eRESEARCH | REGULATORY MANAGEMENT

Date: Monday, May 27, 2019 5:14:34 PM

Print

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:

Understanding Code Synthesis via Functional Magnetic Resonance Imaging

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 Imaging of the Brain

1.2* Principal Investigator:

Westley Weimer
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?
Westley Weimer	PI	EECS - CSE Division	Yes	no	No	no	yes	N/A	yes
Xiaosu Hu	Co-Investigator	UMOR Center Human Growth & Dev	Yes	no	No	no	yes	Yes	yes
Yu Huang	Co-Investigator	EECS - CSE Division	Yes	yes	No	no	yes	Yes	yes
Jessica Kim	Co-Investigator	UMOR Center Human Growth & Dev	Yes	no	No	no	yes	Yes	yes
Ryan Krueger	Co-Investigator	EECS - CSE Division	Yes	yes	No	no	yes	Yes	yes
Kevin Leach	Co-Investigator	EECS - CSE Division	Yes	no	No	no	yes	Yes	yes
Nicholas McKay	Co-Investigator		No	yes	No	no	no	Yes	yes
Zohreh Sharafi	Co-Investigator		N/A	no	No	no	yes	Yes	yes
Tyler Santander	Other		N/A	no	Yes	no	yes	Yes	yes

1.8* Project Summary:

Code synthesis is the creation of computer source code by a developer. Code synthesis occurs as a software developer writes new source code to add or change functionality of a computer program to add or change features or to fix existing problems. Code synthesis is instrumental in the development and maintenance of software. Software developers often (unintentionally) introduce bugs and security vulnerabilities during code synthesis, resulting in low quality software that requires significant additional effort to correct via code review or software maintenance. While many studies have addressed best practices for code review and code style to reduce the likelihood of bugs or vulnerabilities remaining in software, none have approached understanding the cognitive processes involved in code synthesis. This study proposes using functional magnetic resonance imaging (fMRI)

to measure those cognitive processes.

We believe that understanding the correlation between code synthesis and related tasks will inform the software engineering community about how to better assess or train individuals who write software. This study will ask participants to write code and perform similar baseline tasks in the fMRI machine to measure these correlations.

In particular, there are two baselines to which we intend to compare code synthesis. The first is code review, or the systematic examination of computer source code. Code review requires understanding snippets of code to assess whether it contains bugs or vulnerabilities. Participants will be asked to examine short snippets of code and choose whether the code is acceptable.

Secondly, this study will compare code synthesis to English prose writing. Participants will be shown a prompt and asked to write a new sentence or passage in response. This is aimed to mimic the writing aspect of code synthesis. Much like code synthesis involves a developer writing new code to meet a desired behavior, this study will ask participants to communicate ideas in writing in response to a particular question or prompt.

In this study, participants will answer questionnaires about their (1) socioeconomic status and educational attainment, (2) Autism Spectrum Quotient, (3) score on the Positive Affect / Negative Affect Scale (PANAS) and Need for Cognition (NFS), and (4) spatial ability via a Paper Folding Test (PFT). Next, they will complete a training session. Then, they will spent approximately one hour in the fMRI rotating between code synthesis, code review, and English prose writing. They will subsequently complete a short post-questionnaire which will ask them to explain their answers to the previous tasks. This post-questionnaire will be audio-recorded.

The data generated will be used to find correlations between tasks and survey data. We hypothesize that cognitive processes involved in code synthesis will be similar to the prose writing tasks, though we expect differences in the code review task. The similarities between these tasks will help the software engineering community to improve training for individuals involved in software development.

Amendment 85172:

We added four more surveys to be collected from each participant (socioeconomic status, Autism spectrum Quotient, PANAS/NFS, and PFT). These will be collected before their scheduled imaging appointment.

Additionally, we added audio-recording the post-questionnaire for more reliably reporting qualitative aspects of the code and prose synthesis tasks. We will transcribe the audio recordings for analysis as well.

1.9* Select the appropriate IRB:

Health Sciences and Behavioral Sciences

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

3/1/2017

1.11* *Estimated* Duration of Study:

120 minutes per participant, multiple participants over the course of 12 weeks.

01-1. Application Type

1-1.1* Select the appropriate application type.

	Application Type	Description
☑	Human Subjects research **involving interaction or intervention** *(formerly Standard, non-exempt research project - or - Exempt)*	Studies that involve either or both of the following: • Interaction, including communication or interpersonal contact between investigator and subject • Intervention, including both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or subject's environment that are performed for research purposes Interaction/Intervention studies may also have a "secondary research" component.

Does the research involve any of the following:

a. more than minimal risk to participants?

b. use of drugs or medical devices?
c. target prisoners as research subjects?
d. collection of biospecimens from subjects (including blood, saliva, cheek swabs)?

● **Yes** ○ No

☐	**Secondary research** uses of private information or biospecimens	"Secondary research" are studies that involve ONLY re-using private information and/or biospecimens that are collected for some other "primary" or "initial" activity, such as other earlier research studies, a biorepository holding specimens obtained with "broad consent," clinical care, or educational records. Includes Exemption 4 and "not regulated" projects. **Do NOT use this application type for:** • Studies that **also** have an interaction/intervention component, such as primary collection of information or biospecimens for the purposes of the study. (Choose instead "Human subjects research involving **interaction or intervention**.") • Projects involving secondary use of information/biospecimens for **only non-research purposes**, such as QA/QI, case studies on one or two individuals, or use in a class to teach research methods. (Choose instead "Activities **not regulated** as human subjects research.")
☐	Activities **Not Regulated** as human subjects research	Not all activities that involve people, their data, or specimens are covered by the regulations governing human subjects research (45 CFR 46 or 21 CFR 50/56). **IRB review is required** for the following activities **ONLY** to assess compliance with **HIPAA** or other regulations or institutional policies: • Research on existing data or specimens that have been coded before the researcher receives them, but identifiers still exist. • Research Involving Deceased Individuals Only • Pre-review of Clinical Data Sets Preparatory to Research • Standard Public Health Surveillance or Prevention Activities **IRB review is not required for the following activities**, but researchers may wish complete this brief application to generate a determination letter for funding or publication purposes, or to request IRB review to confirm the "Not Regulated" determination: • Case Studies • Class Activities • Journalism/Documentary Activities • Oral History • Quality Assurance and Quality Improvement Activities • Research on Organizations • Research using Publicly Available Data Sets
☐	Projects **lacking immediate plans for involvement of human subjects**, their data, and/or their specimens	Activities such as training grants, program projects, center grants, or multi-phase studies not involving human subjects until later years. Before release of funding, some agencies may require IRB acknowledgement of the future use of human subjects. These projects are sometimes referred to as "umbrella projects" or "dry applications."
☐	**Single-patient Expanded Access Drug or Biologic (Emergency Use or Non-Emergency/Compassionate Use)**	Use of an investigational drug or biologic, outside of a clinical trial, under a single-patient IND issued by the FDA for a patient faced with a serious or life-threatening disease or condition. • Contact the IRB Chair-on-Call as soon as possible once the decision to use the

