PROTOCOL TYPE (VERSION 4)

Which IRB

◉ Medical ○ NonMedical

Protocol Process Type

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

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

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

Which IRB

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

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

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

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

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

Which Protocol Process Type

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

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

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

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

Modification Request Section

0 unresolved comment(s)

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

Select One:

- (•) This modification does not increase risk to study participants.
- ( ) This modification may or will increase risk to study participants.

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

- ( ) Yes (•) No

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

- ( ) Yes (•) No

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

For each proposed modification, include a justification.

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

Adding Prusick to study

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

Evaluation of the Safety, Feasibility, and Preliminary Efficacy of Dorsal Myelotomy and Expansive Duraplasty Performed Either Without or With Autologous Nerve Graft Implantation After Acute Traumatic Spinal Cord Injury (Decompression-Plus).

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.

Decompression-Plus

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

Maximum number of human subjects (or records/specimens to be reviewed) 10

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:	Francis	Room# & Bldg:	800 Rose St.
Last Name:	Farhadi	Speed Sort#:	40536
Middle Name			
Department:	Neurosurgery - 7H853	Dept Code:	7H853
PI's Employee/Student ID#:	12570745	Rank:	
PI's Telephone #:	8593234601	Degree:	MD
PI's e-mail address:	Francis.Farhadi@uky.edu	PI's FAX Number:	
PI is R.N.	○ Yes ◉ No	HSP Trained:	Yes
		HSP Trained Date:	3/4/2022
		RCR Trained:	Yes

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

○ Yes ◉ No

RISK LEVEL

0 unresolved comment(s)

Indicate which of the categories listed below accurately describes this protocol

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

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

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

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

Age level of human subjects: (i.e., 6 mths.; 2yrs., etc..) 18 to 80

Study Population:

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

Provide the following information:

- A description of the subject selection criteria and rationale for selection in terms of the scientific objectives and proposed study design;
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group;
- Justification for the inclusion of vulnerable groups such as children, prisoners, adults with impaired consent capacity, or others who may be vulnerable to coercion or undue influence.

Please consider these resources:
NIH Diversity Policy
FDA Diversity Guidance

Number of Participants: To assess the feasibility of recruitment and of the protocol procedures (specifically the = 48 hours injury-to procedure timeframe), the study will plan to enroll and treat 10 patients.

All participants with American Spinal Injury Association (ASIA) impairment scale A or B acute traumatic spinal cord injuries will be assessed for suitability and prospectively enrolled in the study. Either cervical (C2-C8) or thoracic (T1-T12) level injuries in participants aged 18 to 80 years old will be included. Detailed eligibility criteria are listed below.

The use of immunosuppressive therapy (including methylprednisolone and other corticosteroids) will be discouraged; however, use of such therapy will not require exclusion or discontinuation from the study. Of note, the recent Riluzole study reported that corticosteroids were administered at the time of admission to only ~30% of the patients (while 58% of historic NACTN registry patients had received this treatment).[15, 16]

Inclusion Criteria:
1. Age: = 18 years and = 80 years
2. Written informed consent by patient or legal authorized representative
3. No other life-threatening injury
4. No evidence of sepsis
5. Acute cervical or thoracic SCI with ASIA Impairment Scale grade A or B on admission
6. Non-penetrating SCI at neurologic level from C2 to C8 or T1 to T12
7. The ability to undergo surgical intervention including study procedures through a posterior approach within 48 hours of injury

Exclusion Criteria
1. Unconsciousness or other mental impairment that prevents neurological assessment within the first 48 hours
2. Acute SCI with ASIA Impairment Scale grade C, D or E
3. Spinal cord decompression and spinal stabilization can be safely performed through an anterior-only approach (i.e. posterior approach is not required)
4. Currently involved in another non-observational SCI research study or receiving another investigational drug
5. Other illness (including mental disorder) that could preclude accurate medical and neurological evaluation (at discretion of the principal investigator)
6. Unable to commit to the follow-up schedule
7. A recent history of regular substance abuse (illicit drugs, alcohol), which in the opinion of the investigator would interfere with the subject's participation in the study
8. Any condition likely to result in the patient's death within the next 12 months
9. Prisoner
10. Subjects who in the opinion of the investigator are not suitable for inclusion in the study (reason to be documented).
11. Pregnancy

Attachments

Indicate the targeted/planned enrollment of the following members of minority groups and their subpopulations. Possible demographic sources: Census Regional Analyst Edition, Kentucky Race/Ethnic Table, Kentucky Population Data.
(Please note: The IRB will expect this information to be reported at Continuation Review time for Pre-2019 FDA-regulated Expedited review and Full review applications):

Participant Demographics

	Cisgender Man	Cisgender Woman	TGNB/TGE	Unknown/Not Reported
American Indian/Alaskan Native:				
Asian:				
Black/African American:	2	1		
Latinx:	1	1		
Native Hawaiian/Pacific Islander:				

White:	2	1		
American Arab/Middle Eastern/North African:				
Indigenous People Around the World:				
More than One Race:	1	1		
Unknown or Not Reported:				

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

Attach Type	File Name
ImpairedConsent	Form T - 11Oct23 - 2Di (Clean).pdf

INFORMED CONSENT/ASSENT PROCESS/WAIVER

0 unresolved comment(s)

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

Additional Resources:

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

Consent/Assent Tips:

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

How to Get the Section Check Mark

1. You must:

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

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

Check All That Apply

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

Attachments

Attach Type	File Name
Informed Consent/HIPAA Combined Form	ICF v1 dated 21Nov2023 (clean).pdf

Informed Consent Process:

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

- the circumstances under which consent will be sought and obtained
- the timing of the consent process (including any waiting period between providing information and obtaining consent)
- who will seek consent
- how you will minimize the possibility of coercion or undue influence
- the method used for documenting consent
- if applicable, who is authorized to provide permission or consent on behalf of the subject
- if applicable, specific instruments or techniques to assess and confirm potential subjects' understanding of the information

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

Special considerations may include:

- Obtaining consent/assent for special populations such as children, prisoners, or people with impaired decisional capacity
- *Research Involving Emancipated Individuals*
  If you plan to enroll some or all prospective subjects as emancipated, consult with UK legal counsel **prior to submitting this application to the IRB**. Include research legal counsel's recommendations in the "Additional Information" section as a separate document.
- *Research Involving Non-English Speaking Subjects*
  For information on inclusion of non-English speaking subjects, or subjects from a foreign culture, see IRB Application Instructions for Recruiting Non-English Speaking Participants or Participants from a Foreign Culture.
- *Research Repositories*
  If the purpose of this submission is to establish a research repository describe the informed consent process. For guidance regarding consent issues, process approaches, and sample language see the Sample Repository/Registry/Bank Consent Template.

Once the individual has agreed to the surgery, a member of the study team, authorized to obtain informed consent (e.g. study coordinator), will explain the risk and benefits of participating in the study to the potential participant and/or legal authorized representative (LAR). Any questions that the participant may have will be answered at that time. Participants will be asked to give permission to broadly sharing their data and biosamples.

Because of their injury, participants may not be able to provide written consent. Most will be participants who are able to provide at least verbal consent but may not be able to write given their acute spinal cord injuries. In cases of accompanying significant head or other injuries that prevent direct and reliable communication with the patient, we would approach their LAR for consent.

If the participant provides verbal consent, the consent form will document the method used for communication with the prospective participant and the specific means by which the prospective participant communicated agreement to participate in the study. An impartial third party will witness the entire consent process and sign the consent document. A video tape recording of the consent interview is recommended and when possible will be used. For any participant who required the use of a LAR due to impaired consent capacity, at the first opportunity a participant regains consent capacity, we will re-consent that participant.

The informed consent from the participant will be placed in their medical record and documentation of the informed consent process will be placed in the participant's study binder.

