eResearch M REGULATORY MANAGEMENT

Date: 8/25/2015, 12:01:12 PM

Print Close

01. General Study Information

All questions marked with a red asterisk (*) require a response. Questions without a red asterisk may or may not require a response, depending on those questions' applicability to this study.

1.1* Study Title:

Routine Functional Magnetic Resonance Imaging of the Brain

1.1.1 Full Study Title:

Functional Magnetic Resonance Imaging of the Brain

1.1.2 If there are other U-M studies related to this project, enter the eResearch ID number (HUM#) or IRBMED Legacy study number. Examples of related projects include, but are not limited to:

- Projects funded under the same grant
- IRBMED Legacy study being migrated into eResearch
- Previously approved Umbrella applications (such as Center Grants or approvals for release of funding)
- Previously approved projects for which this is a follow up study

1.2* Principal Investigator:

Luis Hernandez-Garcia

Note: If the user is not in the system, you may Create A New User Account...

1.3 Study Team Members:

Study Team Member	Study Team Role	Appointment Dept	Appointment Selection Complete?	Student	Friend Account	COI Review Required	Edit Rights	Accepted Role?	PEERRS Human Subjects?
Luis Hernandez-Garcia	PI	Magnetic Resonance Imaging Fac	Yes	no	No	no	yes	N/A	yes
John Jonides	Co-Investigator	LSA Psychology	Yes	no	No	no	yes	Yes	yes
Douglas Noll	Co-Investigator	Magnetic Resonance Imaging Fac	Yes	no	No	no	yes	Yes	yes
Scott Peltier	Co-Investigator	Magnetic Resonance Imaging Fac	Yes	no	No	no	yes	Yes	yes
Thad Polk	Consultant	LSA Psychology	Yes	no	No	no	yes	Yes	yes
Ryan Smith	Research Staff	Magnetic Resonance Imaging Fac	Yes	no	No	no	no	Yes	yes

1.8* Project Summary:

This project constitutes an umbrella protocol for routine functional MRI scans conducted at the University of Michigan's functional MRI laboratory. We define "routine" as:
1. Studies that only involve healthy participants
2. Studies that do not involve any contrast agents (e.g., gadolinium)
3. Studies that do not involve any drugs or other medical interventions

The mental tasks performed by the participants and the scientific questions under scrutiny will be determined by individual investigators and reviewed by the University of Michigan's Health Sciences and Behavioral Sciences Internal Review Board (IRB-HSBS). The HSBS protocol should explain whether the use of unusual equipment (for motor control studies, pain studies, etc.) will be used and how.

Note that individual studies that use the fMRI lab for routine scans will be approved with their own separate IRB prior to any specific study activity taking place at the fMRI lab, and that this approval will be verified by the staff of the FMRI laboratory.

Please see the supporting document "fmriproposl_oct26.docx" in the supporting documentation (section 44)

1.9* Select the appropriate IRB:

IRBMED

1.10* *Estimated* Study Start Date (Not required for IRBMED): *(mm/dd/yyyy)*

12/1/2014

1.11* *Estimated* Duration of Study:

10 years

01-1. Application Type

1-1.1* Select the appropriate application type.

Standard, non-exempt, research project

01-2. Standard Study Information

1-2.1* Who initiated this study?

Investigator

If other, please specify:

1-2.2* Are you or any students working on this project being paid from a federally funded training grant?

(●) **Yes** ( ) No

1-2.3 This study is currently associated with the following department. To associate this research with a different department, click Select. If the department has defaulted to "student", click select to specify the department through which this application is being submitted.

Magnetic Resonance Imaging Fac

1-2.4 Will the study utilize resources from the following centers?

Select all that apply:

There are no items to display

1-2.5* Does this study require review by the UM Health System Comprehensive Cancer Center Protocol Review Committee (PRC)?

Yes **No**

1-2.6* Has the scientific merit of this study already been peer reviewed (i.e., reviewed by one or more recognized authorities on the subject)?

Yes **No**

1-2.7* Is this a clinical trial?

Yes **No**

1-2.8* Would the integrity of this research study be compromised if the subject were able to view results of their research tests or medications in the Patient Portal of MyUofMHealth.org? Research results displayed to the subject in MyUofMHealth.org will include: lab results, radiology examinations and outpatient medication lists. Contracts and protocols should be assessed by the Principal Investigator for specific language regarding blinding of subjects and their research results.

(NOTE: Additional actions are required in order to limit the subject's view into their electronic medical record. Contact the IRB for additional information or see additional guidance for blinded studies at http://medicine.umich.edu/medschool/research/office-research/institutional-review-boards/guidance/blinded-studies)

Yes **No**

Study Team Detail

1.4 Team Member:

Luis Hernandez-Garcia
Preferred email: hernan@umich.edu
Business phone 734-763-9254
Business address: Biomedical Engineering 1096 BIRB 48109-2108

1.5 Function with respect to project:

PI

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

yes

1.7 Include this person on all correspondences regarding this application: ***(Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)***

Credentials: *Required for PI, Co-Is and Faculty Advisors*

Upload or update your CV, resume, or biographical sketch.

Name	Version
Hernandez CV | History	0.09

Conflict of Interest Detail: *Required for all roles except Administrative Staff*

Current Disclosure Status in M-Inform: *This study team member has disclosed outside interest(s) or relationship(s) in M-Inform.*

D1 Do you have an outside interest or relationship with a non-UM entity that relates to this research in one of the following ways:

- The entity is sponsoring this research
- The entity's products are used in this research
- The entity has licensed your invention (e.g. device, compound, drug, software, survey, evaluation or other instrument) being used in this research
- Part of the work on this project will be subcontracted to the outside entity
- Other relationship not listed above

no

D2 If "Yes" to the question above, name the entity or entities and provide a brief description of the relationship(s).

