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

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The University of New Mexico Health Sciences Center

Consent and Authorization to Participate in a Research Study

Key Information for "The Impact of Renal Replacement Therapy (RRT) on the Development of Critical Illness Muscle Wasting" (HRRC ID 21-438)

You are being invited to take part in a research study about the impact of Continuous Renal Replacement Therapy (CRRT) on muscle wasting in ICU patients. We are asking you because you have been administered CRRT during your stay in the ICU. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE PURPOSE, PROCEDURES, AND DURATION OF THE STUDY?

By doing this study, we hope to learn if CRRT has an impact on muscle loss in patients admitted to the ICU, a common consequence of ICU admission. The study will consist of 3 parts: (1) ultrasound of a muscle in the leg (rectus femoris) to detect decrease in muscle size, (2) physical function assessments performed by physical therapists or other study members, and (3) collection of blood and CRRT effluent samples for analysis. CRRT effluent is the yellow fluid that is removed the body by CRRT that is similar to urine normally removed from the body by healthy kidneys. Your participation in this research will last about 3 months.

WHAT ARE THE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

By participating in this study, you will help provide important information that can add to the quality of care for ICU patients in the future. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE THE KEY REASONS YOU MIGHT NOT CHOOSE TO VOLUNTEER FOR THIS STUDY?

The study will involve collection of biologic samples, including small amounts of blood, and ultrasound imaging. While the risk of these procedures is minimal, you may experience some discomfort and risk of infection from the blood draw. For a complete description of risks, refer to the Detailed Consent and/or Appendix.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

The person in charge of this study is Dr. J. Pedro Teixeira of the University of New Mexico Health Sciences Center (UNM HSC), Department of Internal Medicine. If you have questions, suggestions, or concerns about this study or want to withdraw from the study, his contact information is 505-272-4751.

If you have any concerns or questions about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm Eastern Time, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

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DETAILED CONSENT
Version 2 27Nov2022

Project Title: **The Impact of Renal Replacement Therapy (RRT) on the Development of Critical Illness Muscle Wasting (HRRC ID 21-438)**

Principal Investigator: J. Pedro Teixeira, MD
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505-272-4751

If you are the legally authorized representative of a person who is being invited to be in this study, the word "you" in this document refers to the person you represent. You will be asked to read and sign this document to give permission for the person you represent to participate in this research study.

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you have severe acute kidney injury (AKI), and will soon be initiated on dialysis, also called renal replacement therapy (RRT) (Cases).

OR- we are inviting you to participate in this research study because you have illness requiring intubation and are at risk for muscle loss while immobile in the intensive care unit (ICU) (Controls).

The purpose of this research study is to determine the impact of RRT on the rate of muscle loss in the intensive care unit (ICU), and the impact of RRT on the trajectory of muscle recovery following hospital discharge. The loss of muscle mass in the ICU can increase the risk of death while in the hospital, can prolong the time of recovery, and can lead to the development of more health problems in the future following hospital discharge.

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HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 20 cases and controls will take part in this study conducted by investigators at the University of New Mexico. Approximately 40 others will be enrolled at the University of Iowa and University of Kentucky.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for the duration of your hospitalization and for visits at 1 month and 3 months following hospital discharge. The time involved in the study in the hospital will be the time spent completing 2 muscle ultrasounds (each approximately 10-20 minutes in length) and the time spent collecting blood (and effluent for CRRT) samples, which will take 5-10 minutes per day for up to 7 days. We will collect data from the electronic medical record regarding outcomes like the number of days spend in the hospital. At the time of hospital discharge, you would undergo a series of muscle strength tests and muscle ultrasound, that are anticipated to take 30- 60 minutes. These procedures will be repeated at your 1- and 3-month visits to determine the trend in muscle recovery.

WHAT WILL HAPPEN DURING THIS STUDY?

For the case population: Before you initiate RRT, or within 24 hours after initiation, you will undergo an ultrasound (US) to determine your muscle mass. The US will be repeated at 48 hours and again at 7 days or at ICU discharge, whichever comes first. The ultrasound will evaluate the size of your rectus femoris muscle, one of the muscles in your thigh. The ultrasound will take approximately 10-15 minutes to complete, and there should be no discomfort outside mild coolness from the ultrasound gel.

The first blood draw will take place before RRT initiation**.** After RRT is started, we will draw blood from the RRT machine daily while you are on CRRT. These blood draws can be taken directly from the RRT machine or from a central line, and so will not require additional needle sticks. The amount of blood taken at each time point is 5 mL (about 1 teaspoon). We will also collect effluent daily after RRT is initiated. Effluent is the waste fluid generated by the CRRT machine (akin to urine).

