Document Coversheet

Study Title: Prospective Evaluation of Mechanomyography Versus Triggered Electromyography for Intraoperative Assessment of Cortical Breaches During Instrumented Lumbar Spine Surgery

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	12/2/2024
NCT Number:	NCT05352048
IRB Number	76122
Coversheet created:	6/16/2025

PROTOCOL TYPE (VERSION 5)

IRB Approval
12/2/2024
IRB # 76122
IRB2

IMPORTANT NOTE: If you select the wrong IRB type or "Protocol Process Type" while your *Initial Review (IR)* application is in draft, or if your IR application has been returned to you for requested revisions or additional information, you may change your selections. You will not be able to change your selections for "Which IRB" or "Protocol Process Type" after initial *approval* of your application (the option to change your selections is not available for MR or CR).

For guidance, see:

- Which IRB?
- Which Protocol Process Type?
- "Getting Started"

Please contact the Office of Research Integrity (ORI) at 859-257-9428, IRBsubmission@uky.edu, or request a consult to resolve any questions regarding your selections *prior* to submitting your Initial Review application.

Which IRB

◉ Medical ○ NonMedical

Protocol Process Type

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

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

EXPEDITED CERTIFICATION

0 unresolved comment(s)

To Be Completed Only If Protocol is to Receive Expedited Review

Applicability

A. Research activities that (1) present no more than *minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
B. The categories in this list apply regardless of the age of subjects, except as noted.
C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
D. The expedited review procedure may not be used for classified research involving human subjects.
E. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review—expedited or convened—utilized by the IRB.

**"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. 45 CFR 46.102(i)*

Check the appropriate categories that apply to your research project:

☑ Study was originally approved by the full IRB at a convened meeting.

☐ 1) Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

A. Research on drugs for which an investigational new drug application is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
B. Research on medical devices for which (i) an investigational device exemption application is not required*; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.**

* Study must meet one of the IDE Exempt categories listed on the Device Form Attachment.
** An approved Device used in research according to its approved labeling is considered Exempt from IDE requirements.
NOTE: Select Category 1 for compassionate use medical device applications or individual patient expanded access investigational drug applications for which FDA has waived the requirement for full review.

☐ 2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

A. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
B. From other adults and children* considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

NOTE: Intravenous (IV), Port, Central, or any other lines are NOT eligible under this category even if the research involves "minimal risk".

*In Kentucky, "child/children" refers to all individuals less than 18 years of age unless the individual(s) is/are legally emancipated. (See Informed Consent SOP for discussion of "Emancipated Individuals" under Kentucky state law.) Individuals less than 18 years of age who are not emancipated meet the federal definition for "child" (e.g., DHHS, FDA, and U.S. Department of Education). Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." If conducting research outside the state of Kentucky, you are responsible for complying with applicable state law.

☐ 3) Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

A. Hair and nail clippings in a nondisfiguring manner;
B. Deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
C. Permanent teeth if routine patient care indicates a need for extraction;
D. Excreta and external secretions (including sweat);
E. Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
F. placenta removed at delivery;
G. Amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
H. Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
I. Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
J. Sputum collected after saline mist nebulization.

☐ 4) Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:

A. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
B. Weighing or testing sensory acuity;
C. Magnetic resonance imaging;
D. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
E. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

☐ 5) Research involving materials (data, documents, records, or specimens) that have been or will be collected solely for non-research purposes (such as medical treatment or diagnosis) as well as research involving existing information or specimens that were previously collected for research purposes, provided they were not collected for the currently proposed research. (Note: Some research in this category may qualify for Exempt review. This listing refers only to research that is not exempt.)
(Note: If submission includes materials previously collected for either non-research or research purposes in a protocol for which IRB approval expired, you may check Category 5. However, a separate category must also be selected for prospective collection of data/specimens obtained solely for research purposes)

☐ 6) Collection of data from voice, video, digital, or image recordings made for research purposes.

☐ 7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)

CONTINUATION REVIEW/FINAL REVIEW

0 unresolved comment(s)

In accordance with federal regulations and/or local policies, the IRB conducts periodic review of all currently approved projects. If you need your IRB approval to continue and you do not complete and submit the required materials in a timely manner, IRB approval will expire at the end of your current approval period.

If you have any questions, please contact the Office of Research Integrity at 859-257-9428 or email IRBsubmission@uky.edu.

To initiate your continuation review (CR)/annual administrative review (AAR), or properly close your study, complete this section and update/correct all other sections of your IRB application as applicable.
*****IMPORTANT*** Before leaving this page to update other sections of your application, be sure to SAVE this section first.**

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1. Status of the Research

Check the statement(s) that best describe(s) the current status of your research:

- ☐ No subjects have enrolled to date.
- ☐ Recruitment and/or enrollment of new subjects or review of records/specimens continue.
- ☐ Study is closed to enrollment, but subjects still receive research-related interventions (e.g., treatment, blood draws).
- ☐ Study enrollment is permanently closed; subjects have completed all research-related interventions; and the study remains active only for long-term follow-up of subjects (see Tool Tip above for info on long-term follow-up of subjects).*
- ☑ Research has progressed to the point that it involves 1) Data analysis, including analysis of identifiable private information or identifiable biospecimens; and/or 2) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care.*
- ☐ The remaining research activities are limited only to data analysis. There is access to records or specimens either directly or through codes or links to the data.*
- ☐ The remaining research activities are limited only to data analysis. There is no subject/record/specimen identifying codes or links to the data; the researcher or research team cannot readily ascertain the subject's identity.*
- ☐ All study activities are complete. IRB approval can be inactivated.

*Possibility that review will move from Full to Expedited.

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2. If subjects have been enrolled within the last year, and the IRB approved a consent/assent form for your study:

Please attach a complete, signed copy for the last two subjects enrolled with **each** consent/assent form/HIPAA form since the last annual review.
(Example: If 3 different approved consent forms were used since the last annual review, please provide the two most recent signed copies of each version for a total of six.)

Attachments

Attach Type	File Name
Entire Signed Consent Form	Study ID - 64. B.J. ICF.pdf
Entire Signed Consent Form	Sutdy ID 065 - R.K. ICF.pdf

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3. Informed Consent

If the study is **open to subject enrollment, please go to the Informed Consent section of the E-IRB Application and verify attachment(s) include:**

- One clean copy in PDF (without the IRB Approval stamp) of the currently approved consent/assent document(s), or,
- If requesting changes to the consent/assent document(s), submit one copy with the changes highlighted (and designate Document Type as "Highlighted"), and one clean copy in PDF (without the changes highlighted).

If the study is **open to subject enrollment and the IRB has waived the requirement to document informed consent, please go to the Informed Consent section of the E-IRB Application and verify attachment(s) include:**

- One clean copy in PDF of the currently approved document used for the informed consent process (e.g., cover letter, phone script), or,
- If requesting changes to the consent/assent document(s), submit one copy with the changes highlighted (and designate Document Type as "Highlighted"), and one clean copy in PDF (without the changes highlighted).

If the study is **closed to subject enrollment, please go to the Informed Consent section of the E-IRB Application and remove Informed Consent Documents designated to get an IRB approval stamp to avoid having them appear valid for enrollment.**

4. Unanticipated Problems Involving Risk to Subjects or Others/Adverse Events Summary & Assessment

Did any **problems/adverse events** occur during the last 12 months?

(•) Yes ( ) No

In the space below, provide a written summary of both unanticipated problems* and available information regarding adverse events since the last review (e.g., initial review or annual/continuing review). The amount of detail provided in such a summary will vary depending on the type of research being conducted; in many cases, such a summary could be a brief statement that there have been no unanticipated problems and that adverse events have occurred at the expected frequency and level of severity as documented in the research protocol, the informed consent document, and investigator's brochure (if applicable). **The summary must include the PI's assessment whether the problems/adverse events warrant changes to the protocol, consent process, or risk/benefit ratio.**

Note: It is the IRB's expectation that all unanticipated problems involving risk to subjects or others or related deaths requiring prompt reporting are submitted in the appropriate time frame (See Policy [PDF]). Your response to this Annual/Continuing Review is considered assurance that all prompt reportable problems/adverse events have been submitted for IRB review.

