

## Document Coversheet

Study Title: Transitioning from Maintenance ECT to Maintenance TMS in Treatment Resistant Depression.

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	1/28/2026
NCT Number:	NCT06682299
IRB Number	95789
Coversheet created:	4/10/2026

**Protocol #:** 95789  
**Short Title:** Maintenance TMS in Treatment Resistant Depression  
**Submitted Date:** 01/22/26

IRB Approval  
1/28/2026  
IRB # 95789  
IRB3  
CLOSED

PROTOCOL TYPE (VERSION 5)

0 unresolved  
comment(s)

**IMPORTANT NOTE:**

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

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

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

For guidance, see:

- [Which IRB should review my research?](#)
- [Which Protocol Process Type?](#)
- ["Getting Started"](#)

Which IRB

☒ Medical ☐ NonMedical

Protocol Process Type

☐ Exemption  
☐ Expedited (Must be risk level 1)  
☒ Full

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

## CONTINUATION REVIEW/FINAL REVIEW

0 unresolved  
comment(s)

Based on your responses to the Continuation Review/Final Review questions, to be in accord with federal policy a final review report must be submitted to properly CLOSE OUT your protocol.

IF YOU WISH TO EXTEND YOUR IRB APPROVAL PERIOD, update your 'Anticipated Ending Date of Research Project' under the Project Information section and include any other supportive documentation for continuation of your study [NOTE: If you wish for your IRB approval to continue, but you do not request an extension and complete and submit your materials in a timely manner, IRB approval will expire at the end of the current approval period.].

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.

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



### 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.

### 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	Consent20250417084101223.pdf

### 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.

\*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:

30

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

0

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:

1

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

1

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.

1 patient discontinued study early to return to previous treatment plan due to return of depressive symptoms

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: 2

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:

**04/01/2026**

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

No records to display.

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	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Asian	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Black or African American	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Latinx	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Native Hawaiian or Other Pacific Islander	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
White	<input type="text"/>	1	<input type="text"/>	<input type="text"/>
American Arab/Middle Eastern/North African	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Indigenous People Around the World	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
More than One Race	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Unknown or Not Reported	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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



Transitioning from Maintenance ECT to Maintenance TMS  
in Treatment Resistant Depression

**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.



Maintenance TMS in Treatment  
Resistant Depression

Anticipated Ending Date of Research Project: 4/1/2026

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

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](mailto:irbreliance@uky.edu).

## PI CONTACT INFORMATION

0 unresolved  
comment(s)**Principal Investigator (PI) role for E-IRB access**

The PI is a UK-affiliated 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\*).

Non-UK individuals ("external") are not eligible for the role of Principal Investigator and cannot create a new application, nor will they be listed in the "Change Principal Investigator" search tool.

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: <input type="text" value="Austin"/>	Room# & Bldg: <input type="text" value="800 Rose Street"/>
Last Name: <input type="text" value="Messner"/>	<a href="#">Speed</a> <a href="#">Sort#:</a> <input type="text" value="40536"/>
Middle Name: <input type="text" value="Raymond"/>	
Department: <input type="text" value="Graduate Medical Education -..."/>	Dept Code: <input type="text" value="H3150"/>
PI's Employee/Student ID#: <input type="text" value="10922889"/>	Rank: <input type="text" value="Resident"/>
PI's Telephone #: <input type="text" value="8593236861"/>	Degree: <input type="text" value="MD, PGY-3"/>
PI's e-mail address: <input type="text" value="austin.messner@uky.edu"/>	PI's FAX Number: <input type="text"/>
PI is R.N. <input checked="" type="radio"/> Yes <input type="radio"/> No	HSP Trained: <input type="text" value="Yes"/>
	HSP Trained Date: <input type="text" value="10/3/2024"/>
	RCR Trained: <input type="text" value="Yes"/>

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

☒ Yes ☐ No



## RISK LEVEL

0 unresolved  
comment(s)

Indicate which of the categories listed below accurately describes this protocol

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

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

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..)  to **Study Population:**

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

Provide the following information:

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

Please consider this [FDA Guidance on Enrollment of Participants from Underrepresented Populations in Clinical Studies](#)



We will approach all patients referred for maintenance ECT and will not exclude patients based upon any sex/gender or racial/ethnic group. Only those determined to be eligible for the study will be offered enrollment.

Inclusion criteria: 1) Patients treated for TRD who have achieved remission through an index series of ECT, 2) Able to provide informed consent, 3) Age between 18 and 70 years, 4) Deemed appropriate for maintenance TMS by their psychiatrist, and 5) Right-handed.

Exclusion criteria: 1) History of seizures or a seizure disorder, 2) Related neurological disorder, or any other medical condition that would preclude TMS treatment determined by the treatment team.

**Attachments**

Indicate the targeted/planned enrollment of the following members of minority groups and their subpopulations. Possible demographic sources: [Kentucky State Census](#), [Kentucky Race/Ethnic Table](#), [Kentucky Population Data](#).

**(Please note: The IRB will expect this information to be reported at Continuation Review time for Pre-2019 FDA-regulated Expedited review and Full review applications):**

Participant Demographics				
	Cisgender Man ⓘ	Cisgender Woman ⓘ	TGNB/TGE ⓘ	Unknown/Not Reported
American Indian/Alaskan Native:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Asian:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Black/African American:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Latinx:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Native Hawaiian/Pacific Islander:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
White:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
American Arab/Middle Eastern/North African:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Indigenous People Around the World:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
More than One Race:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Unknown or Not Reported:	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

If unknown, please explain why:

There is no targeted/planned enrollment of specific minority groups and their subpopulations. Our participant enrollment is intended to be representative of our specific subpopulation (patients with treatment resistant depression in Kentucky).

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

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

**ADDITIONAL INFORMATION:**

- ☐ 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

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 I"](#), complete the form, and attach it using the button below.

**Examples of such conditions include:**

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

**Attachments**

Attach Type	File Name
ImpairedConsent	95789_ImpairedConsent_1104634.doc
ImpairedConsent	95789_ImpairedConsent_Highlight.doc

**INFORMED CONSENT/ASSENT PROCESS/WAIVER****0 unresolved  
comment(s)**

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

Additional Resources:

- [Informed Consent/Assent Website](#)
- [Waiver of Consent vs. Waiver of Signatures](#)
- [Sample Repository/Registry/Bank Consent Template](#)

**Consent/Assent Tips:**

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

- "Highlighted Changes",
- "Phone Script", and
- "Reliance Consent Form",
- "Sponsor's Sample Consent Form".

**How to Get the Section Check Mark**

1. You must:
  - a) provide a response in the text box below describing how investigators will obtain consent/assent, and
  - b) check the box for at least one of the consent items and/or check mark one of the waivers
2. If applicable attach each corresponding document(s) **as a read-only PDF**.
3. If you no longer need a consent document approved (e.g., closed to enrollment), or, the consent document submitted does not need a stamp for enrolling subjects (e.g., umbrella study, or sub-study), only select "Stamped Consent Doc(s) Not Needed".
4. After making your selection(s) be sure to scroll to the bottom of this section and SAVE your work!

**Check All That Apply**

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

**Attachments**

Attach Type	File Name
Informed Consent/HIPAA Combined Form	Informed ConsentHIPAA Combined Form_1194138.pdf
Informed Consent/HIPAA Combined Form	Informed ConsentHIPAA Combined Form_1194140.pdf

**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](#).

Informed consent will be obtained after thorough discussion of the research project, what is required of the participant, the risks and benefits of participation in the study, and the procedures that are in place if/when challenges arise. This will be done by the PI, one of the co-investigators or research assistant during the first encounter with the subject, if they fulfill all eligibility criteria and are interested in study participation.

The research project is not connected to the University of Kentucky ECT service (i.e., a person can be a UK ECT patient and their participation in the research project does not impact their standing in the ECT service and therefore the participation is truly voluntary in nature. If you have questions about the study, you can contact the principal investigator for the study Austin Messner at (859) 323-2778. If you have concerns or questions about your rights and/or welfare as a volunteer in this research, you can contact the staff in the Office of Research Integrity at The University of Kentucky at (859) 257-9428 or toll free at 1-866-400-9428. We will give you a signed copy of this consent form to take with you.

