

Study Title: Total Knee Replacement With Tourniquet Or Irrigation-Coupled Bipolar Device

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	6/22/2023
NCT Number:	NCT04016285
IRB Number	47988
Coversheet created:	1/24/2024

Which IRB

☒ Medical ☐ NonMedical

Protocol Process Type

☐ Exemption
☒ Expedited (Must be risk level 1)
☐ Full

IMPORTANT NOTE: You will not be able to change your selections for "Which IRB" and "Protocol Process Type" after saving this section. If you select the wrong IRB or Protocol Process Type, you may need to create a new application.

See below for guidance on these options, or refer to ORI's "[Getting Started](#)" page. Please contact the Office of Research Integrity (ORI) at 859-257-9428 with any questions prior to saving your selections.

Which IRB

The **Medical IRB** reviews research from the Colleges of:

- Dentistry
- Health Sciences
- Medicine
- Nursing
- Pharmacy and Health Sciences
- and Public Health.

The **Nonmedical IRB** reviews research from the Colleges of:

- Agriculture
- Arts and Sciences
- Business and Economics
- Communication and Information
- Design; Education
- Fine Arts
- Law
- and Social Work

Note: Studies that involve administration of drugs, testing safety or effectiveness of medical devices, or invasive medical procedures must be reviewed by the **Medical IRB** regardless of the college from which the application originates.

Which Protocol Process Type

Under federal regulations, the IRB can process an application to conduct research involving human subjects in one of three ways:

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

The investigator makes the preliminary determination of the type of review for which a study is eligible. Please refer to ORI's "[Getting Started](#)" page for more information about which activities are eligible for each type of review.

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](#).

Modification Request Section**0 unresolved
comment(s)**

***** If this modification changes the scope of your activities to include COVID-19 related research, please insert "COVID19" at the start of your Project and Short Titles.*****

Select One:

- ☒ This modification does not increase risk to study participants.
☐ This modification may or will increase risk to study participants.

Is this modification request due to an Unanticipated Problem/Adverse Event, or Protocol Violation?

- ☐ Yes ☒ No

In your professional opinion, does this modification involve information that might relate to a subject's willingness to continue to take part in the research?

- ☐ Yes ☒ No

If yes, state how the information will be communicated to subjects (i.e., re-consent, send letter, etc.):

For each proposed modification, include a justification.

Example: Jane Doe, MD, is being added as co-investigator because she has expertise with the subjects on this protocol. She has completed human subject protections training, and is authorized to obtain consent.

We are removing Franco S as he is no longer at UK and adding Samuel M as he will take over data collection/analysis on the project.

PROJECT INFORMATION**0 unresolved
comment(s)**

Title of Project: (Use the exact title listed in the grant/contract application, if applicable).

If your research investigates any aspect of COVID-19, please include "COVID19" at the beginning of your Project Title and Short Title



Comparison to short-duration tourniquet Total Knee Arthroplasty (TKA) with the Aquamantys® bipolar sealer and the standard of care in the setting of outpatient TKA: A randomized, double-blinded study

Short Title Description

Please use a few key words to easily identify your study - this text will be displayed in the Dashboard listing for your study.



Aquamantys

Anticipated Ending Date of Research Project: 5/31/2024

Maximum number of human subjects (or records/specimens to be reviewed)

73

After approval, will the study be open to enrollment of new subjects or new data/specimen collection? ☒ Yes ☐ No

PI CONTACT INFORMATION

0 unresolved
comment(s)**Principal Investigator (PI) role for E-IRB access**

The PI is the individual holding primary responsibility on the research project with the following permissions on the E-IRB application:

1. Read;
2. write/edit;
3. receive communications; and
4. submit to the IRB (IR, CR, MR, Other Review*).

If research is being submitted to or supported by an extramural funding agency such as NIH, a private foundation or a pharmaceutical/manufacturing company, the PI listed on the grant application or the drug protocol must be listed as PI here.

Please fill in any blank fields with the appropriate contact information (gray shaded fields are not editable). Required fields left blank will be highlighted in pink after you click "Save".

To change home and work addresses, go to [myUK](#) and update using the Employee Self Service (ESS) portal. If name has changed, the individual with the name change will need to submit a '[Name Change Form](#)' to the Human Resources Benefits Office for entering into SAP. The new name will need to be associated with the individual's Link Blue ID in SAP before the change is reflected in E-IRB. Contact the [HR Benefits Office](#) for additional information.

The Principal Investigator's (PI) contact information is filled in automatically based on who logged in to create the application.

If you are not the Principal Investigator, do NOT add yourself as study personnel.

To change the PI contact information on an application in Researcher edit status:

- click "Change Principal Investigator";
- search for the PI's name using the search feature;
- click "Select" by the name of the Principal Investigator, then "Save Contact Information".

You will automatically be added as study personnel with editing permissions to continue editing the application.

**[Change Principal Investigator:](#)**

First Name:	<input type="text" value="Stephen"/>	Room# & Bldg:	<input type="text" value="Kentucky Clinic K 401"/>
Last Name:	<input type="text" value="Duncan"/>	Speed Sort#:	<input type="text" value="40536"/>
Middle Name:	<input type="text" value="Thomas"/>		
Department:	<input type="text" value="Orthopaedic Surgery - 7H859"/>	Dept Code:	<input type="text" value="7H859"/>
PI's Employee/Student ID#:	<input type="text" value="10522373"/>	Rank:	<input type="text"/>
PI's Telephone #:	<input type="text" value="859-323-5533"/>	Degree:	<input type="text" value="MD"/>
PI's e-mail address:	<input type="text" value="stdunc2@uky.edu"/>	PI's FAX Number:	<input type="text"/>
PI is R.N.	<input type="radio"/> Yes <input checked="" type="radio"/> No	HSP Trained:	<input type="text" value="Yes"/>
		HSP Trained Date:	<input type="text" value="11/14/2021"/>
		RCR Trained:	<input type="text" value="Yes"/>

Do you, the PI, have a [significant financial interest](#) related to your responsibilities at the University of Kentucky (that requires disclosure per the [UK administrative regulation 7:2](#))?

☐ Yes ☒ No

RISK LEVEL**0 unresolved
comment(s)**

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.

*****For Expedited and Exempt Applications, the research activities must be Risk Level 1 (no more than minimal risk to human subjects).*****

Refer to [UK's guidance document](#) on assessing the research risk for additional information.

SUBJECT DEMOGRAPHICS**0 unresolved comment(s)**Age level of human subjects: (i.e., 6 mths.; 2yrs., etc..) to **Study Population:**

Describe the characteristics of the subject population, including age range, gender, ethnic background and health status. Identify the criteria for inclusion and exclusion.

