

Recording consent for leftover tissue TB-SOP-002CD

LOCATION OF AUTHORISED COPIES	<ul style="list-style-type: none"> • SharePoint > SOPs > Current > ICHTB > Consent and Documentation • ICHTB Secretariat.
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Documents related to this SOP:

TB-DOC-PIS1 v7 – PATIENT INFORMATION LEAFLET
 TB-DOC-PC1 Approved Trust consent forms
 TB-SOP-005CD SOP for consenting patients for xenograft studies
 TB-DOC-PIS4 PIS and Consent form for Xenograft studies

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)

- 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: PIS v6 18.04.2018 _____

Signed: *[Signature]* Name (PRINT): A Doctor Date: 19/4/18

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: *[Signature]* Name (PRINT): A PATIENT Date: 19/4/18

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.

