University Hospital Southampton
NHS Foundation Trust

Teenage & Young Adult Wessex Whole Genomics Sequencing standard operating procedure.

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Description	Teenage & Young Adult Wessex Whole Genomics Sequencing standard operating procedure		
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)			
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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
15/05/24	Jo Grout/ Wendy Spencer	1.0	Cancer Care Governance	15/05/2024	15/05/25	New document
04/02/2026	Jo Grout/ Wendy Spencer	2.0	Cancer Care Governance	10/06/2026	01/06/2029	Amendment to process flow chart for clarity. Addition of MDT definition.

2 Index

3 Introduction/executive summary

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.

Genomics is the study of the genes in our DNA, their functions and their influence on the growth, development and working of the body – using a variety of techniques to look at the body's DNA and associated compounds. Cancers are caused by changes in the DNA of a cell which leads to the uncontrolled replication of cells. Some members of the population have variations in their DNA which can also put them at higher risk of developing cancer, these can be passed down from parent to child.

A whole genome sequencing test for cancer may help the patient and healthcare professional to understand:

- Why a patient developed cancer
- The type of cancer a patient may have and how it may behave
- Which treatments may be most effective
- If the patient is at risk of developing other cancers in the future (germline findings)
- Whether family members may be at a higher risk of developing cancer
- The UK is recognised worldwide as a leader in genomics, and the unique structure of the NHS is allowing us to deliver these advances at scale and pace for the benefit of patients and their families.

4 Scope

This SOP is written to provide procedural and clinical governance support /advice on the pathways for Whole Genome Sequencing (WGS) within TYA in partnership with the Genomic Laboratory Hub and pathology departments, to ensure WGS for all eligible service users as a core requirement of The Teenage & Young Adult (TYA) Service Specification (1747) published May

2023. It is worth noting that the National Genomic Test registry for cancer classifies anyone under 25 as paediatric.

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 Principle Treatment Centre (PTC) of the organisation of the PTC and the TYA MDT, in order to 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.

6 Definitions

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
Whole Genomic Sequencing (WGS)	Study of the genes in our DNA, their functions and their influence on the growth, development and working of the body
Multi-Disciplinary Team (MDT)	Team of professionals to ensure a consistent, safe, and high-quality approach to managing TYA patients brought together in a meeting to provide clinical expertise to guide care.

7 Details of procedure to be followed

Procedure see appendix A - process flow chart for cancer type.

7.1 Patients identified as suitable for Whole Genomic Sequencing

While all TYA patients with cancer are all potentially eligible for cancer WGS of paired tumour and germline samples, the decision to proceed should be made by the clinical team based on the availability of a suitable fresh tissue sample and anticipated clinical utility of WGS results according to the specific clinical circumstances. When patients are discussed at MDT, the core MDT members will discuss and document if it is appropriate to offer WGS testing based on likely utility. The decision will be recorded within the MDT outcome.

7.2 Cancer record of discussion

1. Purpose

A record of discussion is an essential part of the whole genome sequencing process. It documents that patients having this test have received all the relevant information that they need to make an informed decision and documents their decision to consent for the test and also their decision for the use of their genomic data and samples to be used for future research in the National Genomic Research Library (NGRL).

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, competency will be assessed by the Whole Genomics Team who will keep a register. As the record of discussion also discusses participation in the NGRL, 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 genomics testing. ‘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.

NHS England- Guide-to-requesting-WGS-cancer-Nov-20.pdf RCP- Consent and confidentiality in genomic medicine Guidance on the use of genetic and genomic information in the clinic 3rd edition, July 2019

3. Prerequisites

Prior to the record of discussion, the patient should have been given the relevant information on whole genome sequencing for cancer and also the NGRL and have an appointment booked for the record of discussion which can be completed face to face or remote.
https://www.england.nhs.uk/wp-content/uploads/2021/07/genome-sequencing-cancer-patient-information-easy-read.pdf

Post discussion the completed record of discussion form should be uploaded to edocs and a copy of the paperwork should be sent to the central and South GLH: bwc.centralsouthglh@hns.net, cc'ing in the Wessex Genomics Laboratory Service (wgs_cancerwgls@uhs.nhs.uk) and the clinical genomes team (WGSwessexgenomics@uhs.nhs.uk) for their reference.

4. Sample Collection

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

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 changes highlighted.

This TYA Wessex Whole Genomic Sequencing SOP will be reviewed after one year as a new document and then again in three 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 WGS testing have been offered.
Lead (name/job title)	Wendy Spencer TYA Wessex Administrator & Project Manager
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

Clinicians guide for requesting whole genome sequencing: cancer - Guide-to-requesting-WGS-cancer-Nov-20.pdf (hee.nhs.uk)

NHS Genomic Medicine Service Record of Discussion form - nhs-genomic-medicine-service-record-of-discussion-form.pdf (england.nhs.uk)

NHS Genomic Medicine Service Genomic Consultee Declaration - nhs-genomic-medicine-service-genomic-consultee-declaration.pdf (england.nhs.uk)

13 Appendices

Appendix A: Whole Genomics Sequencing for TYA cancer patients flow chart