

Nurse Led Diagnostic Biopsies Standard Operating Procedure

V2.0

February 2024

Table of Contents

1. Introduction	3
2. Purpose of this Standard Operating Procedure	4
3. Ownership and Responsibilities.....	4
3.1. Role of the Dermatology Responsible clinician	4
3.2. Role of the Dermatology Department Sister.....	5
3.3. Role of Dermatology Nurse	5
4. Standards and Practice	6
5. Dissemination and Implementation.....	8
6. Monitoring compliance and effectiveness	8
7. Updating and Review.....	9
8. Equality and Diversity	9
Appendix 1. Governance Information	10
Appendix 2. Equality Impact Assessment	13

Data Protection Act 2018 (UK General Data Protection Regulation – GDPR) Legislation.

The Trust has a duty under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed, and documented. We cannot rely on opt out, it must be opt in.

Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 is applicable to all staff; this includes those working as contractors and providers of services.

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1. Introduction

1.1. The urgency for diagnostic biopsies for suspected skin cancers has grown dramatically with the implementation of government cancer waiting time targets (The NHS Plan, 2000). The role of the registered nurse within the Dermatology Department at Royal Cornwall Hospital has expanded to help fulfil the increase demand on the service. The development of nurse led diagnostic biopsy services utilises the expanded role of the Dermatology registered nurse, and further increases the capacity for the provision of a diagnostic biopsy service.

The aim of this standard operating procedure (SOP) is to:

- Ensure safe, efficient, and effective practice for dermatology surgical services.
- Ensure all staff in the dermatology unit are carrying out diagnostic biopsies are adhering to the same practice standards.

1.2. This procedure should be read in conjunction with the following Trust documentation:

- Policy for Consent to Examination or Treatment.
- Policy to Manage Information and Records
- Infection Prevention and Control - Roles and Responsibilities Policy.
- Aseptic Non-Touch Technique (ANTT) Policy.
- Medical Devices Training Policy.
- Needlestick Injuries and Body Fluid Exposure Incidents - Policy for the Management of Sharps Safety Policy.
- Pre-operative Management of Dermatology Patients Clinical Guideline.
- Excision Patient Specific Consent Form.
- Same day procedure form.
- RCHT Standard operating policy for Dermatology skin lesion imaging clinics.
- Dermatology Department Local Procedure for Nurse-Led Diagnostic Biopsies.

- Dermatology Unit Practice Standards Clinical Guideline.
- Dermatology Surgical Practice Standards Clinical Guideline.
- Dermatology Procedure Room Clinical Guideline.
- WHO – 5 Steps to Safer Surgery.

1.3. This version supersedes any previous versions of this document.

2. Purpose of this Standard Operating Procedure

2.1. The aim of this Standard Operating (SOP) is to:

- 2.2.2 Define the safe and effective practice standards that must be adhered to when undertaking diagnostic skin biopsies in the dermatology department.
- 2.2.3 Ensure that consistent practice standards are applied across all dermatology staff who undertake this diagnostic biopsy.

3. Ownership and Responsibilities

The nurse led diagnostic biopsy clinic is shared care between the Responsible Clinician, the Dermatology procedure nurse, and the Departmental Sister, each having their own distinct responsibilities to ensure the best outcome for the patient.

3.1. Role of the Dermatology Responsible Clinician

The Dermatology Responsible Clinicians are:

- To be familiar with the standards expected in this SOP and those related to.
- To ensure the referred patient is suitable for the nurse-led biopsy clinic.
- To explain the biopsy procedure fully to the patient to ensure they consent to have the procedure performed by the procedure nurse.
- To ensure there is a responsible clinician present in the department when a nurse-led diagnostic biopsy is performed, who must remain on site until the biopsy nurse has finished treating all patients.
- To ensure the lesion to be biopsied is clearly marked in accordance with 'The clinical guideline for the preoperative management of patients who require a surgical procedure in the Dermatology department'.

- To ensure the lesion to be biopsied is clearly imaged in accordance with the clinical guideline for the preoperative management of patients who require a surgical procedure in the Dermatology department’.
- To complete the same-day procedure booking form for every biopsy performed on the day.
- To complete a Maxim’s day-case booking form and obtain a clinical image for every biopsy arranged for a future date, in line with the ‘Clinical Guideline for the Pre-operative Management of Patients Who Require a Surgical Procedure in the Dermatology Department’.
- To have documented in the patient’s medical records, the specific type of biopsy required and site.

