ENDOSCOPIC ULTRASOUND WITH FINE NEEDLE BIOPSY VERSUS FINE NEEDLE ASPIRATION WITH ON-SITE CYTOPATHOLOGY IN THE EVALUATION OF SOLID PANCREATIC MASSES: RANDOMIZED SINGLE BLINDED CLINICAL TRIAL

JHU Protocol #: IRB00148609
Protocol Chair/Principle Investigator: Mouen Khashab MD
Johns Hopkins Hospital
Document Date: 02/06/2018
NCT number: NCT03485924

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IRB: Institutional Review Board
Johns Hopkins School of Medicine
1620 McElderry Street
Reed Hall, Suite B-130
Baltimore, MD 21205-1911

If you are using Epic for this study, fax a copy of the signed consent form to 410-367-7382.

Patient I.D. Plate

RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

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Application No.: **IRB00148609**

Principal Investigator: **Mouen Khashab, MD**
1800 Orleans Street
Baltimore, MD, 21287
Telephone Number: 443-287-1960
Fax: 443-683-8335

1. What you should know about this study:

- You are being asked to join a research study. This consent form explains the research study and your part in it. Please read it carefully and take as much time as you need. Ask your study doctor or the study team to explain any words or information that you do not understand.
- You are a volunteer. If you join the study, you can change your mind later. There will be no penalty or loss of benefits if you decide to quit the study.
- During the study, we will tell you if we learn any new information that might affect whether you wish to continue to participate.
- If we think your participation in this study may affect your clinical care, information about your study participation will be included in your medical record, which is used throughout Johns Hopkins. Doctors outside of Johns Hopkins may not have access to this information. You can ask the research team to send this information to any of your doctors.
- When Johns Hopkins is used in this consent form, it includes The Johns Hopkins University, The Johns Hopkins Hospital, Johns Hopkins Bayview Medical Center, Howard County General Hospital, Johns Hopkins Community Physicians, Suburban Hospital, Sibley Memorial Hospital and All Children's Hospital.
- Biospecimens will be collected in this study. Biospecimens may include any of the following: blood, tissue, saliva, urine, bone marrow, cells, etc. Most biospecimens contain DNA, which is the genetic code for each person.
- 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.

- If you would like to review the information for this study, or a summary of the results, ask the study team doctor for the ClinicalTrials.gov study registration number.

2. Why is this research being done?

This research is being done to evaluate two endoscopic ultrasound sampling techniques: endoscopic ultrasound with fine needle aspirate (EUS-FNA) using standard techniques and endoscopic ultrasound with fine needle biopsy (EUS-FNB). All patients will in this study undergo both techniques in a randomized order. We hope to discover the best technique for collecting diagnostic material when patients with a pancreatic mass have an endoscopic ultrasound sampling procedure.

Adults who are scheduled to have an endoscopic ultrasound of pancreatic lesions as part of their clinical care may join.

How many people will be in this study?

A total of 200 participants are expected to take part in this study at multiple sites. About 132 people are expected to take part at Johns Hopkins.

3. What will happen if you join this study?

If you agree to be in this study, we will ask you to do the following things:

- A complete examination of the pancreas will be done during the endoscopic ultrasound (EUS) procedure you are scheduled to have for clinical reasons. The endoscopic ultrasound (EUS) is done by passing a flexible tube with an ultrasound probe through your mouth into your esophagus (the tube food goes through to get into the stomach). If there is an abnormal appearing area within the pancreas on EUS image, there may be a need to biopsy (take tissue from) the area in order to make a diagnosis. The procedure is standard clinical care.
- As part of this research study, you will be assigned to have the two methods of the Endoscopic Ultrasound sampling in a randomly assigned order, like "flipping a coin".
- The EUS sampling will be performed until adequate material is collected.
- If adequate sample is not obtained using the study method, we will change and use the alternate method until adequate specimen is collected.

How long will you be in the study?

