

University of Westminster
Code of Practice Governing the Ethical Conduct of
Research 2011/12

This Code should be read in conjunction with the *Code of Research Good Practice*. Research degree students and their supervisors should also refer to the *Handbook of Regulations and Codes for Research Degree Programmes*.

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1. Guiding Principles

- 1.1 The University is guided by the fundamental principle that research involving humans and/or animals and/or the environment should involve no more than minimal risk to physical or psychological well-being.
- 1.2 The University is concerned to protect the rights, dignity, health, safety and privacy of research participants, the welfare of animals and the integrity of the environment. The University is also concerned to protect the health, safety, rights and academic freedom of researchers and the reputation of the University as a centre for properly conducted, high quality research. This document is written to promote those ends, and to comply with the requirements of external research funding bodies and collaborating organisations.
- 1.3 All research falling within the definition in paragraph 2.1 below, is subject to this Code of Practice Governing the Ethical Conduct of Research (hereafter referred to as the Code) and should take into consideration relevant national codes of practice and/or external guidelines for ethics in research applicable to the discipline and the subject area.
- 1.4 Consideration of ethical implications is required for all such research, prior to commencement, in line with University procedures.
- 1.5 Where codes of professional ethics apply, Schools should decide how these are incorporated in considerations of research ethics. University staff and students are expected to refer to relevant professional codes of practice and comply with them.
- 1.6 The Code ensures that research ethics policy and practice is not in conflict with teaching and learning policy on student-centred learning and with the integration of teaching and research in the University.
- 1.7 Normally, pedagogic research projects conducted for purposes of enhancement of teaching quality and consistent with the normal professional relationship between tutor and student do not need to apply for research ethics approval if there is no likelihood of harm. It may be necessary to consider ethical implications where the researcher is uncertain whether their work is pedagogic or falls outside the normal original agreement between the student and teacher/institution.
- 1.8 Examples of pedagogic research include: data originally obtained to offer advice to students or to diagnose appropriate interventions as well as data originally obtained to develop teaching and learning skills through what are considered standard practices within the profession, such as observation, assessment, intervention, evaluation and monitoring. This could include study of the staff and student experience, curriculum content, teaching and learning methods, learning resources, course management, and teaching and learning facilities.

1.9 Relevant Data Protection legislation and University guidance in data security must be observed in the collection, use, storage, back-up and eventual destruction of all data. (See Addendum C).

2. Definition and Classification of Research

2.1 Research is defined as investigations undertaken in order to gain knowledge and understanding, and to contribute to a body of knowledge. It includes work of direct relevance to the needs of commerce, industry and to the public and voluntary sectors; the invention and generation of ideas; images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction.

2.2 **Class 1** research encompasses research which falls within the definition of this Code and which, after consideration has been found to have no or minimal ethical implications. Ethics approval is not required.

2.3 **Class 2** encompasses research which falls within the definition of this Code, has clear ethical implications and which may cause, or has the potential to cause, harm in any form to participants, investigator, animals or to the environment. Class 2 research must receive approval from a Research Ethics Committee, either at Departmental, School or University level.

2.3.1 Examples of Class 2 include any research which involves:

- children (participants who are under 18 years of age)
- patients
- participants to reveal their medical history
- the collection and use of any material containing human cells from participants
- the administering of drugs, non-food substances, or clinical intervention
- deception of participants
- the procurement of data not already in the public domain that bears on issues of criminality
- vulnerable participants; for example persons sectioned under the Mental Health Act, prisoners or arrestees, or ex-offenders with unspent convictions, persons with mental illness, persons with learning difficulties or brain damage, persons with a reduced level of consciousness, or unconscious, due to trauma or other agents, and persons in vulnerable social and economic situations
- the internet for the procurement of sensitive data
- invasion of privacy, harm to reputation, or adverse representation of individuals or classes of people and social groups
- personal or sensitive data

- 2.3.2 These examples are not exhaustive and advice can be sought from a research ethics adviser in the School, or from the Secretary to the Research Ethics Sub-Committee.
- 2.4 **Class 3** encompasses research for which ethics approval from an external body may be required (**3A**), or where the University is required by an external body to confirm research ethics approval (**3B**).
- 2.4.1 Examples of Class 3A include all research involving NHS patients or NHS data which may require prior NHS Research Ethics Committee consideration, review or approval and an application should be sent directly to the relevant NHS Research Ethics Committee for this purpose. A copy of any approval letter should be lodged with the Research Ethics Sub-Committee.
- 2.4.2 An example of Class 3B is where Research Councils or other external funding bodies for research require evidence of research ethics consideration and approval by the University, to be carried out in line with current practice.