The following adverse events have occurred in the last 12 months:
1. LE DVT
2. Pneumonia
3. SAE – Acute Ischemic Stroke - left PCA
4. Intraoperative CSF leak

The PI has determined that these events have no relation to the study and that there are no changes to the protocol or risk/benefit ratio required.

*For multisite studies, the written summary should describe external events determined to be unanticipated problems involving risk to subjects or others.

5. Subject Info To-Date

Our records for the previously approved IRB application indicate the **IRB approved estimate** of subjects to be enrolled (or records/specimens reviewed) is:

75

Enter the number of enrolled subjects (or records/specimens reviewed) that **have not been previously reported** to the IRB

14

Our records for the previously approved IRB application indicate the previous total # of subjects enrolled (or records/specimens reviewed) since activation of the study is:

51

The new total number of subjects enrolled (or records/specimens reviewed) since activation of the study:

65

Please review the Project Info section for the IRB approved estimate of subjects to be enrolled (or records/specimens reviewed). If this new total exceeds your approved estimate of subjects to be enrolled (or records/specimens reviewed), please update the number in the field for Number of Human Subjects in the Project Info section.

6. Data and Safety Monitoring Board (DSMB)/Plan (DSMP)

If your study is monitored by a DSMB or under a DSMP, attach all documentation (i.e. summary report; meeting minutes) representing Data and Safety Monitoring activities that have not been previously reported to the IRB.

Attachments

7. Since the most recent IRB Initial/Continuation Review Approval:

Have there been any **participant complaints** regarding the research?

○ Yes ◉ No

If yes, in the field below, provide a summary describing the complaints.

Have any **subjects withdrawn** from the research voluntarily or by you as the PI for reasons related to safety, welfare, or problems related to the conduct of the research? If a participant does not meet the screening criteria for a study even if they signed a screening consent it is NOT considered a withdrawal.

○ Yes ◉ No

If yes, in the field below, provide a detailed explanation to the withdrawal(s) including if participants were lost to contact.

Has any **new and relevant literature** been published since the last IRB review, especially literature relating to risks associated with the research?

○ Yes ◉ No

If yes, attach a copy of the literature as well as a brief summary of the literature including, if pertinent, the impact of the findings on the protection of human subjects.

Attachments

Have there been any **interim findings?**

○ Yes ◉ No

If yes, attach a copy of **Interim Findings.**

Attachments

Have **subjects experienced any benefits?**

○ Yes ◉ No

If yes, in the field below, provide a description of benefits subjects have experienced.

Have there been any **inspections/audits/quality improvement reviews** of your research protocol resulting in the need for corrective action in order to protect the safety and welfare of subjects?

○ Yes ◉ No

If yes, please attach documentation evidencing the outcome(s) and any corrective action(s) taken as a result.

Attachments

Was an FDA 483 issued as a result of any inspections/audits?

○ Yes ◉ No

If yes, submit documentation using attachment button above.

8. Risk Level:

Our records for the previously approved IRB application show your research is:

Risk Level: 1

Has something during the course of your research changed the level of risk?

○ Yes ◉ No

If yes, go to the Risk Level section, mark the appropriate risk level, and in the field below, describe why the risk level has changed:

9. Funding/Support:

Our records for the **previously approved** IRB application indicate your research is being submitted to, supported by, or conducted in cooperation with the following external or internal agency(ies) or funding program(s):

- ☐ 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:

Please **update the Funding/Support section of your IRB application** if needed, including the following attachments if they contain changes not previously reported to the IRB:

- A current copy of your **protocol if you are conducting industry/pharmaceutical research;**
- A current **Investigator Brochure** (submit a copy with all changes underlined).
- A **new or revised grant application** for this project.

Did your project receive extramural funding?

◉ Yes ○ No

If yes, please review and correct if necessary, the OSPA Account # information under the **Funding/Support section** of your IRB application.

If the project is externally funded, has the sponsor offered any of the research team enrollment incentives or other personal benefit bonuses? (e.g., cash/check, travel reimbursements, gift checks, etc.)

○ Yes ◉ No ○ N/A

Note: It is University of Kentucky policy that personal benefit bonuses are not allowed. If these conditions change during the course of the study, please notify the IRB.

10. Project Information

Our records for the previously approved IRB application indicate your estimated project end date is:

03/01/2025

If you have a new estimated project end date, please go to the Project Info section and change the date in the field for Anticipated Ending Date of Research Project.

11. Study Personnel

Our records for the previously approved IRB application indicate the following individuals are study personnel on this project (if applicable):

Last Name	First Name
Anderson	Kyla
Arora	Harshit
Darabi	Mohammad Hassan
Dyer	Kriston
Hixson	Jaimie
Iqbal	Ahmad
Lockaby	Suzzanne

Please review the individuals listed above and update your records as needed in the Study Personnel section of the E-IRB application, being sure that each individual listed has completed or is up-to-date on the mandatory human research protection training [see the policy on Mandatory Human Subject Protection Training FAQs (required every three years)].

12. Progress of the Research

To meet federal requirements the IRB is relying on your RESEARCH DESCRIPTION as a protocol summary and their expectation is that it is up-to-date. If the currently approved protocol (or research description) in your E-IRB application is outdated, please make applicable changes, and describe in the field below any substantive changes and explain why they are essential. If none, insert "N/A" in the text field below. If you are closing your study, you may use the space below to summarize the final status of the research.

N/A

Note: No changes in the research procedures should have occurred without previous IRB review. Approval from the IRB must be obtained before implementing any changes.

Provide a brief **summary** of any **modifications that affect subject safety and/or welfare** approved by the IRB since the last initial or continuation review (If none, insert "N/A" in the text field below.):

N/A

Attach one copy of the most recent progress report sent to the FDA, if available. All PI-sponsored IND/IDE studies are required to submit a copy of the FDA progress report.

Attachments

13. Confidentiality/Security

Review your Research Description section and update the Confidentiality portion, if necessary, to describe measures for security of electronic and physical research records (e.g., informed consent document(s), HIPAA Authorization forms, sensitive or private data).

14. Subject Demographics

Our records for the previously approved IRB application indicate the following categories of subjects and controls are included in your research:

- ☐ 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
- ☐ International Citizens
- ☐ Normal Volunteers
- ☐ Military Personnel and/or DoD Civilian Employees
- ☑ Patients
- ☐ Appalachian Population

Please review the Subject Demographics section of your IRB application for accuracy, and note the following:

If during the course of your research 1) any prisoners have been enrolled, OR 2) subjects have been enrolled that became involuntarily confined/detained in a penal institution that have not been previously reported to the IRB, go to Subject Demographic section in your E-IRB application and mark "prisoners" in the categories of subjects to be included in the study, if it is not already marked.

Note: If either 1 or 2 above apply, and you have received funding from the Department of Health and Human Services (HHS), a Certification Letter should have been submitted to the Office for Human Research Protections (OHRP); prisoners and individuals who have become involuntarily confined/detained in a penal institution cannot continue participation in the research until OHRP issues approval. If the Certification has not been submitted, contact the Office of Research Integrity.

Based on the **total # of subjects** who have enrolled, complete the subject demographic section below:

Participant Demographics

	Cisgender Man	Cisgender Woman	TGNB/TGE	Unknown/Not Reported
American Indian/Alaskan Native				
Asian				
Black or African American	1	1		
Latinx				
Native Hawaiian or Other Pacific Islander				
White	33	30		
American Arab/Middle Eastern/North African				
Indigenous People Around the World				
More than One Race				
Unknown or Not Reported				

If unknown, please explain why:

15. Research Sites

Our records for the previously approved IRB application indicate that you are conducting research at the following sites:

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 Schools/Education Institutions

- ☐ Fayette Co. School Systems *
- ☐ Other State/Regional School Systems
- ☐ Institutions of Higher Education (other than UK)

Other Medical Facilities

- ☐ Bluegrass Regional Mental Health Retardation Board
- ☐ Cardinal Hill Hospital
- ☐ Eastern State Hospital
- ☐ Nursing Homes
- ☐ Shriner's Children's Hospital
- ☐ Other Hospitals and Med. Centers

- ☐ Correctional Facilities
- ☐ Home Health Agencies
- ☐ International Sites

Other:

If the above listed sites are not accurate, go to the Research Sites section of the E-IRB application to update the facilities at which research procedures have been or will be conducted.

