Document Coversheet

Study Title: Effects of Unloading and Sleep Restriction on Balance Regulation and Quadriceps Structure and Contractile Function

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	11/14/2025
NCT Number:	NCT05956964
IRB Number	84290
Coversheet created:	3/20/2026

IRB Approval
11/14/2025
IRB # 84290
IRB1

IMPORTANT NOTE:

If you accidentally select the wrong IRB type or "Protocol Process Type" while your Initial Review (IR) application is in draft form (unsubmitted), you may change your selections. Please contact the Office of Research Integrity (ORI) at 859-257-9428, IRBsubmission@uky.edu, or request a consult to resolve any questions regarding your selections *prior* to submitting your Initial Review application.

If your **submitted IR application has been returned to you for requested revisions or additional information,** to streamline the review process **do not make changes** to your selections here **unless instructed to do so by the ORI/IRB.**

Changes to this section cannot be made after initial approval has been issued (the option is not available for MR or CR).

For guidance, see:

- Which IRB should review my research?
- Which Protocol Process Type?
- "Getting Started"

Which IRB

- (•) Medical ( ) NonMedical

Protocol Process Type

- ( ) Exemption
- (•) Expedited (Must be risk level 1)
- ( ) Full

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.

Add Ethan Lengyel to the research team. This UG student will complete data analysis regarding motor unit recruitment during balance. He has already completes HSP and RCR online training

84290

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

Effects of unloading and sleep restriction on balance regulation and quadriceps structure and contractile function

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.

NM balance regulation with ULLS and loss of sleep

Anticipated Ending Date of Research Project: 12/31/2026

Maximum number of human subjects (or records/specimens to be reviewed) 32

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

Are you requesting that the UK IRB serve as the lead IRB for a multi-site study, **OR** that the UK IRB defer review to another IRB? [Click here for "IRB Reliance" help]

○ Yes ◉ No

If "Yes," before completing your IRB application, fill out the Reliance Request Form and submit it to irbreliance@uky.edu.

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:	Lance	Room# & Bldg:	100 Seaton Center
Last Name:	Bollinger	Speed Sort#:	405060017
Middle Name	M		
Department:	Kinesiology - Health Promotio…	Dept Code:	8G040
PI's Employee/Student ID#:	12006667	Rank:	Associate Professor
PI's Telephone #:	8592577904	Degree:	PhD
PI's e-mail address:	lance.bollinger@uky.edu	PI's FAX Number:	
PI is R.N.	○ Yes ◉ No	HSP Trained:	Yes
		HSP Trained Date:	10/25/2023
		RCR Trained:	Yes

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

○ Yes ◉ No

RISK LEVEL

0 unresolved comment(s)

Indicate which of the categories listed below accurately describes this protocol

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

*"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examination or tests.

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

Refer to UK's guidance document on assessing the research risk for additional information.

SUBJECT DEMOGRAPHICS **0 unresolved comment(s)**

Age level of human subjects: (i.e., 6 mths.; 2yrs., etc..) 18 to 50

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 this FDA Guidance on Enrollment of Participants from Underrepresented Populations in Clinical Studies

This study aims to determine how two physiological stimuli commonly experienced by astronauts during space flight (namely unloading and sleep restriction) interact to affect balance regulation and skeletal muscle size, structure, and function. This project is funded by NASA Kentucky through a Research Initiation Award and results are intended to directly inform the scientific community of health risks faced by astronauts. Therefore, we will enroll subjects who fit the general descriptive characteristics of NASA astronauts with regard to age, education, sex, race, physical fitness, and body composition. All subjects will be presumably healthy individuals (age 35-50) with at least a bachelor's degree who are physically active, meet specific physical fitness and body composition criteria, and who have normal sleep patterns. To best mimic anthropometrics of astronauts (which are limited by spacecraft and suit dimensions), subjects must meet specific parameters which are based on previous data from NASA astronauts (https://msis.jsc.nasa.gov/sections/section03.htm#_3.3_ANTHROPOMETRIC_AND).

Since subjects will need to visit the research laboratory three times over two weeks, we expect to recruit subjects from the greater Lexington, KY area. Therefore, demographics of our study population are expected to approximately agree with the population demographics of this region. Due to NASA's considerable efforts to intentionally diversify crew member demographics, we will attempt to recruit those from minority racial groups. Matched pair randomization of this study will attempt to randomize subjects based on biological sex, race, and (when possible) muscle strength. Thus, we plan to recruit at least two subjects from each of the most prevalent racial groups of the region for each sex. TGNB/TGE subjects will not be excluded from participation per se. However, based on estimates of 0.39% of KY adults identifying as transgender (worldpopulationreview.com), it is unlikely that anyone who identifies as TGNB/TGE will enroll in this relatively small study. Importantly, due to the apparent effects of gender-affirming interventions such as hormone therapy on primary research outcomes such as muscle mass and strength (Wiik et al. J Clin Endocrinol Metabol. 2020), those who are undergoing (or have previously undergone) gender-affirming hormone therapy or sexual reassignment surgery will be excluded from participation. In the event that someone who identifies as TGNB/TGE enrolls in our study, they would be randomized for treatment according to biological sex.

Specific Inclusion Criteria Include:
Age between 18 and 50 years
Regularly engaging in aerobic exercise (> 150min/wk) and resistance exercise (>1 time per week) for the past 12 months
Education greater than or equal to bachelor's degree (any field)
Regularly sleep at least 7 hours per night

Specific Exclusion Criteria include:
Age < 18 or > 50 years
Height between <150 (F) or <170 (M) and > 190 cm (both sexes)
Waist circumference < 55cm or > 90cm (F) and < 75cm or > 100cm (M)
Body mass index < 18.5 or > 29.9
Do not regularly sleep between 7 and 9 hours each night
Have a known sleep disorder
Not regularly engaging in exercise for previous 12 months
Blood clotting disorder
Heart arrhythmia
Implanted device which could negatively be affected by electrical impulse or strong magnetic field such as pacemaker, internal defibrillator, or cochlear implant
Diagnosed cardiovascular, pulmonary, renal, or metabolic disease
Pregnancy (within previous 6 months)
Oral contraceptive use (within previous three months)
High resting blood pressure (>140 systolic and/or > 90 diastolic)
Currently or previously undergone gender-affirming therapy (hormone therapy or sexual reassignment surgery)
Low back or leg injury in previous 6 months
Currently taking medication to assist with sleep
Muscle, bone, or joint injury that limits physical activity within previous 6 months
Neurological disorder which affects balance (such as multiple sclerosis or Parkinson's disease)

Attachments

Indicate the targeted/planned enrollment of the following members of minority groups and their subpopulations. Possible demographic sources: Kentucky State Census, 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:	0	0	0	0
Asian:	2	2	0	0
Black/African American:	2	2	0	0
Latinx:	2	2	0	0
Native Hawaiian/Pacific Islander:	0	0	0	0
White:	8	8	0	0
American Arab/Middle Eastern/North African:	0	0	0	0
Indigenous People Around the World:	0	0	0	0
More than One Race:	2	2	0	0
Unknown or Not Reported:	0	0	0	0

If unknown, please explain why:

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

INFORMED CONSENT/ASSENT PROCESS/WAIVER

0 unresolved comment(s)

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

Additional Resources:

- Informed Consent/Assent Website
- Waiver of Consent vs. Waiver of Signatures
- Sample Repository/Registry/Bank Consent Template

Consent/Assent Tips:

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

How to Get the Section Check Mark

1. You must:

   a) provide a response in the text box below describing how investigators will obtain consent/assent, and
   b) check the box for at least one of the consent items and/or check mark one of the waivers

2. If applicable attach each corresponding document(s) **as a read-only PDF**.
3. If you no longer need a consent document approved (e.g., closed to enrollment), or, the consent document submitted does not need a stamp for enrolling subjects (e.g., umbrella study, or sub-study), only select "Stamped Consent Doc(s) Not Needed".
4. After making your selection(s) be sure to scroll to the bottom of this section and SAVE your work!

