Document Coversheet

Study Title: Pilot Study Evaluating the Safety and Efficacy of a Patient-Specific Enteroatmospheric Fistula Isolation and Management Device Independent of Negative Pressure Wound Therapy

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	1/22/2021
NCT Number:	NCT04978090
IRB Number	46641
Coversheet created:	8/23/2023

Combined Consent and Authorization to Participate in a Research Study

KEY INFORMATION FOR: *Pilot Study Evaluating the Safety and Efficacy of a Patient-Specific Enteroatmospheric Fistula Isolation and Management Device Independent of Negative Pressure Wound Therapy.*

We are inviting you to take part in a clinical research study to test the benefits and safety of a customized device to manage enteroatmospheric fistulas in the setting of open abdomen, without negative pressure wound therapy involvement.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?
An enteroatmospheric fistula (EAF) occurs when an abnormal connection develops from your intestine and creates a track from the inside of your intestine through to the outside of your abdomen (to the 'atmosphere'). EAF's occur as complications from open abdomen (OA) surgery, and they can complicate your wound management process. EAF's can leak intestinal contents (drainage) onto the surrounding wound, causing damage and infection. If an EAF develops, the number one priority for wound care becomes isolating the fistula's drainage from the rest of the wound. Researchers want to find out if a new investigational device can help people with EAF's. This device would be designed specifically for you using 3D printing technology, and would act as a shunt, diverting fistula drainage away from your open abdomen wound. Researchers believe the use of this device will streamline the wound care process and improve your overall well-being. The purpose of this study is to determine if this device can be used as an effective enteroatmospheric fistula management strategy. The research procedures will be conducted at the University of Kentucky Hospital, with the potential for continuation upon discharge. If you decide to be in this study and the research team confirms you are able, you will be enrolled in the study for up to one year, or until your EAF is closed, whichever occurs first.

WHAT ARE THE REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?
The study device may help take care of your EAF and wound bed, and improve your overall quality of life as compared to other treatment options. It is designed to decrease the work and time required to change your wound dressings, and to allow you to more easily get up and move around. Information from this study will be used to improve device design and help other patients with enteroatmospheric fistulas in the future. There is no cost to you to participate in this study. All study materials and procedures will be provided free of charge.

WHAT ARE THE REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?
The investigational device is designed to fit securely over your fistula. However, there is a chance that it could slip or move, which might cause leakage and require readjustment. The placement of the device might cause irritation or discomfort. There are other adverse events associated with simply having an EAF that are not related to the use this device.

DO YOU HAVE TO TAKE PART IN THE STUDY?
You do not have to be in this study to get help for your EAF. If you choose not to participate in this study, you will receive the method of treatment determined by your doctor to be best for your situation. This may include negative pressure wound therapy, aquarium dressings, suction units, or various other techniques. Your EAF will most likely eventually require surgery to fix it, regardless of the wound care option used. This study device would only be used to help manage your EAF during the wound care phase.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, OR CONCERNS?
The person in charge of this study is Andrew Bernard, MD, of the University of Kentucky, Department of Surgery. If you have questions, suggestions, or concerns regarding this study, or if you want to withdraw from the study, you may contact him at 859-323-6346. You can also call the research team's pager at 859-330-1488.

If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity at the University of Kentucky between the business hours of 8am and 5pm EST, Mon-Fri at 859-257-9428 or toll free at 1-866-400-9428. We will give you a signed copy of this consent form to take with you.

Continue to the Detailed Consent

Combined Consent and Authorization to Participate in a Research Study

Pilot Study Evaluating the Safety and Efficacy of a Patient-Specific Enteroatmospheric Fistula Isolation and Management Device Independent of Negative Pressure Wound Therapy.

Protocol Number: 46641

Principal Investigator: Andrew Bernard, MD

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?

You are being invited to take part in a research study about enteroatmospheric fistulas (EAF) and wound care. You are being invited to take part in this research study because you have an abdominal wall defect which is open to air. An enteroatmospheric fistula (EAF) occurs when an abnormal connection develops from your intestine and creates a track from the inside of your intestine through to the outside of your abdomen (to the 'atmosphere').

If you volunteer to take part in this study, you will be one of about 5 people to do so at the University of Kentucky.

Legally Authorized Representative

When reading this consent form, please note that the words "you" and "your" refer to the person in the study rather than a legally authorized representative (LAR) who might sign this form on behalf of the person in this study.

You, _____, may be serving as the patient's parent/legally authorized representative (a person designated under applicable law or by a judicial or other body to consent to healthcare treatment on behalf of the subject when the subject is unable such as a guardian or next of kin). In evaluating the following information, you understand that you should attempt to decide what _____ would do if he/she were able to choose whether or not to be in the study. You may also choose whether the patient should participate or not based on what you think is in the patient's best interest. It is up to you to decide if you want the patient to take part in this study. If you would like the patient to join, you must sign the pages at the end of this form to show that you agree they can be part of the study. This is called "giving consent".

WHO IS DOING THE STUDY?

The person in charge of this study is Andrew Bernard, MD (*Principal Investigator, PI*) of University of Kentucky, Department of Surgery. There may be other people on the research team assisting at different times during the study.

WHAT IS THE PURPOSE OF THIS STUDY?

You have been diagnosed with an enteroatmospheric fistula in the setting of open abdomen. An enteroatmospheric fistula (EAF) is an abnormal connection between the inside of your intestine and the outside world. You have fluids leaking out of your intestine. It is a serious complication, usually from open abdominal surgery. An EAF makes managing your open abdomen challenging. Intestinal contents can leak through an EAF into the surrounding wound causing irritation, infection, and/or delayed healing.

Researchers want to find out if a custom fit investigational device can help people with EAF's. Researchers want to do this by using patient-matched devices to isolate the fistula and observing the subsequent wound care process. This device is not yet approved by the Food and Drug Administration (FDA) for commercial use, but is being studied under an Abbreviated Investigational Device Exemption (IDE) protocol allowed by the FDA and monitored by the University of Kentucky.

If you decide to participate in this study, researchers will use 3D printing technology to design a device specific to your fistula and your wound. The device will be used in combination with regular wound dressings and an ostomy appliance for the duration of your hospital stay. Dressing changes will occur when required, as normal, by your healthcare team. Your wound care will not involve any form of negative pressure wound therapy or suction therapy. If your fistula or wound changes shape, researchers will design a new device for you.

HOW DOES THIS DEVICE WORK?

Your intestine is full of waste products, digestive enzymes, and acidic secretions. If those contents leak out of your fistula, they can damage your wound, cause infection, and delay healing. Leakage also causes dressings to fail, requiring more frequent dressing changes. This device is designed to effectively carry those intestinal contents from your fistula into an ostomy bag, in hopes of protecting the surrounding wound and reducing the number of required dressing changes.

Open abdomen wounds are often managed with a vacuum dressing. This dressing involves a vacuum device that is hooked up to dressings in a wound, and "sucks" the wound together, theoretically speeding up healing. However, vacuum dressings that you are connected to the vacuum unit and that you use special dressing supplies, which are expensive and can be difficult to properly place. Researchers believe that for patients with EAF's, the benefits of a vacuum dressing may often be outweighed by its disadvantages.

The device being studied may make care of the EAF more simple. The main goal in caring for an EAF is to allow the drainage from the intestine to get out of the wound and into a bag or collection device. The device being studied is perhaps simpler and therefore, less cumbersome for patients. Because it does not involve elaborate instruments and because it is easy to apply and clean, patients may find this device achieves the goals of wound care (getting drainage from the intestine out of the wound and coverage of the wound) much more simple than either the vacuum dressing or plastic sheeting over the wound. The study device uses standard wound care dressings that are available at any pharmacy. The method of holding the device onto the wound is a simple abdominal binder, which can be washed in the washing machine as needed. The collection of drainage from the intestine requires only a standard stoma appliance bag, which can be purchased through a pharmacy or medical supply store. The device requires no suction, which may permit patients to leave the hospital.

ARE THERE REASONS WHY YOU SHOULD NOT TAKE PART IN THIS STUDY?

You should not participate in this study if you are younger than 18 years old.

WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?

The research procedures will be conducted at the University of Kentucky Hospital. If you decide to be in this study and the study team confirms you are able to take part, you will be in the study for the duration of your hospital stay. Your involvement in the study will have no effect in determining your length of stay in the hospital.

While in the hospital, your EAF and open wound will be closely monitored by your healthcare team to make sure you are safe. This is also where you will have the procedures described in this consent form performed.

In case you are discharged home, the study team and your doctor will work with you to determine your treatment course of action. If you wish to continue using the study device, the study team will evaluate if you can manage its use on your own. If it is determined possible to continue the study at home, the study team will work with home health to make sure the device is properly placed. The study team will also check in with you weekly to monitor your health and the wound management process. The study team will provide you with instruction for cleaning your device.

Whether you are in the hospital or at home, your device will be exchanged every four weeks regardless of condition, to ensure structural integrity.

WHAT WILL YOU BE ASKED TO DO?
While you are in the study, you must:

- Follow the instructions you are given.
- Tell the study doctor or study staff about any changes in your health or the way you feel.
- Tell the study doctor or study staff if you want to stop being in the study at any time.

Study Timeline:
Patients with EAF's can remain in the hospital for different amounts of time, depending on their specific fistula and how their wound is healing. Your doctor will determine the length of your hospital stay. Your participation in this study will have no effect on how long you stay in the hospital. If you decide to participate in this study, the study device will be used in your wound care for the remaining duration of your stay.

If you are discharged home, it is likely that you will have home health nurses visit you to help take care of your wound. If this happens, the home health service may provide the additional supplies needed for dressing changes, aside from the study device, but the home health nurse will not be involved in applying the device. This will be your responsibility.

Data will be collected daily by research personnel or participating healthcare staff while you are in the hospital. You will also periodically be evaluated by research personnel for study purposes. If you remain on the study following your discharge, you will be monitored (weekly) by research staff until your fistula resolves or until the study ends. This may include phone calls with research staff and if able, you may be asked to send photos of your wound to the study team for visualization. You will come back to the clinic as necessary per your surgeon's direction.

If you decide later to leave this study, we will not use this information to locate you.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?
The study device is designed to be comfortable and secure. However, there is a chance it may slip or dislodge. You will be closely monitored by your healthcare team and study personnel in case this happens. The device is also designed to effectively shunt fistula contents away from your wound, but there is no guarantee it will do this perfectly. Every fistula management technique allows some degree of leakage that requires re-dressing of the wound. Fistula leakage can cause irritation, itchiness, skin damage or infection. Again, you will be closely monitored so that if this happens, we can promptly change the dressings.

This device requires the use of an abdominal binder, which is a strap that loops around your body, to hold the device in place. The abdominal binder may cause skin irritation or discomfort if too tight.
If the study device or the abdominal binder is positioned too tight against your skin for too long, it may cause pressure ulceration. Care will be taken to check for ulceration at each dressing change. If you feel like there is too much pressure in a specific spot, tell your healthcare team or study staff.

The study device is made out of medical grade silicone. There is a very small chance that you might be allergic to silicone. You will be asked about allergies before participating in the study, and you will be closely watched to make sure your body doesn't react to the silicone.

