



**Royal Cornwall Hospitals**  
NHS Trust

# **Cervical Sample Taker Requirements Standard Operating Procedure**

**V3.0**

**June 2024**

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### **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.

For more information about your obligations under the Data Protection Act 2018 and UK General Data Protection Regulations 2016/679 please see the Information Use Framework Policy or contact the Information Governance Team

Royal Cornwall Hospital Trust      [rch-tr.infogov@nhs.net](mailto:rch-tr.infogov@nhs.net)

# 1. Introduction

1.1. The NHS cervical screening programme is composed of a complex network of providers. Standardised practice across the UK for cervical samples is essential to provide high quality screening patient pathways across the networks by reducing administrative and technical errors associated with requests, reducing sample report turnaround times and reducing the likelihood of adverse incidents.

Any cervical sampling activity that takes place within the RCHT NHS trust is subject to the professional and governance requirements from regulatory and commissioning bodies; South West Vaccination and Screening Team (SWVaST) part of the South West Commissioning Hub, NHS England and NHS Improvement (NHSEI), Screening Quality Assurance (SQAS). This document is written in accordance with PHE (Public Health England) guidance for acceptance of cervical screening samples in laboratories and pathways, roles and responsibilities [1].

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

## 2. Purpose of this Standard Operating Procedure

National implementation of primary human papilloma virus (HPV) screening has resulted in centralisation of processing laboratories and a change in the sample taker requirements and responsibilities. This document outlines the requirements of sample taker staff within the RCHT NHS Trust to reduce the likelihood of patients receiving incorrect screening, adverse incidents and reduces the time taken for patients to receive their results.

## 3. Ownership and Responsibilities

- Chief Medical Officer (delegation from the Chief Executive); overarching responsibility for service.
- Cervical Screening Provider Lead for (CSPL) RCHT; oversight of the service and appropriate reporting and incident review.
- Cervical sample takers; responsibilities as detailed in this document.

### 3.1. Role of the Managers

Line managers are responsible for ensuring that:

- All sample takers are adequately trained as described in national sample taker training guidance.
- Protocols and procedures consistent with national screening guidance are in place for the:
  - Completion of the screening test and its associated documentation.
  - Safe transport of screening specimens to the cytology laboratory.
  - Access is available to the Cervical Screening Management System

(CSMS) as of 24/06/2024 replacing old system (Open Exeter).

### 3.2. Role of Individual Staff

All staff members are responsible for ensuring that they:

- Receive appropriate initial training to take cervical screening samples.
- Understand how the screening programme operates and their responsibilities within it.
- Keep themselves updated on programme developments and policy to avoid taking inappropriate tests (3-yearly updates).
- Audit their practice routinely and proactively seek advice should they identify any issues.

## 4. Standards and Practice

Sample taker requirements:

	<b>Responsibilities of sample taker</b>	<b>Further information</b>
<b>Sample taker training competency and PIN.</b>	<p>Adequately trained in line with NHS CSP (cervical screening provider) guidance on taking cervical samples.</p> <p>(Sample taker PIN confirms the sample taker is appropriately trained).</p> <p>Up-to-date knowledge about the screening test, results and patient management.</p>	<p>Section 3.1:</p> <p><a href="http://www.gov.uk">Education pathway - GOV.UK (www.gov.uk)</a></p> <p>PIN must only be used by the assigned sample taker.</p> <p>Trainee sample takers must use a unique PIN that identifies them as a trainee.</p> <p>Local training provider; Sentinel Healthcare Southwest Community Interest Company.</p> <p><a href="http://www.learninganddevelopmentcentre.co.uk">www.learninganddevelopmentcentre.co.uk</a></p> <p><a href="mailto:ldc.sentinel@nhs.net">ldc.sentinel@nhs.net</a></p> <p><a href="mailto:shs.cervicalsampletakers1@nhs.net">shs.cervicalsampletakers1@nhs.net</a></p> <p>Sample taker update training:</p> <p><a href="https://www.e-lfh.org.uk/programmes/nhs-screening-programmes/">https://www.e-lfh.org.uk/programmes/nhs-screening-programmes/</a></p>
<b>Access to Cervical Screening Management System (CSMS).</b>	<p>Access to Cervical Screening Management System for; screening history, next test due date, and for completion of test request form.</p> <p>SMARTCARD required with user group enabled</p>	<p>RCHT CSMS Project Lead for user group access:</p> <p><a href="mailto:sharon.fidock@nhs.net">sharon.fidock@nhs.net</a></p> <p>Cervical Screening Management System access check:</p> <p><a href="https://digital.nhs.uk/services/screening-services/national-cervical-screening/new-">https://digital.nhs.uk/services/screening-services/national-cervical-screening/new-</a></p>

