Mass General Brigham

Research Consent Form
General Consent Form Template
Version Date: February 2022

Subject Identification

Protocol Title: Evaluation of the Impact of a Forward Viewing Scope at Time of ERCP

Principal Investigator: Marvin Ryou, MD

Site Principal Investigator:

Description of Subject Population: Adult patients undergoing standard of care ERCP

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information

We are asking you to be in a research study. This form will tell you what you should expect if you agree to be in the study. You will find more information about each of the following points later in this form.

It is your decision whether or not to join the study. We are asking you to be in this study because your doctor has scheduled you for an endoscopic retrograde cholangiopancreatography (ERCP) procedure for the treatment of issues with your pancreas and/or biliary system (this system drains waste from your liver into your intestines). We are doing the research to see if adding an esophagogastroduodenoscopy (EGD) with a forward-viewing endoscope (medical device with a camera and light on the end of it to look inside your body through your mouth) may make it easier to see abnormal tissue in your gastrointestinal tract, that may be missed using a standard side-viewing endoscope during the ERCP exam. If you agree, you will have an EGD prior to

your ERCP exam. You will be in the study for 1 day, only your scheduled exam day, if you decide to stay for the whole study.

The main risks of being in the study are sore throat, difficulty swallowing, nausea, vomiting, bleeding, shoulder pain, infection, perforation (tear), pancreatitis (swelling of the pancreas), aspiration (inhaling a foreign substance into your airway), and abdominal pain.

You might benefit from being in the study because your physician may see important clinical findings that may have been missed during the standard ERCP exam.

If you decide not to be in the study, you will still undergo the ERCP exam as scheduled.

You will not be paid for taking part in this research study.

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Marvin Ryou, MD is the person in charge of this research study. You can call him at 617-983-7420 (7:30am – 5:30pm) or 617-732-6600 to have him paged 24/7. You can also call Michele Ryan at 617-676-5928 M-F 9-5pm with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call Michele Ryan at 617-676-5928.

If you want to speak with someone **not** directly involved in this research study, please contact the Mass General Brigham IRB. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research
- Any pressure to take part in, or to continue in the research study

Detailed Information

Why is this research study being done?

Endoscopic retrograde cholangiopancreatography (ERCP) is the current procedure of choice for the treatment for a variety of biliary system (this system drains waste from your liver into your intestines) and pancreatic disorders with over 500,000 procedures performed each year in the United States. While the endoscope has a side-viewing design (camera looks to the side instead of forward) in order to provide optimal viewing of the biliary and pancreas anatomy during the ERCP procedure, the non-forward field of view limits a complete endoscopic examination of the esophagus (tube that connects your throat to your stomach) and stomach.

We are doing this research to determine how many times there are any abnormal tissue or other problems in your esophagus and stomach that were missed by the traditional ERCP scope by looking at your tissue before the ERCP with a different endoscope. This will be done by adding a forward-viewing EGD exam to the traditional side-viewing ERCP procedure. Additionally, we aim to identify subject symptoms and medical history associated with any abnormal tissue or other problems in your esophagus and stomach that are seen with this EGD/ERCP exam.

The device used in the EGD exam is approved by the U.S. Food and Drug Administration (FDA) to look at the upper gastrointestinal tract.

Who will take part in this research?

We are asking you to take part in this research study because your doctor has recommended that you have a standard ERCP examination of your biliary system and/or pancreas. About 500 people will take part in this study at Brigham and Women's Hospital. Boston Scientific is paying for this research to be done.

What will happen in this research study?

If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures.

You have been previously scheduled to have an ERCP to look at your biliary system and/or pancreas. Your ERCP is part of your standard care and will be done whether or not you choose to participate in this study.

If you take part in this study, a study doctor will perform an additional examination, called an EGD, before your ERCP to look at your esophagus and stomach for any abnormal tissue (lesions). A different study doctor will then perform your ERCP. The doctor performing your ERCP will not know the results of the EGD exam before he/she performs the ERCP. We will compare the findings obtained at the EGD with the findings of the ERCP; we will also examine your symptoms, medical history and prior test results. Participating in this study will add an additional 10 minutes to your procedure time.

Your participation in this study is complete once you are discharged from the Endoscopy Center. There will be no additional visits required for this study. You will be contacted by your physician with the results of the exam at your next follow-up visit that will be scheduled as part of your standard of care plan.

Mass General Brigham has an electronic system that lets your study doctors know if you are admitted to a Mass General Brigham Hospital, or if you visit a Mass General Brigham Hospital Emergency Department. We want to make sure the study doctors know about any possible problems or side effects you experience while you are taking part in the study.

A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example, list of allergies, results of the EGD).

How may we use and share your health information for other research?

The information we collect in this study may help advance other research. If you join this study, we may remove all information that identifies you (for example, your name, medical record number, and date of birth) and use this de-identified data in other research. It won't be possible to link the information back to you. Information may be shared with investigators at our hospitals, at other academic institutions or at for-profit, commercial entities. You will not be asked to provide additional informed consent for these uses.

