

# SPECIMEN MANAGEMENT POLICY

Department / Service:	SCSD
Originator:	Mat Trotman
Accountable Director:	Clinical Director SCSD
Approved by:	Theatres and Anaesthetics Governance Team
	SCSD Governance
Date of approval:	19th December, 2024
Review Date:	19 <sup>th</sup> December, 2027
This is the most	
current document and	
should be used until a	
revised version is in	
place	
Target Organisation(s)	Worcestershire Acute Hospitals NHS Trust
Target Departments	Theatres, Microbiology, pathology, histology, cytology
Target staff categories	Theatre and laboratory staff

#### **Policy Overview:**

There should be systems in place which reduce the risk of errors when tissue and other product samples are obtained in the perioperative setting and transported to different laboratories across WAHT.

#### **Key amendments to this Document:**

Date	Amendment	By:
16 <sup>th</sup> June 2021	New document approved.	Theatres and Anaesthetics
		Governance.
17 <sup>th</sup> November	Amendments to section 5.6 Sentinel Lymph	Theatres and Anaesthetics
2021	node biopsies.	Governance Team,
		SCSD Governance.
19 <sup>th</sup>	Document reviewed and approved	Theatres Governance
December,		Meeting
2024		

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#### 1. Introduction

Specimens are regularly taken during interventional procedures. It is essential that every specimen reaches the relevant area safely, without undue delay and in optimum condition. This policy will set out the systems that are in place to ensure this should occur with every specimen taken across the WAHT theatres.

#### 2. Scope of this document

This document will cover the handling, transport and collection of all specimens obtained from any theatre within WHAT.

#### 3. Definitions

WAHT - Worcestershire Acute Hospitals NHS Trust

#### 4. Responsibility and Duties

#### 4.1. Role of the senior operating surgeon/clinician

The senior operating surgeon/senior clinician/specialist care practitioner maintains overall responsibility for the harvesting of all specimens from the patients or ensuring a suitable individual is assigned the task.

#### 4.2. Role of the Divisional Managers & Divisional Directors of Nursing

Divisional Managers & Divisional Directors of Nursing maintain overall responsibility for compliance with this policy within their areas. This includes ensuring that Senior Managers have agreed and instigated a structure that ensures all staff have been informed, educated and trained appropriately for completion of the agreed task.

#### 4.3. Role of the Theatre/Departmental Managers

Theatre or Departmental Managers assume responsibility for the implementation of this policy daily. They must also ensure that all health, safety and risk management standards are met and maintained. They will also ensure that regular audits are carried out to monitor compliance with this policy.

#### 4.4. Role of Individual Staff

The Trust expects all staff, including temporary members, to always adhere to the principles of this policy.

#### 5. Policy detail

#### 5.1 Collection of Sample

Specimen identification should begin at the time the specimen is harvested from the
patient. The operating surgeon/senior clinician/specialist care practitioner harvesting
the specimen should clarify what the specimen is, including the site if relevant. The

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theatre practitioner must determine the nature and site of the specimen that is being taken by verifying with the operating surgeon/senior clinician/specialist care practitioner the specimen and site of removal e.g.: left breast lump. This information will then guide staff as to the actions that are required for the specific type of specimen being collected.

- Action should be taken to prevent drying out of specimens. Specimens and cultures should be handed off the sterile field as soon as they are taken, and the surgeon/senior clinician/specialist care practitioner has given consent.
- It is imperative that the theatre practitioner checks whether the sample should be
  placed in a container containing preservative or other transport medium, or whether it
  should be a dry specimen. This decision will be guided by the type of specimen. For
  example, most histopathology specimens will be placed in formalin or other specific
  fixative.
- The theatre practitioner, when applicable should relay this information to the circulating practitioner who will assist in the specimen collection process.
- Selecting an appropriate specimen container is an essential part of the collection process when related to the size and purpose of the container. For example, histopathology specimens should be large enough to ensure the specimen floats freely, is completely covered by appropriate fixative and sealed for transportation.
- All staff must follow standard blood and body substance isolation precautions when
  placing the specimen in the container. Precautions also need to be taken to prevent
  any contamination of the outside of the specimen container.
- All staff should adhere to the Control of Substances Hazardous to Health (COSHH)
  Regulations, and local policies for treatment of splash injuries from specimen fixative
  or body fluids.
- When handling/clearing large volumes of a spill/leak, staff should follow the PPE regulations set out in the COSHH assessment for formalin. They should also ensure to follow the appropriate spill clearing methods. For any emergency situations requiring first aid also see the COSHH assessment for formalin.
- All specimens for microbiology should be placed in a specified biohazard bag which
  is sealed before dispatch. Similarly, any other specific requirements for the transport
  of specimens should be actioned in accordance with local requirements.
- If a specimen is collected & it is then decided by the operating surgeon that it does
  not need to be sent for any investigations, the specimen can be disposed of via the
  appropriate waste management process. The used formalin pot (containing used
  formalin) can then be sent to Biochemistry for disposal as agreed with the Quality
  Manager/Specialist Biomedical Scientist for Cellular Pathology.
- Standard blood and body substance isolation precautions should always be used when handling specimens, as all specimens are considered a potential source of infection.
- If specimens cannot be taken to the laboratory within the specified time limits (e.g. specimens taken at night when there is no collection service) they should be stored in accordance with local instructions from the labs concerned. Some specimens without fixatives may need to be stored in a dedicated specimen fridge at a temperature of 4°C, thus minimising the potential for bacterial growth. However, storage at 4°C is inappropriate for specimens in formalin as this will delay fixation of

