

**UNIVERSITY OF ULSTER
POLICY SCREENING PRO-FORMA**

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

Policy on Research Using Human Tissue (2007 Version in development)

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

The aim of the policy, and related procedures, is to establish and clarify best practice within the University with respect to its obligations under the Human Tissue Act 2004.

Who defines or defined the Policy and who implements it?

Further to the enactment of the Human Tissue Act, the government established a Human Tissue Authority (HTA). The HTA is responsible for licensing establishments in respect of collection, storage and use of human tissue within the regulatory framework set out in the 2004. The University applied for a HTA licence in 2006 in respect of its research activities involving human tissue.

Pursuant to the Act, the University is the licence holder (the corporate contact being the Director of Corporate Planning and Governance). The Act also requires the licensee to appoint a Designated Individual. The DI carries responsibility in law for ensuring that the University and its staff and students comply with the Act. The University can also appoint Persons Designated (PDs) at individual locations in which human tissue is stored. The position of PD is formal under the Act. All PDs are responsible to the DI for matters related to or regulated by the Act.

The policy and related procedures have been developed by the University's Human Tissue Act Working Group, which reports to the Research Governance Steering Committee.

The draft policy and procedures can be accessed online via:

<http://www.ulster.ac.uk/research/rg/>

Is the Policy applied uniformly throughout the University?

Yes

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

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

Human Tissue Authority
DHSSPS (NI)
Department of Health
ORECNI

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

Guidance has been received from the HTA, and the University has developed its policies in liaison with the HTA and ORECNI.

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

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

The Human Tissue Act upholds the rights of individuals who submit human tissue for research, irrespective of any of the Section 75 characteristics. Some research may have evidence of higher or lower participation or uptake by the Section 75 characteristics however every study must be ethically considered.

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:

The Human Tissue Act upholds the rights of individuals who submit human tissue for research, irrespective of any of the Section 75 characteristics. Consent is required for the procurement of relevant material from living volunteers which maybe specific to some of the Section 75 characteristics however every study must be ethically considered.

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 Human Tissue Act upholds the rights of individuals who submit human tissue for research, irrespective of any of the Section 75 characteristics. Although no consultations have taken place with relevant groups, organisations or individuals, the Human Tissue Act Working Group (HTAWG) who reported to the Research Governance Steering Committee has considered the policy at length. It is believed that the ethical review process should be able to address any queries and that the nature of the Informed Consent addresses the needs of these groups.

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? No

Please elaborate:

The HTAWG did identify a few issues especially with regard to obtaining consent from minors, vulnerable adults or foreign nationals residing in the UK. It is believed that these issues have been addressed, as all studies identified with such issues must be given permission to proceed by University ethical committees or by the Office for Research Ethics Committees Northern Ireland (ORECNI). Also studies that involve researchers working alone with vulnerable adults or children require the individual researchers to be assessed under the Protection of Children and Vulnerable Adults (NI) Order 2003.

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. N/A

Please elaborate:

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

All Consent forms signed by individuals must be kept for the duration that consent or for the period of time that the sample is retained until it is completely used or disposed off. All requests for consent forms in alternative format will be recorded and reviewed periodically. This policy will be reviewed as guided by the University review processes.

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

No, however the University will consult on the outcome of screening as required under Section 75 of the Northern Ireland Act.

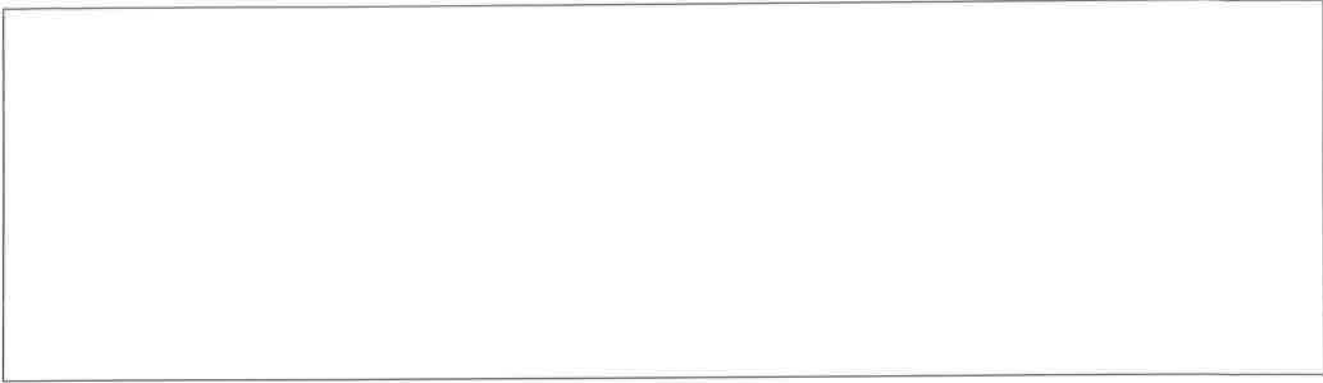
8. Please indicate whether a full impact assessment is recommended. No

Please elaborate

The nature of the legislation and the relationship of it to the University's research activities do not give cause to commission a full impact assessment. The HTAWG did identify a few issues especially with regard to obtaining consent from minors, vulnerable adults or foreign nationals residing in the UK. It is believed that these issues have been addressed, as all studies identified with such issues must be given permission to proceed by University ethical committees or by the Office for Research Ethics Committees Northern Ireland (ORECNI). Also studies that involve researchers working alone with vulnerable adults or children require the individual researchers to be assessed under the Protection of Children and Vulnerable Adults (NI) Order 2003.

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

None



POLICY _____

Time table for impact assessment - N/A

- 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	5
Effect on people's daily lives	5
Effect on economic, social and human rights	3

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

Year 2

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

N/A

Please elaborate

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

Yes

Please elaborate

The Human Tissue Authority who have granted the University a licence to hold relevant material as outline by the Human Tissue Act 2004

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

N/A

**Preliminary
Screening by:**

Leroy Downey

Date: May 2007