		investigational drug or biologic is made. • Submission for IRB review and approval is required, prior to use if feasible. **If this was an emergency use, submit no later than five days after use of the investigational agent.** • This includes both one-time use and continuing therapy.
☐	**Single-patient Expanded Access Device Use (Emergency Use or Non-Emergency/Compassionate Use)**	Use of an investigational device, outside of a clinical trial, when this is the only option available for a patient faced with a serious or life-threatening disease or condition. • Contact the IRB Chair-on-Call as soon as possible once the decision to use the investigational device is made. • Submission for IRB review and approval is required, prior to device use if feasible. **If this was an emergency use, submit no later than five days after use of the investigational device.** • This includes both one-time use and continuing therapy.
☐	**Humanitarian Use Device** (HUD) under a HDE	Non-research, on-label use of an HUD under a Humanitarian Device Exemption (HDE)
☐	Requesting Review by a **Non-UM IRB**	Use ONLY to request deferral of IRB oversight for UM activities to a non-UM IRB.
☐	**Multi-site Research** where U-M is a Coordinating Center and/or IRB of Record	Do not use Multi-site Research application type when U-M is **only** a performance site - select Standard application type. Select when U-M is any of the following: • Data Coordinating Center; • Clinical Coordinating Center; or • IRB of Record for non-U-M sites (for U-M to be IRB of Record you must contact your IRB for prior acknowledgement). When U-M is **also** a performance site, a separate application is required for local site considerations. Refer to special requirements at the IRB website.

01-2. Standard Study Information

1-2.1* Who initiated this study?

Investigator

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.

CoE Electrical & Computer Sci

1-2.5* Is the study related to cancer, cancer risk, or cancer care delivery?

○ Yes ● **No**

1-2.7* 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**

1-2.8* Is this a clinical trial?

○ Yes ● **No**

Study Team Detail

1.4 Team Member:

Westley Weimer

Preferred email: weimerw@umich.edu
Business phone 734-615-9916
Business address: EECS/CSE 4636 Beyster 48109-2121

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

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

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

Name	Version
Westley Weimer Full CV	0.01

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

C1 Do you, your spouse, domestic partner, or dependents have any outside interests or relationships to companies or entities related to this research that the IRB should consider?
Examples of outside interests include, but are not limited to the following:

- receiving compensation whose value could be affected by the study outcome
- IN THE AGGREGATE, expecting to receive compensation from the sponsor of the research of $10,000 or greater in the next year
- having a proprietary interest in the sponsor of the research or a product tested by this research including but not limited to, a patent, trademark, copyright, or licensing agreement, or the right to receive royalties from product commercialization
- individually or collectively, having an ownership interest (equity or stock options) in the sponsor of the research or product being tested whose value cannot be readily determined through reference to public prices
- individually or collectively, having an ownership interest (equity or stock options) in a company or product whose value could be affected by the study outcome
- IN THE AGGREGATE, having an ownership interest (equity or stock options) in the sponsor of the research that exceeds $10,000 or 1% when the sponsor is a publicly traded entity
- receiving significant payments of other sorts with an aggregate value of $10,000 or more (or payment of ANY amount to medical school or hospital employees) made directly by the sponsor of this research for unrestricted research or education, equipment, consultancy, or honorarium
- holding a position of management or leadership in company or entity related to this research including, but not limited to, officer, director, or member of an advisory board.
- providing consulting services or serve on a Speaker's Bureau, either paid or unpaid, to the financial or non-financial sponsor of this study
- when the sponsor is a publicly traded entity, having any ownership interest (equity or stock options) in the sponsor
- expecting to receive any loans, educational support, contributions of in-kind for equipment, or any other non-compensatory payment from the sponsor of the research in the next year

C2 Please provide a detailed description of the outside interest in the box below.

C2.1 Where have you submitted a disclosure of this outside interest?

C2.2 Has a management plan been formalized?

C2.2.1 Click the View Management Plan in M-Inform button below to see your management plan for this study.

C2.2.2 If no, describe the financial interest in sufficient detail to permit the COI Ancillary Committee and the IRB to determine if such involvement represents a potential conflict-of-interest and/or should be disclosed to potential research subjects in the informed consent form.

Study Team Detail

1.4 Team Member:

Xiaosu Hu

Preferred email: xiaosuhu@umich.edu
Business phone 734-615-9390
Business address: DENT Biologic & Material Sciences MBNI 201 Zina Pitcher Pl 48109-5720

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
Hu_CV.pdf	0.07

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

Study Team Detail

1.4 Team Member:

Yu Huang

Preferred email: yhhy@umich.edu
Business phone 734-647-4255
Business address: EECS - CSE Division 3709 Beyster 48109-2121

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
resume.pdf	0.01

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

Study Team Detail

1.4 Team Member:

Jessica Kim

Preferred email: jessjkim@umich.edu
Business phone 734-647-3712
Business address: LSA Psychology B242 East Hall 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
Resume	0.01

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

Study Team Detail

1.4 Team Member:

Ryan Krueger

Preferred email: ryankrue@umich.edu
Business phone
Business address: EECS - CSE Division 2260 Hayward 48109-2121

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
ryan.pdf	0.01

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

Study Team Detail

1.4 Team Member:

Kevin Leach

Preferred email: kjleach@umich.edu
Business phone 734-926-2495
Business address: CSE 2909 Beyster 48109-2121

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
kleach-resume.pdf	0.01

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

Study Team Detail

1.4 Team Member:

Nicholas McKay

Preferred email: njmckay@umich.edu
Business phone
Business address: 48109

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:

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
resume	0.01

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

Study Team Detail

1.4 Team Member:

Zohreh Sharafi

Preferred email: zohrehsh@umich.edu
Business phone
Business address: CSE 2909 Beyster 48109-2121

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.)

No

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

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

Name	Version
zohreh-cv	0.01

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

Study Team Detail

1.4 Team Member:

Tyler Santander

Preferred email: t.santander@psych.ucsb.edu
Business phone
Business address: Dept. of Psychological & Brain Sciences 93106

1.5 Function with respect to project:

Other

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.)