Informed consent is an ongoing process and if conditions or results might affect a participant's willingness to continue in the study, the researchers will communicate the information to the participant/LAR. Emphasis will be placed on ensuring that care will not be affected by an individual's acceptance or refusal to participate in the study. The participant/LAR will be reminded that they may withdraw from participation in this study at any time. A signed informed consent form will be retained by the investigator. The study participant/LAR will receive a copy of the informed consent form.

☐ Request for Waiver of Informed Consent Process

If you are requesting IRB approval to waive the requirement for the informed consent process, or to alter some or all of the elements of informed consent, complete, Section 1 and Section 2 below.

Note: The IRB does not approve waiver or alteration of the consent process for greater than minimal risk research, except for planned emergency/acute care research as provided under FDA regulations. Contact ORI for regulations that apply to single emergency use waiver or acute care research waiver (859-257-9428).

SECTION 1.

Check the appropriate item:

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

☐ I am requesting an alteration of the informed consent process.

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

SECTION 2.

Explain how each condition applies to your research.

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

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

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

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

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

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

Request for Waiver of Signatures

If you are requesting IRB approval to waive the requirement for signatures on informed consent forms, **your research activities must fit into one of three regulatory options**:

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

Select the option below that best fits your study.

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

Option 1

Describe how your study meets these criteria:

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

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

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

Option 2

Describe how your study meets these criteria:

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

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

Option 3

Describe how your study meets these criteria:

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

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

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

STUDY PERSONNEL **0 unresolved comment(s)**

Do you have study personnel who will be assisting with the research?
After selecting 'Yes' or 'No' you must click the 'Save Study Personnel Information' button.

◉ Yes ○ No

Manage Study Personnel

Identify other study personnel assisting in research project:

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

To add an individual via the below feature:

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

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

Study personnel assisting in research project:

Last Name	First Name	Responsibility In Project	Role	AC	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI	Active
Al-Sharshahi	Zahraa	Sub-Investigator	SP	Y	N		P	Y	08/07/2023	Y	N	12/15/2023	N	Y
Ashe	Laura	Project Assistance/Support	DP	N	Y		P	Y	06/05/2023	Y	N	10/09/2023	N	Y
Cassidy	Ryan	Sub-Investigator	SP	Y	N		P	Y	05/08/2023	Y	N	12/15/2023	N	Y
Dyer	Kriston	Study Coordinator	SP	Y	N		P	Y	12/08/2021	Y	N	12/15/2023	N	Y
Gerhardt	Greg	Data Analysis/Processing	SP	N	N	PhD	P	Y	10/02/2023	Y	N	10/09/2023	N	Y
Hartman	Ellen	Project Assistance/Support	DP	N	Y		P	Y	11/03/2023	Y	N	12/15/2023	N	Y
Hixson	Jaimie	Study Coordinator	SP	Y	N		P	Y	10/04/2023	Y	N	10/09/2023	N	Y
Hofler	Ryan	Sub-Investigator	SP	Y	N		P	Y	05/26/2021	Y	N	12/15/2023	N	Y
Lockaby	Suzzanne	Project Assistance/Support	SP	Y	N		P	Y	09/14/2021	Y	N	12/15/2023	N	Y
Motiei-Langroudi	Rouzbeh	Sub-Investigator	SP	Y	N		P	Y	06/07/2023	Y	N	12/15/2023	N	Y
Prusick	Parker	Sub-Investigator	SP	Y	N	MD	P	Y	12/21/2023	Y	N	01/09/2024	N	Y
Quintero	Jorge	Co-Investigator	SP	Y	N	PhD	P	Y	11/03/2023	Y	N	12/15/2023	N	Y
Spear	Terri	Project Assistance/Support	SP	N	N		P	Y	11/03/2023	Y	N	12/15/2023	N	Y
van Horne	Craig	Sub-Investigator	SP	Y	N	MD	P	Y	10/04/2021	Y	N	10/19/2023	N	Y
Wilcox	Jared	Sub-Investigator	SP	Y	N	MD	P	Y	08/28/2023	Y	N	10/09/2023	N	Y
Ross	Zachary	Project Assistance/Support	DP	N	Y		P	Y	11/03/2023	Y	Y	12/15/2023	N	Y

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).

Spinal cord injury (SCI) is associated with devastating personal burdens including paralysis, sensory changes, autonomic dysfunction, and chronic debilitating pain. Few effective treatments have been developed with standard of care consisting of state-of-the-art neurocritical care, timely surgical decompression, and rehabilitation. While a variety of novel neuroprotective and neuroregenerative approaches have been posited, clinical trials to date have failed to demonstrate associated clinical benefits.

Current therapies are primarily aimed at reducing secondary injury processes, which are related to inflammation and ischemia, that persist over days-to-weeks following the primary mechanical insult. Intraparenchymal progressive hemorrhagic necrosis and swelling within the restrictive physical barrier of the pial and dural layers leads to further compression and ischemia, propagating the secondary injury cascade.

Early surgical bony decompression following SCI is thought to improve clinical outcomes, specifically after cervical-level injuries.[1, 2] While few developments have been made in actual surgical techniques beyond bony decompression, early reports suggest that reduction of intraspinal pressure (ISP) could reduce secondary injury.[3, 4] Long-recognized but not clinically employed techniques to reduce ISP involve fashioning a dorsal midline myelotomy to allow for intramedullary decompression of hematoma and necrotic tissue and expansion of the dural compartment by opening the dura and sewing in of an expansive patch.

Interestingly, corollary techniques have long been standard-of-care following cranial trauma: removal of the calvarial bone, evacuation of hematoma, expansive dural closure, and treatment of intra-cranial pressure have been proven effective in several randomized clinical trials.[5]

Each of these steps are also at times used in other domains of spinal surgery, specifically oncologic resections. Despite having been demonstrated as an option to manage spinal trauma by Allen over a century ago, [6] these techniques have not been widely studied or applied in modern spinal surgery.

The data obtained from this study will be used to inform and advance the practice of spinal cord decompression and cell-based therapies following acute SCI. Information on microsurgical technique adjustments, neurocritical nursing care standards, medical management, and ISP metrics may prove invaluable in advancing the feasible and safe aspects of these interventions.

SCI is a severely disabling neurological condition leading to impaired mobility, pain, and autonomic dysfunction. As potentially neuroprotective strategies, dorsal myelotomy and expansive duraplasty (DMED) along with cell-based therapies (e.g., autologous nerve tissue graft implantation, ANGI) are recognized as promising candidates to promote functional recovery. However, no trials of these therapies in patients have yet provided reproducible evidence of clinical efficacy, challenged by small effect sizes, low immune suppression, and low sensitivity study designs.

This pilot study design represents the first stage of a systematic evaluation of DMED +/- ANGI performed in the early/acute phase after SCI. Performance of DMED at early timepoints is expected to have the greatest impact on minimizing the deleterious effect of increased ISP and secondary injury due to PHN, which is known to be ongoing over the first hours and days after SCI. Assessment of the feasibility and safety of performing DMED +/- ANGI represent a critical first step prior to engaging in any larger-scale multicenter evaluations of efficacy.

Future larger-scale phases of the study will focus on elucidating the efficacy of these interventions in protecting against secondary neuronal injury processes and in improving function after SCI. The pilot data generated from this study will prove crucial in seeking a larger award from the National Institutes of Health (NIH) and other funding sources.

