Royal Cornwall Hospitals
NHS Trust

Withdrawal of Consent during an Endoscopic Procedure Standard Operating Procedure

V1.0

June 2025

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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.

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1. Introduction

1.1. Written consent for an endoscopic procedure is taken in advance of the procedure and confirmed by the endoscopist immediately prior to the procedure. However, consent is a dynamic process and a person with capacity is entitled to withdraw consent at any time, including during the performance of a procedure.

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

1.3 Documents used to write this SOP:

1.3.1. Department of Health (2009) Reference guide to consent for examination or treatment, GOV.UK. London: Department of Health.

1.3.2. Everett, S.M., Griffiths, H., Nandasoma, U., Ayres, K., Bell, G., Cohen, M., Thomas-Gibson, S., Thomson, M. and Naylor, K.M.T. (2016) 'Guideline for obtaining valid consent for gastrointestinal endoscopy procedures', Gut, 65(10), pp. 1585–1601.

1.3.3. Everett, S.M., Konstantinos Triantafyllou, Hassan, C., Mergener, K., Tham, T.C., Almeida, N., Antonelli, G., Axon, A., Raf Bisschops, Bretthauer, M., Vianna Costil, Foroutan, F., Gauci, J., Hritz, I., Messmann, H., Pellisé, M., Roelandt, P., Andrada Seicean, Georgios Tziatzios and Andrei Voiosu (2023) 'Informed consent for endoscopic procedures: European Society of Gastrointestinal Endoscopy (ESGE) Position Statement', Endoscopy, 55(10), pp. 952–966.

2. Purpose of this Standard Operating Procedure

2.1. The purpose of this Standard Operating Procedure is to guide clinicians and endoscopy staff if a patient wishes to withdraw consent whilst undergoing an endoscopic procedure.

2.2. It is to ensure that practice adheres to both national guidance and the law.

2.3. The intended outcome is parity of experience for patients in the Endoscopy Department, ensuring that patient autonomy is respected.

3. Ownership and Responsibilities

3.1. Overseeing the withdrawing of consent procedure is the shared responsibility of the Endoscopist and the Endoscopy Nurse working in the procedure room at the time of the procedure, with overview of the Endoscopy Unit Lead and the Endoscopy Clinical Lead.

3.2. **Role of the Endoscopist**

Endoscopists are responsible for:

- Following this SOP.
- Empowering the Endoscopy Team to report high pain scores, distress and withdrawal of consent to the Endoscopist.

- Taking measures to reduce pain during a procedure if necessary.
- Discussing the implications of stopping a procedure with patients if necessary.
- Stopping a procedure if withdrawal of consent persists.
- Documenting reasons for withdrawal of consent and discussions in the Endoscopy Report.

3.3. **Role of the Endoscopy Nurse**

Endoscopy Nurses are responsible for:

- Following this SOP.
- Reporting high pain scores, distress or withdrawal of consent to the Endoscopist.
- Reassuring the patient.
- Discussing the continuation of the procedure with the Endoscopist.
- Completing an incident report via Datix form if this policy is not followed.
- Documenting reasons for withdrawal of consent and discussions in the clinical notes.

3.4. **Role of the Endoscopy Unit Lead**

The Unit Manager is responsible for:

- Disseminating this SOP to nursing staff.
- Ensuring new staff are aware of this SOP
- Ensuring understanding and compliance of this SOP
- Ensuring an incident report via Datix is completed if policy is not followed.

3.5. **Role of the Clinical Endoscopy Lead**

The Clinical Endoscopy Lead is responsible for:

- Disseminating this SOP to all endoscopists.
- Discussing individual cases with the Clinical Governance Lead.

3.6. **Role of the Clinical Governance Lead**

The Clinical Governance Lead is responsible for:

- Discussing individual cases with the Clinical Endoscopy Lead.
- Ensuring incident is investigated and learnings shared

3.7. **Role of Individual Staff**

All staff members are responsible for:

- Following this SOP.
- Adhering to professional standards.

4. Standards and Practice

4.1. **Measures to Manage Withdrawal of Consent**

4.1.1. If a patient requests that an endoscopic procedure is stopped or are believed to be in a significant amount of pain, as reported by either the Endoscopy Nurse or the Airway Assistant, then the procedure should be paused.

4.1.2. Appropriate measures such as reassurance, deflation of gases, additional pain relief and/or sedation, position change or a change in technique should be utilised to reduce pain after discussion with the patient.

4.1.3. The Endoscopy Team must be empowered to report high pain scores to the Endoscopist during the procedure untilising the Gloucester comfort score scale.

4.1.4. If these measures are ineffective and the patient requests again for the procedure to be stopped, the Endoscopist should discuss the risks/consequences of stopping the procedure, and alternative options available to the patient.

4.1.5. If these measures are ineffective and the patient requests again for the procedure to be stopped, the Endoscopist should discuss the risks/consequences of stopping the procedure, and alternative options available to the patient.

4.1.6. If the patient requests to stop the procedure at this point, the Endoscopist should stop advancing the scope.

4.1.7. Where stopping the procedure means a high risk of harm would come to the patient the procedure may be continued. It should be acknowledged that there may be cases of life saving intervention where this is not possible.

4.1.8. The Endoscopist will discuss with the Endoscopy Team in the room and reach consensus before continuing.

4.2. **Withdrawal of Consent in the Sedated Patient**

4.2.1. Despite consent being given prior to a procedure, when a patient has been sedated it is a reasonable assumption that capacity may be impaired and the patient's cooperation and ongoing consent during the procedure may on occasion become questionable. Sedation is unpredictable and patients may become confused or disinhibited.