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;
- Justification for the inclusion of vulnerable groups such as children, prisoners, adults with impaired consent capacity, or others who may be vulnerable to coercion or undue influence.

Please consider these resources:

[NIH Diversity Policy](#)

[FDA Diversity Guidance](#) ⓘ

Inclusion:

- 18 - 85 years of age
- Elected to have standard of care total knee arthroplasty
- Able to provided informed consent
- English speaking
- Able to participate in required follow-up visits and to complete study procedures and questionnaires

Exclusion:

- Participants undergoing revision arthroplasty
- Undergoing simultaneous bilateral arthroplasty
- Unicompartmental arthroplasty
- Functional, cognitive, or social limitations that do not allow safe discharge to home on either postoperative day 0 or 1

Attachments

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 for Pre-2019 FDA-regulated Expedited review and Full review applications):

Participant Demographics				
	Cisgender Man ⓘ	Cisgender Woman ⓘ	TGNB/TGE ⓘ	Unknown/Not Reported
American Indian/Alaskan Native:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Asian:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Black/African American:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Latinx:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Native Hawaiian/Pacific Islander:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
White:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
American Arab/Middle Eastern/North African:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Indigenous People Around the World:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
More than One Race:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Unknown or Not Reported:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

If unknown, please explain why:

Subject enrollment numbers are subject to change. This information will be reported at continuation review

Indicate the categories of subjects and controls to be included in the study. You may be required to complete additional forms depending on the subject categories which apply to your research. If the study does not involve direct intervention or direct interaction with subjects, (e.g., record-review research, outcomes registries), do not check populations which the research does not specifically target. For example: a large record review of a diverse population may incidentally include a prisoner or an international citizen, but you should not check those categories if the focus of the study has nothing to do with that status.

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

ADDITIONAL INFORMATION:

- ☐ 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 Adults
- ☐ Pregnant Women/Neonates/Fetal Material
- ☐ Prisoners
- ☐ Non-English Speaking (translated long or short form)
- ☐ International Citizens
- ☐ Normal Volunteers
- ☐ Military Personnel and/or DoD Civilian Employees
- ☒ Patients
- ☐ Appalachian Population

Please visit the [IRB Survival Handbook](#) for more information on:

- Children/Emancipated Minors
- Students as Subjects
- Prisoners
- Impaired Consent Capacity Adults
- Economically or Educationally Disadvantaged Persons

Other Resources:

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

Assessment of the 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). If there is no direct intervention/interaction you will not need to answer the impaired consent capacity questions.

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

☐ Yes ☒ No

If Yes and you are not filing for exemption certification, go to "[Form T](#)", complete the form, and attach it using the button below.

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**0 unresolved
comment(s)**

For creating 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 edit to match your research project.

Additional Resources:

- [Informed Consent/Assent Website](#)
- [Waiver of Consent vs. Waiver of Signatures](#)
- [Sample Repository/Registry/Bank Consent Template](#)

Consent/Assent Tips:

- If you have multiple consent documents, be sure to upload each individually (not all in a combined file).
- If another site is serving as the IRB for the project, attach the form as a "Reliance Consent Form" so the document will not receive a UK IRB approval stamp; the reviewing IRB will need to stamp the consent forms.
- 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
- "Reliance Consent Form",
- "Sponsor's Sample Consent Form".

How to Get the Section Check Mark

1. You must:
 - a) provide a response in the text box below describing how investigators will obtain consent/assent, and
 - b) check the box for at least one of the consent items and/or check mark one of the waivers
2. If applicable attach each corresponding document(s) **as a read-only PDF**.
3. 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 select "Stamped Consent Doc(s) Not Needed".
4. 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 and/or translated short form)
- ☐ Assent Form
- ☐ Cover Letter (for survey/questionnaire research)
- ☐ Phone Script
- ☒ Informed Consent/HIPAA Combined Form
- ☐ Debriefing and/or Permission to Use Data Form
- ☐ Reliance Consent Form
- ☐ Sponsor's sample consent form for Dept. of Health and Human Services (DHHS)-approved protocol
- ☐ Stamped Consent Doc(s) Not Needed

Attachments

Informed Consent Process:

Using active voice, describe how investigators will obtain consent/assent. Include:

- the circumstances under which consent will be sought and obtained
- the timing of the consent process (including any waiting period between providing information and obtaining consent)

- who will seek consent
- how you will minimize the possibility of coercion or undue influence
- the method used for documenting consent
- if applicable, who is authorized to provide permission or consent on behalf of the subject
- if applicable, specific instruments or techniques to assess and confirm potential subjects' understanding of the information

Note: all individuals authorized to obtain informed consent should be designated as such in the E-IRB "Study Personnel" section of this application.

Special considerations may include:

- Obtaining consent/assent for special populations such as children, prisoners, or people with impaired decisional capacity
- *Research Involving Emancipated Individuals*
If you plan to enroll some or all prospective subjects as emancipated, consult with UK legal counsel **prior to submitting this application to the IRB**. Include research legal counsel's recommendations in the "Additional Information" section as a separate document.
- *Research Involving Non-English Speaking Subjects*
For 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](#).

Prior to entering the study the risks and benefits of participating will be explained to the participant by a member of the study team authorized to obtain informed consent. The informed consent process will take place in the designated private research room at the Good Samaritan Orthopedic offices. Kate Jochimsen, MS, ATC and Cale Jacobs, PhD, ATC will execute the consent process. Both are intimately familiar with the study protocol and features of the implant options available to potential study participants.

Written informed consent from the participant will be placed in their medical record. Documentation of the informed consent process will be placed in the participant's progress notes. A signed informed consent form will be retained by the investigator. The study participant will receive a copy of the informed consent form.

Participants will be encouraged to address any complaint to any member of the study team including the PI. They will be told that they can, at any time, call the Office of Research Integrity at the University of Kentucky at (859) 257-9428 or toll free at 1-866-400-9428.

☐ Request for Waiver of Informed Consent Process

If you are requesting IRB approval to waive the requirement for the informed consent process, or to alter some or all of the elements of informed consent, 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 a waiver of the requirement for the informed consent process.

☐ I am requesting an 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.

Explain how each condition 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.

If you are requesting IRB approval to waive the requirement for signatures on informed consent forms, **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 (e.g., 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 (e.g., 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, 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.

*If the IRB approves a waiver of signatures, participants must still be provided oral or written information about the study. To ensure you include required elements in your consent document, use the **Cover Letter Template** as a guide. There is an [English](#) and a [Spanish](#) version.*



Option 1

Describe how your study meets these criteria:

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

Describe how your study meets these criteria:

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

Describe how your study meets these criteria:

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.