While refinements and combined therapies may prove useful, widespread clinical translation of currently employed cell transplantation protocols will likely face critical logistic and safety-related obstacles, particularly in the most opportune acute phase after SCI. The need for cell culturing and concomitant immunosuppression are fraught with potential complications, especially considering the relative immune compromised state and elevated risk of infections in the acute phase after SCI that can independently negatively impact neurological outcomes.[7]

As such, evaluation of the feasibility and safety of an autologous cell-based implantation paradigm that does not require cell culturing or concomitant immunosuppression appears ideal. Fortuitously, an autologous nerve grafting paradigm has already been established at the University of Kentucky in patients with Parkinson's disease undergoing deep brain stimulator placement.[8, 9]

Significance: There are currently no standard of care neuro-protective strategies for the treatment of acute traumatic SCI. Methylprednisolone is no longer considered standard of care based on its dubious clinical benefit combined with its demonstrated adverse effect on immune function.[14] The sodium-channel blocker, Riluzole, was recently evaluated in a phase 3 trial of 193 patients by the NACTN group.[15, 16] While safety data appeared favorable, efficacy in improving neurologic outcomes was not shown. Other potential therapies are either at the
pre-clinical or early pilot stage.[17]

Progressive hemorrhagic necrosis (PHN) represents an increasingly well-characterized early mechanism of secondary injury that negatively impacts neurologic outcomes. Structural failure of the integrity of intramedullary capillaries, so called ‘capillary fragmentation’ is thought to underlie this acute and dynamic secondary injury process. Animal studies modeling contusional SCIs across different laboratories have revealed a 2-2.5-fold increase in extravasated intramedullary blood within the first 12-24 hours following blunt impact trauma. [18-20]
As such, given the direct linkage between distinct microscopic hemorrhages within the cord and the progressive secondary injury and neurologic deterioration following SCI, it is no surprise that PHN has long been deemed a potential target for therapy dating back over a century.[6] In addition to the parallel PHN induced secondary injury processes involving oxidative stress and the release of toxic substances like heme degradation products, it is noteworthy that PHN also leads to intradural mass effect related to progressive spinal cord swelling, a process that is directly proportional to the severity of the impact. Since early reports suggesting that dorsal myelotomy, a longitudinal midline incision in the spinal cord, together with the removal of “contused tissue were beneficial in injured dogs and humans, only occasional reports of animal studies have shown proof of the benefits from hemorrhagic necrosis removal.[21, 22]

Besides simply allowing for unhindered spinal cord swelling and improvement in intraspinal pressures, DMED also allows an opportunity for an assessment of the potential supplemental and even synergistic effects of cell-based therapies in modulating the local microenvironment after SCI. Implantation of growth-factor producing cells or stem cells has been validated in numerous pre-clinical models of CNS injury and neurodegeneration.[23-26]

More recently, small-scale evaluations of cell-based therapies have been undertaken at various stages after SCI with reassuring safety profiles.[27] However, several important practical limitations have been noted with these protocols that significantly limit the potential for widespread and safe use of cell implantation in the early post-traumatic setting. Most critically, the need for cell culturing and concomitant immunosuppression introduce significant logistic and safety-related considerations, especially considering the relative immune compromised state and elevated risk of infections in the acute phase after SCI that can independently negatively impact neurological outcomes.[7]

As a way to bypass these obstacles, ANGI represents a unique cell-based therapy that can allow for prompt intervention at the injury site without the need for immunosuppression.

Fortuitously, neurosurgery and neuroscience colleagues at the University of Kentucky have already established and validated a reproducible source of cellular tissue from the peripheral nervous system,[8, 9] that contain injured-peripheral nerve tissues shown to include a variety of cells that express several key growth factors and repair molecules including glial cell line-derived neurotrophic factor, brain-derived neurotrophic factor, nerve growth factor, and neurotrophin-3. They have implanted ANGI in to the CNS of 80 participants without any serious adverse events related to the study intervention and with the most common study-related adverse event being paresthesias and acute pain at the lateral aspect of the foot and ankle ipsilateral to the biopsy. Amongst other possible cellular neurotrophic sources 9 contained within these grafts, Schwann cells are known to transdifferentiate after injury into an activated repair phenotype through a c-Jun mediated pathway and produce a host of repair and survival promoting neurotrophins and anti-apoptotic factors.[28]

Objectives

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

Specific Aim 1: Assess whether dorsal myelotomy and expansive duraplasty (DMED) after cervical acute traumatic SCI, performed either without or with autologous nerve graft implantation (ANGI), is safe and feasible (n = 5 each)

Safety: Vital signs, clinical examination findings, and clinical laboratory results will be carefully and continuously monitored during the course of hospitalization. Adverse events (AEs) will be assessed throughout the course of hospitalization through Day 28.

Feasibility: To assess the feasibility of running a larger phase II or III study among this population of patients where treatment must begin within the acute time frame. The number of patients who would otherwise be eligible for the study but did not receive study treatment within the 48-hour time frame (ratio of recruited versus screened) and the rate of recruitment (recruited versus eligible) will be recorded. As part of assessing the procedural feasibility, the number of participants who enrolled and received DMED and who received ANGI will be recorded. To assess the compliance feasibility of the study, the number of participants attending each follow-up visit will also be summarized.

Specific Aim 2: Assess whether intraspinal pressure and metabolism can be reliably measured in real-time after dorsal myelotomy and expansive duraplasty, performed either without or with autologous nerve graft implantation (n =5 each). Participants will be monitored in the neurointensive care unit for 7 days or longer (as needed) postoperatively.

Prior to study initiation, ICU personnel will be trained on all study protocols along with the assistance of the nursing manager / educator. Clinical exams, as part of the standard of care, including International Standards for Neurological Classification of Spinal Cord Injury (ISNCSCI) motor scores, will be obtained daily until day 7, then weekly while admitted. ISP will be monitored in real-time with a commercially available indwelling intradural microsensor. [4] Cerebrospinal fluid for microdialysis will be obtained days 1-4, and 7. [3, 12]

Specific Aim 3: Preliminarily assess whether ANGI, in addition to DMED impacts intraspinal pressure and metabolic measurements.

Study Design

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

- *Clinical Research*: Indicate whether subjects will be randomized and whether subjects will receive any placebo.
- *Community-Based Participatory Research*: If you are conducting community-based participatory research (CBPR), describe strategies for involvement of community members in the design and implementation of the study, and dissemination of results from the study.
- *Qualitative research*: Indicate ranges where flexibility is needed, if a fixed interview transcript is not available, describe interview topics including the most sensitive potential questions.
- *Research Repositories*: If the purpose of this submission is to establish a Research Repository (bank, registry) and the material you plan to collect is already available from a commercial supplier, clinical lab, or established IRB approved research repository, provide scientific justification for establishing an additional repository collecting duplicate material. Describe the repository design and operating procedures. For relevant information to include, see the UK Research Biospecimen Bank Guidance or the UK Research Registry Guidance.

This is a double-blind, 12-month pilot study to evaluate of the safety, feasibility, and preliminary efficacy of dorsal myelotomy and expansive duraplasty performed either without or with autologous nerve graft implantation after acute traumatic spinal cord injury. Ten participants will be allocated to receive either DMED (n=5) or DMED + ANGI (n=5) based on a block design. Participants and assessors will be blinded to group allocation. Excess sural nerve samples will be collected for banking/analysis (may include proteomic, culturing, genomic, cellular analysis).

Attachments

Subject Recruitment Methods & Advertising

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

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

For additional information on recruiting and advertising:

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

Potential participants will be those who arrive for treatment from the UK Neurosurgery service/Farhadi's patients. A clinical member will introduce the study either to the potential participant or the potential participant's LAR. A member of the study team, authorized to obtain informed consent, will then explain the risk and benefits of participating in the study to the potential participant or LAR.

Researchers may participate in radio or TV/video 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.

Researchers may participate in patient group presentations where the study may be discussed.

We will ensure that future advertising used during the study will not be implemented until the IRB has reviewed and approved those ads.

To protect confidentiality, all subjects are assigned a unique number, and this number is used for labeling of all samples and the identification of all laboratory material obtained from subjects, and there is no public release of the name of the subject from whom the material was derived. All data are kept in a password protected computer file or in locked filing cabinets.