If you are adding a new off-site facility, you may also need to update your E-IRB application Research Description, Research Sites, Informed Consent, and other affected sections as well as any documents which will list the off-site facility. Documents needing updating may include, but not limited to:

- Consent forms (attachment under Informed Consent section)
- Brochures (attachment under Additional Info section)
- Advertisements (attachment under Research Description section) ;
- Letter of support (attachment under Research Sites section)).

Please revise applicable sections and attachments as necessary.

16. Disclosure of Significant Financial Interest

Disclosure of Significant Financial Interest:

Our records for the previously approved IRB application indicate that you, your investigators, and/or key personnel (KP) have a significant financial interest (SFI) related to your/their responsibilities at the University of Kentucky (that requires disclosure per the UK administrative regulation 7:2):

○ Yes ◉ No

If you need to update your records, please go to the PI Contact Information section and/or Details for individuals listed in the Study Personnel section to change your response to the applicable question(s).

17. Supplementals

To ensure the IRB has the most accurate information for your protocol you are expected to re-visit the E-IRB application sections and make corrections or updates as needed. At a minimum you are being asked to review the following sections for accuracy:

STUDY DRUG INFORMATION—Please review for accuracy.
STUDY DEVICE INFORMATION—Please review for accuracy.
RESEARCH ATTRIBUTES—Please review for accuracy.
OTHER REVIEW COMMITTEES -- Please review for accuracy.

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

Prospective Evaluation of Mechanomyography Versus Triggered Electromyography for Intraoperative Assessment of Cortical Breaches During Instrumented Lumbar Spine Surgery

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.

MMG vs. EMG for cortical breach detection

Anticipated Ending Date of Research Project: 3/1/2025

Maximum number of human subjects (or records/specimens to be reviewed) 65

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:	Hooman F	Room# & Bldg:	Med Science Bldg MS103B
Last Name:	Farhadi	Speed Sort#:	0298
Middle Name			
Department:	Neurosurgery - 7H853	Dept Code:	7H853
PI's Employee/Student ID#:	12570745	Rank:	Associate Professor
PI's Telephone #:	(859)562-0247	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.

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

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

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

Age level of human subjects: (i.e., 6 mths.; 2yrs., etc..) 18 to 100

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

The study population will include subjects eligible for posterolateral lumbar fusion surgery. Common diagnoses include: lumbar degenerative disc disease, lumbar foraminal stenosis, spondylolisthesis, spondylosis, lumbar radiculopathy, chronic leg and back pain. The study can accommodate 55 subjects but will be stopped once 300 pedicle screws have been placed (potentially prior to the 55 subject enrollment.)

Consecutive subjects will be considered for inclusion in this trial if they satisfy the following criteria.

1. Subject is scheduled to undergo a one-, two-, or three-level posterolateral spinal fusion surgery using Depuy Synthes Expedium pedicle screw instrumentation.
2. Subject must be over the age of 18 years old.
3. Subject has been unresponsive to conservative care for a minimum of 6 months.
4. The subject must in the investigator's opinion, be psychosocially, mentally, and physically able to fully consent and comply with this protocol including the required follow-up visits, the filling out of required forms, and have the ability to understand and provide written informed consent.

Exclusion Criteria

Subjects will be excluded from this trial if they have a preexisting medical condition or comorbidity that makes them a poor candidate for spine surgery or inhibits their ability to complete the standard of care preoperative and postoperative procedures. Criteria considered for exclusion includes:

1. Subject has inadequate tissue coverage over the operative site.
2. Subject has an open wound local to the operative area, or rapid joint disease, bone absorption, or osteoporosis.
3. Subject has a condition requiring medications that may interfere with bone or soft tissue healing (i.e., oral or parenteral glucocorticoids, immunosuppressants, methotrexate, etc.).
4. Subject has an active local or systemic infection.
5. Subject has a metal sensitivity/foreign body sensitivity.
6. Subjects with implanted pacemakers.
7. Subject is morbidly obese, defined as a body mass index (BMI) greater than 45.
8. Subject has any medical condition or extenuating circumstance that, in the opinion of the investigator, would preclude participation in the study.
9. Subject is currently involved in another investigational drug or device study that could confound study data.
10. Subject has a history (present or past) of substance abuse (recreational drugs, prescription drugs or alcohol) that in the investigator's opinion may interfere with protocol assessments and/or with the subject's ability to complete the protocol required follow-up.
11. Subjects who are pregnant or plan to become pregnant in the next 24 months or who are lactating.
12. Subject is involved in or planning to engage in litigation or receiving Worker's Compensation related to neck or back pain. Participation may give a legal team, or case manager inappropriate grounds to deny a claim, blaming residual symptoms or sequela on study participation.
13. Osteoporosis (per the investigator's diagnosis or per a T-score > 2.5 SD below the mean for a young, healthy adult) that may prevent adequate fixation of screws and thus preclude the use of a pedicle screw system.
14. Subjects who have a known or suspected allergy to any of the following antibiotics and/or reagents: vancomycin, aztreonam, meropenem
15. Immune compromised subjects
16. Known sensitivity to device materials
17. Subject is a prisoner.

Attachments

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

Participant Demographics

	Cisgender Man	Cisgender Woman	TGNB/TGE	Unknown/Not Reported
American Indian/Alaskan Native:				
Asian:				
Black/African American:				

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

If unknown, please explain why:

Subjects eligible for posterolateral lumbar fusion surgery will be considered for enrollment. No preference, targeting, or exclusion will occur based on sex or ethnicity.

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

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

- ☐ Children (individuals under age 18)
- ☐ Wards of the State (Children)
- ☐ Emancipated Minors
- ☐ Students
- ☐ College of Medicine Students
- ☐ UK Medical Center Residents or House Officers
- ☐ Impaired Consent Capacity Adults
- ☐ Pregnant Women/Neonates/Fetal Material
- ☐ Prisoners
- ☐ Non-English Speaking (translated long or short form)
- ☐ International Citizens
- ☐ Normal Volunteers
- ☐ Military Personnel and/or DoD Civilian Employees
- ☑ Patients
- ☐ Appalachian Population

ADDITIONAL INFORMATION:

Please visit the IRB Survival Handbook for more information on:

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

Other Resources:

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

Assessment of the potential recruitment of subjects with impaired consent capacity (or likelihood):

☐ Check this box if your study does NOT involve direct intervention or direct interaction with subjects (e.g., record-review research, secondary data analysis). If there is no direct intervention/interaction you will not need to answer the impaired consent capacity questions.

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

○ Yes ◉ No

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

Examples of such conditions include:

- Traumatic brain injury or acquired brain injury
- Severe depressive disorders or Bipolar disorders
- Schizophrenia or other mental disorders that involve serious cognitive disturbances
- Stroke
- Developmental disabilities
- Degenerative dementias
- CNS cancers and other cancers with possible CNS involvement
- Late stage Parkinson's Disease
- Late stage persistent substance dependence
- Ischemic heart disease
- HIV/AIDS
- COPD
- Renal insufficiency
- Diabetes
- Autoimmune or inflammatory disorders
- Chronic non-malignant pain disorders
- Drug effects
- Other acute medical crises

Attachments

INFORMED CONSENT/ASSENT PROCESS/WAIVER

0 unresolved comment(s)

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

Additional Resources:

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

Consent/Assent Tips:

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

How to Get the Section Check Mark

1. You must:

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

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

Check All That Apply

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

Attachments

Informed Consent Process:

Using active voice, in the text box below, describe how investigators will obtain consent/assent. Include:

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

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

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

○ Yes ◉ No

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

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

Special considerations may include:

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

Patients appropriate for inclusion in the study will be identified by clinical staff and faculty during neurosurgical evaluation at scheduled clinic appointments at the Kentucky Neuroscience Institute and University of Kentucky Hospitals. Identified potential subjects will be made aware of the research opportunity and why they are a candidate for inclusion by clinical staff. If the patient is agreeable to learning more, research personnel authorized to obtain consent will meet with the patient. They will be given the consent form and provided ample time to review. The study personnel will then review the consent with the patient and allow the patient to ask any questions they have. It will be made clear which parts of the surgery are standard, occurring regardless of participation in the research study, and which parts of the surgery are experimental.

