Official Title: Critical Illness Myopathy and Trajectory of Recovery in Acute Kidney Injury (AKI) Requiring Continuous Renal Replacement Therapy (CRRT): A Prospective Observational Trial

NCT05287204

Document Date: 1/7/2023

PROTOCOL TYPE (VERSION 4)

0 u
com

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.

This request is to add the University of New Mexico with approval from Reliance. We are also requesting to update the study dates, as the University of New Mexico just receiving funding support, and has requested that funding and study remain open until 9/30/2023. Thus, we have requested to extend dates on the IRB to 9/30/2023.

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

The Impact of RRT on the Development of Critical Illness Muscle Wasting

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.

RRT and CIM

Anticipated Ending Date of Research Project: 9/30/2023

Maximum number of human subjects (or records/specimens to be reviewed) 60

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:	Kirby	Room# & Bldg:	800 Rose St
Last Name:	Mayer	Speed Sort#:	40536
Middle Name	Phillip		
Department:	Physical Therapy - 7N640	Dept Code:	7N640
PI's Employee/Student ID#:	10168378	Rank:	Assistant Professor
PI's Telephone #:	(859) 218-0596	Degree:	DPT, PhD
PI's email address:	kpmaye2@uky.edu	PI's FAX Number:	
PI is R.N. ○ Yes ◉ No		HSP Trained:	Yes
		HSP Trained Date:	5/2/2022
		RCR Trained:	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.

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..) 18yrs to no max age

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

Population will include adult ICU patients.

Inclusion criteria are as follows: AKI requiring RRT, with RRT being initiated within 48 hours of ICU admission.

Exclusion criteria are as follows: RRT of any type prior to ICU admission, underlying muscle disorders/atrophy, including quadriplegia or hemiplegia, history of stroke with residual muscle deficits, liver cirrhosis, alcohol dependence, active malignancy within 1 year, burns, or other baseline neuromuscular disease, pregnant patients, or anticipated inability to engage in weight-bearing testing after discharge (e.g., traumatic/orthopedic surgery).

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:				
Asian:				
Black/African American:				
Latinx:				
Native Hawaiian/Pacific Islander:				
White:				
American Arab/Middle Eastern/North African:				
Indigenous People Around the World:				
More than One Race:				
Unknown or Not Reported:				

If unknown, please explain why:

Unknown at this time, as numbers will be determined by individuals that present with AKI requiring RRT in ICU setting and meet Inclusion/Exclusion criteria.

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)

- ☐ 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

ADDITIONAL INFORMATION:

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

Attach Type	File Name
ImpairedConsent	Form_T_1Dii_Completed (8-3-21).pdf

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 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

Attach Type	File Name
Informed Consent/HIPAA Combined Form	Iowa Consent Form (5-25-22).pdf
Informed Consent/HIPAA Combined Form	RRT-CIM Consent 5-25-22.pdf
Informed Consent/HIPAA Combined Form	HRP-507ta HRRC ID 21-438 Consent (ICU-AW RRT) v2 27Nov2022.pdf

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.

Consent will be obtained in a patient's room, or in a quiet ICU meeting room. If the LAR is not physically present, we would like to be able to coordinate with the nephrology service to ask for consent after consent to initiate CRRT has been obtained. If the person making this phone call is part of the research team, then consent for the study would be obtained on the call immediately following consent to initiate CRRT. If the person making the call is not part of the research team, then said person would obtain CRRT consent and then ask the LAR if they would be interested in a research opportunity. If the LAR indicates interest, then a member of the research team will shortly contact the patient/LAR to discuss.
Subjects should contact the PI and or study staff at the number provided within the informed consent form. In addition, if they have further complaints and need to speak to someone outside of the study team, 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.

e) If the research involves using or accessing identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

- Private information/specimens are “identifiable” if the investigator may ascertain the identity of the subject or if identifiers are associated with the information (e.g., medical records). This could be any of the 18 HIPAA identifiers including dates of service.
- If not using identifiable private information or identifiable biospecimens, insert N/A below.

Request for Waiver of Signatures

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	AC	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI
Botzet	Gregory	Sub-Investigator	DP	Y	Y		P	Y	01/12/2021	Y	N	05/31/2022	N
Fedder	Kelly	Data Collection	SP	Y	N	MS, RD, LD, CNSC	P	Y	05/19/2020	Y	N	10/26/2021	N
Flannery	Alexander	Co-Investigator	SP	Y	N	PharmD, PhD	P	Y	01/26/2022	Y	N	05/31/2022	N
Neyra Lozano	Javier	Co-Investigator	DP	N	Y	MD		N	01/06/2020	Y	N	05/25/2022	N
Ortiz Soriano	Victor	Project Assistance/Support	SP	Y	N	M.D.	P	Y	09/22/2020	Y	N	09/14/2021	N
Redmond	Lucas	Study Coordinator	DP	Y	Y	B.A.	P	Y	04/01/2021	Y	N	07/28/2021	N
Thompson Bastin	Melissa	Co-Investigator	DP	Y	N	PharmD, PhD	P	Y	03/06/2020	Y	Y	05/31/2022	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).