☐ 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.

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

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

Select the option below that best fits your study.

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



#### Option 1

**Describe how your study meets these criteria:**

- a) The only record linking the participant and the research would be the consent document:
- b) The principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves subjects who use illegal drugs).

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

#### Option 2

**Describe how your study meets these criteria:**

- a) The research presents no more than minimal risk to the participant:
- b) Involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script):

#### Option 3


**Describe how your study meets these criteria:**

- a) The subject (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm.
- b) The research presents no more than minimal risk to the subject.
- c) There is an appropriate alternative mechanism for documenting that informed consent was obtained.

## STUDY PERSONNEL

0 unresolved comment(s)

Do you have study personnel who will be assisting with the research?

After selecting 'Yes' or 'No' you must click the 'Save Study Personnel Information' button. 

 Yes  No

## Manage Study Personnel

Identify other study personnel assisting in research project:

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

To add an individual via the below feature:

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

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

Study personnel assisting in research project: 

Last Name	First Name	Responsibility In Project	Role	A C	Contact	Degree	StatusFlag	(HSP)	(HSP)Date	(RCR)	Removed?	Last Updated	SFI	Active
Martin	Paul	Project Assistance/Support	DP	N	N		P	Y	02/13/2024	Y	N	03/17/2025	N	Y
Min	James	Consultant/Advisor	SP	Y	N		P	Y	10/23/2023	Y	N	05/17/2024	N	N
Nill Gomez	Izabella	Project Assistance/Support	SP	Y	N		P	Y	12/08/2024	Y	N	02/06/2025	N	Y
Rakesh	Gopalkumar	Faculty Advisor	DP	Y	Y		P	Y	09/11/2025	Y	N	04/29/2024	N	Y
Garth	Patricia	Project Assistance/Support	SP	N	N		P	Y	10/01/2025	Y	Y	12/18/2025	N	Y
Means	Natalya	Project Assistance/Support	SP	N	N		P	Y	10/30/2025	Y	Y	10/03/2025	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).

## Clinical Context and Question.

Electroconvulsive therapy (ECT) is one of the most efficacious treatments available for treatment-resistant depression (TRD). Although a maintenance ECT protocol exists, multiple barriers limit its use for long-term use. These barriers include procedure tolerability, cognitive side effects, financial burden, and unreliable social support to accompany patients when they come in for these treatments. On the other hand, a different modality of noninvasive neuromodulation called transcranial magnetic stimulation (TMS) can be performed in the outpatient setting and does not need anesthesia. The likelihood of cognitive adverse effects with TMS is much lower than with ECT. Our clinical question encompasses piloting a maintenance TMS regimen to maintain remission in treatment-resistant major depressive disorder.

## Background.

Major depressive disorder (MDD) imposes significant disability and economic burdens on patients (Friedrich, 2017). Treatment-resistant depression encompasses a lack of response to adequate trials of one or more antidepressants from the same or different antidepressant classes (McIntyre et al., 2023). Treatment-resistant depression has an estimated 30-55% prevalence in the general population (McIntyre et al., 2023; Zhdanova et al., 2021). Transcranial magnetic stimulation (TMS) is a treatment option in patients with MDD who have failed 1-2 antidepressant trials (McClintock et al., 2018; McIntyre et al., 2023). With the advent of accelerated protocols like Stanford Neuromodulation Treatment (SNT) for MDD, TMS is increasingly becoming a treatment option for treatment-resistant depression (McIntyre et al., 2023). TMS does not have adverse cognitive effects and, consequently, has a greater patient preference (Berlim et al., 2011; Berlin et al., 2013; Magnezi et al., 2016). TMS is generally safe and well-tolerated (Perera et al., 2016). Although TMS is effective in the acute treatment of MDD, there is sparse data on a consensus maintenance regimen in treatment-resistant depression. Given that the patient population getting TMS for MDD may already be treatment-resistant, relapse rates over time are high in MDD without maintenance TMS sessions (Kedzior et al., 2015; Senova et al., 2019). Therefore, it is imperative to consider individualized TMS treatment regimens to sustain remission (d'Andrea et al., 2023; Matsuda et al., 2023; Rachid, 2018). Akin to the symptom-titrated algorithm-based longitudinal ECT (STABLE) regimen in ECT, it is essential to move towards consensus regimens for maintenance TMS protocols to sustain remission in MDD (Perera et al., 2016; Rachid, 2018; Wilson et al., 2022). Our goal with this proposal is to compare the effectiveness of a maintenance TMS regimen to maintenance ECT.

Berlim, M.T., McGirr, A., Beaulieu, M.M., Turecki, G., 2011. High frequency repetitive transcranial magnetic stimulation as an augmenting strategy in severe treatment-resistant major depression: a prospective 4-week naturalistic trial. *J Affect Disord* 130(1-2), 312-317.

Berlim, M.T., Van den Eynde, F., Daskalakis, Z.J., 2013. Efficacy and acceptability of high frequency repetitive transcranial magnetic stimulation (rTMS) versus electroconvulsive therapy (ECT) for major depression: a systematic review and meta-analysis of randomized trials. *Depress Anxiety* 30(7), 614-623.

Cole, E.J., Phillips, A.L., Bentzley, B.S., Stimpson, K.H., Nejad, R., Barmak, F., Veerapal, C., Khan, N., Cherian, K., Felber, E., Brown, R., Choi, E., King, S., Pankow, H., Bishop, J.H., Azeez, A., Coetzee, J., Rapier, R., Odenwald, N., Carreon, D., Hawkins, J., Chang, M., Keller, J., Raj, K., DeBattista, C., Jo, B., Espil, F.M., Schatzberg, A.F., Sudheimer, K.D., Williams, N.R., 2022. Stanford Neuromodulation Therapy (SNT): A Double-Blind Randomized Controlled Trial. *Am J Psychiatry* 179(2), 132-141.

Cole, E.J., Stimpson, K.H., Bentzley, B.S., Gulser, M., Cherian, K., Tischler, C., Nejad, R., Pankow, H., Choi, E., Aaron, H., Espil, F.M., Pannu, J., Xiao, X., Duvio, D., Solvason, H.B., Hawkins, J., Guerra, A., Jo, B., Raj, K.S., Phillips, A.L., Barmak, F., Bishop, J.H., Coetzee, J.P., DeBattista, C., Keller, J., Schatzberg, A.F., Sudheimer, K.D., Williams, N.R., 2020. Stanford Accelerated Intelligent Neuromodulation Therapy for Treatment-Resistant Depression. *Am J Psychiatry* 177(8), 716-726.

d'Andrea, G., Mancusi, G., Santovito, M.C., Marrangone, C., Martino, F., Santorelli, M., Miuli, A., Di Carlo, F., Signorelli, M.S., Clerici, M., Pettoroso, M., Martinotti, G., 2023. Investigating the Role of Maintenance TMS Protocols for Major Depression: Systematic Review and Future Perspectives for Personalized Interventions. *J Pers Med* 13(4).

Friedrich, M.J., 2017. Depression Is the Leading Cause of Disability Around the World. *JAMA* 317(15), 1517.

Kedzior, K.K., Reitz, S.K., Azorina, V., Loo, C., 2015. Durability of the antidepressant effect of the high-frequency repetitive transcranial magnetic stimulation (rTMS) in the absence of maintenance treatment in major depression: a systematic review and meta-analysis of 16 double-blind, randomized, sham-controlled trials. *Depress Anxiety* 32(3), 193-203.

Kowalski, C.J., Mrdjenovich, A.J., 2013. Patient preference clinical trials: why and when they will sometimes be preferred. *Perspect Biol Med* 56(1), 18-35.

Magnezi, R., Aminov, E., Shmuel, D., Dreifuss, M., Dannon, P., 2016. Comparison between neurostimulation techniques: transcranial magnetic stimulation vs electroconvulsive therapy for the treatment of resistant depression: patient preference and cost-effectiveness. *Patient Preference Adherence* 10, 1481-1487.

Matsuda, Y., Sakuma, K., Kishi, T., Esaki, K., Kito, S., Shigeta, M., Iwata, N., 2023. Repetitive transcranial magnetic stimulation for preventing relapse in antidepressant treatment-resistant depression: A systematic review and meta-analysis of randomized controlled trials. *Brain Stimul* 16(2), 458-461.

