

UNIVERSITY OF ULSTER POLICY SCREENING PRO-FORMA

What is the Policy? (Name/Description of the Policy)

Policy for the Governance of Research involving Human participants and accompanying procedures.

What is the aim, objective or purpose of the Policy?

The Policy aims to ensure that:

- All research on human participants, human material and human data proceeds with the prior knowledge and appropriate consent of the University;
- All research on human participants, human material and human data being conducted by staff or students of the University adheres to current ethical guidelines and any relevant legislation;
- The safety, well-being, rights and dignity of human participants and researchers are safeguarded through a process of ethical review;
- All research on human participants respects the diversity of individuals and groups that might be involved, as described in the University's policies on equality.
- This policy aims to address the main principles of research governance and ethical review and in doing so, to provide guidance on the minimum standards the University expects in all research involving human participants. The guidance, however, is not exhaustive and researchers should ensure that any/all matters relevant to their research are properly addressed. Researchers are ultimately responsible for ensuring their project meets the appropriate scientific and ethical standards.

Who defines or defined the Policy and who implements it?

It is defined by Research Governance Steering Committee, and Research and Innovation Committee, and implemented by the Research Governance Section of the Research Office.

Is the Policy applied uniformly throughout the University? Yes ✓* No

If "no" what are the consequences in terms of the screening process?

*Inasmuch as it applies to areas where research includes human participants.

Who are the stakeholders in relation to this Policy eg, DEL, UCAS?

ORECNI, DHSSPS, Health & Social Care trusts, University researchers – both staff and students, and faculties.

How do we interface with other bodies in relation to implementation of this Policy?

All such research is subject to the Research Governance Framework for Health and Social Care and to the research management procedures of individual Trusts and other public-sector healthcare providers/organisations (including University-based clinics treating NHS referrals, for example). The University and the Trusts have established research agreements which incorporate guidance on the criteria that need to be met and adhered to.

All research on human participants in collaboration with NHS/HSC requires a sponsor. The role of sponsor is to ensure that the research is properly conceived and designed, ethically reviewed and conducted and regularly monitored and reported. The sponsor is also responsible for indemnifying the research.

The University may act as sponsor for research being conducted by its staff and students where the research has been appropriately reviewed and approved to proceed in accordance with University and Trust procedures.

What data are available to facilitate the screening of this Policy?

No personal data is collected on the individual researchers, however the Research Governance section records the names of all investigators associated with individual research projects. These include both staff and students and external collaborators. To date, 1268 names have been recorded.

1. Is there any evidence of higher or lower participation or uptake by the following characteristics?

	Yes	No	Not Known
Religious Belief		✓	
Political Opinion		✓	
Racial Group		✓	
Age		✓	
Marital Status		✓	
Sexual Orientation		✓	
Gender		✓	
Disability		✓	
Dependants		✓	

Note: A broad interpretation should be taken of the word 'evidence'. It should include anecdotal evidence and evidence derived from qualitative analysis or quantitative analysis where available.

Please comment:

2. No comments or complaints regarding participation have been received from any of the investigators and there is no anecdotal evidence of higher or lower participation by the

characteristics listed. The procedures arising from the policy are written to allow research involving vulnerable and 'hard to reach' groups of volunteers to take place. Recruitment and selection of volunteers will depend upon the nature of each research project.

Is there any evidence that different groups have different needs, experiences, issues and priorities in relation to this Policy?

	Yes	No	Not Known
Religious belief		✓	
Political Opinion		✓	
Racial Group		✓	
Age	✓		
Marital Status	✓		
Sexual Orientation		✓	
Gender		✓	
Disability	✓		
Dependants	✓		

Note: A broad interpretation should be taken of the word 'evidence'. It should include anecdotal evidence and evidence derived from qualitative analysis or quantitative analysis where available.

Please comment:

As previously stated the Policy specifically refers to vulnerable groups in order to ensure that they are not excluded from volunteering for research, treated appropriately, and given due protection. This is achieved mainly through good research design and scrutiny by the University Research Ethics Committee.

3. Have consultations with relevant groups, organisations or individuals indicated that policies of this type create problems specific to them?

	Yes	No	Not Known
Religious Belief		✓	
Political Opinion		✓	
Racial Group		✓	
Age		✓	
Marital Status		✓	
Sexual Orientation		✓	
Gender		✓	
Disability		✓	
Dependants		✓	

Note: A broad interpretation should be taken of the word 'evidence'. It should include anecdotal evidence and evidence derived from qualitative analysis or quantitative analysis where available.

Please comment:

The Policy aims to provide protection for vulnerable groups of research participants.

4. Is there an opportunity to promote equality of opportunity or community relations better by altering the Policy, or by working with others, in Government, or in the larger community in the context of this Policy?

Yes No ✓

Please elaborate: The Policy itself does not seek to promote this opportunity. However individual research projects approved by the Policy and procedures could involve working with others to address this and similar issues.

5. If the answer to any of the questions in 1 to 4 is yes, please indicate whether you consider the Policy may significantly impact on the University's obligation to have due regard to the need to promote equality of opportunity.

Yes No ✓

Please elaborate:

6. What data are required in the future to ensure effective monitoring?

N/A

7. In the context of question 3 are there any relevant groups which you believe should be consulted? Please specify

No, all relevant stakeholders have been consulted

8. Please indicate whether a full impact assessment is recommended.

Yes No ✓

Please elaborate

9. Any other comments on the Policy and/screening exercise?

POLICY _____

Time table for impact assessment

- a. On a scale of 1-5, 1 being the highest priority and 5 being the lowest, assess the Policy in terms of priorities for impact assessment.

	1 - 5
Social Need	
Effect on people's daily lives	
Effect on economic, social and human rights	

Please indicate whether you think this policy should be reviewed in year 1,2,3,4 or 5.

Year _____

- b. Is the Policy affected by a strategic planning documents e.g. Agenda for Action, Institutional Plan, Strategic Development Plan?

Yes Y No Y

Please elaborate

- c. Is the Policy affected by the time table established by other relevant public authorities or organisations in relation to common functions?

Yes Y No Y

Please elaborate

- d. What is the scale of expenditure incurred by the Policy?

Preliminary

Date: 14 April 2011

Screening by:

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