No

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

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

Name	Version
SantanderTyler_2019CV.pdf	0.02

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.**

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 forms of funding or support must be added one at a time.**

2.1 Please select all Proposal Approval Forms (PAFs), Awards (AWDs), and/or Unfunded Agreements (UFAs) associated with this study.

☑ **Click here to indicate that a PAF(s) has not been initiated.**

Related PAFs:

ID	Title	PI	Direct Sponsor	Prime Sponsor	State	Has SUBKs?	Related Awards

There are no items to display

Related AWDs:

Award ID	Title	PI	Direct Sponsor	Prime Sponsor	State	Has SUBKs?	Project Period	Awarded PAFs

There are no items to display

Related UFAs:

UFA ID	Title	PI	State	Category	Start Date	End Date

There are no items to display

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

	Type	Department Sponsor	Support Type
View	PI Discretionary Funds	EECS - CSE	Financial

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

☐

2.4* Is there any other financial or non-financial sponsorship or support not covered in the sections above?

○ Yes ● **No**

Internal Sponsor Detail

2.2.1* Department Sponsor/Support:

EECS - CSE

2.2.2* Sponsor Type:

PI Discretionary Funds

If other, please specify:

2.2.3* Support Type:

Financial

2.2.4* Is the support confirmed?

● **Yes** ○ No

2.2.5* Please describe the award/support:

Departmental startup funding for W Weimer.

2.2.6 Upload Supporting Documentation

Name	Version
funding-support.pdf	0.01

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 and/or specimen): Responsible for the management, security and transfer of study data and/or specimens.

If other, please specify.

03-1. Performance Sites

3-1.1* Performance Sites:

Location	Country	"Engaged" in the research?	Performance Site Type	Site Function
University of California - Santa Barbara	USA	no		Analysis
University of Michigan	USA	yes		Qualitative research,Intervention,Storage,Interaction,Analysis,Observation,Recruitment

Performance Site Detail

3-1.2* Location or Institution:

University of California - Santa Barbara

3-1.3 Address:

City Santa Barbara
State CA
Country* USA

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

Select all that apply:

Primary or secondary analysis (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.

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).

IRB approval forthcoming based upon review here at UMich since we are leading the effort.

3-1.8 Upload any location site approval documentation here:

Name	Version
There are no items to display	

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 and/or specimen): Responsible for the management, security and transfer of study data and/or specimens.

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**

5.2* 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)

Adults aged 18-65 who meet the age requirements for undergoing MRI (e.g., no pregnant women or former metalworkers) as well as expertise in CS. No particular subgroups will be excluded.

In particular, the fMRI master protocol excludes the following:

- Individuals under 18
- pregnancy
- claustrophobia
- uncontrollable shaking
- can't lie still for one hour
- metallic or electronic implants in the body (pacemakers or pacemaker wires, open heart surgery, artificial heart valve, brain aneurysm surgery, middle ear implant, hearing aid, braces or extensive dental work, cataract surgery or lens implant, implanted mechanical or electrical device, or artificial limb or joint
- foreign metallic objects in the body (bullets, BBs, pellets, schrapnel, or metalwork fragments)
- current or past employment as machinists, welders or metal workers

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:

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

Minimum Age: 18
Maximum Age: 65If no upper limit, enter "999"

05-1. Research Design

In its review of research applications, the IRB considers whether research procedures are consistent with sound research design in order to yield the expected results. Scientific merit is examined in relationship to the risks and benefits of the research. This section covers the overall research design of the project. Later sections will ask more specific questions about benefits, risks, special review considerations, targeted populations, recruitment strategies, and experimental methodologies/procedures.

5-1.1* Objective: What is the overall purpose of this research study?

We seek to investigate the neural representation of computer programming in humans and relate it to English writing tasks. Results for this study can inform future research about efficient computing pedagogy and software engineering workforce training.

5-1.2* Specific Aim(s): What is (are) the specific aim(s) of this study and/or what hypothesis (hypotheses) is (are) to be tested?

Based on previous research concerning English reading and program comprehension, we hypothesize that similar areas of the brain are engaged when writing code and writing prose.

5-1.3* Background: What prior information or knowledge exists to support the conduct of this study?

The process of designing software, commonly called Software Engineering, involves many stages. While there are several differing models for this process, most of them contain the same core phases: requirements specification, software design, implementation, verification, and maintenance. Briefly, requirements specifications describes the process of deciding how to software is supposed to behave. Then, based upon these requirements, a number of design decisions are made for the software system in the software design stage. Implementation describes the time actually coding the software

system. In the verification stage, software is tested to ensure that it adheres to its specifications. After the software is sufficiently tested, it is deployed for use. Finally, the maintenance stage describes the ongoing process of repairing the software when a defect is found and supporting the users of the software.

While each of these stages takes some time, it has been shown that software maintenance is by far the most time intensive phase of software development. This stems from a number of reasons, but primarily from the fact that it is much more difficult to repair a defect after the development stage. This could be true because the software engineers are less familiar with the code as time goes by, or because making a change to repair a defect can affect other parts of the software that were built on top of the defect. Regardless of cause, it has been empirically shown that the majority of software costs come from this maintenance process. As a result, software companies are eager to deploy any solution that will decrease the time spent in maintenance.

One approach toward this goal is to make fewer mistakes in the initial implementation process. Common practice to address accomplish this includes adopting code review. Code review is the systematic inspection, analysis, evaluation, and revision of code. Among standard software engineering companies it is commonly implemented in the following manner: when an engineer has finished working on code that (s)he would like to submit to the main code base of the project, (s)he submits a pull request which essentially asks a coworker to review the code and, upon acceptance, incorporate it into the main code base. If, however, the reviewer does not accept the pull request, (s)he suggests changes that need to be made to the code before it should be accepted. This practice ensures that both the original coder and another engineer believe that the code is correct before it is incorporated into the main code base. This practice has been shown to drastically reduce the number of defects that reach the main code base of the project. In industry, the process of code review is very commonly used. For example, a software engineer at Facebook cannot submit a code change until at least two coworkers have reviewed and accepted it. While Facebook is a very stringent example, many companies practice some version of this system.

So, while it has been shown that code review is beneficial to companies because it decreases overall costs, it is not understood exactly what is occurring in the brain during the code rewriting activity. This study aims to uncover that information and learn if this information can improve the ways we train or evaluate engineers' code writing skills. For instance, it has been proposed that reading code is very similar to natural language processing. Believing this to be true, it is natural to consider alternative training techniques for software engineers that involve reading and perhaps writing forms of language other than code.