At the time of hospital discharge, you will undergo an ultrasound (US) to determine your muscle mass, and a series of muscle strength tests to determine the strength and functionality of your muscles. The ultrasound will take approximately 10-15 minutes to complete, and there should be no discomfort outside mild coolness from the ultrasound gel. The muscle strength testing will take 30-60 minutes, and there should be no discomfort other than discomfort from the use of your muscles. These tests will be repeated at visits scheduled to take place at 1 month and 3 months following hospital discharge.

For the control population: At the time of hospital discharge, you will undergo an ultrasound (US) to determine your muscle mass, and a series of muscle strength tests to determine the strength and functionality of your muscles. The ultrasound will take approximately 10-15 minutes to complete, and there should be no discomfort outside mild coolness from the ultrasound gel. The muscle strength testing will take 30-60 minutes, and there should be no discomfort other than discomfort from the use of your muscles. These tests will be repeated at visits scheduled to take place at 1 month and 3 months following hospital discharge.

For both groups, we would access your medical record to collect basic information about your case, such as why you developed acute kidney injury (cases), your vital signs, use of certain medications, and

laboratory data. We will not collect information like your social security number or any other information not directly related to this project.

Tissue/Blood/Data Storage for Future Use

As part of this study, we are obtaining blood (and effluent in RRT patients) samples and data from you. We may like to study your blood (and effluent in RRT patients) and data in the future, after this study is over without further consent. Your sample, 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, it may 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.

The tests we might want to use to study your blood or effluent and data may not even exist at this time. Therefore, we are asking for your permission to store your blood and effluent and data so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding critical illness muscle loss, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your blood and effluent and data might be used to develop products tests, or discoveries that could be patented and licensed. In some instances, these may have potential commercial value and may be developed by the Investigators, University of Nex Mexico, commercial companies, organizations funding this research, or others that may not be working directly with this research team. However, donors of blood and effluent and data do not retain any property rights to the materials. Therefore, there are no plans to provide financial compensation to you should this occur.

Your blood samples and data will be stored with a code which may be linked to your medical record number. If you agree now to future use of your blood samples and data but decide in the future that you would like to have it removed from future research, you should contact Dr. J. Pedro Teixeira. However, if some research with your blood samples and data has already been completed, the information from that research may still be used.

Do you give permission for your identifiable samples (blood, effluent) to be stored, used, and shared for future research?

☐ Yes ☐ No Initials _____

Remember, you can still be in the main study even if you even if you do not wish to allow your information and/or specimens stored or shared for future research.

WILL I BE NOTIFIED IF THERE IS AN UNEXPECTED FINDING IN MY BLOOD (OR EFFLUENT, IN CRRT PATIENTS)?

The results from the blood and effluent and data we collect in this research study are not the same quality as what you would receive as part of your routine health care. The blood and effluent and data results will not be reviewed by a physician who normally reads such results. Due to this, you will not be informed of any unexpected findings. The results of your blood and effluent and data will not be placed in your medical record with your primary care physician or otherwise. If you believe you are having symptoms that may require care, you should contact your primary care physician.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Blood collection:
For RRT patients:
When RRT is initiated, there will be labs drawn as part of the usual care provided to patients undergoing this procedure. We will draw our first set of labs at the same time, so there shouldn't be any additional venipuncture as part of this study. Subsequent labs after CRRT initiation will be taken directly from the machine circuit or arterial line. The total amount of blood that we take is 5 mL (or about 1 teaspoon) per day. This amount of blood is small and safe. It will not increase your need for a blood transfusion. 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 CRRT care, so additional risk should be minimal. Risks related to the muscle strength testing could include muscle injury, although these risks are low, and these tests are generally considered minimal risk within the medical community.

For Controls:
Risks related to the muscle strength testing could include muscle injury, although these risks are low, and these tests are generally considered minimal risk within the medical community.

Effluent collection (for RRT patients):
There should be no discomforts or risks associated with collection of effluent. The effluent will be collected directly from the dialysis circuit.

Ultrasound
Ultrasound is a non-invasive imaging procedure. There may be some mild discomfort related to the application of gel or pressure from the probe, but all discomforts are expected to be minimal. There are no known long-term health risks associated with ultrasound.

Confidentiality:
There is potential risk of loss of confidentiality. Efforts will be made to keep your personal information private and confidential. You will be identified by a code, and personal information from you records will not be released without your written permission. Data will be stored on a secure database (REDCap) supported by the University of Kentucky.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study. The study is designed for the researcher to learn more about the effect of kidney injury on the muscles in patients after CRRT initiation. However, we hope that, in the future, other people might benefit from this study from the knowledge gained.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs related to being in this research study. You and/or your medical/hospital insurance carrier will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?