Check All That Apply

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

Attachments

Informed Consent Process:

Using active voice, in the text box below, 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

Will electronic consent form/process be utilized on-site or remotely for this study?

○ Yes ◉ No

If yes, in addition to addressing the above bullet points, describe the e-consent method and platform, including any hyperlinks, videos, or enhancements used to convey information, if applicable. Attach a representation of the e-consent with signature fields. For guidance, see the ORI E-Consent web page.

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.

The research team will recruit subjects via flyers, word-of-mouth, and online databases (researchmatch). Upon identifying potential subjects, the research team will verbally explain the procedures to subjects and set up an initial appointment for enrollment into the study. For email communication, the research team will provide a brief overview of the study (including inclusion and exclusion criteria) and attach a copy of the approved consent document for subjects to review and solicit a time to complete study enrollment. At the study enrollment visit, the research team will supply two hard copies of the consent document and verbally explain the document to subjects in easy-to-understand language. A member of the research team will record and answer any questions subjects might have at this time. After any questions have been answered, participants will voluntarily sign (or opt not to sign) two copies of the informed consent document. A member of the research team will also sign both copies of the consent document. After signatures have been collected, the research team will provide one copy of the signed consent form to subjects and keep the other in a secure location. Following informed consent, the research team will administer screening questionnaires and proceed with subject enrollment (or exclusion) as appropriate. No research related assessments will be performed without a copy of the informed consent form received by a study
representative. Participant screening will occur after completion of informed consent.

Subjects will be informed of appropriate channels for voicing complaints or requesting information regarding this research project. Specifically, subjects will be provided with email and telephone contact information for research personnel, including the principal investigator (PI). Subjects may schedule a meeting with research personnel or the PI if necessary. For face to face meetings, subjects will be provided a guest parking pass to accommodate travel difficulties. Any complaints raised will be documented in hard copy and signed by both the subject and the individual receiving the complaint. If health or safety concerns arise for a specific subject, the PI (Bollinger) will communicate with the medical supervisor (Dr. Nithyanandam) to develop an appropriate plan of action and report the incident to the IRB. If necessary (i.e. safety concerns, health complications, etc.), testing of additional subjects will be suspended until the issue is adequately addressed.

☐ 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 Home 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	Active
Buckler	Regan	Data Collection	SP	N	N	RN	P	Y	04/16/2024	Y	N	03/09/2023	N	Y
Forenback	Denece	Project Assistance/Support	SP	N	N	RN	P	Y	12/07/2023	Y	N	03/09/2023	N	Y
Hughes	Jordan	Data Collection	SP	Y	N	MS	P	Y	08/12/2024	Y	N	08/30/2024	N	Y
Lengyel	Ethan	Data Analysis/Processing	SP	N	N		P	Y	10/19/2025	Y	N	10/20/2025	N	Y
Martin	Claire	Data Collection	SP	N	N		P	Y	11/25/2024	Y	N	01/14/2025	N	Y
McArdle	Jack	Data Collection	SP	N	N		P	Y	01/01/2024	Y	N	01/11/2024	N	Y
Nieto	Alayne	Project Assistance/Support	SP	N	N	RN	P	Y	04/18/2025	Y	N	03/09/2023	N	Y
Nithyanandam	Srikanth	Medical Supervisor	SP	N	N	MD	P	Y	08/28/2024	Y	N	11/29/2022	N	Y
Scrogham	Samantha	Data Analysis/Processing	SP	N	N		P	Y	02/07/2025	Y	N	02/16/2025	N	Y
Sigrist	Scott	Data Collection	SP	Y	N	BS	P	Y	02/24/2025	Y	N	11/28/2022	N	Y
Uchiumi	Masafumi	Data Collection	SP	N	N	MS	P	Y	08/15/2023	Y	N	08/28/2023	N	Y
Best	Stuart	Co-Investigator	DP	Y	N	PhD		Y	01/13/2023	Y	Y	08/27/2025	N	N
Butterfield	Timothy	Co-Investigator	SP	N	N	PhD	P	N	04/22/2020	Y	Y	10/25/2023	N	Y
Caruso	John	Co-Investigator	SP	N	N	PhD	N				Y	01/17/2023	N	Y
Elmore	Eve	Data Collection	SP	Y	N	BS		N	06/25/2022	Y	Y	09/08/2025	N	N
Gamble	Bethanie	Project Assistance/Support	SP	N	N	RN		N	10/03/2022	Y	Y	11/14/2025	N	N
Hardy	Peter	Data Collection	SP	N	N	PhD	P	N	07/05/2022	Y	Y	09/08/2025	N	Y
Manuel	Garrett	Data Collection	SP	N	N	BS		Y	01/23/2023	Y	Y	08/27/2025	N	N
Navarrete	Nicole	Data Collection	SP	N	N		S	N	08/10/2022	Y	Y	09/08/2025	N	Y
Watts	Linda	Project Assistance/Support	SP	N	N	RN		N	11/10/2021	Y	Y	09/08/2025	N	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).

The Artemis program aims to return astronauts to the lunar surface in 2024. During the Apollo missions (1969-1972), astronauts suffered at least 9 falls in 14 lunar extravehicular activities which may be partially due to altered muscle strength and postural control. During spaceflight, astronauts experience a complex array of physiological stimuli including unweighting and altered sleep cycles that may interact to impair muscle strength and postural control – ultimately compromising safety, health, and mission performance. Quadriceps strength decreases by 15% with as little at seven days unloading. Additionally, short-term sleep restriction (~3 days) significantly reduces muscular strength, alters neuromuscular patterns, and impairs postural control. To date, it is unclear how these stimuli interact to affect muscle strength and balance regulation.

Unilateral Lower Limb Suspension (ULLS) is the gold-standard ground-based analog to mimic effects of microgravity on the musculoskeletal system. In this model, subjects ambulate on one leg with a modified shoe and crutches. Thus, one leg serves as a model of muscle unloading and the contralateral limb serves as an internal control. Ongoing research from our lab indicates that reducing sleep from 8 to 5 hours per night for three consecutive nights reduces isometric quadriceps strength by 8%. To understand how unloading and sleep restriction interact to affect muscle function and balance regulation, we will implement a ULLS study design (13 days total) with the final 3 days consisting of regular or restricted sleep. Sleep interventions will follow protocols from our lab which are approved by the non-medical IRB.

Objectives

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

This study aims to determine how quadriceps unloading and sleep restriction interact to affect: Muscle size, muscle architecture, muscle strength, muscle twitch properties, voluntary recruitment of muscle, and ability to maintain balance.

Muscle size and architecture will be assessed by diffusion tensor imaging (DTI) - a novel MR-based imaging technique that allows for quantification of physiological cross sectional area and muscle diffusion properties
Muscle strength, twitch properties, and voluntary recruitment will be assessed using an interpolated twitch experiment on an isokinetic dynamometer.
balance will be assessed using force plates in static stance and when stepping down from a platform

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 project will employ a matched pairs study design. Subjects will complete bilateral quadriceps knee extension muscle testing (interpolated twitch) and balance assessment at baseline. Subjects will then undergo 10 days of ULLS. During this time, subjects will walk with a specialized shoes on the right foot (modified to include a ~5 cm lift) and crutches while attempting to minimize use of muscles in this leg. After 10 days, subjects will be randomized to either sleep adequate (9 hours per night) or sleep restriction (5 hours

per night). Subjects will continue to follow the ULLS protocol throughout the 3 days of sleep intervention. Muscle imaging, bilateral knee extension muscle testing, and balance assessment will be completed at the end of the study. The total study duration will, thus, be 13 days. A graphical depiction of the study design is attached.

