

## **SOP for Recording consent for use in research of material leftover from a procedure.**

All patients undergoing procedures at Imperial College Healthcare Trust should be asked for their consent for their leftover samples and/or data to be used in research. The patient information sheet that must be provided to every patient states their rights to withdraw their consent at any time, and informs them that their sample might be used for research including genetic research. The document also states that research data will not be fed back to them.


Prior to surgery, or provision of other diagnostic sample, the patient is asked for his/her consent to the procedure. There are 3 Trust approved consent for procedure forms – Form 1 relates to consent to a procedure where the patient requires anaesthesia, Form 2 is used specifically for patients aged under 16, where anaesthesia is required, and Form 3 is used where the patient remains conscious throughout the procedure. The approved Trust consent forms (TB-DOC-PC1 and attached at the end to this document) also contain a specific area that relates to consent for the use of leftover material in research. Patients have an opportunity to either agree or disagree to the use of their leftover material for research (Figure 1). Patients must also be given the ICHTB patient information leaflet, attached at the end of this document. The version number of the patient information leaflet should be recorded on the patients' consent form e.g. ICHTB PIS v6 9/11/17 (TB-DOC-PI1 v6). The version of the patient information sheet can be found in the footer of the first page document (see copy at end of this document).

*Figure 1: Section from NHS Trust consent form. The statement relating to the patient information sheet is indicated by an arrow.*

### **Use of Tissues and Fluid Samples for Teaching and Research**

#### **Statement of health professional**

(to be filled in by health professional with appropriate knowledge of the use of tissue and fluid samples for research)

- I have explained that this procedure may involve the collection and use of tissue, blood or fluid samples for teaching and research purposes
-   The patient has received the following leaflet/tape \_\_\_\_\_

Signed \_\_\_\_\_ Name (PRINT) \_\_\_\_\_ Date \_\_\_\_\_

#### **Statement of patient**

- I **AGREE** to the collection and use of tissue, blood or fluid samples for approved research
- I **DISAGREE** to the collection and use of tissue, blood or fluid samples for approved research

Signed \_\_\_\_\_ Name (PRINT) \_\_\_\_\_ Date \_\_\_\_\_

The person taking consent must tick BOTH of the boxes in the upper part of the box relating to Use of Tissues and Fluid Samples for Teaching and Research, state the version of the consent form, sign and date the form and print their name.

The patient must tick ONE of the boxes in the lower section, sign and date the

form and print their name.

Only if BOTH OF THE SECTIONS are completed in full is the consent valid. Only if this is the case should the fact that consent has been given be recorded on the NHS pathology requisition form.

Figure 2: Correctly completed consent form

Use of tissues and fluid samples for teaching and research		
Statement of health professional (to be filled in by health professional with appropriate knowledge of the use of tissue and fluid samples for research)		
<input checked="" type="checkbox"/>	I have explained that this procedure may involve the collection and use of tissue, blood or fluid samples for teaching and research purposes	
<input checked="" type="checkbox"/>	The patient has received the following leaflet/tape: PIS v6 09.11.2017	
Signed: <i>[Signature]</i>	Name (PRINT): A Doctor	Date: 9/2/18
Statement of patient		
<input checked="" type="checkbox"/>	I agree to the collection and use of tissue, blood or fluid samples for approved research	
<input type="checkbox"/>	I disagree to the collection and use of tissue, blood or fluid samples for approved research	
Signed: <i>[Signature]</i>	Name (PRINT): A PATIENT	Date: 9/2/18

Both the Trust Consent forms and the ICHTB Information Sheet are available to order from the NHS Trust centralized ordering system, e-procurement. The two are interlinked on the system so that when further consent forms are ordered by the wards, they are automatically requested to review whether patient information sheets have been ordered to go with the consent forms.

The top copy of the signed form should be inserted into the patient's notes, and the second copy given to the patient, together with the patient information sheet.

A photocopy of the completed consent form must be provided to Tissue Bank staff at the time of delivery of sample to the Pathology Laboratory. If the form is not provided or is incomplete, no material can be taken for cell culture or provided fresh to a researcher, and any frozen material will be placed in quarantine for 7 days (the HTA has confirmed that frozen samples of blood and tissue may remain as part of the diagnostic archive until the diagnostic procedure is completed – usually between 7 and 14 days). If the correctly completed consent form is not supplied to Tissue Bank staff within 7 days, the frozen sample will be disposed of following the NHS Trust's sample disposal policy. Tissue Bank staff will enter information recording consent into the Trust's consent app.

If the material collected is to be used for xenografting, the patient must also be asked to complete the consent form for xenografting following the procedure outlined in TB-SOP-005CD (please see Annex 7).