	Responsibilities of sample taker	Further information
		<p><a href="#">cervical-screening-management-system/cervical-screening-management-system-access-check</a></p> <p>To unlock your Smart card:</p> <p><a href="https://uim.national.ncrs.nhs.uk/selfserviceweapp/unlockCardStart">https://uim.national.ncrs.nhs.uk/selfserviceweapp/unlockCardStart</a></p> <p><a href="#">Resource (learninghub.nhs.uk)</a></p> <p><a href="#">Catalogue (learninghub.nhs.uk)</a></p>
<p><b>Patient Eligibility</b></p>	<p>The sample taker must check that the patient is eligible for a test:</p> <ul style="list-style-type: none"> <li>• Routine recall (aged 24.5 to 64 and invited by call and recall or overdue a test).</li> <li>• Not taken 3 months or more before their due date.</li> <li>• Under surveillance.</li> <li>• Follow up from a previous abnormality.</li> <li>• Sample should not be repeated within 3 months if the previous test was inadequate.</li> <li>• Refer to gynaecology or sexual health / genitourinary medicine (GUM) clinic where required. Brook medical currently provide this service.</li> </ul>	<p>People who are human immunodeficiency virus (HIV) positive should have annual cervical screening tests. On HMR101 form Section 19 complete by circling retroviral infection (5).</p> <p><b>With the exception of people who are HIV positive, there are no circumstances where routine annual screening is indicated</b></p> <p>The sample taker should be aware of when not to take a sample and be familiar with the guidance on assessment for <b>young women with abnormal vaginal bleeding</b> [2].</p> <p>NHSCSP accept tests from people under 25 who are:</p> <ul style="list-style-type: none"> <li>• On routine recall after <b>previously being tested at age 20 in Wales, Scotland, Northern Ireland.</b></li> <li>• From <b>private</b> healthcare and being followed up for a previous abnormal cervical screening test.</li> <li>• Being <b>followed up after an incidental biopsy</b> showing cervical intraepithelial neoplasia (CIN) or cervical glandular intraepithelial neoplasia (CGIN) but have had no prior cytology.</li> </ul> <p>Samples from people <b>65 years of age and over</b> as out-of-programme unless the person has not had an adequate test since their 60th birthday (which should be indicated by the sample taker on the request form).</p> <p><b>Vault cytology</b> is no longer part of the screening programme. People requiring vault</p>

	<b>Responsibilities of sample taker</b>	<b>Further information</b>
		cytology for follow up will normally be managed by their local colposcopy unit.
<p><b>Request form</b> Prepopulated HMR101 request form (<b>A4 size requested by Bristol lab</b>). <b>(Colposcopy requests should be on yellow paper to facilitate sorting in the laboratory).</b></p>	<p>Prepopulated HMR101 request form (A4 size).  should be used to reduce the likelihood of inappropriate sampling and delays in the laboratory. This form is generated from the Cervical Screening management System.</p>	<p><b>Information automatically generated on the prepopulated HMR101 request form:</b></p> <ul style="list-style-type: none"> <li>• Patient's full name (at least first name and surname).</li> <li>• Date of birth.</li> <li>• NHS number.</li> <li>• Address.</li> <li>• The name and address of their GP.</li> <li>• The name and location of sample taker.</li> <li>• The sample taker personal ID number (PIN).</li> </ul> <p><b>All sample takers should provide.</b></p> <ul style="list-style-type: none"> <li>• Clinical data including any previous cervical biopsy results and treatments.</li> <li>• Appropriate clinical details.</li> <li>• The test date.</li> <li>• The reason for the current test.</li> </ul> <p>If you use a non-CSMS e.g., vault cytology card request form for a legitimate reason then explain this on the laboratory on the form.</p> <p>The location of where the sample is taken is crucial for correct patient management. Ensure that the location is clearly presented on the request form and the patients GP details.</p>
<p><b>Patient detail checks.</b></p>	<p>Sample taker must check the details on the downloaded HMR101 request form are correct to prevent sample and form mismatches and to ensure that any correspondence is sent to the correct location.</p>	<p>Correspondence address is correct (patient is contactable in the event that further test or investigations are required).</p> <p>Patient details are correct (Full name and date of birth).</p>
<p><b>Sample vial checks.</b></p>	<p>The sample taker must check that the sample vial must have at least 14 days</p>	<p>The vials must be Hologic ThinPrep© vials. The broom head must not be left in the vial.</p>

