The doctor has explained that you have the following condition: *(Doctor to document in patient’s own words)*

---

This condition requires the following procedure. *(Doctor to document - include site and/or side where relevant to the procedure)*

---

The following will be performed:

An ERCP is where the doctor examines the tubes (ducts) that drain your liver, pancreas and gallbladder. This is done by giving you medication to help you relax. You will lie on the x-ray table on your tummy. The doctor will pass the endoscope, which is a flexible tube with a camera attached which allows the doctor to see the food pipe, stomach and the small bowel. A fine plastic tube will be passed inside the endoscope into the liver and/or pancreas. Contrast material (dye) will be injected and x-rays taken. The doctor may then remove stones and relieve duct blockage. This procedure may or may not require a sedation anaesthetic.

**Common risks and complications** include:

- About 5 people out of every 100 people will get swelling and inflammation of the pancreas (Pancreatitis). This may need pain relief. This usually settles over the next 24-48 hours. It can be severe and need further treatment, which may include treatment in ICU and/or surgery.
- Nausea and vomiting. Faintness or dizziness, especially when you start to move around.
- Headache.
- Pain, redness or bruising at the sedation injection site (either in the hand or arm).
- Muscle aches and pains.
- Allergy to medications given at time of the procedure.
- Uncommon risks and complications include:
  - Less than 1 person in every 200 will have a bleed as a result of the procedure. This can happen if a cut is made in the duct to remove a stone. This is usually stopped through the endoscope.
  - About 1 person in every 100 will have a tear through the bowel or duct wall. This may require a drainage tube in your nose to remove the bile. This complication may sometimes require surgery.
  - Bacteraemia (infection of the blood). This will need antibiotics.
  - The procedure may not be able to be finished due to technical problems.
  - Heart and lung problems such as heart attack or vomit in the lungs causing pneumonia. Emergency treatment may be necessary.
  - Change of anaesthetic from a sedation anaesthetic to a general anaesthetic.
  - ‘Dead arm’ type feeling in any nerve, due to positioning with the procedure – usually temporary.
  - An existing medical condition that you may have getting worse.

**Rare risks and complications** include:

- Systemic and cerebral air embolism
- Stroke resulting in brain damage
- Anaphylaxis (severe allergy) to medication given at the time of procedure
- Death as a result of complications to this procedure is rare.

**D. Significant risks and procedure options**

*(Doctor to document in space provided. Continue in Medical Record if necessary.)*
F. Patient consent

I acknowledge that the doctor has explained:

- my medical condition and the proposed procedure, including additional treatment if the doctor finds something unexpected. I understand the risks, including the risks that are specific to me.
- The anaesthetic/sedation required for this procedure. I understand the risks, including the risks that are specific to me.
- other relevant procedure/treatment options and their associated risks.
- my prognosis and the risks of not having the procedure.
- that no guarantee has been made that the procedure will improve my condition even though it has been carried out with due professional care.
- the procedure may include a blood transfusion.
- tissues and blood may be removed and could be used for diagnosis or management of my condition, stored and disposed of sensitively by the hospital.
- if immediate life-threatening events happen during the procedure, they will be treated based on my discussions with the doctor or my Acute Resuscitation Plan.
- a doctor other than the Consultant may conduct the procedure. I understand this could be a doctor undergoing further training.

I have been given the following Patient Information Sheet/s:

- ERCP
- Blood & Blood Products Transfusion

I was able to ask questions and raise concerns with the doctor about my condition, the proposed procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.

I understand I have the right to change my mind at any time, including after I have signed this form but, preferably following a discussion with my doctor.

I understand that image/s or video footage may be recorded as part of and during my procedure and that these image/s or video/s will assist the doctor to provide appropriate treatment.

On the basis of the above statements,

G. Doctor/delegate statement

I have explained to the patient all the above points under the Patient Consent section (G) and I am of the opinion that the patient/substitute decision-maker/s have understood the information.

Name of Doctor/delegate: .................................................................

Designation: ..................................................................................

Signature: ...................................................................................

Date: ...........................................................................................

H. Interpreter’s statement

I have given a sight translation in
__________________________  

(state the patient’s language here) of the consent form and assisted in the provision of any verbal and written information given to the patient/parent or guardian/substitute decision-maker by the doctor.

Name of Interpreter: .....................................................................

Signature: ..................................................................................

Date: ..........................................................................................
1. **What is an ERCP (gastroendoscopy)?**

An ERCP is where the doctor examines the ducts of your liver, pancreas and gallbladder. This is done by giving you some medication to help you relax. You will lie on the x-ray table on your tummy. The doctor will pass the endoscope, which is a thin, black flexible tube with a camera attached which allows the doctor to see the pictures as it is passed through your mouth, food pipe, stomach and into the first part of the small bowel.

A fine plastic tube will be passed down the endoscope and into the ducts of the liver and pancreas. A contrast material (dye) will be injected into the ducts and x-rays will be taken.

During the procedure, the doctor may remove stones and relieve the duct blockage.

This procedure may or may not require a sedation anaesthetic.

2. **Will there be any discomfort? Is any anaesthetic needed?**

The procedure can be uncomfortable and to make the procedure more comfortable a sedative injection or a light anaesthetic may be given. You may be changed from a sedation anaesthetic to a general anaesthetic.