You will be in this study for the duration of your endoscopy.

4. What are the risks or discomforts of the study?

Participating in this study may or may not increase your risk of biopsy related adverse events.

The risks of the EUS procedure include:

1. Each needle puncture may cause inflammation or scarring of the lining of the digestive tract which may cause pain (1 in 25 people), ulceration (1 in 50), bleeding (1 in 500), accidental poking of a hole in the lining of the stomach or intestines (1 in 1000) or very rarely death (1 in 10,000).
2. Pancreatitis - if a needle biopsy (obtaining abnormal appearing tissue) is performed, this can result in pancreatitis (inflammation of the pancreas) which could (less than 2 in 100) result in prolonged hospitalization and need for surgery or other procedures.
3. Perforation – accidentally poking a hole in the stomach or intestines (1 in 1,500) or an injury to the bowel wall with possible spilling (1 in 1,000) of stomach contents into the body cavity. Perforation can be small requiring 4-5 days hospitalization, but could be severe requiring prolonged hospitalization and/or additional procedures including surgical repair.

There is a risk that information about you could become known to people outside of this study.

There may be side effects and discomforts that are not yet known.

5. Are there risks related to pregnancy?

If you are a woman and believe you may be pregnant, you may not participate in this study. This research may hurt an embryo or fetus in ways we do not currently know. If you are of child-bearing age you will have to undergo a urine pregnancy test. This test must be negative in order for you to take part in the study.

6. Are there benefits to being in the study?

There is no direct benefit to you from being in this study. If you take part in this study, you may help others in the future.

7. What are your options if you do not want to be in the study?

You do not have to join this study. If you do not join, your care at Johns Hopkins will not be affected. You can have a standard Endoscopic Ultrasound and Fine Needle Aspirate outside of study participation.

8. Will it cost you anything to be in this study?

No. You will receive a separate Insurance and Research Participant Financial Responsibility Information Sheet (Sheet).

This Sheet will give you the following information:

- The procedures, tests, drugs or devices that are part of this research and that will be paid for by the study (no cost to you).
- The procedures, tests, drugs or devices that will be billed to you and/or your health insurer. If you have health insurance, you will be responsible for any co-pays or deductibles not covered by your insurance.

9. Will you be paid if you join this study?

No.

10. Can you leave the study early?

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

If you leave the study early, Johns Hopkins may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities**.**

11. How will your privacy be protected?

We have rules to protect information about you. Federal and state laws and the federal medical Privacy Rule also protect your privacy. By signing this form you provide your permission, called your "authorization," for the use and disclosure of information protected by the Privacy Rule.

The research team working on the study will collect information about you. This includes things learned from the procedures described in this consent form. They may also collect other information including your name, address, date of birth, and information from your medical records (which may include information about HIV, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

The research team will know your identity and that you are in the research study. Other people at Johns Hopkins, particularly your doctors, may also see or give out your information. We make this information available to your doctors for your safety.

People outside of Johns Hopkins may need to see or receive your information for this study. Examples include government agencies (such as the Food and Drug Administration), safety monitors, other sites in the study and companies that sponsor the study.

If you are in a cancer study that receives federal funding, the National Cancer Institute (NCI) now requires that we report identifiable information (such as, zip code) about your participation. You may contact the NCI if you have questions about how this information is used.

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

We will use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside Johns Hopkins who receive your information may not be covered by this promise or by the federal Privacy Rule. We try to make sure that everyone who needs to see your information keeps it confidential – but we cannot guarantee that your information will not be re-disclosed.

The use and disclosure of your information has no time limit. You may revoke (cancel) your permission to use and disclose your information at any time by notifying the Principal Investigator of this study by phone or in writing. If you contact the Principal Investigator by phone, you must follow-up with a written request that includes the study number and your contact information. The Principal Investigator's name, address, phone and fax information are on page one of this consent form.