	<b>Responsibilities of sample taker</b>	<b>Further information</b>
	remaining before the <b>expiry date.</b>	Where a sticky label is used for the patient's details, it should not obscure the vial's expiry date or the clear area between each end of the label already on the vial.  The black indicators should just overlap to ensure vial securely closed.
<b>Sampling.</b>	The sample taker is responsible for fully visualising the cervix and sampling the cervix appropriately in accordance with training guidance [3].	
<b>Sample transport.</b>	The sample taker is responsible for the correct packaging of the sample.  <b>In order to prevent delays to or loss of histology cervical samples. Histology samples must not be placed into the Bristol lab transport bags.</b>	To prevent leaks or cross contamination of samples the vial is sealed and placed into its own clear specimen bag.  The request form is placed into the document wallet of the specimen bag.  Orange plastic transportation bags are kept separate from other histology samples in Gynaecology Outpatients Dept.  Multiple samples are then placed into the Bristol laboratory orange bags and stored in a secure location. Cytology samples are documented in sample register and tallied with samples in the bag/s at the close of day. Registered Nurse signs Tracking form.  The Colposcopy Registered Nurse or delegated HCA then take the orange bag/s to the Courier Collection point: Cytology/ Histology Department, 2 <sup>nd</sup> Floor, Tower Block, where they await collection for transportation to the Bristol Laboratory.
<b>Results.</b>	Sample takers must ensure that the patient receives the appropriate follow up and management.	All cervical samples taken at RCHT that require a referral to colposcopy are covered by a direct referral pathway from the reporting laboratory to RCHT colposcopy. However, sample takers should make sure there is a failsafe system in place so they  can assure themselves that a cervical sample result comes back for every test they take and that appropriate action is taken when necessary. Information is available in NHS CSP failsafe guidance [4].

	<b>Responsibilities of sample taker</b>	<b>Further information</b>
<b>Incidents.</b>	Sample takers should communicate events leading to rejection of a sample to the person concerned in an honest and sensitive manner.	<p>They should advise them when another sample should be taken.</p> <p>Repeat samples should not be taken within 3 months of a previous test.</p> <p>This allows sufficient time for the cervical epithelium to regenerate, otherwise a false result may be obtained.</p> <p><b>Sample takers should report and discuss any rejected samples with the CSPL. This should be formally recorded on Datix.</b></p> <p>Always include any sample where the laboratory has rejected the test due to insufficient or conflicting information, or where it has been taken inappropriately.</p> <p>Situations that fulfil the criteria of a 'screening incident' should be managed in line with national screening incident guidance via the CSPL [5].</p>

## 5. Dissemination and Implementation

The trusts document library link for this document will be sent to all sample takers at RCHT.

A local copy will be stored securely within the shared files on the colposcopy server.

The document will be subject to document control procedures and current documents will be removed from the documents library and archived on the colposcopy server upon issue of the new revision.

All revisions of documentation are discussed at the quarterly CSPL meetings and added to monthly reports that are sent to all staff involve in cervical screening at RCHT.

Sample taker training provisions regarding this document are formally provided by the NHSCSP.

## 6. Monitoring compliance and effectiveness

<b>Information Category</b>	<b>Detail of process and methodology for monitoring compliance</b>
<b>Element to be monitored</b>	Monitoring of cervical screening activity at RCHT forms part of the routine quality management system for the service. Areas covered by this document are incorporated into the system.

