POLICY ON CONSENT FOR RESEARCH INVOLVING HUMAN TISSUE

Purpose and Scope

To define the policy for consent for the use of human tissue used in research under the governance of the Lothian NRS BioResource / Tissue Governance Unit..

Responsibilities

Tissue Governance staff involved in consenting.
Any other relevant researchers within NHS Lothian and the University of Edinburgh

References

Human Tissue Act 2004, Human Tissue (Scotland) Act 2006
IHC GCP Principles of Good Clinical Practice
Human Tissue Authority Codes of Practice A and E
UK Policy Framework for Health and Social Care Research 2017.
Adults with Incapacity (Scotland) Act 2000

Definitions

REC – Research Ethics Committee, HTA – Human Tissue Authority,
GCP – Good Clinical Practice

Existing holdings – Material from the living or deceased that was already held at the time the Human Tissue Act came into force on 1st September 2006.

AWI – Adults with Incapacity.

Documentation

QP-TGU-A-OBTACON – Obtaining Informed Consent for BioResource Donation.
QF-TGU-A-CONSENTF – Participant Consent Form (Lothian NRS BioResource)
QF-TGU-PISBRCE – Participant Information Sheet
QP-TGU-A-ACCESSR – Request for access to the BioResource

COPY	1 of 2	ACCORD
Location of Copies		Tissue Governance shared drive.

Authorising signatures

Author:	Frances Rae	**Date:**	05-Feb-2019
Authority for issue:	Craig Marshall	**Date:**	05-Feb-2019

Quality checked:	Craig Marshall	Date:	05-Feb-2019

Staff Review Form

I have read and understood the above Policy

Name	Signature	Date

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1 INTRODUCTION

The Lothian NHS Tissue Governance Unit has been established to ensure appropriate governance of the use of human tissues for research. It is committed to adhere to the Human Tissue (Scotland) Act 2006, the principles of Good Clinical Practice, Human Tissue Authority (HTA) Codes of Practice, General Data Protection Regulation (GDPR) and Data Protection Act 2018, and the standards of the NRS Biorepository accreditation scheme.

This document sets out the Tissue Governance Unit (NHS Lothian) policy on consent, or "authorisation", for research involving human tissue samples. The aim of this policy is to protect the rights, welfare and safety of participants and potential participants involved in projects which use their tissue and associated data.

The Human Tissue (Scotland) Act 2006 came into force from 1st September 2006. The purpose of the Act is to regulate the removal, use, storage and disposal of human tissue from the deceased for scheduled purposes. Research is one of the listed scheduled purposes. The Act has authorisation as its fundamental principle.

2 PRINCIPLES

NHS Lothian requires that all research involving human participants has their fully informed consent and must have received a favourable ethical opinion from an NHS Research Ethics Committee.

This is subject to some exemptions which are outlined below in 2.8.

The giving of consent is a positive act. For consent to be valid, it must be given voluntarily by an appropriately informed person who has the capacity to agree to the research in question.

2.1 All research

2.1.1 NHS Patients have a right to expect that their personal information and samples be used primarily for their own benefit. In circumstances where material may be used for other purposes, eg research, this must be done with the patient's explicit consent apart from some exemptions (See 2.8).

2.1.2 The giving of consent must be a positive act. Consent must be given freely without any perception of coercion.

2.1.3 The potential participant must be provided with good quality, understandable information sheets to enable valid consent. The sheets should be concise and written in simple language easy for lay people to comprehend.

2.1.4 Written consent forms should be used wherever possible for all research involving human participants. (QF-TGU-A-CONSENTF or relevant equivalent)

2.1.5 The information sheet and consent form used should be the versions approved for the study by the appropriate research ethics committee.

2.1.6 It must be made clear to participants that they are free to withdraw consent at any time without having to give a reason and without compromising their clinical care in any way.

2.1.7 It is the responsibility of the Chief Investigator to ensure that consent is taken appropriately. The act of taking consent can be delegated to other members of the clinical care or research team who have the appropriate training and experience.

2.1.8 In the event of anyone who is not any of the above (2.1.7) wishing to consent patients, the R&D office must be contacted as a Research Passport or Honorary NHS contract may be required before patient contact can be made.

2.1.9 The person taking consent must have sufficient knowledge of the information sheets relevant to the research study in order to answer the potential participants' questions.

2.1.10 Consent forms are required to be kept for the length of time deemed necessary by current national guidance covering the specific research that is being carried out.

2.1.11 If a participant has consented to a specific research project, further consent may be required if there is a wish to use the tissue in any other project unless the terms of the original consent allow for generic future use.

2.2 Adults

2.2.1 If an adult is competent, only they are allowed to give consent for themselves. An adult is competent to consent if they can: understand the nature and purpose of the proposed procedure; understand and retain information relevant to the decision; and able to give consideration to the necessary information in order to arrive at a choice.

2.2.2 Any research involving adults who lack the capacity to give consent must be in the best interests of that individual. Generally, if research can be done equally well on those who do have the capacity to consent, the involvement of those who lack capacity to consent must be avoided. However, in some situations it may be in the best interest of the individual to be entered into a study.