If the study personnel obtaining consent is a member of the surgical team, this information will be disclosed to the patient prior to obtaining consent. It will be made clear to the patient that treatment with standard of care surgery, radiographs, and intraoperative monitoring are not dependent on their willingness to participate in the research study. The use of MMG and it's comparison to EMG will be the only part of surgical intervention that is investigational if the patient chooses to consent.
Subject complaints will be directed to the Office of Research Integrity at the University of Kentucky. The primary investigator will also be available to address subject complaints.

☐ 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
Anderson	Kyla	Project Assistance/Support	SP	N	N		P	Y	03/03/2022	Y	N	01/25/2022	N	Y
Arora	Harshit	Project Assistance/Support	SP	Y	N		P	Y	01/06/2024	Y	N	01/17/2024	N	Y
Darabi	Mohammad Hassan	Project Assistance/Support	SP	Y	N		P	Y	12/06/2023	Y	N	01/17/2024	N	Y
Dyer	Kriston	Data Collection	DP	Y	Y		P	Y	06/10/2024	N	N	05/25/2022	N	Y
Hixson	Jaimie	Project Assistance/Support	DP	N	Y		P	Y	10/04/2023	Y	N	02/01/2022	N	Y
Iqbal	Ahmad	Project Assistance/Support	SP	N	N		P	Y	01/09/2024	Y	N	03/22/2024	N	Y
Lockaby	Suzzanne	Medical Supervisor	SP	Y	Y		P	Y	04/08/2024	Y	N	01/25/2022	N	Y
Yazell	Morgan	Study Coordinator	SP	Y	N		P	Y	01/19/2023	Y	Y	11/15/2023	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).

Instrumented lumbosacral(L1-S1) spine fusion is a surgical intervention used to treat diseases of the spine such as lumbar degenerative disc disease, lumbar foraminal stenosis, spondylolisthesis, spondylosis, lumbar radiculopathy, and chronic leg and back pain. The rate of spinal fusion increased 62.3% between 2004 and 2015, with 199,140 cases reported in the United States in 2015. Although complications are infrequent, they do occur, and finding ways to mitigate risk allows for better patient satisfaction, decreases the need for additional surgery, and increases quality of life.

Cortical breach is a common known risk of lumbar fusion, and occurs when the trajectory of the pedicle screw extends outside the wall of the vertebrae, potentially causing injury to the cord or nerve roots. This complication happens in 1.35% of the patient population and can cause pain, numbness and weakness. Currently, triggered electromyography (EMG) is used intraoperatively to monitor if a breach has occurred that is causing impingement. Recent studies have questioned the reliability of EMG due to its lack of improvement in surgical outcomes and increase in surgical costs. A retrospective database review published in 2017 cited the instances of cortical breach at 1.36% with EMG and 1.34% without intraoperative neuromonitoring.

Mechanomyography (MMG) is an alternative to EMG being evaluated for use in lumbar fusions to better detect cortical breaches. MMG monitors muscle activity from deeper in the muscle without invasive electrodes and has a lower signal to noise ratio allowing for more accurate, specific detection of nerve impulses.

Objectives

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

The primary purpose of this prospective study is to assess the comparative sensitivity and specificity of mechanomyography versus triggered electromyography for the intraoperative detection of Grade C, D, or E cortical breaches during instrumented lumbar spine surgery. Secondarily, the this cohort will be validated as representative of the general population undergoing lumbar decompression/fusion surgery. We will assess the improvement of pain and disability scores from completed questionnaires (NRS, ODI v2.1a, and PROMIS Global-10), surgical revisions, as well as hospital readmissions (at 30 days or 90 days). Further, the comparative direct and indirect costs associated with the use of mechanomyography versus electromyography will be assessed in our cohort.

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 study will be conducted soley at the University of Kentucky and is designed as a prospective post-market evaluation of the comparative sensitivity and specificity of mechanomyography versus triggered electromyography for the intraoperative assessment of pedicle breaches during instrumented lumbosacral (L1-S1) spine surgery. The 'control' triggered electromyography will be performed concurrently along with the 'experimental' mechanomyography assessments of all pedicle trajectories. Physiological readings from the

control EMG and the experimental MMG will be recorded and compared to see if one system is more accurate than the other. No data on or about the EMG neuromonitor will be collected as study data. CT-based assessment scales are generally regarded as the current optimal method to characterize the relative success of pedicle screw trajectories. In this study, pedicle screw trajectories will be assessed using the subjects' intra-operative CT/3D reformatted images. At the standard of care 6 week and 3 month follow-up time points, we will also assess for any improvements in pain and disability scores using completed questionnaires (NRS, ODI v2.1a, and PROMIS Global-10). All parts of the surgical procedure and assessments of pedicle screw placement using radiolographic technology will be standard of care for the procedure being performed with the exception of the use of the two neuromonitoring systems that are being compared.

In this study, pedicle screw trajectories will be assessed separately by two study investigators using the subjects' intra-operative CT/3D reformatted images. Trajectory accuracies will be determined using a widely employed 2-mm increment grading system.

The Gertzbein–Robbins classification system will be used to define pedicle breaches and is divided into 5 groups (A-E):

• Grade A - No cortical breach (0 mm)
• Grade B - Pedicle cortical breach < 2 mm
• Grade C - Pedicle cortical breach = 2 to < 4 mm
• Grade D - Pedicle cortical breach = 4 to < 6 mm
• Grade E - Pedicle cortical breach = 6 mm

Success Criteria

Since most authors agree that any breach less than 2 mm of the pedicle is safe (including for medial breaches), radiographic success will be defined as achievement of either grade A or B

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

Members of the neurosurgical team assessing the patients lower back problems will make initial contact with potential participants during clinic visits at the Kentucky Neuroscience Institute and in pre-operative settings in University of Kentucky Hospitals. Those found to be candidates for lumbar spinal fusion will be notified of the opportunity to participate in the research study. If they are agreeable to learning more about the study, a member of the study personnel who is authorized to obtain consent will meet with the patient. Details of the study will be thoroughly discussed and all questions the patient has will be answered. Patients who agree to participate and are not eliminated by exclusionary criteria will be consecutively enrolled. No randomization procedures will be included (all pedicle trajectories will undergo combined evaluation with both 'experimental' mechanomyography and 'control' triggered electromyography). Study personnel will convey declining to participate in the study will not prevent them from proceeding with the standard of care procedures for their diagnosis.
No advertising will be performed

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.

Intra-Operative Procedures

After receiving antibiotic prophylaxis, the patient is placed under general anesthesia and positioned prone. A midline posterior approach is performed, exposing the posterior lumbar elements including the facet joints. Free-hand pedicle screw trajectories will then be fashioned bilaterally at each surgical level with fluoroscopic assistance as needed.

Each pedicle screw trajectory will be independently queried using both triggered electromyography (EMG) and mechanomyography (MMG). In parallel to the EMG assessments, the threshold levels for each trajectory will be individually recorded using the SENTIO MMG ball tip probe, followed by querying of the tap, and finally of the pedicle screw itself. Threshold stimulation data will be recorded for each neuromonitoring device. No data about the EMG device itself will be collected. In case of a suspected thin wall or pedicle breach using either modality, particularly when a triggered EMG current threshold of 10 mA or less is noted, the surgeon will have the option of refashioning the trajectory based on ethical surgical judgment principles. However, the surgeon will need to re-record the new trajectory-specific triggered EMG and MMG threshold stimulation values.

After an acceptable trajectory has been determined and stimulation values recorded, the rest of the surgery will proceed with the standard of care procedures. Following screw placement, the central part of the spinal canal is decompressed by laminectomy in cases of stenosis-related neurogenic claudication. In cases of radicular leg pain related to foraminal stenosis, partial facetectomies will be performed as needed to decompress the associated nerve roots. Titanium rods are then positioned interconnecting the screws on each side. The posterolateral cortical bony surfaces are then fully decorticated and supplemented with graft material on both sides.

