GI Excellence, Inc.
Gastroenterology Associates

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Office Hours: 9 a.m. to 5 p.m., M-F

**Procedure to be at this location:**

Hemet Endoscopy Center
Informed Consent for Gastroenterology Related Procedures
1003 E. Florida Avenue, Suite 104, Hemet CA 92543
(951) 652-2252

# CONSENT TO ENDOSCOPIC RETROGRADE CHOLANGIOPANCREATOGRAM (ERCP) AND RELATED PROCEDURES

1. I hereby authorize Dr._____ and such assistants as may be selected by him or her to perform endoscopic retrograde cholangiopancreatogram (ERCP) and related procedures. I understand that other staff physicians, as well as physicians in residency and fellowship programs, physician assistants and/or nurse practitioners, and nurses, may participate in the procedure under the direction of my physician(s).

2. I have had explained to me the nature of my condition (including health status, diagnosis and prognosis), the procedure to be performed, the nature and probability of the risks involved, the benefits to be reasonably expected, the impossibility of predicting results, the likely result of no treatment, and any alternative treatments or diagnostic procedures and their risks and benefits.

3. **Information provided:** ERCP is a diagnostic procedure that provides information about the bile ducts, the gallbladder, and the pancreas. The bile duct and the pancreatic duct drain into the intestine through a small opening called the ampulla of Vater located just beyond the stomach. This area is reached with a flexible endoscope (long slender tube) passed through the mouth. A thin plastic tube, passed through the endoscope, is inserted into the ampulla of Vater, x-ray contrast material is injected, and x-rays are taken.

X-ray pictures will reveal abnormalities such as stones, tumors, or strictures which block the biliary or pancreatic ducts. Specialized instruments passed through the endoscope can be used to treat these abnormalities. Often it is necessary to make a small incision to enlarge the openings at the end of the bile duct (sphincterotomy) so that it is possible to extract stones or place a tube (stent) through an obstruction.

The ERCP is performed in the endoscopy unit on an x-ray table. It takes 15-45 minutes depending on technical difficulty and the abnormality being treated. An intravenous infusion is started on the hand or forearm for administration of medication. The throat may be anesthetized with a spray or gargle to reduce gagging. You will be given intravenous medication for sedation while you remain conscious during the procedure. You will be able to breathe, but not able to swallow or talk. You will be closely monitored during the procedure.

4. **Limitations.** ERCP and related procedures are successful in over 90% of cases.

5. **Alternatives.** Alternative methods for obtaining direct x-rays of the bile duct or pancreatic duct and relieving obstruction are surgery and transhepatic cholangiography (a bile duct x-ray by a needle through the liver). These alternatives are more invasive and usually associated with a higher risk. Non-invasive tests such as ultrasound and computed tomography (CT Scan) provide information about the bile ducts and pancreas but are not as precise.

6. **Benefits.** ERCP and related therapeutic procedures are used to diagnose and treat serious diseases of the bile ducts and pancreas. As a diagnostic procedure, it is often the safest method that provides information critical for treatment. It is the only method for obtaining direct x-rays of the pancreatic duct. It allows removal of bile duct stones or relief of obstruction without conventional surgery or other high risk methods.

7. **Risks.** ERCP and related therapeutic procedures (sphincterotomy/stone extraction, and stent placement) are usually less risky than alternatives of surgery and other radiologic procedures but serious complications can occur. Risks related to intravenous sedation and use of intravenous medications.

Inflammation of the vein used for injection; bruising at the site of the intravenous line; allergic reactions such as hives, wheezing, and anaphylaxis (an acute life - threatening emergency involving shock and difficulty breathing); problems with heart and lung function (irregular heartbeat and slowed breathing); and rarely, death.

**Risks related to passage of an endoscope into the intestines.**

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A minor soreness in the throat following endoscopy is common. A bite lock will be inserted to protect your teeth and the equipment. **Please let our staff know if you have any loose teeth as we will not be responsible for teeth that fall off during the procedure.** All dentures must be removed prior to starting the procedure. Very rarely, the esophagus, stomach, or duodenum can be perforated during a difficult procedure.

**Risks related to injection of x-ray contrast.**
Pancreatitis (inflammation of the pancreas) occurs in less than 5% of patients. Pancreatitis causes abdominal pain and occasional nausea and vomiting. It is usually mild. Treatment involves hospitalization for intravenous fluids and pain medications. Rarely, pancreatitis can result in more serious illness which requires requires emergency surgical treatment or can result in death.

**Risks related to sphincterotomy (incision of the distal bile duct) stone extraction, and stent placement.**

These therapeutic procedures can result in cholangitis (infection in the bile ducts), hemorrhage, and perforation of the bile ducts or duodenum. Transfusion is occasionally necessary. A small number of patients may require emergency surgery to correct these complications. In rare cases, death can occur.

