

Teenage & Young Adult Wessex Vivo bio bank standard operating procedure

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Description	This Operational Policy sets out the agreed arrangements of the Teenage & Young Adult (TYA) Principal Treatment Centre (PTC) University Hospital Southampton NHS Foundation Trust (UHS).		
Level and type of document	Level 2: applicable to a specified department, care group or division Standard operating procedure – controlled document		
Target audience	Health Care Professionals looking after patients who are diagnosed with a malignant disease between their 16th and 25th birthday. Members of TYA Core and Wessex Network		
List related documents / policies (do not include those listed as appendices)	Teenage & Young Adult 16-18 Diagnostic Pathway (CANC006) YA 16-18 pathway flowchart v2.0 (CANC007)		
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1 Version control

Date	Author(s)	Version created	Approval committee	Date of approval	Date next review due	Key changes made to document
01/11/2024	Wendy Spencer/ Jo Grout TYA Research Team	1.0	Cancer care Governance Group	12/2/25	07/05/2026	New document

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3 Introduction

This Operational Policy sets out the agreed arrangements of the Teenage & Young Adult (TYA) Principal Treatment Centre (PTC) University Hospital Southampton NHS Foundation Trust (UHS). This policy takes into account the requirements of NICE Improving Outcomes Guidance (IOG) for Children and Young People with Cancer (2005, revalidated 2014), relevant cancer site-specific IOGs, the NHS Manual of Cancer Service Quality Measures (2011 update) and the NHS England Specialised Service Specifications for TYA cancer services (2023). The Policy will be reviewed regularly by the TYA Lead Clinician and Lead Nurse.

The Teenage & Young Adult (TYA) Service Specification (1747) published May 2023 specifies that the TYA Principal treatment Centre must ensure that service users are offered the opportunity to have tumour samples banked. In partnership with the TYA Team, TYA Research Team, and Cellular Pathology team as a core service requirement.

Although considerable progress has been made in the treatment of Children and Young People (CYP) cancer, leukaemia and bone marrow failure disorders, future advances are likely to be made through a greater understanding of the underlying biology. To carry out studies of the biology of these CYP disorders, it is vital to have access to large series of samples from these individually rare conditions. These samples need to be of high quality, be pathologically verified, and linked to relevant clinical and genetic data. The VIVO Biobank is formed from a merger of two existing, successful biobanks, the CCLG (Children's Cancer and Leukaemia Group) Tissue Bank, established in 1998, and the Childhood Leukaemia Cell Bank set up under the auspices of Leukaemia Lymphoma Research (LLR; formerly the Leukaemia Research Fund, now Blood Cancer UK) in 2003.

Almost universally, families and young people wish to see some good come out of the difficult situation in which they find themselves. There is widespread support from families of young people with cancer, leukaemia and bone marrow failure disorders, to consent for use of their child's/their own samples in research. This then helps in further understanding of their child's/ their and other children's/young people's cancer.

In many cases, the biology of tumours in the TYA population may be different to that of older adults. We therefore now aim to build on the successes of the CCLG Tissue Bank and the Childhood Leukaemia Cell Bank to bank tumour samples for research from teenagers and young adults, to facilitate research towards a greater understanding of the biology of their cancers.

VIVO Biobank is funded jointly by Cancer Research UK and Blood Cancer UK until 30th June 2027.

4 Scope

This SOP is written to provide procedural and clinical governance support /advice on the pathways for Vivo bio bank tumour sample collections within TYA in partnership with the TYA research team and Cellular Pathology department, to ensure tumour banking is offered for all eligible service users as a core requirement of The Teenage & Young Adult (TYA) Service Specification (1747) published May 2023.

5 Aim/Purpose

The aim of the policy is to inform staff in the hospitals, services and departments that are served by the Southampton TYA PTC of the organisation of the PTC and the TYA MDT. This is to ensure we provide equitable high quality patient services, i.e. the right treatment and age-appropriate care, from the right person or team, in the right place, at the right time.