Acute skeletal muscle wasting is a common consequence of critical illness that occurs in up to 65% of patients admitted to the ICU. Critical illness myopathy (CIM), defined as a deficit in muscle size and strength that develops as a result of an ICU admission, is associated with high rates of short- and long-term morbidity and mortality, including decreased quality of life (QoL) due to persistent functional mobility impairments and inability to perform simple activities of daily living. Muscle dysfunction in the critically ill population is driven by underlying changes in cellular and molecular mechanisms leading to a net catabolic state. Rapid reductions in skeletal mass and strength lead to an increased risk of poor patient outcomes, including physical disability and mortality. The diagnosis of CIM in patients with acute respiratory failure or traumatic injury significantly increases the risk of in-hospital and long-term mortality. Recent data suggests that patients lose, on average, 19-27% of rectus femoris muscle size in the first ten days of critical illness. Little is known, however, about the significance of these changes in a subset of critically ill patients with acute kidney injury (AKI) requiring renal replacement therapy (RRT), also known as dialysis. The gold standard for assessing CIM is measurement by muscle biopsy or the analysis of psoas muscle area on a single cross-sectional CT imaging at the level of the L3 vertebra. Musculoskeletal ultrasound (MKUS), a non-invasive alternative, has gained significant traction over the last decade for assessing muscle in patients with critical illness. Studies have demonstrated that MKUS has excellent inter-rater reliability and high clinical utility, and have suggested that MKUS has strong construct validity. Recent data suggests that MKUS can be reliably performed at the ICU bedside, and our preliminary data suggests that graduate students in a healthcare-related field can reliably be trained to assess muscle mass in the ICU using MKUS in as little as 8 hours of training. Changes in rectus femoris size and quality (echo intensity) measured by MKUS were strongly correlated to muscle biopsies in patients with critical illness. In addition, MKUS measures have been shown to have clinical relevance. In a study of 102 surgical ICU patients, muscle wasting determined by MKUS was associated with increased rates of mortality and skilled nursing facility discharge. Acute kidney injury (AKI) is a commonly encountered condition that complicates 22.7% of all inpatient hospital admissions. More than half of all ICU admissions develop AKI, and 13.5% of all ICU patients will require renal replacement therapy (AKI-RRT) during their ICU stay. AKI is associated with poor short- and long-term prognosis. Even Stage 1 AKI is associated with a 10-fold increase in hospital mortality, and AKI-RRT has an in-hospital mortality rate >50%, making AKI-RRT one of the deadliest patient conditions encountered in U.S. hospitals. Even after discharge, patients with AKI continue to have worse outcomes. A meta-analysis of two million patients evaluating outcomes at least a year after admission showed that in-hospital AKI increased the risk of death. Despite how commonly AKI is observed and despite poor long-term outcomes, the rate of outpatient follow-up in this cohort is low. Therefore, patients with AKI area a high-risk, but underserved, group of patients that warrant further study and intervention. AKI of any stage is know to alter tissue utilization of amino acids. Studies have demonstrated that amino acid levels are reduced in AKI, and multiple, non-essential amino acids become conditionally essential. In addition, AKI leads to a state of increased amino acid oxidation, but reduced amino acid transport into muscle. Use of RRT may further exacerbate the issue by removing significant quantities of amino acids from the plasma. Amino acids are small and easily filtered during RRT, so daily losses of amino acids in effluent can be immense at up to 18 grams daily. While cross-sectional analyses demonstrate high clearance levels of amino acids during RRT, there are currently no published longitudinal data regarding amino acid levels. Because skeletal muscle is the major deposit of protein molecules, with nearly 60% of total body protein in humans, we hypothesize that patients with AKI-RRT are at even higher risk of CIM than critically ill controls without AKI.

Objectives

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

Aim 1: Determine the rate and degree muscle wasting in critically ill patients with AKI-RRT vs historic ICU controls without AKI during ICU stay. Hypothesis 1: Patients with AKI-RRT have faster decline in rectus femoris and tibialis anterior muscle size compared to controls .

Aim 2: Determine the trajectory of muscle recovery in patients following an episode of AKI-RRT compared to matched controls by measuring muscle mass, muscle strength and power, and functional status in patients at discharge and at 1 and 3 months thereafter. Hypothesis 2: Patients with AKI-RRT will have a slower trajectory of muscle recovery following ICU discharge compared to matched patients without AKI.

Aim 3: Use trend analysis to determine that changes in plasma amino acid levels on RRT correlate with lean muscle loss during AKI-RRT and predict lack of muscle recovery at 1 and 3 months. Hypothesis 3: Trends in amino acid levels during treatment with RRT will correlate with MKUS determinations of lean body mass in the short-term and will predict lack of muscle recovery at 1 and 3 months.