McClintock, S.M., Reti, I.M., Carpenter, L.L., McDonald, W.M., Dubin, M., Taylor, S.F., Cook, I.A., O'Reardon, J., Husain, M.M., Wall, C., Krystal, A.D., Sampson, S.M., Morales, O., Nelson, B.G., Latoussakis, V., George, M.S., Lisanby, S.H., National Network of Depression Centers, T.M.S.T.G., American Psychiatric Association Council on Research Task Force on Novel, B., Treatments, 2018. Consensus Recommendations for the Clinical Application of Repetitive Transcranial Magnetic Stimulation (rTMS) in the Treatment of Depression. *J Clin Psychiatry* 79(1).

McIntyre, R.S., Alsouaidan, M., Baune, B.T., Berk, M., Demyttenaere, K., Goldberg, J.F., Gorwood, P., Ho, R., Kasper, S., Kennedy, S.H., Ly-Uson, J., Mansur, R.B., McAllister-Williams, R.H., Murrough, J.W., Nemeroff, C.B., Nierenberg, A.A., Rosenblatt, J.D., Sanacora, G., Schatzberg, A.F., Shelton, R., Stahl, S.M., Trivedi, M.H., Vieta, E., Vinberg, M., Williams, N., Young, A.H., Maj, M., 2023. Treatment-resistant depression: definition, prevalence, detection, management, and investigational interventions. *World Psychiatry* 22(3), 394-412.

Perera, T., George, M.S., Grammer, G., Janicak, P.G., Pascual-Leone, A., Wirecki, T.S., 2016. The Clinical TMS Society Consensus Review and Treatment Recommendations for TMS Therapy for Major Depressive Disorder. *Brain Stimul* 9(3), 336-346.

Rachid, F., 2018. Maintenance repetitive transcranial magnetic stimulation (rTMS) for relapse prevention in with depression: A review. *Psychiatry Res* 262, 363-372.

Senova, S., Cotovio, G., Pascual-Leone, A., Oliveira-Maia, A.J., 2019. Durability of antidepressant response to repetitive transcranial magnetic stimulation: Systematic review and meta-analysis. *Brain Stimul* 12(1), 119-128.

Wilson, S., Croarkin, P.E., Aaronson, S.T., Carpenter, L.L., Cochran, M., Stultz, D.J., Kozel, F.A., 2022. Systematic review of preservation TMS that includes continuation, maintenance, relapse-prevention, and rescue TMS. *J Affect Disord* 296, 79-88.

Zhdanova, M., Pilon, D., Ghelerter, I., Chow, W., Joshi, K., Lefebvre, P., Sheehan, J.J., 2021. The Prevalence and National Burden of Treatment-Resistant Depression and Major Depressive Disorder in the United States. *J Clin Psychiatry* 82(2).

## Objectives

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

Objective 1. To examine the effectiveness of TMS for maintenance treatment of treatment-resistant depression. We hypothesize that administering TMS will be as effective as maintenance ECT to maintain remission in treatment-resistant depression.

Objective 2. To examine the cognitive side effects of M-ECT and M-TMS. We hypothesize that administering Maintenance TMS will result in significantly fewer cognitive side effects than Maintenance ECT.

## 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 will be a patient-preference clinical trial, with patients offered the choice to initiate maintenance TMS versus maintenance ECT after their index ECT sessions for treatment-resistant depression. There will be no randomization or placebo involved in this study.

## Attachments

## Subject Recruitment Methods & Advertising

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

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

For additional information on recruiting and advertising:

- [IRB Application Instructions - Advertisements](#)
- [PI Guide to Identification and Recruitment of Human Subjects for Research](#)

Patients who have achieved remission of treatment resistant depression through an initial course of ECT at the University of Kentucky will be identified by the ECT attending physician as a candidate for this study. Patients receiving ECT on this service do so on an outpatient basis or while admitted to a UK Healthcare operated psychiatric facility (Good Samaritan Hospital or Eastern State Hospital). The primary ECT attending at this time is Dr. James Min who will be the primary individual identifying eligible subjects. In the context of routine patient care, Dr. James Min will discuss the prospect of possibly participating in a research study with the patient and obtain permission to be contacted by primary investigator. Dr. Min may also supply identified patients with attached flyer as a visual aid to assist in his description of the study. Once identified and permission is obtained, their contact information will be communicated to the primary investigator Dr. Austin Messner and they will be contacted to set up an in-person meeting. The in-person meeting will be at 245 Fountain Court, in the research exam room on the second floor. This meeting will be attended by either Dr. Austin Messner or Dr. Gopalkumar Rakesh. During this meeting, Dr. Austin Messner or Dr. Gopalkumar Rakesh will explain the study to the participants and obtain informed consent for the study. Based upon subject preference, the subject will either be enrolled in the TMS or standard of care portion of the study and appropriate consent will be obtained. Research team will remain responsible for administration of TMS however the patient's primary outpatient attending psychiatrists who refer patients for this study will remain responsible for the psychiatric care of the patient and will remain in contact with the patient throughout the study. There will be no advertisements, outreach programs, or financial incentive offered. Only those determined to be eligible for the study will be offered enrollment.

**Attachments**

Attach Type	File Name
Advertising	RecruitmentFlyer.pdf

## Research Procedures

Describe how the research will be conducted.

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

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

Enrollment: Begin July 1, 2024, End June 30, 2025

Study duration: 12 months

Estimated end of the study: December 31, 2025

### Study Process Flow:

On day one of the study patients will be met in person and appropriate consent will be obtained as outlined previously in the "Subject recruitment methods and advertising" section of this proposal. Following obtaining informed consent the patient's medical history will be obtained to again ensure the patient is appropriate for TMS therapy. Medical review will be completed by either Dr. Gopalkumar Rakesh or Dr. Austin Messner and will include review of neurological history (including history of seizures), cardiac history, risk of or plans to become pregnant, metal implants in the body. Then the following rating scales will be applied to all participants at baseline, regardless of choosing maintenance ECT or maintenance TMS:

Antidepressant treatment history form (ATHF) - widely used instrument to systematically assess antidepressant treatment trials and characterize antidepressant treatment resistance

Alcohol use disorder identification test (AUDIT-C) - The Alcohol Use Disorders Identification Test (AUDIT-C) is an alcohol screen that can help identify patients who are hazardous drinkers or have active alcohol use disorders (including alcohol abuse or dependence)

Hamilton Depression Rating Scale (HDRS) - One of the most widely used clinician administered depression scales containing 17 items

Clinical Global Impression (CGI) - a 3-item, clinician-rated scale used to assess global illness severity, overall improvement from the start of treatment, and therapeutic response

Quick inventory of depressive symptomatology (QIDS) - a widely used self-report scale of depression with similar validity to the HDRS

Brief Psychiatric Rating Scale (BPRS) - assesses the level of 18 symptom constructs to assess and screen for other comorbid psychiatric conditions that are not immediately elicited on interview

Drug Abuse Screening Test (DAST-10) - is a 10-item brief screening tool that assesses drug use, not including alcohol or tobacco use, in the past 12 months

Repeatable Battery for the Assessment of Neuropsychological Status Update (RBANS) - brief, individually administered battery to measure cognitive decline or improvement.

Standardized assessment of personality abbreviated scale (SAPAS) - eight question screening tool to detect comorbid personality disorder

Patients who choose maintenance TMS will initiate maintenance TMS sessions on day one of the study and continue any currently prescribed pharmacotherapy. They will initiate TMS treatment within 1 week of last index ECT treatment. They will then follow a schedule of weekly for 4 sessions, every other week for 4 sessions, and monthly for 3 sessions for a total of 11 sessions in 6 months. We will use the TMS paradigm called intermittent theta burst stimulation (iTBS), which was used in the SNT trial (Cole et al., 2022; Cole et al., 2020). At conclusion of the 6 month TMS portion of the study clinical judgement will be used to determine if the patient will return to maintenance ECT treatment. RBANS for assessment of cognition will be completed at the beginning, after 6 months, and at the conclusion of the study as well in both the standard of care and TMS portions of the study.

iTBS session protocol: Patients will undergo iTBS targeting the dorsolateral prefrontal cortex (DLPFC) undergoing 4 sessions in a single day in a titration pattern over a 6 month period. These four sessions will be conducted with 50 minutes between each session. Patients will receive 60 cycles of 10 bursts of three pulses at 50 Hz were delivered in 2-second trains (5 Hz) with an 8-second intertrain interval. Stimulus will be delivered at 90% motor threshold and never above 120% rMT. Targeted stimulation of the left DLPFC will be done using Brainsight software. All participants will be administered the HAMD, QIDS, and CGI before and after each TMS session. These scales will also be administered similarly to patients in the comparison arm receiving maintenance ECT sessions.