STUDY PERSONNEL

0 unresolved comment(s)

Do you have study personnel who will be assisting with the research?

After selecting 'Yes' or 'No' you must click the 'Save Study Personnel Information' button. 

☒ Yes ☐ No

Manage Study Personnel

Identify other study personnel assisting in research project:

- The individual listed as PI in the 'PI Contact Information' section should NOT be added to this section.
- If the research is required for a University of Kentucky academic program, the faculty advisor is also considered study personnel and should be listed below.
Residents and students who are PI's are encouraged to designate the faculty advisor or at least one other individual as a contact with an editor role (DP).
- Role: DP = Editor (individual can view, navigate, and edit the application for any review phase (IR, CR/FR, MR) or 'Other Review', and submit Other Reviews on behalf of the PI.)
- Role: SP = Reader (individual can view and navigate through the currently approved application only.)

To add an individual via the below feature:

- Search for personnel;
- Click "select" by the listing for the person you want to add;
- For each person, specify responsibility in the project, whether authorized to obtain informed consent, AND denote who should receive E-IRB notifications (contact status).

NOTE: Study personnel must complete human subject protection (HSP) and Responsible Conduct of Research (RCR) training before implementing any research procedures. For information about training requirements for study personnel, visit UK's [HSP FAQ page](#), the [RCR Getting Started](#) page, or contact ORI at 859-257-9428. If you have documentation of current HSP training other than that acquired through UK CITI, you may submit it to ORI (HSPTrainingSupport@uky.edu) for credit.

Study personnel assisting in research project: 

Last Name	First Name	Responsibility In Project	Role	A C	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI
Cascia	Nicole	Study Coordinator	DP	Y	N	PhD	P	Y	01/18/2023	Y	N	07/20/2020	N
Conley	Caitlin	Project Assistance/Support	DP	N	N	PhD	P	Y	01/18/2022	Y	N	11/16/2022	N
Landy	David	Sub-Investigator	DP	N	N	MD	P	Y	04/21/2021	Y	N	05/13/2023	N
Lenberger	Natalie	Study Coordinator	SP	Y	N		P	Y	08/17/2020	Y	N	02/12/2022	N
Mounce	Samuel	Data Collection	DP	Y	Y	MD	P	Y	06/12/2023	Y	N	06/22/2023	N
Ashe	Laura	Study Coordinator	DP	N	Y		P	Y	06/05/2023	Y	Y	05/28/2020	N
Ball	Lindsey	Study Coordinator	DP	Y	Y		P	Y	07/22/2021	Y	Y	02/07/2023	N
Bowlds	Hannah	Study Coordinator	DP	N	N		P	Y	08/03/2020	N	Y	05/28/2020	N
Brophy	Kelcie	Study Coordinator	SP	N	N		P	N	09/03/2018		Y	08/29/2019	N
Edwards	Megan	Study Coordinator	DP	Y	N		P	N	04/02/2020	N	Y	06/10/2021	N
Fernand	Anthony	Study Coordinator	DP	N	Y		P	Y	02/21/2023	Y	Y	01/29/2019	N
Goetz	Michael	Study Coordinator	SP	N	N		P	Y	08/26/2022	Y	Y	09/06/2019	N
Hartman	Ellen	Project Assistance/Support	DP	N	Y		P	Y	04/27/2023	Y	Y	05/28/2020	N
Hunt	Emily	Study Coordinator	DP	Y	N		P	N	01/24/2018		Y	07/20/2020	N
Jacobs	Cale	Co-Investigator	DP	Y	N	PhD	P	N	06/18/2020	Y	Y	11/16/2022	N
Jochimsen	Kate	Sub-Investigator	SP	Y	N		P	N	03/01/2018		Y	04/17/2019	N
Rutherford	Marshall	Study Coordinator	DP	Y	Y	MD	P	Y	07/15/2021	Y	Y	02/02/2022	N
Sabatini	Franco	Data Collection	DP	N	N		P	Y	06/28/2022	Y	Y	06/22/2023	N
Sullivan	Breanna	Data Collection	SP	N	N		P	Y	06/28/2021	Y	Y	05/16/2022	N
Wang	Jennifer	Study Coordinator	DP	Y	Y		P	Y	10/20/2020	N	Y	07/29/2021	N

RESEARCH DESCRIPTION

0 unresolved
comment(s)

You may attach a sponsor's protocol pages in the "Additional Information" section and refer to them where necessary in the Research Description. However, each prompt that applies to your study should contain at least a summary paragraph.

Pro Tips:

- 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 supplemental information with your application. During the document upload process, you will be able to provide a brief description of the attachment.

Background

Include a brief review of existing literature in the area of your research. You should identify gaps in knowledge that should be addressed and explain how your research will address those gaps or contribute to existing knowledge in this area. For interventional research, search PubMed and ClinicalTrials.gov for duplicative ongoing and completed trials with same condition and intervention(s).

This study will assess the benefit to both the patient and health care system by allowing patients to safely undergo outpatient or short-stay Total Knee Arthroplasty (TKA) with improved postoperative pain and function with a short-duration tourniquet treatment protocol which includes the FDA-approved Aquamantys Bipolar sealer (Medtronic, Minneapolis, MN). The Aquamantys Bipolar Sealer is a single use, sterile, bipolar device intended to be used in conjunction with the Aquamantys Pump Generator for delivery of radiofrequency (RF) energy and saline for hemostatic sealing and coagulation of soft tissue and bone at the operative site. It is intended for, but not limited to orthopaedic, spine, thoracic and open abdominal surgery.

This study will provide invaluable information for both surgeons and hospital administrators to use when comparing potential treatment options for knee arthroplasty patients, with the end goal of making clinically meaningful improvements to patient care. It will also highlight the clinical importance of maintaining early quadriceps function. Quadriceps dysfunction has been linked to the amount of postoperative swelling (Holm et al., Arch Phys Med Rehabil, 2010). Anecdotally, we have seen a dramatic reduction in the amount of swelling present at the patient's first physical therapy visit on the day of surgery when utilizing a short-duration tourniquet protocol including the Aquamantys. By using Aquamantys to minimize effusion as part of a tourniquet-less TKA protocol, patients may be able to avoid loss of quadriceps function, which may then provide both short- and long-term benefit. Tourniquet-less TKA may reduce complications and readmissions by theoretically reducing fall risk by maintaining quadriceps function. Improved quadriceps function not only reduces fall risk but may allow patients to more rapidly achieve functional milestones after surgery such as walking without an assistive device and navigating stairs.

Objectives

List your research objectives. Please include a summary of intended research objectives in the box below.