Some things that can happen during an allergic reaction are:

- a rash
- having a hard time breathing
- wheezing
- a sudden drop in blood pressure (making you feel dizzy or lightheaded)
- swelling around the mouth, throat, or eyes
- a fast pulse
- sweating

The medical staff will assist you immediately if any of these or other side effects occur during your hospital stay. If it is determined that they were caused by the study device, you will be switched to a different wound management plan. If any of these effects happen when you are discharged home, you should get medical help immediately.

It is possible that other side effects may occur that are not listed here. If you feel like any of these or other side effects are happening, contact your doctor or study staff.

During the course of this study new information concerning risks and advantages of the clinical study or procedures may become known. If this happens, your study doctor will tell you. If you change your mind about being in this study because of this new information, tell your study doctor who will discuss this with you in detail and will provide you with the necessary assistance appropriate to your situation. The study doctor will also tell you if new management strategies become available for your wound.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

The study device may help manage your EAF. Researchers believe that use of the device will result in fewer required dressing changes, faster dressing changes, and easier wound management. The device may help prevent infection or other complication by protecting your wound from EAF leakage. The study device may improve your quality of life by helping you be more mobile, or it may help in allowing you to manage your own wound care at home. Information from this study might help researchers to develop better EAF management therapies in the future.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. If you decide not to take part in this study, your decision will have no effect on the quality of medical care you receive.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

You do not have to be in this study to get help for your EAF. There is no fixed, standardized wound management plan for patients with EAF in OA. If you choose not to be in this study, your doctor will work with you to determine the best management plan for you. The most popular method of managing EAF is a vacuum dressing. The advantage to this system, if it seals well, is convenience and infrequent changes of the dressing/system. However, achieving a seal is difficult in some wounds and in some patients. In wounds that will not tolerate a vacuum dressing many patients are treated with a wound care system that involves sheets of plastic over the wound connected to suction. This wound care system requires continuous suction, and therefore continuous hospitalization. Both the vacuum dressing and the system involving plastic sheeting can require frequent dressing changes, which some

patients find unpleasant and inconvenient. Almost all patients with EAF's will eventually require surgery to resolve the fistula.

WHAT WILL IT COST YOU TO PARTICIPATE?
You and/or your insurance company, Medicare or Medicaid will be responsible for the costs of all care and treatment you receive during this study that you would normally receive for your condition. These are costs that are considered medically reasonable and necessary and will be part of the care you receive if you do not take part in this study.

Participation in the study will not cost you or your insurance company anything extra. The device and any research visits will be provided free of charge.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?
We will make every effort to keep confidential all research records that identify you to the extent allowed by law.

Your information will be combined with information from other people taking part in the study. When we write about the study to share it with other researchers, we will write about the combined information we have gathered. You will not be personally identified in these written materials. We may publish the results of this study; however, we will keep your name and other identifying information private.
We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. You should know, however, that there are some circumstances in which we may have to show your information to other people. For example, the law may require us to show your information to a court or to tell authorities if you report information about a child or adult being abused or if you pose a danger to yourself or someone else.

Officials of the Food and Drug Administration, the University of Kentucky, and the U.S. Government may look at or copy pertinent portions of records that identify you.

CAN YOUR TAKING PART IN THE STUDY END EARLY?
If you decide to take part in the study, you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study. If you choose to withdraw from the study early, the data collected until that point will remain in the study database and may not be removed. If you stop being in the study early, the study doctor or study staff may ask you some questions about being in the study.

The individuals conducting the study may need to withdraw you from the study. This may occur if you are not able to follow the directions they give you, if you are unable to effectively use the device the way it was intended to be used, or if the study staff find that your being in the study causes more risk than benefit to you. Subjects who withdraw or are withdrawn will no longer receive this study device and it is not currently available commercially.

ARE YOU PARTICIPATING OR CAN YOU PARTICIPATE IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?
It is important to let the investigator/your doctor know if you are in another research study. You should also discuss with the investigator before you agree to participate in another research study while you are enrolled in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?
In the event of a medical emergency, dial 911 immediately. If you require emergency care, be sure to tell the emergency care provider about your participation in this study. Contact the study doctor as soon as possible.

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Andrew Bernard, M.D. at 859-323-6346 immediately. You may also call the research team pager, 859-330-1488. Andrew Bernard, M.D. and the study team will determine what type of treatment, if any, is best for you at that time.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed while participating in this study.

The medical costs related to your care and treatment because of research related harm may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances), or may be paid by Medicare or Medicaid if you are covered by Medicare or Medicaid (If you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.).

A co-payment/deductible may be needed by your insurer or Medicare/Medicaid (even if your insurer or Medicare/Medicaid has agreed to pay the costs). The amount of this co-payment/deductible may be costly.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?
This study does not offer any additional rewards for participation.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?
Before you decide whether to accept this invitation to take part in the study, please ask any questions that might come to mind now. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the investigator, Andrew Bernard, M.D. at 859-323-6346. If you have any questions about your rights as a volunteer in this research, contact the staff in the Office of Research Integrity at the University of Kentucky between the business hours of 8am and 5pm EST, Mon-Fri at 859-257-9428 or toll free at 1-866-400-9428. We will give you a signed copy of this consent form to take with you.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?
If the researcher learns of new information in regards to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new informed consent form if the information is provided to you after you have joined the study.

WHAT ELSE DO YOU NEED TO KNOW?
There is a possibility that the data collected from you may be shared with other investigators in the future. If that is the case, the data will not contain information that can identify you unless you give your consent/authorization or the University of Kentucky Institutional Review Board (IRB) approves the research. The IRB is a committee that reviews ethical issues, according to federal, state and local regulations on research with human subjects, to make sure the study complies with these before approval of a research study is issued.

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

WILL YOUR INFORMATION BE USED FOR FUTURE RESEARCH?
All identifiable information (e.g., your name, medical record number, or date of birth) will be removed from the information or samples collected in this study. After we remove all identifiers, the information or samples may be used for future research or shared with other researchers without your additional informed consent.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION
The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information for the purposes related to this research study.

Your health information that may be accessed, used and/or released includes:

- Demographic (personal information) and geographic information including some or all of the following: name, gender, ethnic origin, address, including street, zip codes or equivalent geocodes, relatives' name or address, telephone, medical record number and study numbers, email address
- Dates including birth date, hospital/clinic admission or discharge dates, dates of medical events
- Health and medical history
- Medication history and ongoing medication use
- Social history
- Surgical details
- Health status
- Results of physical exams pertaining to this study
- Results of imaging studies pertaining to this study
- Results of other diagnostic exams pertaining to this study
- Photographs of EAF and/or wound

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity
- Law enforcement agencies when required by law
- University of Kentucky representatives
- University of Kentucky Medical Center
- University of Kentucky Center for Clinical and Translational Science
- U.S. Food and Drug Administration (FDA)
- University of Kentucky Hospital Investigational Drug Service (IDS)
- Other regulatory agencies in the U.S. and other countries

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information would still be regulated by applicable federal and state laws.

You will not be allowed to participate in the research study if you do not sign this form. If you decide not to sign the form, it will not affect your:

- **Current or future healthcare at the University of Kentucky**
- **Current or future payments to the University of Kentucky**
- **Ability to enroll in any health plans (if applicable)**

- **Eligibility for benefits (if applicable)**

After signing the form, you can change your mind and NOT let the researcher(s) release or use your health information (revoke the Authorization). If you revoke the authorization:

- You will send a written letter to: Andrew Bernard, M.D., 800 Rose St., Office C224, Lexington, KY, 40536 to inform him of your decision.
- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).
- You may not be allowed to participate in the study.

The use and sharing of your information has no time limit.

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Mon-Fri at: (859) 323-1184.

You are the subject or are authorized to act on behalf of the subject. You have read this information, and you will receive a copy of this form after it is signed.

_____ _____
Signature of research subject (*if applicable*) or *research subject's legal representative — Date

_____ _____
Printed name of research subject (*if applicable*) or *research subject's legal representative — Representative's relationship to research subject

*(*If, applicable)* Please explain Representative's relationship to subject and include a description of Representative's authority to act on behalf of subject:

_____ _____
Name of [authorized] person obtaining informed consent — Date

_____
Signature of Principal Investigator or Sub/Co-Investigator

CONSENT OF THE PATIENT TO CONTINUE TO BE IN THE STUDY

Your legal representative gave his/her consent for you to be in this research study. This is because you were not able to make your own decision due to your illness. Your condition has now improved. You are being asked to decide whether to continue to be in this study. Your decision is voluntary. This means your decision is up to you.

You have read the information in this form and someone has explained to you what study procedures will be continuing. Your questions have been answered to your satisfaction. You believe you understand all of the information about this study. You have decided to continue taking part in this study.

Signature of research subject	Date
Printed name of research subject	
Name of [authorized] person obtaining informed consent	Date
Signature of Principal Investigator or Sub/Co-Investigator	

PROTOCOL TYPE

Which IRB

◉ Medical ○ NonMedical

Protocol Process Type

○ Exemption
○ Expedited (Must be risk level 1)
◉ Full

IMPORTANT NOTE: Once you have saved your choices under "Which IRB" and "Protocol Process Type", you will not be able to change your selections. If you select the wrong IRB Type and/or your application is deemed eligible for a different Protocol Process Type, it may be necessary to create a new application.

Please see below for guidance on which selections to make, and/or go to ORI's "Getting Started" web page. If you still have questions about which IRB or Protocol Process Type to choose, please contact the Office of Research Integrity (ORI) at 859-257-9428 **prior** to saving your selections.

Which IRB

The **Medical IRB** reviews research emanating from the Colleges of Dentistry; Health Sciences; Medicine; Nursing; Pharmacy and Health Sciences; and Public Health.

The **Nonmedical IRB** reviews research originating from the Colleges of Agriculture; Arts & Sciences; Business & Economics; Communication & Information; Design; Education; Engineering; Fine Arts; Law; and Social Work. The Nonmedical IRB does not review studies that involve administration of drugs, testing safety or effectiveness of medical devices, or studies that involve invasive medical procedures, regardless of from what college the application originates.

Which Protocol Process Type

Under federal regulations, an investigator's application to conduct a research project involving human subjects can be processed by the IRBs in three ways:

- by full review;
- by exemption certification;
- by expedited review.

The preliminary determination that a research project is eligible for exemption certification or expedited review is made by the investigator. For assistance in determining which review process type your IRB application is eligible for, please go to ORI's "Getting Started" web page.

The revised Common Rule expanded exemption certification category 4 for certain secondary research with identifiable information or biospecimens. The regulations no longer require the information or biospecimens to be existing. For more information see the Exemption Categories Tool.

PROJECT INFORMATION

Title of Project: (If applicable, use the exact title listed in the grant/contract application). *** Effective 4/16/2020: If your research involves investigating any aspect of COVID-19, please enter "COVID19" at the start of your Project and Short Titles ***

Pilot Study Evaluating the Safety and Efficacy of a Patient-Specific Enteroatmospheric Fistula Isolation and Management Device Independent of Negative Pressure Wound Therapy

Short Title Description

Note: "Short Title" should consist of a couple key words to easily identify your study - these key words (rather than the whole title) will be displayed on the Dashboard in the listing for your study.