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the specimen. Similarly, in the event of blood cultures being collected arrangements should be made for immediate transfer to microbiology in accordance with local policy.

#### 5.2 Documentation requirements

- After checking with the patient's notes/consent form, the following details should be recorded on the specimen pot label:
- 1. Patient's full name, identification number and, date of birth.
- 2. Ward, hospital, & theatre.
- 3. Nature of the specimen.
- 4. Date/time specimen was taken.
- 5. Nature of fixative.
- 6. Consultant's name.

These details should be recorded on an adhesive label that is attached to the body of the specimen container.

- The same details should also be recorded on the request form, along with the following:
- 1. Medical practitioner's name, clearly and legibly written.
- 2. Medical practitioner's signature.
- 3. Contact details (e.g.: bleep number of the medical practitioner for use in the event that the laboratory may need further clarification or results).
- 4. Details of who the report should be submitted to.

All request forms should be produced using ICE and no paper request forms should be accepted.

- For Microbiology investigations, each specimen container should be accompanied by its own specimen request form i.e. 1 specimen per ICE request form.
- It is essential that a member of the perioperative team labels the specimen container.
  This must be done after the details have been provided but before the specimen is
  placed in the container. To reduce confusion, the label must not be placed on the lid
  of the container.
- The labelled container must be shown to the scrub practitioner in conjunction with the
  details as they are recorded in the patient's notes/consent form. This may be
  achieved by showing the scrub practitioner the notes, consent form or operating list.
  The documentation used must previously have been checked for accuracy of the
  details.
- The information on the investigation request form must correspond with the details on the specimen container and the patient's notes. It must also contain relevant clinical information to assist the laboratory staff.

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- It is the responsibility of the senior clinician/specialist care practitioner to request
  using the ICE system where they should state what investigations are required. This
  should generally be the surgeon, but on occasions may be another medical
  practitioner such as the anaesthetist. Whoever provides the details should supply all
  the information, including clear identification of who they are and their contact details.
- It is extremely important that all information is checked and accurate before the specimen/s leave the operating theatre. The specimen must be accompanied by the relevant documentation.
- Urgency of the specimen should be determined and in the event of it being urgent, the laboratory staff should be notified and those responsible for transporting the specimen should also be aware of the urgent nature of the specimen.
- A log should be kept for tracking the specimen from theatre to the laboratories, this
  log should be signed as well as a printed name and copies should be kept in the
  department as well as one copy to go with the specimens.
- The specimen should be removed from the operating theatre before the next scheduled patient arrives. Allowing specimens to stockpile for removal at the end of the operating list presents a risk and is not recommended.

#### 5.3 Frozen sections

- It is the responsibility of the medical staff to notify the histology department of specimens requiring frozen sections and to complete the appropriate electronic request prior to starting the procedure.
- Specimens for frozen section are placed in dry containers, labelled as stated and must be dispatched immediately to the appropriate department.
- Results of frozen sections should be received and a written record made by a member of medical staff.

#### 5.4 Foreign Bodies

- Foreign bodies must be clearly labelled and retained for inspection.
- Forensic specimens must be saved in accordance with local policies, ensuring that there is always total traceability of the specimen until it reaches its destination.
- Some forensic samples will not necessarily be body tissue (e.g.: a bullet or shot removed during surgery from firearm wounds).

#### 5.5 Orthopaedic implants

- When orthopaedic implants or other mechanical devices (e.g.: ventricular assist devices) are to be removed, care should be taken to ascertain:
- 1. Whether the implant is to be sent for bacterial, pathological, metallurgical or mechanical examination.
- 2. The legal ownership of the implant before any destructive testing is carried out.