The specific goals of study are to compare quadriceps strength, pain, opioid consumption, and patient function during the first three months in the setting of short-stay TKA between patients treated with short-duration tourniquet TKA with the Aquamantys® bipolar sealer versus those treated with the standard of care (tourniquet used throughout the case and no Aquamantys®).

Study Design

Describe and explain the study design (e.g., observational, secondary analysis, single/double blind, parallel, crossover, deception, etc.).

- *Clinical Research:* Indicate whether subjects will be randomized and whether subjects will receive any placebo.
- *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.
- *Qualitative research:* Indicate ranges where flexibility is needed, if a fixed interview transcript is not available, describe interview topics including the most sensitive potential questions.
- *Research Repositories:* If the purpose of this submission is to establish a Research Repository (bank, registry) and the material you plan to collect is already available from a commercial supplier, clinical lab, or established IRB approved research repository, provide scientific justification for establishing 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](#) or the [UK Research Registry Guidance](#).

This is a single site, randomized, double-blind study which will be conducted at the University of Kentucky. This study intends to enroll 70 male and female participants. Participants will be randomized to have TKA either with the aforementioned short-duration tourniquet TKA protocol with Aquamantys or the standard of care (tourniquet used throughout the case with no Aquamantys). Provided patient meet the functional goals necessary for discharge, all patients will be discharged to home on the day of surgery or on postoperative day 1. Participants will be blinded during the course of the study to their assigned group, as will the study personnel performing postoperative assessments and the study's biostatistician.

In order to determine an appropriate sample size, an a priori power analysis was performed. We chose to use isometric quadriceps strength at two weeks as the primary outcome variable. Using an alpha level of 0.05 and the standard deviation and minimal clinically important difference reported by Husted et al. (Trials, 2018) of 0.22 Nm/kg and 0.15 Nm/kg, respectively, a sample size of 70 total patients (35 patients per group) would be 80% powered to detect clinically important differences (G*Power, version 3.1).

Data collection will coincide with four regularly-scheduled patient visits: preoperative and 2, 6, and 12 weeks after surgery. Participants will complete isometric quadriceps testing at each study visit, and will be asked to complete the KOOS, JR, VR-12, and VAS pain scale questionnaires. We will also record the participant's opioid consumption per our standard of care, as well as whether the patient is able to walk without an assistive device and/or self-reports the ability to navigate stairs. Beginning at the 6-week postoperative visit, patients will be asked to complete the five times sit-to-stand test. The primary outcome variable, isometric quadriceps strength at 2 weeks, will be compared between groups using a two-tailed independent t-test. All continuous secondary variables will be assessed using group x time repeated measures ANOVAs. The prevalence of patients that can walk without an assistive device and/or navigate stairs at 2, 6, and 12 weeks will be compared between groups using chi-square or Fisher Exact tests as appropriate.

Attachments

Subject Recruitment Methods & Advertising

Describe how the study team will identify and recruit subjects. Please consider the following items and provide additional information as needed so that the IRB can follow each step of the recruitment process.

- How will the study team identify potential participants?
- Who will first contact the potential subjects, and how?
- Will you use advertisements? If so, how will you distribute those?
- How and where will the research team meet with potential participants?
- If applicable, describe proposed outreach programs for recruiting women, minorities, or disparate populations.
- How you will minimize undue influence in recruitment?
- Attach copies of all recruiting and advertising materials (emails, verbal scripts, flyers, posts, messages, etc.).

For additional information on recruiting and advertising:

- [IRB Application Instructions - Advertisements](#)
- [PI Guide to Identification and Recruitment of Human Subjects for Research](#)

Participants will be identified through the Department of Orthopaedics. The study population will be recruited from Dr. Duncan's patient population that have elected to undergo primary TKA. Once a participant has been deemed to be medically eligible for the study by Dr. Duncan, she or he will meet with a member of the research staff to discuss the study. The recruitment discussion will not include Dr. Duncan and will take place in the designated private research room at the Good Samaritan Orthopedic offices. Dr. Duncan will have a treatment relationship to all participants recruited to the study.

We do not plan to advertise for this study. However, if that should change we will ensure that all future advertising is reviewed and approved by the IRB prior to their implementation.

Attachments

Research Procedures

Describe how the research will be conducted.

- What experience will study participants have?
- What will study participants be expected to do?
- How long will the study last?
- Outline the schedule and timing of study procedures.
- Provide visit-by-visit listing of all procedures that will take place.
- Identify all procedures that will be carried out with each group of participants.
- Describe deception and debrief procedures if deception is involved.

Differentiate between procedures that involve standard/routine clinical care and those that will be performed specifically for this research project. List medications that are explicitly forbidden or permitted during study participation.

Short-duration Tourniquet protocol: Participants randomized to undergo short-duration tourniquet TKA will undergo standard of care TKA with two notable exceptions. First, the standard of care is to use an inflated tourniquet throughout the TKA procedure (approximately 75 minutes). This practice, operationally defined as long-duration tourniquet use for this study, has traditionally done to minimize blood loss and to ease visualization of the joint and joint surfaces by the surgeon during the case.

On the contrary, recent research has identify the practice of short-duration tourniquet only when cementing in the TKA implants to be a safe alternative to long-duration tourniquet use (Wang, 2018). In a recent meta-analysis by Wang et al., short duration tourniquet use was associated with improved early functional outcomes but also with increased intraoperative blood loss when compared to long-duration tourniquet use. However, the prevalence of blood transfusions did not differ between short- and long-duration tourniquet use.

In the current study, participants randomized to the short-duration tourniquet group will only have the tourniquet inflated when cementing the components (approximately 5-10 minutes). The second difference is that the Aquamantys Bipolar Sealer will be used as part of the short-duration tourniquet protocol. The Aquamantys Bipolar Sealer will be used to seal open vessels in the posterior joint capsule to lessen intraoperative bleeding to ensure adequate cement fixation and potentially reduce intraoperative blood loss and postoperative effusion.

Isometric Quadriceps Strength Testing: The participant will sit in a seated position and a stabilizing strap will be placed around the bottom of the participant's shank and attached to a hand-held dynamometer. The participant will be asked to slowly kick the foot as hard as they can into the dynamometer pad placed on the anterior aspect of the participant's distal tibia. One practice trial followed by 3 actual trials will be performed. The participant will receive a 30-second rest in between each trial and a 1-minute rest in between legs for each test to prevent fatigue.