This policy applies to all patients diagnosed with a malignant disease between their 16th and 25th birthday. Patients with certain pre-malignant or benign conditions specified by the relevant site-

specific pathways should also be notified to the TYA service and joint management plans agreed with the TYA MDT.

The aim is to merge the existing Blood Cancer UK Childhood Leukaemia Cell Bank and the Children's Cancer & Leukaemia Group (CCLG) Tissue Bank to create and maintain, with appropriate consent, a national bank of stored tissue samples from children and young people (CYP) with cancer, leukaemia or bone marrow failure disorders, and some benign tumours, suitable for use in biological research projects that aim to improve understanding, diagnosis and treatment of cancers in these age groups. To enable all centres treating CYP with cancer, leukaemia or bone marrow failure disorders, and some benign tumours to routinely take, store and dispatch tissue samples for storage in VIVO Biobank, with appropriate consent, for use in current and/or future research.

To make available to researchers, through a centralised scientific and ethical review process, suitable tissues from VIVO Biobank for projects approved by the VIVO Biobank sample Data and Access Committee following scientific peer review.

To link biological samples with demographic, clinical, treatment, outcome and genetic data held in local and national databases. This includes whole genome sequencing (WGS) data generated by Genomics England as well as a data in the patient care record.

6 Definitions (if necessary)

Standard Operating Procedure (SOP):	A SOP is a set of instructions to be followed in carrying out a given operation, or in a given situation, which lend themselves to a definite or standardised procedure without loss of effectiveness.
Vivo bio bank	tumour banking to be offered for all eligible service users as a core requirement of The Teenage & Young Adult service specification.
TYA	Teenage & Young Adult- refers to patients diagnosed with a malignant disease between their 16th and 25th birthday.
CYP	Children and Young People- refers to anyone from birth to the age of 25.

7 Details of procedure to be followed.

Procedure see [appendix A - process flow chart for cancer type](#).

7.1 Patients identified as suitable for tumor banking.

7.2 Cancer record of discussion/ consent

7.2.1 1.Purpose

A record of discussion is an essential part of the tumour banking process. It documents that patients have received all the relevant information that they need to make an informed decision and documents their decision to consent for tumour samples to be used for future research.

7.2.2 2. Scope

Records of discussion are not role specific but should only be performed by those who have been trained in how to do so. As the record of discussion also discusses participation in the Vivo bio bank, it is advisable to have up to date good clinical practice (GCP) training and ideally informed consent training, especially for individuals who are not registered healthcare professionals. 16 years of age is the age of consent for tumour banking consent. 'Young people 16 and 17 years are presumed to have capacity to consent for themselves' with no need for Gillick competency assessments. For further information please refer to the documents below.

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/research-tissue-banks-and-research-databases/research-tissue-banks-faqs/>

7.2.3 3. Prerequisites

Patient eligibility inclusion criteria

- All TYA in the United Kingdom and Ireland with a suspected or established diagnosis of cancer, leukaemia or bone marrow failure disorders, or some benign tumours, and who are having a diagnostic or therapeutic tissue sampling procedure. There is no strict upper age limit as some samples may come from patients aged >24 years but with paediatric-type cancer.
- Documented informed consent is appropriately provided from the patient and/or parent/guardian.
- Patients in the above categories who have died of, or with an eligible disease, and where informed post-mortem consent has been obtained from a parent/guardian.

Patient exclusion criteria

- Patients known to be infected with HIV, hepatitis B or any other agent posing an infection risk from unfixed material.
- Inability to obtain informed consent from patients or their parent/guardian(s).

Prior to the record of discussion, the patient should have been given the relevant information on Vivo bio bank tumour banking and have an appointment booked for the record of discussion which can be completed face to face or remote.

Post discussion the completed record of discussion form should be uploaded to EDMS recorded on edocs under non speciality documents and patient participation recorded on trial spreadsheet on teams.