To our knowledge, only two previous studies have considered looking at the cognitive processes involved in coding. Understanding understanding source code with functional magnetic imaging was published in the International Conference on Software Engineering in 2014. In this study, the cognitive processes involved in the act of code comprehension - reading and understanding code - are measured in an fMRI. The results of this experiment support the aforementioned claim: reading code is very similar to reading any other natural language. While this study intrigued many researchers in the software engineering community, it did not carry any opportunity for impacting the practices of the field. The other study, Decoding the representation of code in the brain: An fMRI study of code review and expertise, was published in ICSE in 2017 and received a distinguished paper award. This study investigated the neural activity involved in code comprehension and prose review, ultimately finding a distinction between the two tasks. Our study aims to apply many of the same techniques, but learn about a process that is used very commonly in the software engineering field. It is our hope that the results will be both intriguing and impactful to real software companies.

5-1.4* *Briefly* outline the special expertise and qualifications of the PI, Co-Investigators, and/or Faculty Advisors to conduct and/or oversee the particular procedures or activities involved in *this particular study*. This will supplement information provided in the study team CVs.

PI Weimer has previously conducted IRB-approved fMRI research involving software engineering while at the University of Virginia. Research Fellow Kevin Leach and graduate student Yu Huang have both conducted IRB-approved human studies. Co-investigator Santander has previously collaborated with PI Weimer on IRB-approved fMRI human study experiments. All four have published peer-reviewed publications based upon such human studies. Co-investigator Xiaosu Hu and Jessica Kim have experience on medical imaging human studies.

PI Weimer has extensive experience researching program analysis and software engineering.

PI Weimer will be engaged in managing and funding the project, as well as preparing manuscripts for publication. Research Fellow Leach and Graduate Student Huang will both be engaged in recruiting participants, preparing stimuli, conducting each human study trial, analyzing data, and preparing manuscripts for publication. Co-investigator Santander will be responsible for analyzing fMRI-specific data. Co-investigator Xiaosu Hu and Jessica Kim will help with the data analysis.

AME00086288:
Co-Investigator Zohreh Sharafi has experience running IRB human studies related to eye-tracking. In this study, Sharafi will help run subjects through the protocol and collect and analyze research data.

AME00090429:
Co-Investigator Nicholas McKay is an undergraduate researcher who will be applying new analyses to existing research data. He will not be interacting with participants, and will be working only with de-identified research data to gain new insights from our existing data.

5-1.5* Methodology: Describe the design and procedures to be used to accomplish the specific aims of the study. Describe the advantages of any innovative methodologies.

The fMRI portion of this study will be conducted in accordance with the blanket fMRI Master Protocol (HUM00093760).

We will recruit participants from the undergraduate EECS student population. First, we will use mailing lists to email undergraduate CS majors about the study, benefits, risks, compensation, and skill level required. We will also recruit in an undergraduate software engineering course via a 2-3 minute presentation about joining the study. We will wait for participants to contact us via email before scheduling a time to come in.

Amendment 85172: We will email four survey instruments to consenting participants to collect socioeconomic status, their autism spectrum quotient, their PANAS/NFS scores, and their

performance on a paper-folding test. The paragraph below was updated to reflect this addition as well.

After recruitment, we will email the participant the informed consent documents as well as an explanation about informed consent and the study. If they provide their consent, we will subsequently email them four survey instruments to collect socioeconomic and psychological data about the subject. We will schedule a 90-minute session with each participant at the fMRI laboratory. When they arrive, we will sit with them and remind them of the informed consent procedure and the voluntary nature of the study. If they reaffirm their consent, we will give them the background questionnaire to assess their competency with C programming. This questionnaire will take roughly 5-10 minutes and will be completed with a pen and paper. Participants must answer every question correctly to move on. If they do not pass, they will be instructed to leave and be compensated $25. If they pass, they will be required to pass an MRI safety screening. If they do not pass the safety screening, they will be instructed to leave and be compensated $25. Next, they will be shown a short training video about the fMRI study, including example tasks and how they should interact with the study materials. The video will last roughly 10 minutes. After answering any remaining questions, the participant will enter the fMRI and the study will begin. During the study, participants will be given 4 minutes to practice using an fMRI safe keyboard for typing code while in the MRI tube. After this 4 minute block, we will ask them to complete a series of tasks, each 30 seconds long. For the first ~16 minutes, they will be shown code writing tasks. They will be asked to complete a short snippet of code to meet some objective (e.g., assign the variable a certain value). Next, they will be shown a prompt and asked to write new code. Each prompt will be 30 seconds and last a total of ~16 minutes. For the next ~16 minutes, they will be shown prose writing tasks. They will be asked to respond to a prompt (e.g., how do you get dressed in the morning?). For the final ~16 minutes, they will be asked a series of prose editing questions. They will be shown a paragraph of text and a candidate change, and asked whether the change improves the text or not. There will be a 5 second break between each 30 second task, as well as a 2 minute break between each 16 minute block.

After completing the fMRI study, we will ask the participant three additional questions about a response they gave in each block of tasks (i.e., code writing, prose writing, and prose editing). We will record their answers electronically (i.e., in an audio file). Afterwards, the participant is free to leave. The participant will receive $75 compensation for their time.

Amendment 85172:

We will audio-record the participant's post-questionnaire. The post-questionnaire will not ask for any personally identifiable information (although the recording itself is identifying). Within 30 days of the participant's appointment, Leach, Huang, or Krueger will transcribe the audio to plain text stored on an encrypted volume, and then dispose of the original audio files. The paragraph above reflects this change.

We will develop example code writing tasks based upon mid-level undergraduate CS curriculum. They will consist generally of code snippets with missing or mistaken parts that require the participant to write a short piece of code within a 30 second window.

We will acquire prose writing samples based upon standardized tests, including the SAT and ACT. They will generally consist of tasks requiring the participant to write new words or sentences within a 30 second time window.

We will apply techniques from graph theory and statistical machine learning (e.g., GLM) to model spatial dependencies across brain regions and use those to predict (i.e., decode) individual difference factors.

We will apply established techniques for anonymizing the fMRI data by using nifti_tool on the resulting NIFTI data produced by the MRI machine. nifti_tool is a software package from the NIH that allows editing the data produced by the MRI to provide anonymity. https://afni.nimh.nih.gov/pub/dist /doc/program_help/nifti_tool.html.

We plan to retain the anonymized fMRI and exit survey for use in future studies, either for a baseline comparison or as part of a larger scale review study of this and subsequent medical imaging studies we conduct.