Attachments

Research Procedures

Describe how the research will be conducted.

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

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

We propose that intraspinal pressure management starting at the time of surgical decompression following acute SCI alone, or with ANGI, may ultimately provide a meaningful impact to improve functional outcomes and quality of life. As a first step, we propose to systematically assess the safety and feasibility in this at-risk patient population. We will perform dorsal myelotomy to promote hematoma and necrosis evacuation for patients that have sustained severe acute cervical / thoracic SCI. This will be performed along with expansive duraplasty during standard surgical (bony) decompression with or without autologous nerve graft implantation (ANGI) in 5 participants each (n = 10 total). As a cell-based therapy, ANGI allows for a unique opportunity for prompt intervention at the injury site without the need for immunosuppression.

As part of research, participants will have intrathecal pressure probes and microdialysis catheters inserted at the time of surgery. Each participant will undergo a pre-operative MRI to inform the extent of decompression and dural expansion, and a post-operative MRI on day 2 to confirm that surgical goals were achieved. Continuous monitoring of intraspinal pressures, biochemical profiles, adverse events, ASIA impairment scores, and functional independence measures will be performed from the neurointensive care unit to one year postoperatively.

Screening and Registration Procedures - Participants with suspected acute cervical or thoracic SCI will be screened upon arrival to hospital. As part of the standard of care, these evaluations will occur prior to enrollment:
• Vital signs (Temperature, Blood Pressure, Respiration rate, Pulse, O2 saturation, Height, Weight)
• Physical examination and Medical History
• Spinal cord injury (SCI) Time, Cause, and Level of injury
• Demographics and Clinical Variables (age, race, gender, and body mass index (BMI)
• Neurological examination including ISNCSCI motor and sensory assessments
• ECG (12-lead)
• Clinical laboratory tests (complete blood count, chemistry, liver function tests)

Eligible participants will be enrolled and undergo study procedures within the first 48 hours after documented SCI. This injury-to-procedure timeframe appears feasible given the injury-to-admission times reported in recent SCI studies. For instance, in the phase 3 Riluzole study, 94.6% underwent surgical decompression within 24 hours, which was typically preceded by completion of CT and MRI studies.[16]

Study-related Management (standard-of-care) :
• Serial vital signs (temperature, blood pressure, pulse, respiration rate, O2 saturation) and neurologic (International Standards for Neurological Classification of Spinal Cord Injury - ISNCSCI) assessments
• Blood work; CT scans of the spine and head (as indicated); pre- and post-operative MRI of the cervical/thoracic spine

Cervical / thoracic CT studies will reveal the nature of the associated spinal fracture and/or misalignment. Acute SCI management guidelines, most recently revised by a consensus panel in 2013[14], will be adhered to. These guidelines include avoidance of hypoxia and hypotension with induced hypertension as needed to keep mean arterial pressure = 85mmHg for 7 days. The ability to undergo early surgical intervention, which is increasingly recognized as a standard-of-care intervention,[2] constitutes an inclusion criterion for the study.

Surgical Protocol: All subjects will undergo spinal cord decompression and instrumented spinal stabilization through a posterior approach according to standard-of-care guidelines in place at the Department of Neurosurgery, University of Kentucky. The extent of laminectomies will be based on the extent of cord edema as noted on the pre-operating MRI study. All patients will also undergo dorsal myelotomy and expansive duraplasty (DMED) under microscopic magnification. The dorsal dura will be incised longitudinally in the midline with the length once again estimated from the length of the spinal cord edema on the pre-operative MRI. Under high microscopic magnification, the dorsal midline of the spinal cord will be identified to allow for a myelotomy using a microsurgical beaver-blade extending through to the anteroposterior midline. While no attempt will be made to suction or otherwise excise intramedullary spinal cord hematoma, it is understood that spontaneous egress of variable amounts of clotted blood may be noted given the severity of the trauma typically noted in some patients. Following probe insertion (see below), we will then suture an appropriately-sized elliptical patch of artificial dura (e.g., Durepair, Medtronic, Minneapolis, MN) to the dural edges to expand the intradural space. The duraplasty will be supplemented with a patch of fibrin glue (e.g., Tisseel, Baxter, Deerfield, IL).

A total of n = 5 patients will undergo supplemental ANGI procedure in addition to DMED. Once the dorsal myelotomy is completed, the sural nerve will be accessed through a standard neurosurgical approach as employed for biopsy of the sural nerve. A 4 cm incision will

be fashioned starting above the lateral epicondyle and an approximately 2 cm section of the nerve will be excised, placed in normal saline, and appropriately trimmed. Under direct high-magnification microscopic visualization, an approximately 3-5 mm segment (cut into smaller, 0.5 to 1mm segments) of sural nerve/fascicles will be carefully deposited over the dorsal myelotomy site. Great care will be taken to ensure that the subsequent duraplasty is expansive enough such that no additional compressive effect is associated with the ANGI procedure.

Probe / Catheter Insertion: The ISP probe and microanalysis catheter will be inserted in the operating room. During the standard-of-care posterior approach, a 14-gauge introducer will be used to separately tunnel an FDA-approved pressure probe (e.g., Codman Microsensor Transducer®, Integra LifeSciences, Princeton, NJ) and an FDA-approved microdialysis catheter (e.g., M dialysis AB, North Chelmsford, MA) intradurally one level below the injury over the surface of the injured cord and tunneled up to the site of maximal cord swelling as noted on the preoperative MRI study.[4] The ISP probe will be calibrated and it along with the catheter will be advanced subdurally, under the operating microscope, through the dural hole until their tips lie at the site of maximal spinal cord swelling according to the MRI scan. The separate slit dural openings will be covered with fibrin glue (e.g., Tisseel®, Baxter, Deerfield, IL). Standard-of-care postoperative CT studies (when available) will be used to confirm in situ probe positioning.

Intraspinal Pressure and Arterial Blood Pressure Monitoring: The pressure catheter will be connected to a Codman ICP Express monitoring device linked via a ML221 amplifier to a PowerLab running LabChart (AD Instruments, Colorado Springs, CO). Standard-of-care continuous arterial blood pressure monitoring will be performed through a radial arterial line, in turn also connected to the PowerLab system. ISP and blood pressure signals are sampled at approximately 1 kHz, and patients are monitored for up to 7 days following SCI. Data will be analyzed using Labchart (AD Instruments, Colorado Springs, CO) and ICM+ (www.neurosurg.cam.ac.uk/icmpl us). Spinal cord perfusion pressure will be calculated as mean arterial pressure (MAP) – ISP. Of note, ISP will be expected to be different from intrathecal pressure (typically measured in the lumbar spine) as the swollen, injured cord is compressedagainst the dura thus compartmentalizing the intrathecal space.[29]

Microdialysis (MD) Setup and Analysis: Microdialysis will be initiated postoperatively in the neurointensive care unit in all enrolled subjects.[12] Central nervous system fluid will be perfused at 0.3 µL/min using the 106 microdialysis pump (M dialysis AB). MD vials will be changed hourly and analyzed using ISCUSFlex (M dialysis AB) for glucose, lactate, and pyruvate. The lactate-to-pyruvate ratio will be calculated. The first two samples from each subject will be discarded to allow priming of the MD catheter and stabilization of the metabolite concentrations. Metabolite levels will be
compared to corresponding hourly averages of ISP, MAP, and SCPP. As noted by other authors [12], we expect that such a MD protocol will measure spinal cord surface metabolism at the injury site, which is thought to correlate with intraparenchymal injury site metabolism.[30]

Post-treatment follow-up: After surgery, subjects will be followed in the neuro intensive care unit and throughout their hospital stay per routine, standard-of-care clinical guidelines for the management of acute SCI. Following hospital discharge, subjects will then undergo assessments in accordance with the study calendar.