### Motor Threshold

Motor threshold (MT) is defined as the TMS pulse amplitude needed to elicit an EMG response of 50  $\mu$ V peak-to-peak average amplitude in a target muscle. MT is the standard in the field for determining the intensity of TMS for everyone to reduce seizure risk. The MEP for the right first dorsal interosseus (FDI) will be measured with EMG. The scalp region producing the largest amplitude MEP will be identified. At that scalp location, we will determine the TMS intensity eliciting average MEP amplitude of 50  $\mu$ V peak-to-peak in the first DI muscle using an amplitude titration procedure (at least 5/10 trials). Individual MT will be used to determine the intensity of theta burst stimulation for everyone, as recommended by safety guidelines.

### iTBS application

A magnetic coil will be placed on the scalp and held in place with frameless stereotaxic equipment, using a sophisticated method of

coil placement that will coregister scalp positions directly onto an average brain template. This Frameless Stereotaxic BrainSight offers real-time three-dimensional display of cortical localization as the TMS coil is moved across the scalp. This will be used for coil positioning. This system uses a programmed robot arm to precisely position the TMS coil, and maintain its position, within 1 mm of the brain target chosen. Earplugs will be worn to protect hearing and low-volume white noise will be played through TMS compatible headphones to mask the sound of the coil clicks. The intensity of the stimulation will be 120% of resting motor threshold as reported in a previous studies. The participant will be seated comfortably with headphones and earplugs to protect the subject's hearing.

Faculty advisor Dr. Rakesh is an expert in the field of TMS, has completed previous academic research utilizing TMS, and will be readily available throughout the study. A medical doctor, either Dr. Rakesh, Dr. Messner will be present or nearby during all stimulation sessions. No drug, pregnancy, etc. screening results will be obtained from a UK HealthCare laboratory.

Those who choose maintenance ECT will transition to maintenance ECT treatments in the hospital as prescribed by their treating inpatient psychiatrists. On initial visit consent will be obtained and baseline cognitive and behavioral scales assessed as follows: Antidepressant treatment history form (ATHF), alcohol use disorder identification test (AUDIT-C), Hamilton Depression Rating Scale (HDRS), Clinical Global Impression (CGI), quick inventory of depressive symptomology (QIDS), Brief Psychiatric Rating Scale (BPRS), Drug Abuse Screening Test (DAST-10), Repeatable Battery for the Assessment of Neuropsychological Status Update (RBANS), standardized assessment of personality abbreviated scale (SAPAS). Patients will then be asked to return at 6 month and 12 month intervals to repeat HDRS, QIDS, RBANS, and CGI scales.

#### Attachments

### Data Collection & Research Materials

In this section, please provide the following:

- Describe all sources or methods for obtaining research materials about or from living individuals (such as specimens, records, surveys, interviews, participant observation, etc.), and explain why this information is needed to conduct the study.
- For each source or method described, please list or attach all data to be collected (such as genetic information, interview scripts, survey tools, data collection forms for existing data, etc.).
- If you will conduct a record or chart review, list the beginning and end dates of the records you will view.

Research data will be collected primarily through self assessment scales including Antidepressant treatment history form (ATHF), alcohol use disorder identification test (AUDIT-C), Hamilton Depression Rating Scale (HDRS), Clinical Global Impression (CGI), quick inventory of depressive symptomology (QIDS), Brief Psychiatric Rating Scale (BPRS), Drug Abuse Screening Test (DAST-10), Repeatable Battery for the Assessment of Neuropsychological Status Update (RBANS), standardized assessment of personality abbreviated scale (SAPAS).

These methods are necessary to obtain a mental health baseline. As the study progresses the depressive symptom burden will be followed using the HDRS, QIDS, and CGI scales. Tolerance of TMS will also be assessed by TMS side effects scale. Cognitive functioning will also be assessed with the RBANS throughout the study at 6 month and 12 month intervals.

#### Attachments

Attach Type	File Name
DataCollection	QIDS-SR.pdf
DataCollection	bprsform.pdf
DataCollection	DAST-10_Institute.pdf
DataCollection	ATHF.pdf
DataCollection	audit-c-eng.pdf
DataCollection	HAMILTON-DEPRESSION.pdf
DataCollection	CGI.pdf
DataCollection	sapas.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.

Staffing: This study will require 1 attending physician supervisor (Dr. Rakesh), 1 resident physician principal investigator (Dr. Messner) and a research support staff.

Technology: Utilization of TMS machine currently dedicated to research purposes

Space: Will require utilization of already dedicated research space and equipment at the UK Fountain Court location.

The TMS Suite is housed within the department of psychiatry (245 Fountain Court, Lexington, Kentucky 40509) at Kentucky, Lexington. Currently it encompasses one experimental room covering about 600 sq feet on the second floor. We are in the process of purchasing a MagPro X100 stimulator (MagVenture Inc, Atlanta, GA) with booster option and active cooling. The room will also be equipped with a laptop and a chair to provide TMS. The device is capable of producing rTMS over a wide range of parameters such as paired-pulse, theta burst stimulation, and both monophasic and biphasic waveforms. The machine weighs 35 kg and the cart encompassing the machine weighs 16 kg. Dimensions of the machine are 210 x 530 x 400 mm. We are also in the process of purchasing a frameless stereotaxic system (Brainsight Frameless, Rogue Research, Montreal, QC, Canada) for coregistration of TMS coil position on the scalp with underlying cortical anatomy on the individual subject's three-dimensionally rendered MRI scan. This permits navigation of the TMS coil to target cortical structures. Participants are administered TMS in a customized chair for stabilization of head and coil position. A coil holder especially designed for TMS ensures stable coil positioning. The Brainsight Neuronavigation system has three main components: (1) NDI Spectra infrared camera system, (2) stimulator, (3) chair with neck rest. The TMS coil is targeted to a user defined location selected on the individual 3-D Anatomical MRI with fMRI or PET data overlay with less than one millimeter error. The TMS coil is attached to a stimulator unit, which administers the TMS pulses to modulate brain function in a spatially and temporally precise fashion. The subject reclines in the chair and wears a headband equipped with a subject position tracker. The ceiling mounted infrared stereo camera detects the 3-D position of the subject tracker and also the coil position tracker, and continuously feeds this information into the control center software.

## Potential Risks & Benefits

### Risks

- Describe any potential risks – including physical, psychological, social, legal, ability to re-identify subjects, or other risks. Assess the seriousness and likelihood of each risk.
- Which risks may affect a subject's willingness to participate in the study?
- Describe likely adverse effects of drugs, biologics, devices or procedures participants may encounter while in the study.
- *Qualitative research* - describe ethical issues that could arise while conducting research in the field and strategies you may use to handle those situations.
- Describe any steps to mitigate these risks.

### Benefits

- Describe potential direct benefits to study participants – including diagnostic or therapeutic, physical, psychological or emotional, learning benefits. This cannot include incentives or payments.
- State if there are no direct benefits.
- Describe potential benefits to society and/or general knowledge to be gained.

Describe why potential benefits are reasonable in relation to potential risks. If applicable, justify why risks to vulnerable subjects are reasonable to potential benefits.