Attachments

Attach Type	File Name
StudyDesign	Study design with outcomes.pdf

Subject Recruitment Methods & Advertising

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

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

For additional information on recruiting and advertising:

- IRB Application Instructions - Advertisements
- PI Guide to Identification and Recruitment of Human Subjects for Research

Participants will be recruited from the University of Kentucky campus and surrounding area as outlined below. The Center for Clinical and Translational Sciences (CCTS) will assist with recruiting subjects for this project.

Print advertisements: The study may recruit subjects through flyers, brochures, posters, cards for clinic rooms, Research Spotlights, bookmarks placed on campus and in the surrounding community and region, including but not limited to the UK Medical Center, UK Clinics, Good Samaritan Hospital, student center, UHS, the UK Center for Clinical and Translational Research wall mounts, Cardinal Hill, monitor screens, and area facilities and businesses. Print advertisements: The study will recruit subjects through flyers placed on campus and in the surrounding community and region (Study Team will place/remove ads) and research spotlights on digital boards within the College of Education (the PI's home department). See attached flyer.

Internet and Social Media: This study will be advertised on recruitment internet webpages in digital or video form (e.g., UKclinicalresearch.com, ResearchMatch.org, CenterWatch.com, CISCRP, UK, CCTS and may utilize Google Adwords). The study will be promoted via social media, including Facebook boost ads, UK_CCTS Facebook, UK_CCTS Twitter, UK_CCTS Instagram, UK and UKHC social media, and departmental/lab pages. If advertised on UKClinicalresearch.com, the online study flyer will include an option for interested individuals to enter and submit their contact information, they will be asked whether study team can contact them (Yes or No) via study-related text messages, and CCTS will also ask, 'How did you learn about the study? Internet and social media recruitment will follow the terms of use for each site utilized. The study will also be promoted through UK HC monitor screens. Research Participant Registries: Potential participants may be identified from registry databases, including but not limited to ResearchMatch.org*, Wellness Health and You, Sanders Brown Center on Aging, Infectious Disease, Dentistry, and the Markey Cancer Center.

*ResearchMatch.org will be utilized as a recruitment tool for this protocol. ResearchMatch.org is a national electronic, web-basedrecruitment tool that was created through the Clinical & Translational Science Awards Consortium in 2009 and is maintained at Vanderbilt University as an IRB-approved data repository (see IRB #090207)." Once UK IRB approval is obtained the researcher orproxy will upload a flyer with no contact information will by email via ResearchMatch to selected de-identified participants in the ResearchMatch registry. If the de-identified participant selects "Yes, I'm interested!" the researcher or proxy will receive information about participant and they may contact them with more information about their research study. If the participant selects "No, thanks", researcher or proxy will not receive any information from de-identified participant. REDCap prescreening form: The study will employ a pre-screening eligibility survey to determine if a volunteer meets basic inclusion/exclusion criteria. We will build and will administer the eligibility survey on UK's REDCap which provides HIPAA compliant storage on UK servers and encrypted transmission of survey responses. The portable devices do not download the data, it is directly stored into the secure web based connection (https) behind the firewall. All files are password protected once entered into the system. All project data is stored and hosted locally. A link to the eligibility survey will be provided in recruitment materials. The link will also be included in study information sent to ResearchMatch participants who have indicated interest in the study. Before redirecting the volunteer outside of ResearchMatch and to the REDCap survey, the volunteer is once again asked to confirm their interest in completing the pre-screening survey.

Outreach activities: The CCTS attends outreach activities to promote research participation in general (e.g., Roots & Heritage Festival, Latino Festival, Eastern Kentucky University, Transylvania Health fairs, etc.) and will brings all relevant study flyers that are enrolling participants.

UK Public Relations (College/Dept. PR personnel) and UK HealthCare venues: Articles and interviews about the researchers and research study may be promoted via UKNow, Kentucky living, and other media outlets. Research and study-related articles published on UKNow may contain standard language directing interested individuals on where to read more about research and current studies: You can make a difference through participating in research and discovery. To find more information, including a list of current studies at UK and access to studies nationwide, please visit UKclinicalresearch.com or call 859.257.7856 or join the ResearchMatch.org

register to be matched today.

Other recruitment databases: Registries that are owned and operated by non-UK research groups (e.g. partnering groups and Healthrelated Associations).

E-Newsletters and ListServs: This study may also go out on email distribution, listservs, or e- newsletters, e.g., the CCTS list serv, Markey Cancer Affiliates list servs, ResearchMatch.org, Wednesday's Word, Kentucky Office of Rural Health (KORH), Appalachian Translational Research Network (ATRN), etc.

Physician referral letters to community physicians for patient recruitment.

UK Public Relations (College/Dept. PR personnel) and UK HealthCare venues: Articles and interviews about the researchers and research study may be promoted via UKNow, Kentucky living, and other media outlets. Research and study-related articles published on UKNow may contain standard language directing interested individuals on where to read more about research and current studies Paid print advertising: Subjects may be recruited through paid print and digital advertisements, including brochures, magazines, newspaper (e.g., Herald Leader, Bluegrass Area, Courier Journal, Cincinnati Enquirer, Health & Wellness, Chevy Chaser, Hamburg Journal, Business Lexington, Richmond Register or other publications in the surrounding region e.g., Bluegrass Regional print & digital ads, may include Appalachian counties).

Radio (e.g., Sirius, Clear Channel, Cumulus, LM Communications, Public Radio, Pandora, etc.).

Television spots, scrolling information on community stations, and theater screens.

The study may also be advertised through UKPR and UKHC outreach activities. UKHC and CCTS have booths at many events, and researchers and coordinators are invited to attend any events that pertain to their study populations.

Researchers may participate in radio or TV interviews. General information about their research may be presented with a phone number or website url for more study specify information. Consenting members of the research team and/or consenting participants may be interviewed about the study for print, radio, or video which may be distributed via the aforementioned activities.

Word-of-Mouth: An example script for word of mouth recruiting is as follows: "I'm conducting a research study about the effects of sleep restriction and muscle unloading on balance and muscle strength. I'm trying to understand how these stimuli may affect risk of injury for astronauts during lunar exploration missions. This work may also help understand how others suffering these stimuli (like those with extended hospital stays) are affected by these stimuli. I'm looking for healthy subjects who are between the ages of 35 and 50 years old who sleep at least 7 hours every night and who regularly participate in exercise. For this study, subjects will come to the lab three times for 2-2 1/2 hours each visit over the course of about 2 weeks. During this time, subjects will have to walk with crutches and avoid using their left leg at all during the study. During the last three days of the study, half of the subjects will only sleep for 5 hours per night. I will measure balance, and muscle function before and after this time. We will also conduct an MRI of subjects' thigh muscles at the end of the study. Since this study is fairly time-intensive, we are paying subjects $500 if they complete all research procedures. If you're interested in being a subject, you can contact me at:_____."

Attachments

Attach Type	File Name
Advertising	KIN-061_MON_STAMPED.pdf
Advertising	KIN-061a_Flyer-STAMPED.pdf
Advertising	KIN-061a_research match-STAMPED.pdf
Advertising	KIN-061a_social media-Web-STAMPED.pdf
Advertising	KIN-061a Short Video 1-STAMPED.pdf
Advertising	KIN-061a Short Video 2-STAMPED.pdf
Advertising	KIN-061a Short Video 3-STAMPED.pdf
Advertising	KIN-061a Short Video 4-STAMPED.pdf
Advertising	KIN-061a Short Video 5-STAMPED.pdf

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.

Research Procedures
Screening: Following, informed consent, subjects will complete a screening questionnaire to determine if they meet eligibility requirements regarding health history, physical activity, and sleep habits. Additionally, subjects height, weight, and waist circumference will be measured. Those who fall outside of height and weight requirements for space flight will be excluded from participation. Subjects will also complete a short questionnaire regarding their ability to have MRI analysis performed. Those who are ineligible for an MRI procedure will be excluded from participation.

