

Approval for research carried out on human extracted teeth from Birmingham School of Dentistry Tooth Bank under ethical approval no: 14/EM/2811

Generic ethical approval has been obtained for research to be carried out on teeth from Birmingham School of Dentistry Tooth Bank in the experimental areas below. A simple process has been put in place to ensure governance and that the conditions of that approval are adhered to.

- 1) **Testing materials that interface with tooth tissues** - E.g. Evaluation of bonding strengths of filling materials or the ability of filling materials to seal cavities and root canals.
- 2) **Testing of instruments/devices that interface with hard tissues** - Analysis of the surface of teeth when they have been exposed to instruments used in dentistry.
- 3) **Isolation of components within the tooth** - bioactive molecules exist within natural tooth structure, analysis of these molecules and exposure of them to experimental set ups allows study of the reparative process within the tooth.
- 4) **Culture of cells/tissue from extracted teeth** - Cells/tissue from the pulp within the tooth can be harvested and exposed to different conditions allowing analysis by histological, molecular and biochemical techniques to study disease and therapeutic processes.

To use extracted teeth from the tooth bank for research in the areas above a simple form has to be completed to seek internal approval from the Clinical Research Executive Group (CREG). The form can be obtained from and returned to Gay Smith. The approval should be a simple quick process and not take more than a couple of days. On completion of the project the final section of the form will have be completed to comply with the ethical approval. If internal approval is obtained the reference number 09/H0405/33 can be quoted in all related publications.

Please note: any collaborator working outside the University of Birmingham would have to provide **evidence of a valid local ethics research committee approval** and **support from their institution**.

Process for Utilising Generic Ethical Approval for Research on Teeth held within the Tissue Bank under HTA License number 12313 and Ethical Approval Number: 14/EM/2811

This document outlines the process necessary to perform research on extracted teeth under the Dental School's generic ethical approval. Please read carefully and complete the "Application Form".

Before completing the application form please read the SOPs highlighted below which can be found in the relevant appendix.

Section 1: Consent – Appendix 1

Section 2: Collection, Storage and Distribution of Tissue Samples – Appendix 2

Project Submission Protocol:

For research to be carried out on human teeth from the tooth bank approval has to be sought from the CREG (Phil Tomson [PLT] and Iain Chapple [ILC]). Applications should be submitted to **Gay Smith Floor 3, Research Laboratories** using the appropriate form which is attached on the next page (*Appendix 3*). Applicants must have completed the online MRC HTA training module and the BCHCFT training on Consent..

PLT and ILC will assess the application on behalf of the CREG to ensure that they fall within the remit of the generic ethical approval 14/EM/1128 gained 10th Nov 2014 (*Appendix 4*).

Researchers from the University of Birmingham or their collaborators would be able to apply for samples from the tooth bank. Any collaborator working outside the University of Birmingham would have to provide **evidence of a recognised research ethics committee approval and support from their institution and of a relevant materials transfer agreement (MTA) with Birmingham Community Healthcare Foundation Trust (BCHCFT).**

If internal approval is granted then this project is logged and tissue samples are released when required through a requisition log system managed by Gay Smith and submitted annually to the Human Tissue Authority. It is anticipated that approval should be granted within three days of receipt of the completed form. The application form will be logged with the **BBC CLRN RM&G Consortium Office**, who will manage the research management and governance support that is necessary for the approval to be deemed valid via the Human Research Authority (HRA) process.

Researchers should also submit their mini CV (1-2 pages maximum). This must be validated by the researchers own dated signature, and, where appropriate, clearly state their current substantive NHS employer or who their NHS honorary contract is with (normally BCHCFT for Dental School).

When the project is concluded the final section of the form should be completed and a copy sent by Gay Smith to the RM&G Consortium Office for HRA governance procedures.

In the event of any conflicts of interest or grievances with regard to the applications procedure to the research committee, these should be put in writing to the Designated Individual (Iain Chapple) who will manage through the appropriate school committee.