3.2. Role of the Dermatology Department Sister

The Dermatology Department Sister is:

- To be familiar with the standards expected in this SOP and those related to it.
- To ensure adequate staffing levels for the nurse-led biopsy clinic (2x RN in a nurse-led biopsy clinic and 1RN and 1HCA band 3 for a see and treat clinic)
- To ensure adequate training and competence for all nursing staff assigned to the nurse-led biopsy clinic.

3.3. Role of Dermatology Nurse

The Dermatology Nurse is:

- To be familiar with the standards expected in this SOP and those related to it.
- To be competent and confident to carry out skin biopsies, having completed the appropriate training pathway for carrying out nurse-led biopsies.
- They will be accountable for their own practice in line with the NMC code of conduct.
- To ensure that they carry out the procedure in line with the standards required and refer back to the clinician on site if they have any concerns.
- That they are competent to take skin biopsies from all areas of the body except for the vermillion (lip) border.
- To ensure that they do not undertake any biopsy in close proximity to or within the vermillion (lip) border.
- To ensure they take additional caution when carrying out biopsies on the lateral or medial aspects of the digits and the penile shaft.

- To adhere to Trust policies and procedures at all times.
- To ensure knowledge and competence is maintained.
- To confirm patient consent and area to be biopsied, in line with RCHT consent policy.
- To ensure patient is fully informed of appropriate post-procedure care and advice.

4. Standards and Practice

- 4.1. Nurse-led biopsies may only be performed within the Dermatology Department when a Dermatology Doctor is present.
- 4.2. The nurse should only perform diagnostic biopsies for:
 - a) Inflammatory skin conditions or
 - b) Suspected skin tumours.
- 4.3. The nurse must not undertake any biopsy in close proximity to or within the vermillion (lip) border.
- 4.4. The Nurse may ask the responsible clinician to perform the biopsy if she/he feels it is in the best interest of the patient.
- 4.5. **Only patients over 18 years to have nurse-led biopsy**, unless previously discussed and agreed with the individual nurse, and they are happy and competent to perform procedure on a person under 18 years of age.
- 4.6. Nurse led 'Day-case biopsy lists' will be carried out by a Band 6 Registered nurse or above.
- 4.7. Nurse-led 'Same-day' biopsies (see and treat) will be carried out by a registered nurse Band 5 or above.
- 4.8. Only a registered nurse who has been signed-off as independently competent following appropriate training pathway, can take biopsies/curette and cautery/shave excisions, from any site that they feel competent to carry out.
- 4.9. 8mm punch biopsy/excisions can be undertaken by a registered nurse who has completed a recognised surgical training course through the accredited route, or by a registered nurse who has completed the Departmental competency requirement.

- 4.10. The need for a skin biopsy is first identified by a responsible clinician. The referring clinician should indicate clearly the site from where the biopsy needs to be taken, mark this on the skin, clearly describe in the medical record, obtain a digital image for upload to patient record (in line with Clinical Guideline for the preoperative management of patients who require a surgical procedure in the dermatology department).
- 4.11. When a patient undergoes a same day procedure, the Dermatology same day procedure booking form must be completed by the responsible clinician. If there is any doubt as to site or nature of the procedures to be performed, the nurse will not proceed until they have consulted with the responsible clinician.
- 4.12. If time constraints within the department do not allow for same day treatment or there are relevant patient factors to rebook the patient, then they will be re-booked for their procedure and skin marking(s) removed.
- 4.13. The electronic record of patients booked as a day case for a potential nurse led biopsy list will be screened by a senior dermatology clinician or nurse to identify suitable cases. Patients deemed unsuitable for a nurse led list will be booked onto a suitable alternate list.
- 4.14. Patients with more than 2 lesions are not suitable for booking onto a nurse led biopsy day case list.
- 4.15. There will be a named senior dermatology clinician present in the dermatology department to provide advice for each nurse led biopsy list, if required.
- 4.16. For biopsies, if a patient has a pacemaker or internal defibrillator – only silver nitrate or aluminium chloride solution should be used for coagulation purposes.
- 4.17. If the histology form does not state size of punch biopsy, then 4mm will be performed.
- 4.18. The procedure will be explained to the patient at their level of understanding and consent obtained.
- 4.19. The WHO will be completed as per trust policy – ref to 5 steps of safer surgery.
- 4.20. The nurse-led biopsy will be carried out under local anaesthesia.
- 4.21. Details of the procedure are to be documented and signed in the patient's records by the Biopsy Nurse.