Study Team Detail

1.4 Team Member:

John Jonides
Preferred email: jjonides@umich.edu
Business phone 734-764-0192
Business address: Psychology 525 E University 48109-1109

1.5 Function with respect to project:

Co-Investigator

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

yes

1.7 Include this person on all correspondences regarding this application: ***(Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)***

yes

Credentials: *Required for PI, Co-Is and Faculty Advisors*

Upload or update your CV, resume, or biographical sketch.

Name	Version
Jonides vita 2015 | History	0.01
vita 2-11.doc | History	0.01

Conflict of Interest Detail: *Required for all roles except Administrative Staff*

Current Disclosure Status in M-Inform: *This study team member has disclosed outside interest(s) or relationship(s) in M-Inform.*

D1 Do you have an outside interest or relationship with a non-UM entity that relates to this research in one of the following ways:

- The entity is sponsoring this research
- The entity's products are used in this research
- The entity has licensed your invention (e.g. device, compound, drug, software, survey, evaluation or other instrument) being used in this research
- Part of the work on this project will be subcontracted to the outside entity
- Other relationship not listed above

no

D2 If "Yes" to the question above, name the entity or entities and provide a brief description of the relationship(s).

Study Team Detail

1.4 Team Member:

Douglas Noll
Preferred email: dnoll@umich.edu
Business phone 734-764-9194
Business address: Biomedical Engineering 2200 Bonisteel 48109-2099

1.5 Function with respect to project:

Co-Investigator

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

yes

1.7 Include this person on all correspondences regarding this application: ***(Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)***

yes

Credentials: *Required for PI, Co-Is and Faculty Advisors*

Upload or update your CV, resume, or biographical sketch.

Name	Version
Noll Biosketch 13 Jan 2015 | History	0.05

Conflict of Interest Detail: *Required for all roles except Administrative Staff*

Current Disclosure Status in M-Inform: *This study team member has disclosed outside interest(s) or relationship(s) in M-Inform.*

D1 Do you have an outside interest or relationship with a non-UM entity that relates to this research in one of the following ways:

- The entity is sponsoring this research
- The entity's products are used in this research
- The entity has licensed your invention (e.g. device, compound, drug, software, survey, evaluation or other instrument) being used in this research
- Part of the work on this project will be subcontracted to the outside entity
- Other relationship not listed above

no

D2 If "Yes" to the question above, name the entity or entities and provide a brief description of the relationship(s).

Study Team Detail

1.4 Team Member:

Scott Peltier

Preferred email: spelt@umich.edu
Business phone 734-647-8077
Business address: Functional MRI Lab 1088 BIRB 48109-2108

1.5 Function with respect to project:

Co-Investigator

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

yes

1.7 Include this person on all correspondences regarding this application: ***(Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)***

yes

Credentials: *Required for PI, Co-Is and Faculty Advisors*

Upload or update your CV, resume, or biographical sketch.

Name	Version
Peltier Bio 43015 | History	0.03

Conflict of Interest Detail: *Required for all roles except Administrative Staff*

Current Disclosure Status in M-Inform: *This study team member has disclosed outside interest(s) or relationship(s) in M-Inform.*

D1 Do you have an outside interest or relationship with a non-UM entity that relates to this research in one of the following ways:

- The entity is sponsoring this research
- The entity's products are used in this research
- The entity has licensed your invention (e.g. device, compound, drug, software, survey, evaluation or other instrument) being used in this research
- Part of the work on this project will be subcontracted to the outside entity
- Other relationship not listed above

no

D2 If "Yes" to the question above, name the entity or entities and provide a brief description of the relationship(s).

Study Team Detail

1.4 Team Member:

Thad Polk
Preferred email: tpolk@umich.edu
Business phone 734-647-6982
Business address: Psychology 530 Church St. 48109-1043

1.5 Function with respect to project:

Consultant

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

yes

1.7 Include this person on all correspondences regarding this application: ***(Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)***

yes

Credentials: *Required for PI, Co-Is and Faculty Advisors*

Upload or update your CV, resume, or biographical sketch.

Name	Version
Thad Polk's CV | History	0.08

Conflict of Interest Detail: *Required for all roles except Administrative Staff*

Current Disclosure Status in M-Inform: *This study team member has disclosed outside interest(s) or relationship(s) in M-Inform.*

D1 Do you have an outside interest or relationship with a non-UM entity that relates to this research in one of the following ways:

- The entity is sponsoring this research
- The entity's products are used in this research
- The entity has licensed your invention (e.g. device, compound, drug, software, survey, evaluation or other instrument) being used in this research
- Part of the work on this project will be subcontracted to the outside entity
- Other relationship not listed above

no

D2 If "Yes" to the question above, name the entity or entities and provide a brief description of the relationship(s).

Study Team Detail

1.4 Team Member:

Ryan Smith
Preferred email: rysm@umich.edu
Business phone 734-936-8757
Business address: Magnetic Resonance Imaging Fac 2360 Bonisteel Blvd. 48109-2108

1.5 Function with respect to project:

Research Staff

1.6 Allow this person to EDIT the application, including any supporting documents/stipulations requested during the review process:

no

1.7 Include this person on all correspondences regarding this application: ***(Note: This will include all committee correspondence, decision outcomes, renewal notices, and adverse event submissions.)***

no

Credentials: *Required for PI, Co-Is and Faculty Advisors*

Upload or update your CV, resume, or biographical sketch.

