

Consent and Authorization Form

COMIRB
APPROVED
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Principal Investigator: Mihir Wagh

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Study Title: Evaluation of pancreatic cystic lesions via EUS-guided fine needle aspiration with and without micro forceps biopsies: A randomized controlled study

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all your questions. Please read the information below and ask questions about anything you do not understand before deciding whether or not to take part.

Why is this study being done?

This study investigates the best way to diagnose the lesion on your pancreas.

You are being asked to be in this research study because you have been referred for evaluation of a lesion on your pancreas. Pancreas lesions or cysts are a very common finding. They are usually discovered during an imaging study such as a CT or MRI that is being done for a different reason. You are here for a procedure today to determine what this lesion is in the pancreas. There are many different possibilities for what this could be, and many types of pancreatic cysts. Some are benign or insignificant and some are more concerning as they can turn into pancreatic cancer. Because of this, we need to make sure we can give you an accurate diagnosis.

Today you are here for an endoscopic ultrasound, which is a procedure where we look closely at the lesion in the pancreas to determine the cause. If it looks like a cyst that we can sample, we typically will take a tissue sample, or biopsy, from the cyst through the endoscope. There are two ways to do this. One approach is to use a needle to get a sample of cyst fluid. Another approach is to use a biopsy forceps to obtain a sample of tissue. Additionally, these two methods can be combined. Both are well-established safe and effective methods for diagnosis of pancreatic cysts, but there is no agreement as to the best method. We are looking to compare these two methods.

Other people in this study

Up to 350 people from three United States centers will be enrolled in the study.

Up to 200 people from your area will participate in the study.

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What happens if I join this study?

If you join the study, you will be randomly assigned to one of the two intervention arms, 1) Sampling of cyst fluid with a needle or 2) Sampling of cyst fluid with a needle in addition to taking a biopsy of the cyst wall. Both approaches are performed with use of endoscopic ultrasound. Additionally, as part of standard care, the physician performing your procedure will describe the features and characteristics of the suspected pancreatic cyst.

The study team will reach out to you at two different points to see if you have experienced any adverse events:

- 1) Up to 72 hours post-procedure to collect information about adverse events the first 24 hours and
- 2) At day 30 to collect data AE data from the previous 30 days.

The study team may also review and collect information from your procedure for the following year.

What are the possible discomforts or risks?

Discomforts you may experience while in this study include any adverse events at the following time periods:

Immediately post procedure up to 24 hours: shortness of breath, reaction to the medication/sedation, nausea, vomiting, abdominal pain, coughing, bleeding perforation, change in blood pressure or heart rate.

Immediately post procedure up to 30 days: pancreatitis (inflammation of the pancreas).

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it cannot be guaranteed.

The study may include risks that are unknown at this time.

What are the possible benefits of the study?

This study is designed for the researcher to learn more about diagnosing pancreatic cysts. However, there is no guarantee that your health will improve if you join this study. Also, there could be risks to being in this study. If there are risks, these are described in the section describing the discomforts or risks.

Are there alternative treatments?

There may be other ways of diagnosing your pancreatic cyst.

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You should talk to your doctor about your choices. Make sure you understand all of your choices before you decide to take part in this study. You may leave this study and still have these other choices available to you.

Who is paying for this study?

This research is being sponsored by University of Colorado School of Medicine, Division of Gastroenterology and US Endoscopy.

Will I be paid for being in the study?

You will not be paid to be in the study.

Will I have to pay for anything?

It will not cost you anything to be in the study. You or your insurance will be responsible for all procedure costs because all procedures are considered standard of care.

Is my participation voluntary?

Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you leave this study, you will still receive your normal medical care. The only medical care that you will lose is the medical care you are getting as part of this study. You might be able to get that same kind of medical care outside of the study. Ask your study doctor.

Can I be removed from this study?

The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason.

What happens if I am injured or hurt during the study?

If you have an injury while you are in this study, you should call *Dr. Mihir Wagh* immediately. *His* phone number is [720-848-2777](tel:720-848-2777).

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

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Who do I call if I have questions?

The researcher carrying out this study is [Dr. Wagh](#). You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call [Dr. Wagh](#) at 720-848-2777. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call [Dr. Wagh](#) with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Who will see my research information?

The University of Colorado Denver (UCD) and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include

- University of Colorado Denver
- University of Colorado Hospital

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use, and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the UCD and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information, but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

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Mihir S. Wagh, MD, FACG, FASGE.
University of Colorado Interventional Endoscopy
Division of Gastroenterology
1635 Aurora Court, F735
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- University of Colorado School of Medicine, Division of Gastroenterology and US Endoscopy, who is paying for this research study
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who oversee making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator. [To ensure proper evaluation of test results, your access to these study results may not be allowed until after the study is completed].

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Your social security number
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records
- Testing for sickle cell
- Tissue samples and the data with the samples.
- Billing or financial information

What happens to data, tissue, blood, and specimens that are collected in this study?

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The data collected in this study will be de-identified and only used for research purposes. Any tissue, blood, or specimens collected in this study will be stored as standard of care.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature: _____

Date: _____

Print Name: _____

Consent form explained by: _____

Date: _____

Print Name: _____