Post-treatment follow-up: Day 28 (± 7 days), Day 42 (± 7 days)
• Review unresolved AEs
• Record additional AEs/SAEs
• ASIA Impairment Scale

Post-treatment Follow-up: Day 84 (± 14 days), Day 182 (± 14 days) and Day 365 (± 30 days)
• Review unresolved AEs
• Record additional SAEs
• ASIA Impairment Scale
• Spinal Cord Independence Measure (vIII)

Attachments

Attach Type	File Name
ResearchProcedures	Table of Events v1 dated 21 Nov 23 (Clean).pdf
ResearchProcedures	Table of Events v1 dated 21 Nov 23 (HL).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.

Either a member of the research team or the participant/LAR will provide the information collected on the following forms. This information is pivotal to our study.

We will collect the following from the participants:
· Demographic information (Name, initials, gender, race, age, study number, mailing address, home phone number, social security number, ID number (if applicable)
· Dates including date of birth, hospital admissions/discharges, study visits

· Results of physical exams, EKGs, MRIs, CT imaging, and other diagnostic and medical procedures related to this study
· Medical and medication information related to this study
· American Spinal Injury Association Assessment
· Spinal Cord Independence Measure
· ISP, arterial blood pressure, and microdialysis measurements
· Peripheral nerve tissue

The following data collection forms will be used:
- ASIA-ISCOS Worksheet 10-2019
- SCIM-Spinal Cord Independence Measure vIII

Attachments

Attach Type	File Name
DataCollection	ASIA-ISCOS-Worksheet_10.2019.pdf
DataCollection	SCIM-SPINAL CORD INDEPENDENCE MEASURE vIII.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.

This pilot study will be undertaken with colleagues in the Department of Neurosurgery and at the Spinal Cord and Brain Injury Research Center (SCOBIRC) at the University of Kentucky. As such, our group of investigators will have access to world-class infrastructure and mentorship. Specifically, investigators with experience in sophisticated data analysis will critically contribute to the interpretation of continuous ISP and spinal fluid metabolic measurements. Fortuitously, neurosurgery and neuroscience colleagues at the University of Kentucky have also established and validated a reproducible source of cellular tissue from the peripheral nervous system that contain injured-peripheral nerve tissues shown to include a variety of cells that express several key growth factors and repair molecules. The availability of this validated implantation model bypasses the need for cell culturing and concomitant immunosuppression that introduce significant logistic and safety related considerations; this is especially the case considering the relative immune compromised state and elevated risk of infections in the acute phase after SCI that can independently negatively impact neurological outcomes.

The participants will be followed by Francis Farhadi, MD, PhD his research team, which includes the coordinator, and the professional staff of the spinal cord center. Emergency medical equipment, medications and supplies are available in the hospital and KNI to handle any untoward reaction. This project will utilize the EDT to obtain clinical/claims data associated with the inclusion/exclusion criteria provided in the study design.

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 risks listed are risks associated with the research-only procedures and that risks associated with standard of care procedures will be addressed with the participants in separate discussions with providers/consents/etc.

DMED: The potential risks of DMED relate to exposure of the intradural compartment (opening and closure of the dural membrane) and the midline dorsal myelotomy. Although rare (estimated at < 1%), there is a possibility of intraparenchymal and/or intradural

bleeding with associated neurological worsening. As per standard-of-care guidelines, all participants will be closely monitored in the neurosurgery ICU for any signs or neurological worsening and will undergo further diagnostic imaging as indicated. Despite water-tight closure of the dura with an expansive dural substitute patch, there is also a potential risk of spinal fluik leak and pseudomeningocele formation (estimated risk of 5%). As per standard-of-care guidelines, wound healing will be closely monitored during the post-operative period for any evidence of swelling or abnormal fluid collection.

ISP and microdialysis monitoring: Although routine standard-of-care measures will be taken to prevent surgical-site infection, the presence of indwelling cathethers / probes is associated with an additional risk of infection (estimated at 1%). As per standard-of-care guidelines, all participants will be closely monitored for any signs of systemic or surgical-site infection during the post-operative period in the neurosurgical ICU and following transfer to progressive care.

Blood draw: Blood samples will be taken during the study. Using a needle to remove blood from a vein. It may be necessary to try more than once to draw blood. Participants might feel pain or be light-headed from this and may have the following at the site of the needle stick when blood is drawn:
• Additional bleeding at the site of the blood draw
• Temporary discomfort
• Bruising
• Infection (rarely)

Sural nerve graft harvesting procedures. The surgical risk is minimal and this part of the protocol is considered a minor surgery and employs a surgical approach that is used for sural nerve biopsies. The incision is ~3cm in length located above and behind the lateral aspect of the ankle. The sural nerve is a sensory nerve that supplies sensation to the lateral aspect of foot and heel. Participants in previous studies have reported either a temporary sensory loss or permanent loss of sensation to a small dermatomal patch on the outer aspect of the foot and/or heel. For this participant population, this would not be a concern. Although this study does involve grafting, participants will donate their own tissue. This eliminates the risk of graft rejection and obviates the need for immunosuppressant medications typically used with other transplant studies.

Magnetic Resonance Imaging (MRI): The MRI may be with or without contrast agent and participants may notice discomfort, tingling or warmth in the lips, metallic taste in the mouth, tingling in the arm, nausea, or headache. These symptoms go away quickly. There is also a small risk of an allergic reaction to the contrast agent.

Sedation (Diazepam): Respiratory depression, Suicidality, Dependency and abuse, Bradycardia, Hypotension, Syncope, Depression, Anterograde amnesia, Headache, Nausea, Tremor, Dystonia

Genetic or genomic testing is possible: Even without the participant’s name or identifiers, genetic information is unique to them. The results of genetic research apply to both the participant and their family members. Genetic information used improperly to discriminate or support negative stereotypes could cause the participant their family distress. The researchers do not know whether future technology will make it possible for someone to trace the participant’s genetic information back to them.

There may be additional risks associated with banking specimen samples such as the risks associated with blood draws and the potential for a breach of confidentiality.

Social Risks: Breach of confidentiality could impact insurability, employability, reproduction plans, family relationships, immigration status, paternity suits, and stigmatization, if applicable.

There is a federal law called the Genetic Information Nondiscrimination Act (GINA). Generally, GINA makes it illegal for health insurance companies, group health plans, and most employers to discriminate against a person based on their genetic information. Be aware that GINA does not protect the participant against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. It also does not prohibit discrimination on the basis of an already known genetic disease.

There is no guarantee that the subjects will receive any benefit from taking part in this study.

Safety Precautions: Provisions to guard against the potential risks and discomforts above are as follows: Every precaution to prevent a direct study injury will be taken by medical personnel and the investigators. The research participant will be followed by physicians, fellows, registered nurses and other research staff members for the duration of the participant's participation. Routine care can be provided by the hospital staff.

Emergency medical equipment, medications and supplies will be at the physician's disposal should the participants have an acute untoward reaction. The participants will be monitored for clinical adverse experiences throughout study therapy.

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).

Patients with acute traumatic cervical SCI are routinely admitted to the ICU for close observation of respiratory and hemodynamic parameters. Particularly for patients with upper-cervical injuries, there is a low threshold for instituting assisted ventilation given their well-known loss of respiratory drive and associated increase in physiologic dead space. Hemodynamic parameters are also carefully monitored in real-time in the neurosurgery ICU via an arterial line (placed per standard-of-care guidelines). For several days after SCI (up to seven days), mean arterial pressure (MAP) measurements are kept ? 85 mmHg to promote optimal perfusion of the spinal cord

and to minimize secondary injury processes. Finally, standard extradural surgical decompression is now widely accepted as appropriate in the treatment of acute traumatic cervical SCI to potentially enhance neurological outcomes (doi: 10.1001/jamasurg.2022.4454). As per standard-of-care guidelines, patients are offered early (? 24h) decompression for acute traumatic SCI when medically feasible and based on individual considerations.