Five Times Sit-to-Stand Test: The five-repetition sit-to-stand is commonly used to measure mobility and function in older adults. Participants are positioned in a standard 16" office chair with their arms at their sides and back located against the back of the chair. Participants are instructed to "Please stand up straight as quickly as you can 5 times, without stopping in between. Keep your arms folded across your chest. I'll be timing you with a stopwatch. Ready, begin." The test is timed using a stopwatch and the timer is stopped when the individual achieves a standing position on the 5th trial. To ensure safety, we will utilize a four-legged chair that does not have wheels, and the chair will be placed so it backs against a wall to prevent the chair from moving during the test. While the participant will be asked to complete the test without using the chair's armrests, the armrests are available for balance should they need assistance. If at any visit the participant cannot complete one practice repetition of sit to stand without using the armrests, we will not ask them to participate in the test at that visit.

Patient-Reported Outcomes: Participants will be asked to complete four questionnaires at each study visit. Participants will be asked to complete the Knee injury and Osteoarthritis Outcome Score, Joint Replacement (KOOS JR) questionnaire which is a 7-item instrument validated to assess patient outcomes following knee arthroplasty. Other questionnaires will include the Veterans Rand-12 (VR-12) which is a 12-item instrument that assesses physical and mental health and a Visual Analogue Scale (VAS) to assess pain and patient confidence in their knee. In addition, a study-specific questionnaire will be used to assess whether the patient is able to ambulate without an assistive device and to determine the method by which the patient navigates stairs (one-step at a time, requires the use of a handrail, etc.).

Attachments

Attach Type	File Name
ResearchProcedures	Aquamantys Page 4 Study Flow Chart.pdf

Data Collection & Research Materials

In this section, please provide the following:

- Describe all sources or methods for obtaining research materials about or from living individuals (such as specimens, records, surveys, interviews, participant observation, etc.), and explain why this information is needed to conduct the study.
- For each source or method described, please list or attach all data to be collected (such as genetic information, interview scripts, survey tools, data collection forms for existing data, etc.).
- If you will conduct a record or chart review, list the beginning and end dates of the records you will view.

Please view the attached documents

Attachments

Attach Type	File Name
DataCollection	Knee Function Questionnaire.docx
DataCollection	KOOS-JR-2015.pdf
DataCollection	Visual Analogue Scale.docx
DataCollection	VR12.pdf

Resources

Describe the availability of the resources and adequacy of the facilities that you will use to perform the research. Such resources may include:

- Staffing and personnel, in terms of availability, number, expertise, and experience;
- Computer or other technological resources, mobile or otherwise, required or created during the conduct of the research;
- Psychological, social, or medical services, including equipment needed to protect subjects, medical monitoring, ancillary care, or counseling or social support services that may be required because of research participation;
- Resources for communication with subjects, such as language translation/interpretation services.

All research procedures will be carried out at the UK Good Samaritan Hospital and UK Healthcare Joint Reconstruction and Replacement offices. The participants will be followed by Dr. Duncan and his research team which includes physicians, physician assistants, and clinical research coordinators during the study.

Potential Risks & Benefits

Risks

- Describe any potential risks – including physical, psychological, social, legal, ability to re-identify subjects, or other risks. Assess the seriousness and likelihood of each risk.
- Which risks may affect a subject's willingness to participate in the study?
- Describe likely adverse effects of drugs, biologics, devices or procedures participants may encounter while in the study.
- *Qualitative research* - describe ethical issues that could arise while conducting research in the field and strategies you may use to handle those situations.
- Describe any steps to mitigate these risks.

Benefits

- Describe potential direct benefits to study participants – including diagnostic or therapeutic, physical, psychological or emotional, learning benefits. This cannot include incentives or payments.
- State if there are no direct benefits.
- Describe potential benefits to society and/or general knowledge to be gained.

Describe why potential benefits are reasonable in relation to potential risks. If applicable, justify why risks to vulnerable subjects are reasonable to potential benefits.

Aquamantys Bipolar Sealer: Delicate body structures could be damaged by hot saline run-off. We will use proper suctioning and other protective measures during surgery to reduce this risk.

Isometric Quadriceps Strength and Sit-to-Stand Testing: The possible risks for participation in this study are minimal. Participants may injure their leg during the performance of the functional testing; however, all precautions will be taken to prevent this. All functional testing will be carried out by a trained member of the research team. It is also possible that some participants may experience muscle soreness following the strength and functional testing. However, this soreness will not be significantly greater than that which they may experience in response to starting a new exercise during physical therapy. If the functional testing is deemed unsafe for the participant to complete they will not complete the testing at that session.

Participation in the study may not result in any benefits to participants. This study may help doctors better understand different materials used in hip replacements that may help others in the future.

Available Alternative Opportunities/Treatments

Describe alternative treatments or opportunities that might be available to those who choose not to participate in the study, and which offer the subject equal or greater advantages. If applicable, this should include a discussion of the current standard of care treatment(s).

There are no alternative treatments to this study other than not participating in this study. The participant may receive either short or long duration tourniquet use without being in the study as both methods of surgery are currently utilized.

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Records, Privacy, and Confidentiality

Specify where the data and/or specimens will be stored and how the researcher will ensure the privacy and confidentiality of both. Specify who will have access to the data/specimens and why they need access.

Describe how data will be managed after the study is complete:

- If data/specimens will be maintained, specify whether identifiers will be removed from the maintained information/material.
- If identifiers will not be removed, provide justification for retaining them and describe how you will protect confidentiality.
- If the data/specimens will be destroyed, verify that this will not violate [retention policies](#) and will adhere to applicable facility requirements.

If this study will use de-identified data from another source, 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 collaborators not affiliated with UK.

For additional considerations:

[Return of Research Results or Incidental Research Findings](#)

[HIPAA policies](#)

[FERPA policies](#)

[Procedures for Transfer agreements](#)

[Information regarding multi-site studies](#)

[NIH Genomic Data Sharing \(GDS\) Policy](#)

[Digital Data](#)

The investigative team maintains the right to keep, preserve, use and dispose of the findings of this investigation in accordance with Food and Drug Administration (FDA) guidelines. Investigational records from this study will be maintained in a confidential manner; participant names will not be associated with any published results.

When we write about or share the results from the study, we will write about the combined information. We will not reveal the participant names or other identifying private information. We will make every effort to prevent anyone who is not on the research team from knowing that participant gave us information, or what that information is.

The participant should know that in some cases we may have to show their information to other people. For example, the law may require us to share their information with:

a court or agencies, if they have a reportable disease/condition;

authorities, if the participant reports information about a child being abused; or if they pose a danger to themselves or someone else.

The study information collected from the participation in the study will be entered into a secure computer system called REDCap.