Name	Version

There are no items to display

Conflict of Interest Detail: *Required for all roles except Administrative Staff*

Current Disclosure Status in M-Inform: *This study team member has not yet disclosed in M-Inform.*

D1 Do you have an outside interest or relationship with a non-UM entity that relates to this research in one of the following ways:

- The entity is sponsoring this research
- The entity's products are used in this research
- The entity has licensed your invention (e.g. device, compound, drug, software, survey, evaluation or other instrument) being used in this research
- Part of the work on this project will be subcontracted to the outside entity
- Other relationship not listed above

no

D2 If "Yes" to the question above, name the entity or entities and provide a brief description of the relationship(s).

02. Sponsor/Support Information

The following sections request details about the current or pending sponsorship/support of this study. Consider all of the choices below and complete the appropriate sections.

* Note: At least one of the following sections must be answered. Multiple sponsors or sources of support must be added one at a time.

2.1 External Sponsor(s)/Support:

Type	Name	Other Direct Sponsor/Support	Support Type	Has PAF?

There are no items to display

2.5 Internal UM Sponsor(s)/Support: [Including department or PI discretionary funding]

	Type	Department Sponsor	Support Type
View	Other	Magnetic Resonance Imaging Fac	Both Financial and Non-financial

2.8 Check here if the proposed study does not require external or internal sponsorship or support:

☐

Internal Sponsor Detail

2.6* Department Sponsor/Support:
Magnetic Resonance Imaging Fac

2.6.1* Sponsor Type:
Other

If other, please specify:

the scans in this protocol will be supported by a variety of sources external and internal. Some of the internal sources will be discretionary funds, others internal UM grants.

2.6.2* Support Type:
Both Financial and Non-financial

2.6.3* Is the support confirmed?

○ Yes ◉ **No**

2.7 Upload Supporting Documentation

Name	Version

There are no items to display

03. UM Study Functions

3.1* Indicate all functions that will be performed at University of Michigan locations.

Select all that apply:

- Interaction (e.g., information gathering, survey, interview, focus groups, etc.)
- Intervention (e.g., use of drug or device, medical procedures, educational intervention, group intervention, social/psychological intervention etc.)
- Observation of behavior (direct or indirect)
- Qualitative research (e.g., 'member checking', open-ended questions, etc.)
- Storage (data/specimen)

If other, please specify.

03-1. Performance Sites

3-1.1* Performance Sites:

Location	Country	"Engaged" in the research?	Site Function
University of Michigan	USA	yes	Qualitative research,Intervention,Storage,Interaction,Observation

Performance Site Detail

3-1.2* Location or Institution:

University of Michigan

3-1.3 Address:

City

State

Country* USA

3-1.4* Function of this location with respect to this study:

Select all that apply:

- Interaction (e.g., information gathering, survey, interview, focus groups, etc.)
- Intervention (e.g., use of drug or device, medical procedures, educational intervention, group intervention, social/psychological intervention etc.)
- Observation of behavior (direct or indirect)
- Qualitative research (e.g., 'member checking', open-ended questions, etc.)
- Storage (data/specimen)

If other, please specify:

3-1.5* Will this site be "engaged" in the conduct of the research?

(●) **Yes** ( ) No

3-1.6 If known, provide the Federalwide Assurance (FWA) number for this location.

FWA00004969

3-1.7 If applicable, indicate what organization, agency or government office has reviewed this research and provided its approval (e.g., IRB, ethics committee, school district office, prison official, nursing home administrator).

3-1.8 Upload any location site approval documentation here:

Name	Version

There are no items to display

05. Research Design

5.1* Is there a stand-alone scientific protocol document and/or research plan associated with this application?

(●) **Yes** ( ) No

5.1.1* Click ADD to attach the document(s) electronically.

Name	Version
FMRI protocol for umbrella IRB | History	0.01

5.1.2* Indicate the section where each of the following are covered in the attached protocol:

Objective	section 1 (Objective)
Specific Aim/Hypothesis	section 1 (Objective)
Background Information	section 2(Background Information)
Methodology	section 3 (Methods)
Statistical Design	section 9 (Statistical Design)

5.1.3* Study team Experience: Briefly outline the experience and competence of the study team to pursue the proposed study.

Our team has directed and/or managed research scanning at the functional MRI laboratory for the last fifteen years with great success.
In brief, Drs. Luis Hernandez-Garcia, Douglas Noll and Scott Peltier are experts in MR physics and engineering, including the development of functional MRI acquisition and analysis techniques. Dr. John Jonides is a cognitive neuroscientist with extensive expertise in neuroimaging and behavioral studies.

5.2* Will the involvement of ANY subjects in this study be limited to analysis of their existing data or specimens?

( ) Yes (●) **No**

5.3* Will the study involve recruitment and/or participation of subjects in order to produce new data *(e.g., surveys, interaction, intervention)*? *[Require sections 8-1 and 11-3]*

(●) **Yes** ( ) No

5.4* List the inclusion and exclusion criteria for this study population and/or data set. *(If covered in attached protocol, indicate section)*

Inclusion criteria:
individuals older than 18 years of age

Exclusion Criteria:
Pregnancy
Claustrophobia
metallic or electronic implants in the body.

In addition to the exclusion criteria set forth by the fMRI laboratory, the lab will also follow specific study exclusion criteria in accordance with individual protocols

5.5 Identify any racial, ethnic, or gender group(s) that will be specifically excluded from participation in this research study and provide a compelling justification for such exclusion:

No ethnic or gender group is specifically excluded from participation in this research

5.6* Indicate the age range (in years) of the subject population in this study.

Minimum Age: 18
Maximum Age: 85 If no upper limit, enter "999"

06. Benefits and Risks

6.1 * Describe the potential benefits of this research to society.

Functional MRI can yield insights into how the brain works and also about the differences in brain function and structure in neurological and psychiatric disorders.

6.2 * Will results of the research be communicated back to the subjects?

