THE UNIVERSITY OF IOWA

Human Subjects Office/
Institutional Review Board (IRB)
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Iowa City, Iowa 52242-1098
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irb@uiowa.edu
http://research.uiowa.edu/hso

IRB ID #: 201808820

To: Henning Gerke

From: IRB-01 Univ of Iowa, DHHS Registration # IRB00000099, DHHS Federalwide Assurance # FWA00003007

Re: Randomized controlled trial comparing SharkCore FNB needles with Acquire FNB needles regarding specimen quality and Diagnostic accuracy.

Protocol Number:
Protocol Version:
Protocol Date:
Amendment Number/Date(s):

Approval Date: 10/12/18

Next IRB Approval Due Before: 10/11/19

Type of Application:	**Type of Application Review:**	**Approved for Populations:**
☒ New Project	☒ Full Board:	☐ Children
☐ Continuing Review	Meeting Date: 10/11/18	☐ Prisoners
☐ Modification	☐ Expedited	☐ Pregnant Women, Fetuses, Neonates
	☐ Exempt	

Source of Support:

Investigational New Drug/Biologic Name:
Investigational New Drug/Biologic Number:
Name of Sponsor who holds IND:

Investigational Device Name:
Investigational Device Number:
Sponsor who holds IDE:

This approval has been electronically signed by IRB Chair:
William McGinnis, MD
10/12/18 1634

IRB Approval: IRB approval indicates that this project meets the regulatory requirements for the protection of human subjects. IRB approval does not absolve the principal investigator from complying with other institutional, collegiate, or departmental policies or procedures.

Agency Notification: If this is a New Project or Continuing Review application and the project is funded by an external government or non-profit agency, the original HHS 310 form, "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption," has been forwarded to the UI Division of Sponsored Programs, 100 Gilmore Hall, for appropriate action. You will receive a signed copy from Sponsored Programs.

Recruitment/Consent: Your IRB application has been approved for recruitment of subjects not to exceed the number indicated on your application form. If you are using written informed consent, the IRB-approved and stamped Informed Consent Document(s) are attached. Please make copies from the attached "masters" for subjects to sign when agreeing to participate. The original signed Informed Consent Document should be placed in your research files. A copy of the Informed Consent Document should be given to the subject. (A copy of the *signed* Informed Consent Document should be given to the subject if your Consent contains a HIPAA authorization section.) If hospital/clinic patients are being enrolled, a copy of the IRB approved Record of Consent form should be placed in the subject's electronic medical record.

Continuing Review: Federal regulations require that the IRB re-approve research projects at intervals appropriate to the degree of risk, but no less than once per year. This process is called "continuing review." Continuing review for non-exempt research is required to occur as long as the research remains active for long-term follow-up of research subjects, even when the research is permanently closed to enrollment of new subjects and all subjects have completed all research-related interventions and to occur when the remaining research activities are limited to collection of private identifiable information. Your project "expires" at 12:01 AM on the date indicated on the preceding page ("Next IRB Approval Due on or Before"). You must obtain your next IRB approval of this project on or before that expiration date. You are responsible for submitting a Continuing Review application in sufficient time for approval before the expiration date, however the HSO will send a reminder notice approximately 60 and 30 days prior to the expiration date.

Modifications: Any change in this research project or materials must be submitted on a Modification application to the IRB for prior review and approval, except when a change is necessary to eliminate apparent immediate hazards to subjects. The investigator is required to promptly notify the IRB of any changes made without IRB approval to eliminate apparent immediate hazards to subjects using the Modification/Update Form. Modifications requiring the prior review and approval of the IRB include but are not limited to: changing the protocol or study procedures, changing investigators or funding sources, changing the Informed Consent Document, increasing the anticipated total number of subjects from what was originally approved, or adding any new materials (e.g., letters to subjects, ads, questionnaires).

Unanticipated Problems Involving Risks: You must promptly report to the IRB any serious and/or unexpected adverse experience, as defined in the UI Investigator's Guide, and any other unanticipated problems involving risks to subjects or others. The Reportable Events Form (REF) should be used for reporting to the IRB.

Audits/Record-Keeping: Your research records may be audited at any time during or after the implementation of your project. Federal and University policies require that all research records be maintained for a period of three (3) years following the close of the research project. For research that involves drugs or devices seeking FDA approval, the research records must be kept for a period of three years after the FDA has taken final action on the marketing application.

Additional Information: Complete information regarding research involving human subjects at The University of Iowa is available in the "Investigator's Guide to Human Subjects Research." Research investigators are expected to comply with these policies and procedures, and to be familiar with the University's Federalwide Assurance, the Belmont Report, 45CFR46, and other applicable regulations prior to conducting the research. These documents and IRB application and related forms are available on the Human Subjects Office website or are available by calling 335-6564.

