

Title:	Research Ethics Policy
Approved by:	Academic Board
Date of implementation:	1 March 2015
Date of next major review:	September 2018

SECTION 1 – INTRODUCTION _____	2
Purpose _____	2
Scope _____	2
Legislative & Regulatory Context _____	2
Equality & Diversity _____	2
SECTION 2 - POLICY STATEMENT _____	2
SECTION 3 - GENERAL PRINCIPLES _____	3
SECTION 4 – COMMITTEE FRAMEWORK _____	3
SECTION 5 – APPLICATION & APPEAL PROCEDURE _____	5
SECTION 6 – DOCUMENT GOVERNANCE _____	7
Responsibility _____	7
Version Control and Change History _____	7
Document Review _____	7
Appendix 1 – Figure 1: University Research Ethics Committee Framework	8

SECTION 1 - INTRODUCTION

1.1 Purpose

1.1.1 The purpose of this policy is to establish and promote good ethical practice in the conduct of academic research. Specifically it aims to provide:

- an over-arching framework of principles designed to promote a quality research culture, where excellence is promoted and key elements such as effective leadership, openness, accountability and honesty, are maintained and enhanced;
- a clear understanding of the internal structures the University has in place to review its practices and activities in relation to research.

1.2 Scope

1.2.1 This policy applies to all those conducting research within, or on behalf of, the University, including staff, persons holding honorary University appointments, visiting researchers, undergraduate, postgraduate taught and research students (including visiting scholars and students).

1.2.2 In cases where a research project is being conducted by academics from more than one institution it is expected that the relevant ethical clearance for the project is sought from the lead institution (normally the institution at which the Principal Investigator is employed) and that other partner Institutions are informed of outcomes and issues.

1.3 Legislative and Regulatory Context

1.3.1

Name
Research Council Regulations (various)
Animals (Scientific Procedures) Act 1986
Governance Arrangements for Research Ethics Committees (UK Health Depts., 2011)
Ethical frameworks and policies of the National Charities and Learned Societies (various)

1.4 Equality and Diversity

1.4.1 This policy will undergo a comprehensive Equality Impact Assessment to comply with the University's legislative responsibilities.

SECTION 2 – POLICY STATEMENT

2.1 It is the University's policy to establish and promote the highest possible standards of ethical practice in the conduct of academic research. Although the University is a diverse and multidisciplinary community, incorporating a range of research traditions, it is committed to protecting the rights, dignity, safety and privacy of research subjects, the wellbeing of animals and ensuring the protection of the environment. It is also concerned that risks to the health and safety of researchers is minimised and their academic freedom is maintained.

SECTION 3 – GENERAL PRINCIPLES

- 3.1 The University will undertake the ethical review of all research projects involving primary research with human beings (or their data), irrespective of funding source, except that which falls under the remit of Department of Health approved ethics committees (in which case it will be referred to the appropriate committee), or otherwise where it is subject to specific statutory arrangements. In cases where research is being conducted outside of the UK researchers falling under the scope of this policy must also adhere to any legal and ethical requirements relating to the country/institution in which they are working.
- 3.2 For certain types of research (e.g. research involving the NHS), external ethics committees already exist to consider research proposals. Their use for such research is compulsory. In such cases, neither University RECs nor the University Research Committee is empowered to give the research proposal ethical approval.
- 3.3 All research involving human participants, human material or human data requires ethical approval. The requirement for ethical review does not include research where information about human participants is publicly and lawfully available (e.g. census data, population statistics published by government departments, court reports and personal letters/diaries in public libraries).
- 3.4 The University has established and published a Code of Practice for Research within which is included a set of fundamental principles to ensure the protection of human participants. This Code of Practice for Research can be found at the University website here: <https://www.ntu.ac.uk/research/research-at-ntu/research-integrity>. The University seeks to ensure that all research falling within the scope of this policy satisfies these principles and the Code of Practice.
- 3.5 No living person, human tissues, or data or tissues relating to recently deceased persons, or animals (including animals living in their natural habitat) should be used for any project that does not have a serious research, educational or training purpose.
- 3.6 As well as the **University's** own policies, committees and sub-committees must take into account relevant professional ethical codes and the policies of research sponsors. In cases where it can be demonstrated that there exists a difference in ethical standards between the **University's** policy and those of the relevant professional body or research sponsor, committees shall apply whichever is considered the highest standard of ethical practice.

SECTION 4 – COMMITTEE FRAMEWORK

- 4.1 University Research Committee (URC)
 - 4.1.1 Its purpose, roles and responsibilities include the following:
 - To monitor the application of this Policy across the University, to review periodically associated procedures and identify areas requiring change and development to disseminate best practice;
 - To advise, inform, and update Colleges and Schools on new legal and sponsor research ethics requirements;
 - To approve College, cross-College and School procedures for research ethics approval and monitoring;

- To consider reports from College Research Committees on ethical monitoring and approval, and to offer advice and recommendations as appropriate on the operation of local procedures;
- To assure the provision of appropriate ethics training for all staff undertaking research, including those who are supervising other staff and students involved in research projects and courses;
- To consider and offer guidance where requested on appeals against relevant College and cross-College Research Ethics fora;
- To withdraw or suspend the approval of a research proposal or the approval of an ongoing research project due to serious concerns regarding its ethical status;
- To seek clarification from external advisors or other expert bodies on matters of policy and practice related to research ethics;
- To provide reports to University committees as requested and annually to the Board of Governors.

NB: The URC may delegate various elements of these responsibilities to one or more sub-committees, in keeping with **the University's** structures.