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#### 5.6 Sentinel Lymph node biopsies

- It must be considered that sentinel lymph node biopsies can be slightly radioactive.
- The specimen must be stored in a dedicated storage cupboard at the operating hospital (ALEX/KTC) until it is transported.
- Collection of these samples is from Main theatre at AGH, however at KTC the theatre staff transport the specimens to the loading bay for collection.
- Specimens are transported from the operating hospital (ALEX/KTC) on the day after surgery, to Histopathology at WRH.
- They are transported as a biological rather than radiological hazard due to the low levels of radioactivity by this point, although they do still contain some radioactivity. They are transported in green/teal coloured specimen bags (UN3373) which are clearly labelled as sentinel specimens only with a label clearly stating, "Sentinel Specimens" and each bag has guidance in case of spillage.
- Sectioning/analysis can be carried out on the day of arrival in Histopathology as radioactivity in samples is very low.
- Measurements of waste generated during analysis in Histopathology in WRH e.g. scalpels swabs gloves etc. have shown no significant radioactive contamination so no need to store that waste in Histopathology.
- Specimens are held in store at Histopathology WRH for at least 24 hours so by time
  of "disposal" are no longer active and can be disposed of using the usual clinical
  waste routes.

#### 5.7 Retained products of Conception

- Foetal tissue must be treated in accordance with Health Service Guidelines HSG 1991/19 (NHS Management Executive 1991).
- Tissue must remain as a single specimen and must not be split or separated. If the surgeons request to split the product, under no circumstances should this occur.
- It is imperative that personal wishes are respected in relation to a foetus or foetal tissue. If the patient has requested no examination, then a casket should be used.
- Laboratory staff should be informed of any personal wishes expressed if a foetus or foetal tissue needs to be sent for pathological examination.
- A separate consent form should be filled out by a member of the surgical team with the patient, that will give the patient's wishes regarding the specimens that are retrieved. The consent form should be signed by the patient and witnessed by the clinician and accompany the specimen to the laboratory.
- This type of specimen must be sent for histopathology or cytogenetics and not both.
- Theatre staff must ensure that all forms are completed fully and signed by the
  appropriate clinicians. This includes ensuring that only one box is ticked per side,
  however if "take home" is ticked, as well as Histological or Cytogenetics, then the
  product goes to the relevant department and will be returned to the patient after
  testing has taken place.
- If the patient was asleep and more than one of the patient's wishes were ticked, then the consultant is to make the decision as to where the product goes. In this circumstance, this must be documented on the form next to whichever choice was

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made, and that it was discussed with the consultant, and this was their decision. The form should also be signed by the consultant.

See Appendix 1 for the guidance provided by the Trust's End of Life Products of Conception Lead (New Pregnancy Tissue Examination Consent Form).

#### 5.8 Transporting Specimens to WRH from KTC and AGH

- An identified UN3373 container appropriately labelled will be kept in the theatre department for the daily collection of specimens. These will consist of the following: -
- 1. SLNB specimens teal container.
- 2. Histology specimens with or without formalin (some Histology specimens are sent dry) blue container. Dry specimens (assuming frozen sections) should be sent directly to the lab. Everything else should be fixed in formalin.
- 3. Microbiology purple container.
- Ensure that Microbiology and Cellular pathology bags are sent separately as this may cause delays in processing.
- Potted and labelled specimens will be placed in the UN3373 container by the theatre team.
- Theatre staff will seal the bag with a tamper proof tag and complete the theatre specimen book provided.
- A specimen log form will be completed by theatre staff. The form will be completed
  with the date, time, name and signature of the person placing the specimen in the
  container. The total number of specimens in the container will also be recorded; the
  form will be placed in the bag and retained by the lab for their record.
- Prior to the porters removing the container, theatre staff will check the tamper proof seals. This will provide assurance to the porters and the laboratory staff that the contents are accounted for and have not been tampered with. There should be no reason this tag is removed until the container arrives at the correct lab at WRH.
- KTC Theatre staff will seal the container with a red tamper proof tag and take the specimen container to the designated specimen collection point in the Kidderminster laboratory on the ground floor of C block.
- Specimen containers will be collected by the portering/driver teams at times agreed with each site.

#### 5.9 Template prostate biopsy

- Template prostate biopsy require special consideration as the samples are required to be transported to London for analysis.
- At AGH, the polystyrene boxes for transport should be brought up from pathology. At KTC there is a supply kept in the theatre department.
- Theatre staff should contact biochemistry at WRH to arrange TNT collection. The
  contacts for this are on a rotational basis, but have been identified by the Urology &
  Gynaecology Theatre Team Leader at KTC as <a href="mailto:sarah.price23@nhs.net">sarah.price23@nhs.net</a>, or

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<u>gillian.fallows@nhs.net</u>. This is for the specimen to be transported to the HCA Lab in London, and this should occur as soon as any template biopsy is identified to be scheduled on the theatre list.