Appendix 3: Application for Human Extracted Teeth from Birmingham School of Dentistry Tooth Bank

PRE STUDY		
Name: Email: Phone: CV Attached: Completed MRC HTA e-training		Research Supervisor: Consortium R&D No:
Project start date:		Estimated finish date:
Title:		
Aims and Objectives:		
Outline of methodologies:		
Estimated number of teeth required:		
MID-STUDY TOOTH DISPENSING LOG		
Number of teeth	Date	Released by (Print Name & Signature)
POST STUDY SUMMARY		
Finish date:		
Number of teeth used:		
Method of disposal:		
Study outcomes:		

Any collaborator working outside the University of Birmingham is required provide **evidence of a valid local ethics research committee** and **support from their institution**.

Appendix 4: Birmingham School of Dentistry Approval

Internal authorisations confirm:	✓
1) This project falls within the remit of Generic Ethical Approval 09/H0405/33	
2) This project is not a clinical trial	
3) The researcher's suitability to undertake this project has been assessed	
4) This project will not be delegated to sub-contractors	
5) There are no risks to NHS duty of care	
6) Acceptance of project costs	
7) Feasibility of conducting the project protocol	
8) Adequate facilities are available for implementing project	
9) Any implications for support departments have been assessed	
10) Applicant has completed MRC HTA online training module & BCHCFT Consent training	

Authorised by:

Phil Tomson*

Iain Chapple*

* Delete as appropriate

Signed:

Date:

Please return this to CLRN RM&G Consortium Office by one of the following methods:

Scanned copy by e-mail:

consortiumrmg@uhb.nhs.uk

Fax:

0121 627 2843

Post:

BBC CLRN RM&G Consortium
Unit 1, West Wing, Institute of Research and Development,
Birmingham Research Park,
Vincent Drive,
Birmingham B15 2SQ

CURRICULUM VITAE

Name:	
Present appointment: <i>(Job title, department, and organisation.)</i>	
Address: <i>(Full work address.)</i>	
Telephone number:	Email address:
Qualifications:	
Professional registration: <i>(Name of body, registration number and date of registration.)</i>	
Previous and other appointments: <i>(Include previous appointments in the last 5 years and other current appointments.)</i>	
Research experience: <i>(Summary of research experience, including the extent of your involvement. Refer to any specific clinical or research experience relevant to the current application.)</i>	
Research training: <i>(Details of any relevant training in the design or conduct of research, for example in the Clinical Trials Regulations, Good Clinical Practice, Consent, HTA MRC training or other training appropriate to non-clinical research. Give the date of the training.)</i>	
Relevant publications: <i>(Give references to all publications in the last two years plus other publications relevant to the current application.)</i>	
Signature:	Date:

Appendix 1

Standard Operating Procedure for Obtaining Consent for the use of “Waste Teeth” from NHS Patients.

Background

This SOP is concerned with obtaining informed verbal consent from patients for the retention, storage and use of waste tissue for research purposes within Birmingham Dental School and Hospital. It does not cover formal research projects where ethical approval and formal written consent is required. This is to be read in conjunction with Birmingham Community Healthcare Foundation Trust (BCHCFT) “for consent to examination and treatment” – see HTA protocol file.

For the purposes of this SOP, *waste teeth* refers to tissue obtained as part of a procedure that is performed on a patient for clinical reasons, but which is not required for diagnostic purposes, and which would otherwise be discarded alongside other clinical waste.

Protocol for Obtaining Consent to Retain Extracted Teeth

- The consent process must 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.
- Explain to the patient that the teeth concerned are waste tissues that have no diagnostic value and would normally be carefully discarded.
- Explain that such teeth can be useful for experimentation in various studies, e.g. we frequently need to try out new stains or to extract proteins, but no diagnostic information will be obtained that may result in new discoveries concerning issues that affect that patient’s care or management.
- Explain that the teeth will be anonymous at the point of collection and completely un-identifiable in the laboratory.
- If in poor condition or unsuitable, the teeth may be disposed of immediately within the laboratory.
- The research performed may be any type of unspecified research, but any extracted cells/tissue will not be immortalised to create cell lines.
- The teeth may be stored for many years in a secure environment and if ever discarded, they will be discarded according to correct Trust protocols (by disposal in anatomical waste bins or amalgam waste containers for those teeth containing amalgam).
- If the patient agrees to the storage and use of their waste teeth, record this fact in their clinical notes and date and sign the entry. The term “CRT” may be used (Consent to Retain Teeth).