Unloading Intervention: The research team will provide participants with a pair of shoes to wear throughout the study. The right shoe will be modified to include a 5cm (approximately 2") rocker-style platform which will keep the left leg suspended during walking. Participants will also be provided with a pair of short crutches to assist with walking. A member of the research team will assist subjects in familiarization with completing daily living tasks (walking, ascending/descending stairs, transitioning between sitting and standing, transitioning between sitting and lying, and using arms or contralateral leg to move the suspended limb). The research team will also provide subjects with compression stockings to wear on the suspended limb throughout the duration of the study. Participants will be given written instructions regarding use of the ULLS system. Participants will be instructed to treat the left leg as though it were completely unable to move on its own and cannot bear any body weight.

Managing risk of DVT: To minimize risk of DVT, we have consulted the study physician (Dr. Srikanth Nithyanandam) and received consultation from an orthopedic surgeon (Dr. Austin Stone). An email thread outlining this conversation is attached as well as a paper describing methods for mitigating risk in the ULLS model. These experts recommend a combination of therapies to minimize risk of DVT. Subjects will take an 81mg aspirin once per day. This dosage of aspirin performs similarly to heparin therapy in managing DVT risk post-operatively (O'Toole et al. NEJM 2023). Although high dose aspirin therapy moderately attenuates muscle atrophy in denervated rats (Wan et al. Annals Translational Med 2020), we believe the low level aspirin therapy will have minimal impact on study outcomes. Additionally, subjects will wear a compression stocking during ambulatory times (cooking, work, exercise, etc). Subjects will be provided an intermittent pneumatic compression device about the calf. Subjects will be instructed to use this device during periods that they are sedentary (watching TV, reading, etc). Subjects will also be advised to consume adequate amounts of water throughout the study. Additionally, subjects will be provided with a series of passive, range-of-motion exercises for the hip, knee, and ankle joints. A member of the research team will demonstrate these exercises and assist participants in becoming familiar with these exercises. A printed copy of exercise instructions will also be provided. Participants will be instructed to complete these exercises at least twice daily (approximately 10-15 min) along with their typical exercise program and record on an exercise log that is provided. Subjects will be counseled on the signs and symptoms of DVT. Subjects will be advised to seek immediate medical treatment if they experience discoloration, pain, and/or high temperature of the suspended leg. Depending on results of symptom screening during daily follow up with subjects, a d-dimer test may be performed to assess risk of clot formation. These strategies for managing DVT risk largely agree with - and indeed are likely more conservative than - those of similar researchers who implement the ULLS model (Bleeker Am J Physiol Regul Integr Comp Physiol 2004).

Sleep protocol: Subjects will be instructed to sleep for 9 hours each of the first 10 nights of the study between the hours of 9:00pm and 6:00am. Subjects will complete the Pittsburg Sleep Quality Index form at baseline, day 10, and the final day of the study. Every day of the study, subjects will complete a sleep diary record. The research team will provide subjects with a wrist-worn actigraphy device to provide objective measures of sleep. Subjects will wear this device every day of the study. De-identified data will be stored on a mobile app on a university-owned device. No identifiable information will be associated with these data. Subjects will complete a six-item sleep diary each morning of the study.

Follow up and Randomization: A member of the research team will communicate with subjects at least every 24h using the subjects' preferred method of contact (phone or email). During this exchange, we will assess and record any negative symptoms associated with ULLS and sleep protocols. In accordance with email communication with Dr. Nithyanandam (see attached email communication), if subjects report symptoms consistent with deep vein thrombosis (DVT) such as swelling, redness, point tenderness, and elevated temperature of the lower leg, and/or pain, they will be advised to seek immediate medical attention. Additionally, the research team will follow up with subjects via phone call 30 days after the end of their participation in this study to record any complications (i.e. falls) associated with participation in this research project.

After the 10th night of ULLS, subjects will return to the research laboratory for follow up and randomization. We will measure the circumference of the calf muscles of each leg using a flexible tape measure. A non-contact, infrared thermometer will be used to measure surface temperature of the calf muscles. It is expected that the suspended leg will be approximately 1-2C cooler and 1-2cm larger than the loaded limb if subjects are appropriately following ULLS guidelines (Adams Aviat Space Environ Med 1994, Schulze

Med Sci Sports Exerc 2002). Subjects will be randomized to either sleep adequate (SA) or sleep restriction (SR) in a matched-pairs manner. Subjects will be matched based on sex, race, and (when possible) muscle strength (within 30Nm). Subjects randomized to the SA condition will continue to follow the same sleep protocol for the final 3 days of the study. Those randomized to SR will be instructed to go to sleep only between the hours of 1:00am and 6:00am.

Muscle Strength Assessment: Before and after the ULLS and sleep protocols, subjects will complete a series of muscle function tests. Subjects will be instructed to refrain from engaging in exercise for 24 hours and not to consume any caffeine prior to this test. Due to potential effects for chronobiology to affect muscle strength (particularly in the sleep restricted state), all assessments will be completed between 8:00am and 11:00am. All muscle tests will be completed bilaterally.

Following a 5 minute warm up on a bicycle ergometer, we will assess quadriceps muscle function using an isokinetic dynamometer. Subjects will sit upright in an isokinetic dynamometer (Biodex System 4) with the knee at 60° flexion. All muscle strength measures will be accompanied by measures of surface electromyography. The skin above the vastus lateralis will be shaved, lightly abraded, and wiped with an alcohol wipe. A small sensor (approximately 0.5” x 1.25”) will be adhered to the skin via double-sided tape. Subjects will be instructed to extend their knee as forcefully as possible for 5 seconds. Participants will be allowed five attempts with 60 seconds between each effort. The highest value will be recorded as the maximal voluntary isometric contraction (MVIC). Next, subjects will complete a series of submaximal of 10 second submaximal isometric contractions (10, 30, 50, 70, and 90% MVIC). A screen displaying real-time torque output will be shown to subjects. Subjects will be asked to extend their knee and maintain a stable torque output at a specified amount. Individual regression lines will be developed to determine the EMG-torque relationship. Coefficient of variance (CV) of torque output will be used to determine ability to sustain stable torque output.

Quadriceps twitch properties (electromechanical delay [EMD], peak twitch torque [PTT], rate of torque development [RTD], relaxation rate [RR], and post-activation potentiation [PAP]) and voluntary activation (VA) will be assessed with an interpolated twitch (ITT) experiment as we have previously published (Carpenter et al. Scan J Med Sci Sports 2022). Torque and electromyography (EMG) data will be time synchronized for data analysis. Gel electrode pads will be placed over the femoral nerve and just proximal to the patellar tendon. Square wave, constant current, doublet pulses (400V, 200µs, 10µs delay) from an electrical stimulator (Digitimer DS7A - spec sheet provided) will be used to evoke twitches prior to, during, and following an MVIC. The pulse current (120% of that needed to elicit a maximal twitch response) will be determined during individual dose-response experiments at the first testing session. To eliminate effects of varying electrical current on data in subsequent tests, current will be kept consistent for all future testing sessions. In our hands, typical current used is approximately 200-300mA. Post-study muscle strength measures will be normalized to PCSA to account for variations in parallel contractile elements between loaded and unloaded limbs.

Balance Assessment: Static and dynamic balance will be assessed using a dual force plate system (ForceDecks by Vald Performance, Newstead QLD, Australia). Participants will be given the opportunity to practice each assessment before they complete it. During the Single Leg Stand (SLS), participants will be asked to stand on one leg and maintain their balance for 15 seconds. The SLS trial will be repeated once for both legs with eyes open, as well as once on each leg with eyes closed. During the Single Leg Land and Hold, participants will step off a wooden platform (height = 12 inches) and land with one leg only in the middle of the respective force plate. As soon as the participant lands, they will be asked to maintain their position for 10 seconds. The procedure will be repeated three times for both legs. A member of the research team will monitor subjects during this test and assist subjects in regaining balance if they perceive the subject is close to falling.