An intra-operative CT/3D reformatted study (using 2-mm slices) will be performed in all cases immediately after all the hardware installation is completed. The pedicle breach determination measurements (primary outcome) will be based on these intra-operative scans. As per standard-of-care considerations, the surgeon will once again have the option of revising a screw trajectory based on the imaging findings, but will once again be required to re-record the new trajectory-specific triggered EMG and MMG threshold stimulation values. Post-operative care, including X-rays will follow the standard of care for subjects who undergo fusion procedures.

Data will be collected during and immediately after the surgery according to the parameters described by the study case report forms. All intra-operative and peri-operative complications (e.g. excessive blood loss, hematoma, vascular injury, etc.) will be reported and recorded as a complication in the study case report forms.

Per standard of care, post-operative reassessments occur at 6 weeks (± 1 week) and at 3 months (± 2 weeks) including a clinical and radiographic exam. Investigators will use these visits to obtain data from clinical examinations and assess:
• subject compliance with postoperative care instructions,
• ability to return to work and normal activity, and
• any procedure related or device related adverse events since discharge from the hospital
• review of medication usage
• progress towards fusion consolidation
• Neurological status

Subjects will be required to complete self assessment forms
• Each subject will be asked to complete follow-up ODI v2.1a, PROMIS Global-10, and Back / Leg Pain NRS forms at each follow-up visit.

Radiographic assessment: Each subject will undergo a CT/3D reformatted scan intra-operatively to assess for pedicle screw placement. Each subject will also undergo AP and lateral x-rays at the 6 week as well as the 3 month visit with flexion/extension x-rays at the 3 month visit. Imaging obtained is standard for the procedure being performed and will occur regardless of participation in this study.

Attachments

Attach Type	File Name
ResearchProcedures	Oswestry Disability Index.pdf
ResearchProcedures	Numeric Rating Scale for Pain.pdf
ResearchProcedures	SF-36v2.pdf
ResearchProcedures	PROMIS-10.f2f07d80.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.

Within 60 days prior to the surgery date,the following information will be collected:
• Demographic data including year of birth, gender, weight, and height
• Medical history, including a complete history of spinal disorder(s) (non-operative or operative treatments performed)
• Physical examination
• X-Rays
• Current pain medications and other drug therapies.
• Neurological status

Data to be collected during and immediately after the surgery includes:
• Diagnosis
• Duration of surgery
• Threshold values for EMG and MMG devices.
• Blood loss
• OR time
• Length of hospital stay
• Instrumentation used
• Type of procedure
• Surgical levels
• All intra-operative and peri-operative complications.

Data collected at the post-operative 6 weeks and 3 month follow up includes:
• subject compliance with postoperative care instructions
• ability to return to work and normal activity, and
• any procedure related or device related adverse events since discharge from the hospital
• review of medication usage
• progress towards fusion consolidation
• Neurological status
Subject self-assessment: Patient completed forms
• Subject completed follow-up ODI v2.1a, PROMIS Global-10, and Back / Leg Pain NRS forms at each follow-up visit.
• Radiographic assessments: Each subject will undergo a CT/3D reformatted scan intra-operatively to assess for pedicle screw placement. Each subject will also undergo AP and lateral x-rays at the 6 week as well as the 3 month visit with flexion/extension x-rays at the 3 month visit.

Attachments

Attach Type	File Name
DataCollection	IIS Study Calendar.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.

Study personnel will use secure, password protected computer work stations at the University of Kentucky medical center and the Kentucky clinic will be used to access and view subject information. Additional subject information may also be found in REDCap, a secure database system. Paper forms will be stored in locked offices, were only the study team has access

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.

Per the attached device information for usage document potential adverse events associated with SENTIO MMG include nerve damage, burns, sepsis, heart failure, CNS effects such as seizure and pulmonary failure. Such events could be serious but are very unlikely, occurring in less the 1% of cases. Both of these devices are standard of care and these risks are associated with the surgical procedure and present regardless of study participation. These risks will be discussed with the patient during the surgical consenting process, and any condition or comorbidity (e.g pacemakers) that would place the subject at a known increased risk has been included in the criteria for exclusion. The combination of two devices, which is a deviation from standard of care, equates to no quantifiable additional risks for subjects because the process involves sequentially placing an EMG and then a MMG probe on the already inserted pedicle screw to assess for respective electrical responses.The potential AEs are inherent risks for the FDA approved device, and not a result of the study procedures themselves. No clinical decisions will be made pertaining to the results of the monitoring systems utilized in the research setting.

A breach in confidentiality is unlikely, but possible and could lead to psychological distress.
There is no anticipated direct benefit to the participating subjects. Results obtained in this study will help determine the better modality in determining pedicle breaches in patients undergoing instrumented lower back surgery. Proper training of the surgeon by the device manufacture decreases the likelihood of adverse events occurring from device use. Data obtained in this study could help increase the safety of future lumbar spine fusions with non-invasive technology, improving surgical outcomes for future patients.

Risks of confidentiality breach will be minimized by following practices to maintain the confidentiality of the data.

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).

If a patient does not want to participate in the study, the only alternative is to proceed with the standard of care surgery without the use of MMG. All other routine modalities and imaging will still occur.

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

Data of interest will be collected from the patients medical chart in Epic, and radiology reports and images from PACS. Information to be collected from each patient prior to surgery may include demographic information such as year of birth, gender, weight, and height. Medical history including a complete history of spinal disorders and any previous treatments performed, physical examination, x-rays, current medications and drug therapies and neurological studies will be collected.

Data collected during and immediately after surgery includes: diagnosis, duration of surgery, blood loss, OR time, length of hospital stay, instrumentation used, type of procedure, surgical level(s), and readings from intraoperative neuromonitoring devices. In addition, all intra-operative and peri-operative complications (e.g. excessive blood loss, hematoma, vascular injury, etc.) will be reported and recorded as a complication in the study CRFs.

Post-operative data will be collected during routine clinical assessments at 6 weeks and 3 months after surgery. The information collected at these visits will include: compliance with post-operative care instructions, ability to return to work and normal activities, adverse events since hospital discharge that relate to the procedure or device, medication usage, evaluation for fusion consolidation, and neurological status. Patient surveys and forms ODI v2.1a, PROMIS Global-10, and Back / Leg Pain NRS will be recorded, and results from AP and lateral and flexion/extension x-rays.
The data for this study will be organized and stored on a secure REDCap database, CT images and x-rays will remain in the PACS radiology software. All electronic forms will be stored on University of Kentucky computers requiring unique username and password for access. Documents such as surveys, radiology reports, adverse events, and other data points taken from the subjects medical chart and recorded on the case report form will be kept in locking cabinets in the study coordinators office with lock and key entry to the office, and keypad lock into the department. Access to subject data will be limited to study personnel, and the code used to create study ID numbers will be kept confidential by the PI and the study coordinator.

The study is expected to span 36 months. Data will be retained for 6 years after the closure of the study per sponsor requirements. Since the only identifier being used is the study ID assigned at enrollment, there will be no identifiers removed from data sets. The source code will be destroyed with the participant data once retention requirements are met. Once the required time has passed, electronic data will be ran through a confidential, secure data shredder and paper documentation will be disposed of in the blue confidential PHI document containers in the Kentucky
Neuroscience Institute for incineration.
The surgeon/PI has been trained in the use and safety features of the device to mitigate the risks associated with its use. To prevent breach of confidentiality, only members of the study personnel will be given access to participant in formation. Workstations used to access the subjects information are password protected and all electronic medical records are encrypted and behind a firewall. REDCap, OneDrive, and
Microsoft Teams are all password protected, encrypted, and require permission to access the contents. Papers will be stored in locked cabinets in rooms requiring keypad access or key lock access in the investigator and/or coordinators offices.

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

Payment

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

There are no payments or incentives being offered to participants.

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.

There are no associated costs to subjects for testing the device.

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.

Adverse and serious adverse events will be reviewed daily up to hospital discharge and following surgery and up to 3 months post-operatively. Reportable events are those considered to be serious, unexpected and related to the study procedure.