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 prospective, non-blinded, non-randomized study to assess the impact of CRRT on critical illness muscle wasting. As the study is observational and non-interventional in nature, there will be no placebo administered in the course of the study. Patients will be identified based on conversations with ICU and Nephrology consult teams (in addition to chart screening) to determine which patients are likely to receive RRT therapy due to AKI and critical illness. In the first aim, patients will undergo musculoskeletal ultrasound (MKUS) assessments within 24 hours of CRRT initiation, and again at 48 hours and 168 hours. In addition, blood will be drawn at these timepoints and stored for later analysis. In Aim 2, the trajectory of muscle mass recovery will be determined through visits at the time of hospital discharge (to be completed within the hospital), and then at 1 and 3 months thereafter, which will entail separate visits. At these sessions, patients with AKI-RRT and matched controls will undergo measurements of muscle mass, strength, and function at hospital discharge and at 1- and 3-months following discharge. Measurements will include MKUS to determine CSA and muscle echogenicity in the RF and TA muscles. We will evaluate muscle strength by measuring: 1) Medical Research Council sum score (MRC-ss), a measure of global peripheral muscle strength that is the current clinical standard for diagnosing ICU-AW34, 2) Maximal isometric knee extensor and dorsiflexion muscle strength measured as peak force production and rate of force development38, and 3) Maximal isometric grip strength 40. Muscle power will be measured by the repetitive 5x sit-to stand test a reliable and validate measure of lower-extremity power. Physical function and frailty will be measured using 1) the Short Performance Physical Battery (SPPB), 2) six-minute walk test (6MWT), and 3) Clinical Frailty Scale. SPPB is a performance-based composite test with a total of 12 points including components of balance, chair to stand test, and 4-meter habitual gait speed. The 6-MWT assesses the distance a subject can walk in six minutes providing a global marker of physical function and representation of cardiopulmonary endurance. We will summarize descriptive statistics at each timepoint including mean and standard deviation or median and interquartile range, as appropriate. Independent t-tests and Mann-Whitney U tests for non-parametric data will be used as appropriate to compare differences in the testing outcomes between cases and controls at each timepoint. Two-way repeated measures ANOVA will be performed to assess the within change in muscle metrics over time and between group comparisons to understand the trajectories of muscle recovery.

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

Patients will be recruited in Intensive Care Units. Methods of identification will include the use of any information available to the researchers/their colleagues because this person is a patient, or the use of any information considered to be PHI, or review of patient/clinic records. We will ask the Nephrology consult team to alert us when patients are going to start RRT, and we will obtain information (name and room number) that will allow us to locate and identify the patient for purposes of consent. We will only store information in REDCap secure data storage, and will not disclose identifiers to individuals who are not part of the research team, or not already part of the patient's research team. We plan to remove identifiers from the REDCap database upon completion of the project. If a patient (or LAR) is approached to participate and chooses not to, we will at that time remove any existing data from the database regarding that patient.

N/A

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.

What RRT subjects will be asked to do/what happens in the study (in sequential order):
- Blood and effluent will be collected at the start of CRRT, at 48 hours, and on day 7 or ICU discharge, whichever comes first. The blood draw for research is 5 mL per draw.
- At hospital discharge, the patient will undergo a series of muscle strength and function tests including 1)Medical Research Council sum score (MRC-ss), a measure of global peripheral muscle strength that is thecurrent clinical standard for diagnosing ICU-AW, 2) Maximal isometric knee extensor and dorsiflexion muscle strength measured as peak force production and rate of force development, and 3) Maximal isometric grip strength. Muscle power will be measured by the repetitive 5x sit-to stand test a reliable and validate measure of lower-extremity power. Physical function and frailty will be measured using 1) the Short Performance Physical Battery (SPPB), 2) six-minute walk test (6MWT), and 3) Clinical Frailty Scale. SPPBis a performance-based composite test with a total of 12 points including components of balance, chair to stand test, and 4-meter habitual gait speed.

The time period over which procedures will occur:
- Ultrasound will be completed at 2 time points: baseline (CRRT initiation) and 7 days after CRRT initiation OR ICU discharge (whichever comes first)
- Muscle strength/function will be assessed at hospital discharge, and at 1 and 3 months thereafter.

The time commitment for the subject for individual visits/procedures
- The time commitment will be 10-20 minutes for 2 ultrasound procedures as above, and the time needed to collect the research blood and effluent, which is likely to be <10 minutes daily for 7 days or until ICU discharge, whichever is first.
- Muscle strength/function assessment is anticipated to take 30-60 minutes.

Long-term follow-up and how it occurs
- Patients will be seen at 1 and 3 months follow-ups in the outpatient setting. Visit times and dates will be arranged prior to discharge if possible, or via telephone after discharge.