3. Responsibilities

- 3.1 Although the responsibility for ethics considerations in research lies with the individual researcher, the onus is on the University to provide transparent procedures for approval and scrutiny to ensure that checks and balances are in place so that research conducted by staff, and research with which it is associated in any way, adheres to acceptable ethical standards.
- 3.2 The Code requires Schools and Centres to demonstrate that they have given consideration to ethical implications of research, to approval processes and to implementation of the Code in the relevant discipline(s).
- 3.3 Deans of School and Heads of Department hold management responsibility for notification to all staff of their individual responsibilities under this Code, and for ensuring that all research with ethical implications undertaken in their School or Department complies with the Code.
- 3.4 A named individual/research ethics co-ordinator is to be designated to take responsibility for all aspects of research ethics within the School or Centre, to include knowledge of relevant ethics codes of practice for research, and to record research ethics applications for annual audit and monitoring.
- 3.5 Where undergraduate or postgraduate students are undertaking research as part of the learning activities of a taught course, they shall be under the active responsible supervision of a member of staff known as the 'supervisor' who will ensure that they comply with this Code.
- 3.6 All research whether undertaken by a group or by individuals must have a Principal Investigator who shall take responsibility for compliance with this Code.

- 3.7 Supervisors are in the first instance responsible for the classification of undergraduate and postgraduate student research. Where it is not clear which class the proposed research falls into, advice should be sought from a designated named individual/research ethics co-ordinator, or from the Secretary to the Research Ethics Sub-Committee.
- 3.8 Individual staff members and students are required to comply with this Code.
- 3.9 For cross-school projects, or where there is collaboration with an external organisation, responsibility shall lie with one named Principal Investigator.
- 3.10 The Research Ethics Sub-Committee will seek expert guidance or advice as required through the co-opted membership policy; any external advisor will abide by the Committee's confidentiality requirements.
- 3.11 The Research Ethics Sub-Committee shall report to the University Ethics, Corporate and Social Responsibility Committee (ECSRC).

4. Research ethics approval process

- 4.1 The process of consideration of ethical implications may involve the operation of a School or Departmental Research Ethics Committee.
- 4.2 Guidance and relevant pro formas on how to apply for research ethics approval, together with a copy of the *Code of Practice* and *Guidelines for Completion of the Form* will be available via the University intranet/internet.
- 4.3 Following NHS Research Ethics Committee or other external approval (if such is granted) a copy of the original application form and an Approval Letter should be sent to the Secretary of Research Ethics Sub-Committee.
- 4.4 Generic approval may be granted by the Research Ethics Sub-Committee for research which is conducted on a regular basis either as part of an ongoing research project, or as part of module delivery within a course, and which does not vary substantially from an approved protocol.
- 4.5 Where generic approval is granted, it will be granted until such time when a relevant programme of study, protocol or legal requirement is due for review. It will be the Principal Investigator's and/or Head of Department's responsibility to inform the Research Ethics Sub-Committee of any such changes.

5. Procedure

- 5.1 The University aims to promote good academic practice in research by asking individual researchers to complete and retain an initial assessment document to demonstrate that ethical implications have been considered. Where there are ethical implications, an Ethics Approval form must be completed and submitted to the appropriate Research Ethics Committee.
- 5.2 All research students must complete an Application to Register and research proposals should be scrutinised and signed off by a supervisor, the School

Research Director and Dean. This provides evidence that ethical implications have been considered and emphasises research ethics consideration as good academic practice.

- 5.3 Ethics implications should be considered at the design phase of all undergraduate student research project preparations when proposals are scrutinised by a supervisor. This is where an assessment form could be introduced at School level, to record research projects and to be used for monitoring and audit as required.
- 5.4 Applications for research ethics approval are dealt with at respectively Departmental, School, or University level (Research Ethics Sub-Committee).
- 5.5 All applications for research ethics approval to the Research Ethics Sub-Committee should be submitted using the research ethics approval application forms available via the University intranet/internet.
- 5.6 Applications must be prepared in accordance with the format approved by the Research Ethics Sub-Committee. Applications from students must be checked and signed by the supervisor. Staff applications must be signed by the Dean of School, or School Research Director or their nominee, as appropriate.
- 5.7 Ethical approval shall be obtained before the commencement of any research which has ethical implications. A Research Ethics Committee may allow part of the research to commence, prior to full approval being granted, for those aspects of the research which do not relate to the ethical implications but which are intended to contribute to the final piece of research.
- 5.8 A School Research Director, Supervisor or other designated named person/research ethics co-ordinator will be available to give advice concerning the ethical implications of an application.
- 5.9 A Research Ethics Committee reserves the right to request modifications or clarifications of any applications/proposals.
- 5.11 A Principal Investigator or researcher cannot attend any discussion involving their own research proposal even if they are members of the relevant committee, unless invited. Members must also declare any special interest including personal, school, departmental or financial etc. If the Committee Chair is involved in any such conflict of interest(s) then the vice-Chair or nominee will take over until the discussion is concluded.
- 5.12 Dates of Research Ethics Sub-Committee meetings will normally be published in the University Calendar. Applications for Research Ethics Sub-Committee approval should reach the Secretary no later than ten working days before the meeting at which they are to be considered.