Will you get the results of this research study?

It is important to remember that research results are not always meaningful and are not the same as clinical tests. However, as the ERCP and EGD examinations are considered part of your standard of care, you will receive the results of these exams immediately following the procedure and they will also be detailed in your medical record. While you should not expect to get any information about the other results of your participation in this research, if experts from the study

decide that research results from your information are of high medical importance, we will attempt to contact you. In some situations, follow-up testing might be needed in a certified clinical lab. You and your medical insurer may be responsible for the costs of these follow-up tests and any follow-up care, including deductibles and co-payments.

What are the risks and possible discomforts from being in this research study?

Risks due to the standard of care ERCP procedure will be discussed with your physician prior to your exam. The risks of adding the EGD are similar to the risks of the ERCP procedure, which will slightly increase your chances of having an unexpected medical problem that could happen due to the procedure and/or anesthesia (adverse event).

Risks of General Anesthesia:

Your anesthesiologist will discuss these risks with you before your procedure. If you decide to participate in this study, you will receive an additional 10 minutes of anesthesia due to the study procedures.

Risks of Endoscopic Procedure (including ERCP and EGD):

Expected risks or discomforts anticipated as a result of an endoscopic procedure include (1 in 5 patients):

- Sore throat, hoarseness, lump in throat feeling (globus pharyngitis)
- Temporary difficulty (dysphagia) or painful swallowing (odynophagia) due to swelling or tissue manipulation
- Nausea, gagging, or vomiting
- Left shoulder pain from C02 insufflation – Carbon Dioxide (CO2) is put into your GI tract through the endoscope to expand the tissue so that the doctor can see all around the area that they are in. CO2 is absorbed or soaked up by your body so you do not feel as bloated or have a lot of gas after the procedure.
- Temporary abdominal or other pain which can be treated with standard pain medication

Rare risks or discomforts as a result of an endoscopic procedure (1 in 1000 patients):

- Injury of mouth and/or teeth, bite block related injury
- Persistent painful or difficulty swallowing (odynophagia or dysphagia) requiring intervention
- Bleeding
- Perforation of the esophagus or stomach
- Scraping of the esophagus, stomach or other parts of the GI tract (Abrasion)
- Bruising or swelling (Hematoma/edema)
- Deep cut or tear (Laceration) of the esophagus or stomach
- Esophageal tear
- Bloating
- Excessive burping (Dyspepsia)
- Diarrhea
- Infection
- Abnormal connection (Fistulae) between inner organs
- Vomiting
- Nose bleeding from nasal intubation
- Vocal cord bumps (nodules) due to intubation
- Hiccups
- Limited neck mobility
- Swelling of the pancreas (Pancreatitis)

There may be other risks that are unknown at this time.

What are the possible benefits from being in this research study?

Potential benefits include identification of clinically significant findings including but not limited to swollen or enlarged veins in your esophagus (esophageal varices), ulcers, bleeding, or abnormal tissue, that may not have been visualized during the ERCP. The findings of this study may benefit future patients if changes are made to clinical care and workflow at Brigham and Women's Hospital Endoscopy Center.

Can you still get medical care within Mass General Brigham if you don't take part in this research study, or if you stop taking part?

Yes. Your decision won't change the medical care you get within Mass General Brigham now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should you do if you want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will you be paid to take part in this research study?

You will not be paid to participate in this study.

We may use your information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your information is used for this purpose.

What will you have to pay for if you take part in this research study?

Study funds will pay for certain study-related items and services. You/your health insurer will be responsible for the cost of the ERCP because this would be needed for your care even if you are not in the study. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if you are injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the beginning of this consent form.

If you take part in this research study, how will we protect your privacy?

Federal law requires Mass General Brigham to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Who may see, use, and share your identifiable information and why they may need to do so:

- Mass General Brigham researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Mass General Brigham ethics board or an ethics board outside Mass General Brigham that oversees the research

- A group that oversees the data (study information) and safety of this study
- Non-research staff within Mass General Brigham who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other:

Some people or groups who get your identifiable information might not have to follow the same privacy rules that we follow and might use or share your identifiable information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your identifiable information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your identifiable information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your identifiable information for any mailing or marketing list. However, once your identifiable information is shared outside Mass General Brigham, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire.

The results of this research study may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with the law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent of Non-English Speaking Subjects Using the "Short Form" in the Subject's Spoken Language

Statement of Hospital Medical Interpreter

As someone who understands both English and the language spoken by the subject, I interpreted, in the subject's language, the researcher's presentation of the English consent form. The subject was given the opportunity to ask questions.

Hospital Medical Interpreter	Date	Time (optional)

OR

Statement of Other Individual (Non-Interpreter)

As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name	Date	Time (optional)

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