Research Tissue Bank Management Protocol

Project Title:	Childhood Ocular Inflammatory Disease Research Tissue Biobank (CHOIR)
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Signatures

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1 ABBREVIATIONS

CHOIR	Childhood Ocular Inflammatory Disease Research
DI	Designated Individual
PI	Principal Investigator
GCP	Good Clinical Practice
HTA	Human Tissue Act / Human Tissue Authority
ICF	Informed Consent Form
NRES	National Research Ethics Service
PIS	Participant/ Patient Information sheet
R&D	NHS Trust R&D Department
REC	Research Ethics Committee
RTB	Research Tissue Bank
SOP	Standard Operating Procedure

2 BACKGROUND

Childhood uveitis (intraocular inflammation) comprises a heterogenous group of rare disorders. The UK incidence of childhood uveitis has been indirectly estimated at 5/100,000 children per annum, consistent with other industrialised nations. These disorders are classified anatomically (anterior, intermediate or posterior structures), or by the presence of associated systemic disease. An estimated 40% to 60% of children with uveitis have Juvenile of disorders, which are characterised by chronic joint inflammation that develops under the age of 16 and persists for more than 6 weeks.

Between 10% - 25% of children affected by uveitis reach adulthood having permanently lost

Tears obtained using filter paper strip (Schirmer strip) collection

Tissues considered excess from surgery on the eye including uveal tissue (iris samples) and intraocular fluid (aqueous)

Stool / faeces

Saliva

4.2.2 The data collected will include:

Basic information including patient's hospital and NHS number, age and sex, ethnic group, sample site and nature of the tissue obtained will be collected. Information regarding clinical

5 PROCEDURES

5.1 Donor identification

Potential donors will be identified initially by clinicians/nurses caring for the patient or by trained health care professionals in pediatric or adult ophthalmology and rheumatology clinics.

5.2 Informed Consent

5.2.1. From young people / adults

Informed consent will be collected according to the HTAs Code of Practice on consent. The patient or healthy volunteer will be approached for consent by a research nurse, doctor or trained assistant as appropriate. Consent forms can be found in the **Appendix.**

The consent discussion will be noted in the medical record along with the signed consent form. When a patient gives consent for donation, the CHOIR Biobank will be informed by direct contact between the clinical teams and Biobank members. A copy of the consent form will be retained in the CHOIR Biobank records in support of sample and data collection.

5.2.2. From parents/guardians

The parents of children up to 16 years of age will be approached by their consultant, a member of their clinical team or a member of the research team, to ask if they are happy to

appropriate written consent obtained. Parents and children will be aware that any decision they make will not impact on their treatment in any way and that they are free to withdraw consent at any time.

Young people whose parents / carers have consented to their participation in the study will be reapproached for consent - when they reach age 16 years.

6 MANAGEMENT OF THE CHOIR BIOBANK

Day to day activities will be overseen by the CHOIR Biobank manager or deputy manager who will act under the guidance of ICH R&D Governance and the HTA representative. Operational matters such as equipment maintenance and tracking of samples will be the responsibility of both CHOIR and UCL. Governance and policy matters for the Biobank will be the responsibility of ICH R&D Governance. We will comply with the following HTA requirements:

The CHOIR Biobank manager and PIs will attend the HTA training at ICH and will read online material (go to https://www.hta.gov.uk/hta-codes-practice-and-standards-0)

CHOIR Biobank freezers will be on alarm system, labelled with HTA stickers with contact name and number, and stored in rooms with coded access doors.

The CHOIR Biobank manager will manage the use of the system/database that allows all samples to be traced.

6.1 Tissue Procurement

6.1.1 Tissue collection centres

The CHOIR Biobank will collect and store samples collected from:

Great Ormond Street Hospital

6.1.2 Collection numbers

Initially we aim to accrue samples from no more than 50 individuals annually.

If the CHOIR Biobank were to acquire financial support we would aim to collect and store samples from approximately 250 individuals/annum. We shall seek donors from centres

All user access applications will be received by the CHOIR Biobank manager and will be checked to ensure that the type and quantity of samples requested are available for issue. If the required samples are available in the Biobank, the researchers will be requested to submit a written application that includes the Principa

access to patient identifier will be linked by a hospital number that can only be accessed from the NHS Trust database that supplied the material. All documents will be stored securely and only accessible by CHOIR Biobank staff and authorised personnel. The study will comply with the Data Protection Act that requires data to be anonymised as soon as it is practical to do so.

The patient information sheets reflect the guidance produced for researchers and study coordinators on the implications of the GDPR for the delivery of research in the UK. (https://www.hra.nhs.uk/hra-guidance-general-data-protection-regulation/)

7.2 Donors with language difficulties

Potential donors with special communication needs will be approached by the healthcare team responsible for the patient with the help of translators provided by the relevant NHS Trust. Every effort will be made to provide potential donors with an information leaflets written in their native language. Consent will only then be obtained with the help of translators provided by the Trust. If there are any concerns that the donor does not fully understand samples will not be taken.

7.3 Informing participants of clinically relevant research

Results for individual patients from initial research studies will not be relayed back to the patient their hospital doctor or their GP. The CHOIR Biobank is a research facility and does not conduct diagnostic tests. It is explicitly clarified in the consent form that the donors will not be notified of results of research carried out on their specific samples.

7.4 Withdrawal of consent

Each sample is allocated a unique identifier and is linked to clinical details by means of a stand-alone computer database and paper records. Any sample which is released by the CHOIR Biobank will have details recorded including date of release, PI of the project, title of the project, type of tests to be performed and whenever applicable date of return, and in case of destruction, reason for destruction, date of destruction and by whom. If donors withdraw

8 DATA HANDLING AND RECORD KEEPING

8.1.5 Audits

Records including annual audits of sample numbers, access committee decisions and MTAs will be stored electronically with the CHOIR Biobank manager. These will be stored on a secure PC and backed up through a cloud-based file hosting service.

8.2 Data preservation

Records in all formats containing personal data will be created, stored and disposed of in

of practice. All primary data will be retained for no longer than the
retention schedule.

8.3 Data security

8.3.123 Data security standards

Data subjects have a right of access to their personal data, including some unstructured manual personal data. Subject access requests must be made in writing
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these collaborations will be charged for. This additional income will help underwrite some of the long term salary costs.

10 REFERENCES

Rahman N, Petrushkin H, Solebo AL. Paediatric autoimmune and autoinflammatory

11 APPENDIX

11.1 List of other appropriate documents

	APPROVED VERSION / DATE
PATIENT INFORMATION SHEET (PARENT)	

ASSENT FORM (CONTROL SIBLING)