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 (1.55)
The Medicines for Human Use (Clinical Trials) Regulations 2004, (SI 2004 No.1031)
The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006, (SI 2006 No 1928)
Declaration of Helsinki, Clarification of 5th Revision, 2004.
HTA Code of practice 1, HTA Code of practice 9, 33 – 54
Research Governance Framework 2.6

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-CNSNTCOS - Lothian NRS Bioresource consent form (cosmetics version).

QF-TGU-PISBRCOS - Participant Information Sheet Lothian NRS Bioresource (cosmetics version).

QF-TGU-A-CONSENCR - Lothian NRS Bioresource consent form (colorectal version)

COPY	1	Tissue Governance SOP folder
Location of Copies		

Authorising signatures

Author:		**Date:**	
Authority for issue:		**Date:**	
Quality checked:		**Date:**	

Staff Review Form for Standard Operating Procedures

I have read and understood the above Standard Operating Procedure

Name	Signature	Date

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 member of the research team.

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.

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 s 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 the boxes on the front page of the consent form are initialled by the patient **and not ticked or crossed**.

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

3.13 Check that the form has been completed accurately.

3.14 Sign and date the Consent Form as witness. Do not make any marks on the consent form on behalf of the patient. The patient must fill in the relevant parts themselves.

3.15 Make two photocopies of the signed Consent Form.

3.16 Give one copy to the patient, put the signed copy in the patient file, and a copy to the BioResource or appropriate 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:			

3.11 Ensure that the boxes on the front page of the consent form are initialled by the patient **and not ticked or crossed**.

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

3.13 Check that the form has been completed accurately.

3.14 Sign and date the Consent Form as witness. Do not make any marks on the consent form on behalf of the patient. The patient must fill in the relevant parts themselves.

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