Randomized controlled trial comparing SharkCore FNB needles with Acquire FNB needles regarding specimen quality and Diagnostic accuracy.

PI: Henning Gerke
IRB ID #: 201808820

Project Details

I. Project Introduction

I.1 ***Project to be reviewed by:***
IRB-01

I.2 ***Project Title:***
Randomized controlled trial comparing SharkCore FNB needles with Acquire FNB needles regarding specimen quality and Diagnostic accuracy.

I.3 ***Short Title (optional):***

I.4 ***Provide a short summary of the purpose and procedures of the study proposed in this IRB application.***

- ***DO NOT include information on studies not proposed in this application.***
- ***Use LAY terminology only. This must be easily understandable by IRB community members and nonscientists.***
- ***DO NOT cut and paste technical abstracts from funding applications that may not be understood by a general audience.***

Endoscopic ultrasound-guided fine needle aspiration (EUS-FNA) has been established as an effective technique for sampling tissue inside and around the gastrointestinal tract, including the pancreas, liver, lymph nodes, and adrenal glands. EUS-FNA is convenient, minimally invasive, and safe procedure with an estimated sensitivity of 75%-92% and a specificity of 82%-100%.
Diagnosis of various pathologies in the GI tract including solid pancreatic masses, mediastinal or gastric lymph nodes, gastrointestinal submucosal lesions, and peri-rectal lesions require adequate tissue architecture and immunohistochemical analysis. This is difficult to obtain and is frequently insufficient with EUS-FNA cytology alone. The core tissue is required to improve the diagnostic yield and obtain histologic diagnosis along with immunostaining to establish specimen adequacy. In past 1 year two new needle EUS needle (Shark Core)and Acquire EUS needles has been introduced to improve diagnostic accuracy, tissue yield, and potentially obtain a core tissue sample. So far, no prospective studies have compared these two needles to see which one is better for overall diagnostic accuracy. Our goal is to perform a prospective analysis to compare the diagnostic yield and safety profile of these 2 new EUS needle.

I.5 ***Specify your research question(s), study aims or hypotheses (do not indicate "see protocol")***
Is the new Acquire FNB needle (Boston Scientific, Natick, MA) non-inferior in diagnostic accuracy, histologic yield of the sample obtained, number of needle passes required to obtain the tissue sample, ability to get tissue core to allow IHC staining and molecular diagnostics and side effect profile, when compared to SharkCore needle (Medtronic, Dublin, Ireland)?

I.6 ***Background and significance and/or Preliminary studies related to this project.***
(do not indicate "see protocol")
We have data showing an improved yield of tissue using EUS SharkCore biopsy needle. We recently have started using the new Acquire EUS needle in our clinical practice. We need to evaluate the efficacy and compare Acquire needle with SharkCore needle to see which needle provide overall better diagnostic accuracy. No study thus far has done a head-to-head trial.

I.7 ***Literature cited / references (if attaching a grant or protocol enter N/A).***
1. Adler DG, Witt B, Chadwick B et al. Pathologic evaluation of a new endoscopic ultrasound needle designed to obtain core tissue samples: A pilot study. Endosc Ultrasound. 2016 May-Jun;5(3):178-83.
2. Kandel P, Tranesh G, Nassar A et al. EUS guided fine needle biopsy sampling using a novel fork-tip needle: a case control study. Gastrointest Endosc. 2016 Dec;84(6):1034-1039.
3. Gerke H, Rizk MK, Vanderheyden AD, et al. Randomized study comparing endoscopic ultrasound-guided Trucut biopsy and fine needle aspiration with high suction. Cytopathology 2010;21:44-51.
4. Mitri RD, Rimbas M, Attili F, Fabbri C, Carrara S, Di Maurizio L, Inzani F, Repici A, Gasbarrini A, Costamagna G, Larghi A. Performance of a new needle for endoscopic ultrasound-guided fine-needle biopsy in patients with pancreatic solid lesions: A

retrospective multicenter study. Endosc Ultrasound [Epub ahead of print] [cited 2018 Aug 5]. Available from: http://www.eusjournal.com/preprintarticle.asp?id=213652.