### Risk:

#### Risks with TMS

Seizure is a theoretical risk with TMS. In the Rossi et al. report it was stated that "The occurrence of seizures has been extremely rare, with most of the few new cases receiving rTMS protocols exceeding previous guidelines, often in patients under treatment with drugs which potentially lowered the seizure threshold." As Rossi et al. delineate, "rare" means that 16 cases (out of tens of thousands of rTMS sessions over the last two decades) of seizure related to rTMS have been reported. Eight occurred before safety parameters were established in 1997. Of the other eight reports, six occurred either when the safe rTMS parameters were exceeded or other safety guidelines ignored, and the actual occurrence of a seizure has been questioned in the other two (i.e., convulsive syncope or pseudoseizure may have occurred). In a workshop convened by the National Institute for Neurological Disorders and Stroke (NINDS) in 1996, researchers in the field agreed upon a set of rTMS consensus safety guidelines, including recommended stimulation parameters and contra-indications, and these consensus guidelines have been recently updated (Rossi et al., 2009). Widespread adherence to the 1996 guidelines has resulted in the virtual elimination of inadvertent seizures in rTMS studies (Rossi et al., 2009). Theta burst stimulation (TBS) that we will use in this study has been documented to be extremely safe. The risk of seizure with TBS is 0.1% (Rachid, 2017). There has been only one seizure instance reported with continuous TBS in a subject with no previous history of epilepsy but was sleep deprived after a long flight (Oberman and Pascual-Leone, 2009). The most commonly reported side effect of rTMS is headache. This headache is typically of a muscle-tension type. It usually develops during or immediately after the stimulation and may last for minutes to hours following the end of the stimulation. It is typically limited to the day of stimulation, and usually responds promptly to single doses of over the counter pain medications. Neck pain or scalp pain may also occur. Both are usually managed easily with over-the-counter analgesics. As noted in Rossi et al. (2009), Loo and colleagues reported mild and transient changes in auditory threshold in two depressed patients following a 2-4 week rTMS course of rTMS (16). Cases of tinnitus have been reported after rTMS treatments. In addition, recently in a study investigating the effects of rTMS on symptoms of depression, a patient experienced moderate to severe tinnitus after an rTMS session in which earplugs were not used. Rossi et al. recommended that hearing protection always should be worn during rTMS application, and that individuals with cochlear implants not receive rTMS. In the current study, earplugs will be worn by all subjects during rTMS procedures. Individuals with cochlear implants will be excluded from participation. Risks to the unborn children of pregnant women receiving rTMS are unknown. Pregnant women will be excluded in this study. If sexually active, the subject must agree to use appropriate contraceptive measures for the duration of the study. Medically acceptable contraceptives include: (1) surgical sterilization (such as a tubal ligation or hysterectomy), (2) approved hormonal contraceptives (such as birth control pills, patches, implants or injections), (3) barrier methods (such as a condom or diaphragm) used with spermicide, or (4) an intrauterine device (IUD). Contraceptive measures such as Plan B (TM), sold for emergency use after unprotected sex, are not acceptable methods for routine use. If the subject has any uncertainty about whether they could be pregnant, another urine pregnancy test will be performed before

they can participate in this protocol.

Other plausible risks include breach of confidentiality, development of suicidal thoughts, worsening depression, and syncope (neurocardiogenic in nature). Vasodepressor (neurocardiogenic) syncope is a common reaction to anxiety and psycho-physical discomfort. It is a common experience that may occur more often than epileptic seizures during TMS testing and treatment.

#### Benefit:

Patients will be able to trial a less invasive treatment option for the long term management of treatment resistant depression at no direct cost. This treatment modality also eliminates barriers to treatment including tolerability, financial burden, and unreliable social support. Participation in the study is completely voluntary, and there will be no pressure or time constraints regarding the decision to participate. If subjects experience headaches, they can withdraw without any ramifications pertaining to their respective clinic. There are no other benefits to the participants except for the good will of helping the progress of scientific research. The information learned from this study may aid our understanding of the role of the TMS in modulating cognition and brain function in patients with treatment resistant depression.

#### References pertinent to this section

Rossi S, Hallett M, Rossini PM, Pascual-Leone A. Safety of TMS. Safety, ethical considerations, and application guidelines for the use of transcranial magnetic stimulation in clinical practice and research. Clin Neurophysiol. 2009;120(12):2008-39.  
Rachid F. Safety and Efficacy of Theta-Burst Stimulation in the Treatment of Psychiatric Disorders: A Review of the Literature. J Nerv Ment Dis. 2017;205(11):823-39.  
Oberman LM, Pascual-Leone A. Report of seizure induced by continuous theta burst stimulation. Brain Stimul. 2009;2(4):246-7.

### 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).

Standard of care for the treatment of treatment-resistant depression that is responsive to electroconvulsive therapy (ECT) is a combination of maintenance ECT and pharmacotherapy. In this open label patient-preference clinical trial patients will be able to choose between the standard of care and TMS treatment. They will also be able to discontinue TMS treatment and return to standard of care ECT treatment at any point. Alternative options to enrollment in the study include continuing maintenance ECT without enrolling in the study as well as discontinuing all maintenance treatment options without enrollment in the study. Patients who opt to not participate in the study are at no disadvantage.

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### Records, Privacy, and Confidentiality

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

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

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

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

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

For additional considerations:

[Return of Research Results or Incidental Research Findings](#)

[HIPAA policies](#)

[FERPA policies](#)

[Procedures for Transfer agreements](#)

[Information regarding multi-site studies](#)

[NIH Genomic Data Sharing \(GDS\) Policy](#)

[Digital Data](#)

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

Data will be stored on HIPAA compliant University of Kentucky computers. Data will be maintained after the study and all patient identifiers will be removed.

Personal information of participants (Subjects' age, comorbid medical or psychiatric illnesses, history of substance use, depressive symptom scales, previous adverse effects with TMS, medication history) will be stored in an excel sheet on a protected laptop at

P208, 2nd floor, UK Department of Psychiatry at 245 Fountain Court (In a locked office and behind a protected fire door). Data sharing will be restricted to the coded data. Data will be kept for a minimum of 7 years, and electronically destroyed by UK Policy A13-050 and UK Policy A05-055.

**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.

No monetary compensation or incentives will be 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.

Patients will not be charged for any services conducted in the TMS arm of the study. However, ECT treatments will be billable services performed in the hospital and will not be paid for by the study. The patient will be solely responsible for the insurance coverage and cost of ECT treatments.

### 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.

Monitoring the progress of clinical investigations and the safety of participants:

The depressive symptom burden of patients will be monitored regularly using the HAMD, CGI, and QIDS at each patient encounter. Cognitive performance will also intermittently be evaluated using the RBANS. These metrics provide objective scores and normative ranges and are a combination of self report by patients as well as provider administration leaving minimal opportunity for bias or conflict of interest. These scales will be implemented by multiple different investigators who will be in direct supervision of one another throughout the study. Primary investigator will also be directly supervised by faculty supervisor to ensure compliance and accuracy of scores. The frequency of these assessments will range from weekly to monthly depending on the stage of the study the patient is in. If at any point a patient develops significant recurrence of depressive symptom burden and are determined to need to be removed from the study by either PI or faculty advisor they will be recommended to resume standard of care which is maintenance treatment with ECT. Patients will also be able to self remove themselves from the experimental component of the study and return to standard of care that is ECT at any time.

We will monitor the safety of participants, i.e., potential adverse events resulting from participation; and have procedures to safeguard against adverse events. We will actively screen and exclude any potential participants with a history of seizure disorder. We will also monitor every study session with a physician on site for every stimulation session. In case a seizure were to occur, having a physician on site in the room with the participant will help us in managing the event. All staff will also be trained in how to provide first aid in the event of a seizure ie lay the participant on their side and move any objects that can cause harm out of their vicinity. We will also monitor for side effects after every stimulation session including headaches and neck pain. We will assure data accuracy and protocol compliance, including quality-control procedures in place to assure data accuracy and completeness. Appropriate procedures range, for example, from regular data verification and protocol compliance checks performed by a data manager and a principal investigator, to a formal external data audit process by an external agent. We will report Unanticipated/Anticipated Problems/Adverse Event Reporting per the IRB reporting requirements.

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

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

- list the biological specimens and/or information that will be kept
- briefly describe the types, categories and/or purposes of the future research

- describe any risks of the additional use
- describe privacy/confidentiality protections that will be put into place
- describe the period of time specimens/information may be used
- describe procedures for sharing specimens/information with secondary researchers
- describe the process for, and limitations to, withdrawal of specimens/data

#### 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 or samples 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 or samples 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.

#### 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.

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 Hospital
- Food and Drug Administration

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).