We will not collect personally identifiable information except for the audio recording of the post questionnaire. The email address, name, and mailing address of each participant will be used to scheduling time in the MRI and as part of compensating them through HSIP. However, these are separate from the study proper and will not be retained as part of the research data. After the participant has finished, we will delete previous electronic correspondence. We will retain the subject's email address for 30 days after completion of their scan to notify them of any incidental findings made during their scan.

An MRI technician will conduct the scan on the subject. If the technician makes an incidental finding during the scan of the subject, PI Weimer or Research Fellow Leach will follow up with the subject via email (originally acquired during scheduling). We will communicate the technician's findings to the subject, and suggest that they follow up with a physician to properly asses the incidental finding.

5-1.6* Statistical Design: Describe the statistical design of the research study, including methods used to analyze data.

1) We intend to collect basic demographic information from participants so that we can determine if differences in age, gender, sex, programming language, and levels of experience affect the neural activations associated with these tasks; and

2) We will employ techniques from graph theory and statistical machine learning (e.g., GLM) to model spatial dependencies across brain regions and use those to predict (i.e. decode) individual difference factors.

AME00090429:

3) We will employ novel statistical techniques to attempt improving insights gained from this data. For instance, we will employ GIMME analyses and other statistical techniques to distinguish between when subjects were writing code vs. writing prose. Additionally, we will employ techniques to understand brain activity for longer blocks of time--our study used 60 second blocks for some stimuli,

while existing techniques generally function well for 30 second blocks or shorter.

06. Benefits and Risks

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

There are no direct health benefits to the participants. The primary benefits of the study are best realized at the societal and scientific levels. The data gained from this study, along with the conclusions drawn from it, will help shape and improve the software engineering workforce's code synthesis and review skills through improvements in training.

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?

There are no direct risks to society at large.

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	HUM00138634	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.)

HUM00138634

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%):**

Risks associated with fMRI 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.

We collect fMRI data and audio recordings of the post questionnaire, all of which are stored on an encrypted volume. As with any networked enterprise, there is a risk that a data breach will occur, which may result in compromising the collected data. To minimize this risk, we will store research data on an encrypted volume on a server kept in a locked office. The research data will be anonymized, so that it cannot be used to learn the identity of individual participants, even if the data is decrypted.

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.

	Risk Level	Description
●	**No more than minimal risk**	**A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of a routine physical examination. (Note: The definition of minimal risk for research involving prisoners differs somewhat from that given for non-institutionalized adults.) Refer to the Risk Grid for more information.**
○	Minor increase over minimal risk	While this risk category may be used to classify research involving adult subject populations, it must be considered in the evaluation of risk in research involving children as defined in 45 CFR 46 sections 404-407*** Risks are more severe than those defined as “No more than minimal risk” and less severe than those described as “Moderate” on the Risk Grid.
○	Moderate risk	Refer to the Risk Grid for more information.
○	High risk	Requires scrutiny in regards to the likelihood of direct benefits, and whether or not benefits clearly outweigh risks. Refer to the Risk Grid for more information.

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

Potential risks in this study include claustrophobia and discomfort in the MRI scanning environment. Moreover, subjects will be given a demonstration of the speed with which they can be removed from the MRI scanner if they feel they need to quit the experiment in the middle of an experiment. Note: The procedures used in this MRI study do not use any contrast agents.

There are no direct health benefits to the participants. The primary benefits of the study are best realized at the societal and scientific levels. The data gained from this study, along with the conclusions drawn from it, will help shape and improve the software engineering workforce’s code synthesis and review skills through improvements in training.

Great care is taken to minimize the risks inherent in the MRI environment such that risk of physical injury is extremely unlikely, and risk of significant psychological discomfort is likewise minimal. The risk-benefit ratio is therefore acceptable.

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 protected health information (PHI)? PHI is:

- **information about a subject's 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 HIPAA-covered entity (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, radiopharmaceuticals, 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? [IRBMED 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.

We will use fMRI as a way of collecting neural activation data of participants during software engineering tasks. We are not evaluating the fMRI device itself.

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* Is the research testing or utilizing a health-related mobile software application that is:

- Designed for a handheld (e.g., smartphone) or wearable mobile device (e.g., exercise tracking), or
- Tailored to a mobile platform (i.e., a handheld commercial or off-the-shelf computing platform, with or without wireless connectivity) but executed (run) from a server

and the mobile software application/platform performs any of the following:

- Uses a built-in feature of a device such as light, vibration, or camera to perform a medical device function.
- Connects or links to an existing device to control its operation, function, or energy source.
- Uses patient-specific data from a connected device including a sensor or electrode to monitor, manipulate, calculate, or analyze information.
- Conveys diagnostic information, or provides education materials or encouragement.
- Performs calculations, conversions, measurements or interpretations.

○ Yes ● **No**

7-2.3* Will the subjects be exposed to any ionizing radiation during the course of this study? [Require Section 21]

○ Yes ● **No**

7-2.4* Will any organs, tissues, or cells from humans (including fetal tissue) or animals be administered to the subjects for the purposes of this study? [Require Section 22]

○ Yes ● **No**

7-2.5* 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:

30

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

Location or Institution	Total	
University of California - Santa Barbara		
Adults	0	
Children	0	
University of Michigan		
Adults	30	
Children	0	
Total from all University of Michigan sites:		**30**

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.

Participants will be identified by their presence in various Computer science venues (classes, labs, etc.). Graduate students, undergraduate students, professors, and community members would all be considered eligible if they demonstrate the required programming expertise for completing the programming tasks. Other participants may learn of the study by word of mouth from a study team member and may be eligible if they can demonstrated the required expertise.

Subjects will be contacted directly via email, letter, or presentation in group setting with consent then obtained individually in a private setting. We will send announcement emails to the departmental email lists to which undergraduate majors are subscribed. We will not obtain a list of individual email addresses.

We require participants with programming and software engineering experience consistent with the content taught in PI Weimer's course (Software engineering), and thus will actively recruit in that class. Research Fellow Leach or graduate student Huang will recruit once during the semester during a class period (4:30pm in BBB 1607). To mitigate concerns of coercion, we will take the following steps:

1) PI Weimer will not advertise or be involved in the selection or recruitment of participants. Instead, Research Fellow Leach or graduate student Huang will provide a presentation (~2 minutes) advertising the study and offering Leach's email address as a point of contact. Students interested in participating will be encouraged to email Leach to establish an appointment to meet for the fMRI study.
2) Students will not be given extra credit, and students will have the option to participate after final course grades have been submitted.

While we will need to interact with participants via email for scheduling, we will not record or retain their names or email addresses during this study. Rather, we will keep the email address for scheduling purposes only, and delete correspondence and addresses after the participant finishes 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?