Back to Top

Records, Privacy, and Confidentiality

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

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

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

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

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

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

The investigative team maintains the right to keep, preserve, use and dispose of the findings of this investigation in accordance with University of Kentucky Records Management and IRB policies and guidelines. Investigational records from this study will be maintained in a confidential manner; subject names will not be associated with any published results.

All clinical information obtained will be considered to be part of the patient's medical chart and will be treated as such according to standard HIPAA guidelines and regulations. Stored electronic data will be stored in encrypted and password protected devices. Binders will be kept in a locked cabinet in the office of the study coordinator. Research records will be maintained at 740 S. Limestone K005, Lexington, KY 40536. During and after this study, the subjects' identity will be kept confidential to the extent permitted by law. Patients will be identified by a code, and, except as set forth below, personal information from subjects' records will not be released to any third party without written permission.

The records may be reviewed, by local site personnel, agents of the University of Kentucky, the Institutional Review Board may review the study records including those with identifying information.

Incidental findings: The researchers currently list in the ICF that if they learn of new information in regard to this study, and it might change participant's willingness to stay in this study, the information will be provided to the participant. In addition, findings may be offered to study participants if they meet the following criteria:

a) The finding has important health implications for the participant, and the associated risks are established and substantial.
b) The finding is actionable, that is, there are established therapeutic or preventive interventions or other available actions that have the potential to change the clinical course of the disease.
c) The test is analytically valid or in the case of imaging, qualified professionals interpret the scan and the disclosure plan complies with all applicable laws. Study investigators will be available to discuss results.

REDCap: REDCap (Research Electronic Data Capture) is a secure web-based application tool used for building and managing surveys and databases used for research, created by Vanderbilt University. Vanderbilt developed a Consortium of institutions to share this research and data capture tool. The Consortium was launched in 2006 and has Consortium partners including the University of Kentucky. The security of the application is largely dependent on the IT infrastructure and environment in which REDCap is hosted, not the software itself. Vanderbilt has a list of best practices that were utilized when installing and hosting the REDCap instance locally. For more information on Consortium Partners, please view http://www.project-redcap.org/consortium.php.

The University of Kentucky REDCap instance was installed in the CCTS & IBI Enterprise Data Center (EDC) in 2008 and is in the Lee Todd, Jr. Building at 789 South Limestone on the University of Kentucky campus. The web server and the database server are located on separate servers behind a firewall with in-house control with UK's campus network. In addition, in order to maintain secure communications, the web server has a secured security license (SSL) and is located on https://redcap.rdmc.org/redcap/. Research data is stored locally and is backed up daily using MySQL Administrator software using Windows Server software.

REDCap implements authentication of users that log into the system. All accounts are set up using the LinkBlue ID and are password

protected. Furthermore, the software has an auto logout feature included. Once a REDCap user creates a project, they are the owner and have full rights to the project. Once study personnel/users are added by the owner, user rights or privileges are established. User rights can be for view only, edit only, or view and edit. User rights or access can be further limited to individual case forms within the project. Custom locking of case report forms or digital signatures are another feature that can be assigned in the user rights section of the project. REDCap maintains a built-in audit trail that logs all user activity and pages viewed. The logging record can be viewed by those with proper user rights.

Data exportation is defined within the user rights section and can be limited by the project owner as a full data set or as a deidentified data set. Data is exported into comma delimited (CSV) files which can be uploaded into Excel, SAS, SPSS, STATA, or R for analysis. Advanced features of deidentification include removal of free form text, removal of dates, date shifting that keeps the integrity of the date interval, and/or removal of fields tagged as identifiers. REDCap also has an internal email function for large data sets or sensitive data. This feature can be used to send emails to non-REDCap users as well. The file is stored on REDCap and allows nonusers to log in using a secure password to download the files (password to access email is sent in a separate email to the user).

REDCap stores its system data and project information in various relational database tables within a single MySQL database. All data submitted via the web server by the researcher is encrypted while transmitted. The portable devices do not download the data, it is directly stored into the secure web-based connection (https) behind the firewall. This reduces the liability and possibility of researchers losing protected health information. All files are password protected once entered into the system. All project data is stored and hosted locally. No data is ever shared with Vanderbilt or the consortium partners.

REDCap software uses various methods to protect against malicious users that attempt to identify or exploit any security vulnerabilities in the system. In REDCap, all data is intentionally filtered, sanitized, and escaped for every query string data found in the URL while accessing REDCap. Server environment variables that are vulnerable to forgery by users are checked and sanitized. All user submitted data is filtered for any possible harmful mark-up tags (scripts) and then escaped prior to ever being displayed on a web page within the application. SQL queries sent to the database server from REDCap are properly escaped prior to being sent. User defined data used within the SQL query has the data type checked to prevent any mismatching of data types (makes sure a number is really a number). The processes of filtering, sanitation, data type checking, and escaping all help to protect against methods of attacks.

The Consortium has grown to 6506 active institutional partners in 153 countries with 2,400,000 users since 2006. The University of Kentucky currently has over 2500 users with over 5300 projects in production and another 5900 projects in development. All members of the Consortium are active in the future development of REDCap functionality and software testing.

Subject charts, video, recordings, and any other items containing confidential items will be stored in a safe place overnight and not left on the desk. Charts will not be left in an area where others might have access to them. Use of the HIPAA-compliant REDCapTM database management system will be used to store study data. Electronic information will also be stored on OneDrive, Microsoft Teams, UK Healthcare servers, or UK study personnel computers that are password protected and encrypted.

Binders will be kept in a locked cabinet in the office of the study coordinator. Study coordinator will serve to manage theaccess to the information. The study information collected from the subjects' participation in the study will be collected and stored in paper charts and in the REDCapTM database management system.

Any electronic information will be stored behind password/firewall PC and/or encrypted external hard drives. Nerve graft tissue and blood will be collected in coded tubes and stored in a locked facility with limited access.

Summary genomic and medical information may be placed into scientific databases along with data from other research participants. Genomic data and health information would not be labeled with identifiable information. The researchers ask participants/LAR to opt-in/opt-out if they want to provide their consent to sharing tissue samples and health information with other investigators.

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

◉ Yes ○ No

Payment

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

Participants will receive a payment for participating in this study as follows:
• $200 after the Day 182 visit and $200 after completing the Day 364 visit toward reimbursement for travel expenses.

The total compensation for completing the study will be $400 provided they undergo the final two study visits. If they receive $600 or above by participating in research, it is potentially reportable for tax purposes.

Participants will receive a Cash Card at the end of each visit they complete as compensation for that visit.

The information and samples provided by participants will no longer belong to them and might be used in studies that lead to new products for research, diagnosis or treatment. There is no plan to keep participants informed of findings from these studies. These products might have some commercial value. There are no plans to provide financial compensation to the participant should this occur.

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.

The participants and/or their insurance company, Medicare or Medicaid will be responsible for the costs of all care and treatment they receive during this study that they would normally receive for their condition. These are costs that are considered medically reasonable and necessary and will be part of the care they receive if they do not take part in this study.

Participants or their insurer will be responsible for all costs associated with:
• SCI (Cervical/Thoracic) assessment done at screening,
• Standard of care surgical management of SCI,
• 2 MRIs performed at screening and Day 2,
• CT scan preformed at screening,
• laboratory tests performed at screening and follow-up visits,
• EKG performed at screening
• Clinical visits associated with AIS and SCIM assessments

The study-related procedures, and study visits will be provided at no charge to the participant or their insurance company.