Data will be stored in full compliance with institutional and governmental regulations regarding privacy and security. To protect the privacy of participants and maintain confidentiality, no identifiers (e.g., name, social security number, date of birth) will be directly linked to the data. Participant initials will be collected in the Electronic Data Capture system, and will be listed at the top of each of the visit electronic case report forms as an additional source of verification for study staff that they are entering data in the correct subject's form. The collection of initials is meant to assist in avoiding data entry errors that may result from confusion of subject ID numbers. These initials will solely be used by each specific site and will not be used in any way to re-identify the individual for whom data were collected centrally.

All participant data collected through the case report forms will be stored in the secure Electronic Data Capture system, which is encrypted and restricts access to individuals with proper credentials. Protected health information (PHI) will be encrypted and kept confidential. Though case report forms will be completed electronically, hard copy documents with participant identifiers will be stored in locked, secure areas to protect participant data.

Officials of the Food & Drug Administration, UK Institutional Review Board, Medtronic and the Center for Clinical and Translational Science may look at or copy pertinent portions of the participant records.

Provisions to guard against the potential risks and discomforts discussed in section 9 are as follows: Every precaution to prevent a direct study injury will be taken by medical personnel and the investigators. The research participant will be followed by physicians, fellows, registered nurses and other research staff members for the duration of the participant's hospitalization. Routine care will be provided by the hospital staff. Emergency medical equipment, medications and supplies will be at the physician's disposal should the participants have an acute untoward reaction.

The participants will be monitored for clinical adverse experiences throughout study therapy. Throughout the study, all adverse events will be monitored and recorded.

UK IRB policies state that IRB-related research records must be retained for a minimum of 6 years after study closure. Do you confirm that you will retain all IRB-related records for a minimum of 6 years after study closure?

☒ Yes ☐ No

Payment

Describe the incentives (monetary or other) being offered to subjects for their participation. If monetary compensation is offered, indicate the amount and describe the terms and schedule of payment. Please review [this guidance](#) for more information on payments to subjects, including restrictions and expectations.

Participants will be paid \$50.00 following for taking part in this study. Payment will be prorated and participants will receive \$12.50 for each of the four study visits. Payment will be received in the form of a check 3-4 months after the surgery.

Costs to Subjects

Include a list of services and/or tests that will not be paid for by the sponsor and/or the study (e.g., MRI, HIV). Keep in mind that a subject will not know what is “standard” – and thus not covered by the sponsor/study – unless you tell them.

Participants and/or their insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that they would normally receive for any conditions they may have. These are costs that are considered medically necessary and will be part of the care participants receive even if they do not take part in this study.

The University of Kentucky may not be allowed to bill the participant's insurance company, Medicare, or Medicaid for the medical procedures done strictly for research.

The following costs will be paid for by the study:

- Isometric quadriceps testing
- Sit-to-stand test
- KOOS JR Questionnaire
- VR-12 questionnaire
- VAS pain scale.
- Functional questionnaire

In Case of Study Related Injuries: Salient Surgical Technology, Inc., received FDA 510K clearance on Aug 29, 2011 (see appendix A). On July 11, 2011, Medtronic acquired Salient Surgical Technologies (see appendix B). This device is being used for an approved indication and is not considered investigational to this study. The use of this device is also part of the investigator's standard of care. Either the participant or their insurance will be billed for the costs of the medical care.

Data and Safety Monitoring

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

- If you are conducting greater than minimal risk research, or your clinical investigation is NIH-funded, 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, 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.



Monitoring for adverse events will be conducted in real-time by the study investigators and study coordinators. This study will fall under the UK Center for Clinical and Translational Science's Quality Improvement Program. Clinical site auditing is conducted to ensure that the rights and well-being of human subjects are protected, that the reported trial data are accurate, complete, and verifiable, and that the conduct of the trial is in compliance with the currently approved protocol/amendment(s), with GCP, and with applicable regulatory requirement(s).

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Future Use and Sharing of Material (e.g., Data/Specimens/Information)

If the material collected for this study will be used by members of the research team or shared with other researchers for future studies, please address the following:

- list the biological specimens and/or information that will be kept
- briefly describe the types, categories and/or purposes of the future research
- describe any risks of the additional use
- describe privacy/confidentiality protections that will be put into place
- describe the period of time specimens/information may be used
- describe procedures for sharing specimens/information with secondary researchers
- describe the process for, and limitations to, withdrawal of specimens/data

N/A

Are you recruiting or expect to enroll **Non-English Speaking Subjects or Subjects from a Foreign Culture**? (does not include short

form use for incidentally encountered non-English subjects)

☐ Yes ☒ No

Non-English Speaking Subjects or Subjects from a Foreign Culture

Recruitment and Consent:

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.

When recruiting Non-English-speaking subjects, provide a consent document in the subject's primary language. After saving this section, attach both the English and translated consent documents in the "Informed Consent" section.

Cultural and Language Consultants:

The PI is required to identify someone who is willing to serve as the cultural consultant to the IRB.

- This 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 be involved with the study or have any interest in its IRB approval.
- Please include the name, address, telephone number, and email of the person who agrees to be the cultural consultant for your study.
- ORI staff will facilitate the review process with your consultant. Please do not ask them to review your protocol separately.

For more details, see the IRB Application Instructions on [Research Involving Non-English Speaking Subjects or Subjects from a Foreign Culture](#).

Local Requirements:

If you will conduct research at an international location, identify and describe:

- relevant local regulations
- data privacy regulations
- applicable laws
- ethics review requirements for human subject protection

Please provide links or sources where possible. If the project has been or will be reviewed by a local ethics review board, attach a copy in the "Additional Information/Materials" section. You may also consult the current edition of the [International Compilation of Human Research Standards](#)

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:

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

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

☐ Yes ☒ No


If the sponsor-investigator has completed equivalent sponsor-investigator training, submit documentation of the content for the IRB's consideration.

[Attachments](#)

HIPAA**0 unresolved
comment(s)**

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

STUDY DRUG INFORMATION

0 unresolved
comment(s)

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 [Investigational Drug Service \(IDS\) pharmacies \(Oncology or Non-Oncology\)](#). 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](#).

Complete and attach the required [Study Drug Form](#) picking "Study Drug Form" for the document type. Any

applicable drug documentation (e.g., Investigator Brochure; approved labeling; publication; FDA correspondence, etc.) should be attached using "Other Drug Documentation" for the document type.



Attachments

STUDY DEVICE INFORMATION

0 unresolved
comment(s)

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:

Aquamantys Bipolar Sealer

Is the study being conducted under a valid Investigational Device Exemption (IDE), Humanitarian Device Exemption (HDE) or Compassionate Use?

☐ Yes ☒ No

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

IDE/HDE Submitted/Held by:

Sponsor: ☐

Held By:

Investigator: ☐

Held By:

Other: ☐

Held By:

☐ Check if this is a Treatment IDE or Compassionate Use under the Food and Drug Administration (FDA) 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 SOP](#).