II. Research Team

II.1 ***Principal Investigator***

Name	E-mail	College
Henning Gerke	henning-gerke@uiowa.edu	Carver College of Medicine

II.2 ***Team Members***

UI Team Members

Name	E-mail	College	Contact	Key Prsn	UI COI	VAMC COI	Consent Process Involvement	Deactivated
Henning Gerke, MD	henning-gerke@uiowa.edu	Carver College of Medicine	Yes	Yes	No		Yes	No
Barakat Aburajab Altamimi, MD, MBBS	barakat-aburajabaltamimi@uiowa.edu	Carver College of Medicine	No	Yes	No		Yes	Yes
Sumant Arora, MD	sumant-arora@uiowa.edu	Carver College of Medicine	No	Yes	No		Yes	Yes
Munish Ashat, MD	munish-ashat@uiowa.edu	Carver College of Medicine	Yes	Yes	No		Yes	Yes
Rami El Abiad, MD	rami-elabiad@uiowa.edu	Carver College of Medicine	Yes	Yes	No		Yes	No
Donna Evans, BSN	donna-evans@uiowa.edu	Carver College of Medicine	No	No	No		Yes	No
Nancy Gupta, MD	nancy-gupta@uiowa.edu	Graduate College	No	Yes	No		Yes	Yes
Yazan Hasan, MD	yazan-hasan@uiowa.edu	Carver College of Medicine	No	Yes	No		Yes	No
Debi Heitshusen, BSN RN, BSN	debi-heitshusen@uiowa.edu	Carver College of Medicine	No	No	No		Yes	No
Ethan Hoover, BA	ethan-hoover@uiowa.edu	Carver College of Medicine	No	No	No		Yes	No
Chris Jensen, MD	chris-jensen@uiowa.edu	Carver College of Medicine	Yes	Yes	No		No	No
Jena Neuhaus, RN	jena-neuhaus@uiowa.edu	Carver College of Medicine	No	No	No		Yes	No

Name	E-mail	College	Contact	Key Prsn	UI COI	VAMC COI	Consent Process Involvement	Deactivated
Arvind Rangarajan Murali, MD	arvind-murali@uiowa.edu	Carver College of Medicine	Yes	Yes	No		Yes	No
John Sagar, BS	john-sagar@uiowa.edu	Carver College of Medicine	No	No	No		Yes	No
Jessica Valestin, BS	jessica-valestin@uiowa.edu	Carver College of Medicine	Yes	Yes	No		Yes	No
James Vancura, MD	james-a-vancura@uiowa.edu	Carver College of Medicine	No	Yes	No		Yes	No
Sagar Vishal, MD	sagar-vishal@uiowa.edu	Carver College of Medicine	No	Yes	No		Yes	Yes

Non-UI Team Members

Name Institution Location FWA Role DHHS Contact Key Prsn UI COI VAMC COI Consent Process Involvement Email

Nothing found to display.

II.3 ***The Principal Investigator of this study is:***

Faculty

II.6 ***Identify the key personnel. The system will automatically designate the PI and all faculty members on the project as "key personnel." For information about other team members who should be designated as "key personnel" please click on the help information.***

Name	Is Key Personnel
Henning Gerke, MD	Yes
Barakat Aburajab Altamimi, MD, MBBS	Yes
Sumant Arora, MD	Yes
Munish Ashat, MD	Yes
Rami El Abiad, MD	Yes
Donna Evans, BSN	No
Nancy Gupta, MD	Yes
Yazan Hasan, MD	Yes
Debi Heitshusen, BSN RN, BSN	No
Ethan Hoover, BA	No
Chris Jensen, MD	Yes
Jena Neuhaus, RN	No
Arvind Rangarajan Murali, MD	Yes
John Sagar, BS	No
Jessica Valestin, BS	Yes
James Vancura, MD	Yes
Sagar Vishal, MD	Yes

II.5 ***Select research team member who is the primary contact for study participants.***

Munish Ashat

III. Funding/Other Support

III.1 ***Funding Sources***

Type	Source	Grant Title	Name of PI on Grant
No Funding			

* new source name

III.3 ***Does any member of the research team have a financial conflict of interest related to this project according to the Conflict of Interest in Research policy? If yes, please indicate which members below.***

Name	Has Conflict of Interest
Henning Gerke, MD	No
Barakat Aburajab Altamimi, MD, MBBS	No
Sumant Arora, MD	No
Munish Ashat, MD	No
Rami El Abiad, MD	No
Donna Evans, BSN	No
Nancy Gupta, MD	No
Yazan Hasan, MD	No
Debi Heitshusen, BSN RN, BSN	No
Ethan Hoover, BA	No
Chris Jensen, MD	No
Jena Neuhaus, RN	No
Arvind Rangarajan Murali, MD	No
John Sagar, BS	No
Jessica Valestin, BS	No
James Vancura, MD	No
Sagar Vishal, MD	No