Magnetic Resonance Imaging (MRI): Diffusion Tensor Imaging (DTI), a specialized form of MRI will be used to quantify muscle volume, physiological cross-sectional area (PCSA), fascicle orientation, and diffusion properties similar to what we have previously published (Carpenter et al. Scan J Med Sci Sports 2022). Subjects will lay supine, with a 14.5cm thick pad under the knees to increase subject comfort and to slightly flex the knee (~10°) to elongate and straighten the quadriceps. A spine array coil will be placed on the MR-scanner table and a flexible body coil wrapped around the subject’s upper thighs and centered over mid-thigh. Subjects will enter the MRI bore with their feet first. For most subjects, their head and face will remain outside of the bore of the MRI machine. Subjects will be provided headphones during this procedure to minimize noise, but will be instructed to stay awake during this procedure. All scans will be bilateral (i.e. both thighs will be imaged). DSI Studio, an open-access software, will be used to analyze raw images. Muscle volume and fiber track length will be used to calculate physiological cross sectional area (PCSA = volume/fascicle length) of individual quadriceps muscles. Anisotropic measures such as fractional anisotropy (FA), mean diffusivity (MD), radial diffusivity (RD), and axial diffusivity (AD), which are related to muscle fiber type and strength will be measured.

Attachments

Attach Type	File Name
ResearchProcedures	DS7A-DS7AH-HV-Current-Stimulator.pdf
ResearchProcedures	email communication.pdf
ResearchProcedures	Recommendations from Ortho Surg..pdf
ResearchProcedures	Bleeker. ULLS can cause DVT.pdf
ResearchProcedures	Research Procedures.pdf
ResearchProcedures	Participant Instructions.pdf
ResearchProcedures	Exercise Record.pdf

Data Collection & Research Materials

In this section, please provide the following:

- Describe all sources or methods for obtaining research materials about or from living individuals (such as specimens, records, surveys, interviews, participant observation, etc.), and explain why this information is needed to conduct the study.

- For each source or method described, please list or attach all data to be collected (such as genetic information, interview scripts, survey tools, data collection forms for existing data, etc.).
- If you will conduct a record or chart review, list the beginning and end dates of the records you will view.

This study will collect some questionnaire/survey data for tracking physical activity and sleep. These forms will contain subject Identification number, but will not contain any identifiable information. All questionnaire/survey data will be stored separately from consent documents to preserve subject privacy. The following data will be collected for this study:

1. Screening Questionnaire: This form (attached) will be used for screening participants for inclusion/exclusion. This form will be administered immediately after subjects sign informed consent documents. Page 1 of this form asks for self-report health history to screen for participation. Page 2 of this survey asks questions regarding physical activity that will be used for screening. Additionally, page 2 contains questions regarding shoe size as well as gender and racial identity. Answers to these questions will not be used for screening purposes. Rather, these specific items will be used to assist the research team in fitting subjects with appropriate equipment for ULLS and matched pair randomization. To control for potential influence of confounding variables, match pair randomization will be based on subjects' biological sex and race. Therefore, we will ask subjects to self-report age, gender identity and race to ensure adequate matching of subjects.

Page 3 of the screening questionnaire asks those who are biologically female questions regarding menstruation and birth control use. These questions will not be used for subject screening, but to assist the research team in developing an appropriate study timeline. There is compelling evidence that muscle strength varies throughout the menstrual cycle for females who are not taking birth control. Specifically, quadriceps strength and relaxation time appear to be significantly greater mid-cycle (Sarwar et al. J Phys 1996). However, due to the duration of our experimental protocol, it is not feasible to conduct all muscle testing at the mid-point of the menstrual cycle. To avoid testing in the mid-point of the menstrual cycle, we will also ask females to report menopause status, birth control methodology (if any), start date of most recent menstrual cycle, and typical cycle length. This will allow us to develop a time course for this study which will avoid testing at the mid-point of the menstrual cycle.

2. Anthropometrics: For subjects who are included in the study, we will measure height and weight and calculate BMI. Additionally, waist circumference will be measured. Since anthropometrics are a limitation regarding who may qualify for space flight, these anthropometrics will be used to screen participants who do not fit the characteristics of the intended study population.

3. Sleep data: We will use two self-report measures of sleep through this study - the Pittsburg Sleep Quality Index (PSQI) and a sleep diary record. These forms are attached here. Subjects will complete the PSQI at baseline, after 10 days of ULLS, and at the end of the study. Participants will complete this sleep diary record each day of the study. The sleep diary contains questions regarding use of caffeine, alcohol, and sleep medications. These will be used to help the research team understand how these factors which commonly affect sleep may affect ability to adhere to the sleep protocol or impact primary research outcomes, especially following the sleep restriction portion of the study.

Additionally, we will record objective measures of sleep through a wrist-worn actigraphy-based system. Data will be provided to the research team by a mobile app. To preserve subject privacy, no identifiable information will be provided when setting up the sleep monitoring device.

4. Physical activity records: Participants will complete the International Physical Activity Questionnaire (attached) at baseline, after 10 days of ULLS, and at the end of the study. We will also ask subjects to complete an exercise record each day to assess compliance with the passive exercise protocol and to ensure they refrain from other strenuous exercise 24 hours prior to testing.

5. Muscle Function and Electromyography: Quadriceps torque data will be measured using an isokinetic dynamometer during various conditions. Specifically, we will measure torque during maximal voluntary isometric contraction (MVIC), at varying submaximal efforts with biofeedback, and in response to a twitch stimulus. Data will be stored on a shared-use desktop computer associated with the isokinetic dynamometer. Additionally, data will be wirelessly transmitted to another machine to allow for time-synchronization of torque and electromyography data. Electromyography data from the thigh muscles will be measured by electrodes adhered to the skin with double-sided tape. Data will be stored according to subject ID; no identifying information will be stored on these computers. Electronic copies of de-identified data will be stored on these devices and password-protected computers owned by the university of Kentucky. Electronic data may also be saved on university protected cloud services such as OneDrive.

6. Balance Assessment: Static and dynamic balance will be assessed using a dual force plate system (ForceDecks by Vald Performance, Newstead QLD, Australia). No identifiable information will be saved to the electronic system; only subject ID will be used to save data on the mobile app associated with these force plates. Electromyography of thigh and calf muscles will be measured through electrodes attached to the skin by double-sided tape.

7. Thigh MRI: MRI screening (form attached) will be completed after informed consent and health history screening. MRI images will be collected by trained staff within UK's Magnetic Resonance Imaging and Spectroscopy Core (MRISC) on a fee basis. Specifically, non-invasive imaging of both thighs will be completed (approximately 30 minutes). Images will be saved to compact disks or other mobile hardware and transferred to the research team. Compact disks will be stored in a locked file cabinet in the PIs office. No identifiable information will be used when storing MRI scans.

Attachments

Attach Type	File Name
DataCollection	Subject Sleep Instructions 12.2.22.pdf
DataCollection	MRI screening form.pdf
DataCollection	Anthropometrics Screening.pdf

DataCollection	Screening Questionnaire.pdf
DataCollection	IPAQ.pdf
DataCollection	PSQI.pdf

Resources

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

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

Informed consent, screening, muscle function testing, and balance assessment will take place in the biodynamics lab within the Multidisciplinary Sciences Building (Room B04A) or within the exercise physiology lab of Seaton Center (multiple rooms). This facility houses an isokinetic dynamometer (Biodex S4), wireless electromyography (Delsys Trigno Avanti), muscle stimulator (Digitimer DS7A), and train-delay generator (Digitimer DG2) needed for these procedures. The PI will directly train all research personnel regarding use this equipment and appropriate protocols. Data from muscle strength testing will be stored (with no identifying information) on password-protected, University-owned desktop PCs in this facility. Portable force decks (VALD force decks) will be moved to this room for testing as needed. Data from theses devices will be streamed to a mobile app on a university-owned portable device. No identifiable information will be used to store data on the mobile app.

