eResearch M REGULATORY MANAGEMENT SAND

Date: Tuesday, August 25, 2015 12:14:34 PM

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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:
Sample IRB Application for Behavioral Studies using the Approved Routine fMRI Protocol

1.1.1 Full Study Title:

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

HUM00093760 - Routine Functional Magnetic Resonance Imagining of the Brain

1.2* Principal Investigator:
Cynthia Shindledecker
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?
Cynthia Shindledecker	PI		N/A	no	No	no	yes	N/A	yes
Thad Polk	Co-Investigator		N/A	no	No		yes	No	no
Mary Ramirez	Co-Investigator		N/A	no	No	no	yes	No	yes

1.8* Project Summary:
Describe your project.

1.9* Select the appropriate IRB:
Health Sciences and Behavioral Sciences

1.10* *Estimated* Study Start Date (Not required for IRBMED): *(mm/dd/yyyy)*
7/1/2015

1.11* *Estimated* Duration of Study:
Whatever is appropriate

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.
Vice President for Research

1-2.4 Will the study utilize resources from the following centers?
Select all that apply:
There are no items to display

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**

Study Team Detail

1.4 Team Member:
Cynthia Shindledecker
Preferred email: cshindle@umich.edu
Business phone 734-615-9466
Business address: Health Sciences & Behavioral Suite 1169 Bldg 520 48109-2800

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

There are no items to display

Financial Interest Screening Questions for Study Team Members Not Affiliated with the University of Michigan: *Required for all roles except Administrative Staff*

Below, you be asked several questions intended to identify Financial Interests and relationships that may be relevant to **THIS RESEARCH**. These may include Intellectual Property Interests (IP interests), as well as relationships with entities whose interests may affect/be affected by this research. If relevant to this research, you should also consider companies that compete commercially with the research sponsor or the manufacturer of the study drug, device or other investigational item if you know that the competitor's Financial Interests would reasonably appear to be affected by this research.

In relation to **THIS RESEARCH**, for the past 12 months, do you or your Family member (your spouse, domestic partner, or dependent) have or anticipate having any of the following Financial Interests:

F1. Are any *activities* or *relationships* with an entity, whether paid or unpaid, where that entity's financial interests could be affected by this research? Examples include service on a board of directors, service on a scientific advisory board, consultant, officer, manager, or partner.

no

F2. An *Equity Interest* in any publicly traded or privately owned entity whose financial interests could be affected by this research, including but not limited to shares of stock or stock options? DO NOT include equity held in a mutual, pension, or investment fund over which you have no control with regard to investment decisions.

no

F3. An investorship or ownership interest in any *Intellectual Property (IP)* that is being tested, evaluated, developed in, or its commercial value will be affected by this research? This includes IP that is the subject of a copyright, issued patent or a patent application (regardless of whether it has been licensed or optioned).

no

F4. Any payments over $5,000 (USD) received for the past 12 months (apart from any payments from the University of Michigan), including salary, honoraria, fees, or other forms of compensation or anything of value, from any entity that has a financial interest in this research?

no

F5. If any of the above is answered "yes", you must complete this form and upload the completed form below.

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:
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
Thad Polk's CV | History	0.02

Financial Interest Screening Questions for Study Team Members Not Affiliated with the University of Michigan: *Required for all roles except Administrative Staff*

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F3. An investorship or ownership interest in any *Intellectual Property (IP)* that is being tested, evaluated, developed in, or its commercial value will be affected by this research? This includes IP that is the subject of a copyright, issued patent or a patent application (regardless of whether it has been licensed or optioned).

F4. Any payments over $5,000 (USD) received for the past 12 months (apart from any payments from the University of Michigan), including salary, honoraria, fees, or other forms of compensation or anything of value, from any entity that has a financial interest in this research?

F5. If any of the above is answered "yes", you must complete this form and upload the completed form below.

Study Team Detail

1.4 Team Member:

Mary Ramirez
Preferred email: mramirez@umich.edu
Business phone 734-615-9464
Business address: IRB-HSBS 2800 Plymouth Rd, Bldg 520,1169 48109-2800

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
PI CV 2015 | History	0.01

Financial Interest Screening Questions for Study Team Members Not Affiliated with the University of Michigan: *Required for all roles except Administrative Staff*

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In relation to **THIS RESEARCH**, for the past 12 months, do you or your Family member (your spouse, domestic partner, or dependent) have or anticipate having any of the following Financial Interests:

F1. Are any *activities* or *relationships* with an entity, whether paid or unpaid, where that entity's financial interests could be affected by this research? Examples include service on a board of directors, service on a scientific advisory board, consultant, officer, manager, or partner.

no

F2. An *Equity Interest* in any publicly traded or privately owned entity whose financial interests could be affected by this research, including but not limited to shares of stock or stock options? DO NOT include equity held in a mutual, pension, or investment fund over which you have no control with regard to investment decisions.

no

F3. An investorship or ownership interest in any *Intellectual Property (IP)* that is being tested, evaluated, developed in, or its commercial value will be affected by this research? This includes IP that is the subject of a copyright, issued patent or a patent application (regardless of whether it has been licensed or optioned).

no

F4. Any payments over $5,000 (USD) received for the past 12 months (apart from any payments from the University of Michigan), including salary, honoraria, fees, or other forms of compensation or anything of value, from any entity that has a financial interest in this research?

no

F5. If any of the above is answered "yes", you must complete this form and upload the completed form below.