6. Decisions

- 6.1 Following consideration of each Application for Ethics Approval, a Research Ethics Committee decision shall be either:

- to approve the application either in full or subject to conditions or modifications
 - not to approve the application with or without an invitation to submit a revised or new application
- 6.2 The applicant(s) shall be notified of the Committee's decision within ten working days of the meeting at which the application was considered.
- 6.3 Any application which has been approved subject to minor modifications should be submitted with revisions as required to the Committee Secretary within 10 working days of the response from the Committee having been provided to the applicant and supervisor. The research should not normally begin until such modifications have been provided and approved by the Committee or separately by Chair's action.
- 6.4 If a proposal has been rejected and new information becomes available, a revised application may be submitted.
- 6.5 A Research Ethics Committee may require that changes are made to a research protocol for health and safety reasons.
- 6.6 Ethical approval may be granted, with the Committee's approval, outside the Committee.
- 6.7 Approval shall normally be for the duration of the research project which should be stated in the application form.

7. Appeals

- 7.1 An appeal against a decision by a Departmental or a School Ethics Committee may be made to the Research Ethics Sub-Committee only on the grounds that there has been demonstrable material irregularity in the conduct of the Committee's procedures. The decision of Research Ethics Sub-Committee will be final.
- 7.2 The appellant shall submit his/her appeal in writing to the Research Ethics Sub-Committee no later than 10 working days after the receipt of the relevant Committee's decision.
- 7.3 An appeal against a decision with reference to an application considered by the Research Ethics Sub-Committee may be made to the Academic Registrar or nominee only on the grounds that there has been demonstrable material irregularity in the conduct of the Research Ethics Sub-Committee procedure.
- 7.4 The appellant shall submit in writing his/her appeal to the Academic Registrar or nominee no later than 10 working days after the receipt of the Research Ethics Sub-Committee's decision.
- 7.5 The conclusion of an appeal may determine:

- That the appeal is upheld and refer it back to the Research Ethics (Sub-) Committee for review; or
- That the original decision of the Research Ethics (Sub-) Committee is upheld and that no further action be taken.

7.6 The result of an appeal will be notified in writing to the appellant within 10 working days of the decision being reached.

Addendum A: Participants in Research

1. Recruitment of Participants and Declaration of Incentives

- 1.1 The proposed method of selection and recruitment and intended numbers of participants in research should be clearly explained in the research protocol, together with a rationale.
- 1.2 Any proposed financial incentive to participate, other fee, or expense reimbursement made to volunteers and/or participants should be declared and will be subject to the approval of a Research Ethics Committee.
- 1.3 Any proposed financial or other incentive to participate to staff or Departments should be declared in the research protocol and to participants.
- 1.4 Care should be taken in the selection of participants to ensure that the proposed research does not expose them to potential harm because of an existing medical or psychological condition.
- 1.5 Researchers and principal Investigators should ensure that a professional relationship is maintained with participants at all times.

2. Obtaining Informed Consent

- 2.1 Explicit informed consent must be obtained orally or in writing and must be documented before any research can begin. If oral consent is being sought, this must be documented by the principal investigator and a reason for not gaining written consent should be provided to a Research Ethics Committee as appropriate.
- 2.2 Written consent may not be required, for example, when research is part of ongoing teaching and research demonstrations or on work-based learning courses related to improvement of the student's professional practice. Verbal consent can be acceptable in, for example, telephone interviewing.
- 2.3 Informed consent in this Code of Practice is defined as: participant's consent given freely and independently, in the absence of coercion, in light of information provided on the participant information form. Principal Investigators are required to inform participants about anything that would affect their decision to take part.
- 2.4 The Participant Information Sheet should inform the participant of the following in plain, jargon-free language:
 - the aims of the research
 - what the participant is required to do
 - harm which might occur as a result of participating
 - the right to complain, and to whom, in the event of a problem in the research
 - the right to withdraw, or withdraw their data, from the investigation
 - arrangements ensuring the confidentiality and privacy of the participant and protection of the data