IV. Project Type

IV.1 ***Do you want the IRB to give this project***
Regular (expedited or full board) review

IV.2 ***Enter the date you will be ready to begin screening subjects/collecting data for this project. (If you do not have a specified date, add "upon IRB approval")***
08/24/2018

IV.3 ***Are you requesting a waiver of informed consent/authorization (subjects will not be given any oral or written information about the study)?***
No

V. Other Committee Review

V.1 ***Does this project involve any substance ingested, injected, or applied to the body?***

- ***Do not answer yes, if the involvement includes a device, wire, or instrument***

No

V.2 ***Are any contrast agents used for any purpose in this study?***
No

V.9 ***Will any subject be asked to undergo a diagnostic radiation procedure (including radiographic, nuclear medicine, DEXA)?***
No

V.14 ***Will any subject be asked to undergo a radiation therapy procedure (including external beam therapy, brachytherapy, or nuclear medicine therapy)?***
No

V.20 ***Does this project involve the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human research participant?***
No

V.21 ***Will any portion of this project be conducted in the CRU, or does it use any CRU resources?***
No

V.22 ***Will this project use:***

- ***any resource/patients of the Holden Comprehensive Cancer Center***
- ***involve treatment, detection, supportive care, or prevention of cancer***

No

V.25.a ***Will the study involve <u>any</u> of the following activity at UI Health Care, even if subjects or their insurance will not be billed for the item or service, and regardless of the study funding source (including studies with departmental or no funding)?***

- ***Procedures, tests, examinations, hospitalizations, use of Pathology services, use of clinic facilities or clinical equipment, or any patient care services, including services conducted in the Clinical Research Unit; or***
- ***Physician services or services provided by non-physicians who are credentialed to bill (ARNPs, Physician Assistants, etc.)***

Yes

V.25.b ***Will there be any procedures or services that may happen as part of a subject's regular medical care and as part of the study?***
Yes

V.25.c ***Will any study equipment or devices be supplied by a study sponsor?***
No

V.25.e ***Is there or will there be an internal budget for this study?***
No

V.25.f ***Is there or will there be an external budget for this study?***
No

V.26 ***The study involves Department of Nursing Services and Patient Care nursing, nursing resources or evaluates nursing practices at UI Health Care.***
No

VI. Subjects

VI.1 ***How many adult subjects do you expect to consent or enroll for this project?***
150

VI.2 ***What is the age of the youngest adult subject?***
18.0

VI.3 ***What is the age of the oldest adult subject?***
85.0

VI.4 ***What is the percentage of adult male subjects?***
50

VI.5 ***What is the percentage of adult female subjects?***
50

VI.6 ***How many minor subjects do you expect to consent or enroll for this project?***
0

VI.13 ***Describe EACH of your subject populations***

- ***Include description of any control group(s)***
- ***Specify the Inclusion/Exclusion criteria for EACH group***

Inclusion Criteria:
Patients ≥ 18 years of age referred for EUS
Lesions requiring histologic diagnosis:
• Mesenchymal tumors
• Autoimmune pancreatitis
• Granulomatous disease
• Indeterminate hepatitis
• Confirmatory immunochemistry to establish a diagnosis (i.e. pancreatic neuroendocrine tumor)
• Lymphoma
• Solid tumors
• Previously non-diagnostic FNA

Exclusion Criteria:
• Uncorrectable coagulopathy (INR > 1.5)
• Uncorrectable thrombocytopenia (platelet < 50,000)
• Uncooperative patients
• Pregnant women (women of childbearing age will undergo urine pregnancy testing, which is routine for all endoscopic procedures)
• Refusal to consent form
• Cystic lesions
• Inaccessible lesions to EUS (proximal to sigmoid colon or distal to second duodenum)

VI.14 ***Provide an estimate of the total number of subjects that would be eligible for inclusion in each of your study populations (include your control population if applicable)***
Answer: Approximately 350 patients are referred to UIHC GI department for EUS-FNB procedures. Out of these 350 patients around 200 patients will meet the inclusion criterion.

VI.15 ***Describe how you will have access to each of your study populations in sufficient number to meet your recruitment goals.***
Inpatients with imaging findings of mass in GI tract that need a biopsy, Outpatient referrals from outside providers requesting EUS to help diagnosis of possible malignancy.