○ Yes ◉ **No**

6.3 * Describe any direct risks to the public or community, which could result from this research?

none.

6.4 * Does this project involve study arms that have differing levels of benefit or risks to subjects?

○ Yes ◉ **No**

6.5 * Benefits and Risks:

Click "Add" to begin entering the benefit and risk level detail information associated with this study.

	Name	Risk Level	Direct Benefit
View	HUM00093760	No more than minimal risk	no

Benefits and Risk Level Detail

If a study involves multiple arms or phases that pose different levels of risk or direct benefits to subjects, then create an entry for each arm or phase using the "OK and Add Another" option at the bottom of this page. Only one entry is necessary if the risk level and the direct benefit to subjects is the same for the entire project, even if the study involves multiple arms or phases.

6.5.1 * Name of Arm (experimental group, study wave, etc.)

HUM00093760

6.5.2 * Description of Arm (experimental group, study wave, etc.)

6.6 * Are there potential direct benefits of this research to the subjects?

○ Yes ◉ **No**

6.7 * Provide a description of the foreseeable risks to subjects. For studies involving multiple arms or phases, enter the risks for this arm or phase only.

Provide a description of the foreseeable risks to the subjects.

For EACH identified risk, include:

- **Likelihood of the risk,**
- **Seriousness to the subject; and**
- **What measures will be taken to minimize the risk (for example, study design includes the substitution of procedures already being performed on the subject for diagnostic or treatment purposes, or in a study of Post-Traumatic Stress Disorder, the investigator takes steps to identify, manage, or refer as appropriate, subjects for whom the study may evoke very difficult emotions)**

If possible, please use the following categories to assess the likelihood:

- **"Common" (i.e., approximate incidence > 25%)**
- **"Likely" (i.e., approximate incidence of 10-25%)**
- **"Infrequent" (i.e., approximate incidence of 1-10%)**
- **"Rare" (i.e., approximate incidence < 1%):**

[1] There is a minor risk of discomfort or anxiety from being in the confined space of the MRI scanner. We will provide pads and blankets to make you as comfortable as possible. You will be able to talk to us throughout the study, and you will be able let us know right away if you want to stop the study and get out of the scanner.

[2] The MRI scanner makes loud, vibrating noises. You will wear foam earplugs to reduce the loud noises made by the scanner and prevent any hearing damage.

[3] Some studies, like this one, have the potential to cause "peripheral nerve stimulation" (PNS). PNS is a light touching sensation on the skin surface, lasting only for a few seconds. It may cause mild discomfort, but is not harmful to you. The MRI machine is operated within FDA guidelines so the potential for inducing PNS is low.

[4] Sometimes, subjects report a temporary, slight dizziness, light-headedness or nausea during or immediately after the scanning session. If you feel dizzy or light-headed, we will have you get up slowly from the scanner.

[5] Because the strong electromagnetic fields can move metal objects and cause heating, there is a risk that loose objects (jewelry, keys) outside your body could be accelerated by the magnetic field and strike you, causing you injury. There is also a risk that the magnetic fields could disturb a metal fragment in your body, interfere with an implanted device, such as a pacemaker or neurostimulator, or cause metal (including foil-backed medication patches) on or in your body to heat up, causing you harm. We keep the environment around the MRI scanner completely free of loose metal objects that could be moved by the magnetic field, and we will make sure that you have no metal on your body that could be affected by the MRI scanner. We will also ask you questions and have you complete an MRI screening form to make sure that you have no metal inside your body that would cause you harm during the MRI scan.

[6] There is the potential that a magnetic resonance image may reveal an abnormality that is already in your body, such as a cyst or tumor. Many such abnormalities are not clinically significant, but you may need or want to investigate them further. Such a finding might require additional studies, and maybe even treatment, which would not be paid for by the investigators, the sponsor, or the University of Michigan.

[7] There is an unlikely risk of breach of confidentiality. This risk will be minimized at the FMRI lab by not labeling any of the collected information by subject name, but rather by a subject ID that does not reflect the subject's identity or other personal information.

6.8 * What is the level of risk of harm to the subjects, resulting from this arm of the research? For studies involving multiple arms or phases, enter the level of risk for this arm or phase only.

No more than minimal risk

6.9 * Discuss why the risks to the subjects are reasonable in relation to the anticipated benefits.

Functional MRI may ultimately provide a greater understanding of the human brain and may advance the treatment of neurological and psychological disorders. Since the risks are so minimal, the benefit to risk ratio is excellent.

07. Special Considerations

7.1* Does this study involve human tissue or biological specimens (use, collection, or secondary analysis) ***(e.g. blood, urine, bone marrow, skin, etc.)? [Require Section 18]***

(•) **Yes** ( ) No

7.1.1* Will genetic analysis be performed on any specimens acquired in conjunction with this study? ***[Require Section 20]***

( ) Yes (•) **No**

7.2* Does this study involve the secondary analysis of a pre-existing data set, including data associated with any specimens identified in response to question 7.1? ***[Require Section 24]***

( ) Yes (•) **No**

7.3* Will the research involve the access, collection, use, maintenance, or disclosure of University of Michigan protected health information (PHI)? PHI is:

- **information about a subjects past, present, or future physical or mental health, the provision of healthcare to a subject, or payment for the provision of healthcare to a subject; AND**
- **maintained by a University of Michigan school, department, division, or other unit that is part of the University's HIPAA-covered component (e.g. healthcare provider, healthcare plan, or healthcare clearinghouse).**

[Require Section 25]

( ) Yes (•) **No**

07-1. Special Considerations - Continued

7-1.1* Will subjects receive payment or other incentives for their participation in the study? ***[Require Section 13]***