Variables collected from the chart will include the following:
- Demographic data (Age, Gender, Race, BMI)
- SOFA or APACHE score at initiation
- Comorbidities (Charlson Score)
- Cause of AKI (Sepsis, post-surgical, etc.)
- Location of ICU (medical vs surgical)
- Laboratory data at baseline (BMP, CBC, lactate, albumin, INR)
- Daily laboratory data
- % Volume overload at initiation and daily
- CRRT variables (BFR, dose, therapy fluid flow rate, UF, filtration fraction).
- Reason for filter loss
- Time to death (censored for patient drop out or loss to follow up)
- In-hospital Mortality
- Time to renal recovery (censored for interfering events)
- Renal Recovery at hospital discharge

What Control subjects will be asked to do/what happens in the study (in sequential order):
- At hospital discharge, the patient will undergo a series of muscle strength and function tests including 1)Medical Research Council sum score (MRC-ss), a measure of global peripheral muscle strength that is the current clinical standard for diagnosing ICU-AW, 2) Maximal isometric knee extensor and dorsiflexion muscle strength measured as peak force production and rate of force development, and 3) Maximal isometric grip strength. Muscle power will be measured by the repetitive 5x sit-to stand test a reliable and validate measure of lower-extremity power. Physical function and frailty will be measured using 1) the Short Performance Physical Battery (SPPB), 2) six-minute walk test (6MWT), and 3) Clinical Frailty Scale. SPPBis a performance-based composite test with a total of 12 points including components of balance, chair to stand test, and 4-meter habitual gait speed.

The time period over which procedures will occur:
- Muscle strength/function and MKUS will be assessed at hospital discharge, and at 1 and 3 months thereafter.

The time commitment for the subject for individual visits/procedures
- The time commitment will be 10-20 minutes for ultrasound procedures as above, and muscle strength/function assessment is anticipated to take 30-60 minutes.

Long-term follow-up and how it occurs
- Patients will be seen at 1 and 3 months follow-ups in the outpatient setting. Visit times and dates will be arranged prior to discharge if possible, or via telephone after discharge.

Variables collected from the chart will include the following:
- Demographic data (Age, Gender, Race, BMI)
- SOFA or APACHE score at ICU admission

Comorbidities (Charlson Score)
- Cause of respiratory failure (COPD, PNA, etc.)
- Location of ICU (medical vs surgical)
- Laboratory data at baseline (BMP, CBC, lactate, albumin, INR)
- Daily laboratory data

Patients lost to follow-up:
-We will attempt to contact patients prior to their appointment to remind them about the 1 and 3 month visits, and we will attempt telephone contact of patients lost to follow-up.

Attachments

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.

Screening-related questions include:
1) Are you (or the patient if LAR) receiving dialysis regularly?
2) Do you (or the patient if LAR) an underlying muscle disorder such as paralysis, neuromuscular disorder, or myopathy?
3) Have you (or the patient if LAR) been diagnosed with cirrhosis?
4) Have you (or the patient if LAR) been treated for a cancer of any kind within the past year?

What RRT subjects will be asked to do/what happens in the study (in sequential order)
- Blood and effluent will be collected at the start of CRRT, at 48 hours, and on day 7 or ICU discharge, whichever comes first. The blood draw for research is 5 mL per draw.
- At hospital discharge, the patient will undergo a series of muscle strength and function tests including 1)Medical Research Council sum score (MRC-ss), a measure of global peripheral muscle strength that is the current clinical standard for diagnosing ICU-AW, 2) Maximal isometric knee extensor and dorsiflexion muscle strength measured as peak force production and rate of force development, and 3) Maximal isometric grip strength. Muscle power will be measured by the repetitive 5x sit-to stand test a reliable and validate measure of lower-extremity power. Physical function and frailty will be measured using 1) the Short Performance Physical Battery (SPPB), 2) six-minute walk test (6MWT), and 3) Clinical Frailty Scale. SPPBis a performance-based composite test with a total of 12 points including components of balance, chair to stand test, and 4-meter habitual gait speed.

Variables collected from the patient's chart for case subjects will include:
- Demographic data (Age, Gender, Race, BMI)
- SOFA or APACHE score at initiation
- Comorbidities (Charlson Score)
- Cause of AKI (Sepsis, post-surgical, etc.)
- Location of ICU (medical vs surgical)
- Laboratory data at baseline (BMP, CBC, lactate, albumin, INR)
- Daily laboratory data
- % Volume overload at initiation and daily
- CRRT variables (BFR, dose, therapy fluid flow rate, UF, filtration fraction).
- Reason for filter loss
- Time to death (censored for patient drop out or loss to follow up)
- In-hospital Mortality
- Time to renal recovery (censored for interfering events)
- Renal Recovery at hospital discharge

What Control subjects will be asked to do/what happens in the study (in sequential order)

- At hospital discharge, the patient will undergo a series of muscle strength and function tests including 1)Medical Research Council sum score (MRC-ss), a measure of global peripheral muscle strength that is the current clinical standard for diagnosing ICU-AW, 2) Maximal isometric knee extensor and dorsiflexion muscle strength measured as peak force production and rate of force development, and 3) Maximal isometric grip strength. Muscle power will be measured by the repetitive 5x sit-to stand test a reliable and validate measure of lower-extremity power. Physical function and frailty will be measured using 1) the Short Performance Physical Battery (SPPB), 2) six-minute walk test (6MWT), and 3) Clinical Frailty Scale. SPPBis a performance-based composite test with a total of 12 points including components of balance, chair to stand test, and 4-meter habitual gait speed.

