TAYSIDE MEDICAL SCIENCE CENTRE RESEARCH GOVERNANCE POLICY

CLINICAL RESEARCH PROJECTS INVOLVING HUMAN TISSUE

POLICY NUMBER:	TASC POLICY 010 v3
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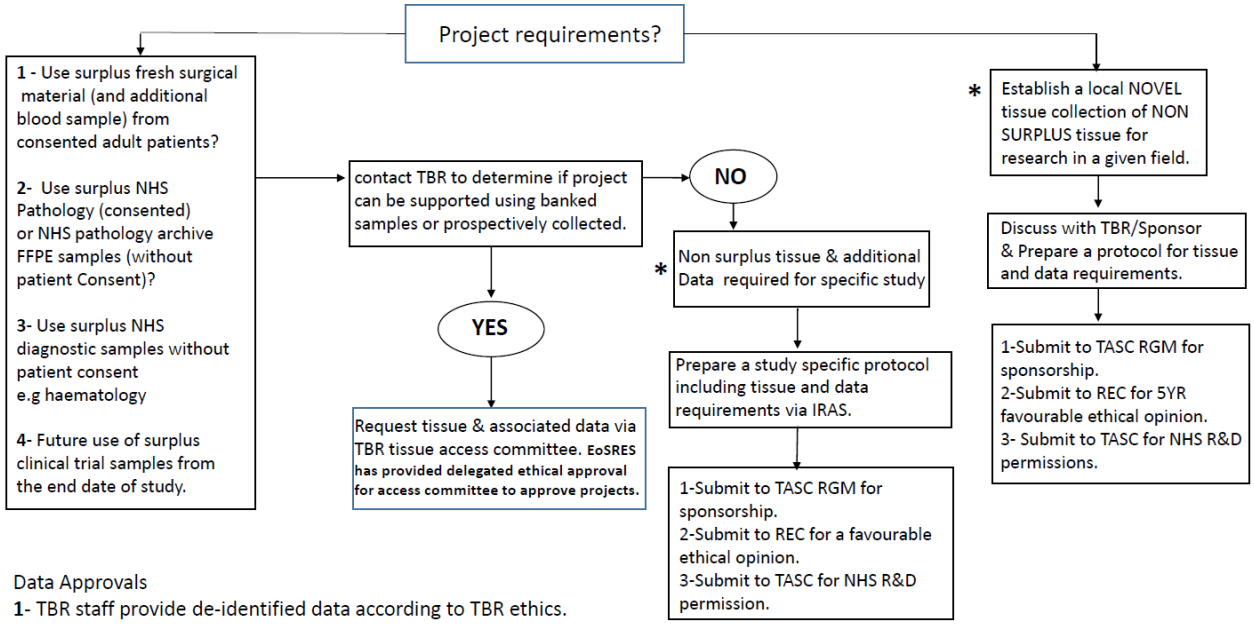
EFFECTIVE DATE:	05 May 2022
REVIEW DATE:	05 May 2024

1 Applicability and Purpose

This policy applies to a) TASC staff involved in the sponsorship, ethical approval, R&D approval or management of projects that involves the use of human tissue b) all staff and students whose duties or research involve the collection, transport, storage and use of human tissue and c) staff within the Tayside Biorepository (TBR).

The purpose of this policy is to ensure that projects that require the collection of human tissue and associated data within the University of Dundee are approved though the most appropriate channel and that tissue collections held out-with the Tayside Biorepository are registered and maintained.

2 Approvals for projects that require human tissue and associated data



Data Approvals
1- TBR staff provide de-identified data according to TBR ethics.
2- TBR staff provide de-identified data according to TBR ethics.
3- Researcher to obtain Caldicott approvals for data and notify TBR manager or contact the Tayside Safe Haven.
4- Future use of clinical trial data is via the Custodian and must comply with local data policies and regulations.
*- Data approvals through sponsor & Caldicott or contact the Tayside Safe Haven.

3 Registration of human tissue with Tayside Biorepository

Human Tissue must be acquired, treated, stored and disposed of with respect. All work involving the use of relevant human tissue within the University of Dundee must be conducted using best practice in accordance with the guidance and direction from the Human Tissue (Scotland) Act 2006 and Scottish Accreditation of Tissue Biorepositories.

The Tayside Biorepository is responsible for overseeing the governance of all local collections of human tissue intended for use in research within the University of Dundee/NHS Tayside ("internal" use) or human tissue transferred by the University of Dundee for use in research by a third party ("external" use). This includes tissue that has NHS Research Ethics Committee (REC) approval and includes Clinical Trials of Investigational Medicinal Product (CTIMPs) and Non CTIMPS that collect human tissue samples from NHS patients.

Tissue collections must be registered with Tayside Biorepository to provide information about the type of tissue, the number of samples and where these samples are stored within the University of Dundee/ NHS Tayside. It is important that registrations are monitored regularly to ensure that the information is up to date and relevant. At the end of a clinical study the biorepository must be informed so that appropriate support can be provided if required for the registration, future use or destruction of tissue samples especially where staff may be due to leave NHS Tayside or University of Dundee.

Tayside Biorepository shall provide the following:

1- Tayside Biorepository manager will support all registrations.

2- An annual reminder letter to register new collections or update existing collections shall be sent to researchers as a Hot Tip by the Tayside Biorepository manager.

3- Tayside Biorepository shall support in making surplus tissue more widely available or if appropriate shall support disposal of samples.

DOCUMENT HISTORY

Version Number	Edited by (Job Title)	Effective Date	Details of editions made
1.0	Sharon King Tayside Biorepository Manager	14/01/2019	New.
2.0	Sharon King Tayside Biorepository Manager	05/05/2020	Clarification on when to register sample collections with TBR and the support that TBR can provide to researchers
3.0	Sharon King	05/05/2022	Amendment to heading and flow diagram (section 2).

APPROVALS

Sign		Date
APPROVED BY: *Signature* Linda Martindale	Dr Linda Martindale, Interim Dean, School of Health Sciences, University of Dundee – on behalf of TASC Research Governance and Oversight Committee	27.04.22
APPROVED BY: *Signature*	Professor Russell Petty, R&D Director, NHS Tayside	24 MAY 2022