( ) Yes (•) **No**

7-1.2* Will subjects undergo healthcare-related treatments or procedures (standard of care and/or research) as part of the study? ***[Require Section 14]***

( ) Yes (•) **No**

7-1.3* Does this study involve the deception or concealment of subjects? ***[Require Section***

27]

○ Yes ◉ **No**

7-1.4* **Excluding routine email correspondence, does this study involve the use of the Internet or email as an integral part of the research design or will sensitive information be transmitted by e-mail?** ***[Require Section 28]***

○ Yes ◉ **No**

7-1.5* **Will the study collect data using surveys, interviews, or focus groups?** ***[Require Section 29]***

○ Yes ◉ **No**

7-1.6* **Does this study require subjects to listen to an audio recording or view images?** ***[Require Section 31]***

◉ **Yes** ○ No

7-1.7* **Will any drugs, biologics, nutritional** ***(e.g., herbal or alternative medication)*** **supplements or other material be administered, implanted, or applied to the subjects as the object of the study?** ***[Require Section 15]***

○ Yes ◉ **No**

7-1.8* **Will the study involve a placebo** ***(drug, device, procedure, intervention, surgery, etc.)*** **control group?** ***[Require Section 17]***

○ Yes ◉ **No**

7-1.9* **Will the study involve human embryonic stem cells (hESCs) or induced pluripotent stem cells?** ***[Require Section 19]***

○ Yes ◉ **No**

7-1.10* **Will the study have a Data and Safety Monitoring Plan (DSMP)?** ***[Require Section 32]***

◉ **Yes** ○ No

7-2. Special Consideration - Continued

7-2.1* **Will any devices be used, administered, implanted, or applied to the subjects, or will human specimens be used to test in vitro diagnostic devices?**
[Non-IRB HSBS and Non-IRB Dearborn Applications Require Section 16]

◉ **Yes** ○ No

7-2.2* **Will the subjects be exposed to any ionizing radiation during the course of this study?** ***[Require Section 21]***

○ Yes ◉ **No**

7-2.3* **Will any organs, tissues, or cells from other humans** ***(including fetal tissue)*** **or animals be administered to the subjects for the purposes of this study?** ***[Require Section 22]***

○ Yes ◉ **No**

7-2.4* **Does this study involve a gene transfer intervention or an intervention based on recombinant DNA technology?** ***[Require Section 23]***

○ Yes ◉ **No**

08. Subject Participation

8.1* Please indicate the number of subjects to be enrolled from ALL study locations to achieve the goal of the study:

99999999

8.2* Enter the estimated number of subjects to be enrolled at each University of Michigan site:

Location Or Institution	Total
University of Michigan	
Adults	999999
Children	0
Total from all University of Michigan sites:	**999999**

08-1. Subject Recruitment

8-1.1* At what point in the study are you planning on beginning the recruitment of subjects?

0-2 years after approval

8-1.2* Indicate which of the following established subject pools, if any, will be used for recruitment.

Select all that apply:

N/A

Provide Related UM IRB Project Number or Subject Pool Description:

8-1.3* Describe the manner in which potential study subjects will be recruited. List how, when, who will recruit and where they will be recruited. Include any provisions to protect or maintain subject privacy.

subject recruitment procedure will vary from protocol to protocol. It will be reviewed by the HSBS-IRB

8-1.3.1 If applicable, how will prospective subjects' healthcare providers *(e.g., physician, dentist, etc.)* be involved in the recruitment and/or be notified of their individual patients' participation in the study?

subject recruitment procedure will vary from protocol to protocol. It will be reviewed by the HSBS-IRB

8-1.4* Explain how the recruitment strategy is equitable and represents the population required for the study. *If the information is covered in the attached protocol, please indicate section.*

subject recruitment procedure will vary from protocol to protocol. It will be reviewed by the HSBS-IRB

8-1.5* Does the recruitment strategy involve contacting individuals multiple times in an effort to secure their initial enrollment into the study?

○ Yes ◉ **No**

8-1.6* Indicate which methods will be used for recruitment?

Check all that apply:

Other

If other please specify:

subject recruitment procedure will vary from protocol to protocol. It will be reviewed by the HSBS-IRB

8-1.7 How will any email, address, and/or telephone lists be obtained?

subject recruitment procedure will vary from protocol to protocol. It will be reviewed by the HSBS-IRB

8-1.8* What materials will be used for recruitment? ***The IRB must approve all recruitment materials.***

See Help for important information regarding the requirements for recruitment materials

Check all that apply:

Pre-screening questions

None

If other please specify:

subject recruitment procedure will vary from protocol to protocol. It will be reviewed by the HSBS-IRB

If Web pages will be used, provide the Web address (URL) for the location where the pages will be posted (also upload the content of the pages below):

Upload recruitment materials here:

See Help for more information about working with documents (e.g. uploading, downloading, and editing).

Name	Version
safety screening form | History	0.01

☐ **Check here if any of the materials are not available electronically.**

Note: *Study Teams are encouraged to scan and upload documents. See Help for a list of sites with scanning facilities*

09-1. Subject Populations

9-1.1* Is the research designed to include or allow the following populations?