Does the intended use of any research device being tested (not clinically observed) 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.

Complete and attach the required [Study Device Form](#), picking the "Study Device Form" for the document type. Any applicable device documentation (e.g., Manufacturer information; patient information packet; approved labeling; FDA correspondence, etc.) should be attached using "Other Device Documentation" for the document type.



Attachments

Attach Type	File Name
Study Device Form	121918, Form P, Aquamantys - (Clean).pdf

RESEARCH SITES**0 unresolved
comment(s)**

To complete this section, ensure the responses are accurate then click "SAVE".

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

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), including:

- 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.
- Supportive documentation, including letters of support, can be attached below.
- NOTE: 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. For instance, the other site(s) may need to complete their own IRB review, or a cooperative review arrangement may need to be established with non-UK

sites.

- Questions about the participation of non-UK sites/personnel should be discussed with the ORI staff at (859) 257-9428.

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

Describe the role of any non-UK site(s) or non-UK personnel who will be participating in your research.

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, describe the plan for the management of reporting unanticipated problems, noncompliance, and submission of protocol modifications and interim results from the non-UK sites:

C) If your research involves collaboration with any sites and/or personnel outside the University of Kentucky, then it is considered multisite research and IRB reliance issues will need to be addressed. This may include national multi-center trials as well local studies involving sites/personnel external to UK. If you would like to request that the University of Kentucky IRB (UK IRB) serve as the lead IRB for your study, or if you would like the UK IRB to defer review to another IRB, please contact the IRBReliance@uky.edu.

RESEARCH ATTRIBUTES

0 unresolved
comment(s)

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
- ☐ Alcohol/Drug/Substance Abuse Research
- ☐ Biological Specimen Bank Creation (for sharing)
- ☐ Cancer Research
- ☐ CCTS-Center for Clinical & Translational Science
- ☐ Certificate of Confidentiality
- ☒ Clinical Research
- ☐ Clinical Trial - Phase 1
- ☒ Clinical Trial
- ☐ Collection of Biological Specimens for internal banking and use (not sharing)
- ☐ Community-Based Participatory Research
- ☐ Deception
- ☐ Educational/Student Records (e.g., GPA, test scores)
- ☐ Emergency Use (Single Patient)
- ☐ Gene Transfer
- ☐ Genetic Research
- ☐ GWAS (Genome-Wide Association Study) or NIH Genomic Data Sharing (GDS)
- ☐ Human Cells, Tissues, and Cellular and Tissue Based Products
- ☐ Individual Expanded Access or Compassionate Use
- ☐ International Research
- ☐ Planned Emergency Research Involving Exception from Informed Consent
- ☐ Recombinant DNA
- ☐ Registry or data repository creation
- ☐ Stem Cell Research
- ☐ Suicide Ideation or Behavior Research
- ☐ Survey Research
- ☐ Transplants
- ☐ Use, storage and disposal of radioactive material and radiation producing devices
- ☐ Vaccine Trials

For additional requirements and 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](#)
- [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, storage and disposal of radioactive material and radiation producing devices](#)

FUNDING/SUPPORT**0 unresolved
comment(s)**

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. [i](#)

☐ 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:

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.):

Click applicable listing(s) for additional requirements and 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](#)
- [\(DoJ\) Department of Justice or Bureau of Prisons](#)
- [\(DoE\) Department of Energy Summary and Department of Energy Identifiable Information Compliance Checklist](#)
- [\(EPA\) Environmental Protection Agency](#)

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.

The research involves use of Department of Defense (DoD) funding, military personnel, DoD facilities, or other DoD resources.
(See [DoD SOP](#) and [DoD Summary](#) 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)

[Assurance/Certification Attachments](#)

OTHER REVIEW COMMITTEES

0 unresolved
comment(s)

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
- ☐ Radiation Safety Committee
- ☐ Radioactive Drug Research Committee
- ☐ Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)
- ☐ Graduate Medical Education Committee (GME)
- ☐ Office of Medical Education (OME)

- [Institutional Biosafety Committee \(IBC\)](#) - Attach required IBC materials
- [Radiation Safety Committee \(RSC\)](#) - For applicability, see instructions and attach form
- [Radioactive Drug Research Committee \(RDRC\)](#)
- [Markey Cancer Center \(MCC\) Protocol Review and Monitoring Committee \(PRMC\)**](#) - Attach MCC PRMC materials, if any, per instructions.
- [Office of Medical Education \(OME\)](#)
- [Graduate Medical Education Committee \(GME\)](#)

Attachments

**** If your study involves cancer research, be sure to select "Cancer Research" in the "Research Attributes" section.** ORI will send 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 PRMC review is not required. Your IRB application will be processed and reviewed independently from the PRMC review.

ADDITIONAL INFORMATION/MATERIALS

0 unresolved
comment(s)

Do you want specific information inserted into your approval letter? ☐ Yes ☒ No

Approval Letter Details:

If you wish to have specific language included in your approval letter (e.g., serial #, internal tracking identifier, etc...), type that language in the box below exactly as it should appear in the letter. The text you enter will automatically appear at the top of all approval letters, identical to how you typed it, until you update it. Don't include instructions or questions to ORI staff as those will appear in your approval letter. **If these details need to be changed for any reason, you are responsible for updating the content of this field.**

Additional Materials:

If you have other materials you would like to include for the IRB's consideration, check all that apply and attach the corresponding documents using the Attachments button below.

- ☐ Detailed protocol
☐ Dept. of Health & Human Services (DHHS) approved protocol (such as NIH sponsored Cooperative Group Clinical Trial)
☒ Other Documents

Protocol/Other Attachments

Attach Type	File Name
Other	Aquamantys 510k letter.pdf
Other	Memo Aquamantys.docx

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.

To view the materials currently attached to your application, click "All Attachments" on the left menu bar.

SIGNATURES (ASSURANCES)**0 unresolved
comment(s)****Introduction**

All IRB applications require additional assurances by a Department Chairperson or equivalent (DA), and when applicable, a Faculty Advisor or equivalent (FA). This signifies the acceptance of certain responsibilities and that the science is meritorious and deserving of conduct in humans. The person assigned as DA *should not* also be listed in the Study Personnel section, and the individual assigned as FA *should* be listed in the Study Personnel section.

For a list of responsibilities reflected by signing the Assurance Statement, refer to ["What does the Department Chairperson's Assurance Statement on the IRB application mean?"](#)

For a detailed illustration of how to complete this section, please review the short video tutorial "Signatures (Assurance) Section - How to Complete" in the [E-IRB Video Tutorial Library](#). 