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 Human Research Standards](#)

Does your study involve **HIV/AIDS research and/or screening for other reportable diseases (e.g., Hepatitis**

☐ Yes ☒ No

#### HIV/AIDS Research

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

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

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

#### PI-Initiated FDA-Regulated Research

Is this an investigator-initiated study that:

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

☒ Yes ☐ No

#### PI-Sponsored FDA-Regulated Research

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

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

No sponsor obligations have been transferred to a commercial sponsor, contract research organization (CRO), contract monitor, or other entity.

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

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

☒ Yes ☐ No

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

[Attachments](#)

## HIPAA

0 unresolved  
comment(s)Is HIPAA applicable? ☒ Yes ☐ No

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

I have attached a HIPAA Waiver of Authorization. ☐ Yes ☒ No

Attachments

## STUDY DRUG INFORMATION

0 unresolved  
comment(s)

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

**The term drug may include:**

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

**Does this protocol involve a drug including an FDA approved drug; unapproved use of an FDA approved drug; and/or an investigational drug?**☐ Yes ☒ No

If yes, complete the questions below. Additional [study drug guidance](#).

**LIST EACH DRUG INVOLVED IN STUDY IN THE SPACE BELOW**

Drug Name:

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

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

☐ Investigational Drug Service (IDS) UK Hospital

Other Location:

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

☒ Yes ☐ No

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

IND Submitted/Held by:

Sponsor: ☐Held By: Investigator: ☐Held By: Other: ☐Held By: 

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

See [FDA's Expanded Access Program Information for Individual Patient Expanded Access INDs](#), and attach the following:

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

For guidance and reporting requirements at the conclusion of treatment see the [Expanded Access SOP](#).

Complete and attach the required [Study Drug Form](#) picking "Study Drug Form" for the document type. Any applicable drug documentation (e.g., Investigator Brochure; approved labeling; publication; FDA correspondence, etc.) should be attached using "Other Drug Documentation" for the document type.



Attachments

## STUDY DEVICE INFORMATION

0 unresolved  
comment(s)

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

**A DEVICE may be a:**

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

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

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

☒ Yes ☐ No

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

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

LIST EACH DEVICE BEING TESTED IN STUDY IN THE SPACE BELOW

Device Name:

MagProX100 with Magoption Magnetic Stimulator

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

☐ Yes ☒ No

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

IDE/HDE Submitted/Held by:

Sponsor: ☐

Held By:

Investigator: ☐

Held By:

Other: ☐

Held By:

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

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

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

For guidance and reporting requirements at the conclusion of treatment see the [Medical Device SOP](#).

Does the intended use of any research device being tested (not clinically observed) in this study meet the regulatory definition [\[FDA's PDF\]](#) of Significant Risk (SR) device?

☐ Yes. Device(s) being tested in this study presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

☒ No. All devices being tested in this study do not present a potential for serious risk to the health, safety, or welfare of subjects/participants.

Complete and attach the required [Study Device Form](#), picking the "Study Device Form" for the document type. Any applicable device documentation (e.g., Manufacturer information; patient information packet; approved labeling; FDA correspondence, etc.) should be attached using "Other Device Documentation" for the document type.

**Attachments**

Attach Type	File Name
Other Device Documentation	MagVenture X100 Magoption Catalog.pdf
Study Device Form	TMSDeviceUpdate.pdf
Study Device Form	95789_StudyDevice_1186320Highlight.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. When attaching reliance documents, please ensure that you select the correct 'Document Type' from the drop-down menu. See below for the "Document Types" in bold, followed by examples of reliance documents for each type:
  - **Individual Investigator Agreement (IIA)**
    - A completed Individual Investigator Agreement

- **IRB Approval (Non-UK)**
  - A Letter of Approval from a Non-UK IRB
- **IRB Authorization Agreement (IAA)**
  - A SMART IRB Agreement
  - An OHRP Agreement
  - A DoD Agreement
  - An IREx Reliance Notification
  - Any Reliance Agreement
- **Letter of Support & Local Context**
  - A Letter of Support from an organization at which some research activities are occurring
  - Communications Plan
  - Local Context Form

Please reach out to [IRBReliance@uky.edu](mailto:IRBReliance@uky.edu) if you have any questions or concerns.

- **NOTE:** If the non-UK sites or non-UK personnel are engaged in the research, there are additional federal and university requirements which need to be completed for their participation. For instance, the other site(s) may need to complete their own IRB review, or a cooperative review arrangement may need to be established with non-UK sites.
- Questions about the participation of non-UK sites/personnel should be discussed with the ORI staff at (859) 257-9428.

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

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](mailto:IRBReliance@uky.edu).

## RESEARCH ATTRIBUTES

0 unresolved  
comment(s)

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

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

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 study involve one or more human subjects prospectively assigned into one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes? **If yes, your study meets the NIH definition of a clinical trial.**

☒ 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

For additional requirements and information:

- [Cancer Research \(MCC PRMC\)](#)
  - [Certificate of Confidentiality](#) (look up "Confidentiality/Privacy...")
  - [CCTS \(Center for Clinical and Translational Science\)](#)
  - [Clinical Research](#) (look up "What is the definition of....")
  - [Clinical Trial](#)
  - [Collection of Biological Specimens for Banking](#) (look up "Banks, Repositories, Registries...")
  - [Collection of Biological Specimens](#) (look up "Repositories, Registries, Specimen/Tissue Banks...")
  - [Community-Based Participatory Research](#) (look up "Community-Engaged...")
  - [Data & Safety Monitoring Board](#) (DSMB)
- \*For Medical IRB: [Service Request Form](#) for CCTS DSMB
- [Data & Safety Monitoring Plan](#)
  - [Deception](#)

- ☐ 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 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

\*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 "Banks, Repositories, ...Genetic/Genomic Data Sharing...")
- [Gene Transfer](#)

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

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

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

- [Use, storage and disposal of radioactive material and radiation producing devices](#)

## FUNDING/SUPPORT

0 unresolved  
comment(s)

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

☒ Not applicable

## Check All That Apply

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

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.):

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

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

## 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 form.) Check the following if needed:

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

Assurance/Certification Attachments

## OTHER REVIEW COMMITTEES

0 unresolved  
comment(s)

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

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

☐ Yes ☒ No

## Additional Information

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

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

Attachments

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

## ADDITIONAL INFORMATION/MATERIALS

0 unresolved  
comment(s)

Do you want specific information inserted into your approval letter? ☐ Yes ☒ No

## Approval Letter Details:

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

## Additional Materials:

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

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

Attach Type	File Name
Other	IRB Reliance Documentation.pdf

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

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

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

## SIGNATURES (ASSURANCES)

0 unresolved  
comment(s)

## Introduction

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

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

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



## Required Signatures:

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

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

Hover your mouse cursor here for additional instructions.



First Name	Last Name	Role	Department	Signee Return Comment	Date Signed	
Teresa	Gevedon	Department Authorization	Psychiatry		08/05/2024 04:03 PM	<a href="#">View/Sign</a>
Austin	Messner	Principal Investigator	Graduate Medical Education		06/17/2024 07:35 AM	<a href="#">View/Sign</a>
Gopalkumar	Rakesh	Faculty Advisor	Psychiatry		06/14/2024 03:59 PM	<a href="#">View/Sign</a>
Elizabeth	Arnold	Other Signee	Psychiatry		07/26/2024 04:41 PM	<a href="#">View/Sign</a>

## 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

**Principal Investigator's Assurance Statement**

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

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

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

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

**\*You will be able to "sign" your assurance after you have sent your application for signatures (use Submission section). Once all Assurance Statement signatures have been acquired, return to this section to submit your application to ORI.**

**Faculty Advisor's Assurance Statement**

☒ This is to certify that I have reviewed this research protocol and that I attest to the scientific merit of this study; to the qualifications of the investigator(s) to conduct the project; that facilities, equipment, and personnel are adequate to conduct the research; and that continued guidance will be provided as appropriate.