Before all endoscopy procedures begin, the doctor will insert a drip into a vein in your hand or forearm. This is where the sedation or anaesthetic is injected.

3. **What is sedation?**

Sedation is the use of drugs that give you a ‘sleepy-like’ feeling. It makes you feel very relaxed during a procedure that may be otherwise unpleasant or painful.

You may remember some or little about what has occurred during the procedure.

Anaesthesia is generally very safe but every anaesthetic has a risk of side effects and complications. Whilst these are usually temporary, some of them may cause long-term problems.

The risk to you will depend on:

- personal factors, such as whether you smoke or are overweight.
- whether you have any other illness such as asthma, diabetes, heart disease, kidney disease, high blood pressure or other serious medical conditions.

4. **What are the risks of this specific procedure?**

There are risks and complications with this procedure. They include but are not limited to the following.

**Common risks and complications** include:

- About 5 people out of every 100 people will get swelling and inflammation of the pancreas (Pancreatitis). This may need pain relief. This usually settles over the next 24-48 hours. It can be severe and need further treatment, which may include treatment in ICU and/or surgery.
- Nausea and vomiting. Faintness or dizziness, especially when you start to move around.
- Headache.
- Pain, redness or bruising at the sedation injection site (either in the hand or arm).
- Muscle aches and pains.
- Allergy to medications given at time of the procedure.

**Uncommon risks and complications** include:

- Less than 1 person in every 200 will have a bleed as a result of the procedure. This can happen if a cut is made in the duct to remove a stone. This is usually stopped through the endoscope.
- About 1 person in every 100 will have a tear through the bowel or duct wall. This may require a drainage tube in your nose to remove the bile. This complication may sometimes require surgery.
- Bacteraemia (infection of the blood). This will need antibiotics.
- The procedure may not be able to be finished due to technical problems.
- Heart and lung problems such as heart attack or vomit in the lungs causing pneumonia. Emergency treatment may be necessary.
- Change of anaesthetic from a sedation anaesthetic to a general anaesthetic.
- ‘Dead arm’ type feeling in any nerve, due to positioning with the procedure – usually temporary.
• An existing medical condition that you may have getting worse.

**Rare risks and complications** include:
- Systemic and cerebral air embolism
- Stroke resulting in brain damage.
- Anaphylaxis (severe allergy) to medication given at the time of procedure.
- Death as a result of complications to this procedure is rare.

5. **What are you responsibilities before having this procedure?**

You are less at risk of problems if you do the following:
- Tell your doctor if you could be pregnant as X-rays are used as part of the procedure.
- Bring all your prescribed drugs, those drugs you buy over the counter, herbal remedies and supplements and show your doctor what you are taking. Tell your doctor about any allergies or side effects you may have.
- Do not drink any alcohol and **stop recreational drugs** 24 hours before the procedure. If you have a drug habit please tell your doctor.
- If you take Warfarin, Persantin, Clopidogrel (Plavix or Iscover), Asasantin or any other drug that is used to thin your blood ask your doctor if you should stop taking it before the procedure as it may affect your blood clotting. Do not stop taking them without asking your doctor.
- Tell your doctor if you have:
  - had heart valve replacement surgery.
  - received previous advice about taking antibiotics before a dental treatment or a surgical procedure.

6. **Preparation for the procedure**

You should not eat or drink anything for at least 6 hours before the procedure to make sure you have an empty stomach, which is necessary for a safe examination.

7. **What if the doctor finds something wrong?**

Your doctor may take a biopsy (a very small piece of the bowel lining) to be examined at Pathology.

Biopsies are used to identify many conditions even if cancer is not thought to be the problem.

8. **What if I don’t have the procedure?**

Your symptoms may become worse and the doctor will not be able to give you the correct treatment without knowing the cause of your problems.

9. **Are there other tests I can have instead?**

Generally not. An MRI scan can be used to gather some information but cannot be used for treatment. Other treatment options include drainage under X-ray control and surgery.

10. **What can I expect after this procedure?**

Usually you remain in the recovery area for about 2 hours until the effect of the sedation wears off.

Your doctor will tell you when you can eat and drink. Most times this is straight after the procedure.

You may experience bloating or pass wind because of the air introduced during the procedure.

You will be told what was found during the examination or you may need to come back to discuss the results, and to find out the results of any biopsies that may have been taken.

Your doctor may recommend dietary restrictions for 1-2 days after the procedure.

11. **What are the safety issues?**

Sedation will affect your judgment for about 24 hours. For your own safety and in some cases legally:
- Do NOT drive any type of car, bike or other vehicle. You must be taken home by a responsible adult person.
- Do NOT operate machinery including cooking implements.
- Do NOT make important decisions or sign a legal document.
- Do NOT drink alcohol, take other mind-altering substances, or smoke. They may react with the sedation drugs.
- Have an adult with you on the first night after your surgery.

Notify the hospital Emergency Department straight away if you have:
- severe ongoing abdominal pain.
- a fever.
- sharp chest or throat pain.
- have redness, tenderness or swelling for more than 48 hours where you had the injection for sedation (either in the hand or arm).
- bleeding which can occur up to 3 weeks after the procedure. Symptoms of bleeding include dizziness, fainting or passing blood or black bowel movements.

**Notes to talk to my doctor about:**

....................................................................................................................................................................
....................................................................................................................................................................
....................................................................................................................................................................

Page 2 of 2