Variables collected from the patient's chart for control subjects will include:
- Demographic data (Age, Gender, Race, BMI)
- SOFA or APACHE score at ICU admission
- Comorbidities (Charlson Score)
- Cause of respiratory failure (COPD, PNA, etc.)
- Location of ICU (medical vs surgical)
- Laboratory data at baseline (BMP, CBC, lactate, albumin, INR)
- Daily laboratory data

Attachments

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.

The research procedures will be carried out at the University of Kentucky Medical Center, as well as at the University of Iowa and University of New Mexico. The participants will be followed at the University of Kentucky by Dr. Mayer and his research team which includes: physicians, certified nurses, and clinical research coordinator during the study period, while activities at Iowa will be supervised by Dr. Benjamin Griffin; activities at the University of New Mexico will be supervised by Dr. Joao P Teixeira.

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.

Risk of blood draw will be minimized by drawing from RRT circuit once RRT is initiated. Accessing the dialysis circuit or arterial line for obtaining the research blood samples may increase the risk of infection. However, we will try as much as possible to combine these draws with labs that will be drawn anyway as part of routine RRT care, so additional risk should be minimal. Because ultrasound is a non-invasive imaging modality, risks of ultrasound are minimal. The risks of injury during assessment of muscle strength and function is minimal. There is a risk of loss of confidentiality, which we will minimize by using REDCap for data storage, and by removing identifying data as soon as the project is completed and published.
There are no direct benefits to the patient. The findings will not be communicated to the primary team, and will not be used to inform the patient's care in any way. With regards to society and general knowledge, AKI-RRT is a procedure with a very high rate of mortality (>50%). Patients who develop muscle loss after AKI-RRT initiation are at even further risk of of morbidity and mortality. If AKI-RRT is shown to precipitate muscle loss due to amino acid removal, with slower rates of muscle recovery, this information can be used in future trials to study interventions such as the addition of amino acids to the dialysate/replacement fluid or early initiation of physical therapy/mobilization while on CRRT that would decrease sarcopenia development in this susceptible patient population, in order to

improve patient-centered outcomes.

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).

N/A

Back to Top

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

Research materials will include biologic samples, ultrasound imaging, paper/hard copy records, and electronic records. Biologic samples will be taken in the form of blood draws and effluent collection. These samples are necessary for the assessment of amino acid loss in patients with AKI-RRT. Ultrasound imaging is necessary for the assessment of muscle loss in patients in an ICU setting. Hard copy/electronic records are necessary for the screening and enrollment process.
Biologic samples - We will use a coding system rather than directly identifying information on the specimens. The code will be stored in REDCap. Samples will be stored in a secure lab space.

Paper/hard copy records - After signed consent is obtained, a copy will be made and given to the patient or LAR. The original consent documents will be given to the PI, and kept in a secure location that will be locked when not in use. Paper records, where applicable, will be stored at 800 Rose Street MN576 Lexington, KY. This room is locked at all times when unoccupied.

Electronic records - REDCap will be used for data storage. REDCap is a University-supported, server-based program designed to securely store data. It is password protected, and will be de-identified if downloaded.

This will be a multi-site study, but no materials, other than de-identified data, will be shared between sites. Furthermore, these sites will be added via a modification request once IRB approval has been obtained.
Risk of blood draw will be minimized by drawing from the CRRT circuit once CRRT is initiated or from a central line. Tests of muscle strength and function will be performed by appropriately trained research team members. There is a risk of loss of confidentiality, which we will minimize by using REDCap for data storage, and by removing identifying data as soon as the project is completed and published.

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

Back to Top

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.

N/A

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.

N/A

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.

N/A (Study is not expected to be greater than minimal risk)

Future Use and Sharing of Research Data

If the results of 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

All data are deidentified and will only be accessible by the study team. We will utilize redcap database for storage of data which is a secure, password protected data warehouse, and we will use shared folders using Mircorsoft OneDrive, which is protected and only accessible to individuals with access until the study team has disseminated findings. Data will be stored according to the IRB policy up to 6 years after study completion.

Blood and effluent collected by the study teach will coded with research ID and no patient identifiers will be used. The specimens will be stored in freezer inside the lab of the secure nephrology research lab which is only accessible to study team members that have a key.

As stated in the consent language subjects will have the options to agree for storage of data in the future, after this study is over without further consent. The samples, information, and/or data may be stored for later use in a central repository or other national repositories sponsored by the National Institutes of Health or other Federal agencies. If this happens, data and samples will be stripped of identifiers (such as name, date of birth, address, etc). Other qualified researchers who obtain proper permission may gain access to your sample and/or data for use in approved research studies that may or may not be related to in the purpose of this study.

The samples will not be used for whole genome sequencing.

Subjects also have the options and contact information to opt out of the data and sample storage at a later date.

