

Guidance by the MRC on the conduct of medical research, and by ESRC on the conduct of social science research, provided on behalf of all Research Councils, must be observed.

**Health and Safety**

The Research Organisation is responsible for ensuring that a safe working environment is provided for all individuals associated with a research project. Its approach and policy on health and safety matters must meet all regulatory and legislative requirements and be consistent with best practice recommended by the Health & Safety Executive.

Appropriate care must be taken where researchers are working off-site. The Research Organisation must satisfy itself that all reasonable health and safety factors are addressed.

The Research Councils reserve the right to require the Research Organisation to undertake a safety risk assessment in individual cases where health and safety is an issue, and to monitor and audit the actual arrangements made.

**Misconduct and Conflicts of Interest**

The Research Organisation is required to have in place procedures for governing good research practice, and for investigating and reporting unacceptable research conduct, that meet the requirements set out in the Concordat to Support Research Integrity (2012) and the Research Councils’ Code of Conduct and Policy on the Governance of Good Research Conduct (2009) and any subsequent amendments. The Research Organisation must on request provide information on its management of research integrity and ethics in response to the Research Councils’ assurance questions, as described at: [http://www.rcuk.ac.uk/funding/researchintegrity/](http://www.rcuk.ac.uk/funding/researchintegrity/)

The Research Organisation must ensure that potential conflicts of interest in research are declared and subsequently managed.

**Appendix 3: ‘High-Risk’ Projects**

Work in either of the 2 categories of research project explained in the Research Ethics Governance Policy (section 4.2.) which also carries particular risks, may
require clearance by the University Directorate/Finance Office. In addition to “high-risk” human participation in research projects, other high-risk attributes may include:

1. Projects entailing complex collaborative and contractual arrangements with external partners;
2. Work with external partners or organisations that may give rise to particular concerns;
3. High-risk clinical trials and other experimental research which may carry hazards warranting additional insurance provision or legal/contractual advice;
4. Research which may require access to security sensitive material and as such is subject to the University’s Prevent Duty (see http://www.universitiesuk.ac.uk/policy-and-analysis/reports/Documents/2012/oversight-of-security-sensitive-research-material.pdf)
5. Any other forms of risk which are by their nature not covered by the usual ethical clearance procedures.

Completion of the online Research Ethics Risk Assessment Form accessed at https://uwloffice365live.sharepoint.com/Pages/Research.aspx will help to identify if the project is considered high-risk.