- There is specific paperwork that must be completed. AGH Theatres keep this in the storeroom of theatre 5, whilst KTC have it in a folder within a trolley inside theatre 3.
- Collection of samples is from the loading bay on both sites.

#### 6. Implementation

#### 6.1 Plan for implementation

 This policy will be implemented and disseminated through the theatre communication routes to include staff meetings and the 08.00AM huddle. The policies will be located and stored on the electronic document library and there will be links to them from the theatre intranet homepage.

#### 6.2 Training and awareness

• All staff should be competent to complete all documentation relating to specimens as well as being competent to use theatre spillage kits.

#### 7. Monitoring and compliance

 Theatres should also conduct their own audit to monitor compliance with this policy and ensure strict adherence where appropriate.



Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: (Responsible for also ensuring actions are developed to address any areas of non-compliance)	Frequency of reporting:
	WHAT?	HOW?	WHEN?	WHO?	WHERE?	WHEN?
	These are the 'key' parts of the process that we are relying on to manage risk. We may not be able to monitor every part of the process, but we MUST monitor the key elements, otherwise we won't know whether we are keeping patients, visitors and/or staff safe.	make sure the key parts of the process we have identified are being followed?	Be realistic. Set achievable frequencies. Use terms such as '10 times a year' instead of 'monthly'.	Who is responsible for the check? Is it listed in the 'duties' section of the policy? Is it in the job description?	Who will receive the monitoring results? Where this is a committee the committee's specific responsibility for monitoring the process must be described within its terms of reference.	Use terms such as '10 times a year' instead of 'monthly'.

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#### 8. Policy Review

This Policy with be reviewed every two years. Revisions can be made ahead of the
review date when the procedural document requires updating. Where the revisions
are significant and the overall policy is changed, the author must ensure the revised
document is taken through the standard consultation, approval and dissemination
processes.

#### 9. References

References:	Code:
Standards & Recommendations for Safe Perioperative Practice – Fifth Edition (2022).	

#### 10. Background

#### 10.1 Consultation

Name	Designation
Lianne Binns	Previous Theatre Matron.
Mathew Trotman	Previous Theatre Matron.
Andy Fryer	Previous Countywide Theatres Recruitment & Development Lead.
Senior Team	
Leaders	
R&D team leaders.	

10.2 Approval process

Name	Designation
Julian Berlet	Previous Divisional Medical Director – Specialised Clinical Services
Tracy Pearson	Previous Divisional Director of Operations – SCSD
Amanda Moore	Previous Divisional Director of Nursing – SCSD
Stephen	Divisional Medical Director - Surgery
Goodyear	

#### 10.3 Equality requirements

A brief description of the findings of the equality assessment (see Supporting Document 1).

#### 10.4 Financial risk assessment

A brief description of the financial risk assessment (see Supporting Document 2).

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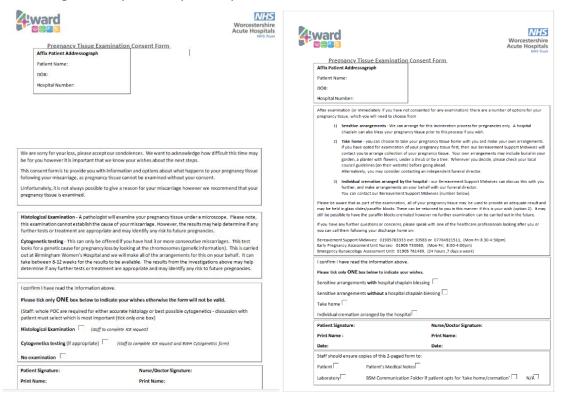
#### Appendix 1

# New Pregnancy Tissue Examination Consent Form

#### DO NOT SPLIT PRODUCT

It is no longer acceptable for products of conception to be split or separated - the tissue must remain as a single specimen. This specimen must then be sent for histopathology OR cytogenetics and NOT both. If the patient has requested no examination then casket should be used.

- Make sure all forms are properly filled out and signed correctly.
- Make sure only one box is ticked per side.
- If take home is ticked as well as Histological or Cytogenetics then the product goes to the relevant department and will be returned to the patient after testing has taken place.
- If for whatever reason the patient was asleep and more than one of the patient's wishes
  were ticked, then the consultant is to make the decision as to where the product goes. If this
  happens we <u>MUST</u> make a note on the form next to whichever choice was made that it was
  discussed with the consultant and this is their decision. Get the consultant to then sign next
  to it.
- If the surgeons request to split the product under no circumstances should this occur.