The research team will also familiarize participants with the ULLS system (shoes, compression stockings, and crurtches) at the biodynamics lab. Participants will be given the chance to practice navigating level walking, ascending/descending stairs, transitioning between sitting/standing, transitioning between lying/sitting, and re-positioning the left leg with use of arms or contralateral leg. Additionally, this facility will be used to familiarize passive exercise for the the knee and ankle.

Magnetic Resonance Imaging will be conducted at the Magnetic Resonance Imaging and Spectroscopy Center (40 Whitney Hendrickson Building room). A member of the research team will assist subjects with transportation between these locations and assist MRISC staff with data collection. MRI procedures will be completed by MRISC staff. Data will be stored on PCs associated with MRI equipment per standard practice of this core facility. Data files will be provided to the research team through compact disks or university-owned external hard drives. MRISC will directly train all research personnel on data collection procedures.

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.

The major risks associated with this study include:

1. Deep Vein Thrombosis (DVT) - Prolonged disuse can result in DVT which may lead to pulmonary thromboembolism. To our knowledge, there is one report of DVT after 10d of ULLS and the estimated risk of DVT using ULLS is approximately 2.7% (Bleeker JAP-Reg Integ Comp Physiol 2004). In accordance with recommendations from this paper, we are implementing use of compression stockings and passive range of motion exercises for the suspended leg to minimize DVT risk. Use of compression stockings and passive range of motion of the ankle are advocated by UK's Gill Heart Institute to reduce risk of DVT (https://ukhealthcare.uky.edu/gill-heart-vascular-institute/conditions/vascular/deep-vein-thrombosis). The research team will communicate frequently with subjects via phone or email throughout the study to assess for development of symptoms. The medical supervisor, Dr. Nithyanandam will provide medical guidance as needed. Per Dr. Nithyanandam's recommendation, we will administer a d-dimer test if subjects report symptoms consistent with DVT. Those with symptoms and elevated d-dimer will be referred for medical care.

Proposed MRI assessments will be cross-sectional images of the mid-thigh region. Since DVT most commonly occurs in the lower leg (below the knee), it is unlikely that this procedure would be able to identify presence of DVT.

2. Loss of muscle size and strength - Given the duration of our study, we expect the ULLS model to reduce quadriceps muscle size by approximately 5% and strength by approximately 15-20% in the suspended limb (Hackney Eur J Appl Physiol 2014, Tesch J Appl Physiol 2016). Recent data (Sarto, J Physiol 2022) indicate that muscle size and strength loss from 10 days of ULLS are recovered with 21 days of exercise training. Data from our lab indicate that our sleep restriction model may reduce strength by about 8% which is fully recovered after returning to habitual sleep for seven nights. Therefore, loss of muscle size and strength are not expected to be of sufficient magnitude or duration to impair health status over the long term.

3. interference with daily activities - the ULLS and sleep protocols may significantly adversely affect daily quality of life for participants. The magnitude of the ULLS impact on daily life will be similar to that experienced when recovering from a sport-related injury or lower-limb surgery, but with a shorter time course. Sleep restriction may impair mental function, mood state, and ability to operate equipment. The magnitude of sleep restriction (5 hours of sleep for three consecutive nights) is a similar to sleep disturbances which subjects would likely experience at some point in life due to excessive stress or even voluntarily-inflicted by lifestyle choices. In our lab, subjects completing this sleep restriction protocol complain of increased tiredness, but there have been no major complaints regarding this intervention.

4. Discomfort from electrical stimulation - the electrical stimulus used in this study rarely results in residual pain after the testing protocol. In our hands, no subjects have reported discomfort resulting from this protocol the following day. It is also possible that subjects could experience muscle soreness following knee extension testing if they do not perform this exact exercise as part of their regular strength training. However, by recruiting physically active subjects, we anticipate this level of discomfort would be similar to that experienced after a difficult exercise session.

Subjects are not expected to directly benefit from engaging in this study. Our subjects may enjoy knowing information about their muscle strength, muscle size, or even sleep habits. We will reveal these data to subjects if they request it at the end of the study. The major benefit of this study is that it will advance the scientific understanding regarding the interaction of sleep restriction and unloading on muscle function and balance regulation. Apart from the obvious application to astronauts undergoing space flight, these stimuli are commonly experienced by other populations such as those undergoing prolonged hospital stays. Therefore, findings from this study may be applicable to settings beyond space flight.

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).

The only other available alternative is to choose not to participate in this research.

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Records, Privacy, and Confidentiality

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

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

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

If this study will use de-identified data from another source, describe what measures will be taken to ensure that subject identifiers are not given to the investigator.

If applicable, describe procedures for sharing data/specimens with collaborators not affiliated with UK.

For additional considerations:
Return of Research Results or Incidental Research Findings
HIPAA policies
FERPA policies
Procedures for Transfer agreements
Information regarding multi-site studies
NIH Genomic Data Sharing (GDS) Policy
Digital Data

The new data security compliance requirements under 28 CFR Part 202 are in effect as of 10/6/25. For any questions please contact Sara Poll, UK's Research Security Administrator, researchsecurity@uky.edu

Hard copies of consent forms, screening documents, and data (when needed) will be stored in the PI's office (201 Seaton) in a locked

file cabinet behind a locked door. Hard copies of consent forms and other screening documents and data files will be kept separately to avoid potentially identifying subjects. Electronic data will be stored on password-protected, university-owned computers in the lab where the data were collected. Electronic data may also be stored (de-identified) on university-owned external hard drives and to the cloud (OneDrive) using university accounts.
All electronic data will be de-identified (i.e. stored with subject number and no other identifiers). An electronic file linking subject name and study ID number will be stored on a university-owned, password-protected computer behind a locked door. This will be the only record linking subject ID and identifiable information. Only members of the research team will have access to the data. Records will be maintained for six years after study closure.

To encourage scientific transparency, NASA requires data to be uploaded to data repositories at the conclusion of the study. De-identified data will be posted to appropriate data repositories at the conclusion of the study in a manner consistent with NASA requirements.

☑ **UK IRB policies state that IRB-related research records must be retained for a minimum of 6 years after study closure. Check this item to confirm that you will retain all IRB-related records for a minimum of 6 years after study closure.**

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.

Subjects will be compensated with $500 after all research procedures are complete. Subjects who do not complete the study will not receive remuneration. Assuming a total of 6-7.5 hours of time commitment to complete testing sessions, this amounts to an hourly pay rate of $66.67 to 83.33. However, it should be noted that our ULLS and sleep intervention involve considerable adaptations to daily living for the duration of the study. Given the 13d duration of this study, subject compensation per day will be $38.46. Therefore, we believe this financial incentive will encourage subject participation and adherence, but will fall well below the amount that could be considered coercion to participate.

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.

Costs of all research procedures will be covered by the research team. This includes all equipment, materials, supplies, etc. The research team will provide specially modified shoes and crutches for the ULLS. The research team will pay for all MRI scans and d-dimer tests if needed. Thus, there are no costs to subjects to participate in this research. However, the research team will not cover costs of medical treatment that may be needed as a result of participating in this research.

It is expected that subjects will lose some muscle mass (~5%) and strength (~15%) over the course of this study in their left leg. Previous studies have shown this level of strength loss returns about 3-4 weeks after resuming normal daily activities, including resistance exercise. There are some health risks associated with prolonged unloading such as ULLS. The study design aims to limit these risks and has provided a medical supervisor to advise regarding potential complications. However, the research team will not pay for medical expenses arising from health complications associated with this study. Any expenses associated with treating complications from research procedures would be the responsibility of the study participant.

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.