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.

Any adult eligible for fMRI can participate in this study provided they demonstrate the required programming expertise for completing the programming tasks. Every candidate participant will be assessed for minimal expertise using the same set of questions after receiving informed consent. This minimal expertise is consistent with students who have passed EECS280 and/or EECS281.

A number of MRI-safety exclusion criteria are used in the blanket IRB and common throughout MRI-related research. For safety purposes, we exclude candidates who may have magnetic metal in their bodies (e.g., metal shavings from metalworking).

Advertisements will be made broadly in relevant classes as well as in public bulletin board spaces in relevant buildings so as to reach the broadest eligible audience.

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:
Face-to-face contact (e.g. during a health care visit or an interview at a home address, etc.)
Email
Public advertisement (e.g., bulletin boards, newspapers, radio, TV, websites, or on-hold telephone scripts, etc.)

If other please specify:

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

CSE departmental or class-specific email list will be used. These are lists like cse-ugrads@umich.edu, which is an address that broadcasts announcements to all subscribed individuals. We plan to use an email list to which the undergraduate CS majors are subscribed and email lists associated with the undergraduate software engineering course.

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
Flyers
Oral scripts
Email messages

If other please specify:

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
⟲ ⟷	email-recruitment.docx	0.04
⟲	knowledge-assessment.docx	0.02
⟲ ⟷	mri-ad.docx	0.03
⟲ ⟷	recruitment-script.docx	0.03
⟲	safety_screening.pdf	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. Survey Populations

9.1* Is the study limited to a survey of either:

- The general adult population (aged 18 or older); or
- A subgroup of the general population which does not specifically target:

- Pregnant women and/or fetuses
- Lactating women
- Women of child-bearing potential
- Prisoners
- Cognitively impaired adults
- College students
- Economically or educationally disadvantaged persons
- Patients of the study team
- Employees, students or trainees of the study team
- Family members of the study team

where the survey is the sole interaction with the subject and does not pose more than minimal risk?

○ Yes ● **No**

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?

With signature:

- [x] **Comprehensive written**
- [ ] Written assent for cognitively or decisionally impaired adults

Without signature (waiver of documentation):

- [ ] Comprehensive written
- [ ] Comprehensive oral consent script
- [ ] Assent for cognitively or decisionally impaired adults

Waivers of informed consent:

- [ ] Request for waiver of informed consent/parental permission/legally authorized representative consent (Note: no longer required for screening/recruitment)
- [ ] Request for waiver of assent for cognitively or decisionally impaired adults

Other:

- [ ] Short form, comprehensive oral script, and witness
- [ ] Request for alteration of informed consent requirements
- [ ] Pre-existing consent(s) covers this activity
- [ ] Re-consent/assent subjects for use of existing data/records/specimens for a new research purpose

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.

Upon receiving email from interested participants, we will email the informed consent documents back to them. We will not proceed with scheduling until receiving informed consent. Subjects will also be given a written form explaining all of the details of the experiment consistent with the fMRI blanket IRB. Subjects will be given as much time as they require to read, understand, and sign off on the informed consent form.

Additionally, once the participant arrives for their scheduled scan, research Fellow Kevin Leach and/or graduate student Yu Huang will sit with the subject and explain the experiment, the process of the study, their rights, risks, and benefits, and reaffirm their consent.

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
	fMRI_umbrella_consent_170206.pdf	0.01
⟷	IRB-HSBS_fMRI_consent_template_final_Oct_2015-clean.docx	0.08

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:

Parking

Travel

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.

Participants are interviewed in private before the fMRI scan. We do not collect personal information from them as part of the research data, except for an audio recording of their post questionnaire. We assess their C language competency using a short written test and ask about their expertise based upon years of experience programming.

Participants will be assigned unique numbers. Physiological data collected from the fMRI and survey data will be stored along with the unique number. fMRI anatomical data will be de-identified to prevent facial reconstruction in the event of a data breach. Moreover, their audio recording will be transcribed to plain text, and their audio recording will be deleted.

Amendment 85172:

We will audio-record the participant's post-questionnaire. This audio file will be stored on an encrypted volume separate from the other research data collected about each participant, organized by participant ID number. Huang, Leach, or Krueger will transcribe the audio within 30 days of the participant's post-questionnaire, at which point we will delete the original audio file. The paragraphs above reflect this addition.

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
Restricted access
Secure laptop
Individual ID plus password protection
Encryption of digital data
Network restrictions
Security software (firewall, anti-virus, anti-intrusion) is installed and regularly updated on all servers, workstations, laptops, and other devices used in the project
Safe disposition/destruction of data or devices, as appropriate (e.g., shredding paper documents, destroying disks or thumb drives, secure erasure of electronic media)

If other please specify:

11.4* Does either statement apply to this research:

Research has NIH, CDC, or FDA funding, or other federal funding from an agency that automatically issues a Certificate of Confidentiality as part of the terms of the award:

The study will include identifiable sensitive information, identifiable biospecimens, individual human-level genomic data/biospecimens, or any information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

or

Research does NOT have NIH, CDC, or FDA funding, or other federal funding from an agency that automatically issues a Certificate of Confidentiality as part of the terms of the award:

The study will include identifiable, sensitive information or identifiable biospecimens that, if revealed, might place the subjects at risk for personal safety, criminal or civil liability, or damage to their financial standing, employability, insurability, 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**

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

Select all that apply:

Retain for future research use - requires Section 11-4

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 participants will complete a skills-based questionnaire before entering the MRI machine in person with pen and paper. The questionnaire will be graded quickly. If they do not answer all of the questions correctly, they will receive some compensation ($25) and their participation will end at that point.

We will ask participants after their trial ends how they prefer to be compensated (whether they complete the fMRI trial, are removed for inability to complete the test, or decide to withdraw). We will collect the relevant information to submit to HSIP for remuneration.

The participants will be shown the operation of the MRI, and will be given the opportunity to experience going into the tube once before beginning the actual study. Participants will be instructed that they can leave the study at any time for any reason. The fMRI is equipped with a 'panic' button. The subject will be instructed to use the button for any reason if they decide they no longer want to participate.

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?

Destroy any electronic data related to the participant securely, and destroy copies of the survey used to filter participants.

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?

For follow up work and dissemination to the academic community. This domain of research is largely unexplored and related data is difficult to obtain. The academic community would benefit greatly from having (anonymized) data available for comparison in subsequent studies.

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.***

PI Weimer has secure office space allocated in the Beyster building for storing sensitive information. Only PI Weimer and Research Fellow Leach will have key access to the office.