VI.16 ***Do you plan to recruit/enroll non-English speaking people?***
No

VI.18 ***Do you propose to enroll any of the following in this study as subjects?***

- ***Employee of the PI or employee of a research team member***
- ***Individual supervised by PI or supervised by member of research team***
- ***Individual subordinate to the PI or subordinate to any member of the research team***
- ***Student or trainee under the direction of the PI or under the direction of a member of the research team***

No

VI.20 ***Will subjects provide any information about their relatives?***
No

VI.23 ***Will anyone (other than the subject) provide you with information about the subject (e.g. proxy interviews)?***
No

VI.26 ***Is this project about pregnant women?***
No

VI.27 ***Will this project involve fetuses?***
No

VI.28 ***Does this project involve adult subjects who may be incompetent or have limited decision-making capacity on initial enrollment into the study?***
No

VI.32 ***Does this project involve subjects whose capacity to consent may change over the course of the study?***
No

VI.37 ***Does this project involve prisoners as subjects?***
No

VII.A. Project Description (A)

VII.A.1 ***Where will project procedures take place (check all that apply)?***
- UIHC - Digestive Health Center

VII.A.2 ***Is this project also being conducted by other researchers at their own sites (e.g. a multi-site collaborative project)?***
No

VII.B. Project Description (B)

VII.B.1 ***Does this project involve any of the following (Check all that apply):***

- ☐ **Registry** – The collection and maintenance of data (not including biologic samples) in which: (1) the individuals in the registry have a common or related condition(s), and/or (2) the individuals in the registry are interested in being contacted for future studies by investigators other than those listed in Section II of this project.(UI Guide)
- ☐ **Repository** – The collection, storage, and distribution of human biologic samples and/or data materials for research purposes. Repository activities involve three components: (i) the collection of data and/or specimens such as blood, tissue, saliva, etc.; (ii) the storage of data or specimens, and data management function; and (iii) the sharing of data/specimens with recipient investigators other than the original investigators. (paraphrased from OHRP)
- ☐ **Expanded Access** – A process regulated by the Food and Drug Administration (FDA) that allows manufacturers to provide investigational new drugs to patients with serious diseases or conditions who cannot participate in a clinical trial. Examples of expanded access include non-protocol access to experimental treatments, including protocol exception, single-patient IND, treatment IND, compassionate use, emergency use, continued access to investigational drug, and parallel track (ClinicalTrials.gov & FDA).
- ☑ **Clinical (or Treatment) trial** – A prospective biomedical or behavioral research study of new treatments, new drug or combinations of drugs, new devices, or new approaches to surgery or radiation therapy. (NIH and ClinicalTrials.gov & FDA)
- ☐ **Physiology intervention/study** – A pharmacologic or measurement study aimed at understanding basic mechanisms of disease and/or of normal human physiology, often without any therapeutic intent (though a clinical trial could include such components, often labeled as "translational" or "basic science" aims.) Measurements in such studies could include, but are not limited to, a blood draw, EKG, EEG, MRI, auditory or sensory testing, checking vital signs, DEXA scans, eye tracking, specimen collection, exercise, fasting, special diets, etc.
- ☐ **Behavioral intervention/study** – May be used to refer to studies of individual or group behavior. This option does not include drugs, biologics, or devices but could include psychotherapy, lifestyle counseling, behavior modification, etc.
- ☐ **Diagnostic trial** – Protocol designed to evaluate one or more interventions aimed at identifying a disease or health condition (ClinicalTrials.gov & FDA)
- ☐ **Non-clinical** – any college/department that would regularly submit to IRB-02
- ☐ **Other**

VII.B.1.a ***Does this project involve any of the following (Check all that apply):***

- ☐ **Phase I trials** – include initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients (ClinicalTrials.gov & FDA)
- ☐ **Phase II trials** – include controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common short-term side effects and risks(ClinicalTrials.gov & FDA)
- ☐ **Phase III trials** – include expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labeling(ClinicalTrials.gov & FDA)
- ☑ **Phase IV trials** – studies of FDA-approved drugs to delineate additional information including the drug's risks, benefits, and optimal use(ClinicalTrials.gov & FDA)

VII.B.1.b ***Provide the NCT (National ClinicalTrials.gov Identifier) number***
NCT03672032

VII.B.2 ***Does this project involve a drug washout (asking subject to stop taking any drugs s/he is currently taking)?***
No

VII.B.6 ***Will any subjects receive a placebo in this study when, if they were not participating, they could be receiving an FDA-approved treatment for their condition?***
No

VII.B.11 ***Is there a separate, written protocol that will be submitted in addition to this IRB New Project form? (Note: a grant application is not considered to be a protocol)***
No

VII.B.18 ***Does this project involve testing the safety and/or efficacy of a medical device?***
Yes

VII.B.19 ***Describe in detail procedures in place for maintaining device shipment and receipt records:***
We are already using SharkCore and Aquire needles on a daily basis. Both devices are FDA approved and we have been using a SharkCore needle for > 1 year and Acquire needle > 2 months. These will be used in SOC procedures and the staff in DHC will track these as part of a typical procedure.