A member of the research team will contact subjects at least every 24h throughout the study using the subjects' preferred method of contact (phone call or email). During this exchange, we will specifically ask participants regarding symptoms which may be associated with development of deep vein thrombosis (DVT). Specifically, we will ask participants regarding: compliance with exercise protocol and compression stocking use, throbbing, cramping, pain/tenderness, and swelling in the suspended leg, skin discoloration of the suspended limb, noticeable warmth in the suspended limb, or noticeable visual changes in the veins of the lower leg. During the sleep intervention, we will also ask participants regarding their perceived level of fatigue, ability to complete daily living tasks, and safety (driving, etc). Responses to all questions will be recorded by a member of the research team. Importantly, research subjects will be provided with the PI's mobile phone number and email address and encouraged to contact him in the event of any untoward symptoms regarding DVT or sleep restriction. If subjects report symptoms any symptoms of DVT during the study, they will be referred to Dr. Nithyanadam for medical advice. Subjects reporting excessive fatigue will be encourage to find alternative methods for transportation during the sleep restriction portion of the study. The PI will immediately report any adverse event or major complaints regarding the

study intervention to the IRB. If subjects develop major health complications related to our study intervention, we will cease subject enrollment until a safer alternative intervention is established and approved by the IRB.

Consent documents, screening documents, and hard copies of data (when needed) will be stored in a locked file cabinet behind a locked door in 201 Seaton (the PIs office). Consent forms will be stored separately from all other documents to avoid inadvertently disclosing subject identity. Electronic records will be stored with no identifiable information on the password-protected, university-owned machines at the location where data were collected. These electronic records may be transferred to university-owned external hard drives (maintained in the PIs office) and shared with members of the research team through cloud platforms (i.e. OneDrive) maintained by the university. Following conclusion of the study, de-identified raw data for major outcomes will be posted to data sharing repositories per NASA requirements. These data may contain subject characteristics such as age, sex, height, and weight, but will not contain any information which could lead to subject identification.

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

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

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

Dr. Bollinger will retain data for future studies. Specific data of interest include:
1. Muscle function assessments
2. EMG activity data
3. MRI data

Recently published data from our lab indicate that diffusion tensor imaging data (from MRI) relate to contractile properties in the knee extensors during a stimulated twitch. Dr. Bollinger is interested in continuing this line of investigation and plans to pursue apply for additional external research support (including NIH, NSF, and/or NASA) to investigate use of this technology as a non-invasive means of assessing contractile properties of skeletal muscle. Data stored for these purposes would contain no identifiable information. However, basic subject characteristics such as age, sex, height, and weight would be retained in this data set as these have previously been shown to relate to diffusion properties of muscle. Future use of data is expected to take place within three years after the study is closed.

In an effort to increase transparency of scientific data, NASA requires all sponsored research to post data to a NASA-supported, publicly available online repository. Our data are most applicable to the Life Science Data Archive (https://nlsp.nasa.gov/explore/lsdahome). Per NASA requirements, primary data outcomes (subject characteristics, strength, EMG activity, balance performance, and muscle size) will be posted to the LSDA respository following publication of our first manuscript from this project. Again, no identifiable information would be included in this dataset.

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-Initiated FDA-Regulated Research

Is this an investigator-initiated study that:

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

○ Yes ◉ No

PI-Sponsored FDA-Regulated Research

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

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

IRB policy requires mandatory training for 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.)

I have attached a HIPAA Waiver of Authorization. ○ Yes ◉ No

Attachments

STUDY DRUG INFORMATION

0 unresolved comment(s)

Drugs are articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease and articles (other than food) intended to affect the structure or any function of the body of man or other animals.

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).

See 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)

Medical devices are intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man or other animals.

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 [FDA's PDF] of Significant Risk (SR) device?

- Yes. Device(s) being tested 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 being tested 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 (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. When attaching reliance documents, please ensure that you select the correct 'Document Type' from the drop-down menu. See below for the "**Document Types**" in bold, followed by examples of reliance documents for each type:
  - **Individual Investigator Agreement (IIA)**
    - A completed Individual Investigator Agreement

- IRB Approval (Non-UK)
- A Letter of Approval from a Non-UK IRB

- IRB Authorization Agreement (IAA)
- A SMART IRB Agreement
- An OHRP Agreement
- A DoD Agreement
- An IREx Reliance Notification
- Any Reliance Agreement

- Letter of Support & Local Context
- A Letter of Support from an organization at which some research activities are occurring
- Communications Plan
- Local Context Form

Please reach out to IRBReliance@uky.edu if you have any questions or concerns.

- 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:

No experimental (data collection) procedures will be conducted off-site. However, due to the nature of this project, participants will complete some research procedures as part of their daily lives. 1) Participants will perform sleep intervention in their primary place of residence. 2) Participants will complete ULLS intervention while maintaining their typical daily activities. 3) Participants will complete some questionnaires off-site.

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

John Caruso, PhD (University of Louisville) has expertise implementing the ULLS model. Dr. Caruso is serving as a subawardee on the grant related to this project. His roles will involve consulting regarding ULLS and data analysis/interpretation. Drs. Bollinger and Best will regularly meet with Dr. Caruso to discuss all aspects of the project.

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

Attachments

Attach Type	File Name
-IRB Approval (non-UK)	UL IRB Outcome_Letter.pdf
-IRB Authorization Agreement	UKY IRB 84290 SMART IRB reliance Louisville 03022023.pdf
-Letter of Support & Local Context	UK Communication Plan UKY IRB 84290.pdf

B) 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)

Instructions: For various reasons, it is necessary to determine whether your research activities meet the definition of clinical research and/or a clinical trial. Your responses to the next series of questions will make that determination. For more details on the definitions, go to ORI's clinical research vs. clinical trial web page or visit NIH's decision tree for the NIH Clinical Trial definition.

Contact the Clinical Research Support Office (CRSO) if your study provides clinical services (e.g., labs, biopsies, tissue samples, physical exams, PT, counseling) regardless of payer (grant, federal, UK, industry), utilizes UKHC space, or meets the NIH definition of a clinical trial (thereby requiring registry with CT.gov) as your study will need to be entered in OnCore to ensure appropriate regulatory tracking and billing. Visit CRSO FAQs for more information; requests for CCTS/CRSO services can be submitted via their service request form. For other questions, you can contact the CRSO Director, Jessica Heskel.

My research activities include one or more of the following:

Patient-oriented research regarding mechanisms of human disease, therapeutic interventions, clinical studies, or development of new technologies
○ Yes ◉ No

Material of human origin (such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects
○ Yes ◉ No

Epidemiologic or Behavioral Studies
○ Yes ◉ No

Outcomes Research or Health Services Research
○ Yes ◉ No

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

☑ Not applicable

Check All That Apply

☐ Academic Degree/Required Research
☐ Alcohol/Drug/Substance Abuse Research
☐ Biological Specimen Bank Creation (for sharing)
☐ Cancer Research
☐ CCTS-Center for Clinical & Translational Science
☐ Certificate of Confidentiality
☐ Collection of Biological Specimens for banking and use
☐ Community-Based Participatory Research
☐ Deception
☐ Educational/Student Records (e.g., GPA, test scores)
☐ Emergency Use (Single Patient)
☐ Gene Transfer
☐ Genetic Research
☐ NIH Genomic Data Sharing (GDS) (databases such as GWAS, dbGaP, GenBank)
☐ Treatment with Human Cells, Tissues, and Cellular and Tissue Based Products
☐ Individual Expanded Access or Compassionate Use

For additional requirements and information:

- Cancer Research (MCC PRMC)
- Certificate of Confidentiality (look up "Confidentiality/Privacy...")
- CCTS (Center for Clinical and Translational Science)
- Clinical Research (look up "What is the definition of....)
- Clinical Trial
- Collection of Biological Specimens for Banking (look up "Banks, Repositories, Registries...")
- Collection of Biological Specimens (look up "Repositories, Registries, Specimen/Tissue Banks...")
- Community-Based Participatory Research (look up "Community-Engaged...")
- Data & Safety Monitoring Board (DSMB)