We collect identifiers necessary to reimburse the participants via HSIP. However, these identifiers will be deleted once the participant has received their reimbursement. We collect audio recordings of the participant's post questionnaire; other identifiers are not stored or collected as part of the research data. Research data will be stored on encrypted volumes secured by a passphrase that will be shared between PI Weimer, Research Fellow Leach, and UCSB collaborator Tyler.

All data will be de-identified to protect participant confidentiality. This includes de-identifying the anatomical brain information obtained from the MRI and transcribing the audio recording to plain text.

13. Subject Payments Or Other Incentives

Completion of this section is required based on the response provided to question 7-1.1 or 7-3.3.

13.1* Indicate all payments or other incentives provided to subjects for their participation in this study:

Select all that apply:

Cash

Check

Payment Voucher

If other, please specify:

13.2* If the subject is a child (under the age of majority), are any of the payments or incentives intended for the parent/guardian of the child?

N/A

13.3* Estimate the maximum total payment (including cash, checks, gift cards, and other cash-equivalent incentives) that an individual subject could receive for participating in this research in a single calendar year.

$26-$100

13.3.1* Please indicate what information you will be collecting from subjects in order to distribute their incentive or compensation.

Select all that apply:

Name

Address

Email

13.4* Describe the frequency of the payments or incentives. If applicable, list any healthcare procedure(s) that will be provided to subjects at no charge.

One payment will be issued within a month of the conclusion of the study. If a participant is found ineligible during the fMRI safety screening or skills assessment, they will receive $25.

The payment will be given based upon the participant's preference. We will collect the participant's name, address, and email address so that HSIP can compensate them as appropriate.

13.5* What is the justification for offering these payments or incentives?

The study will take approximately 1.5 hours of the participants' time. Additionally, participants are required to have a minimal expertise with computer science. We want to compensate participants for their time at a reasonable rate (i.e., $50/hr for a typical software developer).

13.6* What is the plan to compensate subjects withdrawing from the research prior to completing the entire study.

Participants will still receive compensation even if they decide to withdraw. If they withdraw during the study, they will receive $75. If they are excluded based on the skills assessment or fMRI safety screening, they will receive $25.

29. Survey Research

Completion of this section is required based on the response provided to question 7-1.5.

29.1* Provide a list of all surveys and interviews used in the study:

Name	# of Questions	Duration	Sensitive?	Disturbing?
Austism Spectrum Quotient	50	10 minutes	no	no
Background questionnare	6	5-10 minutes	no	no
need for cognition	18	5 minutes	no	no
Paper Folding Test	20	10 minutes	no	no
positive affect/negative affect score	60	10 minutes	no	no
post questionnaire	3	5-10 minutes	no	no
socioeconomic	6	5 minutes	no	no

29.13* Will the research involve the use of focus groups?

○ Yes ● **No**

29.14* Is any of the material disturbing?

○ Yes ● **No**

Survey Detail

29.2* Survey or interview name:

Austism Spectrum Quotient

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

○ Yes ● **No**

29.4* In what manner will the survey or interview be conducted (e.g., in-person, Internet, mail, telephone, etc.)? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.*

This survey will be emailed to the participant before their scheduled fMRI scan.

29.5* What is the predicted response rate?

100 %

29.6* What is the total number of questions?

50

29.7* What is the anticipated cumulative amount of time required for each subject?

10 minutes

29.8* What is the total number of interviews/data collection interactions with an individual subject?

1

29.9* Does the survey or interview contain questions of a sensitive nature (e.g., mental illness, sexual abuse, illicit drug use, etc.)?

○ Yes ● **No**

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

○ Yes ● **No**

29.11* Has the survey instrument been validated or used in standard practice?

● **Yes** ○ No

29.11.1* If yes, describe the origin of the instrument.

Cohen et al. The Autism-Spectrum Quotient (AQ): Evidence from Asperger Syndrome/High-Functioning Autism, Males and Females, Scientists and Mathematicians. Journal of Autism and Developmental Disorders, Vol. 31, No. 1, 2001

29.12* Upload the survey instrument here.

Name	Version
asq-tyler5.pdf	0.01

Survey Detail

29.2* Survey or interview name:

Background questionnare

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

○ Yes ● **No**

29.4* In what manner will the survey or interview be conducted (e.g., in-person, Internet, mail, telephone, etc.)? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.*

Before entering the fMRI to complete the study, participants will be asked to complete a form with questions on it in-person.

29.5* What is the predicted response rate?

100 %

29.6* What is the total number of questions?

6

29.7* What is the anticipated cumulative amount of time required for each subject?

5-10 minutes

29.8* What is the total number of interviews/data collection interactions with an individual subject?

2

29.9* Does the survey or interview contain questions of a sensitive nature (e.g., mental illness, sexual abuse, illicit drug use, etc.)?

○ Yes ● **No**

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

○ Yes ● **No**

29.11* Has the survey instrument been validated or used in standard practice?

● **Yes** ○ No

29.11.1* If yes, describe the origin of the instrument.

This questionnaire was used in previously peer-reviewed, IRB-approved research.

29.12* Upload the survey instrument here.

Name	Version
background-questionnaire.docx	0.02

Survey Detail

29.2* Survey or interview name:

need for cognition

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

○ Yes ● **No**

29.4* In what manner will the survey or interview be conducted (e.g., in-person, Internet, mail, telephone, etc.)? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.*

This survey will be emailed to the participant before their scheduled fMRI scan

29.5* What is the predicted response rate?

100 %

29.6* What is the total number of questions?

18

29.7* What is the anticipated cumulative amount of time required for each subject?

5 minutes

29.8* What is the total number of interviews/data collection interactions with an individual subject?

1

29.9* Does the survey or interview contain questions of a sensitive nature (e.g., mental illness, sexual abuse, illicit drug use, etc.)?

○ Yes ● **No**

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

○ Yes ● **No**

29.11* Has the survey instrument been validated or used in standard practice?

● **Yes** ○ No

29.11.1* If yes, describe the origin of the instrument.

Cacioppo, Petty, & Kao, 1984

29.12* Upload the survey instrument here.

Name	Version
NFC-tyler2.pdf	0.01

Survey Detail

29.2* Survey or interview name:

Paper Folding Test

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

○ Yes ● **No**

29.4* In what manner will the survey or interview be conducted (e.g., in-person, Internet, mail, telephone, etc.)? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.*

This survey will be given to the participant in person after completing the post questionnaire.

29.5* What is the predicted response rate?

100 %

29.6* What is the total number of questions?