K.Tyler - 19/07/24

Supporting Document 1 – Equality Impact Assessment Form

To be completed by the key document author and included when the document is submitted to the appropriate committee for consideration and approval.





# Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form Please read EIA guidelines when completing this form

#### Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council	Herefordshire CCG
Worcestershire Acute Hospitals NHS Trust	✓	Worcestershire County Council	Worcestershire CCGs
Worcestershire Health and Care NHS Trust		Wye Valley NHS Trust	Other (please state)

Name of Lead for Activity	Rebecca Price

Details of individuals	Name	Job title	e-mail contact
completing this assessment	Rebecca Price	Countywide Theatres Quality & Governance Team Leader	rebecca.price9@nhs.net
Data accessment	20/42/2024		
Date assessment	20/12/2024		

#### Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	Title: Specimen Management Policy.
What is the aim, purpose and/or intended outcomes of this Activity?	To outline the systems in place which reduce the risk of errors when tissue and other product samples are obtained in the perioperative setting and transported to different laboratories across WAHT.

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Who will be affected by the development & implementation of this activity?		Service User Patient Carers Visitors		Staff Communities Other
Is this:	<ul> <li>☑ Review of an existing activity</li> <li>☑ New activity</li> <li>☑ Planning to withdraw or reduce a service, activity or presence?</li> </ul>			
What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff groups affected, complaints etc.	<ul> <li>Standards &amp; Recommendations for Safe Perioperative Practice – Fifth Edition (2022).</li> <li>Discussion with the Quality Manager/Specialist Biomedical Scientist for Cellular Pathology in WAHT.</li> <li>The policy was circulated to the Theatre Matrons, Theatre Managers &amp; the Clinical Lead for Governance in Theatres &amp; Anaesthetics, for their comments &amp; for their review.</li> <li>The policy was reviewed by the Theatres Directorate Governance meeting group.</li> </ul>			
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)	<ul> <li>Discussion with the Quality Manager/Specialist Biomedical Scientist for Cellular Pathology in WAHT.</li> <li>The policy was circulated to the Theatre Matrons, Theatre Managers &amp; the Clinical Lead for Governance in Theatres &amp; Anaesthetics, for their comments &amp; for their review.</li> <li>The policy was reviewed by the Theatres Directorate Governance meeting group.</li> </ul>			
Summary of relevant findings	No concerns were raised in terms of equality impact.			

### Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. Please tick one or more impact box below for each Equality Group and explain your rationale. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential positive impact	Potential <u>neutral</u> impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age		X		This policy does not appear to impact positively or negatively on this equality group.
Disability		Х		This policy does not appear to impact positively or negatively on this equality

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Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
				group.
Gender Reassignment		Х		This policy does not appear to impact positively or negatively on this equality group.
Marriage & Civil Partnerships		X		This policy does not appear to impact positively or negatively on this equality group.
Pregnancy & Maternity		Х		This policy does not appear to impact positively or negatively on this equality group.
Race including Traveling Communities		Х		This policy does not appear to impact positively or negatively on this equality group.
Religion & Belief		Х		This policy does not appear to impact positively or negatively on this equality group.
Sex		Х		This policy does not appear to impact positively or negatively on this equality group.
Sexual Orientation		Х		This policy does not appear to impact positively or negatively on this equality group.
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)		Х		This policy does not appear to impact positively or negatively on this equality group.
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals		Х		This policy does not appear to impact positively or negatively on this equality

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Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
that arise from the unequal distribution of social, environmental & economic conditions within societies)				group.

#### Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
	n/a	n/a	n/a	n/a
How will you monitor these actions?	n/a			
When will you review this EIA? (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation)	When this policy is next due for review, or if there are any changes to the policy in the meantime. Also, if there is an impact identified on any of the equality groups mentioned above.			

#### Section 5 - Please read and agree to the following Equality Statement

#### 1. Equality Statement

- 1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation
- 1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.
- 1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	R.Price
Date signed	20/12/2024

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Comments:	
Signature of person the Leader Person for this activity	R.Price
Date signed	20/12/2024
Comments:	























#### Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and included when the document is submitted to the appropriate committee for consideration and approval.

ID	Financial Impact:	Yes/No		
1.	Does the implementation of this document require any additional Capital resources	No		
2.	Does the implementation of this document require additional revenue	No		
3.	Does the implementation of this document require additional manpower	No		
4.	Does the implementation of this document release any manpower costs through a change in practice	No		
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff			
Other comments:				

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