  *For Medical IRB: Service Request Form for CCTS DSMB

- Data & Safety Monitoring Plan
- Deception*

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

- Emergency Use (Single Patient) [attach

- ☐ International Research
- ☐ Planned Emergency Research Involving Exception from Informed Consent
- ☐ Recombinant DNA
- ☐ Registry or data repository creation
- ☐ Stem Cell Research
- ☐ Suicide Ideation or Behavior Research
- ☐ Survey Research
- ☐ Transplants
- ☐ Use, storage and disposal of radioactive material and radiation producing devices
- ☐ Vaccine Trials

Emergency Use Checklist] (PDF)

- Genetic Research (look up "Banks, Repositories, ...Genetic/Genomic Data Sharing...")
- Gene Transfer

*For gene transfer research, also go to the E-IRB Application Other Review Committees section, and checkmark Institutional Biosafety Committee

- International Research (look up "International & Non-English Speaking")
- NIH Genomic Data Sharing (GDS) Policy (PDF)
- Planned Emergency Research Involving Exception to Informed Consent*

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

- Use, storage and disposal of radioactive material and radiation producing devices

FUNDING/SUPPORT

0 unresolved comment(s)

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

☐ 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

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-look up "Does the IRB Charge a Fee..."]
- 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

Other:

Kentucky NASA Space Grant Consortium - Research Initiation Award

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.):

Kentucky NASA Space Grant Consortium - Research Initiation Award

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
- Radioactive Drug Research Committee (RDRC)
- Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)** - Attach MCC PRMC materials, if any, per instructions.
- Office of Medical Education (OME)
- Graduate Medical Education Committee (GME)

Attachments

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

ADDITIONAL INFORMATION/MATERIALS

0 unresolved comment(s)

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

Approval Letter Details:

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

Additional Materials:

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

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

Protocol/Other Attachments

Attach Type	File Name
Other	IRB Requested Revisions.pdf

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

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

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

SIGNATURES (ASSURANCES)

0 unresolved comment(s)

Introduction

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

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

For a detailed illustration of how to complete this section, please review the short online video tutorial "Signatures (Assurance) Section - How to Complete." Otherwise, follow the steps below.

Required Signatures:

Individuals chosen as signees may remove the application from their Inbox without signing the Assurance Statement by clicking "Return to PI" with a comment about why it is being returned (e.g., specific edits are deemed necessary).

The PI, and personnel chosen as a contact, will receive an email notification that edits are needed, and can find the draft application in both the "Draft" folder and the "Signatures Status" folder located in the menu in the left margin of the default Inbox page. The researcher does not have a 'reply' option to the signee's comments and must make the requested edits directly in the application, or communicate outside the E-IRB system as to why not. Once the response is finalized, the researcher must re-visit the "Assurances Required" section to click the "Return to Signee" button for their re-consideration; the signee will receive an email notification at that time.

Hover your mouse cursor here for additional instructions.

First Name	Last Name	Role	Department	Signee Return Comment	Date Signed	
Heather	Erwin	Department Authorization	Kinesiology - Health Promotion		12/02/2022 04:09 PM	View/Sign
Lance	Bollinger	Principal Investigator	Kinesiology - Health Promotion		12/02/2022 02:31 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). Once all Assurance Statement signatures have been acquired, 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		0.074	ecr236	11/14/2025 5:47:49 PM
	Advertising	KIN-061a Short Video 5-STAMPED.pdf	CCTS PRS video5	0.311	lmbo233	4/25/2024 12:14:17 PM
	Advertising	KIN-061a Short Video 4-STAMPED.pdf	CCTS PRS video4	0.300	lmbo233	4/25/2024 12:14:00 PM
	Advertising	KIN-061a Short Video 3-STAMPED.pdf	CCTS PRS video3	0.340	lmbo233	4/25/2024 12:13:42 PM
	Advertising	KIN-061a Short Video 2-STAMPED.pdf	CCTS pRS video2	0.308	lmbo233	4/25/2024 12:13:24 PM
	Advertising	KIN-061a Short Video 1-STAMPED.pdf	CCTS PRS video1	0.367	lmbo233	4/25/2024 12:13:08 PM
	Advertising	KIN-061a_social media-Web-STAMPED.pdf	social media.stamped	0.470	lmbo233	4/16/2024 1:42:51 PM
	Advertising	KIN-061a_research match-STAMPED.pdf	Research match email.stamped	0.121	lmbo233	4/16/2024 1:42:37 PM
	Advertising	KIN-061a_Flyer-STAMPED.pdf	Flyer PR stamped	0.514	lmbo233	4/16/2024 1:42:16 PM
	Advertising	KIN-061_MON_STAMPED.pdf	digital monitors	0.562	lmbo233	7/21/2023 7:06:04 AM
	-IRB Authorization Agreement	UKY IRB 84290 SMART IRB reliance Louisville 03022023.pdf	UKY IRB 84290 SMART IRB reliance Louisville	0.199	scbe223	3/3/2023 9:06:24 AM
	-IRB Approval (non-UK)	UL IRB Outcome_Letter.pdf	UL IRB letter	0.094	lmbo233	3/2/2023 3:08:59 PM
	-Letter of Support & Local Context	UK Communication Plan UKY IRB 84290.pdf	Communication Plan	0.307	lmbo233	3/2/2023 3:07:46 PM
	ResearchProcedures	Bleeker. ULLS can cause DVT.pdf	Managing risk of DVT in ULLS model	0.037	lmbo233	2/2/2023 1:51:15 PM
	ResearchProcedures	Recommendations from Ortho Surg..pdf	Email communication with physicians	0.237	lmbo233	2/2/2023 1:50:45 PM
	ResearchProcedures	email communication.pdf	email communication regarding DVT	0.433	lmbo233	1/17/2023 2:27:48 PM
	AddInfoProduct	IRB Requested Revisions.pdf	IRB Requested Revisions	0.232	scbe223	1/12/2023 4:08:39 PM
	DataCollection	Subject Sleep Instructions 12.2.22.pdf	Sleep Diary Questionnaire	0.421	lmbo233	12/2/2022 2:18:48 PM
	ResearchProcedures	Exercise Record.pdf	Exercise record	0.408	lmbo233	12/2/2022 2:01:55 PM
	ResearchProcedures	Participant Instructions.pdf	Participant Instructions	0.112	lmbo233	12/2/2022 1:44:26 PM
	ResearchProcedures	Research Procedures.pdf	Research procedures	0.413	lmbo233	12/2/2022 12:07:28 PM
	DataCollection	Screening Questionnaire.pdf	Screening Questionnaire	0.116	lmbo233	12/2/2022 10:01:45 AM
	DataCollection	Anthropometrics Screening.pdf	Anthropometrics Screening	0.006	lmbo233	12/2/2022 10:00:14 AM
	DataCollection	MRI screening form.pdf	MRI screening	0.137	lmbo233	11/29/2022 2:37:48 PM
	ResearchProcedures	DS7A-DS7AH-HV-Current-Stimulator.pdf	Electrical Stimulator Spec. Sheet	1.344	lmbo233	11/28/2022 2:45:06 PM
	DataCollection	PSQI.pdf	Pittsburg Sleep Quality Assessment	0.113	lmbo233	11/28/2022 2:41:11 PM
	DataCollection	IPAQ.pdf	Physical Activity Questionnaire	0.129	lmbo233	11/28/2022 2:40:22 PM
	StudyDesign	Study design with outcomes.pdf	study design graphic	0.470	lmbo233	11/28/2022 2:25:18 PM

Statistical Analysis Plan NCT05956964

The statistical analysis plan consists of using linear mixed models to examine interactive effects of limb and time on primary research outcomes. No differences between sleep groups were observed, therefore the data will be combined and include sleep duration as a covariance in all analyses.