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

Information retained from this study will include data such as diagnosis qualifying participants for spinal fusion, recordings from EMG and MMG devices, surgical information such as spine levels involved and number of screw trajectories, and results from clinical assessments such as PROMIS 10 and Oswestry Disability Index. Other information that may be kept could include participant sex, age, and comorbidities, as this data will likely be significant in future research regarding disease research, progression, and identifying factors that influence outcomes. No identifiable or personal health information will be maintained. Therefore, no additional or ongoing risks to the subjects exists. The information will be maintained indefinitely, and any researcher not included as study personnel will have to provide an approved IRB protocol prior to the sharing of any data. A data usage agreement may be required depending on the nature of the research, and will be assessed on a case by case basis. Once data has been de-identified, it will not be possible to remove information from the database.

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).

The principal investigator has authored over 20 investigator initiated trials in their career as a neurosurgeon and assures that this study will be conducted according to all provisions of the associated IRB and Good Clinical Practice guidelines that have their origin in the Declaration of Helsinki. All stipulations, clinically and administratively, including all statements as to confidentiality, will be strictly adhered to according to regional and national regulatory requirements.

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

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

◉ Yes ○ No

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

Attachments

Attach Type	File Name
SponsorInvTraining	GCP for Clinical Trials. Farhadi.pdf

HIPAA

0 unresolved comment(s)

Is HIPAA applicable? ◉ Yes ○ No

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

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

Attachments

STUDY DRUG INFORMATION

0 unresolved comment(s)

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:

SENTIO MMG

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

Attach Type	File Name
Study Device Form	eIFU-0902-90-171 Rev A.pdf
Study Device Form	ori-f11100-form-p-investigational-devices_Completed.pdf

RESEARCH SITES

0 unresolved comment(s)

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

A) Check all the applicable sites listed below at which the research will be conducted. If none apply, you do not need to check any boxes.

UK Sites

- ☐ UK Classroom(s)/Lab(s)
- ☑ UK Clinics in Lexington
- ☐ UK Clinics outside of Lexington
- ☐ UK Healthcare Good Samaritan Hospital
- ☑ UK Hospital

Schools/Education Institutions

- ☐ Fayette Co. School Systems *
- ☐ Other State/Regional School Systems
- ☐ Institutions of Higher Education (other than UK)

***Fayette Co. School systems, as well as other non-UK sites, have additional requirements that must be addressed. See ORI's IRB Application Instructions - Off-site Research web page for details.**

Other Medical Facilities

- ☐ Bluegrass Regional Mental Health Retardation Board
- ☐ Cardinal Hill Hospital
- ☐ Eastern State Hospital
- ☐ Norton Healthcare
- ☐ Nursing Homes
- ☐ Shriner's Children's Hospital
- ☐ Veterans Affairs Medical Center
- ☐ Other Hospitals and Med. Centers

- ☐ Correctional Facilities
- ☐ Home Health Agencies
- ☐ International Sites

Research activities conducted at performance sites that are not owned or operated by the University of Kentucky (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.

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

Attachments

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

RESEARCH ATTRIBUTES

0 unresolved comment(s)

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

My research activities include one or more of the following:

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

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

Epidemiologic or Behavioral Studies
○ Yes ◉ No

Outcomes Research or Health Services Research
◉ Yes ○ No

Does your research involve one or more human subjects prospectively assigned into one or more health-related biomedical or behavioral interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes?
○ Yes ◉ No

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

☑ Not applicable

Check All That Apply

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

For additional requirements and information:

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

  *For Medical IRB: Service Request Form for CCTS DSMB

- Data & Safety Monitoring Plan
- Deception*

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

- Emergency Use (Single Patient) [attach Emergency Use Checklist] (PDF)
- Genetic Research (look up "Specimen/Tissue

Informed Consent

- ☐ Recombinant DNA
- ☐ Registry or data repository creation
- ☐ Stem Cell Research
- ☐ Suicide Ideation or Behavior Research
- ☐ Survey Research
- ☐ Transplants
- ☐ Use, storage and disposal of radioactive material and radiation producing devices
- ☐ Vaccine Trials

Collection...")

- Gene Transfer
- HIV/AIDS Research (look up "Reportable Diseases/Conditions")
- Screening for Reportable Diseases [E2.0000] (PDF)
- International Research (look up "International & Non-English Speaking")
- NIH Genomic Data Sharing (GDS) Policy (PDF)
- Planned Emergency Research Involving Waiver of Informed Consent*

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

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

FUNDING/SUPPORT

0 unresolved comment(s)

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

☐ Not applicable

Check All That Apply

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

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

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

Other:

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.):

DePuy Synthes
Acc #3048115584

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.**

CR 2025 -Enrollment and participant follow-up complete.

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
Protocol	IIS Protocol Form_MMG vs EMG_Farhadi_Jan 20 2022.docx

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

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

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

SIGNATURES (ASSURANCES)

0 unresolved comment(s)

Introduction

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

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

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

Required Signatures:

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

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

Hover your mouse cursor here for additional instructions.

First Name	Last Name	Role	Department	Signee Return Comment	Date Signed	
Craig	van Horne	Department Authorization	Neurosurgery		02/11/2022 10:36 AM	View/Sign
Hooman F	Farhadi	Principal Investigator	Neurosurgery		02/14/2022 02:19 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)

***** If this Continuation Review entails a change in the scope of your activities to include COVID-19 related research, please insert "COVID19" at the start of your Project and Short Titles.*****

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.

Principal Investigator's Assurance Statement

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

1. Having reviewed all the investigational data from this study, including a compilation of all internal and external unanticipated problems.
2. Having reviewed, if applicable, information from the sponsor including updated investigator brochures and data and safety monitoring board reports.

I also attest that I have reviewed pertinent materials concerning the research and concluded either:

A. The human subject risk/benefit relationship is NOT altered, and that it is not necessary to modify the protocol or the informed consent process,
OR,
B. The human subject risk/benefit relationship has been altered, and have previously submitted or am including with this continuation review submission, a modification of the research protocol and informed consent process.

☑ By checking this box, I am providing assurances for the applicable items listed above.

Your protocol has been submitted.

Download all

	Document Type	File Loaded	Document Description	File Size	Modified By	Mod Date
	ApprovalLetter	ApprovalLetter.pdf		0.083	jchine2	12/2/2024 2:15:05 PM
	CR_EntireConsent	Sutdy ID 065 - R.K. ICF.pdf	Signed consent form #2	0.486	jlhend3	11/7/2024 11:14:43 AM
	CR_EntireConsent	Study ID - 64. B.J. ICF.pdf	Signed consent form #1	0.476	jlhend3	11/7/2024 11:14:00 AM
	SponsorInvTraining	GCP for Clinical Trials. Farhadi.pdf		0.404	jlhend3	3/7/2022 8:35:51 AM
	DataCollection	IIS Study Calendar.pdf	Calendar of events	0.116	jlhend3	3/3/2022 7:54:48 AM
	StudyDevice	ori-f11100-form-p-investigational-devices_Completed.pdf	DEVICE FORM	0.595	pkma223	2/16/2022 7:55:50 AM
	StudyDevice	eIFU-0902-90-171 Rev A.pdf	Device - instructions for usage	9.509	pkma223	2/16/2022 7:55:22 AM
	ResearchProcedures	PROMIS-10.f2f07d80.pdf		0.147	jlhend3	2/7/2022 2:47:43 PM
	ResearchProcedures	SF-36v2.pdf		1.361	jlhend3	2/7/2022 2:47:24 PM
	ResearchProcedures	Numeric Rating Scale for Pain.pdf	NRS pain rating scale	0.178	jlhend3	2/7/2022 2:46:54 PM
	ResearchProcedures	Oswestry Disability Index.pdf	Disability survey	0.356	jlhend3	2/7/2022 2:46:07 PM
	AddInfoProtocol	IIS Protocol Form_MMG vs EMG_Farhadi_Jan 20 2022.docx		0.118	jlhend3	2/1/2022 9:50:39 AM