**\*\*If the Principal Investigator is completing this project to meet the requirements of a University of Kentucky academic program, in addition to Department Authorization, the student's faculty advisor should sign the Assurance Statement. The student's faculty advisor is accepting a supervisory role in guiding the student in conducting regulatory compliant research and therefore must be certified in human research protection training throughout the life of the protocol.**

**Other Signee's Assurance Statement**

☒ This is to certify, that at the request of the Principal Investigator (PI), I have reviewed this research protocol and agree it is appropriate per departmental/college policy and/or procedures and I will support the PI as needed.



## SUBMISSION INFORMATION

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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:

- The human subject risk/benefit relationship is unaffected, mitigated, or eliminated by closure of the study and all pertinent materials for closure of the research are being submitted to the IRB for consideration.

☒ 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
	StudyClosure	StudyClosure.pdf		0.079	ovmo223	1/29/2026 8:37:26 AM
	CR_EntireConsent	Consent20250417084101223.pdf		0.343	arme233	1/22/2026 10:04:57 AM
	AddInfoProduct	IRB Reliance Documentation.pdf	IRB Reliance Documentation	0.227	jlkear0	3/7/2025 1:54:39 PM
	Advertising	RecruitmentFlyer.pdf		0.293	arme233	11/14/2024 4:40:39 PM
	Informed ConsentHIPAA Combined Form	Informed ConsentHIPAA Combined Form_1194140.pdf	TMS	0.648	arme233	9/27/2024 10:42:09 AM
	Informed ConsentHIPAA Combined Form	Informed ConsentHIPAA Combined Form_1194138.pdf	Standard of Care	0.581	arme233	9/27/2024 10:41:42 AM
	StudyDevice	95789_StudyDevice_1186320Highlight.pdf	TMS Device Highlight	0.846	arme233	9/11/2024 10:52:54 AM
	ImpairedConsent	95789_ImpairedConsent_Highlight.doc	Updated Form T Highlighted	0.083	arme233	9/11/2024 10:49:16 AM
	ImpairedConsent	95789_ImpairedConsent_1104634.doc	Updated Form T 9/5/24	0.083	arme233	9/5/2024 3:56:19 PM
	OtherDeviceDocumentation	MagVenture X100 Magoption Catalog.pdf	Manufacturer Information	2.661	arme233	9/5/2024 3:47:14 PM
	StudyDevice	TMSDeviceUpdate.pdf	TMS Device Form Revised 9/5/24	0.846	arme233	9/5/2024 3:46:46 PM
	AdditionInfoConsiderations	95789 Messner.pdf	IRB Request For Minor Revisions Letter	0.091	braisor	8/29/2024 3:13:23 PM
	DataCollection	sapas.pdf	SAPAS	0.085	arme233	5/6/2024 7:22:03 PM
	DataCollection	CGI.pdf		0.058	arme233	4/30/2024 10:30:46 AM
	DataCollection	HAMILTON-DEPRESSION.pdf		0.060	arme233	4/30/2024 10:30:37 AM
	DataCollection	audit-c-eng.pdf		0.110	arme233	4/30/2024 10:30:32 AM
	DataCollection	ATHF.pdf		0.379	arme233	4/30/2024 10:30:23 AM
	DataCollection	DAST-10_Institute.pdf		0.131	arme233	4/30/2024 10:30:19 AM
	DataCollection	bprsform.pdf		0.070	arme233	4/30/2024 10:30:04 AM
	DataCollection	QIDS-SR.pdf		0.021	arme233	4/30/2024 10:29:57 AM

## Protocol Changes

No Changes

There are no recorded changes tracked for this protocol.

## Study Personnel Changes:

Protocol Number: 95789  
CLOSED

No comments



## Consent and Authorization to Participate in a Research Study

### **KEY INFORMATION FOR Theta Burst Stimulation for Treatment Resistant Depression: TMS Group**

We are asking you to choose whether to volunteer for a research study about the effects of non-invasive, non-significant risk transcranial magnetic stimulation on the long-term maintenance treatment of depression. We are asking you because you fulfill eligibility criteria for the study and were determined to be a candidate for maintenance ECT by your primary psychiatrist. You are also being asked to participate because you have expressed interest in participating in this study, and because you passed the medical screen. If you volunteer to take part in this study, you will be one of about 30 people to do so at the University of Kentucky. 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 learn more about how multiple sessions of non-invasive, non-significant risk transcranial magnetic stimulation influences the long-term prevention of worsening depressive symptoms. By doing this study, we hope to learn if transcranial stimulation is just as good as your current treatment (ECT) at preventing worsening depression. Your participation in this research will last 12 months. This is a research project, not a treatment program. The transcranial stimulation we use is called transcranial magnetic stimulation (TMS). TMS has been approved by the Food and Drug Administration (FDA) as a treatment for depression and in this study TMS is being used to investigate the long term or "maintenance" treatment of depression. However, the proposed use of the TMS in the study is investigational and has not been approved by the FDA.

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

This research study may have direct benefit to you by offering a less invasive long-term treatment for depression. The study will inform us about how effective transcranial magnetic stimulation is in treating depression long-term compared to ECT. For a complete description of benefits, refer to the Detailed Consent.

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

This study requires you to come to 245 Fountain Court 11 times over the course of 6 months for TMS treatments. At the conclusion of this 6 months a clinical judgment will be made regarding a return to maintenance ECT for the remaining 6 months of the study. You will spend a total of 12 months in this study. If this will be an issue, you may not want to volunteer for this study. For a complete description of risks from the study, refer to the Detailed Consent. If you experience headaches from the TMS procedure, you can withdraw from the study without ramifications regarding your clinical care.

#### **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 Austin Messner MD of the University of Kentucky, Department of Psychiatry at 859-382-7611 during regular business hours. If outside regular business hours, please contact the Psychiatry department On Call Group at (859) 226- 7063 and explain to the physician that you are a study participant.

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?**

You should not participate if you have a history of seizures or a seizure disorder, related neurological disorder, history of previous adverse events with TMS.

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

The research procedures will be conducted at University of Kentucky TMS Research Suite, Department of Psychiatry, 245 Fountain Court, Lexington, Kentucky 40509 and Good Samaritan Hospital. You will need to come to fountain court 11 times during the study over the first 12 months. Each of those visits will take about 4 hours. The total amount of time you will be asked to volunteer for this study is 44 hours over the next 12 months.

### **WHAT WILL YOU BE ASKED TO DO?**

If you agree to take part in this study, in your first visit, you will be asked to sign and date this consent form prior to any procedures. You will then undergo multiple different psychiatric and cognitive tests to assess your baseline. You will then undergo your first TMS mapping and treatment which is outlined in detail below. TMS treatments thereafter will consist of TMS treatment in four 10 minute sessions all occurring 1 hour apart. You will also participate in behavioral and cognitive tests in the 50 minutes between each TMS treatment. Your treatment schedule for TMS is as follows: weekly for 4 sessions, every other week for 4 sessions, and monthly for 3 sessions. During the study you will continue to have your depressive symptoms and cognitive function monitored through screening tools and interviews. At the conclusion of the 6 month TMS period a clinical decision will be made regarding your need to return to maintenance ECT.

The TMS equipment consists of an electric stimulator and a wire coil. Turning the stimulator on and off produces brief electrical currents in the coil, and these currents create a short-lived magnetic field around that coil (also called a 'magnetic pulse'). The wire coil is coated in plastic in order to insulate the stimulator current, it is shaped like an '8', and it is a little larger than a letter-size piece of paper. When the coil is held close to the head, and it generates a magnetic pulse, the pulse can induce very small electric currents in the part of the brain that is closest to the coil. These currents are similar to the currents that the neurons in the brain produce when communicating with each other. By inducing these currents with the TMS coil, we can temporarily change the way that brain region functions, either making the region work harder or less hard. Before applying TMS, the study doctors will need to determine what strength of stimulation to use for you by establishing your personal "motor threshold" – a measure of the excitability of the area of the human brain called the motor cortex. To establish this threshold, the study doctor or a member of the study staff will first place the stimulator over the part of your brain that controls the motor activity in your right hand. You will hear a clicking sound and feel a tapping sensation at your scalp. The stimulator will be adjusted to give just enough energy so that the motor region of the brain sends signals to your hand muscles, to make your hand twitch. The smallest amount of energy required to make your hand twitch is called the "motor threshold." Everyone has a different motor threshold. This procedure will take about 20 minutes and will be done only on day one of the study. During the TMS session, you will be seated comfortably in a chair. Earplugs will be worn to protect your hearing. Your head will be held steady by a frame with a chin rest and the TMS coil holder frame, and study staff will ensure your comfort during the entire procedure. The study staff will administer the magnetic stimulation. You will be required to sit still while you receive the stimulation. To block out the clicking noise of the TMS procedure, we will provide you with earplugs.