- If the patient refuses to donate their extracted teeth and does not wish to retain them themselves, then the teeth are placed in a yellow burn bin with routine clinical waste.
- Place the teeth in the designated container in ground floor (Oral Surgery), first floor (R1 and R3), second floor (R2 and R4) and GA facility.
- Extracted teeth will be collected weekly or upon request by a nurse by a designated technician.
- Due to the nature of storage of the material, it will not be possible to withdraw waste extracted teeth once donated.

Appendix 2

RECEIPT AND STORAGE OF HUMAN TEETH.

Extracted teeth are collected from the Oral Surgery Clinic (ground floor), Restorative clinics 1 & 3 (floor 1), Restorative clinics 2 & 4 (floor 2) and the GA facility of the Birmingham Dental Hospital.

Teeth are collected for histological, biochemical and molecular characterisation of human dental tissue and cells. Depending on the protocol being followed, the teeth may be collected in 10% neutral buffered formalin, sterile saline/PBS, culture media or 15mM sodium azide.

Protocol

On Receipt of the teeth

10% Neutral buffered formalin.

20 ml of 10% Neutral buffered formalin are placed into a sterile universal container. Teeth collected in this solution are fixed for 4 days then washed in running tap water for about 1 hour. The formalin is discarded in a designated sink. The teeth are either processed for histological examination or stored at -20°C in the Tooth bank freezer. Collection pots are washed thoroughly.

15mM Sodium azide

Teeth required for biochemical analysis are collected in 15mM sodium azide, which is used as a bacteriostat. Approximately 200ml of the relevant solution are placed in a plastic screw top pot, the lid of which has been modified to house a removable silicon bung which allows the staff on the clinic to place teeth into the pot with minimal risk of any splashing. The pot is labelled with appropriate hazard signs.

Waste solution and blood from the specimens are washed down a designated sink with copious amounts of water and the teeth washed under running water for several hours. The teeth are then stored at -20°C. The collection pots are washed thoroughly in running water prior to soaking in a 10% bleach solution overnight, before finally being rinsing in tap water.

For teeth collected in sterile saline, PBS or Media

Teeth collected in sterile saline, PBS or culture media are generally required for their pulps and are used immediately following extraction. The teeth are collected in sterile universals containing about 20 ml of the required solution.

Waste solution is treated in 10% bleach and collection pots are disposed of in the clinical waste.

Waste Teeth

Waste teeth containing amalgam are disposed of in the 'amalgam waste bin labelled for 'Human Teeth Only'. All other teeth and associated tissues are disposed of sharps bins marked 'Human Teeth Only'.

Storage and Archiving.

The total number of teeth collected from the clinics is recorded in the tooth log prior to sorting the teeth into types required for various on-going teaching and research projects. This should include teeth that are collected for immediate use also.

Teeth are selected and stored in appropriately labelled plastic boxes at -20°C in the School of Dentistry Tooth Bank. Their numbers and storage box numbers are recorded in the Tooth log, held in the Freezer Room 3-RLA-18 in the research laboratories, along with the number of teeth discarded. The date and the donating clinic are also noted.

The total number of teeth stored and distributed is recorded in the Monthly tooth log.

Adverse Event

In the event of there being a problem with the Tooth Bank freezer the teeth can be removed and stored temporarily in a -20 chest freezer located in the General Laboratory 3-RLA-11 in the Research Laboratories

Requisition for Teeth

Persons requiring teeth for teaching purposes must fill in the “Requisition for Teeth Form”, giving their name, the date and supervisor of the project along with brief details of the work to be undertaken. The teeth will be sorted and supplied by designated personnel. The number and type of teeth supplied will be recorded in the tooth log and the method of disposal will be discussed and recorded.

Persons requiring teeth for research purposes must submit an application to the school Research Committee (See Summary Of Tissue bank Management section 3 Project Submission Protocol). Once approval is obtained a file is set up containing a tooth dispensing log. For researchers external to these premises proof of ethical approval must be provided copied and signed.