I understand that body positioning during the procedure may result in injury to nerves or blood vessels (numbness, tingling, pain or circulation problems). Rarely, such injury could be serious or even permanent. I understand that precautions are taken to minimize the occurrence of such injuries.

8. I understand that the practice of medicine and surgery is not an exact science. I acknowledge that no guarantees have been made to me concerning the results of the procedure(s).

9. I understand that during the course of the procedure(s), unforeseen conditions may arise or be discovered which require the performance of additional procedures. I hereby consent to the performance of such additional procedures as my physician believes to be necessary or advisable.

10. I hereby authorize GI Excellence, Inc. to dispose of or to retain for diagnostic, therapeutic, research, or educational purposes any tissues, organs, or body parts which are removed as a necessary part of the procedure.

11. I understand that GI Excellence, Inc. may from time to time photograph or videotape a surgical procedure or treatment of particular scientific interest for the advancement of medical care and education, unless I expressly request otherwise. In such instances, the identity of the patient remains totally confidential.

12. I understand that I may require a transfusion of blood and/or blood product(s) during my treatment. I understand that blood or blood products will be administered to me only if my physician determines that I need the transfusion. I understand that the benefits of receiving a transfusion include: (i) for red blood cells the prevention of hypoxemia (low oxygen level) which impairs organ function; (ii) for platelets, plasma, cryoprecipitate, and clotting factors - prevention or cessation of bleeding, bruising, hemorrhage into a vital organ, gastrointestinal tract, or brain. I also understand that the risk associated with a transfusion include common, unusual and rare risks, which include but are not limited to: (i) **Common:** fever and/or chills, allergic reaction (hives, itching, wheezing); (iii) **Rare:** hemolytic transfusion reaction (destruction of red blood cells, sometimes associated with kidney damage, shock and death), anaphylaxis (severe allergic reaction with difficulty breathing, shock), transmission of hepatitis, HIV (the virus that causes AIDS), or other infection. I understand that alternatives to transfusion may include, but are not limited to (i) no transfusion, accepting present condition and risks; (ii) donating and receiving my own blood (autologous transfusion, only available before certain planned elective surgery when significant blood loss is expected); and (iii) that other alternatives may include_____, I consent to the transfusion of blood or blood products if my physician determines that it is necessary for my well-being.

13. I understand that GI Excellence, Inc. may participate in teaching and that students in various affiliated health care programs may observe and participate in my care under the supervision of licensed professional staff members, unless I expressly request otherwise. I also understand that, on occasion, physicians, health program students and medical equipment company representatives not affiliated with GI Excellence, Inc. are allowed to observe, but not participate in, surgical procedures under the supervision of appropriate GI Excellence, Inc. personnel, unless I expressly request otherwise. These individuals are required to respect patient dignity and confidentiality.

**Physician's Statement**
I have discussed the proposed procedure, including the above information and the risks, benefits and alternatives to this proposed treatment and have answered the patient's questions.

_____ _____
Physician/PA/NP Date and Time of Consent

Continued next page.

**Patient's Consent Statement**
I have read the above and had it explained to me. I have had the opportunity to discuss the procedure with the physician and have had my questions answered to my satisfaction. I consent to the treatment.

_____ _____
Signature of Patient Date and Time of Consent

If patient signs with a mark:_____
Signature of Witness to Patient Making Mark

**COMPLETE ONLY IF PATIENT IS AN UNEMANCIPATED MINOR* OR IS OTHERWISE UNABLE TO CONSENT:**

Authorized Representative for Unemancipated Minor (under age 18 years); Parent, Legal Guardian, Foster Parent with DSS Authorization or DSS (See Informed Consent Policy).

Authorized Representative for Adult Unable to Consent: Health are Agent, Legal Guardian, Next of Kin (See Informed Consent Policy).

_____ _____
Pint Name of Patient's Authorized Representative Date and Time of Consent

_____ _____
Signature of Patient's Authorized Representative Relationship to Patient (see above)

**If telephone consent, two witnesses must hear consent,. Indicate name of authorized representative, date and relationship in spaces provided. Write "telephone consent" on representative's signature line.**

_____ _____
Signature of Witness Signature of Witness Date and Time of Consent

**IF TRANSLATOR ASSISTED WITH INFORMED CONSENT PROCESS**

_____
Print Name of Translator

_____
Relationship to Patient or Department / Agency of Translator

Should you have any further questions or concerns, please don't hesitate to give us a call.

Please read everything in this literature thoroughly and call us should you have questions or see our webpage: www.gi-excellence.com . We can be reached at (951) 652-2252.