Recording consent for extra tissue **TB-SOP-003CD**

LOCATION OF AUTHORISED COPIES	• SharePoint > SOPs > Current > ICHTB > Consent and Documentation • ICHTB Secretariat.

Documents related to this SOP:

TB-DOC-PIS1 v7 – PATIENT INFORMATION LEAFLET
TB-SOP-005CD SOP for consenting patients for xenograft studies
TB-DOC-PIS4 PIS and Consent form for Xenograft studies
TB-DOC-PC2 Approved Trust consent forms

SOP for recording consent for

- **Extra samples of fluid or biopsy material taken at the same time at which the same type of sample is being taken for diagnosis**
- **Non-invasive samples from a patient**
- **Swabs during a diagnostic procedure (e.g. insertion of a rectal or vaginal probe)**

Patients often undergo a number of diagnostic tests prior to their operation, or provide samples of fluid (e.g. blood, urine) as part of routine follow- up after their operation. Patients may be approached to provide an additional sample or samples at these times, specifically for research. Where the sample is an extra tissue sample, these will be routed via the diagnostic Histopathology Department Where these samples comprise a fluid sample, these may be stored directly by the researchers, providing that they comply with the mechanism outlined below.

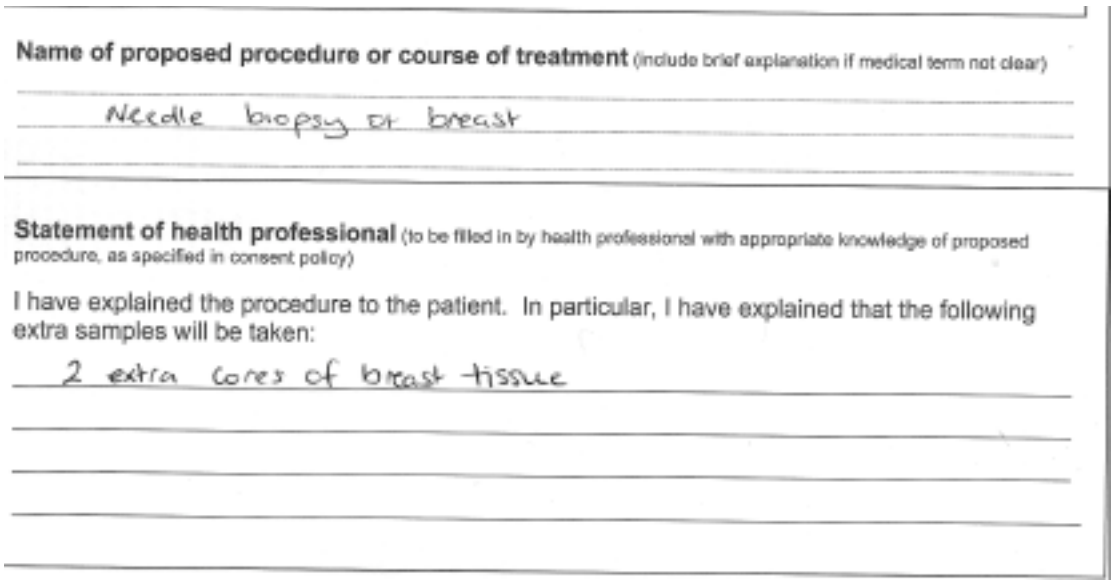
Imperial researchers are also involved in a number of projects to use alternative methods to aid diagnosis and monitoring of patients. These projects often use samples such as urine, breath, saliva, sweat or faeces, or taking of swabs during insertion of a probe as part of a diagnostic procedure. Obtaining these samples from patients pose little risk to the patient, but when combined with samples taken at biopsy or surgery offer a potential benefit to future patients in terms of minimizing surgical intervention. We have therefore sought REC approval to be able to consent patients prior to undergoing a procedure for multiple alternative samples in addition to a sample obtained during an invasive procedure. This should be documented following the protocol outlined below.