Protocol Changes

Protocol Number: 76122

Click link to sort Changed Date
Additional Information/Materials AdditionalInformation changed by jlhend3 on 11/7/2024 12:56:40 PM
~~M~~CR ~~Mar.~~ 2024~~4~~5 ~~- Addition of A. Iqbal to SP~~Enrollment and participant follow-up complete.
Expedited Categories XPCategory0 changed by jlhend3 on 11/22/2024 9:29:55 AM
Y
Expedited Categories XPCategory1 changed by jlhend3 on 11/22/2024 9:29:55 AM
N
Expedited Categories XPCategory2 changed by jlhend3 on 11/22/2024 9:29:55 AM
N
Expedited Categories XPCategory3 changed by jlhend3 on 11/22/2024 9:29:55 AM
N
Expedited Categories XPCategory4 changed by jlhend3 on 11/22/2024 9:29:55 AM
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Expedited Categories XPCategory5 changed by jlhend3 on 11/22/2024 9:29:55 AM
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HIPAA HIPAADeIdentificationCertForm changed by jlhend3 on 11/7/2024 12:49:51 PM
~~N~~
Informed Consent ElectronicConsent changed by jlhend3 on 11/7/2024 12:49:09 PM
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Informed Consent InformedConsentHIPAACombinedForm changed by jlhend3 on 11/22/2024 9:33:48 AM
~~Y~~N
Informed Consent StampedConsent changed by jlhend3 on 11/22/2024 9:33:48 AM
~~N~~Y
Project Information IsSubEnrollDataSpecimen changed by jlhend3 on 11/22/2024 9:32:08 AM
~~Y~~N
Project Information SubjectCount changed by jlhend3 on 11/22/2024 1:45:22 PM
~~7~~65
Research Attributes ClinicalResearch changed by jlhend3 on 11/7/2024 12:54:14 PM
~~Y~~
Research Attributes ClinicalTrial changed by jlhend3 on 11/7/2024 12:54:14 PM
N
Research Attributes ClinicalTrial changed by jlhend3 on 11/7/2024 12:54:14 PM
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Research Attributes EpidemiologicBehavioralStudies changed by jlhend3 on 11/7/2024 12:54:14 PM
N
Research Attributes MaterialOfHumanOrigin changed by jlhend3 on 11/7/2024 12:54:14 PM
Y
Research Attributes NotApplicable changed by jlhend3 on 11/7/2024 12:54:21 PM
~~N~~Y
Research Attributes OutcomesHealthServicesResearch changed by jlhend3 on 11/7/2024 12:54:14 PM
Y
Research Attributes PatientOrientedResearch changed by jlhend3 on 11/7/2024 12:54:14 PM
Y
Research Sites MultisiteLeadInvestigator changed by jlhend3 on 11/7/2024 12:50:39 PM
~~N~~

Study Personnel Changes:

Project Information Comment by Joanne Hines - ORI to PI on 11/22/2024 11:50:06 AM
Please update the total enrolled - closing to enrollment at 65 total subjects (taken from Continuation section)?

KEY INFORMATION FOR A PROSPECTIVE EVALUATION OF MECHANOMYOGRAPHY VERSUS TRIGGERED ELECTROMYOGRAPHY FOR INTRAOPERATIVE ASSESSMENT OF CORTICAL BREACHES DURING INSTURMENTED LUMBAR SURGERY

We are inviting you to take part in a research study designed to determine if there is a significant difference between two forms of nerve monitoring used during surgery of the lower back. Electromyography is currently one of the most common types of monitoring used, and this study's goal is to determine if mechanomyography is more accurate. We are asking you because you will be having spine surgery requiring the use of hardware to treat the issues with your lower back. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this study is to determine how well mechanomyography (MMG) and electromyography (EMG) prevent cortical bone breaches, or the pinching of a nerve from screw placement, in patients having lower back surgery requiring hardware. Both MMG and EMG are devices approved by the FDA to detect the location of nerves during surgery so they can be avoided. The results from both tests will be compared to one another to determine if one is better at accurately locating nerves than the other. The study will not change the type of surgery being performed or the care you receive. The only difference between the research study surgery and the standard surgery performed is the use of the two monitoring systems to detect nerve locations before placing screws or other hardware in the spine. By doing this study, the goal is to learn if there is a significant difference in the ability of MMG and EMG to detect nerves during surgery.

The study will last 3 years. Your participation in this research will last about 3 months and include office visits before surgery, the operation, and office visits scheduled at 6 weeks and 3 months after surgery.

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

Volunteering for this study will provide surgeons and the medical community with more knowledge about detecting nerve locations in the spine during surgeries. It will help determine which monitoring system is more accurate, and therefore better to use. For a complete description of benefits, refer to the Detailed Consent.

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

You might choose to not volunteer for this study if you are not willing/able to complete the requirements after surgery such as timely follow-up appointments, examinations, and surveys. You may also decline to volunteer if you do not want your medical information securely saved outside of your medical chart. For a complete description of risks, refer to the Detailed Consent and/or Appendix.

If you choose not to volunteer, your surgery will continue as planned using the current standard of care surgery without the use of monitoring for research purposes.

DO YOU HAVE TO TAKE PART IN THE STUDY?

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

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact the principle investigator – Francis Farhadi, MD, Department of Neurosurgery, 800 Rose St. MS103B; Lexington KY, 40536.

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

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

Subjects will be excluded from this trial if they satisfy any of the following criteria.

1. Subject has a metal sensitivity/foreign body sensitivity.
2. Subject is currently involved in another investigational drug or device study that could confound study data.
3. Subject has a history (present or past) of substance abuse (recreational drugs, prescription drugs or alcohol) that in the investigator's opinion may interfere with protocol assessments and/or with the subject's ability to complete the protocol required follow-up.
4. Subjects who are pregnant or plan to become pregnant in the next 24 months or who are lactating.
5. Subject is involved in or planning to engage in litigation or receiving Worker's Compensation related to neck or back pain. Participation may give a legal team, or case manager inappropriate grounds to deny a claim, blaming residual symptoms on study participation.
6. Subjects who have a known or suspected allergy to any of the following antibiotics and/or reagents: vancomycin, aztreonam, meropenem

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

The research procedures will be conducted at the University of Kentucky Medical Center. Data for the study will be obtained during your standard of care office visits, surgical procedure, and hospital stay for your spine diagnosis. This includes a pre-operative office visit, the time spent in the hospital for your surgery and recovery, and 2 post-operative office visits at 6 weeks and 3 months. The total amount of time you will be asked to volunteer for this study is estimated to be 3 hours over 3 months. Please note, this does not include time spent for standard of care procedures and assessments like the time spent in the hospital for recovery or time spent in radiology, as those are not a direct result of the study.

WHAT WILL YOU BE ASKED TO DO?

Within 60 days prior to the surgery date, at your preoperative appointment the following information will be collected: data including year of birth, gender, height and weight, medical history, a complete history of spinal disorder(s) (non-operative or operative treatments performed), current pain medications and other drug therapies, and neurological status. A physical examination will be conducted and preoperative x-rays the be taken. You will be required to complete three surveys to document your level of disability, your physical, mental, and social health, and your leg/back pain before surgery.

By consenting to participate, you agree to electromyography (EMG) being used as a "control" to locate nerves along your spinal column to help determine the placement of screws. At the same time, mechanomyography (MMG) will be performed to see if it can provide the location of nerves as well. The MMG is the device being researched. Data recorded during and just after your surgery will include: diagnosis, how long the surgery lasts, blood loss, length of hospital stay, type of surgery, hardware used during surgery, what levels of your spine are being operated on, the readings from the EMG and MMG devices, and any complications experienced during the surgery or while in the hospital. The MMG monitoring is the only part of the procedure that will be research oriented. All other aspects of your surgery and hospital stay will be the normal, standard care for your diagnosis.

After surgery, you will be required to attend two office visits that include research aspects (postoperative office visit(s) not associated with the study should be anticipated to check the healing of your surgical wound). The first office visit where study information will be collected is to be scheduled for 6 weeks (+/-1 week) after surgery. The second will be 3 months (+/- 2 weeks) after surgery. Data collected at these visits may include compliance with instruction given after surgery, the ability to return to work and other normal activities, any adverse events related to the surgery that have occurred after being discharged from the hospital, current medication use, progress toward bone growth, and neurological status. X-rays will also be

taken at both visits to help monitor healing. All office visits and images (X-rays/CTscans) taken are standard of care for the surgery you will be receiving, but will be used as data points for the research study. In addition, you will be required to repeat the three surveys that assess your level of disability, physical, mental, and emotional health, and leg/back pain.