This study will be funded by a grant from the Western States Consortium, composed of six institutions with Clinical and Translational Sciences Award (CTSA) Program institutions. This means that the University of New Mexico is receiving payments to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary for conducting this study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Dr. J. Pedro Teixeira at 505-272-4751 immediately. Dr. Teixeira will determine what type of treatment, if any, is best for you at that time. It is important for you to understand that the University of New Mexico does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of New Mexico will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm will be your responsibility; or

- may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances); or
- may be paid by Medicare or Medicaid if you are covered by Medicare or Medicaid (If you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.).

A co-payment/deductible may be needed by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be costly. You do not give up your legal rights by signing this form.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law, and all signed consent forms will be retained and securely stored at the University of New Mexico. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Federal government regulatory agencies,
- Auditing departments of the University of New Mexico or the University of Kentucky
- The Institutional Review Board (IRB, a committee that reviews and approves research studies) at the University of Kentucky or the Institutional Review Board at the University of New Mexico

To help protect your confidentiality, you will be identified by a code known only to the research team. Data will be stored on a secure database supported by the University of Kentucky. Paper copies of this consent will be stored in a locked drawer in a secured office on the UNM HSC campus. Badge access is needed to enter the building after hours and only the study principal investigator (Dr. Teixeira) has access to the key to the locked drawer. Biospecimens will be stored in a secure lab requiring a UNM

HSC badge for entry. The biospecimens will be stored with a code, so samples cannot be linked to you without the master list secured on the University of New Mexico database site (secured access folder on HSC central IT managed network storage). Electronic data will be stored within REDCap, which is a secure data storage platform operated by the University of Kentucky. If data is transferred for statistical analysis, names and other identifying information will be removed beforehand.

If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

The University of New Mexico Hospital generally requires that we document your participation in research occurring in a UNM HSC facility. This documentation will be in either your medical record or a database maintained on behalf of the institution reflecting that you are participating in this study. The information included will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

CAN SOMEONE ELSE END MY PARTICIPATION IN THIS STUDY?

Under certain circumstances, the researchers might decide to end your participation in this research study earlier than planned. This might happen because in our judgment it would not be safe for you to continue, because your condition has become worse.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: J. Pedro Teixeira, MD at 505-272-4751.

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Office of Research Integrity, 405 Kinkead Hall, University of Kentucky, Lexington, KY 40506 (859) 257-9428, email: rs_ORI@uky.edu General information about being a research subject can be found by clicking "Participants" on the Office of Research Integrity web site, https://www.research.uky.edu/office-research-integrity. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Office of Research Integrity at the number above.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

The privacy law, HIPAA (Health Insurance Portability and Accountability Act), requires researchers to protect your health information. The following sections of the form describe how researchers may use your health information.

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

- **Physical exams, blood tests, and other diagnostic and medical procedures, as well as medical history.**
- **Demographic information, including: name, age, height/weight, address/telephone number, and medical record number (MRN)**

The Researchers may use and share your health information with:

- **The Institutional Review Boards at the University of Kentucky or the University of New Mexico;**
- **Law enforcement agencies when required by law;**
- **University of New Mexico representatives;**
- **UNM HSC and their representatives**
- **Health systems outside of UNM for which you have a patient relationship;**
- **Federal regulatory agencies [i.e., the Food and Drug Administration (FDA), National Institutes of Health (NIH)]**
- **Clinical & Translational Science Center (CTSC)**

The researchers agree to only share your health information with the people listed in this document. Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information may still be regulated by applicable federal and state laws.

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

- **Current or future healthcare at the University of New Mexico;**
- **Current or future payments to the University of New Mexico;**
- **Ability to enroll in any health plans (if applicable); or**
- **Eligibility for benefits (if applicable).**

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

- **Send a written letter to: Dr. J. Pedro Teixeira (MSC10-5550, 1 University of New Mexico, Albuquerque, NM 87131-0001) to inform him of your decision.**
- **Researchers may use and release your health information already collected for this research study.**
- **Your protected health information may still be used and released should you have a bad reaction (adverse event).**

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

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the UNM HSC Privacy Officer between the business hours of 8am and 5pm MT, Monday-Friday at (505) 272-1493.

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INFORMED CONSENT SIGNATURE PAGE (HRRC ID 21-438)

You are participating or are authorized to act on behalf of the participant. This consent includes the following:

- Key Information Page
- Detailed Consent

You will receive a copy of this consent form after it has been signed.

_____ _____

Signature of research subject, *or if applicable, *research subject's legal representative* **Date**

_____

Printed name of research subject

_____

**If applicable, printed name of research subject's legal representative*

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

_____ _____

Printed name of [authorized] person obtaining informed consent/HIPAA Authorization Date

_____

Signature of [authorized] person obtaining informed consent/HIPAA Authorization

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