



Standard Operating Procedure for Obtaining Consent for the Use of Tissues in Research

Background

This SOP is concerned with obtaining consent from patients for the retention, storage, and use of tissue for research purposes within Birmingham Dental School and Hospital. It does not cover formal research projects where ethical approval and written consent on a specific approved consent form is required. This SOP is intended to be read in conjunction with Birmingham Community Healthcare's policy for "Consent to Examination and treatment."

Protocol for Obtaining Consent for the use of Tissues in Research

- The consent process should be identical to that followed for routine clinical practice on conscious patients. The patient must therefore be "competent" to provide consent.
- Under no circumstances should coercion be used to obtain tissue; the patient has the right to refuse consent and to withdraw consent at any time.
- Explain to the patient that either the tissue concerned is waste tissue that has no diagnostic value and would normally be carefully discarded or that the tissue being taken is for research purposes only.
- Explain that the tissue will be stored anonymously and the only coding used for the tissue will be the patient's individual hospital number. The laboratory staff will not have access to their clinical notes and only the consultant in charge of their care or the HTA Designated Individual could access the notes to obtain further appropriate information if requested.
- Use the Participant Information Sheet (PIS) "Donating Samples for Medical Research" to facilitate discussion with the patient and ensure they are fully informed. The consent form (ICF) attached to this should be used to record the patient's informed consent. The consent form should also be signed by the researcher receiving consent.
- A signed copy of the PIS/ICF should be given to the patient to take away with them. Another copy should have the patient's hospital number written on the top and be scanned in to the patient's electronic medical record, a third copy should be forwarded to the Research Coordinator, 3rd Floor, School of Dentistry for storage in the Tissue Bank Master File.
- Place the sample in an appropriate secure container and supply 3 barcode labels but remove the patient's name with scissors.
- Use the Sample Donation Form to record a description of the sample and processing instructions
- The container should be taken personally to the 3rd Floor Labs along with the Sample Donation Form.

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