Recording consent for obtaining extra samples

Patients can be approached for extra samples at any time during their patient journey at which they would provide a similar sample for diagnosis, or where that sample is non-invasive (e.g. urine, breath, saliva, sweat or faeces) patient may be approached for their consent during a pre-biopsy or surgical appointment relevant to their procedure. For example, patients presenting at a Breast Clinic in preparation for a biopsy to be taken for diagnostic purposes may be asked for consent to provide non-invasive samples of the type listed above, and an extra core biopsy samples for research, or patients presenting at a later date for an endoscopy may be asked to agree to provide a samples of urine, breath or saliva for comparison with an extra sample taken specifically for research during their endoscopy procedure. Consent must be documented on the Trust approved form "Consent for Extra Samples" (TB-DOC-PC2). Patients must also be given the Tissue Bank patient information sheet v6 18/4/18 (TB-DOC-PI1 v6) "Tissue Bank: Information for patients, relatives and carers".

The approved Trust consent forms contain a box that is completed by the person taking consent. This box details the extra samples that will be taken specifically for research (see Fig 1 – breast biopsy and endoscopy are given as examples only). The person taking consent should have been trained appropriately.

Figure 1A: Recording extra samples taken for research – extra biopsy only


Name of proposed procedure or course of treatment (include brief explanation if medical term not clear)

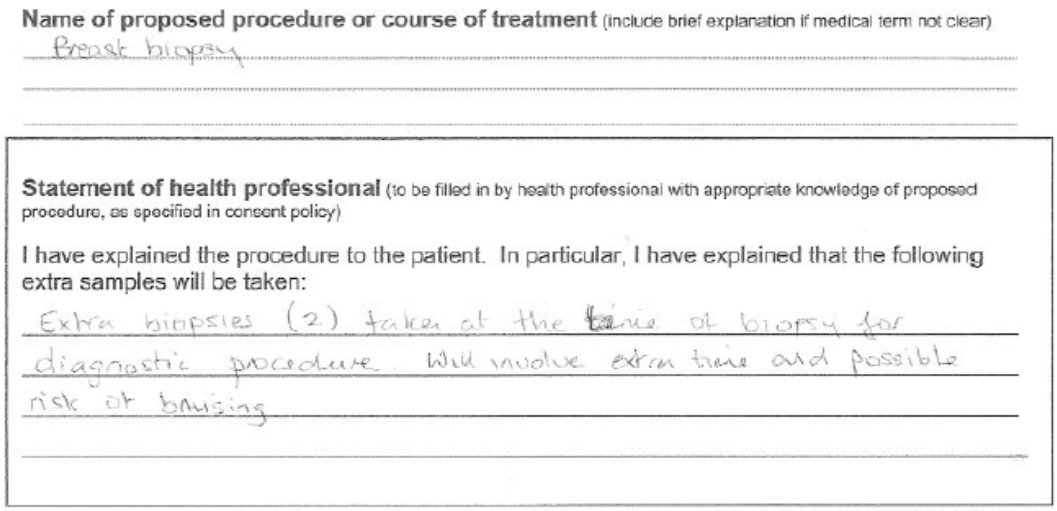
Needle biopsy of breast

Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the patient. In particular, I have explained that the following extra samples will be taken:

2 extra cores of breast tissue

Fig 1B: Recording consent for non-invasive samples and an extra biopsy - breast



Name of proposed procedure or course of treatment (include brief explanation if medical term not clear)

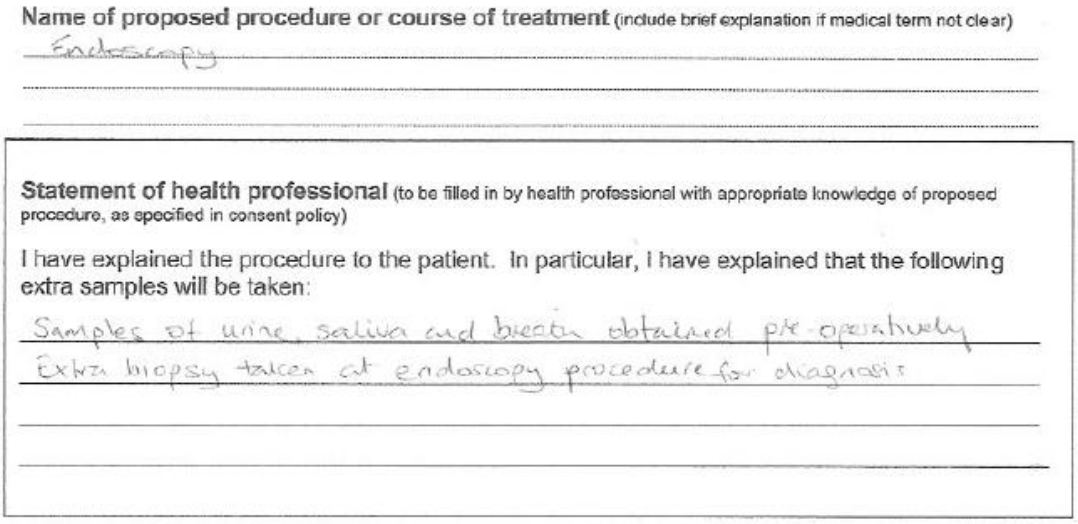
Breast biopsy

Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the patient. In particular, I have explained that the following extra samples will be taken:

Extra biopsies (2) taken at the time of biopsy for diagnostic procedure. Will involve extra time and possible risk of bruising

Fig1C: Recording consent for non-invasive samples and an extra biopsy – endoscopy



Name of proposed procedure or course of treatment (include brief explanation if medical term not clear)

Endoscopy

Statement of health professional (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the patient. In particular, I have explained that the following extra samples will be taken:

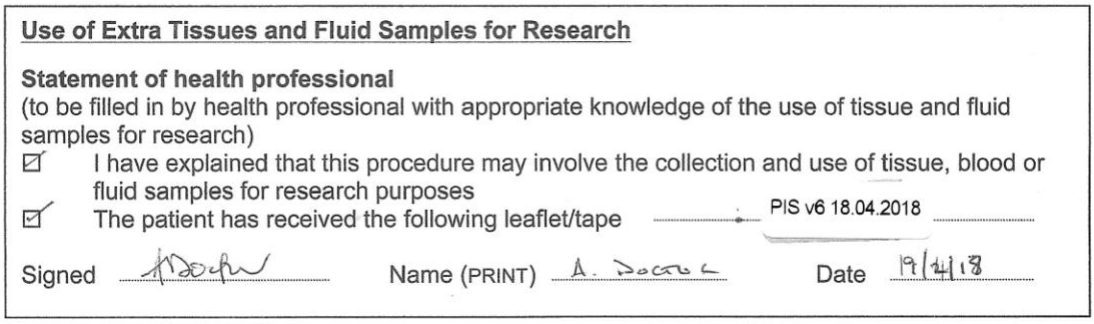
Samples of urine, saliva and breath obtained pre-operatively

Extra biopsy taken at endoscopy procedure for diagnosis

It is important that all sample formats requested from the patient are included in the statement of the health professional

The person taking consent must also complete a second box (Fig 2) by ticking BOTH boxes and recording the version number of the patient information leaflet provided to the patient. The current version is version 6. The version number is given at the bottom of the first page of the leaflet. The person taking consent must sign and date this box and print their name.

Figure 2: Recording information given to the patient by the person taking consent



Use of Extra Tissues and Fluid Samples for 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 research purposes