Select all that apply

☑ **Normal, healthy subjects**

☑ **Adults** *age 18 and older*

☐ **Minors able to consent** *to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted (e.g. emancipated minors or minors seeking treatment for certain conditions.)*
Children and/or Viable Neonates *(i.e. persons who have not yet reached the legal*

- [ ] *age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted) [Require Sections 33 and 41]*
- [ ] **Neonates of uncertain viability and/or nonviable neonates** *(do not check this box if the research is solely retrospective. For retrospective research regarding neonates of uncertain viability, check the box for 'Children'. See Help for additional information.) [Require Section 34]*
- [ ] **Individuals and/or products involving human in vitro fertilization**
- [ ] **Pregnant women and/or fetuses** *[Require Sections 35 and 41]*
- [ ] **Lactating women** *[Require Section 36]*
- [x] **Women of child-bearing potential** *[Require Section 37]*
- [ ] **Prisoners** *(If the research includes a study population that is likely to become incarcerated during the conduct of the research, also select this category) [Require Section 38 and 41]*
- [ ] **Cognitively impaired adults** *[Require Sections 39 and 41]*
- [ ] **College students** *[Require Sections 40 and 41]*
- [ ] **Economically or educationally disadvantaged persons** *[Require Section 41]*
- [ ] **Patients of the study team** *[Require Section 41]*
- [ ] **Employees, students or trainees of the study team** *[Require Section 41]*
- [ ] **Family members of the study team** *[Require Section 41]*
- [x] **Unknown, unspecified population**

10. Informed Consent - Adults

10.1* What type of informed consent will be obtained from adults or minors legally able to consent to treatments or procedures involved in the research?

Select all that apply:

Comprehensive written

10.1.2* Describe the process to seek and obtain informed consent and/or assent from adults. If requesting a waiver of documentation of assent, provide justification here.

Prior to scanning the participants, they will be given an informed consent document to read and sign. The investigators or designees will be on hand to answer any questions that the participant may have.

10.1.3* Is the cognitive capacity of the subjects expected to change significantly during the study?

○ Yes ◉ **No**

10-1. Informed Consent

10-1.1* All documents related to consent, assent, permission, and or debriefing documents, including oral scripts must be uploaded here. If you are requesting a waiver of documentation of informed consent, upload a copy of any written materials to be provided to participants, and provide a written description of any information to be provided orally.

Name	Version
Consent-Clean-HUM00093760 | History	0.02
Consent-Tracked | History	0.03

10-1.1.1* Does the Informed Consent use the sentences required for Applicable Clinical Trials: "A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."?

○ Yes ◉ **No**

10-1.2* Will the subjects be audiotaped, videotaped, or photographed (identifiable images of subject) during the research?

○ Yes ◉ **No**

10-1.3* Is there a substantial likelihood that the research will be conducted among a non-English-speaking population?

○ Yes ◉ **No**

10-1.4* Indicate which anticipated costs could be the full or partial responsibility of the subject.

Check all that apply:

No anticipated costs

If other, please specify:

10-1.5* Is the study designed to collect identifiable information from primary research subjects about other individuals, including family members?

○ Yes ◉ **No**

10-1.6* At the conclusion of this study, will specimens and/or data be retained for future research use?

◉ **Yes** ○ No

10-1.7* Does the informed consent document explicitly notify subjects that their data and/or specimens will be stored for future research?

○ Yes ◉ **No**

10-1.8* Are subjects required to agree to retention of their data and/or specimens as a condition of participating in the research?

○ Yes ◉ **No**

11. Confidentiality/Security/Privacy

11.1* Will the study team access any data that is linked to a subject's identity by name or other identifier or code? *[Require Section 11-1]*

○ Yes ◉ **No**

11.2* Explain how the subjects' privacy will be protected.

Study records that contain subject names (safety screening, payment, and consent forms) will be secured by the PI in a locked cabinet. Access will be limited to the PI. All other study data, images, test results will be numerically coded and will not be linkable to the subjects.
MRI data collected will be coded with a unique identifier and provided to the respective study team according to their established protocol

11.3* How will the study team protect research records, data, and/or specimens against inappropriate use or disclosure, or malicious or accidental loss or destruction in order to protect the confidentiality of subject data?

Select all that apply:

- Locked office
- Locked cabinet or storage unit
- Individual ID plus password protection
- Routine electronic back up

If other please specify:

11.4* Will the research generate information that, if revealed, might place the subjects at risk of personal safety, criminal or civil liability, or damage to their financial standing, employability, or reputation [Require Section 11-2]

○ Yes ◉ **No**

11.5* Will data be provided to a repository as part of a data sharing agreement?

◉ **Yes** ○ No

11.5.1* Please indicate the repository:

Select all that apply:

- Other

If Other, please specify:
Imaging data will be kept on servers under encrypted, secure access and on digital media (DVD) under a locked cabinet. The data labels will not contain any personal information that can be linked to individual participants.

11.6* What will happen to the data and/or any specimens at the conclusion of this study?

Select all that apply:

- Retain for study recordkeeping purposes
- Retain for future research use - requires Section 11-4

11.6.2* If the data and/or specimens will be retained for study recordkeeping purposes,

provide the following information (if covered in the attached protocol, please indicate section):

- expected duration of the retention period,
- any changes in the conditions or arrangements for storage of research data/specimens during the retention period, if different from those listed above in question 11.3.

Image data will be stored electronically on hard disk and archived on DVD media. The hard disks are only accessible via user name and password and the DVD's will be kept in a locked room. All electronic image information will be filed under each subject's individual ID code to protect their identity.

11-3. End of Subject Participation

11-3.1* What specific criteria will be used to prematurely end a particular subject's participation in the study (If covered in attached protocol or informed consent, indicate specific location).

The study will be terminated if the subject experiences excessive discomfort from being inside the MRI scanner or if he/she experiences Peripheral Nerve Stimulation or noticeable heating from the radiofrequency transmitter.

11-3.2* If a participant withdraws from the research, what is the plan to use, disclose, store, or destroy the participant's data and/or specimen?

data will be destroyed if subject requests that his/her data not be used. Otherwise we will keep useable data.

11-4. Retention of Data and/or Specimens Detail

Retention may be for future research by the investigator and/or the creation of a bank or repository.

Completion of this section is required based on the response provided to question 11.6.

11-4.1* What is the intent or purpose of retaining the data and/or specimens?