2018 EAF Device

Anticipated Ending Date of Research Project: 10/1/2021

Number of human subjects (or records/specimens reviewed): 5

Study is/will be open to new subject enrollment or data/specimen collection: (•) Yes ( ) No

RISK LEVEL

Indicate which of the categories listed below accurately describes this protocol

- ○ (Risk Level 1) Not greater than minimal risk
- ◉ (Risk Level 2) Greater than minimal risk, but presenting the prospect of direct benefit to individual subjects
- ○ (Risk Level 3) Greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.
- ○ (Risk Level 4) Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of subjects.

*"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests [45 CFR 46.102(i)]

Download UK's guidance document on assessing the research risk for additional information on risk [PDF]

SUBJECT DEMOGRAPHICS

Age level of human subjects: (i.e., 6 mths.; 2yrs., etc..) 18 to and older

Indicate the targeted/planned enrollment of the following members of minority groups and their subpopulations. Possible demographic sources: Census Regional Analyst Edition, Kentucky Race/Ethnic Table, Kentucky Population Data.
(Please note: The IRB will expect this information to be reported at Continuation Review time):

Enter Numbers Only!

Ethnic Origin	#Male	#Female
American Indian/Alaskan Native:		
Asian:		
Black/African American:		
Hispanic/Latino:		
Native Hawaiian/Pacific Islander:		
White/Caucasian:		
Other or Unknown:		

If unknown, please explain why: Males and females will be enrolled.

Indicate the categories of subjects and controls to be included in the study. Depending on the subject category applicable to your research you may be required to complete additional forms. [Note, if the study does not involve direct intervention or direct interaction with subjects, (e.g., record-review research, outcomes registries), do not check mark populations which the research does not specifically target. For instance, a large record review of a diverse population may incidentally include a prisoner or an international citizen, but, if the focus or intent of the study has nothing to do with that status, you do not need to check those category(ies).]

Check All That Apply (at least one item must be selected)

- ☐ Children (individuals under age 18)
- ☐ Wards of the State (Children)
- ☐ Emancipated Minors
- ☐ Students
- ☐ College of Medicine Students
- ☐ UK Medical Center Residents or House Officers
- ☐ Impaired Consent Capacity

ADDITIONAL INFORMATION:

Please visit the IRB Survival Handbook under the named topic:

- Children/Emancipated Minors
- Students as Subjects
- Prisoners
- Impaired Consent Capacity Adults: Link to required Form

And/Or:

Adults

- ☐ Pregnant Women/Neonates/Fetal Material
- ☐ Prisoners
- ☐ Non-English Speaking
- ☐ International Citizens
- ☐ Normal Volunteers
- ☐ Military Personnel and/or DoD Civilian Employees
- ☑ Patients
- ☐ Appalachian Population

- UKMC Residents or House Officers [see requirement of GME]
- Non-English Speaking [see instructions for recruitment and E-IRB Research Description section on same topic]
- International Citizens [HTML] (DoD SOP may apply [PDF])
- Military Personnel and/or DoD Civilian Employees (DoD SOP may apply [PDF])

The next questions involve assessment of the study relative to potential recruitment of subjects with impaired consent capacity (or likelihood).

☐ Check this box if your study does not involve direct intervention or direct interaction with subjects (e.g., record-review research, secondary data analysis). (you will not need to answer the impaired consent capacity questions)

Does this study focus on adult subjects with any of the clinical conditions listed below that present a high *likelihood* of impaired consent capacity or *fluctuations* in consent capacity? (see examples below)

○ Yes ◉ No

If Yes, go to the following link and complete and attach the indicated form unless you are filing for an exemption certification: https://ris.uky.edu/ori/oriforms/formt/Scale.asp

Examples of such conditions include:

- Traumatic brain injury or acquired brain injury
- Severe depressive disorders or Bipolar disorders
- Schizophrenia or other mental disorders that involve serious cognitive disturbances
- Stroke
- Developmental disabilities
- Degenerative dementias
- CNS cancers and other cancers with possible CNS involvement
- Late stage Parkinson's Disease
- Late stage persistent substance dependence
- Ischemic heart disease
- HIV/AIDS
- COPD
- Renal insufficiency
- Diabetes
- Autoimmune or inflammatory disorders
- Chronic non-malignant pain disorders
- Drug effects
- Other acute medical crises

Attachments

INFORMED CONSENT/ASSENT PROCESS/WAIVER

For your informed consent attachment(s), please download the most up-to-date version listed in "All Templates" under the APPLICATION LINKS menu on the left, and revise to be in accord with your research project.

Additional Resources:

- Sample Repository/Registry/Bank Consent (Word)
- Instructions for Proposed Informed Consent Document
- Instructions for Proposed Assent Form

Consent/Assent Tips:

- **If you have multiple consent documents, be sure to upload each individually (not all in a combined file).**
- **Changes to consent documents (e.g., informed consent form, assent form, cover letter, etc...) should be reflected in a 'tracked changes' version and uploaded separately with the Document Type "Highlighted Changes".**
- **It is very important that only the documents you wish to have approved by the IRB are attached; DELETE OUTDATED FILES -- previously *approved* versions will still be available in Protocol History.**
- **Attachments that are assigned a Document Type to which an IRB approval stamp applies will be considered the version(s) to be used for enrolling subjects once IRB approval has been issued.**
  Document Types that do NOT get an IRB approval stamp are:
  - **"Highlighted Changes",**
  - **"Phone Script", and**
  - **"Sponsor's Sample Consent Form".**

How to Get the Informed Consent Section Check Mark

1. **You must check the box for at least one of the consent items and/or check mark one of the waivers, then if applicable attach the corresponding document(s) as a PDF (if open to enrollment).**
2. **If you no longer need a consent document approved (e.g., closed to enrollment), or, the consent document submitted does not need a stamp for enrolling subjects (e.g., umbrella study, or sub-study), only check mark the "Stamped Consent Doc(s) Not Needed".**
3. **After making your selection(s) be sure to scroll to the bottom of this section and SAVE your work!**

Check All That Apply

- ☐ Informed Consent Form (and/or Parental Permission Form)
- ☐ Assent Form
- ☐ Cover Letter (for survey/questionnaire research)
- ☐ Phone Script
- ☑ Informed Consent/HIPAA Combined Form
- ☐ Debriefing and/or Permission to Use Data Form
- ☐ Sponsor's sample consent form for Dept. of Health and Human Services (DHHS)-approved protocol
- ☐ Stamped Consent Doc(s) Not Needed

Attachments

Attach Type	File Name
Informed ConsentHIPAA Combined Form	Form C ICF EAF Device rev1 clean.pdf

☐ Request for Waiver of Informed Consent Process

If you are requesting IRB approval for waiver of the requirement for the informed consent process, or alteration of some or all of the elements of informed consent (i.e. medical record review, deception research, or collection of biological specimens), complete Section 1 and Section 2 below.

Note: The IRB does not approve waiver or alteration of the consent process for greater than minimal risk research, except for planned emergency/acute care research as provided under FDA regulations. Contact ORI for regulations that apply to

single emergency use waiver or acute care research waiver (859-257-9428).

SECTION 1.

Check the appropriate item:

☐ I am requesting waiver of the requirement for the informed consent process.

☐ I am requesting alteration of the informed consent process.

If you checked the box for this item, describe which elements of consent will be altered, and/or omitted, and justify the alteration.

SECTION 2.

The IRB may consider your request provided that **all** of the following conditions apply to your research and are appropriately justified. Explain in the space provided for each condition how it applies to your research.

a) The research involves no more than minimal risk to the subject.

b) The rights and welfare of subjects will not be adversely affected.

c) The research could not practicably be carried out without the requested waiver or alteration.

d) Whenever possible, the subjects or legally authorized representatives will be provided with additional pertinent information after they have participated in the study.

☐ Request for Waiver of Documentation of Informed Consent Process

If you are requesting IRB approval for waiver of the requirement for documentation of informed consent (i.e. telephone survey or mailed survey, internet research, or certain international research), **your research activities must fit into one of three regulatory options**:

1. The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves participants who use illegal drugs).
2. The research presents no more than minimal risk to the participant and involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script).
3. The participant (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm, and the research presents no more than minimal risk to the subject and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Select the option below that best fits your study, and explain in the space provided how your study meets the criteria for the selected regulatory option.

Note: The IRB cannot waive the requirement for documentation or alter the consent form for FDA-regulated research unless it meets Option #2 below. FDA does not accept Option #1.

Note: Even if a waiver of the requirement for documentation is approved by the IRB, participants must still be provided oral or written (e.g., cover letter) information including all required and appropriate elements of consent so they have the knowledge and opportunity to consider whether or not to participate. To help ensure required elements are included in your consent document, please use the **Cover Letter Template** as a guide: *English*- [WORD], Spanish- [WORD] The cover letter template was developed specifically for survey/questionnaire research; however, it may be useful as a guide for developing a consent document for other types of research as well.

○ **Option 1**

a) The only record linking the participant and the research would be the consent document:

b) The principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves subjects who use illegal drugs).

Under this option, each participant (or legally authorized representative) must be asked whether (s)he wants to sign a consent document; if the participant agrees to sign a consent document, only an IRB approved version should be used.

○ **Option 2**

a) The research presents no more than minimal risk to the participant:

b) Involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script):

○ **Option 3**

a) The subject (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm.

b) The research presents no more than minimal risk to the subject.

c) There is an appropriate alternative mechanism for documenting that informed consent was obtained.

RESEARCH DESCRIPTION

****!!!PLEASE READ!!!** Known Issue: The below text boxes do not allow symbols, web addresses, or special characters (characters on a standard keyboard should be ok). If something is entered that the text boxes don't allow, user will lose unsaved information.**

Workaround(s):

- **Save your work often to avoid losing data.**
- **Use one of the attachment buttons in this section, or under the Additional Information section to include the information with your application. During the document upload process, you will be able to provide a brief description of the attachment.**

Background: Provide an introduction and background information. Describe past experimental and/or clinical findings leading to the formulation of your study. For research involving investigational drugs, describe the previously conducted animal and human studies. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section, however, a summary paragraph must be provided in the text box below. For research that involves FDA approved drugs or devices, describe the FDA approved uses of this drug/device in relation to your protocol. Attach a copy of the approved labeling as a product package insert or from the Physician's Desk Reference in the applicable E-IRB "Study Drug" or "Study Device" section.

An enteroatmospheric fistula (EAF) is defined as an abnormal connection between the intestinal lumen and the outside environment. EAF's can occur spontaneously or as complications of open abdominal (OA) surgery related to cancer, inflammatory bowel disease, Crohn's disease, trauma, or adhesion lysis. From any etiology, EAF's in OA are extremely difficult to manage, and have been associated with high mortality rates for many years [9]. EAF output (bowel contents) can leak into the surrounding wound, leading to persistent inflammation and infection. Fistula output can irritate or damage the skin, further delaying wound healing. Leakage also causes seals and wound dressings to fail, requiring frequent and time-consuming dressing changes. Therefore, protecting the OA wound bed from the fistula's effluent is essential to the healing process. Containment of fistula effluent has been attempted with countless variations of pouching devices, suction devices, dressings, or a combination of these. In recent years, negative pressure wound therapy (NPWT) has gained popularity in wound care as it is reported to enhance epithelization and expedite tissue healing [2]. However, there continues to be a lack of firm clinical evidence regarding NPWT efficacy in the setting specific to EAF/OA patients [4]. In addition, NPWT confines the patients to the wall or to V.A.C. units, restricting mobility and quality of life. NPWT also requires expensive, special dressings and access to V.A.C. (Vacuum Assisted Closure) units. Patients who wish to continue NPWT at home must rent these units and pay out of pocket for home health visits and the special NPWT dressings, an option that is simply not feasible for most. Management of EAF/OA patients with NPWT is not reliable, affordable, or even accessible for many patients, and for this reason, various methods of EAF/OA wound care continue to be used depending on the individual case and available resources. In all methods of management, however, the problem of containing the fistula's output and protecting the healing wound remains a challenge.