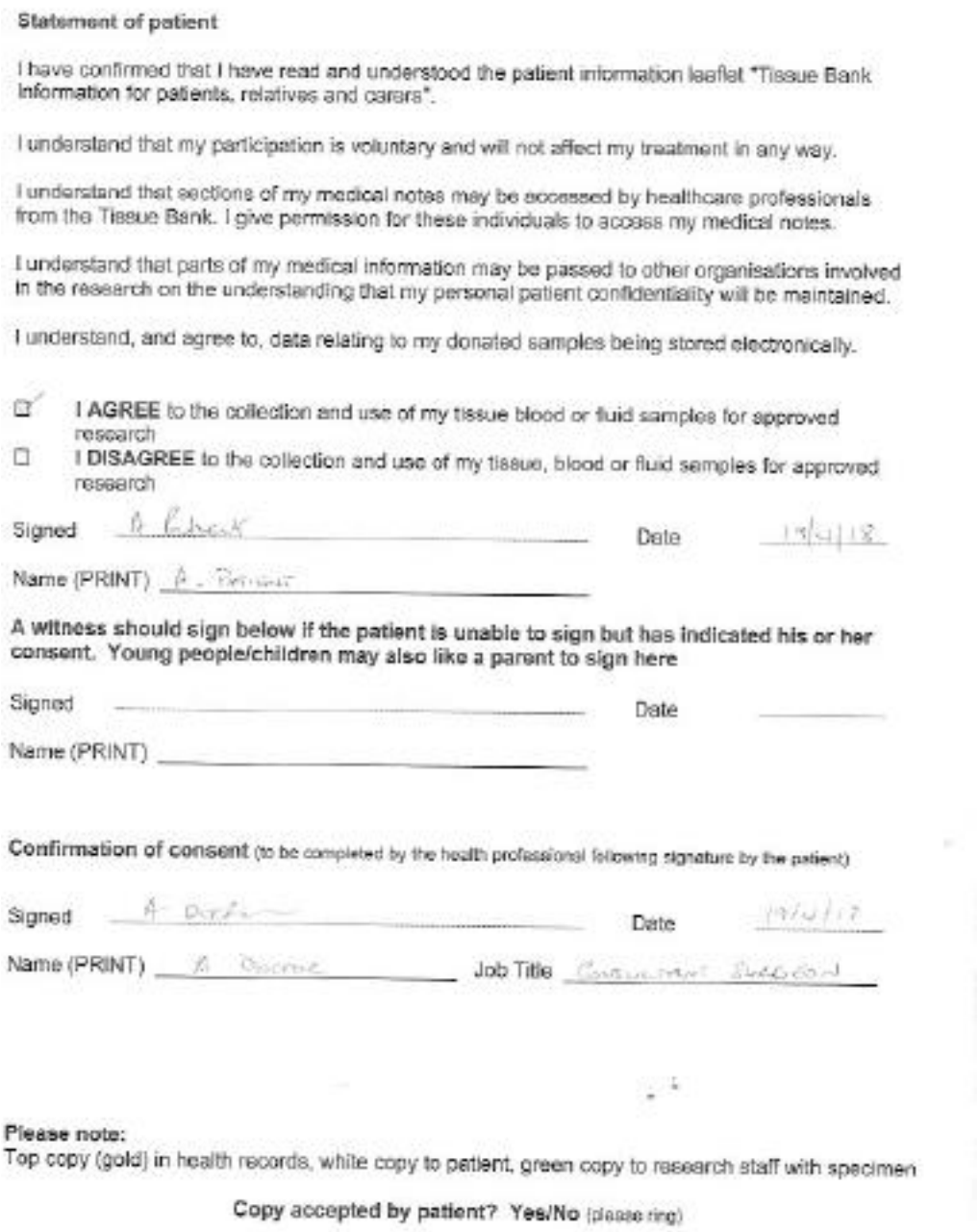
☑ The patient has received the following leaflet/tape PIS v6 18.04.2018

Signed [signature] Name (PRINT) A. Doctor Date 19/4/18

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 patient information leaflet (currently version 6), sign and date the form and print their name.

In addition, the patient must tick ONE of the boxes in the section shown below, sign and date the form and print their name. (See Figure 3).

Figure 3: Recording patient consent



Statement of patient

I have confirmed that I have read and understood the patient information leaflet "Tissue Bank Information for patients, relatives and carers".

I understand that my participation is voluntary and will not affect my treatment in any way.

I understand that sections of my medical notes may be accessed by healthcare professionals from the Tissue Bank. I give permission for these individuals to access my medical notes.

I understand that parts of my medical information may be passed to other organisations involved in the research on the understanding that my personal patient confidentiality will be maintained.

I understand, and agree to, data relating to my donated samples being stored electronically.

☑ **I AGREE** to the collection and use of my tissue blood or fluid samples for approved research

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

Signed _____ Date _____

Name (PRINT) _____

A witness should sign below if the patient is unable to sign but has indicated his or her consent. Young people/children may also like a parent to sign here

Signed _____ Date _____

Name (PRINT) _____

Confirmation of consent (to be completed by the health professional following signature by the patient)

Signed _____ Date _____

Name (PRINT) _____ Job Title _____

Please note:
Top copy (gold) in health records, white copy to patient, green copy to research staff with specimen

Copy accepted by patient? Yes/No (please ring)

Only if ALL of the sections are completed in full is the consent valid.

Both the Trust Consent forms and the Patient 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 Tissue Bank can provide these forms to you if you are unable to access the

Trust system, but you will be charged a cost recovery fee.

The top copy should be inserted into the patient's notes, the white copy given to the patient, and the blue copy should accompany the sample to the pathology department or be filed with the sub-collection documentation by the PI for the sub-collection or their designated deputy.

If the material collected is to be used for xenografting, the patient must also be asked to complete the consent form for xenografting (TB-DOC-PI4) following the procedure outlined in TB-SOP-005CD.

Change control log

Original version number	change requested by	reason for request	New version number	Date revised