

Consent for ERCP

Endoscopic Retrograde Cholangiopancreatography

IMPORTANT

Please follow the steps below, BEFORE you attend your appointment:

Step 1. Read the patient information leaflet provided which explains your ERCP, what to expect when you come to hospital and how to prepare for the test.

Step 2. Read this consent form which includes information about the procedure.

Step 3. Once you have read the consent form and patient information leaflet, if you have further questions, please contact the endoscopy unit between 8.30am – 3pm, Monday to Friday on 020 8725 1913.

Step 4. Please bring the consent form with you on the day of the procedure to sign with the doctor undertaking the procedure.

Consent for ERCP
(Flexible camera examination of bile or pancreatic ducts using x-rays & dye)

(please complete or affix label)
Surname:.....
First Name:.....
Date of birth:.....MRN No:.....
Male ☐ Female ☐ Other ☐

Statement of patient's understanding of ERCP:

I understand the intended benefit of the ERCP is to aid diagnosis and/or facilitate treatment of conditions in the bile or pancreatic ducts. This may involve one or more of the following interventions:

- Sphincterotomy (a small cut at the opening of the bile duct) ☐
- Sphincteroplasty (stretching the opening of the bile duct with a balloon) ☐
- Stone extraction (removal of stones from the bile duct) ☐
- Stent insertion (placing a plastic or metal tube in the bile or pancreatic ducts) ☐
- Tissue sampling (taking brushings or biopsies from within the ducts or its opening) ☐
- Cholangioscopy (direct visualisation of the ducts with a thin flexible camera) ☐
- Other: ☐

I have read and understood that:

- The time taken to perform the procedure is variable and could last between 30 to 90 minutes depending on what intervention is planned.
- An anaesthetic spray will be applied to the back of my throat to reduce my gag reflex and allow for easier passage of the endoscope. The effects of the spray normally wear off by the end of the procedure.
- It is necessary for me to have sedation intravenously for this procedure.
- A diclofenac suppository (an anti-inflammatory medication) may be inserted into my rectum (back passage), once sedated, to reduce the risk of acute pancreatitis.
- During the ERCP, there is a risk of causing any of the following complications:
 - Bleeding (<1:200 cases)
 - Perforation (small tear in the bowel wall) (<1:500 cases), or bile leak (<1:200 cases)
 - Pancreatitis (inflammation of the pancreas) (3:100 in mild cases) - can be serious and even fatal
 - Missed abnormalities
 - Serious infection such as cholangitis (infection of the bile ducts)
 - Aspiration (fluid entering the lungs/chest infection)
 - Adverse reaction to sedation or any medication given during the procedure
 - Life-threatening complications (<1:500 cases)
 - Other:

Where the risks pertaining to me differ, the consenting clinician will discuss these with me.

- It may not be possible to undertake or complete the ERCP (2% of cases). Further treatment options will be discussed with me if this occurs.

What are the alternatives?

A percutaneous transhepatic cholangiography (PTC - radiologically-guided access to the bile ducts through the skin) is an alternative to ERCP. Occasionally, a PTC or surgery may become necessary after ERCP. Your clinician will discuss these with you if appropriate.

Statement of agreement to proceed with ERCP:

I understand:

- the information provided to me regarding the ERCP, including the reasons for it, the risks and benefits and any alternatives.
- I have the right to change my mind at any time, including after I have signed this form.
- the endoscopist performing the procedure will have appropriate experience, or if performed by a trainee they will be closely supervised by an experienced endoscopist.
- that digital images are an integral part of the procedure and will be part of my medical record.
- any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.
- and agree that samples (biopsies, brushings) removed as part of the procedure may be used for diagnosis and audit and stored / disposed of as appropriate and in a manner regulated by appropriate ethical, legal and professional standards.
- additional procedures may become necessary during my procedure to assist diagnosis and treatment or to manage complications. I have listed below any procedures which I **do not wish** to be carried out without further discussion.
Please list:

Please answer the following questions before signing the form below: (Please circle)

I consent to receiving blood products in the event of a medical emergency. **Yes / No**

If I answered No above, I have an advance directive / living will relating to aspects of my current medical care and an official copy has been provided (including Jehovah's Witness Statement). **Yes / No**

I agree that anonymised endoscopy images and/or videos from my procedure may be used for teaching and training purposes. **Yes / No**

Patient signature:.....**Date:**.....

Name (PRINT):.....

A witness should sign below if the patient is unable to sign but has indicated their consent.

Signed:.....Date:.....

Name (PRINT):.....

Statement of interpreter (where appropriate)

I have interpreted the information to the patient to the best of my ability and in a way in which I believe they can understand.

Interpreter's signature:.....Date:.....

Name (PRINT):.....OR phone ref no:

Hospital use only:

Statement of health professional:

- **I have confirmed the patient is to receive:** (tick all applicable)
 - ☐ Local anaesthesia
 - ☐ Conscious sedation
 - ☐ Deep sedation
 - ☐ General anaesthesia
 - ☐ Diclofenac per rectum
 - ☐ Other:
- **I have confirmed that the patient understands the information provided, has no further questions and wishes to go ahead with the procedure.**
- **I have confirmed that a procedure specific patient information leaflet has been provided.**

Signed: Date:

Name (PRINT): Job title:

Copy accepted by patient: yes / no (please circle)
TOP COPY: CASE NOTES BOTTOM COPY: PATIENT