Enteroatmospheric fistulas in the setting of open abdomen not only pose a challenge to manage clinically but place a substantial burden on the healthcare system and greatly impact patient life. After the development of an EAF, surgeons must wait an average of 6-12 months before surgical resolution [3, 8] This is because the wound and surrounding skin must be allowed to heal. With this extended interval of time between EAF development and safe surgical resolution, wound management takes on a unique importance. Often, the patient must remain in the hospital for the duration of the OA healing time because the wound's management is so labor-intensive. Depending on the patient, dressing changes can be required every 4-24 hours. Dressing changes themselves can easily run 1-2 hours long (properly cutting or fitting dressings to seal off the fistula from the surrounding wound bed consumes most of the dressing change time). Dressing changes can also be costly. If the patient is managed with NPWT, expensive GranuFoam or Reticulated Open Cell Foam dressings are required, and V.A.C. units would need to be rented throughout the duration. It is estimated that care of a severe EAF patient with NPWT can cost the hospital up to $10,000 per day [6]. For such care to be provided outside the hospital, the patient would need to negotiate payment with their insurance or pay out of pocket. V.A.C. units and NPWT dressing kits cost $130-160 per day without insurance contribution. Because most patients cannot manage their wound care themselves, they would also need to pay for home health visits daily or multiple times per day, which vary based on insurance [13]. Understandably, most EAF/OA patients cannot afford the hundreds of dollars per day that NPWT would cost outside of the hospital.

We propose an updated method of EAF isolation. This study will assess the efficacy of a custom fitted device designed to isolate EAF effluent independent of NPWT. To do this, we will utilize 3D printing technology to design patient-matched devices that more easily and effectively separate the patient's fistula and any emanated intestinal contents from the surrounding wound. Each EAF/OA patient is different and requires individualized care to properly manage. EAF's can vary in output, size, shape, location, and depth, and patient's wound beds can vary likewise. By using 3D printing's customizability to match our device to accommodate each of these variables, we can create a functionally efficient wound care device. The patient-fitted device will easily fit around each patient's fistula, streamlining the labor-intensive step of fistula dressing. Enteric contents will flow from the fistula, through the device, into an external ostomy appliance, to be changed as necessary.

Our device application would offer a cheaper, more convenient alternative to traditional management methods. The design and production of each device will all be done within the University of Kentucky by study personnel for a few dollars per device (see attachment A for more manufacturing details). Once produced, healthcare staff simply place the device over the patient's fistula, dress the surrounding wound as normal (no need for special NPWT dressings or airtight seals), and attach an ostomy bag to collect effluent. We anticipate the use of our device will reduce the frequency of dressing changes and the time required for each dressing change. In addition, isolation devices can be cleaned and re-used until the patient's fistula or wound bed changes shape enough to

necessitate a new device. This will further decrease management costs and the device's ease of use potentially provides patients the opportunity to manage their EAF's on their own.

We anticipate the use of this device will vastly reduce the cost, both labor costs and dressing supply costs, of managing EAF patients as compared to NPWT management. We believe it will greatly improve patient mobility, comfort, quality of life, and offer an easier way to manage enteroatmospheric fistulas than many current options. Ultimately, using this device for EAF care could provide a cost effective but efficacious option for patients that cannot afford or do not wish to participate in NPWT management. This study will collect financial data in addition to clinical data points and at its conclusion we will conduct an in-depth cost analysis.

Due to patenting prior art, similar fistula isolation devices being trialed [4], and commercialization issues, we are not seeking a novel medical device patent. The device design, the novelty of its 3D printing manufacturing process, and its significant customizability differentiate it substantially enough from prior art to not infringe on patenting or copyright laws but do justify this clinical investigation. This study has no commercial interests and we are not seeking to market our device at this time.

This device would be classified as a Class II wound care device. Because of that classification, it does not necessitate an Investigational Device Exemption (IDE) from the FDA, unless it is determined to pose Significant Risk (SR) to the patient. Thus, our study is contingent on the University of Kentucky IRB determining the use of our device as Non-Significant Risk (NSR). Due to prior, similar devices being deemed NSR, we believe our device should likewise be approved. The novelty of our device involves its production and customizability, not its composition. All materials used are FDA approved for biocompatibility, and our 3D printers are also FDA approved for clinical use (see attachment A for more details and safety information). The open abdomen setting in which this device would be used is a non-sterile, externally located field and our device meets all FDA Good Manufacturing Practices in such settings. If the IRB approves our device as NSR, this study will be conducted as an IDE-expediated study, falling solely under University of Kentucky IRB regulation.

References

1. Bobkiewicz et al. Management of enteroatmospheric fistula with negative pressure wound therapy in open abdomen treatment: a multicenter observational study. International Wound Journal 2016; 14.

2. Bruhin A, Ferreira F, Chariker M, Smith J, Runkel N. Systematic review and evidence based recommendations for the use of negative pressure wound therapy in the open abdomen. International Journal of Surgery 2014;12:1105–14.

3. Di Saverio S, Tarasconi A, Inaba K, Navsaria P, Coccolini F, Costa Navarro D, Mandrioli M, Vassiliu P, Jovine E, Catena F, Tugnoli G. Open abdomen with concomitant enteroatmospheric fistula: attempt to rationalize the approach to a surgical nightmare and proposal of a clinical algorithm. Journal of American College of Surgeons 2015;220:e23–33.

4. Gregor, S., Maegele, M., Sauerland, S., Krahn, JF., Peinemann, F., Lange, S. "Negative Pressure Wound Therapy, a Vacuum of Evidence?" Archives of Surgery 143.2 (2008): 189-96.
5. Heineman, et. al. Collapsible Enteroatmospheric Fistula Isolation Device : A Novel, Simple Solution to a Complex Problem. Journal of American College of Surgeons 2015; 221:e7-14.

6. Hoedema, Rebecca E., and Sree Suryadevara. "Enterostomal Therapy and Wound Care of the Enterocutaneous Fistula Patient." Clinics in Colon and Rectal Surgery 23.3 (2010): 161–168.
7. Majercik S, Kinikini M, White T. Enteroatmospheric fistula: from soup to nuts. Nutrition in Clinical Practice 2012;27:507–12.

8. Marinis A, Gkiokas G, Argyra E, Fragulidis G, Polymeneas G, Voros D. "Enteroatmospheric Fistuae"-Gastointestinal Openings in the Open Abdomen: A Review and Recent Proposal of Surgical Technique. Scandinavian Journal of Surgery 2013.

9. Martinez JL, Luque-de-Leon E, Mier J, Blanco-Benavides R, Robledo F. Systematic management of postoperative enterocutaneous fistulas: factors related to outcomes. World Journal of Surgery 2008;32:436–43.

10. Schecter, WP, Hirshberg, A, Chang, DS: Enteric fistulas: Principles of management. Journal of American College of Surgeons 2009;209:484–491

11. Tavusbay C, Genc H, Cin N, Kar H, Kamer E, Atahan K, Haciyanli M. Use of a vacuum-assisted closure system for the management of enteroatmospheric fistulae. Surgery Today 2015;45(9):1102–11.

12. Terzi C, Egeli T, Canda AE, Arslan N. Management of enteroatmospheric fistulae. International Wound Journal 2014;11:17–21.

13. Daley, Barbara. Cost of V.A.C. and Home Health. UK Healthcare Trauma and Acute Care Surgery Case Manager. E-mail correspondence.

Objectives: List your research objectives. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section, however, a summary paragraph must be provided in the text box below.

Our primary objective is to create a viable EAF management solution independent of NPWT.
Our secondary objectives include observing a decrease in required dressing changes, a decrease in healthcare costs to patients, and an increase in patient satisfaction.

Study Design: Describe the study design (e.g., single/double blind, parallel, crossover, etc.). Indicate whether or not the subjects will receive placebo medication at some point in the research procedures. Also, indicate whether or not the subjects will be randomized in

this study. You may reference sponsor's protocol pages and attach as an appendix in the E-IRB "Additional Information" section, however, a summary paragraph must be provided in the text box below. (Including the study design table from a sponsor's protocol is helpful to IRB members.)

Community-Based Participatory Research: If you are conducting community-based participatory research (CBPR), describe strategies for involvement of community members in the design and implementation of the study, and dissemination of results from the study.

Research Repositories: If the purpose of this submission is to establish a Research Repository (bank, registry) indicate whether the material you plan to collect would or would not be available from a commercial supplier, clinical lab, or established IRB approved research repository. Provide scientific justification for establishment of an additional repository collecting duplicate material. Describe the repository design and operating procedures. For relevant information to include, see the UK Research Biospecimen Bank Guidance [PDF] or the UK Research Registry Guidance [PDF]

This will be a pilot series of several case reports involving a small number (5) of patients. We will manage and follow patients (daily) for the remaining duration of their hospital stay and (weekly) if they continue study participation in the outpatient setting. We will collect data for the duration of the patient's study involvement to assess the device's medical efficacy. Data collected will be analyzed to determine the ability of the device to isolate fistula effluent, number of required dressing changes, average time of dressing changes, and patient quality of life. A cost analysis will also be performed.

Attachments

Back to Top

Study Population: Describe the characteristics of the subject population, such as anticipated number, age range, gender, ethnic background and health status. Identify the criteria for inclusion and exclusion. Explain the rationale for the use of special classes such as fetuses, pregnant women, children, institutionalized, adults with impaired consent capacity, prisoners, economically or educationally disadvantaged persons or others who are likely to be vulnerable.

If women or minorities are included, please address how the inclusion of women and members of minority groups and their subpopulations will help you meet your scientific objectives. Exclusion of women or minorities requires clear and compelling rationale that shows inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be excluded routinely from participation in clinical research.

Provide the following information:

- A description of the subject selection criteria and rationale for selection in terms of the scientific objectives and proposed study design;
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group;
- The proposed dates of enrollment (beginning and end);
- The proposed sample composition of subjects.

You may reference grant application/sponsor's relevant protocol pages and attach as an appendix using the below attachment button, however, a summary paragraph must be provided in the text box below.

Candidates for this study are patients aged 18 and older admitted to the ICU or trauma and acute care ward at UK hospital.
a. Inclusion Criteria
i. Patient in stable condition, as determined by attending physician
ii. Patient has an EAF in the setting of OA
iii. Patient EAF is determined to require surgical resolution
b. Exclusion Criteria:
i. Patient unstable, as determined by attending physician
ii. Patient deemed to be at significant risk of complication

Attachments

Subject Recruitment Methods & Privacy: Using active voice, describe plans for the identification and recruitment of subjects, including how the population will be identified, and how initial contact will be made with potential subjects by those having legitimate access to the subjects' identity and the subjects' information.

Describe the setting in which an individual will be interacting with an investigator or how and where members of the research team will meet potential participants. If applicable, describe proposed outreach programs for recruiting women, minorities, or disparate populations as participants in clinical research. Describe steps taken to minimize undue influence in recruiting potential participants.