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

There are no items to display

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

☑

03. UM Study Functions

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

Select all that apply:

- Recruitment (including screening)
- 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.)
- Primary or secondary analysis (data/specimen)
- 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,Analysis,Observation,Recruitment

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:

- Recruitment (including screening)
- 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.)
- Primary or secondary analysis (data/specimen)
- 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
Protocol for Specific Study (placeholder doc) | History	0.01

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

Objective	Answer these questions for this specific study
Specific Aim/Hypothesis	Answer these questions for this specific study
Background Information	Answer these questions for this specific study
Methodology	Note that the proposed study will employ procedures approved in the fMRI Master Protocol. Include plan for handling incidental findings. Answer these questions for this specific study
Statistical Design	Answer these questions for this specific study

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

Describe.

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 (required by fMRI protocol): Adults between the ages of 18 and 85
Inclusion criteria (additional inclusion criteria specific to this study):

Exclusion criteria (required by fMRI protocol): Pregnancy, claustrophobia, uncontrollable shaking, unable to lie still for one hour or metallic or electronic implants in the body

Also any history or an implant of pacemaker or pacemaker wires, open heart surgery, artificial heart valve, brain aneurysm surgery, middle ear implaint, hearing aid, braces or extensive dental work, cataract surgery or lens implant, implanted mechanical or electrical device, artificial limb or joint.

Also excluded is anyone having a history foreign metallic object in body including bullets, BBs, pellets, shrapnel or metalwork fragments.

Exclude individuals who have worked as machinists, welders or metal workers

Exclusion criteria (additional exclusion criteria specific to this study):

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:

Exclusion criteria specific to this study

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.
For this study.

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?
As appropriate for this study

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	fMRI Scanning	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.)
fMRI Scanning

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%):

Describe the risks (associated with this specific study) and how you will mitigate:

Indicate that the risks associated with fMRI scanning are outlined in the Master Protocol and described in the informed consent document. Risks associated with the Routine fMRI protocol will always be no more than minimal.

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.
As appropriate for the study

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**

7.2 * 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

7-2.1.1* Describe all devices that are the OBJECT of the study, or ARE RELEVANT to the study. If this study is designed to test the safety or efficacy of any of these devices, then this project is FDA-regulated and must be reviewed by IRBMED.

The study will use the General Electric fMRI scanner (K091028) in the U-M functional MRI laboratory. The device has been assessed for safety and registered with the BEU.

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:

123

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	123
Children	0
Total from all University of Michigan sites:	**123**

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.

As appropriate to the study

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?**

n/a - research involving patients must be reviewed by IRBMED

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.***

As appropriate to the study

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:

As appropriate to the study

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

As appropriate to the study

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

Other

If other please specify:

Prescreeing questions apply to all fMRI research. Other materials as appropriate to the study

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.pdf | 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]*
- ☑ **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]*
- ☐ **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.

As appropriate to research. Investigators may wish to select waiver of documentation of informed consent for behavioral component of the research if it is minimal risk.

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
IRB-HSBS fMRI consent template.docx | History	0.01

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.

Address as appropriate for study

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:

Other

If other please specify:
As appropriate to the study

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:
fMRI image repository - Imaging data will be kept on servers with secure access and on digital media (DVD) in 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.

As appropriate to the study. fMRI images are stored as described in Section 11.5.1 above.

11-1. Identifiable Data

Completion of this section is required based on the response provided to question 11.1.

11-1.1* Indicate how subjects are identified in the research records.

Select all that apply:

Coded or Indirect Identifiers - data record includes a link to direct identifiers (e.g., name, initials, phone number, SSN, or medical record number linked to data record but stored separately)

11-1.2* Explain the necessity for collecting or maintaining data linked to subjects' identities. If the information is covered in the attached protocol, please indicate section.
As appropriate to the study.

11-1.3* How long will the identifiers be retained?
As appropriate to the study.

11-1.4* Will individually identifiable sensitive data be accessed, collected, used, maintained, or disclosed in the study?

○ Yes ⊙ **No**

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.

Other criteria as appropriate to the study

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?

As appropriate to the study

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?

Appropriate to the study. fMRI images will be retained for future development of signal processing techniques, models and statistical analyses that might benefit fromt he 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.***

As appropriate to the study. For fMRI images, see description in 11.5.1 above.

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

There are no items to display

☑ **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**

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

37.1.1* List the study procedures that may pose risks to pregnant women or fetuses.

fMRI scanning may pose a risk to a fetus.

37.1.2* Describe the steps that will be taken prior to the conduct of these procedures to confirm that subjects are not pregnant.

Women who are unsure whether they are pregnant will be asked to take a urine pregnancy test provided by the fMRI lab at no cost to the participant.

37.1.3* Describe the measures that will be required to prevent pregnancy during or, if applicable, following subjects' exposure to the study procedures. Specify the duration of the preventative measures.

n/a

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
IRBMED APPROVED FMRI STANDARD PROTOCOL CONSENT.pdf | History	0.01

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45. End of Application

Accept Roles

Below is a list of study team members who have not yet accepted their roles.

Study team members must accept all of their roles before the PI will be allowed to submit the application.

Study Team Member	Roles To Accept
Mary Ramirez	Co-Investigator
Thad Polk	Co-Investigator

Click on the activity below to notify any of the study team members listed above to accept their roles:

Notify Study Team Members to Accept Roles

Available Activities

Error Check

Move to Ready to Submit Inbox

Documents Reminder

Following is a list of items you have indicated are pending or cannot be provided electronically.
These items will be added to the list of outstanding contingencies, and should be promptly submitted to the IRB and any other required compliance committees. Failure to do so may delay review of the application.

- Audiovisual materials
  Jump to 31. Watching/Listening to Audiovisual Materials