OBTAINING INFORMED CONSENT FOR BIORESOURCE DONATION

Purpose and Scope

To define the procedure to be followed by staff obtaining written informed consent for donation of surplus tissue and data to the Lothian NRS BioResource.

Responsibilities

Research nurses and other consenters.

Clinical Care team

References

ICH-GCP guidelines
2005 EU Directive on GCP
HTA Code of practice A and E,
UK Policy Framework for Health and Social Care Research 2017

Definitions

SOP – Standard Operating Procedure, HTA – Human Tissue Authority

ICH-GCP – International Conference on Harmonisation – Good Clinical Practice

Documentation

QP-TGU-A-CONPOL – Tissue Governance Policy for Consent for Research Involving Human Tissue.

QF-TGU-A-CONSENTF - Lothian NRS Bioresource generic consent form.

QF-TGU-PISBRCE - Participant Information Sheet Lothian NRS Bioresource (generic version).

QF-TGU-A-CONSENTX - Lothian NRS Bioresource consent form (xenograft version).

QF-TGU-PISBRCX - Participant Information Sheet Lothian NRS Bioresource (xenograft version).

QF-TGU-A-CONENDO - Lothian NRS Bioresource consent form (GI version).

QF-TGU-PISENDO - Participant Information Sheet Lothian NRS Bioresource (GI version).

QF-TGU-A-CONSCTRC - SCOTRRCC consent form.

QF-TGU-PISSCTRC - Participant Information Sheet SCOTRRCC.

QF-TGU-A-CONSSCR - Lothian NRS Bioresource consent form (stem cell version).

QF-TGU-PISSCR - Participant Information Sheet Lothian NRS Bioresource (stem cell version).

QF-TGU-A-CNSNTSK - Lothian NRS Bioresource consent form (skin version)

QF-TGU-A-PISBRSK - Participant Information Sheet Lothian NRS Bioresource (skin version).

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

Authorising signatures

Author:	Frances Rae	**Date:**	19-May-2020
Authority for issue:	Craig Marshall	**Date:**	19-May-2020
Quality checked:	Craig Marshall	**Date:**	19-May-2020

TABLE OF CONTENTS

1 INTRODUCTION

This SOP describes the procedure for obtaining written informed consent for tissue and data donation to the Lothian NRS BioResource.

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 activity in question. Consent may be withdrawn by the patient at any time, and without giving a reason.

2 RESPONSIBILITIES

Consent for donation of surplus tissue and data must be obtained by a member of the patient's clinical care team, a research nurse or other appropriately trained delegated consenter or member of the research team with approval to do so.

3. PROCEDURE

3.1 Prior to approaching a patient for consent, the staff member must have read and understood the information in the appropriate Patient Information Sheet, and Consent Form.

3.2 Only patients who are aware of, and understand, their medical diagnosis should be approached.

3.3 Check that all patient information is correct.

3.4 Ensure patient has been given appropriate documentation (Patient Information Sheet, Consent Form, and any other relevant information - See section on documentation).

3.5 If possible patients should be given at least 24 hours to consider whether they wish to give consent.

3.6 Enquire as to whether the patient has any questions or concerns relating to the information in the Patient Information Sheet, and answer them as fully as possible in plain language.

3.7 Explain to the patient that there is no obligation to participate and that consent can be withdrawn at any time, without affecting their treatment now or in the future. Explain that if they withdraw consent, any tissue or patient data collected for research purposes will be destroyed but that some residual data will be retained by us to record their withdrawal of consent.

3.8 Talk through the consent form with the patient and explain each individual statement. Allow sufficient time for them to ask questions, and answer them as fully as possible in plain language.

3.9 Ask if they are willing to participate.

3.10 If so, ask them to complete, sign and date the Consent Form.

3.11 Ensure that all questions on the second page of the consent form are clearly circled Yes or No and not crossed out.

3.12 Check that the form has been completed accurately.

3.13 Sign and date the Consent Form as witness. Do not make any marks on the consent form on behalf of the patient unless you need to verify a patient's illegible signature or mark, for example if they are partially sighted. The patient must fill in the relevant parts themselves as far as possible.

3.14 Make two photocopies of the signed Consent Form.

3.15 Give one photocopy to the patient and place one photocopy in the medical notes. The copy from the medical notes may be uploaded on to Trak then shredded. The original should be retained by the researcher for the study file.

Document Review History

Review date	Version	New Version	Reviewed by
13-May-2011	1.0	1.1	Frances Rae
Summary of changes			
Page 5 added: 3.11 Check that the form has been completed accurately. 3.14 Changed to reflect that the signed copy goes into the patient file, and a copy goes to the BioResource.			
Review date	**Version**	**New Version**	**Reviewed by**
19-Sep-2011	1.1	1.2	Frances Rae
Summary of changes			
Page 5 added: 3.15 Fill in form QF-TGU-A-RECCONF (Record of Consented Sample) and return to BioResource along with the signed consent form.			
Review date	**Version**	**New Version**	**Reviewed by**
19-Sep-2012	1.2	1.2	Frances Rae
Summary of changes			
No changes other than updated review date.			
Review date	**Version**	**New Version**	**Reviewed by**
29-Oct-2014	1.2	1.2	Frances Rae
Summary of changes			
No changes other than updated review date.			
Review date	**Version**	**New Version**	**Reviewed by**
13-Oct-2015	1.2	1.3	Frances Rae
Summary of changes Changes as below:			

Review date	Version	New Version	Reviewed by
13-Oct-2017	1.3	NA	Frances Rae
Summary of changes			
No changes other than updated review date			

Review date	**Version**	**New Version**	**Reviewed by**
12-Feb-2019	1.3	1.4	Frances Rae
Summary of changes			
3.16 Give one copy to the patient, and one in the study file. The original should be placed in the patient file but may be uploaded on to Trak and then shredded.			
Review date	**Version**	**New Version**	**Reviewed by**
25-Jul-2019	1.4	1.5	Frances Rae
Summary of changes			
3.7 amended to include that residual data may be retained by us following withdrawal. 3.16 amended to say the original consent form should be retained by the researcher because the version in the medical notes may be uploaded to Trak then shredded			
Review date	**Version**	**New Version**	**Reviewed by**
20-May-2020	1.5	1.6	Frances Rae 
Summary of changes			
3.11 removed as it referred to initialling the boxes on the first page of the consent form. The boxes have now been removed from all versions. Under **Documentation**, Cosmetics version has been removed as this version of the consent form is no longer in use. 3.13 Amended to state that the consenter may need to verify a patient signature where illegible eg if the patient is partially sighted.			