VII.B.20 ***Who will be responsible for maintaining these shipment and receipt records?***
Both needles are already in use in daily clinical practice in Digestive health center (DHC) at UIHC. Regular shipments are received by device procurement department as any other instruments used on daily basis in DHC. These will be used in SOC procedures and the staff in DHC will track these as part of a typical procedure.

VII.B.21 ***Describe in detail procedures in place for tracking use and disposition of devices described in this study:***
The SharkCore and Acquire needle will be disposed into a Sharps container present is each procedure room. These will be used in SOC procedures and the staff in DHC will track these as part of a typical procedure.

VII.B.22 ***Who will be responsible for maintaining these use and disposition tracking records?***
Both needles are currently under use, on daily basis at DHC. Once the needle barcode is scanned during procedure into EPIC we can discard the package inserts for recycling. These will be used in SOC procedures and the staff in DHC will track these as part of a typical procedure.

VII.B.23 ***Describe in detail procedures in place to limit access to authorized study personnel for the storage, control, and dispensing of the investigational devices. (For example, investigational devices are kept in a locked area away from approved devices or have a keyed interlock, and only study personnel authorized to dispense the device have the keys)***
Since both SharkCore and Acquire needle are FDA approved for EUS guided biopsy and already in use at UIHC these are present in Omnicells which can only be opened with a password. Every time a needle is used the barcode specific for that needle is scanned into EPIC.

VII.B.24 ***Is the device FDA-approved for the way it will be used in this study?***
Yes

VII.C. Project Description (C)

VII.C.1 ***Does this project involve any research on genes or genetic testing/research?***
No

VII.D. Project Description (D)

VII.D.1 ***Check all materials/methods that will be used in recruiting subjects (you will need to attach copies of all materials at the end of the application):***

- Use of any information available to the researchers or their colleagues because this person is a patient OR use of any information considered to be Protected Health Information (PHI) OR review of patient/clinic records - GI inpatient team/Clinic providers will consult the investigator and study investigator will follow-up with the patient. We also get referrals from outside providers for EUS to help in the diagnosis of malignancy for which EUS biopsy is paramount.
- Referral from colleague - Patients are referred to GI clinic for evaluation and to take Biopsy of mass seen on imaging studies. We will review the images and make sure that the patient meets the criterion for endoscopic ultrasound and Biopsy before recruiting them into study population.

VII.D.2 ***List the individual data elements you will need to access/use from the patient or clinic records to identify potential subjects for recruitment***
age,sex, reason for hospitalization, diagnosis, date of diagnosis, medication history, travel history (if available), past medical history, imaging study (including but not limited to CT abdomen/pelvis/chest with and without contrast; MRI abdomen/pelvis and Chest, PET scan whole body), lab tests- CBC,BMP, INR, LFT,CEA, CA19-9, AFP, Pathology results.

VII.D.3 ***Describe why you could not practicably recruit subjects without access to and use of the information described above***
we would not know who to approach without assessing PHI and it will be impractical to do an endoscopic ultrasound on all patients coming to the digestive health clinic.

VII.D.4 ***Describe why you could not practicably obtain authorization from potential subjects to review their patient or clinic records for recruitment purposes.***
A large number of patients are referred to the digestive health clinic and it will be practically impossible to obtain authorization from all of them as very few will meet the eligibility criterion.

VII.D.5 ***Describe plans to protect the identifiers from improper use or disclosure***
All data will be stored in a locked office with access only to research team members. Any electronic information will be kept on PI's password protected shared drive, accessible only by team members.

VII.D.6 ***Describe plans to destroy identifiers at the earliest opportunity consistent with conduct of the research***
Identifying information will be removed from the screening lig after the study has been closed.

VII.D.7 ***Does the research team agree that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the study, or for other research for which the use or disclosure of the requested information would be permitted by the HIPAA Privacy Rule***
Yes

VII.D.8 ***Will a member of the research team discuss the study with the subject in person prior to the subject agreeing to participate?***
Yes

VII.D.9 ***Describe the physical location where the consent process will take place:***
Digestive Health Center

VII.D.10 ***Will a member of the research team discuss the study with the subject by phone prior to the subject agreeing to participate?***
No

VII.D.12 ***Who will be involved in the consent process (including review of consent document, answering subjects' questions)?***