Costs associated with treating any injury suffered while participating in this study will be the responsibility of the participants or their insurer. Participants will be advised to ask their insurer if they have any questions regarding their insurer’s willingness to pay these costs; this includes contacting Medicare or Medicaid if they are covered by Medicare, or Medicaid.

A co-payment/deductible may be required by their insurer or Medicare/Medicaid even if the insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be substantial.

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.

All research personnel who work with participants their data or their research samples will have completed training in the protection of human research participants per guidelines issued by ORI. This protocol will receive final approval by the institutional IRB.

The standing independent Data Safety Monitoring Board (DSMB) as chartered by the University of Kentucky Center for Clinical and Translations Science (CCTS) will be used to monitor the safety of this study. The DSMB will review subject recruitment, AE’s, side effects, laboratory results, dropouts, protocol violations, and inclusion/exclusion criteria. SAE will be identified by investigators and monitored by the DSMB. The DSMB will meet tri-annually or as needed. More frequent meetings will take place if side effects or other problems are prevalent.

The PI will be responsible for ensuring participants’ safety on a daily basis. This protocol will be continuously monitored in real-time by the principal investigator, study team, and study coordinator for adverse events (AEs).

AEs will be graded according to intensity.
• Mild: Discomfort noticed but no disruption of normal daily activity.
• Moderate: Discomfort sufficient to reduce or affect normal daily activity.
• Severe: Incapacitating with inability to work or perform normal daily activity.

The attribution scale for AE reporting will be as follows.
• Definitely There is clear evidence to suggest a causal relationship, and other possible contributing factors can be ruled out.
• Probably: There is evidence to suggest a causal relationship, and the influence of other factors is unlikely.
• Possibly: There is some evidence to suggest a causal relationship.
• Unrelated: AE is judged to be clearly due to extraneous causes and does not meet the above criteria.

The relationship of the AE to DMED +/- ANGI will be specified by the investigators as either unrelated, possibly/probably related, and definitely related. When considering the potential relationship of an AE, the study investigators’ assessment will include consideration of the incidence of complications anticipated in the SCI population in the absence of these procedures. For instance, in 485 subjects with acute SCIs recruited into the NACTN database, 1376 total complications were recorded during the initial hospitalization.[11]

The UK reporting categories to the IRB will be used:

· Prompt Reporting of an Unanticipated problem involving risk to subjects or others (including Unanticipated serious or life-threatening AEs) and anticipated or unanticipated research-related deaths to the IRB and Institutional Biosafety Committee. The UK IRB Policy on Unanticipated Problem and Safety Reporting will be followed.
· Continuation Review Reporting if any problems/AEs occurred within 12 months before the continuation review request for a written summary of all problems/AEs involving subjects since the study was initiated, whether anticipated or unanticipated, serious or not serious, life-threatening or not life-threatening, or related or not related to the IRB. The UK IRB has specific reporting requirements for external funding agencies that comply with the requirements of each specific agency.

Monitoring of adverse events. Adverse events will be monitored via exams, vital signs, lab tests, review of subject's medical chart, etc. and documented. Each visit will be documented with a progress note in the research chart.

In addition to presenting a summary of all AEs, where possible, a comparison of AEs occurring in study subjects vs. those occurring in matched historical controls, as captured in the North American Clinical Trials Network (NACTN) registry will be made. To facilitate this comparison, AEs will be grouped into one of 8 systems as reported in the NACTN registry: cardiac, pulmonary, hematology, gastrointestinal/genitourinary, infections, skin, failure of stabilization, and neuropsychiatric.[10, 11] These AEs will be described further with respect to the specific name of the event (that is, the "type" of event; for example, for cardiac events, the type could be bradycardia or other dysrhythmia, cardiac arrest, etc.). Severity ("intensity", as per the NACTN chart) as well as relatedness to the study procedures will also be assessed. The frequency of AEs, as well as mortality (all-cause and system-related), will be compared to that of a matched cohort from the NACTN registry.[10, 11]

All issues of patient care disruption, failure of recording and methodology will be addressed in real-time throughout study period.

Personnel education, missed events, equipment concerns, and care outside trial parameters will be reviewed by Investigators monthly. These data will inform the assessment of feasibility of recordings as per study methodology, and allow for improvements in design for subsequent clinical trials.
Data will be collated and reviewed quarterly throughout the study period. Issues regarding missing data points as well as the potential need for safety-related protocol changes will be discussed with Investigators on an ongoing basis. Interim analysis will be performed yearly with biostatistician support. These analyses will compare study data to historical institutional cohorts. While the study is not powered for endpoint/secondary analyses of motor scores and functional outcomes, the data will be expected to inform power analyses for further study phases.[13]

Back to Top

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

Researchers will remove participant's name or other direct identifiers from their information or samples. The researchers will label their information or samples with a code and will store the key separately from the master code list. Only select staff will have access to the list that links the code.

Banking of tissue specimens: Peripheral Nerve: A small sample (approximately 1 cm) of the peripheral nerve obtained during surgery will be kept at the University of Kentucky under the direction of the PI for research purposes indefinitely. The nerve tissue collected will not be needed for the diagnosis or management of the participant's health and will not interfere with the graft that will be implanted during the main part of the study. The results of any testing done on the samples will not be shared with the participant.

No additional tissue will be taken. If participants agree, the tissue samples obtained for this research study may be tested immediately or may be frozen and examined later.

Donated samples may be tested for markers that might indicate how the nerve graft is working. Samples may undergo genetic testing as part of understanding the mechanisms or markers involved in nerve grafting and how an individual's genetics may affect the outcome. Participants will be informed that genetic information is unique to the participant, making it possible for someone to trace the information.

Samples will be kept until the researchers receive written notice from the participant that they wish to have their sample destroyed. However, the information and samples that have already been used or shared may not be withdrawn. Subjects will be advised that destruction of their sample may not be possible because the sample may no longer exist.

Data Sharing: The focus of this study is SCI, but participants will be asked at the time of consent, their willingness to permit sharing of data and biospecimens.

STORING AND SHARING PARTICIPANT INFORMATION OR SPECIMEN SAMPLES FOR FUTURE USE:

The researchers will remove participant's name or other direct identifiers from their information or samples. The researchers will label the information or samples with a code and will store the key separately from the master code list. Only select staff will have access to the list that links the coded information.

Identifiable or de-identified information or samples may be shared with other researchers within the University of Kentucky without additional informed consent, provided an Institutional Review Board (IRB) has approved this action.

A researcher who receives participant information or specimens will sign an agreement. They will store participant information in a secure database and these individuals will sign a confidentiality agreement.

Are you recruiting or expect to enroll **Non-English Speaking Subjects or Subjects from a Foreign Culture**? (does not include short form use for incidentally encountered non-English subjects)

○ Yes ◉ No

Non-English Speaking Subjects or Subjects from a Foreign Culture

Recruitment and Consent:

Describe how information about the study will be communicated to potential subjects appropriate for their culture, and if necessary, how new information about the research may be relayed to subjects during the study.
When recruiting Non-English-speaking subjects, provide a consent document in the subject's primary language. After saving this section, attach both the English and translated consent documents in the "Informed Consent" section.

Cultural and Language Consultants:

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

- This person should be familiar with the culture of the subject population and/or be able to verify that translated documents are the equivalent of the English version of documents submitted.
- The consultant should not be involved with the study or have any interest in its IRB approval.
- Please include the name, address, telephone number, and email of the person who agrees to be the cultural consultant for your study.
- ORI staff will facilitate the review process with your consultant. Please do not ask them to review your protocol separately.