<b>Information Category</b>	<b>Detail of process and methodology for monitoring compliance</b>
<b>Lead</b>	Cervical Screening Provider Lead (CSPL).
<b>Tool</b>	Existing quality management system.
<b>Frequency</b>	Monthly monitoring as part of the existing quality management system.
<b>Reporting arrangements</b>	<p>Monthly monitoring as part of the existing quality management system will be distributed to all cervical screening staff at RCHT. The monthly reports are discussed and minuted at the quarterly CSPL meetings.</p> <p>A 6 monthly and annual report are generated by the CSPL for the Chief Medical Officer / Chief Executive. This report is sent to PHE and SQAS (Screening Quality Assurance Service).</p> <p>Any incidents will be managed in accordance with the trust incident management processes and in accordance with the requirements of the NHSCP.</p> <p>Any risks identified with areas outlined in this document will be raised on the trust risk register and managed as part of the quality management system for the service.</p>
<b>Acting on recommendations and Lead(s)</b>	Cervical Screening Provider Lead and Chief Medical Officer.
<b>Change in practice and lessons to be shared</b>	Changes in practice and lessons to be shared will be conducted in accordance with processes embedded in the existing quality management system for cervical screening services at RCHT.

## 7. Updating and Review

This document should be reviewed by the CSPL every three years or when a new guidance is published from PHE.

## 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
<b>Document Title:</b>	Cervical Sample Taker Requirements Standard Operating Procedure V3.0
<b>This document replaces (exact title of previous version):</b>	Cervical Sample Taker Requirements Standard Operating Procedure V2.0
<b>Date Issued / Approved:</b>	August 2024
<b>Date Valid From:</b>	August 2024
<b>Date Valid To:</b>	August 2027
<b>Author / Owner:</b>	Cervical Screening Provider Lead
<b>Contact details:</b>	01872 252360
<b>Brief summary of contents:</b>	Cervical sample taker requirements
<b>Suggested Keywords:</b>	Cervical samples, sample taker requirements, NHSCSP
<b>Target Audience:</b>	<b>RCHT:</b> Yes <b>CFT:</b> No <b>CIOS ICB:</b> No
<b>Executive Director responsible for Policy:</b>	Chief Medical Officer
<b>Approval route for consultation and ratification:</b>	Cervical Screening Provider Lead Group and Gynaecology Business and Governance Meeting
<b>Manager confirming approval processes:</b>	Caroline Chappell
<b>Name of Governance Lead confirming consultation and ratification:</b>	Tamara Thirlby

Information Category	Detailed Information
<b>Links to key external standards:</b>	<ol style="list-style-type: none"> <li>1. Guidance for acceptance of cervical screening samples in laboratories and pathways, roles and responsibilities <a href="https://www.gov.uk/guidance/guidance-for-acceptance-of-cervical-screening-samples-in-laboratories-and-pathways-roles-and-responsibilities">Guidance for acceptance of cervical screening samples in laboratories and pathways, roles and responsibilities - GOV.UK (www.gov.uk)</a></li> <li>2. Guidance on assessment for young women with abnormal vaginal bleeding <a href="https://publishing.service.gov.uk/guidance/doh-guidelines-young-women.pdf">doh-guidelines-young-women.pdf (publishing.service.gov.uk)</a></li> <li>3. Sample taker training <a href="https://www.gov.uk/guidance/cervical-screening-cervical-sample-taker-training">Cervical screening: cervical sample taker training - GOV.UK (www.gov.uk)</a></li> <li>4. Cervical Screening failsafe <a href="https://www.gov.uk/guidance/cervical-screening-cytology-reporting-failsafe-primary-hpv">Cervical screening: cytology reporting failsafe (primary HPV) - GOV.UK (www.gov.uk)</a></li> <li>5. Managing safety incidents in the NHS screening programmes <a href="https://www.gov.uk/guidance/managing-safety-incidents-in-nhs-screening-programmes">Managing safety incidents in NHS screening programmes - GOV.UK (www.gov.uk)</a></li> </ol>
<b>Related Documents:</b>	None
<b>Training Need Identified?</b>	No
<b>Publication Location (refer to Policy on Policies – Approvals and Ratification):</b>	Internet and Intranet
<b>Document Library Folder/Sub Folder:</b>	Clinical/ Gynaecology

### Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
25/11/2020	V1.0	Initial issue.	Leonie Glinski; Cervical Screening Provider Lead
09/03/2023	V2.0	Section 4 Standards of practice- sample transport updated to reflect improved sample tracking. Section 4 training resources.	Lee Russ; Cervical Screening Provider Lead (CSPL)

Date	Version Number	Summary of Changes	Changes Made by
18/06/2024	V3.0	<p>Section 1: 1.1 Change of title of commissioning body South West Vaccination and Screening Team (SWVaST) part of the South West Commissioning Hub.</p> <p>Section 3: 3.1 Role of Managers. Access is available to the Cervical Screening Management System (CSMS) as of 24/06/2024 replacing old system (Open Exeter).</p> <p>Section 4 Standards and practice: Updated training resources and access to CSMS added in.</p>	Lee Russ; Cervical Screening Provider Lead (CSPL)

**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](mailto:rcht.inclusion@nhs.net)

Information Category	Detailed Information
<b>Name of the strategy / policy / proposal / service function to be assessed:</b>	Cervical Sample Taker Requirements Standard Operating Procedure V3.0
<b>Department and Service Area:</b>	Gynaecology
<b>Is this a new or existing document?</b>	Existing
<b>Name of individual completing EIA</b> (Should be completed by an individual with a good understanding of the Service/Policy):	Gynaecology Business and Governance Group
<b>Contact details:</b>	01872 252360

Information Category	Detailed Information
<b>1. Policy Aim - Who is the Policy aimed at?</b>  (The Policy is the Strategy, Policy, Proposal or Service Change to be assessed)	Cervical sample takers.
<b>2. Policy Objectives</b>	Outlines the requirements for sample taker at RCHT.
<b>3. Policy Intended Outcomes</b>	Compliance with NHS CSP requirements and safe, effective sampling.
<b>4. How will you measure each outcome?</b>	Monitoring as part of the existing cervical screening quality management system.
<b>5. Who is intended to benefit from the policy?</b>	Patient and sample takers.

Information Category	Detailed Information
<b>6a. Who did you consult with?</b> (Please select Yes or No for each category)	<ul style="list-style-type: none"> <li>• Workforce: Yes</li> <li>• Patients/ visitors: No</li> <li>• Local groups/ system partners: No</li> <li>• External organisations: No</li> <li>• Other: No</li> </ul>
<b>6b. Please list the individuals/groups who have been consulted about this policy.</b>	<b>Please record specific names of individuals/ groups:</b> Cervical Screening Provider Lead Group. Gynaecology Business and Governance Meeting.
<b>6c. What was the outcome of the consultation?</b>	Approved.
<b>6d. Have you used any of the following to assist your assessment?</b>	<b>National or local statistics, audits, activity reports, process maps, complaints, staff, or patient surveys:</b> 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
<b>Age</b>	No	Eligibility for testing based on age of patients criteria set by NHSCSP.
<b>Sex</b> (male or female)	No	All patients with a cervix.
<b>Gender reassignment</b> (Transgender, non-binary, gender fluid etc.)	No	All patients with a cervix.
<b>Race</b>	No	Any information provided should be in an accessible format for the parent/ carer/ patient's needs- i.e., available in different languages if required/ access to an interpreter if required.

Protected Characteristic	(Yes or No)	Rationale
<b>Disability</b> (e.g. physical or cognitive impairment, mental health, long term conditions etc.)	No	Those parent/ carer/ patients with any identified additional needs will be referred for additional support as appropriate- i.e., to the Liaison Team or for specialised equipment.  Written information will be provided in a format to meet the family's needs e.g., easy read, audio etc.
<b>Religion or belief</b>	No	All staff should be aware of any beliefs that may impact on the decision to treat and should respond accordingly.
<b>Marriage and civil partnership</b>	No	
<b>Pregnancy and maternity</b>	No	
<b>Sexual orientation</b> (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: Gynaecology Business and Governance Group.

**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](#)