The Sheffield Biorepository

Pathology Bank Consent Policy Statement

Document History	
Document Number	*BIO:Policy:11*
Created By	*Dr Simon Cross*
SUPERSEDED	*Steven Haynes*
Version	*1.2*
Date	*19/02/2019*
Review Date	*19/02/2020*
Approved by	*Kevin Corke*

The University Of Sheffield.

1. Background

This policy statement covers the consent of tissue collected and stored as part of the Sheffield Pathology Tissue Bank. The tissue bank contains a legacy of tissue stored before the Human Tissue Act was passed and tissue that was sampled as tissue surplus to diagnostic requirements from therapeutic operations and so not requiring patient consent.

2. Consent statement

The two types of specimens which we have collected since the enactment of the Human Tissue Act are diagnostic resection specimens of brain tumours and therapeutic resection specimens of soft tissue sarcomas.

In all cases the tissue that we sample for the tissue bank is taken in such a way as to not compromise the reporting of the resection specimen i.e. these samples are small, are not taken from any of the resection margins of the tumour and are not taken from apparently unique areas of the team. These specimens are thus essentially surplus to the diagnostic requirements of reporting the specimen. However there are some instances in which fresh frozen tissue from the tumour will be required for a diagnostic test that cannot be carried out on paraffin embedded material. In such a case material could be taken from the tumour tissue bank and transferred to the NHS in order to those diagnostic tests to be carried out. We thus wait for a period of three months to elapse before determining that the small samples in the tumour tissue bank are entirely surplus to diagnostic requirements. After that time we continue to store these samples and they are then available for research purposes provided that the researcher has obtained specific Ethics Committee approval and specific NHS trust R&D approval.

Because of the route of acquisition of tissue into the tumour tissue bank we recognize that it will not be possible to obtain the overarching Ethics Committee approval to dispense tissue from the tumour tissue bank without the individual researcher having their own specific Ethics Committee approval. All tissue dispensed from the tumour tissue bank is dispensed in anonymised format from which the personal details of the patient cannot be retrieved. The basic processes described above are summarised in the two upended flow diagrams.

Since the material that is collected in the tumour tissue bank is surplus to diagnostic requirements (once the initial 3 months period has passed) and is dispensed in an anonymised fashion we believe that its use falls within Sections 1(8) and 1(9) of the Human Tissue Act, which allow the use of anonymised archival residual tissue from operations in biomedical

research without specific patient consent provided that this research has received appropriate ethics committee approval.

3. Associated Documents

	Document	Document Reference
1	HTA code of practice	BIO:POLICY:07
2		
3		