Required Signatures:

First Name	Last Name	Role	Department	Date Signed	
Stephen	Duncan	Principal Investigator	Orthopaedic Surgery	11/19/2018 11:27 PM	View/Sign
Carolyn	Hettrich	Department Authorization	Orthopaedic Surgery	11/19/2018 02:49 PM	View/Sign

Principal Investigator's Assurance Statement

I understand the University of Kentucky's policies concerning research involving human subjects and I agree:

1. To comply with all IRB policies, decisions, conditions, and requirements;
2. To accept responsibility for the scientific and ethical conduct of this research study;
3. To obtain prior approval from the Institutional Review Board before amending or altering the research protocol or implementing changes in the approved consent/assent form;
4. To report to the IRB in accord with IRB/IBC policy, any adverse event(s) and/or unanticipated problem(s) involving risks to subjects;
5. To complete, on request by the IRB for Full and Expedited studies, the Continuation/Final Review Forms;
6. To notify the Office of Sponsored Projects Administration (OSPA) and/or the IRB (when applicable) of the development of any financial interest not already disclosed;
7. Each individual listed as study personnel in this application has received the mandatory human research protections education (e.g., CITI);
8. Each individual listed as study personnel in this application possesses the necessary experience for conducting research activities in the role described for this research study.
9. To recognize and accept additional regulatory responsibilities if serving as both a sponsor and investigator for FDA regulated research.

☒ Furthermore, by checking this box, I also attest that:

- I have appropriate facilities and resources for conducting the study;
- I am aware of and take full responsibility for the accuracy of all materials submitted to the IRB for review;
- If applying for an exemption, I also certify that the only involvement of human subjects in this research study will be in the categories specified in the Protocol Type: Exemption Categories section.
- If applying for an Abbreviated Application (AA) to rely on an external IRB, I understand that certain items above (1, 3, 4, 7-8) may not apply, or may be altered due to external institutional/IRB policies. I document my agreement with the [Principal Investigator Reliance Assurance Statement](#) by digitally signing this application.

***You will be able to "sign" your assurance after you have sent your application for signatures (use Submission section). Please notify the personnel required for signing your IRB application after sending for signatures. Once all signatures have been recorded, you will need to return to this section to submit your application to ORI.**

Department Authorization

☒ This is to certify that I have reviewed this research protocol and that I attest to the scientific validity and importance of this study; to the qualifications of the investigator(s) to conduct the project and their time available for the project; that facilities, equipment, and personnel are adequate to conduct the research; and that continued guidance will be provided as appropriate. When the principal investigator assumes a sponsor function, the investigator has been notified of the additional regulatory requirements of the sponsor and by signing the principal investigator Assurance Statement, confirms he/she can comply with them.

*If the Principal Investigator is also the Chairperson of the department, the Vice Chairperson or equivalent should complete the "Department Authorization".

**IF APPLICABLE FOR RELIANCE: I attest that the principal investigator has been notified of the regulatory requirements of both the Reviewing and Relying IRBs, according to the information provided in the E-IRB application. The attached Reliance Assurance Statement, signed by the principal investigator, confirms that he/she can comply with both sets of IRB requirements.

SUBMISSION INFORMATION**0 unresolved
comment(s)**

Each Section/Subsection in the menu on the left must have a checkmark beside it (except this Submission section) indicating the Section/Subsection has been completed. Otherwise your submission for IRB review and approval cannot be sent to the Office of Research Integrity/IRB.













If applicable, remember to update the Approval Letter Details text box under the Additional Information section

If your materials require review at a convened IRB meeting which you will be asked to attend, it will be scheduled on the next available agenda and you will receive a message to notify you of the date.

If you are making a change to an attachment, you need to delete the attachment, upload a highlighted version that contains the changes (use Document Type of "Highlighted Changes"), and a version that contains the changes without any highlights (use the appropriate Document Type for the item(s)). Do **not** delete approved attachments that are still in use.

Your protocol has been submitted.

[Download all](#)

	Document Type	File Loaded	Document Description	File Size	Modified By	Mod Date
	ApprovalLetter	ApprovalLetter.pdf		0.079	klars2	6/23/2023 8:24:58 AM
	AddInfoProduct	Memo Aquamantys.docx	Memo & Response to Comment	0.012	Fmsa224	5/16/2023 3:45:26 PM
	AdditionInfoConsiderations	Rutherford HSP citiCompletionReport.pdf	RutherfordHSP	0.150	cajaco2	7/29/2021 7:36:34 AM
	AdditionInfoConsiderations	JenniferWangHSP.pdf	Jennifer Wang HSP certificate	0.400	cajaco2	10/20/2020 2:20:56 PM
	StudyDevice	121918, Form P, Aquamantys - (Clean).pdf	121918 Form P, Aquamantys (Clean)	0.840	abfern0	1/14/2019 9:56:16 AM
	AddInfoProduct	Aquamantys 510k letter.pdf	Aquamantys 510K Letter	0.304	abfern0	11/15/2018 9:36:18 AM
	AdditionInfoConsiderations	AuthorizationAssuranceForm05292018.pdf	Department Authorization Letter	0.033	abfern0	11/15/2018 9:28:10 AM
	ResearchProcedures	Aquamantys Page 4 Study Flow Chart.pdf	Aquamantys Page 4 Study Flow Chart	0.012	abfern0	11/14/2018 12:05:08 PM
	DataCollection	VR12.pdf	THE VETERANS RAND 12-ITEM HEALTH SURVEY (VR-12)	0.249	abfern0	11/14/2018 11:22:12 AM
	DataCollection	Visual Analogue Scale.docx	Visual Analogue Scale	0.013	abfern0	11/14/2018 11:21:02 AM
	DataCollection	KOOS-JR-2015.pdf	KOOS, JR. KNEE SURVEY	0.145	abfern0	11/14/2018 11:20:03 AM
	DataCollection	Knee Function Questionnaire.docx	Knee Function Questionnaire	0.015	abfern0	11/14/2018 11:17:46 AM

Protocol Changes

Protocol Number: 47988

No Changes
There are no recorded changes tracked for this protocol.

Study Personnel Changes:

12337801		12651264	
Name	Mounce, Samuel	Name	Sabatini, Franco
Email	sdmo244@uky.edu	Email	Franco.Sabatini@uky.edu
Role 1	DP	Role 1	DP
Role 2	Data Collection	Role 2	Data Collection
Is Contact	Y	Is Contact	N
Room		Room	
Dept Code		Dept Code	
Dept Desc		Dept Desc	
SFI		SFI	N
Is PIRN		Is PIRN	

No comments