4.2 College Research Committees (CRC)

4.2.1 Following the disbandment of CRCs the URC shall, until further notice, assume the responsibilities formerly undertaken by CRCs. These include the following:

- Overall responsibility for the application of the University Research Ethics Policy;
- To establish/maintain one or more College, School, or discipline-level Research Ethics Committees appropriate to the context of the College's disciplinary mix, the requirements of specific funding or professional bodies, relevant legislative requirements and the anticipated volume of work. In the case of the Professional Doctorate Research Ethics Committee (PDREC) the committee should be established/maintained so as to be appropriate to the disciplinary mix of the various Schools and Colleges it supports, as well as the specific funding or professional bodies, relevant legislative requirements and the anticipated volume of work;
- To agree committee and sub-**committees'** membership and terms of reference which must establish clarity about the relationships between them and their reporting line to the URC;
- To oversee the establishment of working methods and approvals procedures for the consideration of any research proposals that require ethical review. This may include an expedited procedure for straightforward or non-contentious proposals. These procedures, together with the membership of any approvals committees and sub-committees, must be approved by the URC which may delegate this responsibility to a committee or sub-committee where one is in place;

NB: In the case of the Animal Welfare and Ethical Review Body (AWERB), the committee does not have the authority to issue ethical approvals. Instead it provides an advisory role to applicants who apply to the Home Office to seek ethical approval and license for their research activities relating to animals. It also ensures compliance with the Animals (Scientific Procedures) Act 1986 and the European Directive 2010/63/EU on the protection of animals used for scientific purposes:

- To establish an approval process that is capable of identifying those projects that require ethical review because they involve research with living persons, human tissues, recently deceased persons, or with animals;
- To take responsibility for reviewing and approving all research falling within the scope of this policy;
- To monitor projects (where monitoring is a condition of approval) which give rise to ethical issues during the life of the research;
- To develop and approve research ethics toolkits, including standard consent forms, participant information sheets and protocols relating to security, confidentiality, anonymisation and retention of data;
- Annual overview reports and regular reports of the decisions reached by sub-committees will be considered by appropriate College Management Teams.

NB: The URC may delegate various elements of these responsibilities to one or more committees and sub-committees, in keeping with **the University's** structures.

All relevant committees and sub-committees will keep comprehensive records of their proceedings and decisions.

SECTION 5 – APPLICATION AND APPEALS PROCEDURE

5.1 Applications for Ethical approval

5.1.1 In considering applications for ethical approval, sub-committees of the URC (including PDREC) will have regard to the following matters, where they are relevant to the project:

- The risk of physical, emotional or reputational harm to research participants, and steps to be taken to mitigate it;
- The risk of physical or emotional harm to the researcher, and steps to be taken to mitigate it;
- Arrangements for recruiting research participants, and for obtaining informed consent, including, for example, copies of participant information sheets and consent forms;
- Justifications for the use of observation or covert surveillance, or the employment of methods that are not transparent to research participants;
- Arrangements for assuring the security and confidentiality of personal data and of any personal artefacts or human tissues collected for the projects, especially any to be stored or processed off-site;

- Arrangements for retention, anonymisation and disposal of personal data, artefacts or tissues at the end of the project or as otherwise required by research sponsors or legal provisions;
- Arrangements for debriefing research participants;
- Arrangements for reporting and dealing with any adverse reactions to the project;
- Ensuring that DBS checks at the appropriate level (where this is required) are undertaken where researchers propose to work in settings where children or vulnerable adults may be present.

5.2 Appeals

5.2.1 In cases where ethical approval is not granted, or significant modifications to the proposed research are required, detailed written feedback must be provided to the applicant and, in the case of research students, to the student's Director of Studies or Lead Supervisor, whichever is applicable.

5.2.2 Where it is not possible to resolve the issue informally, applicants shall have the right of appeal, initially to the sub-committee of the URC taking the decision. If this is not successful, and the applicant remains unsatisfied, the applicant may request that the appeal be considered by the URC whose decision shall be final. The URC may seek advice from its dedicated sub-committee, if it has established one, or may establish an *ad hoc* committee of experienced persons for the purpose of hearing the appeal.

5.2.3 Where there are statutory requirements that dictate different arrangements for considering appeals, these will take precedence over the procedures set out in this Policy.

Researchers who are subject to their own professional code of conduct should note that (a) their own ethics policies may be more stringent than those set out in this policy and that their own professional codes will bind the researcher; and (b) failure to comply with ethics approval may amount to serious professional misconduct **which the University is obliged to report to the researcher's professional body.**

5.2.4 In the case of research activities which fall under the remit of the Animals (Scientific Procedures) Act 1986, there is no right of appeal to the Animal Welfare and Ethical Review Body (AWERB).

SECTION 6 – DOCUMENT GOVERNANCE

6.1 Responsibility

Policy Owner	Pro Vice Chancellor (Research)
--------------	--------------------------------

6.2 Version Control and Change History

Version Number	Approval Date	Approved by	Amendment
2.0	07/10/15	URC	No changes were made.
3.0	19/10/2016	URC	Several minor changes were made, focusing principally on the specific referencing of the Professional Doctorate Research Ethics Committee.

6.3 Document Review

- 6.3.1 The Policy and Procedure will be reviewed by the URC in association with the trade unions, employee representatives, managers and appropriate research committees in response to statutory changes, changes in University procedures or structures or as a result of the monitoring of the application of the procedure. In any event, the Policy and Procedure will be reviewed every two years.

Figure 1: University Research Ethics Committee Framework