Name	Consent Process Involvement
Henning Gerke, MD	Yes
Barakat Aburajab Altamimi, MD, MBBS	Yes
Sumant Arora, MD	Yes
Munish Ashat, MD	Yes
Rami El Abiad, MD	Yes
Donna Evans, BSN	Yes
Nancy Gupta, MD	Yes
Yazan Hasan, MD	Yes
Debi Heitshusen, BSN RN, BSN	Yes
Ethan Hoover, BA	Yes
Chris Jensen, MD	No
Jena Neuhaus, RN	Yes
Arvind Rangarajan Murali, MD	Yes
John Sagar, BS	Yes
Jessica Valestin, BS	Yes
James Vancura, MD	Yes
Sagar Vishal, MD	Yes

VII.D.15 ***Check all materials that will be used to obtain/document informed consent:***
- Consent Document

VII.D.16 ***Are you requesting a waiver of documentation of consent (either no subject signature or no written document)?***
No

VII.D.19 ***Before the subject gives consent to participate are there any screening questions that you need to directly ask the potential subject to determine eligibility for the study?***
No

VII.D.25 ***After the subject agrees to participate (signs consent), are there any screening procedures, tests, or studies that need to be done to determine if the subject is eligible to continue participating?***
No

VII.D.27 ***Discuss how much time a potential subject will have to agree to consider participation and whether or not they will be able to discuss the study with family/friends before deciding on participation.***
The potential subject may take as long as the subject needs to consider about participation in the study. The potential subject may also discuss the study with family and friends before making their decision whether or not to participate.

VII.D.28 ***How long after the subject agrees to participate do study procedures begin?***
Immediately

VII.D.29 ***Provide a description of the enrollment and consent process for adult subjects***

- ***Describe each study population separately including control population***
- ***Include when recruitment and consent materials are used***
- ***Use 3rd person active voice "The Principal Investigator will identify subjects. For example, the principal investigator will identify potential subjects, the study coordinator will discuss the study with subjects over the telephone and schedule the first study visit, etc..."***
- ***Describe the steps that will be taken by the research team to minimize the possibility of coercion or undue influence during the consent process***

University of Iowa GI/Liver division performs approximately 350 EUS a year. Most of these patients are seen in GI clinic first and investigators will go over all the imaging findings to help them understand why the procedure is being done. Once, all their or family members questions are answered satisfactorily the investigator will schedule the patient for EUS guided Biopsy.
The patient will then undergo EUS guided Biopsy with either SharkCore EUS-FNB needle or Acquire EUS-FNB Needle. The purpose of the research study is to compare 2 FDA approved needles (SharkCore and Acquire EUS-FNB needles) in their efficacy to obtain adequate tissue sample and help make accurate histological diagnosis.
The subject will be informed that their decision to participate in the study will not affect their clinical care they receive, so as to minimize the possibility of feeling coercion. An informed consent will be signed on the day of study.

VII.D.37 ***Does the study include any form of deception (e.g., providing participants with false information, misleading information, or withholding information about certain study procedures)?***

Examples:

- ***Procedure includes a cover story that provides a plausible but inaccurate account of the purposes of the research.***
- ***Participants will be provided with false information regarding the particular behaviors of interest in the research.***
- ***Procedures include a confederate pretending to be another participant in the study.***
- ***Participants will be told that the research includes completion of a particular task, when in fact, that task will not be administered.***
- ***Study is designed to introduce a new procedure (or task) that participants are not initially told about.***
- ***If yes, a waiver of informed consent must be requested under question IV.3.***

No

VII.E. Project Description (E)

VII.E.1 ***Will subjects be randomized?***
Yes

VII.E.1.a ***Will any subjects be blinded to which study arm they have been assigned?***
No

VII.E.2 ***Describe randomization scheme/assignment including ratio such as 1:1, 2:1 etc.***

we will use 1:1 randomization.

VII.E.3 ***Will any questionnaires, surveys, or written assessments be used to obtain data directly from subjects in this study?***
No

VII.E.5 ***Does this project involve creating any audiotapes, videotapes, or photographs?***
No

VII.E.6 ***Provide a detailed description in sequential order of the study procedures following the consent process - DO NOT cut and paste from the Consent Document.***

Describe study populations separately if they will be participating in different procedures - include CONTROL population if applicable.