A study calendar detailing what will occur during each phase of the study is located in the appendix section of this consent.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

The device being investigated monitors nerve signals in a non-invasive manner. Although this device is already FDA approved and non-intrusive, there are some risks associated with its use. Since neuromonitoring is standard for the surgery you will be receiving, these risks will be discussed during the surgical consenting process. The combination of two devices, which is a deviation from standard of care, equates to no quantifiable additional risks for subjects because the process involves sequentially placing an EMG and then a MMG probe on the already inserted pedicle screw to assess for respective electrical responses.

Your data obtained from the study will be stored on university computers. Therefore, it is possible your data could be accessed in the case of a data breach. We will be collecting the minimal identifiable data needed to conduct our research which will help prevent your identity from being known, even if a breach occurs. The information provided for the study will only be accessible to personnel listed on the study protocol. All university computers require unique user names and passwords for access, and all digital data is encrypted and protected by a firewall. All paper copies of documents will be kept in the coordinator's office requiring a key for entry.

There is always a chance that any medical treatment can harm you. The research treatments/procedures in this study are no different. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

You will not get any personal benefit from taking part in this study. However, if you take part in this study, information learned may help others with your condition.

IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to take part in the study, there are no other choices except not to take part in the study. Your standard of care spine surgery will proceed whether you consent or decline to participate in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

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

The University of Kentucky may not be allowed to bill your insurance company, Medicare, or Medicaid for the medical procedures done strictly for research. Therefore, these costs will be paid by the sponsor, DePuy Synthes.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private. We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. If you decide to participate in this study, you will be assigned a subject ID number to decrease the likelihood of your identity being exposed in the case of a breach. Only the study coordinator and select study personnel will have access to the ID number codes. Data will be stored on a secure REDCap database and electronic forms will be stored on password protected computers on a University of Kentucky IT secured network. Paper forms will be stored in locked offices where only the study team has access.

You should know that in some cases we may have to show your information to other people. For example, the law may require or permit us to share your information with:

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

- authorities, such as child or adult protective services, if you report information about a child or elder being abused;
- authorities or a mental health professional if you pose a danger to yourself or someone else (e.g. suicidal thoughts).

To ensure the study is conducted properly, the University of Kentucky, and DePuy Synthes may look at or copy pertinent portions of records that identify you.

We will make every effort to safeguard your data, but as with anything online, we cannot guarantee the security of data obtained by way of the Internet. Third-party applications used in this study may have Terms of Service and Privacy policies outside of the control of the University of Kentucky.

REDCap is a secure, web-based program to capture and store data at the University of Kentucky. We will make every effort to safeguard your data in REDCap. However, given the nature of online surveys, we cannot guarantee the security of data obtained by way of the Internet.

CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?

It is recognized that your participation in this trial is entirely voluntary, and that you can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study. It is also recognized that the investigator, at his/her discretion, may withdraw a subject from this study based upon his/her professional judgment. If the subject is withdrawn for any reason at any time a final evaluation form will be completed and the Sponsor will be notified. If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.
- you develop a severe concurrent medical illness during the trial

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may not take part in this study if you are currently involved in another research study involving investigational drugs or devices. It is important to let the investigator/your doctor know if you are in another research study. You should discuss this with the investigator/your doctor before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Dr. Farhadi at (859)562-0247 immediately.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm will be paid by the sponsor, Depuy Synthes with some exceptions. The exception could be your failure to follow instructions.

You do not give up your legal rights by signing this form.

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will not receive any rewards or payment for taking part in the study.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

The only identifier being used is the study ID assigned at enrollment, because of this, there will be no identifiers to remove from data sets. The source code will be destroyed with your data once the sponsors retention requirements are met. We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Generally, tests done for research purposes are not meant to provide clinical information. We will not provide you with individual research results.

WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?

The research staff would like to contact you in the future with information about participating in additional studies. If so, it will be limited to 2 times per year.

Do you give your permission to be contacted in the future by the Kentucky Neuroscience Institute regarding your willingness to participate in future research studies?

☐ **Yes** ☐ **No** **Initials**_____

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 75 people at UK to do so.

DePuy Synthes is providing financial support and/or material for this study. The information that you are providing will no longer belong to you. The research may lead to new clinical or educational knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives if this occurs.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

WILL YOUR INFORMATION (OR SPECIMEN SAMPLES) BE USED FOR FUTURE RESEARCH?

All identifiable information (e.g., your name, medical record number, or date of birth) will be removed from the information collected in this study. This means that no link or code to your identity will be kept. After all identifiers have been removed, the information may be used for future research or shared with other researchers without your additional informed consent. Once you give your permission to have your de-identified information or samples stored, they will be available indefinitely and cannot be removed due to the inability to identify them. Any researcher who is not part of the study personnel will be required to present an approved IRB protocol prior to any data being shared.

AUTHORIZATION TO USE OR DISCLOSE YOUR IDENTIFIABLE HEALTH INFORMATION

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

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

- Your age, gender, height, and weight
- Medical history related to the study, including detailed history of spinal disorders
- Results from physical and neurological exams
- Imaging results from CTs and x-rays
- Intraoperative and perioperative details such as surgery duration, blood loss, and complications
- Results from surveys you have completed

The Researchers may use and share your health information with:

- The University of Kentucky's Institutional Review Board/Office of Research Integrity;
- Law enforcement agencies when required by law;
- University of Kentucky representatives;
- UK HealthCare and their representatives;
- Health systems outside of UK for which you have a patient relationship;
- Center for Clinical and Translational Science (CCTS)
- Depuy Synthes

If you become pregnant anytime during the study you must inform the study doctor.

The researchers agree to only share your health information with the people listed in this document.

Should your health information be released to anyone that is not regulated by the privacy law, your health information may be shared with others without your permission; however, the use of your health information may still be regulated by applicable federal and state laws.

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

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

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

- Send a written letter to:

  H Francis Farhadi, M.D. Department of Neurosurgery
  University of Kentucky Medical Center
  800 Rose St MS 103B
  Lexington, KY 40536.

  to inform him of your decision.

- Researchers may use and release your health information **already** collected for this research study.
- Your protected health information may still be used and released should you have a bad reaction (adverse event).

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

If you have not already received a copy of the Privacy Notice, you may request one. If you have any questions about your privacy rights, you should contact the University of Kentucky's Privacy Officer between the business hours of 8am and 5pm EST, Monday-Friday at (859) 323-1184.

Appendix: Study Visits Calendar

Procedure	Visit 1 Baseline	Procedure Day 0	Discharge	Visit 2 6 Weeks (± 7 days)	Visit 3 3 Months (± 14 days)
Informed Consent	X				
Demographics	X				
Medical History	X				
Physical Exam	X		X	X	X
Neurological Exam	X		X	X	X
Device / Procedure Related Adverse Events		X	X	X	X
Surgical Details		X			
NRS back and leg	X			X	X
ODI v2.1a / PROMIS Global-10	X			X	X
AP, lateral, flexion, extension X-rays	X		X	X	X
CT		X			
Revision surgeries or re-operations (assessed)				X	X

INFORMED CONSENT SIGNATURES

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

Signature of research subject	**Date**
Printed name of research subject	
Printed name of [authorized] person obtaining informed consent and HIPAA authorization	Date

Statistical Analysis Plan

Descriptive statistics will be used to summarize the study data. Measures of central tendency (mean, median and mode) and frequencies and percentages implemented to report the continuous and categorical variables, respectively. The paired and unpaired t-tests will be used to evaluate the differences in the average values of the continuous variables across the two groups. Categorical variables will be compared using the chi-squre tests. The diagnostic performances of the two devices in detecting screw breaches will be evaluated using receiver operator characteristic (ROC) curve analysis, with sensitivity and specificity calculated. A p-value < 0.05 will be considered statistically significant and all statistical analysis will be conducted using R Studio.