Informed consent will be requested from the patient for the collection, storage and use of tissue samples. These samples may be taken at the same time as clinically mandated tests, or as samples surplus to diagnostic needs. Consent procedures will be in accordance with the requirements of the Human Tissue Act.

It is the responsibility of all centres to ensure that appropriate informed consent has been obtained and retained locally, and to document when consent has been obtained and by whom. Patients consent will be uploaded to the patients edocs records. Consent records must be available for inspection as part of external audits requested by VIVO Biobank or the Human Tissue Authority (HTA).

7.2.4 4. Sample Collection

The relevant site-specific pathway protocol will be followed for the required sample collection.

For solid samples, sample receipt, processing, storage and transfer to the Newcastle central Biobank facility will take place at Principal Treatment centres in close liaison with the VIVO

Biobank managers and other members of the Biobank research team. - Samples will be stored locally and collected at regular intervals to be stored at Newcastle Biobank.

For liquid samples, sample receipt, processing, storage and dispatch will take place at UK Biocentre in close liaison with the VIVO Biobank managers. Samples should be sent immediately same day where possible to Uk Bio centre Milton Keynes. If this is not possible sample should be stored as directed in the following sop- Z:\DivC\Paeds\SHARE\PB Research Office\PAED ONC CLINICAL TRIALS\OPEN TRIALS\VIVO\SOPs

The patient registration form should be sent to – e.cragg@nhs.net, emma.paizes@nhs.net, t.adetoro1@nhs.net, or anne.thomson6@nhs.net.

8 Implementation

The SOP will be displayed on the Staffnet, sent to the relevant Care Group clinical teams and shared with the Wessex Network with the expectation it will be cascaded to all relevant staff. All medical and nursing staff caring for Teenagers and Young Adults should have knowledge that this testing service is provided where the consultant deems appropriate and the contents of the guideline.

9 Roles and responsibilities

This Operational Policy sets out the agreed arrangements of the Teenage & Young Adult (TYA) Principal Treatment Centre (PTC) University Hospital Southampton NHS Foundation Trust (UHS) and Designated Hospitals across the Wessex region.

All staff who work with TYA cancer patients have a responsibility to ensure that they are aware of this SOP and its contents. They should clearly document their rationale if they have not complied with the recommendations detailed in this SOP. It is the responsibility of department managers, consultants, team leaders and education leaders to ensure appropriate staff are aware of this SOP.

10 Document review.

All Trust policies will be subject to a specific minimum review period of one year; we do not expect policies to be reviewed more frequently than annually unless changes in legislation occur or new evidence becomes available. The maximum review period for policies is every three years. The author of the policy will decide an appropriate frequency of review between these boundaries.

Where a policy becomes subject to a partial review due to legislative or national guidance, but the majority of the content remains unchanged, the whole document will still need to be taken through the agreed process as described in this policy with highlighted changes.

This Teenage & Young Adult Wessex Vivo bio bank standard operating procedure will be reviewed after one year as a new document and then again in two years.

11 Process for monitoring compliance.

The purpose of monitoring is to provide assurance that the agreed approach is being followed. This ensures that we get things right for patients, use resources well and protect our reputation.

Our monitoring will therefore be proportionate, achievable and deal with specifics that can be assessed or measured.

Key aspects of this policy will be monitored:

Element to be monitored	All patients discussed at TYA MDT and deemed appropriate for Tumour banking have been offered.
Lead (name/job title)	TYA Research Team
Tool	Edocs/ MDT Records
Frequency	Annually by Audit
Reporting arrangements	Core members of TYA MDT, Wessex Network members will receive a copy of the annual audit.

Where monitoring identifies deficiencies actions plans will be developed to address them.

12 References

VIVO Biobank Protocol v1b August2023 IRAS reference number: 3278

13 Appendices

13.1 Appendix A : Vivo Bio Bank for TYA Cancer Patients.

<https://staffnet.uhs.nhs.uk/TrustDocsMedia/DeptDivSpecific/DivB/Cancer/TYO-tumour-banking/TYA-VIVO-BioBank-Flowchart-Appendix-A.pdf>