2.2.3 Any study involving AWI (Adults with Incapacity) must be approved by a REC which is recognised to review AWI studies. This is currently Scotland A REC.

2.2.4 If lack of capacity is temporary, then full consent must be sought as soon as capacity is regained.

2.2.5 If the adult is unable to read and/or write, an impartial witness (i.e. healthcare professional) or legally acceptable representative must sign the consent form on their behalf, provided they have witnessed the participant reading (or being read) the consent form and indicating their willingness to participate. The reason for this must also be noted on the consent form.

2.2.6 **Please note that the Tissue Governance / BioResource ethical approval (15/ES/0094) does not permit consenting adults with incapacity.**

2.3 Research involving children

2.3.1 Under the Human Tissue (Scotland) Act 2006, any child of 12 years or over must consent to donate their tissue to a research study if they are competent to do so. It is the policy of the Tissue Governance Unit that this is applicable to tissue from living and deceased donors. A person with parental responsibility for the child can consent on his/her behalf only if the child has not made a decision and is not competent to do so or chooses not to make the decision despite being competent to do so. However, the person with parental responsibility should be involved in the decision-making process along with the child.

2.3.2 If a child is under 12 years of age or lacks the capacity to consent, consent can be given on their behalf by any one person with parental responsibility.

2.3.3 **Please note that the Tissue Governance / BioResource ethical approval (15/ES/0094) does not permit consenting children under 16.**

2.4 Research involving healthy volunteers

2.4.1 When research involves NHS staff or associated students it must be made clear that if they do not wish to participate this will not affect their career development and educational progression.

2.5 Research involving tissue and/or organs from the deceased

2.5.1 Consent is required for research in connection with disorders, or the functioning, of the human body. This applies to all tissue removed at post mortem from 1st September 2006.

2.6 Research involving DNA analysis

2.6.1 Section 45 of the Human Tissue Act 2004 applies throughout the whole of the UK, including Scotland, and imposes a legal requirement for qualifying consent when storing tissue with the intention to perform DNA analysis. This is applicable to tissue from the living or the deceased.

2.7 Foetal Tissue

2.7.1 The law does not distinguish between foetal tissue and other tissue from the living. Foetal tissue of less than 24 weeks gestation is considered to be the mother's tissue and, because of the sensitivity surrounding pregnancy loss, consent should always be sought for the use of foetal tissue in research. (HTA code of Practice A; (141).

2.7.2 Consent should also be sought for the research use of non-foetal products of conception eg placenta, membranes, umbilical cord, amniotic fluid where required and even where the tissue is non identifiable.

2.8 Circumstances where consent may not be required

2.8.1 Existing holdings of tissue collected prior to 1st September 2006. However, the research must always have a favourable NHS REC approval. This applies to the living and the deceased.

2.8.2 The Tissue Governance / Lothian NRS BioResource ethical approval (15/ES/0094) permits the use of material collected for diagnostic purpose for research without consent provided that it has fulfilled the purpose for which it was collected, is now surplus to requirements and

that all released samples and linked data are anonymised to the researcher. An application must be submitted to Tissue Governance for this purpose. (QP-TGU-A-ACCESSR)

2.8.3 If more than 100 years has elapsed since a person's death, consent to undertake research on the tissue is not required.

2.8.3 Any material manufactured outside the body e.g. cell lines.

3 MONITORING AND AUDIT

The implementation of this policy will be audited as part of the programme of internal audit of research tissue governance by the Tissue Governance Unit.

Document Review History

Review date	Version	New Version	Reviewed by
21-Jun-2011	1.0	1.0	Frances Rae
Summary of changes			
No changes made other than change of review date.			
Review date	**Version**	**New Version**	**Reviewed by**
20-Jun-2012	1.0	1.0	Frances Rae
Summary of changes			
No changes made other than change of review date.			
Review date	**Version**	**New Version**	**Reviewed by**
17-Jul-2014	1.0	1.1	Frances Rae
Summary of changes			
2.1.8 added to reflect that a research passport or honorary contract may be required. Previous statement for 2.2.2 removed. "It should be assumed that a person is competent to make a decision unless there is reason to believe otherwise." 2,2.3 added 2.2.6 added 2.7.2 added 2.3.3 added 2.8.2 added.			
Review date	**Version**	**New Version**	**Reviewed by**
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Summary of changes			

Ethical approval number is now 15/ES/0094

Review date	Version	New Version	Reviewed by
12-Oct-2017	1.2	1.2	Frances Rae

Summary of changes

No changes other than review date

Review date	Version	New Version	Reviewed by
30-Jan-2019	1.2	1.3	Frances Rae

Summary of changes

Introduction
Addition of sentence about GDPR
2.7.1 Change of wording to "Foetal tissue of less than 24 weeks gestation is considered to be the mother's tissue and, because of the sensitivity surrounding pregnancy loss, consent should always be sought for the use of foetal tissue in research"