Please note: Based upon both legal and ethical concerns, the UK IRB does not approve finder's fees or "cold call" procedures made by research staff unknown to the potential participant. The ORI/IRB does not control permission to any UK listserv, mass mailing list, etc. Investigators must secure prior approval for access and use from owners/managers.

For additional details, see topic "Recruitment of Subjects/Advertising" on ORI's IRB Survival Handbook web page and the PI Guide to Identification and Recruitment of Human Subjects for Research [PDF].

Patients will be identified by the principal investigator or via CCTS data push review. CCTS analysts will configure a data 'push' within the electronic medical record that will send a daily list of patients meeting some of the study criteria to approved study personnel. This list will include hospital medical record numbers, which will be used to further review patients for eligibility. When a patient is deemed eligible, approved study personnel will approach the patient/LAR for informed consent. If consent is obtained, the research procedures will begin immediately, and data collection initiated. Patients that refuse study participation will receive standard care as determined by their attending physician.

Back to Top

Advertising: Specify if any advertising will be performed. If yes, please see "IRB Application Instructions - Advertisements" for instructions on attaching copies of the information to be used in flyers or advertisements. Advertisements must be reviewed and approved by the IRB prior to use. For additional details, see topic "Recruitment of Subjects/Advertising" on ORI's IRB Survival Handbook web page for the *PI Guide to Identification and Recruitment of Human Subjects for Research* [D7.0000] document [PDF]. If you will be recruiting subjects via advertising at non-UK owned or operated sites, you should include a copy of written permission from that site to place the advertisement in their facilities.

Note: Print and media advertisements that will be presented to the public also require review by UK Public Relations (PR) to ensure compliance with UK graphic standards, and equal opportunity language. See Advertising Instructions for PR contacts.

N/A

Attachments

Informed Consent Process: Using active voice, describe the consent/assent procedures to be followed, the circumstances under which consent will be sought and obtained, the timing of obtaining informed consent, whether there is any waiting period between informing the prospective subject and obtaining consent, who will seek consent., steps taken to minimize the possibility of coercion or undue influence, the method used for documenting consent, and if applicable who is authorized to provide permission or consent on behalf of the subject. Note: all individuals authorized to obtain informed consent should be designated as such in the E-IRB "Study Personnel" section of this application.

Describe provisions for obtaining consent/assent among any relevant special populations such as children (see Children in Research Policy [PDF] for guidance), prisoners (see Summary of Prisoner Regulations [PDF] for guidance), and persons with impaired decisional capacity (see Impaired Consent Capacity Policy [PDF] for guidance). Describe, if applicable, use of specific instruments or techniques to assess and confirm potential subjects' understanding of the nature of the elements of informed consent and/or a description of other written materials that will be provided to participants or legally authorized representatives. If you have a script, please prepare it using the informed consent template as a guide, and submit it on a separate page.

Informed Consent for Research Involving Emancipated Individuals
If you plan to enroll some or all prospective subjects as emancipated, consult with UK legal counsel **when preparing the IRB application and prior to submitting the application to the IRB**. Include legal counsel's recommendations (legal counsel's recommendations may be attached in the E-IRB "Additional Information" section as a separate document, if necessary). For a complete definition of emancipated minors, see the section on *Emancipated Individuals* in the Informed Consent SOP [PDF].

Informed Consent for Research Involving Non-English Speaking Subjects
If you are recruiting non-English speaking subjects, the method by which consent is obtained should be in language in which the subject is proficient. Describe the process for obtaining informed consent from prospective subjects in their respective language (or the legally authorized representative's respective language). In order to ensure that individuals are appropriately informed about the study when English is their second-language, describe a plan for evaluating the level of English comprehension, and the threshold for providing a translation, or explain why an evaluation would not be necessary. For additional information on inclusion of non-English speaking subjects, or subjects from a foreign culture, see IRB Application Instructions for Recruiting Non-English Speaking Participants or Participants from a Foreign Culture.

Research Repositories
If the purpose of this submission is to establish a research repository describe the informed consent process. For guidance regarding consent issues, process approaches, and sample language see the Sample Repository/Registry/Bank Consent Template [PDF]

Due to the level of acuity required for enrollment into this study, it is anticipated that each patient who meets study criteria will also require evaluation to determine if they are "decisionally challenged individuals." Each patient identified for inclusion will be evaluated, as part of our research standard operating procedures, for his or her ability to understand and make an educated decision to provide informed consent for study participation. Study staff will approach the patient for study and review the informed consent document (study protocol, procedures, risks/benefits, alternatives and the voluntary nature of the research) with the patient, and then administer the University of California, San Diego Brief Assessment of Capacity to Consent (UBACC) tool before asking them to sign the consent document. Capacity to consent will be evidenced by the patient scoring a minimum of one on each item and a minimum of two on items four, and six. These items reflect and demonstrate whether they have to participate in the study and what they will be required to do as a part of this study. A study investigator will evaluate the patient and document his/her findings in the patient chart. If the patient is deemed to be decisionally challenged and not appropriate to consent for themselves, approved study personnel will contact the their LAR for consent. A full consent discussion will be held at which time the study protocol, procedures, risks/benefits, alternatives and the voluntary nature of the research will be explained by the study staff.

There will be an opportunity for the patient/LAR to ask questions and for a private consideration/discussion with family if needed. If the patient/LAR wishes to be involved in the trial the study procedures will begin following consent signature. A note to the patient file will be written to explain how the patient meets the study criteria, the process of informed consent and the nature of the discussion, and who participated in the consent process. This note will be generated by the study personnel obtaining consent.

In cases where the LAR provides initial consent, patients that become able to understand and provide consent to continue participation in the study will be approached for re-consent when appropriate. The UBACC tool will also be used for patients who were originally considered decisionally impaired, but are being approached for re-consent at a later time.

Back to Top

Research Procedures: Describe the research procedures that will be followed. Identify all procedures that will be carried out with each group of subjects. Differentiate between procedures that involve standard/routine clinical care and those that will be performed specifically for this research project.

Study participants will receive a custom manufactured device to isolate effluent from their EAF. Prior to device production, research personnel will draft a digital rendering from either a recent abdominal CT scan or physical measurements of the patient's fistula and wound bed. The Computer Aided Design (CAD) program used to draft and render the device will be AutoDesk Fusion360. Once the digital draft is prepared, a negative mold will be generated. The negative mold is then exported as a buildable file to a 3D printer. 3D printing facilities used in this study will be in-house through the UK General Surgery CATS (Center for Advanced Technology and Stimulation). Printers used will be a Makerbot 2X FDM printer. Using this printer, a mold of the custom device will be manufactured, and then by pouring liquid resin into the mold, and allowing it to cure (solidify), the device will be produced.

Silicone has historically been used in many various medical applications. Its safety and its biocompatibility has been documented for applications far more rigorous than the one being described here. Following production, the complete silicone device will immediately be available for cleansing, and transport to the acute care ward by research personnel. The device will be applied to the patient by his/her nursing staff at the next dressing change. The device is designed to smoothly fit over the patient's fistula and seal to the base of the wound. It will provide enough support to anchor surrounding dressings, resist collapse, and be malleable enough to not cause significant discomfort to the patient. The underlying and surrounding wound bed will be dressed as normal at the nursing staff's discretion. An ostomy bag may be attached to the anterior phalange of the device with stoma paste, and its contents emptied as necessary. An abdominal binder will hold the device in place, flush with the surrounding skin.

Devices are designed to be re-usable. Following a fistula-specific dressing change, the device will be detached from the ostomy bag and any adhesives. It will be cleaned at bedside with soap and water, allowed to dry, and then be evaluated for re-use. If the device has not been damaged, and the patient's fistula has not changed shape dramatically, the device can be re-applied, and dressed as before. The open abdomen wound environment is inherently non-sterile, so sterilization prior to and between uses will not be necessary. Our silicone devices will be applied externally only.

Devices will be exchanged every (4) weeks regardless of condition to ensure structural integrity.

Study participants will remain in the ICU/acute care/surgical ward that they were previously admitted to under their attending physician's care, for the remaining duration of their hospital stay. Study involvement will have no effect on determining hospital length of stay, discharge rates, re-admittance, or hospital placement. Data will be collected daily by research personnel or participating healthcare staff while patients remain in the hospital. Patients will periodically be evaluated by research personnel for study purposes. When patients are medically ready for hospital discharge, they (or their LAR, if not yet appropriate for consent) will be involved in a discussion with the PI and their attending physician (if not the PI) on options regarding their transition of care. If patients wish to continue study participation as outpatients, the research team will educate the patient and/or patient's family on device management. If the team decides the patient can effectively manage their device at home, they will be given the option to continue study participation as outpatients. Most EAF patients that are discharged home still require home health visits to manage their wounds. Home health staff will be allowed to dress the surrounding wound bed as normal once the patient has applied their fistula device. Home health staff will be consulted prior to patient discharge on the nature of the study and any concerns addressed. Outpatient study participants will be monitored (weekly) by research staff until fistula resolution or study termination. This will be achieved via phone calls and if able, patients may send photos of their wound to the study team for visualization. Patients will come back to the clinic as necessary per their surgeon's direction. Patients will be given instructions on proper device application and cleaning practices as outpatients. Importantly, patients will be instructed to use water and regular dish soap rather than industrial cleaners, to avoid dishwasher appliances, and to avoid forceful scrubbing or drying of the device.

Attachments

Attach Type	File Name
ResearchProcedures	Outpatient Device Cleaning Form.pdf
ResearchProcedures	Attachment B.pdf
ResearchProcedures	Attachment A rev 1.pdf
ResearchProcedures	UBACC.pdf

Data Collection: List the data or attach a list of the data to be collected about or from each subject (e.g. interview script, survey tool, data collection form for existing data).

If the research includes survey or interview procedures, the questionnaire, interview questions or assessment scales should be included in the application (use attachment button below).

The data collection instrument(s) can be submitted with your application in draft form with the understanding that the final copy will be submitted to the IRB for approval prior to use (submit final version to the IRB for review as a modification request if initial IRB approval was issued while the data collection instrument was in draft form).

Note: The IRB approval process does not include a statistical review. Investigators are strongly encouraged to develop data management and analysis plans in consult with a statistician.

Data collection will be conducted by study personnel or participating healthcare staff and stored in a secure online application (Sharepoint) within the University of Kentucky.
Primary data points to be collected:
a. Patient satisfaction/quality of life, as determined by pain rating, mobility scale, and subjective satisfaction questionnaires
i. Pain rating 1-10
ii. Mobility scale-standard assessment at UK (similar to BMAT)
iii. Patient satisfaction can be a version of TAM (technology acceptance model) model, tweaked for patients instead of providers. Give at study completion. Focus on intention to use in future and ease of use.
b. Number of required dressing changes per day (fistula-specific dressing changes)
c. Average time of required fistula-specific dressing changes
d. Terminal wound management that the patient is transitioned to upon study completion
e. Listing of supplies used each fistula-specific dressing change
f. Assessment of new technology acceptance by staff-TAM model. Give TAM to nursing staff at study's completion.
g. If possible and if patient consent is obtained, we will video record the first few device applications/dressing changes per patient case. We will use this video evidence to better design application protocols and strategies in the future.

h. Adverse event assessment form-see Attachment B.
Secondary data points to be analyzed (following study completion):
i. Cost of patient management with device (estimate per week)
j. Effectiveness of device isolation, as determined by infection/complication occurrence, observed leakage, hospital LOS, and resolution times.

