SOP for consenting patients for Xenograft studies

Before any patient is approached for consent for xenografting studies, the study must firstly be approved by the Application Review Panel.

Collecting material for use in xenografts requires additional specific consent. Patients must first be consented using either the left over material/surgical consent form, where material is being obtained as part of an operation, or the extra samples consent form where material is being obtained at the same time as a diagnostic biopsy and provided with the current version of the ICH Tissue Bank Patient Information Leaflet (v6 18/4/18)

Following consent documented on one of the two forms referred to above, patients should be provided with the patient information sheet and consent form for Xenograft studies (TB-DOC-PI4 v1 dated 25/9/13). This document explains to the patient what a xenograft is and that this procedure involves the use of animals. The patient is asked to tick three boxes that specify that they have read and understood the information provided on xenografting, that they understand that tissue will be implanted into mice, and that they consent to this. The patient must then sign and date the form and the form must be countersigned and dated by the researcher taking consent.