To allow for future development of signal processing techniques, models and statistical analyses that may benefit from the existing data.

11-4.2* Where will you store the data and/or specimens?

Only at the University of Michigan

If Other Institutions, please specify:

11-4.3* Describe the arrangements for the storage conditions, management, and security of the data and/or specimens. ***Include the following as applicable:***

- ***Personnel access to data and/or specimens***
- ***Whether identifiers will be removed and the key to any code destroyed***
- ***For coded data and/or specimens, indicate who holds key to the code and where it is stored in relation to the data and/or specimens***
- ***Storage plan***
- ***Plan to protect privacy in transfer to other collaborators.***

All study data, images, test results will be numerically coded and will not be linkable to the subjects. Study records that contain subject names include safety screening, payment, and consent forms and will have access limited to the investigators.

Study records that contain subject names (safety screening, payment, and consent forms) will be secured by the PI in a locked cabinet.

16. Devices

Completion of this section is required based on the response provided to question 7-2.1 or 7-3.8.

16.1* For all devices to be used at the Hospital and Health Centers, has the Biomedical Engineering Unit (BEU) assessed all devices for safety and tagged or registered all devices?

- (•) **Yes**
- ( ) No
- ( ) Not Applicable

16.2* In the questions that follow, list all devices that will be used (including in vitro), administered, implanted, or applied as the object of the study, or are relevant to the study.

16.2.1 Devices Not Approved or Not Cleared for Marketing by the FDA:

Name	IDE Number	Risk Designation
There are no items to display		

16.2.12 Devices being used "Off-Label" or for a Non-Approved Indication or in a Non-Approved Population that have already been Approved (PMA) or Cleared (510(K)) or exempted from the (510(K)) requirements by the FDA:

Name	IDE Number	Risk Designation
There are no items to display		

16.2.28 Devices being used "On-Label" that have already been Approved (PMA) or Cleared (510(k)) or exempted from the (510(k)) requirements by the FDA:

	Name
View	Magnetic Resonance Imaging Scanner

FDA Approved Device:

16.2.29* What is the generic name or descriptor of the device? Include trade names if available.

Magnetic Resonance Imaging Scanner

16.2.30* Please enter the FDA 510(K) or Premarket Approval (PMA) number.

K081028

16.2.31* What is the source of the device? Include both supplier and manufacturer if different.

General Electric

16.2.32* What is the purpose of the device and how will it be used in the study? *Include any post-manufacturing modifications to the device.*

To image organs using magnetic resonance images. It will be used to collect time series (movies) of such images of the brain in order to study how the brain works.

16.2.33* What is the frequency and total duration of use of the device for an individual subject?

It will be used for a maximum of two hours. The subject may be scanned more than once for the study.

16.2.34* Is this device the OBJECT of the study?

○ Yes ◉ **No**

18. Biological Specimens

Completion of this section is required based on the response provided to question 4-1.1, 7.1, or 7-3.1.

18.1* List all of the human biological specimens that will be used in the study.

18.1.1 Blood obtained directly from subjects for the purpose of this research.

Only key fields are displayed. Click on the link below to view all details.

Collection Schedule

There are no items to display

18.1.4 Non-blood specimens obtained directly from subjects for the purpose of this research study, NOT from specimens removed for medically indicated reasons.

Only key fields are displayed. Click on the link below to view all details.

Kinds Of Specimens

View urine. If the subject is unsure of whether she is pregnant, the FMRI laboratory will provide a urine pregnancy test at no cost to the subject.

18.1.9 Blood or non-blood residual or to-be-discarded specimens.

Only key fields are displayed. Click on the link below to view all details.

Kinds Of Specimens

There are no items to display

18.1.15 Blood or non-blood existing, banked, human biological specimens.

Only key fields are displayed. Click on the link below to view all details.

Kinds Of Specimens

There are no items to display

18.2* Is there a link between the biological specimens and the identity of the person from whom the material originated?

○ Yes ◉ **No**

Direct Collection Non–Blood Specimen

18.1.5* What kinds of biological specimens will be used?

urine. If the subject is unsure of whether she is pregnant, the FMRI laboratory will provide a urine pregnancy test at no cost to the subject.

18.1.6* By what method will the biological specimens be collected?

The subject will be asked to take the pregnancy test in the restroom. This involves urinating on a testing device.

18.1.7* Who will collect the biological specimens from the subjects? Specify source name and primary contact *(e.g., directly from physician, UMHS clinical pathology labs, UMHS delivery rooms, remote institutions, etc.)*

The subject will conduct the test themselves (the FMRI will provide instructions if necessary).

18.1.8* Describe the specimen collection schedule, including frequency, duration *(first to*

***last collection)*, and amount *(size, weight, or volume)*. Indicate the total amount to be collected from each subject and show how this amount was calculated from the frequency, duration, and amount per collection as indicated.**

This will be done only one time and only if the subject is unsure of whether they are pregnant.

31. Watching/Listening to Audiovisual Materials

Completion of this section is required based on the response provided to question 7-1.6.

31.1* Please upload copies of all audio-visual materials used in the research.

Name	Version
brief description of audio visual materials. | History	0.01

☐ **Check here to indicate that the material is not available electronically.**

31.2* Are any of the materials likely to produce psychological discomfort or negative feelings in the subjects?

○ Yes ◉ **No**

32. Data Safety And Monitoring Plan

Completion of this section is required based on the response provided to question 7-1.10.

The principal investigator (PI) has the ultimate responsibility for the conduct of this research study. The study-specific scientific protocol should include detailed information about tests and procedures employed to safeguard the health and safety of the subjects. Additionally, the PI must prepare a specific data and safety monitoring plan taking into account national guidelines and the study's complexity, risk, and size. The plan should include the administrative processes for recording and evaluating the data quality and integrity. The plan should also specify the responsibilities of research team members and the schedules for reviewing and reporting study progress and adverse events.