- technical protection of the data
 - contact details of the Principal Investigator/Supervisor
 - the requirement to report any symptoms which may occur
 - how the participant will be informed of the results of the research if applicable
 - the intended use(s) of the results of the research.
- 2.5 A copy of the Participant Information Sheet must be retained together with the signed Consent Form and stored suitably in the records of the investigation. A copy of the Participation Information Sheet should also be made available for the participant to take away.
- 2.6 Some participants may lack the competence to give their informed consent to participate in research, for example:
- Children: If school children are asked to be participants in a school-based environment, the Supervisor shall inform the Head Teacher of the school of what is proposed and obtain their permission for pupils to take part. The parent(s) or guardian(s) consent should also be sought. Such permission is in addition to, not instead of, individual consent previously described. Minors must be informed that they have the same rights as an adult. Where required, evidence of Criminal Records Bureau clearance must be provided.
 - Those who lack competence for other reasons: In situations where participants are unable to give consent due to legal reasons, or are not able to understand fully the nature and consequences of what is proposed, written permission to participate must be obtained from the parent, guardian, person in authority, or person with legal responsibility for the participant. Such participants should be allowed to participate only on grounds of minimal hazard, absence of alternatives and sufficient potential social or medical benefit. Psychological illness, or brain damage may or may not be sufficient to render the participant incompetent to give consent.
- 2.7 Where the participant is vulnerable (medically, socially and/or psychologically), greater care needs to be taken in obtaining consent. Legal constraints need to be checked before a third person can give any consent.
- 2.8 In cases where participants have limited command of written English the information and consent form, and any other explanatory materials must be translated into their first language. When participants have limited command of written texts in their first language, oral versions of these documents must be accessible and subsequently documented in written form.
- 2.9 Participants may also withdraw their data from the investigation as far as it is possible. In the case of a participant leaving the investigation, any comments made, or explanations given, should be recorded and kept by the investigator.
- 2.10 Deception should only be used if there is strong scientific justification, whether it is in terms of the research or as a public interest justification.

- 2.11 Potential participants should be allowed sufficient time to reflect on the decision to participate and to seek advice from individuals with appropriate expertise as necessary. There should be sufficient time for reflection between giving consent and participation.

3. Safeguarding of Participants

- 3.1 All reasonable measures must be taken to safeguard the participants' health, to protect their psychological well-being, and to respect their privacy. The researcher is also viewed as a participant in the research and should take steps to protect his/her own health and well-being at all stages of the research.
- 3.2 Any deception considered necessary should not involve the participant in any unjustifiable risk, such as unexpected anxiety or distress, lowering of self-esteem, or any form of psychological or physical harm. Where deception is used, revelation should normally follow participation as a matter of course, and the Research Ethics Sub-Committee will expect that this provision be designed into the investigative procedure.
- 3.3 Principal investigators shall encourage participants to report any unusual or unexpected effects during or after the investigation, demonstration, research or experiment to the Principal Investigator. The Participant Information Form must be explicit enough to encourage participants to report any such effects and give information about the support available both during and after the research.
- 3.4 Any serious event affecting a participant or Investigator, or other persons, during or after a research project must be reported without exception or delay to the Research Ethics Sub-Committee by the Principal Investigator. The research must be halted immediately.
- 3.5 Participants should be informed of their right to appropriate support were there to be a subsequent adverse effect.
- 3.6 Changes from an approved protocol may be allowed if there is danger or risk to the participant or Investigator, or other persons. Subsequently such changes to the process must be reported to the Research Ethics Committee for approval. The research shall be halted immediately and until such approval is received.

Addendum B: Location of Research

1. Joint Research Activities

- 1.1 Staff or students who wish to carry out research on human participants or animals outside University premises, must obtain written permission from any collaborating organisation as well as from the University of Westminster.
- 1.2 Principal Investigators who are not University employees or University enrolled students, and who wish to carry out research on University premises, must conform to the University's *Code of Practice for Research Ethics*.
- 1.3 Principal Investigators who are not employees of the University shall state this on their Application for Research Ethics Committee approval.
- 1.4 In the case of collaborative investigations or investigations involving non-employees of the University, a Research Ethics Committee will focus on Section 6 (Insurance), and Section 8 of the application form (External Approval), before considering the proposed investigation further. In the case of collaborative projects, the Research Ethics Committee may agree either to accept ethical approval granted elsewhere or to require that University approval be granted before the project may commence.