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:
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 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

Attach Type	File Name
Waiver	Full HIPAA Waiver Approval Letter.pdf
Waiver	HIPAA FORM K - WAIVER OF AUTHORIZATION (9-20-21)_jan.pdf

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:

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

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:

Data and adverse events will be deidentfied and shared to primary investigator at University of Kentucky. Data will be shared through REDCap reporting of adverse events which will notify the study team at University of Kentucky. Dr. Mayer and study team will submit adverse events directly related to the study to IRB within 24 hours of being notified. Adverse events unrelated to the study will be recorded and reported at the continuation review.

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

	For additional requirements and information:
☐ Academic Degree/Required Research	• Cancer Research (MCC PRMC) • Certificate of Confidentiality (look up "Confidentiality/Privacy...") • CCTS (Center for Clinical and Translational Science)
☐ Alcohol/Drug/Substance Abuse Research	• Clinical Research (look up "What is the definition of....)
☐ Biological Specimen Bank Creation (for sharing)	• Clinical Trial
☐ Cancer Research	• Collection of Biological Specimens for Banking (look up "Specimen/Tissue Collection...")
☐ CCTS-Center for Clinical & Translational Science	• Collection of Biological Specimens (look up "Specimen/Tissue Collection...")
☐ Certificate of Confidentiality	• Community-Based Participatory Research (look up "Community-Engaged...")
☑ Clinical Research	• Data & Safety Monitoring Board (DSMB) *For Medical IRB: Service Request Form for CCTS DSMB
☐ Clinical Trial - Phase 1	
☑ Clinical Trial	
☑ Collection of Biological Specimens for internal banking and use (not sharing)	• Data & Safety Monitoring Plan
☐ Community-Based Participatory Research	• Deception* *For deception research, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"
☐ Deception	
☐ Educational/Student Records (e.g., GPA, test scores)	
☐ Emergency Use (Single Patient)	• Emergency Use (Single Patient) [attach Emergency Use Checklist] (PDF)
☐ Gene Transfer	• Genetic Research (look up "Specimen/Tissue Collection...")
☐ Genetic Research	• Gene Transfer
☐ GWAS (Genome-Wide Association Study) or NIH Genomic Data Sharing (GDS)	• HIV/AIDS Research (look up "Reportable Diseases/Conditions") • Screening for Reportable Diseases [E2.0000] (PDF)
☐ Human Cells, Tissues, and Cellular and Tissue Based Products	• International Research (look up "International & Non-English Speaking")
☐ Individual Expanded Access or Compassionate Use	• NIH Genomic Data Sharing (GDS) Policy (PDF)
☐ International Research	• 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"
☐ 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	• Use, storage and disposal of radioactive material and radiation producing devices
☐ Vaccine Trials	

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.

☐ 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:

Western States Consortium

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

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.):

N/A

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 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.**

The University of New Mexico is approved for study enrollment until September 30, 2023.

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	Teixeira CTSC Pilot Award Letter - signed (1).pdf
Other	IAA with UKentucky-PI J.Teixeira.pdf
Other	ICU-AW RRT consent update IRB modification approval.pdf
Other	ICU-AW RRT consent update IRB modification.pdf
Protocol	Protocol 7-19-21.doc

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)

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?"

Required Signatures:

First Name	Last Name	Role	Department	Date Signed	
Robert	English	Department Authorization	Physical Therapy	05/30/2022 05:39 PM	View/Sign
Kirby	Mayer	Principal Investigator	Physical Therapy	05/26/2022 06:00 PM	View/Sign

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.

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.