4.2.2. In the sedated patient assessing capacity during a procedure can be difficult, therefore, the decision to stop the procedure is a matter of clinical judgement. The clinician needs to balance the decision to stop the procedure between the level of distress being experienced by the patient and whether it is necessary and in the best interests of the patient to complete the endoscopy at that time.

4.2.3. If the patient expresses the procedure to be stopped whilst under the influence of conscious sedation the endoscopist should try to establish whether the patient has the capacity to withdraw consent. If the endoscopist is certain capacity is lacking, it may still be justified to continue the procedure in the patient's best interest, although this should not be used as an excuse to ignore distress.

4.2.4. In assessing best interests, one must consider not only the medical best interests but also the patient's moral, social and welfare best interests.

4.2.5. Processes set out in 4.1.1 and 4.1.2 must be followed for sedated patients.

4.2.6. In the case where a patient lacks capacity and/or a consent form 4 consent has been implemented, it may be justified to continue in the person's best interest.

4.2.7. The reasons for withdrawal of consent and a short summary of any discussion should be documented in the Endoscopy Report and patient profile.

4.2.8. Any incidence of non-compliance of withdrawal of consent SOP should be reported using the Trust Incident reporting and management system (DATIX).

5. Dissemination and Implementation

5.1. This procedure will be available on the organisation's document library.

5.2. There will be a hard copy available to view within the Endoscopy Unit and with the equipment for satellite clinics.

5.3. The Clinical Endoscopy Lead will be responsible for the dissemination of this procedure to medical staff.

5.4. The procedure will be emailed to existing specialty colleagues and highlighted at specialty business and governance meetings.

5.5. This procedure will be emailed to the Endoscopy Nursing Team.

5.6. This procedure will be included when training new members of staff.

6. Monitoring compliance and effectiveness

Information Category	Detail of process and methodology for monitoring compliance
Element to be monitored	Non-compliance with this procedure.
Lead	Clinical Governance Lead.
Tool	Datix system.
Frequency	On a case-by-case basis when a Datix is submitted.
Reporting arrangements	Each incidence will be dealt with on a case-by-case basis by the Clinical Governance Lead and the Endoscopy Clinical Lead.
Acting on recommendations and Lead(s)	Each incidence will be dealt with on a case-by-case basis by the Clinical Governance Lead and the Endoscopy Clinical Lead.
Change in practice and lessons to be shared	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 SOP will be reviewed every three years or earlier depending upon national guidance.

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:	Withdrawal of Consent During an Endoscopic Procedure Standard Operating Procedure V1.0
This document replaces (exact title of previous version):	New document
Date Issued / Approved:	June 2025
Date Valid From:	June 2025
Date Valid To:	June 2028
Author / Owner:	Louise Moffitt, Consultant Nurse, Clinical Endoscopist / Sarah Dyer Endoscopy Clinical Lead.
Contact details:	01872 253247.
Brief summary of contents:	Withdrawal of consent during procedures in Endoscopy.
Suggested Keywords:	Endoscopy. Consent.
Target Audience:	**RCHT:** Yes **CFT:** No **CIOS ICB:** No
Executive Director responsible for Policy:	Chief Medical Officer.
Approval route for consultation and ratification:	Business and Governance Meeting.
Manager confirming approval processes:	Ian Moyle-Browning, Head of Nursing (HoN), Specialist Services and Surgery (SSS).
Name of Governance Lead confirming consultation and ratification:	Michele Reed, SSS.
Links to key external standards:	https://www.gov.uk/government/publications/reference-guide-to-consent-for-examination-or-treatment-second-edition

Information Category	Detailed Information
Related Documents:	To be read in conjunction with the: • Consent Policy – Link • Endoscopy Operational Policy – Link
Training Need Identified:	No.
Publication Location (refer to Policy on Policies – Approvals and Ratification):	Internet and Intranet.
Document Library Folder/Sub Folder:	Clinical/Endoscopy.

Version Control Table

Date	Version Number	Summary of Changes	Changes Made by
June 2025	12.0	Changed to current trust template.	Louise Moffitt, Consultant Nurse, Clinical Endoscopist

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 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:	Withdrawal of Consent During an Endoscopic Procedure Standard Operating Procedure V1.0
Department and Service Area:	Specialist Surgery and Services.
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):	Louise Moffitt, Consultant Nurse, Clinical Endoscopist
Contact details:	01872 253247.

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)	The purpose of this Standard Operating Procedure is to guide clinicians and endoscopy staff if a patient wishes to withdraw consent whilst undergoing an endoscopic procedure.
2. Policy Objectives	It is to ensure that practice adheres to both national guidance and the law.
3. Policy Intended Outcomes	The intended outcome is parity of experience for patients in the Endoscopy Department, ensuring that patient autonomy is respected.
4. How will you measure each outcome?	Governance, Datix.
5. Who is intended to benefit from the policy?	Patients and Colleagues.

Information Category	Detailed Information
6a. Who did you consult with? (Please select Yes or No for each category)	• Workforce: Yes • Patients/ visitors: No • Local groups/ system partners: No • External organisations: Yes • Other: No
6b. Please list the individuals/groups who have been consulted about this policy.	Endoscopy User Group.
6c. What was the outcome of the consultation?	Agreed.
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	
Marriage and civil partnership	No	

Protected Characteristic	(Yes or No)	Rationale
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: Louise Moffitt, Consultant Nurse, Clinical Endoscopist.

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