4.22. Any problems encountered by the nurse whilst performing the biopsy must be reported to the responsible clinician.

4.23. The specimens must be checked for accurate labelling before sending to the laboratory.

4.24. The patient will be given verbal and written post-operative instructions and wound care advice prior to leaving the department.

5. Dissemination and Implementation

5.1. This policy will be available on the RCHT Dermatology shared folder. There will also be a hard copy available to view within the Dermatology Department.

5.2. The Departmental Sister will be responsible for ensuring the biopsy nurse has been suitably trained before delegating this task.

5.3. The theoretical knowledge underpinning the biopsy procedure will be achieved through an appropriate competency pathway, reading and experientially working under supervision by a competent, skilled person and then being signed off as competent.

5.4. Records of staff competency will be available within the Dermatology unit.

6. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	All of the policy to be monitored.
Lead	Dermatology unit Sister /Biopsy Nurses/Dermatology Staff.
Tool	Non-Applicable.
Frequency	Monitoring will be an ongoing practice within the department
Reporting arrangements	Any concerns regarding the ongoing implementation of this procedure should be reported to the Lead Nurse in Dermatology who will investigate and report back to consultants/staff.
Acting on recommendations and Lead(s)	Any recommendations/changes to this procedure will be reported at the departmental and nurses' meeting and changes implemented.
Change in practice and lessons to be shared	Required changes to practice will be identified and actioned immediately. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders.

7. Updating and Review

This Standard Operating Procedure will be reviewed every 3 years.

8. Equality and Diversity

8.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the [Equality Diversity And Inclusion Policy](#) or the [Equality and Diversity website](#).

8.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.

Appendix 1. Governance Information

Information Category	Detailed Information
Document Title:	Nurse Led Diagnostic Biopsies Standard Operating Procedure V2.0.
This document replaces (exact title of previous version):	Nurse Led Diagnostic Biopsies Standard Operating Procedure V1.0.
Date Issued / Approved:	January 2024.
Date Valid From:	February 2024.
Date Valid To:	February 2027.
Author / Owner:	Paulette Hunkin – Clinical Matron. Leanne Knapp – Dermatology Sister.
Contact details:	07917488377 / 01872 253254.
Brief summary of contents:	The distinct responsibilities of dermatology department clinicians, sisters and nurses.
Suggested Keywords:	Nurse-led biopsies, biopsies, nurse-led.
Target Audience:	RCHT: Yes CFT: No CIOB ICB: No
Executive Director responsible for Policy:	Chief Medical Officer.
Approval route for consultation and ratification:	Speciality, SSS Senior Management team, Governance meeting, SSS Care Board.
Manager confirming approval processes:	Roz Davies.
Name of Governance Lead confirming consultation and ratification:	Maria Lane.
Links to key external standards:	None required.

Information Category	Detailed Information
<p>Related Documents:</p>	<ul style="list-style-type: none"> • Policy for Consent to Examination or Treatment. • Policy to Manage Information and Records. • Infection prevention and control - roles and responsibilities policy. • Aseptic non touch technique (ANTT) policy. • Medical Devices Training Policy. • Needlestick Injuries and Body Fluid Exposure Incidents - Policy for the Management of. • Sharps Safety Policy. • Clinical Guideline for the Pre-operative Management of Dermatology Patients Who Require a Surgical Procedure. • Excision Patient Specific Consent Form. • Same day procedure form. • RCHT Standard operating policy for Dermatology skin lesion imaging clinics. • Dermatology department local procedure for Nurse-led diagnostic biopsies. • Dermatology unit practice standards clinical guideline • Dermatology surgical practice standards clinical guideline. • Dermatology procedure room clinical guideline. • WHO – 5 steps to safer surgery.
<p>Training Need Identified:</p>	<p>No.</p>
<p>Publication Location (refer to Policy on Policies – Approvals and Ratification):</p>	<p>Internet and Intranet.</p>
<p>Document Library Folder/Sub Folder:</p>	<p>Clinical / Dermatology.</p>

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
05/02/2021	V1.0	Initial issue.	Paulette Hunkin
January 2024	V2.0	Related documents, from the exceptions of the nurse-led procedures.	Paulette Hunkin, Leanne Knapp

All or part of this document can be released under the Freedom of Information Act 2000.

