

Title:	Research Ethics Policy & Procedure
Approved by:	Academic Board
Date of implementation:	1 st March 2015
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CONTENTS

<u>SECTION</u>	<u>TITLE</u>	<u>PAGE</u>
1	Introduction	2
2	General Principles	2
3	Role of Research Ethics Committees	3
4	Applications & Appeals Procedure	4
5	Governance	5

1 Introduction

1.1 Purpose

- 1.1.1 The purpose of this policy and procedure is to establish and promote the highest possible standards of ethical practice in the conduct of academic research.
- 1.1.2 The University 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.
- 1.1.3 Specifically the policy & procedure aims to provide:
 - 1.1.3.1 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;
 - 1.1.3.2 clarity about internal procedures and 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.

2 General Principles

- 2.1 The University requires the ethical review of all research projects involving primary research with human beings (or their data), irrespective of funding source.
- 2.2 In the majority of cases, a review would be undertaken by an NTU Research Ethics Committee. However, in some instances this may be undertaken by external research ethics committees, such as those operated by the NHS, as appropriate.
- 2.3 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.
- 2.4 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 Research Ethics Committees nor the University Research Committee is empowered to give the research proposal ethical approval.

- 2.5 All projects involving living persons, human tissues, or data or tissues relating to recently deceased persons, or animals (including animals living in their natural habitat) should have a serious research, educational or training purpose.
- 2.6 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 (for example census data, population statistics published by government departments, court reports and personal letters/diaries in public libraries).
- 2.7 The University has a *Code of Practice for Research* which includes a set of fundamental principles to ensure the protection of human participants. This Code of Practice for Research can be found here:
<https://www.ntu.ac.uk/research/research-environment-and-governance/governance-and-integrity>
- The University requires that all research falling within the scope of this policy satisfies these principles and the Code of Practice.
- 2.8 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.

3 Role of Research Ethics Committees

- 3.1 Such Sub-Committees (research ethics committees) as established by the University Research Committee shall assume responsibility for the application of the University Research Ethics Policy & Procedure.
- 3.2 Research ethics committees should ensure they are appropriate to the context of the disciplinary mix of research they will be reviewing, the requirements of specific funding or professional bodies, relevant legislative requirements and the anticipated volume of work.
- 3.3 Each committee should agree membership and terms of reference, oversee the establishment of working methods and approval procedures for the consideration of any research proposals that require ethical review and produce an annual overview report on decisions reached for consideration by the University Research Committee.
- 3.4 In addition to taking responsibility for reviewing and approving all research falling under its jurisdiction each research ethics committee should develop and approve research ethics toolkits, including standard consent forms, participant information sheets and protocols relating to security, confidentiality, anonymisation and retention of data.
- 3.5 All research ethics committees should keep comprehensive records of their proceedings and decisions.

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.

- 3.6 Relevant School Associate Deans for Research or the Research Office can provide guidance on the most appropriate research ethics committee to which applications should be submitted.

4 Application and Appeals Procedure

4.1 Applications for Ethical approval

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

- 4.1.1.1 The risk of physical, emotional or reputational harm to research participants, and steps to be taken to mitigate it;
- 4.1.1.2 The risk of physical or emotional harm to the researcher, and steps to be taken to mitigate it;
- 4.1.1.3 Arrangements for recruiting research participants, and for obtaining informed consent, including, for example, copies of participant information sheets and consent forms;
- 4.1.1.4 Justifications for the use of observation or covert surveillance, or the employment of methods that are not transparent to research participants;
- 4.1.1.5 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;
- 4.1.1.6 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;
- 4.1.1.7 Arrangements for debriefing research participants;
- 4.1.1.8 Arrangements for reporting and dealing with any adverse reactions to the project;
- 4.1.1.9 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.

4.1.2 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.

4.1.3 Where it is not possible to resolve the issue informally, applicants shall have the right of appeal.

4.2 Appeals

- 4.2.1 Where there are statutory requirements that dictate different arrangements for considering appeals, these will take precedence over the procedures set out in this Policy.
- 4.2.2 Researchers who are subject to their own professional code of conduct should note that:
- 4.2.2.1 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
- 4.2.2.2 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.
- 4.2.3 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).

5 Governance

- 5.1 The University Research Committee (URC), chaired by the Deputy Vice-Chancellor - Research and Innovation and reporting to the Academic Board, maintains overall responsibility for the development and monitoring of this policy and associated procedures.
- 5.2 The University Research Committee may delegate various elements of these responsibilities to one or more sub-committees, in keeping with the University's structures.
- 5.3 Responsibility

Policy Owner	Deputy Vice-Chancellor - Research and Innovation
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5.4 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.

4.0	11/12/2018	URC	Key updates adopted to incorporate sector best practice and recommendations from the UK Research Integrity Office.
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5.5 Document Review

5.5.1 The Policy and Procedure will be reviewed by the URC in association with the trade unions, 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.

5.5.2 In any event, the Policy and Procedure will be reviewed every two years.