2. Research Conducted Abroad

- 2.1. The Principal Investigator and/or supervisor must consider ethical implications of research conducted outside the UK.
- 2.2 The Principal Investigator and/or supervisor is advised to make every attempt to gain ethical approval from a relevant independent body abroad, where applicable, in addition to any ethical approval sought at the University.
- 2.3 The local review and ethical approval of research carried out abroad is a necessity because the ethical acceptability of the research must be in accordance with local customs, traditions and beliefs.
- 2.4 University members must ensure the University insurance will cover them for any research conducted abroad and must obtain a letter to this effect from the University before they travel. See Addendum C, Section 2.

3. Location of the Investigation & Apparatus

- 3.1 The Principal Investigator and/or supervisor will ensure that any specific locations proposed for research are appropriate to the type of study and the risk involved.
- 3.2 An inspection of the proposed premises or location may be carried out by a University Research Ethics Committee at its discretion.
- 3.3 A Research Ethics Committee will need to be satisfied by the Principal Investigator that all equipment and apparatus intended to be used will be safe

and properly maintained in accordance with the standards and procedures laid down by University Health and Safety Guidelines.

Addendum C: Data Protection Requirements and Insurance

1. Data Security and Confidentiality

- 1.1 Relevant Data Protection legislation and University guidance in data security must be observed in the collection, use, storage, back-up and eventual destruction of all data.
- 1.2 The Principal investigator shall be responsible for safeguarding the confidentiality of participant data.
- 1.3 The recording of investigations and handling of all personal data must comply with the Data Protection Act 1998. A copy of the Act and additional advice is available from the Secretary to the Research Ethics sub-Committee.
- 1.4 Information about named participants shall be communicated only to clinicians involved with their care (in the case of medical studies) or to researchers involved in the research. In all other cases the identity of participants must be protected.
- 1.5 With respect to computerisation of participant data, proposals for investigations involving storage of participants' names and other personal data should indicate reasons for holding such data, and the intended maximum period of retention with details of the steps proposed to minimise the risk of a breach of confidentiality. All participant data must be handled in accordance with the Data Protection Act 1998.
- 1.6 The following guidelines on security arrangements for any recorded information should be adhered to:
 - Explicit consent must be obtained from the participants to use their data.
 - Systems used for the storage of data should be located on ISLS' secure network infrastructure on the firewall so that access control measure and auditing policies can be enforced.
 - Desktop/laptops used by researchers should always be fully patched and regularly scanned for software vulnerabilities.
 - All the data held on recordable data should be password protected as a minimum security measure, to protect the contents if they are lost.
 - Any recordable media such as discs, tapes films or USB devices containing identifiable personal data should be stored securely.
 - Access to the data should be directly supervised by a designated system manager and permitted only to those authorised by the Dean of School.
 - Knowledge of procedures and passwords to access any medical or research data of named individuals should be held securely and be made available only to those authorised.
 - File protection should be in operation on computer systems used to hold named data.
 - Transmission of identifiable personal data across public communication lines should be avoided at all times. Where this is absolutely necessary, the prior approval of a Research Ethics Committee is required.

- The Data Protection Act 1998 requires that the participant's informed consent be sought where personal information is to be used and that those who have access to the information, or receive copies of it, are clearly identified.

2. Insurance protection

- 2.1 All participants in an investigation must be protected by insurance.
- 2.2 The University of Westminster maintains in force a Public Liability Policy, which indemnifies it against legal liability for accidental injury to persons (other than its employees) and for accidental damage to the property of others. The University holds a comprehensive portfolio of insurance cover, including Professional Indemnity (inc Directors and Officers cover) and Clinical Trials Cover. This insurance cover relates to claims arising within normal activities of the University.
- 2.3 The Research Ethics Sub-Committee may require, as part of the Application for Approval, either written confirmation that the University of Westminster insurers are content for their policy to apply, or that appropriate additional insurance cover has been arranged. It is the responsibility of the Dean of School to ensure, through the University Procurement Manager, that appropriate insurance cover is arranged if the investigation falls outside the scope of the University's Public Liability Policy; details of such cover should be attached with the application form.
- 2.4 Participants must be clearly informed before the investigation of their rights to insurance cover in the event of accident, injury, or ill health arising as a result of taking part in the research.
- 2.5 Before considering research ethics approval the Research Ethics Committee may require evidence of how all investigators will be indemnified against relevant risk.
- 2.6 Where the investigation involves the use of equipment or non-food substances manufactured outside the UK, it will be assumed that the manufacturer has liability insurance. If in doubt, confirmation should be sought from the manufacturer.