Attachments

Attach Type	File Name
DataCollection	Inpatient Data Collection Form rev1 clean.pdf
DataCollection	Inpatient Data Collection Form rev1 tracked.pdf
DataCollection	Outpatient Data Collection (weekly) rev1 clean.pdf
DataCollection	Outpatient Data Collection (weekly) rev1 tracked.pdf
DataCollection	Outpatient Dressing Change Data Collection Form.pdf

Resources: Describe what resources/facilities are available to perform the research (i.e., staff, space, equipment). Such resources may include a) staffing and personnel, in terms of availability, number, expertise, and experience; b) psychological, social, or medical services, including counseling or social support services that may be required because of research participation; c) psychological, social, or medical monitoring, ancillary care, equipment needed to protect subjects; d) resources for subject communication, such as language translation services, and e) computer or other technological resources, mobile or otherwise, required or created during the conduct of the research. Please note: Some mobile apps may be considered mobile medical devices under FDA regulations (see FDA Guidance). Proximity or availability of other resources should also be taken into consideration, for example, the proximity of an emergency facility for care of subject injury, or availability of psychological support after participation.

Research activities conducted at performance sites that are not owned or operated by the University of Kentucky, at sites that are geographically separate from UK, or at sites that do not fall under the UK IRB's authority, are subject to special procedures for coordination of research review. Additional information is required (see IRB Application Instructions - Off-Site Research web page); supportive documentation can be attached in the E-IRB "Additional Information" section. Provide a written description of the role of the non-UK site(s) or non-UK personnel who will be participating in your research. The other site may need to complete its own IRB review, or a cooperative review arrangement may need to be established. Contact the Office of Research Integrity at (859) 257-9428 if you have questions about the participation of non-UK sites/personnel.

If the University of Kentucky is the lead site in a multi-site study, or the UK investigator is the lead investigator, describe the plan for managing the reporting of unanticipated problems, noncompliance and submission of protocol modifications and interim results from the non-UK sites.

Patients will be followed by the general surgery research program, consisting of physicians, nurses, pharmacists, and other staff during the duration of the study. All usual care for the patient will be provided by their respective staff. Patients will be periodically evaluated by the research team for study purposes. All standard emergency equipment will be at the hospital staff's disposal should an emergent situation arise. If at any point during the study, the study device is deemed unsafe or to cause more risk to the patient than standard management, patients will be immediately reverted to standard wound care protocols. Resources for device production include AutoDesk Fusion360 software programs, the general surgery/CATS lab Makerbot FDM 3D Printer, ABS filament, medical grade liquid silicone, and appropriate cleansing materials. Data collection will be completed on paper forms identified by an assigned subject number and will not contain PHI. This data will be entered into an excel spreadsheet which will be kept on the secure SharePoint site, and will also be identified by the assigned subject number. A master list linking the assigned subject number with the patient's name and MRN will also be kept on the secure SharePoint site.

Potential Risks: Describe any potential risks or likely adverse effects of the drugs, biologics, devices or procedures subjects may encounter while in the study. Please describe any physical, psychological, social, legal or other risks and assess their likelihood and seriousness.

Potential risks with this 3D printed device are the same or less than those associated with standard EAF/OA management. Please see attachment B for a listing of potential risks associated with EAF/OA management.

Back to Top

Safety Precautions: Describe the procedures for protecting against or minimizing any potential risks, *including risks of breach of confidentiality or invasion of privacy*. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse events, or unanticipated problems involving subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects. If vulnerable populations other than adults with impaired consent capacity are to be recruited, describe additional safeguards for protecting the subjects' rights and welfare.

Patients will be followed by physicians, nurses, and other staff throughout the patient's hospital stay and study duration. Skin and wound protection and patient comfort will be a priority when applying dressings and the 3D printed device. Any emergent developments will be handled per standard of care by the respective healthcare team. Patient information will remain confidential at all times within the patient's medical record, the paper study source records (which will be kept under lock and key in the PI's office [C207] or the General Surgery Research office [C243] when not in use), and within the secure SharePoint site once entered into electronic database. Only the patient's healthcare team and approved research personnel will have access to patient information. Patient information will be used only for clinical management and research purposes.

Benefit vs. Risk: Describe potential benefits to the subject(s); include potential benefits to society and/or general knowledge to be gained. Describe why the risks to subjects are reasonable in relation to the anticipated benefit(s) to subjects and in relation to the importance of the knowledge that may reasonably be expected to result. If you are using vulnerable subjects (e.g., impaired consent capacity, pregnant women, etc…), justify their inclusion by describing the potential benefits of the research in comparison to the subjects' vulnerability and the risks to them. For information about inclusion of certain vulnerable populations, see the IRB/ORI Standard Operating Procedure for Protection of Vulnerable Subjects [C3.0100] [PDF].

a. Risk: skin irritation, device dislodgement, potential fistula leakage, abdominal binder discomfort.
b. Benefit: increased patient mobility, decreased patient and system cost, decreased dressing changes, decreased dressing change time, increased patient quality of life, potential decreased fistula leakage.

Available Alternative Treatment(s): Describe alternative treatments and procedures that might be advantageous to the subjects, should they choose not to participate in the study. This should include a discussion of the current standard of care treatment(s).

Patients that refuse study participation will receive appropriate EAF/OA management in accordance with their attending physician's directions.

Back to Top

Research Materials, Records and Privacy: Identify the sources of research material obtained from living human subjects. Indicate what information (specimens, records, data, genetic information, etc.) will be recorded and whether use will be made of existing specimens, records or data. Explain why this information is needed to conduct the study.

Return of Research Results or Incidental Findings (if applicable):
If research has the potential to identify individual results or discover incidental findings that could affect the health of a subject, describe plans to assess, manage, and if applicable disclose findings with individual subjects or provide justification for not disclosing. For IRB expectations, refer to the UK IRB "Frequently Asked Questions (FAQs) on the Return of Research Results or Incidental Research Findings" [PDF].

The investigative team maintains the right to keep, preserve, use and dispose of the findings from this investigation. Investigational records from this study will be maintained confidentially. Recorded information is detailed in section 9. Subjects' names will not be included in any published results. Data will be studied to analyze device efficacy and viability.

Confidentiality: Specify where the data and/or specimens will be stored and how the researcher will ensure the privacy and confidentiality of both. Please address the following items or indicate if the following has been addressed in a HIPAA or Limited Review form:

- physical security measures (e.g., locked facility, limited access);
- data security (e.g., password-protection, data encryption);
- who will have access to the data/specimens and identifiers;
- safeguards to protect identifiable research information (e.g., coding, links, certificate of confidentiality);
- procedures employed when sharing material or data, (e.g., honest broker if applicable, written agreement with recipient not to re-identify, measures to ensure that subject identifiers are not shared with recipients).
- management after the study

Describe whether data/specimens will be maintained indefinitely or destroyed. If maintained, specify whether identifiers will be removed from the maintained information/material. If identifiers will not be removed, provide justification for retaining them. If the data/specimens will be destroyed, describe how and when the data/specimens will be destroyed. For multi-site studies, the PI consults the study sponsor regarding retention requirements, but must maintain records for a minimum of six years after study closure. Also, specify who will access the identified data/specimens, and why they need access. If applicable, describe what measures will be taken to ensure that subject identifiers are not given to the investigator. If applicable, describe procedures for sharing data/specimens with entities not affiliated with UK.

HIPAA/FERPA Minimal Access Standards: The IRB expects researchers to access the minimal amount of identifiers to conduct the study and comply with applicable HIPAA and Family Educational Rights and Privacy Act (FERPA) requirements. If data are going to be collected, transmitted, and/or stored electronically, for appropriate procedures please refer to the guidance document "Confidentiality and Data Security Guidelines for Electronic Data" [PDF].

Cloud storage: For storage of data on cloud services other than UK OneDrive, please verify security settings are sufficient and in accordance with respective departmental, UK Corporate Compliance, and/or UK Information Technology requirements.

Creation of digital data application/program: If a research protocol involves the creation and/or use of a computer program or application, mobile or otherwise, please specify whether the program/application is being developed by a commercial software developer or the research team and provide any relevant information regarding the security and encryption standards used, how data is stored and/or transmitted to the research team, what information about the subjects the program/application will collect, etc. For relevant information to include, see Considerations for Protocol Design Concerning Digital Data [PDF]. The IRB may require software programs created or used for research purposes be examined by a consultant with appropriate Internet technology expertise to ensure subject privacy and data are appropriately protected.

NIH-funded genomic research: The National Institutes of Health (NIH) Genomic Data Sharing (GDS) Policy sets forth expectations that ensure the broad and responsible sharing of genomic research data consistent with the informed consent of study participants from which the data was obtained. If you are submitting genomic data to an NIH data repository, describe your NIH data sharing plan.

Management after study: Describe how the collected data/specimens will be managed after the end of the study. Specify whether identifiers will be removed from the maintained information/material. If identifiers will not be removed, provide justification for retaining them and specify what steps will be taken to secure the data/specimens (e.g., maintaining a coded list of identifiers separate from the data/specimens).

If the data/specimens will be destroyed, describe how, when, and why this will be done. Note that destruction of primary data may violate NIH and NSF retention and sharing requirements, journal publication guidance, and University Data-Retention policies. Additionally, primary data may be necessary for other purposes (to validate reproducibility, for data sharing, or for evidence in various investigations). PIs should carefully consider whether the destruction of data is justified.

The investigator is responsible for retaining signed consent and assent documents and IRB research records for at least six years after study closure, as outlined in the Study Closure SOP [PDF]. If the research falls under the authority of the FDA or other regulatory agencies, or a study sponsor is involved, additional requirements may apply.

Back to Top

Investigational records from this study will be maintained confidentially. Subjects' names will not be included in any published results. All collected data will be used for clinical management and research only.

Back to Top

Payment: Describe the incentives (e.g., inducements) being offered to subjects for their time during participation in the research study. If monetary compensation is offered, indicate how much the subjects will be paid and describe the terms and schedule of payment. (It is IRB policy that provision should be made for providing partial payment to subjects who withdraw before the completion of the research. Monetary payments should be prorated or paid in full.)

N/A

Costs to Subjects: Describe any costs for care associated with research (including a breakdown of standard of care procedures versus research procedures), costs of test drugs or devices, and research procedure costs that are the subject's responsibility as a consequence of participating in the research. Describe any offer for reimbursement of costs by the sponsor for research related injury care.

None

Data and Safety Monitoring: The IRB requires review and approval of data and safety monitoring plans for greater than minimal risk research, clinical research, or NIH-funded/FDA-regulated clinical investigations.

If you are conducting greater than minimal risk research, clinical research, or your clinical investigation is NIH-funded/FDA-regulated, describe your Data and Safety Monitoring Plan (DSMP). Click here for additional guidance on developing a Data and Safety Monitoring Plan.

If this is a *non-sponsored investigator-initiated* protocol considered greater than minimal risk research, clinical research, or your clinical investigation is FDA-regulated, *and* if you are planning on using a Data and Safety Monitoring Board (DSMB) as part of your DSMP, click here for additional guidance for information to include with your IRB application.