Components of this plan relating to the protection of subject privacy and data confidentiality should already have been included in the Confidentiality/Security section of this application.

Additionally, certain members of the research team must complete the PEERRS mandatory training on human subject protection. This includes personnel joining the study team after the initiation of the study.

The Risk Level has been indicated as:

Name	Risk Level	Direct Benefit
HUM00093760	No more than minimal risk	no

32.1* Indicate who will provide study information and instructions to the subjects beyond what is included in the informed consent document.

Select all that apply:

Study Coordinator/Research Assistant
Nursing/Professional Support Staff

If other, please specify:

32.2* Indicate who will obtain informed consent from the subjects.

Select all that apply:

Study Coordinator/Research Assistant

Nursing/Professional Support Staff

If other, please specify:

32.3* Indicate who will collect and record study data.

Select all that apply:

Study Coordinator/Research Assistant

Nursing/Professional Support Staff

If other, please specify:

32.4* Indicate what mechanism(s) will be used for monitoring subjects and identifying adverse events.

Mechanism (Select at least one:)	Conducted by:
☐ Direct interviews/ physical exams conducted by:	Select all that apply: There are no items to display If other, please specify
☐ Review of lab work, tests, procedures, etc. by:	Select all that apply: There are no items to display If other, please specify
☐ Telephone follow-up conducted by:	Select all that apply: There are no items to display If other, please specify
☑ Self-reporting by subject	Instructions must be included in the Informed Consent Document.
☐ Other	If other, please specify

Reminder: Adverse Events that come to the attention of any member of the study team must be reported to the PI in a timely manner.

32-1. Data and Safety Monitoring Plan - AE Reporting

Adverse Event (AE) Reporting

32-1.1* Adverse events will be reported to:

Organization	Reporting Mechanism
IRB	eResearch AE/ORIO submission

If other, please specify:

32-1.2* Indicate the AE reporting timetable that will be used to report adverse events to

the IRB:

Standard IRBMED AE reporting timetable

32-1.3* Affirm that the adverse events will be reported to the IRB according to the following generalized AE GRADING SCALE:

- 0 - No adverse event
- 1 - Mild AE – No treatment needed
- 2 - Moderate AE – Resolved with treatment
- 3 - Severe AE – Inability to carry on normal activities, required professional medical attention
- 4 - Life-threatening or disabling AE
- 5 - Fatal AE

32-1.4* Will Serious Adverse Events (SAEs) be categorized according to the following FDA definition?

Yes

- Death
- A life-threatening adverse drug experience
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant disability/incapacity
- A congenital anomaly/birth defect
- Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

32-1.5* Affirm that either the principal investigator or a co-investigator will determine the ATTRIBUTION/RELATEDNESS for each adverse event.

- Definitely related
- Probably related
- Possibly related
- Unlikely to be related
- Definitely not related

32-1.6* Affirm that the EXPECTEDNESS will be assigned for each adverse event according to the following definitions:

- Unexpected adverse events (i.e., has NOT been addressed or described in one or more of the following: Informed consent document(s) for this study, IRB application for this study, grant application or study agreement, protocol or procedures for this study, investigators' brochure or equivalent (for FDA regulated drugs or devices), DSMB/DSC Reports, published literature, other documentation)
- Expected adverse events (i.e., has been addressed or described in one or more of the following: Informed consent document(s) for this study, IRB application for this study, grant application or study agreement, protocol or procedures for this study, investigators' brochure or equivalent (for FDA regulated drugs or devices), DSMB/DSC Reports, published literature, other documentation, or characteristics of the study population)

32-2. Data Safety and Monitoring Plan - Monitoring the Study

Monitoring the Study

32-2.1* Indicate the frequency with which the study team will conduct scheduled assessments of study recruitment, data integrity and quality, adverse events, withdrawals, and compliance with protocol plan.

Monthly

If other, please specify:

32-2.2* Study oversight and safety monitoring may be required based on the nature, size, and complexity of the study. Indicate the responsible entities.

Select all that apply:

No additional monitoring is required – the nature, size, and complexity of this study does not require additional safety monitoring to that provided by the IRB.

If other, please specify:

If no additional monitoring is required, jump to 32-2.3.

32-2.2.1 Provide the names and areas of expertise of those providing this additional monitoring

32-2.2.2 Indicate the frequency with which the additional monitoring activities will be conducted.

If other, please specify:

32-2.2.3 Indicate the data that will be reviewed.

Select all that apply:

There are no items to display

32-2.2.4 If a DSMB or DSC charter exists, upload it here.

Name	Version

There are no items to display

32-2.3* Monitoring reports will be provided to:

Organization	Reporting Mechanism
IRB (required)	eResearch AE/ORIO submission

If other, please specify:

37. Women of Child Bearing Potential

Completion of this section is required based on the response provided to question 9-1.1.

37.1* Is there a potential that any of the study procedures pose significant physical or psychological risks to women who are or may be pregnant, or to a fetus?

○ Yes ◉ **No**

44. Additional Supporting Documents

44.1 Please upload any additional supporting documents related to your study that have not already been uploaded. Examples include, but are not limited to, data collection sheets, newsletters, subject brochures, and instructional brochures.

Name	Version
Proposal for IRBMED umbrella protocol for functional MRI | History	0.01

44.2 If the study sponsor requires that the IRBMED approval letter contain a list of supporting documents, list the names of the documents in the box below as they should appear on the IRBMED approval letter:

45. End of Application

The form was successfully submitted. Click 'Exit' or 'Finish' to leave the form.