### **WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?**

Because of your participation in this study, you are at risk for the following side effects. You should discuss these with the researchers and your regular health care provider. The most serious known risk of TMS is the production of a seizure. TMS procedures are associated with a very low risk of seizures. Out of tens of thousands of people given various forms of TMS to date, 16 people have been reported to have had a seizure. TMS can produce a seizure when a series of pulses is given at high power and when repeated series of pulses are given extremely close together. This study will use only levels of TMS that are within safety guidelines. Levels of TMS that fall within the safety guidelines have not been associated with seizure in appropriately screened individuals. No seizures have occurred in normal volunteers with the dosage of TMS used in this study. To minimize this risk, we will medically screen you for any of the known characteristics that could lead to seizure. For example, if you have epilepsy you cannot participate in this study. You will be visually monitored during the TMS for any signs of seizure or muscle twitching. In spite of these precautions, there is a chance that you will experience a seizure. Should this occur, our study doctor will be called and will assess if you need to be taken to the Emergency Department at UK Medical Center. If you have a seizure, you may require hospital admission and follow-up

neurological evaluation. Having had a seizure may make it difficult for you to obtain medical insurance, future employment, and to drive. It is not known whether having had one seizure will make a person more prone to have future seizures. Should you have a seizure caused by TMS in this protocol, we will provide you with a letter documenting that the seizure was experimentally induced. The most common side effect of TMS is a "muscle-tension" type headache. We expect that about three out of ten people may experience a headache with the types of TMS used in this study. We will make every effort to reduce any discomfort by adjusting the position of the TMS coil on your head, altering the stimulation output of the coil, or taking breaks as required. If a headache occurs, it usually starts during or immediately after the TMS and lasts from minutes to hours after TMS. The headache usually goes away with standard over-the-counter pain medications. Neck pain may also occur. You may also experience some discomfort on your head where the coil is held. This is due to contraction of scalp muscles. Temporary numbness of the face has also been reported in rare instances that may last for several weeks after treatment. The click noises produced by the TMS procedure are loud enough to be damaging to your ears. You will therefore be required to wear earplugs, provided by the experimenter. Additional side effects considered to be rare in TMS are dizziness, memory impairment, trouble concentrating, and acute mood changes. If these occur, these effects do not last long (minutes to hours, but not day) and will resolve without need for treatment. There may be other risks that are currently unknown. The long-term effects of TMS are not known. There is also a risk of potential loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

There is always a chance that any research procedure can harm you. The research 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. If you experience any adverse events (a bad effect) after leaving the study, please contact Austin Messner MD, Primary Investigator, Department of Psychiatry at 859-382-7611 during regular business hours. If outside regular business hours, please contact the Psychiatry department On Call Group at (859) 226-7063 and explain to the physician that you are a study participant. For women of child-bearing potential: The risks of exposure to magnetic fields during pregnancy are unknown.

### **WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?**

Some people who undergo maintenance TMS have experienced continued remission of depressive symptoms of treatment resistant depression. These benefits are not guaranteed. If successful, this treatment modality would eliminate barriers to treatment including tolerability, financial burden, and unreliable social support. Furthermore, 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 other choices such as continuing standard of care treatment without participation in the study.

### **WHAT WILL IT COST YOU TO PARTICIPATE?**

For TMS treatments the University of Kentucky will not bill your insurance company, Medicare, or Medicaid for the study as it is done strictly for research. You will not incur any costs related to TMS, should you decide to participate in this study.

For ECT treatments 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.

### **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.

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).
- The Food and Drug Administration (FDA)

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

#### **CAN YOU CHOOSE TO WITHDRAW FROM THE STUDY EARLY?**

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.

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,
- we find that your participation in the study is more risk than benefit to you

The study intervention, medication, and/or device will no longer be provided to you and may not be available for purchase. This may occur for a number of reasons.

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

You may take part in this study if you are currently involved in another research study. 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 Austin Messner MD or Gopalkumar Rakesh, MD at 859-323-6021 immediately. After business hours, please call the Psychiatry department On Call Group at (859) 226-7063 and explain to the physician that you are a study participant. The physician will determine what type of treatment, if any, is best for you at that time. Other numbers of contact include:

- Austin Messner MD Pager 859-330-1928
- In case of medical emergency call 911 or report to nearest emergency department.
- If suicidal ideation were to arise or any other safety concerns related to psychiatric conditions please call 911, 988, or report to nearest emergency department

Austin Messner MD or Gopalkumar Rakesh, MD will determine what type of treatment, if any, is best for you at that time.

It is important for you to understand that the University of 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 your responsibility;

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

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

#### **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?**

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.

There is a slight possibility that during a research project, an investigator could discover something that could affect the health of you or your family. If this occurs, the finding will be reviewed by faculty supervisor Gopalkumar Rakesh, MD to determine if it is in your best interest to contact you.

Do you give permission for us to contact you about research results or incidental findings that are determined to be important to you/your family's health? (Incidental findings are unforeseen findings discovered during the course of the research that may affect you or your family's health).

☐ Yes ☐ No \_\_\_\_\_ Initials

You may also withdraw your consent to be contacted with information about research results or incidental findings by sending a written request to 245 Fountain Ct Lexington KY 40509.

### **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 regarding your willingness to participate in future research studies?

☐ Yes ☐ No \_\_\_\_\_ Initials

### **WHAT ELSE DO YOU NEED TO KNOW?**

The primary investigator Austin Messner MD is in psychiatry residency training. He will be guided in this research by Gopalkumar Rakesh, MD There may be other people on the research team assisting at different times during the study.

Science journals and agencies that fund research often ask researchers to share their data. Sharing data lets researchers explore new questions and repeat studies. Results of a research study become stronger when they are proven more than once. We may put data from you and other people that take part in the research, into scientific databases. If you volunteer to take part in this study, you will be one of about 30 people to do so. The data may be kept in the large databases forever. Some databases are open to anyone on the internet. Some limit access to approved researchers. We will not include your name and other information that could identify you. No one would know just from looking at the data that the information came from you.

### **WILL YOUR INFORMATION 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 or samples 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 stored, they will be available indefinitely and cannot be removed due to the inability to identify them.

## **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:**

- Health information that may be accessed includes procedural and preprocedural history and physical reports of ECT procedures and any other pertinent psychiatric documentation recorded during the study period.

### **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
- UK Health system (EPIC, the electronic medical records) and health systems outside of UK for which you have a patient relationship;
- The Food and Drug Administration (FDA)

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: Austin Messner MD 245 Fountain Ct Lexington KY 40509 to inform them 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**

A description of this clinical trial will be available on <https://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.

## INFORMED CONSENT SIGNATURES

This consent includes the following:

- Key Information Page
- Detailed Consent

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

_____ <b>Signature of research subject</b> <i>or, if applicable, parent or guardian</i>	_____ <b>Date</b>
_____ <b>Printed name of research subject</b> <i>or, if applicable, parent or guardian</i>	
_____ Printed name of [authorized] person obtaining informed consent and HIPAA authorization	_____ <b>Date</b>

## Statistical Analysis Plan

Descriptive statistics will be used to summarize baseline demographic and clinical characteristics of participants, including means and standard deviations for continuous variables and frequencies and proportions for categorical variables. The primary analysis will compare the two groups on maintenance of antidepressant benefit over the study period, as measured by repeated depression severity assessments, including the Hamilton Depression Rating Scale (HDRS), Quick Inventory of Depressive Symptomatology (QIDS), and Clinical Global Impression (CGI), which are administered longitudinally in both groups. Group differences over time will be evaluated using repeated-measures methods such as linear mixed-effects models to account for within-subject correlation and unequal numbers of observations across participants. Secondary analyses will compare cognitive outcomes, measured with the RBANS, between the maintenance TMS and maintenance ECT groups at baseline and follow-up. Statistical significance will be set at  $\alpha = 0.05$  (two-tailed).