If relying on an independent agent or committee for DSMB services, it is the PI's responsibility to establish the services with the agent or committee. Please be reminded that the PI must submit DSMB reports to the IRB via modification or continuing review.

A Data and Safety Monitoring Board will be created to objectively evaluate the study results throughout the course of the study. This board will examine patient adverse events and patient outcomes. The Data and Safety Monitoring Board will consist of a physician (surgeon) and a nurse not affiliated with the study in any way. The DSMB will meet twice for each patient; at 2 weeks post-device initiation or prior to discharge (whichever is first), and at 2 months post-device initiation. The DSMB will review real time data collected by the investigators regarding device usage as detailed in the Data Collection sub-section.

Our Data and Safety Monitoring Plan will include criteria for stopping study enrollment and terminating device usage. These include:
i. Development of an acute allergic reaction following device usage
ii. Development of a new EAF, from device use or originating spontaneously
iii. Inability to manage device usage at home, as determined by the investigative team
iv. Unsatisfactory effluent control, as determined by the investigative team
1. Persistent inability of the device to control fistula contents, even after remodeling, refitting, and other modifications have been attempted.

Adverse Events and Serious Adverse Events will be reported per IRB guidelines. Our AE assessment guide is attached (attachment

B). Complications associated with clinical care and underlying disease, and not related the EAF (section 1.1), will not be reported. Patient safety will be monitored normally by hospital staff.

Back to Top

Subject Complaints: Describe procedures (other than information provided in consent document) for handling subject complaints or requests for information about the research. The procedures should offer a safe, confidential, and reliable channel for current, prospective, or past research subjects (or their designated representative) permitting them to discuss problems, concerns and questions, or obtain information.

If any patient has a complaint at any time during study participation, they may contact their healthcare team or the research personnel and their issues will be discussed. All patients have the right to discontinue study participation at any time.

Does your research involve **Non-English Speaking Subjects or Subjects from a Foreign Culture**?

(•) Yes ( ) No

Non-English Speaking Subjects or Subjects from a Foreign Culture

Describe how information about the study will be communicated to potential subjects appropriate for their culture, and if necessary, how new information about the research may be relayed to subjects during the study.

Include contact information for someone who can act as a cultural consultant for your study. The person should be familiar with the culture of the subject population and/or be able to verify that translated documents are the equivalent of the English version of documents submitted. The consultant should not have any direct involvement with the study. If you do not know someone who would be willing to act as your cultural consultant, the Office of Research Integrity will try to find someone to fill this role (this may delay the approval process for your protocol). Please include the name, address, telephone number, and email of the person who will act as the cultural consultant for your study. For more details, see the IRB Application Instructions on Research Involving Non-English Speaking Subjects or Subjects from a Foreign Culture.

For recruitment of Non-English speaking subjects, the consent document needs to be in the subject's native language. Download the informed consent template available in the E-IRB "Informed Consent/Assent Process" section and use it as a guide for developing the consent document. (Note: Your translated consent document can be attached to your application in the "Informed Consent" section; **be sure to save your responses in this section first.**)

If research is to be conducted at an international location, identify local regulations, laws, or ethics review requirements for human subject protection. If the project has been or will be reviewed by a local Ethics Committee, attach a copy of the review to the UK IRB using the attachment button below. You may also consult the current edition of the International Compilation of Human Research Standards

If a non-English speaker or patient from a foreign culture is identified for potential study enrollment, a cultural consultant will be requested from the office of Research Integrity if determined necessary to effectively conduct the informed consent process.

Does your study involve **HIV/AIDS research and/or screening for other reportable diseases (e.g., Hepatitis C, etc…)**?

○ Yes ◉ No

HIV/AIDS Research

If you have questions about what constitutes a reportable disease and/or condition in the state of Kentucky, see ORI's summary sheet: "Reporting Requirements for Diseases and Conditions in Kentucky" [PDF].

HIV/AIDS Research: There are additional IRB requirements for designing and implementing the research and for obtaining informed consent. Describe additional safeguards to minimize risk to subjects in the space provided below.

For additional information, visit the online IRB Survival Handbook to download a copy of the "Medical IRB's requirements for Protection of Human Subjects in Research Involving HIV Testing" [D65.0000] [PDF], and visit the Office for Human Research Protections web site for statements on AIDS research, or contact the Office of Research Integrity at 859-257-9428.

PI-Sponsored FDA-Regulated Research

Is this an investigator-initiated study that:

Back to Top

1) involves testing a Nonsignificant Risk (NSR) Device, or
2) is being conducted under an investigator-held Investigational New Drug (IND) or Investigational Device Exemption (IDE)?

◉ Yes ○ No

PI-Sponsored FDA-Regulated Research

If the answer above is yes, then the PI assumes the regulatory responsibilities of both the investigator and sponsor. The Office of Research Integrity provides a summary list of sponsor IND regulatory requirements for drug trials [PDF], IDE regulatory requirements for SR device trials [PDF], and abbreviated regulatory requirements for NSR device trials [PDF]. For detailed descriptions see FDA Responsibilities for Device Study Sponsors or FDA Responsibilities for IND Drug Study Sponsor-Investigators.

- Describe your (the PI's) experience/knowledge/training (if any) in serving as a sponsor (e.g., previously held an IND/IDE); and
- Indicate if you have transferred any sponsor obligations to a commercial sponsor, contract research organization (CRO), contract monitor, or other entity (provide details or attach FDA 1571).

This study represents an investigator-initiated study testing an NSR device, contingent upon NSR determination by the IRB. The PI assumes regulatory responsibilities of both the investigator and the sponsor. We have reviewed the FDA's 21 CFR 812.2 (b) documents detailing the responsibilities of sponsors with NSR device studies and are willing to comply with all abbreviated IDE requirements.

IRB policy requires mandatory training for all investigators who are also FDA-regulated sponsors (see Sponsor-Investigator FAQs). A sponsor-investigator must complete the applicable Office of Research Integrity web based training, (drug or device) before final IRB approval is granted.

Has the PI completed the mandatory PI-sponsor training prior to this submission?

○ Yes ◉ No

If you (the PI) have completed equivalent sponsor-investigator training, you may submit documentation of the content for the IRB's consideration.

Attachments

Attach Type	File Name
SponsorInvTraining	Bernard CITI GCP Medical Devices certificate 11.12.18.pdf

HIPAA

Is HIPAA applicable? ◉ Yes ○ No

(Visit ORI's Health Insurance Portability and Accountability Act (HIPAA) web page to determine if your research falls under the HIPAA Privacy Regulation.)

If yes, check below all that apply and attach the applicable document(s):

☐ HIPAA De-identification Certification Form

☑ HIPAA Waiver of Authorization

Attachments

Attach Type	File Name
Waiver	Form K HIPAA Waiver EAF rev 1 signed 11.13.18.pdf

STUDY DRUG INFORMATION

The term drug may include:

- FDA approved drugs,
- unapproved use of approved drugs,
- investigational drugs or biologics,
- other compounds or products intended to affect structure or function of the body, and/or
- complementary and alternative medicine products such as dietary supplements, substances generally recognized as safe (GRAS) when used to diagnose, cure mitigate, treat or prevent disease, or clinical studies of e-cigarettes examining a potential therapeutic purpose.

Does this protocol involve a drug including an FDA approved drug; unapproved use of an FDA approved drug; and/or an investigational drug?

○ Yes ◉ No

If yes, complete the questions below. Additional study drug guidance.

LIST EACH DRUG INVOLVED IN STUDY IN THE SPACE BELOW

Drug Name:

Note: Inpatient studies are required by Hospital Policy to utilize the Investigational Drug Service (IDS). Use of IDS is highly recommended, but optional for outpatient studies. Outpatient studies not using IDS services are subject to periodic inspection by the IDS for compliance with drug accountability good clinical practices.

Indicate where study drug(s) will be housed and managed:

☐ Investigational Drug Service (IDS) UK Hospital

Other Location:

Is the study being conducted under a valid Investigational New Drug (IND) application?

○ Yes ○ No

If Yes, list IND #(s) and complete the following:

IND Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

☐ Checkmark if the study is being conducted under FDA's Expanded Access Program (e.g., Treatment IND) or if this is an Individual Patient Expanded Access IND (FDA Form 3926).

FDA's Expanded Access Program Information for Individual Patient Expanded Access INDs, and attach the following:

- FDA Form 3926;
- FDA expanded access approval or correspondence;
- Confirmation of agreement from manufacturer or entity authorized to provide access to the product.

For guidance and reporting requirements at the conclusion of treatment see the "Expanded Access SOP" [PDF].

Please also complete and attach the Study Drug Form (PDF) (required):

Attachments

STUDY DEVICE INFORMATION

A DEVICE may be a:

- component, part, accessory;
- assay, reagent, or in-vitro diagnostic device;
- software, digital health, or mobile medical app;
- other instrument if intended to affect the structure or function of the body, diagnose, cure, mitigate, treat or prevent disease; or
- a homemade device developed by an investigator or other non-commercial entity and not approved for marketing by FDA.

For additional information, helpful resources, and definitions, see ORI's Use of Any Device Being Tested in Research web page.

Does this protocol involve testing (collecting safety or efficacy data) of a medical device including an FDA approved device, unapproved use of an approved device, humanitarian use device, and/or an investigational device?

◉ Yes ○ No

[Note: If a marketed device(s) is only being used to elicit or measure a physiologic response or clinical outcome, AND, NO data will be collected on or about the device itself, you may answer "no" above, save and exit this section, (Examples: a chemo drug study uses an MRI to measure tumor growth but does NOT assess how effective the MRI is at making the measurement; an exercise study uses a heart monitor to measure athletic performance but no safety or efficacy information will be collected about the device itself, nor will the data collected be used for comparative purposes against any other similar device).]

If you answered yes above, please complete the following questions.

LIST EACH DEVICE BEING TESTED IN STUDY IN THE SPACE BELOW

Device Name:

EAF Device

Is the study being conducted under a valid Investigational Device Exemption (IDE) or Humanitarian Device Exemption (HDE) application? See UK HUD SOP (PDF) for guidance.

○ Yes ◉ No

If Yes, list IDE or HDE #(s) and complete the following:

IDE/HDE Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

☐ Check if this is a Treatment or Compassionate Use IDE under the Food and Drug Administration (FDA) Early Expanded Access program.

For Individual or Small Group Expanded Access, see FDA's Early Expanded Access Program Information, and attach the following:

- FDA expanded access approval or sponsor's authorization;
- An independent assessment from an uninvolved physician, if available;
- Confirmation of agreement from manufacturer or entity authorized to provide access to the product.

For guidance and reporting requirements at the conclusion of treatment see the "Medical Device Clinical Investigations, Compassionate Use, and Treatment IDE SOP" [PDF]

Does the intended use of any device used in this study meet the regulatory definition of Significant Risk (SR) device?

- ○ Yes. Device(s) as used in this study presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.
- ◉ No. All devices, as used in this study do not present a potential for serious risk to the health, safety, or welfare of subjects/participants.

Please also complete and attach the Study Device Form (PDF) (required):

Attachments

Attach Type	File Name
StudyDevice	Form P Study Device Attachment rev1.pdf

RESEARCH SITES

In order for this section to be considered complete, you must click "SAVE" after ensuring all responses are accurate.