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	jlkear0	1/9/2023 7:47:20 AM
	Stamped Consent Form	Iowa Consent Form (5-25-22).pdf		0.376	jlkear0	1/9/2023 7:47:19 AM
	Stamped Consent Form	RRT-CIM Consent 5-25-22.pdf		0.471	jlkear0	1/9/2023 7:47:19 AM
	Stamped Consent Form	HRP-507ta HRRC ID 21-438 Consent (ICU-AW RRT) v2 27Nov2022.pdf		0.737	jlkear0	1/9/2023 7:47:19 AM
	Informed ConsentHIPAA Combined Form	HRP-507ta HRRC ID 21-438 Consent (ICU-AW RRT) v2 27Nov2022.pdf		0.737	kpmaye2	12/21/2022 10:29:09 AM
	AddInfoProduct	ICU-AW RRT consent update IRB modification.pdf	Proof of modification submission to update consent form at UNM - IRB	0.172	kpmaye2	12/21/2022 10:27:07 AM
	AddInfoProduct	ICU-AW RRT consent update IRB modification approval.pdf	Approval of updated consent from UNM	0.108	kpmaye2	12/21/2022 10:26:28 AM
	AddInfoProduct	IAA with UKentucky-PI J.Teixeira.pdf	IAA reliance agreement with UNM	0.264	kpmaye2	11/14/2022 12:01:00 PM
	AddInfoProduct	Teixeira CTSC Pilot Award Letter - signed (1).pdf	CTSA funding approval	0.215	kpmaye2	11/10/2022 1:05:06 PM
	Informed ConsentHIPAA Combined Form	RRT-CIM Consent 5-25-22.pdf	Informed Consent/HIPAA Combined Form_5-25-22	0.469	lare226	5/25/2022 12:08:38 PM
	Informed ConsentHIPAA Combined Form	Iowa Consent Form (5-25-22).pdf	Iowa Consent Form	0.374	lare226	5/25/2022 11:41:13 AM
	AdditionInfoConsiderations	Iowa Additional Information - Email Correspondence (5-3-22).docx	Iowa Additional Information Requested - Email Correspondence (5-3-22)	0.009	lare226	5/3/2022 2:01:10 PM
	AdditionInfoConsiderations	Iowa approval-memo_Partial HIPAA.docx	Iowa - Partial HIPAA Authorization	0.098	lare226	5/3/2022 1:57:59 PM
	AdditionInfoConsiderations	RRT-CIM Consent_29Nov2021 IowaHSOv2.docx	Iowa - Consent Form	0.082	lare226	5/3/2022 1:56:56 PM
	AdditionInfoConsiderations	UK Communication Plan Form UK reviewing - IowaHSO (1).pdf	Iowa - Communication Form	0.307	lare226	4/19/2022 7:40:21 AM
	AdditionInfoConsiderations	Relying Site Form when UK Reviews - Iowa HSO (1).pdf	Iowa - Relying Site From When UK Reviews	0.236	lare226	4/19/2022 7:39:57 AM
	AdditionInfoConsiderations	Iowa Local Context Master Form v.082020.FINAL.pdf	Iowa Local Context Master Form	0.342	lare226	4/19/2022 7:39:31 AM
	AdditionInfoConsiderations	SMART IRB LOA with Iowa.pdf	IRB RELIANCE Agreement	0.191	lare226	4/14/2022 3:57:39 PM
	Waiver	Full HIPAA Waiver Approval Letter.pdf	Waiver of Authorization Approval	0.118	scbe223	10/6/2021 10:37:27 AM
	Waiver	HIPAA FORM K - WAIVER OF AUTHORIZATION (9-20-21)_jan.pdf	HIPAA Waiver of Authorization_9-20-21	0.185	lare226	9/20/2021 2:39:38 PM
	AdditionInfoConsiderations	IRB Requested Revisions.pdf	IRB Requested Revisions	0.268	scbe223	9/2/2021 1:11:42 PM
	ImpairedConsent	Form_T_1Dii_Completed (8-3-21).pdf	Form T 1Dii_Completed_8-3-21	1.381	lare226	8/3/2021 12:25:08 PM
	AddInfoProtocol	Protocol 7-19-21.doc	Protocol_7-19-21	0.392	lare226	7/30/2021 7:32:27 AM

Protocol Changes

Protocol Number: 71153

IsAdditionalInformation changed by kpmaye2 on 11/10/2022 1:05:23 PM

~~N~~Y

ModificationJustification changed by kpmaye2 on 11/14/2022 11:59:14 AM

This request is to add the University of New Mexico with approval from Reliance. We are also requesting to update the study dates, as the University of New Mexico just receiving funding support, and has requested that funding and study remain open until 9/30/2023. ~~THe UNM site is approved by the sponsor for funding tor 10/1/2022 to 09/30/2023.~~ Thus, we have requested to extend dates on the ~~i~~IRB to 9/30/~~2023, instead May~~ 2023.

RelianceConsentForm changed by kpmaye2 on 11/10/2022 12:36:00 PM

N

Additional Information/Materials AdditionalInformation changed by kpmaye2 on 11/14/2022 12:01:09 PM

The University of New Mexico is approved for study enrollment ~~from October 1, 2022 to~~until September 30, 2023.

Additional Information/Materials AdditionalInformation changed by kpmaye2 on 11/10/2022 1:05:23 PM

The University of New Mexico is approved for study enrollment from October 1, 2022 to September 30, 2023.

Additional Information/Materials IsAdditionalInformation changed by kpmaye2 on 11/10/2022 1:05:23 PM

~~N~~Y

Additional Information/Materials OtherDocuments changed by kpmaye2 on 11/10/2022 1:05:23 PM

Y

Project Information ProjectEndDate changed by kpmaye2 on 11/10/2022 1:33:56 PM

9/~~1~~30/2023 12:00:00 AM

Project Information ProjectEndDate changed by kpmaye2 on 11/10/2022 1:26:05 PM

~~5/39/~~1/2023 12:00:00 AM

Project Information SubjectCount changed by kpmaye2 on 11/10/2022 1:26:43 PM

~~8~~60

Project Information SubjectCount changed by kpmaye2 on 11/10/2022 1:26:33 PM

~~6~~80

Research Description FutureUseAndSharing changed by kpmaye2 on 11/10/2022 1:51:46 PM

All data are deidentified and will only be accessible by the study team. We will utilize redcap database for storage of data which is a secure, password protected data warehouse. We will not share data with secondary researcher. , and we will use shared folders using Mircorsoft OneDrive, which is protected and only accessible to individuals with access until the study team has disseminated findings. Data will be stored according to the IRB policy up to 6 years after study completion. ¶