DESCRIBE:

- ***What subjects will be asked to do/what happens in the study (in sequential order)***
- ***The time period over which procedures will occur***
- ***The time commitment for the subject for individual visits/procedures***
- ***Long-term followup and how it occurs***

Subjects come to a pre-procedure room on the day of the procedure. The investigator will again go over the risk and benefit of procedure and indication of the procedure. Once the consent form is signed, a large bore IV cannula is placed and the subject will be taken to the DHC procedure room. Once all the team members required to perform the procedure are in the room we will do a time-out to make sure current patient and procedure are performed. A time-out is done by asking the subject to tell his full name with date of birth and describe in his own words what procedure is planned for subject today. If all the things match the investigator will go ahead and start the sedation.
All EUS-FNB was performed in the standard manner using linear echoendoscopes. All EUS-FNB procedures were performed by 1 of 2 highly experienced endosonographers (Henning Gerke or Rami EL-Abiad).
The needle to be used (SharkCore vs Acquire) will be decided based on randomization software. The needle was then used to puncture the target lesion in standard fashion. Aspirated cellular materials will be expressed into the slide by advancing the stylet. The remainder will be expressed onto filter paper and submitted for cell block preparation. Your medical information including diagnosis, date of diagnosis, date of admission, blood test results, and medications received will be reviewed for analysis.

VII.E.7 ***Will you attempt to recontact subjects who are lost to follow-up?***
No - followup is not required in this study

VII.E.9 ***Will subjects be provided any compensation for participating in this study?***
No

VIII. Risks

VIII.1 ***What are the risks to subjects including***
- emotional or psychological
- financial
- legal or social
- physical?
loss of confidentiality is the risk of study.

VIII.2 ***What have you done to minimize the risks?***

- ***If applicable to this study ALSO include:***
  - ***How you (members of your research team at Iowa) will monitor the safety of individual subjects.***
  - ***Include a description of the availability of medical or psychological resources that subjects might require as a consequence of participating in this research and how referral will occur if necessary (e.g. availability of emergency medical care, psychological counseling, etc.)***

Risk of patients confidentiality is minimized by identification of data and sample via numbers only, with access to data limited to PI and Co-investigator only.

VIII.3 ***Does this study have a plan to have an individual or committee review combined data from all subjects on a periodic basis (such as summary or aggregate safety and/or efficacy data)?***
No

IX. Benefits

IX.1 ***What are the direct benefits to the subject (do not include compensation or hypothesized results)?***
There is no direct benefit to the patients.

IX.2 ***What are the potential benefits to society in terms of knowledge to be gained as a result of this project?***
We hope to identify a better needle that can be used in the future as this will help in better overall safety profile and higher diagnostic accuracy leading to less repeat procedure and delays in appropriate therapy.

X. Privacy & Confidentiality

X.1 ***What are you doing to protect the privacy interests of the subjects?***
We will only collect the subject data required for the study and no more. Informed consents are performed in private rooms.

X.2 ***Are you collecting the Social Security Number of any subjects for any purpose?***
No

X.4 ***How will information/data be collected and stored for this study (check all that apply):***

- Electronic records (computer files, electronic databases, etc.) - Electronic records (computer files, electronic databases, etc.) - Networked computers at UIHC will be used to collect data from EPIC, Data will be saved in a password protected spreadsheets and stored in a password protected computer, Only PI and research team will have access.
  - Name - Shari Lewison
  - Title - Director, Information Security
  - University Job Classification - Faculty/Staff

X.5 ***Do the confidentiality protections indicated above allow only members of the research team to access the data/specimens?***
Yes

X.7 ***Does your study meet the NIH criteria for a Certificate of Confidentiality or will you be applying for Certificate of Confidentiality?***
No

XI. Data Analysis

XI.1 ***Describe the analysis methods you will use, including, if applicable, the variables you will analyze***
we will follow general good statistical practices, including examination of numerical and graphical summaries, an interpretation that reflects estimates, and confidence intervals rather than just p values.and checking for all models assumptio,s. We will perform a univariate analysis, controlling for confounders, as appropriate. All analysis will be performed using StataCorp.2011. Stata Statistical Software: Release 12.College Station, TX: StataCorp LP. The diagnostic accuracy will be calculated considering malignant diagnoses as a true positive. For benign diagnoses, we used
clinical impression and imaging characteristics and a clinical course that was either consistent with (in diagnostic cases) or inconsistent with (in non-diagnostic cases) the study diagnosis.

XI.2 ***Provide the rationale or power analysis to support the number of subjects proposed to complete this study.***
The Diagnostic accuracy of the SharkCore needle is around 80%. Considering a non-inferiority margin of 10% we will need 75 patients in each group.

XII. Future Research

XII.1 ***Do you wish to keep any information about subjects involved with this research project so that members of the current research team may contact them in the future for your own research projects?***
No

XII.2 ***Do you wish to keep any information about subjects involved with this research project so that other researchers may contact them for future research?***
No

XII.4 ***Does this project involve storing any data, tissues or specimens for future research?***
No