A) Check all the applicable sites listed below at which the research will be conducted. If none apply, you do not need to check any boxes.

UK Sites

- ☐ UK Classroom(s)/Lab(s)
- ☐ UK Clinics in Lexington
- ☐ UK Clinics outside of Lexington
- ☐ UK Healthcare Good Samaritan Hospital
- ☑ UK Hospital

Schools/Education Institutions

- ☐ Fayette Co. School Systems *
- ☐ Other State/Regional School Systems
- ☐ Institutions of Higher Education (other than UK)

***Fayette Co. School systems, as well as other non-UK sites, have additional requirements that must be addressed. See ORI's IRB Application Instructions - Off-site Research web page for details.**

Other Medical Facilities

- ☐ Bluegrass Regional Mental Health Retardation Board
- ☐ Cardinal Hill Hospital
- ☐ Eastern State Hospital
- ☐ Norton Healthcare
- ☐ Nursing Homes
- ☐ Shriner's Children's Hospital
- ☐ Veterans Affairs Medical Center
- ☐ Other Hospitals and Med. Centers

- ☐ Correctional Facilities
- ☐ Home Health Agencies
- ☐ International Sites

List all other non-UK owned/operated locations where the research will be conducted:*

*A letter of support and local context is required from non-UK sites. See *Letters of Support and Local Context* on the IRB Application Instructions - Off-Site Research web page for more information.

Attachments

B) Is this a multi-site study for which you are the lead investigator or UK is the lead site? ◉ Yes ○ No

If **YES**, you must describe the plan for the management of reporting unanticipated problems, noncompliance, and submission of

protocol modifications and interim results from the non-UK sites in the E-IRB "Research Description" section under *Resources*.

If the non-UK sites or non-UK personnel are *engaged* in the research, there are additional federal and university requirements which need to be completed for their participation, such as the establishment of a cooperative IRB review agreement with the non-UK site. Questions about the participation of non-UK sites/personnel should be discussed with the ORI staff at (859) 257-9428.

RESEARCH ATTRIBUTES

Indicate the items below that apply to your research. Depending on the items applicable to your research, you may be required to complete additional forms or meet additional requirements. Contact the ORI (859-257-9428) if you have questions about additional requirements.

☐ Not applicable

Check All That Apply

- ☐ Academic Degree/Required Research
- ☐ Aging Research
- ☐ Alcohol Abuse Research
- ☐ Cancer Research
- ☐ Certificate of Confidentiality
- ☑ CCTS-Center for Clinical & Translational Science
- ☐ Clinical Research
- ☐ Clinical Trial
- ☐ Clinical Trial Multicenter(excluding NIH Cooperative Groups)
- ☐ Clinical Trial NIH cooperative groups (i.e., SWOG, RTOG)
- ☐ Clinical Trial Placebo Controlled Trial
- ☑ Clinical Trial UK Only
- ☐ Collection of Biological Specimens
- ☐ Collection of Biological Specimens for Banking
- ☐ Community-Based Participatory Research
- ☑ Data & Safety Monitoring Board
- ☐ Data & Safety Monitoring Plan
- ☐ Deception
- ☐ Drug/Substance Abuse Research
- ☐ Educational/Student Records (e.g., GPA, test scores)
- ☐ Emergency Use (Single Patient)
- ☐ Genetic Research
- ☐ Gene Transfer
- ☐ GWAS (Genome-Wide Association Study) or NIH-funded study generating large scale genomic data
- ☐ International Research
- ☐ Internet Research
- ☐ Planned Emergency Research Involving Waiver of Informed Consent
- ☐ Pluripotent Stem Cell Research
- ☐ Recombinant DNA
- ☐ Survey Research
- ☐ Transplants
- ☐ Use of radioactive material, ionizing radiation, or x-rays [Radiation Safety Committee review required]
- ☐ Vaccine Trials

Click applicable listing(s) for additional requirements and/or information:

- Cancer Research (MCC PRMC)
- Certificate of Confidentiality (look up "Confidentiality/Privacy...")
- CCTS (Center for Clinical and Translational Science)
- Clinical Research (look up "What is the definition of....)
- Clinical Trial (look up "What is the definition of....)

  Determine if research meets NIH definition of clinical trial;
  *Reminder: Ensure compliance with applicable requirements including:
  - Clinicaltrials.gov registration;
  - Good Clinical Practice (GCP) training; and
  - Consent Posting Requirement [PDF] for federal funded trials.

- Collection of Biological Specimens for Banking (look up "Specimen/Tissue Collection...")
- Collection of Biological Specimens (look up "Specimen/Tissue Collection...")
- Community-Based Participatory Research (look up "Community-Engaged...")
- Data & Safety Monitoring Board (DSMB)

  *For Medical IRB: Service Request Form for CCTS DSMB

- Data & Safety Monitoring Plan
- Deception*

  *For deception research, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- Emergency Use (Single Patient) [attach Emergency Use Checklist] (PDF)
- Genetic Research (look up "Specimen/Tissue Collection...")
- Gene Transfer
- HIV/AIDS Research (look up "Reportable Diseases/Conditions")
- Screening for Reportable Diseases [E2.0000] (PDF)
- International Research (look up "International & Non-English Speaking")
- NIH Genomic Data Sharing (GDS) Policy (PDF)
- Planned Emergency Research Involving Waiver of Informed Consent*

  *For Planned Emergency Research Involving Waiver of Informed Consent, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- Use of radioactive material, ionizing radiation or x-rays for research

FUNDING/SUPPORT

If the research is being submitted to, supported by, or conducted in cooperation with an external or internal agency or funding program, indicate below all the categories that apply.

☑ Not applicable

Check All That Apply

- ☐ Grant application pending
- ☐ (HHS) Dept. of Health & Human Services
  - ☐ (NIH) National Institutes of Health
  - ☐ (CDC) Centers for Disease Control & Prevention
  - ☐ (HRSA) Health Resources and Services Administration
  - ☐ (SAMHSA) Substance Abuse and Mental Health Services Administration
- ☐ (DoJ) Department of Justice or Bureau of Prisons
- ☐ (DoE) Department of Energy
- ☐ (EPA) Environmental Protection Agency
- ☐ Federal Agencies Other Than Those Listed Here
- ☐ Industry (Other than Pharmaceutical Companies)
- ☐ Internal Grant Program w/ proposal
- ☐ Internal Grant Program w/o proposal
- ☐ National Science Foundation
- ☐ Other Institutions of Higher Education
- ☐ Pharmaceutical Company
- ☐ Private Foundation/Association
- ☐ U.S. Department of Education
- ☐ State

Other:

Click applicable listing(s) for additional requirements and/or information:

- (HHS) Dept. of Health & Human Services
- (NIH) National Institutes of Health
- (CDC) Centers for Disease Control & Prevention
- (HRSA) Health Resources & Services Administration
- (SAMHSA) Substance Abuse & Mental Health Services Administration
- Industry (Other than Pharmaceutical Companies) [IRB Fee Info]
- National Science Foundation
- (DoEd) U.S. Department of Education [PDF]
- DoJ) Department of Justice or Bureau of Prisons ([PDF]
- (DoE) Department of Energy Summary [PDF] and Department of Energy Identifiable Information Compliance Checklist [PDF]
- (EPA) Environmental Protection Agency [PDF]

Specify the funding source and/or cooperating organization(s) (e.g., National Cancer Institute, Ford Foundation, Eli Lilly & Company, South Western Oncology Group, Bureau of Prisons, etc.):

Add Related Grants

If applicable, please search for and select the OSPA Account number or Electronic Internal Approval Form (eIAF) # (notif #) associated with this IRB application using the "Add Related Grants" button.
If required by your funding agency, upload your grant using the "Grant/Contract Attachments" button.

Add Related Grants

Grant/Contract Attachments

The research involves use of Department of Defense (DoD) funding, military personnel, DoD facilities, or other DoD resources.

(See DoD SOP [PDF] and DoD Summary [PDF] for details)

○ Yes ◉ No

Using the "attachments" button (below), attach applicable materials addressing the specific processes described in the DoD SOP.

DOD SOP Attachments

Additional Certification: (If your project is federally funded, your funding agency may request an Assurance/ Certification/Declaration of Exemption form.) Check the following if needed:

☐ Protection of Human Subjects Assurance/Certification/Declaration of Exemption (Formerly Optional Form – 310)

OTHER REVIEW COMMITTEES

If you check any of the below committees, additional materials may be required with your application submission.

Does your research fall under the purview of any of the other review committees listed below? [*If yes, check all that apply and attach applicable materials using the attachment button at the bottom of your screen.*]

○ Yes ◉ No

	Additional Information
☐ Institutional Biosafety Committee	• Institutional Biosafety Committee (IBC)--Attach required IBC materials
☐ Radiation Safety Committee	• Radiation Safety Committee (RSC)-- For applicability, see instructions and/or upload form [WORD] [PDF]
☐ Radioactive Drug Research Committee	• Radioactive Drug Research Committee (RDRC)--information
☐ Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)	• Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)**--Attach MCC PRMC materials, if any, per instructions
☐ Graduate Medical Education Committee (GME)	• See requirement of Office of Medical Education (OME)
☐ Office of Medical Education (OME)	• See requirement of Graduate Medical Education Committee (GME)

Attachments

**** If you are proposing a study involving cancer research, be sure to have "Cancer Research" marked in the E-IRB "Research Attributes" section.** If your study involves cancer research, ORI will provide a copy of your research protocol to the Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC). The MCC PRMC is responsible for determining whether the study meets the National Cancer Institute (NCI) definition of a clinical trial and for issuing documentation to you (the investigator) which confirms either that PRMC approval has been obtained or that PRC review is not required. Your IRB application will be processed and reviewed independently from the PRMC review.

ADDITIONAL INFORMATION/MATERIALS

Do you want specific information inserted into your approval letter? ◉ Yes ○ No

Approval Letter Details (e.g., serial #):

Submission Description: If you wish to have specific details included in your approval letter (e.g., serial #, internal tracking identifier, etc…), type in the box below exactly what you wish to see on the approval letter. What you type will automatically appear at the top of all approval letters, identical to how you typed it, until it is changed by you (Hint: don't include instructions or questions to ORI staff as those will appear in your approval letter). **If these details need to be changed as a result of revisions, continuation review, or modifications to the application, you are responsible for updating the content of the field below accordingly.**

IRB 006

Protocol/Product Attachments - For each item checked, please attach the corresponding material.

- ☐ Detailed protocol
- ☐ Dept. of Health & Human Services (DHHS) approved protocol (such as NIH sponsored Cooperative Group Clinical Trial)
- ☐ Drug Documentation (e.g., Investigator Brochure; approved labeling; publication; FDA correspondence, etc.)
- ☐ Device Documentation (e.g., Manufacturer information; patient information packet; approved labeling; FDA correspondence, etc.)
- ☐ Other Documents

Protocol/Product Attachments

NOTE: [Instructions for Dept. of Health & Human Services (DHHS)-approved protocol]

If you have password protected documents, that feature should be disabled prior to uploading to ensure access for IRB review.

Additional Materials:

If you have other materials you would like to include in your application for the IRB's consideration, please attach using the Attachments button below.

[To view what materials are currently attached to your application, go to "Application Links" in the menu bar on the left and click "All Attachments".]

Attachments