If you do cancel your authorization to use and disclose your information, your part in this study will end and no further information about you will be collected. Your revocation (cancellation) would not affect information already collected in the study, or information we disclosed before you wrote to the Principal Investigator to cancel your authorization.

12. What treatment costs will be paid if you are injured in this study?

Johns Hopkins does not have a program to pay you if you are hurt or have other bad results from being in the study. However, medical care at Johns Hopkins is open to you as it is to all sick or injured people.

The costs for any treatment or hospital care you receive as the result of a study-related injury that are not covered by a health insurer will be billed to you.

By signing this form you will not give up any rights you have to seek compensation for injury.

13. What other things should you know about this research study?

a. What is the Institutional Review Board (IRB) and how does it protect you?

The Johns Hopkins Medicine IRB is made up of:

- Doctors
- Nurses
- Ethicists
- Non-scientists
- and people from the local community.

The IRB reviews human research studies. It protects the rights and welfare of the people taking part in those studies. You may contact the IRB if you have questions about your rights as a participant or if you think you have not been treated fairly. The IRB office number is 410-955-3008. You may also call this number for other questions, concerns or complaints about the research.

When the Johns Hopkins School of Medicine Institutional Review Board (IRB) reviews a study at another site, that site (institution) is solely responsible for the safe conduct of the study and for following the protocol approved by the Johns Hopkins IRB.

b. What do you do if you have questions about the study?
Call the principal investigator, Dr. Mouen Khashab at 443-287-1960. If you wish, you may contact the principal investigator by letter or by fax. The address and fax number are on page one of this consent form. If you cannot reach the principal investigator or wish to talk to someone else, call the IRB office at 410-955-3008.

c. What should you do if you are injured or ill as a result of being in this study?
If you think you are injured or ill because of this study, call Dr. Mouen Khashab at 443-287-1960 during regular office hours.

If you have an urgent medical problem related to your taking part in this study, Dr. Mouen Khashab at 443-287-1960 during regular office hours and 410-955-6070 after hours and on weekends.

d. What happens to Data and Biospecimens that are collected in the study?
Johns Hopkins and our research partners work to understand and cure diseases. The biospecimens and/or data you provide are important to this effort.

If you join this study, you should understand that you will not own your biospecimens or data, and should researchers use them to create a new product or idea, you will not benefit financially.

With appropriate protections for privacy, Johns Hopkins may share your biospecimens and information with our research sponsors and partners.

14. What does your signature on this consent form mean?

Your signature on this form means that: You understand the information given to you in this form; you accept the provisions in the form and you agree to join the study. You will not give up any legal rights by signing this consent form.

WE WILL GIVE YOU A COPY OF THIS SIGNED AND DATED CONSENT FORM

Signature of Participant	(Print Name)	Date/Time

Signature of Person Obtaining Consent	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

ONLY CONSENT FORMS THAT INCLUDE THE JOHNS HOPKINS MEDICINE LOGO CAN BE USED TO OBTAIN THE CONSENT OF RESEARCH PARTICIPANTS.

DOCUMENTATION OF PHYSICIAN/MID-LEVEL PROVIDER CONSENT

My signature below indicates that I have discussed the risks, benefits, and alternatives, answered any questions, and believe the participant is able to make an informed choice to join the study.

Signature of Physician/Mid-Level Provider	(Print Name)	Date/Time

Signature of Participant	(Print Name)	Date/Time

NOTE: A COPY OF THE SIGNED, DATED CONSENT FORM MUST BE KEPT BY THE PRINCIPAL INVESTIGATOR; A COPY MUST BE GIVEN TO THE PARTICIPANT; IF YOU ARE USING EPIC FOR THIS STUDY A COPY MUST BE FAXED TO 410-367-7382; IF YOU ARE NOT USING EPIC A COPY MUST BE PLACED IN THE PARTICIPANT'S MEDICAL RECORD (UNLESS NO MEDICAL RECORD EXISTS OR WILL BE CREATED).

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