¶

Blood and effluent collected by the study teach will coded with research ID and no patient identifiers will be used. The specimens will be stored in freezer inside the lab of the secure nephrology research lab which is only accessible to study team members that have a key. We do not expect to have left-over samples for future research. We are only collecting enough samples f ¶

¶

As stated in the consent language subjects will have the options to agree for storage of data in the future, after this study is over without further consent. The samples, information, and/or data may be stored for later use in a central repository or other national repositories sponsored by the National Institutes of Health or othe planned analyses. Thus, there is no plan to use data or samples in future studiesr Federal agencies. If this happens, data and samples will be stripped of identifiers (such as name, date of birth, address, etc). Other qualified researchers who obtain proper permission may gain access to your sample and/or data for use in approved research studies that may or may not be related to in the purpose of this study. ¶

¶

The samples will not be used for whole genome sequencing. ¶

¶

Subjects also have the options and contact information to opt out of the data and sample storage at a later date.

Research Description FutureUseAndSharing changed by kpmaye2 on 11/10/2022 1:42:47 PM

All data are deidentified and will only be accessible by the study team. We will utilize redcap database for storage of data which is a secure, password protected data wearehouse. We will not share data with secondary researcher. Blood and effluent collected by the study teach will coded with research ID and no patient identifiers will be used. The specimens will be stored in freezer inside the lab of the secure nephrology research lab which is only accessible to study team members that have a key. We do not expect to have left-over samples for future research. We are only collecting enough samples for the planned analyses. Thus, there is no plan to use data or samples in future studies.

Research Description FutureUseAndSharing changed by kpmaye2 on 11/10/2022 12:57:44 PM

All data are deidentfied and will only be accessible by the study team. We will utilize redcap database for storage of data which is a secure, password protected data wearhouse. We will not share data with secondary researcher.

Research Description IsRecordPrivacyConfidential changed by kpmaye2 on 11/10/2022 12:57:44 PM

Y

Research Description Resources changed by kpmaye2 on 11/10/2022 1:54:07 PM

The research procedures will be carried out at the University of Kentucky Medical Center, as well as at the University of Iowa and University of New Mexico. The participants will be followed at the University of Kentucky by Dr. Mayer and his research team which includes: physicians, certified nurses, and clinical research coordinator during the study period, while activities at Iowa will be supervised by Dr. Benjamin Griffin; activities at the UNniversity of New Mexicoco will be supervised by Dr. Joao P Teixeira.

Research Description Resources changed by kpmaye2 on 11/10/2022 1:42:47 PM

The research procedures will be carried out at the University of Kentucky Medical Center, as well as at the University of Iowa. The participants will be followed at the University of Kentucky by Dr. ¶
Mayer and his research team which includes: physicians, certified nurses, and clinical research coordinator during the study period, while activities at Iowa will be supervised by Dr. Benjamin Griffin; activities at the UNiversity of New Mexioc will be supervised by Dr. Joao P Teixeira.

Research Description StudyPopulation changed by kpmaye2 on 11/10/2022 12:57:44 PM

Population will include adult ICU patients. ¶

¶
~~Inclusion criteria are as follows: AKI requiring RRT, with RRT being initiated within 48 hours of ICU admission.~~ ¶
¶
~~Exclusion criteria are as follows: RRT of any type prior to ICU admission, underlying muscle disorders/atrophy, including quadriplegia or hemiplegia, history of stroke with residual muscle deficits, liver cirrhosis, alcohol dependence, active malignancy within 1 year, burns, or other baseline neuromuscular disease, pregnant patients, or anticipated inability to engage in weight-bearing testing after discharge (e.g., traumatic/orthopedic surgery).~~

Research Sites MultiSiteDesc changed by kpmaye2 on 11/10/2022 1:56:53 PM

Data and adverse events will be deidentfied and shared to primary investigator at ~~UKY. Primary investigator will submit adverse events and deviations to IRB within 24 hours of being notified~~niversity of Kentucky. Data will be shared through REDCap reporting of adverse events which will notify the study team at University of Kentucky. Dr. Mayer and study team will submit adverse events directly related to the study to IRB within 24 hours of being notified. Adverse events unrelated to the study will be recorded and reported at the continuation review.

Research Sites MultiSiteDesc changed by kpmaye2 on 11/10/2022 1:00:06 PM

Data and adverse events will be deidentfied and shared to primary investigator at UKY. Primary investigator will submit adverse events and deviations to IRB within 24 hours of being notified.

Study Personnel Changes:

No Changes

There are no recorded changes to study personnel.

Protocol Type Comment by Jennifer Kearns - ORI to IRB/PI on 11/21/2022 11:21:45 AM

Please confirm that UNM accepts the language in the consent document.

Protocol Type Comment by Jennifer Kearns - ORI to IRB/PI on 11/21/2022 11:21:34 AM

The consent should state that UK will not pay for injuries. The consent template includes standard language.

Protocol Type Comment by Jennifer Kearns - ORI to IRB/PI on 11/21/2022 11:21:18 AM

Please remove the HIPAA authorization language, since UK does not serve as the Privacy Board for other institutions.