20

29.7* What is the anticipated cumulative amount of time required for each subject?

10 minutes

29.8* What is the total number of interviews/data collection interactions with an individual subject?

1

29.9* Does the survey or interview contain questions of a sensitive nature (e.g., mental illness, sexual abuse, illicit drug use, etc.)?

○ Yes ● **No**

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

○ Yes ● **No**

29.11* Has the survey instrument been validated or used in standard practice?

● **Yes** ○ No

29.11.1* If yes, describe the origin of the instrument.

Vz-2-BRACE scoring instrument for spatial ability.

29.12* Upload the survey instrument here.

Name	Version
PFT-tyler4.pdf	0.01

Survey Detail

29.2* Survey or interview name:

positive affect/negative affect score

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

○ Yes ● **No**

29.4* In what manner will the survey or interview be conducted (e.g., in-person, Internet, mail, telephone, etc.)? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.*

This survey will be emailed to the participant before their scheduled fMRI scan.

29.5* What is the predicted response rate?

100 %

29.6* What is the total number of questions?

60

29.7* What is the anticipated cumulative amount of time required for each subject?

10 minutes

29.8* What is the total number of interviews/data collection interactions with an individual subject?

1

29.9* Does the survey or interview contain questions of a sensitive nature (e.g., mental illness, sexual abuse, illicit drug use, etc.)?

○ Yes ● **No**

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

○ Yes ● **No**

29.11* Has the survey instrument been validated or used in standard practice?

● **Yes** ○ No

29.11.1* If yes, describe the origin of the instrument.

1994, David Watson and Lee Anna Clark

29.12* Upload the survey instrument here.

Name	Version
panas-x-tyler3.doc	0.01

Survey Detail

29.2* Survey or interview name:

post questionnaire

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

○ Yes ● **No**

29.4* In what manner will the survey or interview be conducted (e.g., in-person, Internet, mail, telephone, etc.)? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.*

in-person, after successful completion of the fMRI trial, we will sit with the participant and ask them each question based upon responses provided to a random subset of tasks they were given during the fMRI.

29.5* What is the predicted response rate?

100 %

29.6* What is the total number of questions?

3

29.7* What is the anticipated cumulative amount of time required for each subject?

5-10 minutes

29.8* What is the total number of interviews/data collection interactions with an individual subject?

1

29.9* Does the survey or interview contain questions of a sensitive nature (e.g., mental illness, sexual abuse, illicit drug use, etc.)?

○ Yes ● **No**

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

○ Yes ● **No**

29.11* Has the survey instrument been validated or used in standard practice?

○ Yes ● **No**

29.12* Upload the survey instrument here.

Name	Version
post-questionnaire.pdf	0.01

Survey Detail

29.2* Survey or interview name:

socioeconomic

29.3* Is the design or development of this survey instrument dependent on receipt of funding or hiring of personnel?

○ Yes ● **No**

29.4* In what manner will the survey or interview be conducted (e.g., in-person, Internet, mail, telephone, etc.)? *Special Note: For electronic surveys, the eResearch ID number must be included in the informed consent document (uploaded in section 10-1) or other material that serves as the informed consent.*

This survey will be emailed to the participant before their scheduled fMRI scan.

29.5* What is the predicted response rate?

100 %

29.6* What is the total number of questions?

6

29.7* What is the anticipated cumulative amount of time required for each subject?

5 minutes

29.8* What is the total number of interviews/data collection interactions with an individual subject?

1

29.9* Does the survey or interview contain questions of a sensitive nature (e.g., mental illness, sexual abuse, illicit drug use, etc.)?

○ Yes ● **No**

29.10* Is the survey or interview likely to produce psychological discomfort or negative feelings in the subjects?

○ Yes ● **No**

29.11* Has the survey instrument been validated or used in standard practice?

● **Yes** ○ No

29.11.1* If yes, describe the origin of the instrument.

This survey has been used in IRB-approved studies at UCSB's Psychology department.

29.12* Upload the survey instrument here.

Name	Version
DemographicsSES-tyler1.docx	0.01

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
example-stimuli-slideset.pdf	0.01
training video	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
HUM00138634	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:

Co-I

If other, please specify:

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

Select all that apply:

Co-I

If other, please specify:

32.3* 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:** Co-I If other, please specify
☑ Review of lab work, tests, procedures, etc. by:	**Select all that apply:** PI Co-I 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**
☐ DSMB/DSC/independent monitor	
☐ UMHS Cancer Center DSMB	
☐ Federal oversight agencies (FDA, RAC, etc)	
☐ Sponsor (federal, industry, private, etc)	
☐ Other	

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?

N/A - not FDA-regulated

- 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:

- [x] **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.**
- [ ] Independent monitor
- [ ] Internal committee
- [ ] Sponsor
- [ ] Data and Safety Monitoring Board (DSMB) or Data Safety Committee (DSC)
- [ ] UMHS Cancer Center DSMB
- [ ] Other

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
[x]	**IRB (required)**	**eResearch**
[ ]	Federal oversight agencies (FDA, RAC, etc.)	
[ ]	Sponsor (federal, industry, private, etc.)	
[ ]	Other	

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

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

MRI excludes pregnant women from participating.

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

As part of the safety screening for the MRI, participants are asked if they are pregnant. The fMRI laboratory provides a free urine-based pregnancy test for women who are unsure whether they are pregnant. Women who indicate or test that they are pregnant will be excluded.

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.

The fMRI laboratory provides a free urine-based pregnancy test for women who are unsure whether they are pregnant. Women who indicate or test that they are pregnant will be excluded.

41. Subjects Vulnerable to Coercion

Completion of this section is required based on the response provided to question 9-1.1 or 9-2.1.

The following subject populations, vulnerable to coercion or undue influence, have been identified for inclusion in the study.

College Students

41.1* What is the justification for the inclusion of these subject populations?

We require participants who are relatively competent programmers. Additionally, we require participants that have a certain level of felicity with core software engineering concepts (e.g., C programming, version control, code review). PI Weimer's undergraduate software engineering course covers relevant material and thus provides a population of appropriately-skilled students.

41.2* Describe the additional safeguards that have been included in this study to protect the rights and welfare of these subjects.

Students will not be recruited by PI Weimer. Students will not receive extra credit and their course grade will not be influenced by their participation in the study. All anatomical data will be de-identified before analysis. While we will collect audio recordings of participants' post questionnaire, we will transcribe these audio files to plaintext. Further, we will not retain other personally identifiable information after each participant receives their compensation.

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
IRB-HSBS_fMRI_consent_template_final_Oct_2015.docx	0.04