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

Local Requirements:

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

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

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

Does your study involve **HIV/AIDS research and/or screening for other reportable diseases (e.g., Hepatitis C, etc…)**?
○ Yes ◉ No

HIV/AIDS Research

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

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

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

PI-Sponsored FDA-Regulated Research

Is this an investigator-initiated study that:

1) involves testing a Nonsignificant Risk (NSR) Device, or
2) is being conducted under an investigator-held Investigational New Drug (IND) or Investigational Device Exemption (IDE)?
○ Yes ◉ No

PI-Sponsored FDA-Regulated Research

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

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

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

Has the sponsor-investigator completed the mandatory PI-sponsor training prior to this submission?
○ Yes ○ No

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

Attachments

HIPAA

0 unresolved comment(s)

Is HIPAA applicable? ◉ Yes ○ No

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

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

☐ HIPAA De-identification Certification Form

☑ HIPAA Waiver of Authorization

Attachments

Attach Type	File Name
Waiver	Full HIPAA Waiver Approval Letter.pdf
Waiver	HIPAA Waiver signed.pdf

STUDY DRUG INFORMATION

0 unresolved comment(s)

The term drug may include:

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

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

○ Yes ◉ No

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

LIST EACH DRUG INVOLVED IN STUDY IN THE SPACE BELOW

Drug Name:

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

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

☐ Investigational Drug Service (IDS) UK Hospital

Other Location:

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

○ Yes ○ No

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

IND Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

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

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

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

For guidance and reporting requirements at the conclusion of treatment see the Expanded Access SOP.

Complete and attach the required Study Drug Form picking "Study Drug Form" for the document type. Any

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

Attachments

STUDY DEVICE INFORMATION

0 unresolved comment(s)

A DEVICE may be a:

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

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

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

○ Yes ◉ No

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

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

LIST EACH DEVICE BEING TESTED IN STUDY IN THE SPACE BELOW

Device Name:

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

○ Yes ○ No

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

IDE/HDE Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

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

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

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

For guidance and reporting requirements at the conclusion of treatment see the Medical Device SOP.

Does the intended use of any research device being tested (not clinically observed) in this study meet the regulatory definition of Significant Risk (SR) device?

- Yes. Device(s) 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.
- NOTE: If the non-UK sites or non-UK personnel are engaged in the research, there are additional federal and university requirements which need to be completed for their participation. For instance, the other site(s) may need to complete their own IRB review, or a cooperative review arrangement may need to be established with non-UK sites.

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

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

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

Attachments

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

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

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

RESEARCH ATTRIBUTES

0 unresolved comment(s)

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

☐ Not applicable

Check All That Apply

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

FUNDING/SUPPORT

0 unresolved comment(s)

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

☐ Not applicable

Check All That Apply

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

Other:

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

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

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

KSCHIRT

Add Related Grants

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

Add Related Grants

Grant/Contract Attachments

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

○ Yes ◉ No

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

DOD SOP Attachments

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

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

Assurance/Certification Attachments

OTHER REVIEW COMMITTEES

0 unresolved comment(s)

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

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

○ Yes ◉ No

Additional Information

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

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

Attachments

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

ADDITIONAL INFORMATION/MATERIALS

0 unresolved comment(s)

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

Approval Letter Details:

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

SN 002 - Adding Parker Prusick to SP list

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
Other	Biosafety Registration B22-4006-M2 Exp 083025.pdf
Other	Same-Surgical-Procedure-Exception-under-21-CFR-1271.15(b)- Questions-a.pdf
Other	Serial 002 cover Memo.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:

First Name	Last Name	Role	Department	Date Signed	
Craig	van Horne	Department Authorization	Neurosurgery	10/20/2023 01:45 PM	View/Sign
Francis	Farhadi	Principal Investigator	Neurosurgery	10/17/2023 06:42 PM	View/Sign

Department Authorization

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

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

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

Principal Investigator's Assurance Statement

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

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

activities in the role described for this research study.
9. To recognize and accept additional regulatory responsibilities if serving as both a sponsor and investigator for FDA regulated research.

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

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

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

SUBMISSION INFORMATION

0 unresolved comment(s)

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

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

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

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

Your protocol has been submitted.

Download all

	Document Type	File Loaded	Document Description	File Size	Modified By	Mod Date
	ApprovalLetter	ApprovalLetter.pdf		0.083	scbe223	1/9/2024 3:06:12 PM
	Stamped Consent Form	ICF v1 dated 21Nov2023 (clean).pdf		0.300	scbe223	1/9/2024 3:06:12 PM
	AddInfoProduct	Serial 002 cover Memo.pdf	Sn 002 cover memo	0.044	llashe2	1/9/2024 10:09:11 AM
	Waiver	Full HIPAA Waiver Approval Letter.pdf	Waiver of Authorization Approval	0.139	scbe223	12/4/2023 12:42:15 PM
	AddInfoProduct	Same-Surgical-Procedure-Exception-under-21-CFR-1271.15(b)- Questions-a.pdf	FDA Guidance - Same Day Surgical Procedure Exceptions	0.077	llashe2	11/22/2023 12:55:35 PM
	AddInfoProduct	Biosafety Registration B22-4006-M2 Exp 083025.pdf	Biosafety approval letter	0.121	llashe2	11/22/2023 12:46:00 PM
	Waiver	HIPAA Waiver signed.pdf	HIPPA Waiver (signed)	0.084	llashe2	11/22/2023 12:36:30 PM
	ResearchProcedures	Table of Events v1 dated 21 Nov 23 (HL).pdf	Table of Events v1 dated 21 Nov 23 (HL)	0.135	llashe2	11/22/2023 12:27:18 PM
	ResearchProcedures	Table of Events v1 dated 21 Nov 23 (Clean).pdf	Table of Events v1 dated 21 Nov 23 (Clean)	0.175	llashe2	11/22/2023 12:25:32 PM
	Informed ConsentHIPAA Combined Form	ICF v1 dated 21Nov2023 (clean).pdf	ICF v1 dated 21 Nov 23 Clean	0.335	llashe2	11/22/2023 12:11:35 PM
	AddInfoProduct	IRB Requested Revisions.pdf	IRB Requested Revisions	0.264	scbe223	11/16/2023 4:18:37 PM
	ImpairedConsent	Form T - 11Oct23 - 2Di (Clean).pdf	IRB Form T - 2Di	0.263	llashe2	10/11/2023 12:51:40 PM
	DataCollection	SCIM-SPINAL CORD INDEPENDENCE MEASURE vIII.pdf	SCIM- Spinal Cord Independence Measures vIII	0.115	llashe2	10/10/2023 10:06:46 AM
	DataCollection	ASIA-ISCOS-Worksheet_10.2019.pdf	ASIA-ISCOS Worksheet, Oct 2019	0.275	llashe2	10/10/2023 10:06:11 AM

Protocol Changes

Protocol Number: 91630

Click link to sort Changed Date
Additional Information/Materials AdditionalInformation changed by llashe2 on 1/9/2024 10:09:22 AM
SN 004 ¶
Adding ¶
- Ryan Cassidy ¶
- Ryan C. Hofler ¶
- Rouzbeh Motiei-Langroudi ¶
- Kris Dyer ¶
- Zahraa F Al-Sharshahi ¶
- Ellen Hartman ¶
- Terri Spear ¶
¶
Removing: Zachary Ross ¶
¶
Role change Quintero added consenting privileges and gave Lockaby consenting privileges2 - Adding Parker Prusick to SP list

Study Personnel Changes:

Status	PPIdentity	ProtocolID	PersonID	RoleInProtocol	IsContact	LastName	FirstName	Email	DeptCode	RoomBuilding	SpeedSort	PhoneNum	DeptDesc	AuthorizedConsent	ResponsibilityInProject	Degree	Rank	StatusFlag	IsRemoved	ModBy	ModDate	SFI	IsPIRN	MiddleName
Updated	800933	93463	12710317	SP	N	Prusick	Parker	Parker.Prusick@uky.edu						Y	Sub-Investigator	MD		P	N	llashe2	1/9/2024 9:57:58 AM	N		

No comments