All Policies, Strategies and Operating Procedures, including Business Plans, are to be kept for the lifetime of the organisation plus 6 years.

This document is only valid on the day of printing.

Controlled Document.

This document has been created following the Royal Cornwall Hospitals NHS Trust [The Policy on Policies \(Development and Management of Knowledge Procedural and Web Documents Policy\)](#). It should not be altered in any way without the express permission of the author or their Line Manager.

Appendix 2. Equality Impact Assessment

Section 1: Equality Impact Assessment (EIA) Form

The EIA process allows the Trust to identify where a policy or service may have a negative impact on an individual or particular group of people.

For guidance please refer to the Equality Impact Assessment Policy (available from the document library) or contact the Equality, Diversity, and Inclusion Team
rcht.inclusion@nhs.net

Information Category	Detailed Information
Name of the strategy / policy / proposal / service function to be assessed:	Nurse Led Diagnostic Biopsies Standard Operating Procedure V2.0
Department and Service Area:	Specialist Services and Surgery.
Is this a new or existing document?	Existing.
Name of individual completing EIA (Should be completed by an individual with a good understanding of the Service/Policy):	Paulette Hunkin – Clinical Matron.
Contact details:	07917488377 / 01872 253254.

Information Category	Detailed Information
1. Policy Aim - Who is the Policy aimed at? (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	Responsible clinicians and nursing staff who are part of the nurse led diagnostic biopsy clinic.
2. Policy Objectives	The nurse led diagnostic biopsy clinic is shared care between the Responsible Clinician, Dermatology procedure nurse, and the Departmental Sister, each having their own distinct responsibilities to ensure the best outcome for the patient.
3. Policy Intended Outcomes	The aim of this standard operating procedure (SOP) is to ensure safe, efficient, and effective practice for dermatology surgical services. Also, to ensure all staff in the dermatology unit are carrying out surgical procedures are adhering to the same practice standards.
4. How will you measure each outcome?	Monitoring will be an ongoing practice within the department.

Information Category	Detailed Information
5. Who is intended to benefit from the policy?	Staff involved in any part of a patients pathway for a nurse-led diagnostic biopsy.
6a. Who did you consult with? (Please select Yes or No for each category)	<ul style="list-style-type: none"> • Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: No • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	Please record specific names of individuals/ groups: Specialty – Clinicians, nursing staff, clinical matron.
6c. What was the outcome of the consultation?	Approved.
6d. Have you used any of the following to assist your assessment?	National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys: No.

7. The Impact

Following consultation with key groups, has a negative impact been identified for any protected characteristic? Please note that a rationale is required for each one.

Where a negative impact is identified without rationale, the key groups will need to be consulted again.

Protected Characteristic	(Yes or No)	Rationale
Age	No	
Sex (male or female)	No	
Gender reassignment (Transgender, non-binary, gender fluid etc.)	No	
Race	No	
Disability (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	
Religion or belief	No	

Protected Characteristic	(Yes or No)	Rationale
Marriage and civil partnership	No	
Pregnancy and maternity	No	
Sexual orientation (e.g. gay, straight, bisexual, lesbian etc.)	No	

A robust rationale must be in place for all protected characteristics. If a negative impact has been identified, please complete section 2. If no negative impact has been identified and if this is not a major service change, you can end the assessment here.

I am confident that section 2 of this EIA does not need completing as there are no highlighted risks of negative impact occurring because of this policy.

Name of person confirming result of initial impact assessment: Paulette Hunkin, Leanne Knapp.

If a negative impact has been identified above OR this is a major service change, you will need to complete section 2 of the EIA form available here:
[Section 2. Full Equality Analysis](#)