eRESEARCH | REGULATORY MANAGEMENT

Date: Monday, June 28, 2021 12:50:57 PM

Print Close

View: 01. General Study Information
Section: 01. General Study Information

01. General Study Information

The forms menu on the left displays all sections and pages of the application. Pages in **bold** are required. Pages in *italics* may not apply to your project. Use the "Continue" button to advance through the smartform, as it will only display the sections that must be completed.

All questions marked with a red asterisk (*) are required. Questions without a red asterisk may or may not be required, depending on their relevance to the study.

1.1* Study Title:

Understanding Code Review Process 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
HUM00138634 – Understanding Code Synthesis via Functional Magnetic Resonance Imaging

1.1.3* Does this application include the study of COVID-19?

For example:

- **testing or studying the COVID-19 virus,**
- **exploring treatment options,**
- **studying the impact of the COVID-19 pandemic (This could included epidemiological, social, behavioral, or educational research).**

Note: Answer "Yes" only if this project includes the study of COVID-19. Inclusion of study procedures solely intended to allow the research to be conducted under pandemic constraints, such as remote interactions with subjects, remote consenting, or at-home drug delivery are not considered the study of COVID-19.

◯ Yes ◯ No

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
Yu Huang	Co-Investigator		No	yes	No	no	yes	Yes	yes
Kevin Leach	Co-Investigator	EECS - CSE Division	Yes	no	No	no	yes	Yes	yes
Zohreh Sharafi	Co-Investigator		N/A	no	No	no	yes	Yes	yes
Tyler Santander	Other		N/A	no	Yes	no	yes	Yes	no

1.8* Project Summary:

Code review is the software quality check activity by a developer. Code review occurs as a software developer wants to add new source code or edit existing source code of a computer program to add or change features or to fix existing problems. Code review refers to the activity that other developers (reviewers) read and check the code changes and decide to merge it into the software or not. Software developers often (unintentionally) introduce bugs and security vulnerabilities in their code, resulting in low quality software that requires significant additional effort to correct. Code review is to lower the chance of inserting bugs into the software by having other developers check the code before merging into the software.

In a code review activity, reviewers can see a pull request made by a developer that includes changes of the code, the identity information of the developer and the comments made by the developer explaining why he/she made the changes. Finally, reviewers decide to whether merge the changes into the software or reject the changes. While many studies have explored the characteristics of code changes that affect the code review results, none have approached understanding the cognitive processes involved in code review. Also, some studies have revealed that the gender information of the authors might introduce bias of the reviewers' decisions. But no studies has been done to reveal the cognitive process about potential bias from the author information in code review. This study proposes using functional magnetic resonance imaging (fMRI) to measure those cognitive processes.

We believe that exploring the cognitive load of code reviews will inform the software engineering community about how to better assess or train individuals who write software. It is also very important for the community to understand where the bias come from in code reviews and provide an equal environment for the software developers. This study will ask participants to read code in the fMRI machine to measure these cognitive process.

In particular, there are two factors about code reviews that we intend to measure. The first is important factors of computer source code in code reviews. Participants will be asked to examine short pull requests and make their own decisions to accept or reject a pull request. Secondly, this study will compare the effect of the author information of pull requests in code reviews. In the pull requests, participants will be shown an avatar of the author indicating if the code changes are made by a female/male developer or by an automatic software repair tool. To mimic the real code review environment but not introducing any bias from races, the name information of the author will not be displayed on the screen. All the pull requests are from open source software projects in the software engineering community. All the author avatars to the pull requests are randomly selected among avatars of a male developer, a female developer and an automatic software repair tool.

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), (4) spatial ability via a Paper Folding Test (PFT), (5) age, gender, sex, programming language, speaking languages, levels of experience and GPA (in a background survey) and (6) a simple test of C++ programming. Next, they will complete a training session. Then, they will spent approximately one hour in the fMRI reading pull requests. They will subsequently complete a short post-questionnaire which will ask them to explain their decisions to the previous pull requests. After everything is finished, we will debrief the participants about the authors' avatar pictures shown in the pull requests that the pictures are randomly assigned to the pull requests. Lastly, we will pay the participants for the compensation of their time.

The data generated will be used to explore the cognitive process and bias in code reviews and also to find correlations between tasks and survey data. We hypothesize that cognitive processes involved in code reviews will be related to the author identity. The exploration and understanding of code review process will help the software engineering community to improve training for individuals involved in software development and create an equal software environment.

Begin Ame00091189
This amendment includes the following updates: add a electronic survey in the post-survey section (before debriefing). This electronic survey is based on the Harvard Implicit Association Test on Gender and Science. The survey is implemented on our secured server. It shows several words about male (e.g., man, boy, uncle) and female (e.g., woman, girl, aunt) as well as science words (e.g., Mathematics, English, Astronomy, History) and ask the participants to relate between gender words and science words to test their implicit association between gender and science. I also updated the consent form to inform the participants about this post survey.
End Ame00091189

1.9* Select the appropriate IRB:

Health Sciences and Behavioral Sciences

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

4/1/2019

1.11* *Estimated* Duration of Study:

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

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

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)	0.01

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

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

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

- Provides financial or non-financial support for this project;
- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

No

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

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

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)	0.01

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

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

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

- Provides financial or non-financial support for this project;
- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

No

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

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Kevin Leach

Preferred email: kjleach@umich.edu
Business phone 999-999-9999
Business address: CSE 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
kleach-resume.pdf(0.01)	0.01

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

Current Disclosure Status in M-Inform: *This study team member has indicated in M-inform that they do not have any outside interests to disclose.*

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

- Provides financial or non-financial support for this project;
- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

No

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

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

Study Team Detail

1.4 Team Member:

Zohreh Sharafi

Preferred email: zohrehsh@umich.edu
Business phone
Business address: CSE 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
zohreh-cv(0.01)	0.01

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

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

D1 Do you or your family members **have an** outside activity, relationship, or interest **with a** non-UM entity**, where the non-UM entity:**

- Provides financial or non-financial support for this project;
- Supplies a product used in this project (e.g., an app, device, compound, drug, software, survey, evaluation) either for free or at a cost (e.g., purchased);
- Holds an option or license to intellectual property used in this project (e.g., a device, compound, drug, software, survey, evaluation, code, data, schematics, algorithms) that you or your family member developed;
- Will perform work on this project (e.g., subcontract, service agreement, unfunded agreement); or
- Has a financial stake in the outcome of this research?

No

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

View: VIEW000072_customAttributes._attribute186_Study Team Detail
Section: 01. General Study Information

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.)

Yes

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)	0.02
SantanderTyler_2020CV.pdf(0.01)	0.01

Financial Interest and Relationship 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**.

If you are an investigator on this project who is working on behalf of a company/organization **directly** involved in this project (i.e., funding the research, contracted to perform a portion of the research, providing the drug/device/app being studied), your salary from that company/organization **is not** considered a Financial Interest (note, ownership of the company would be).

In relation to **THIS RESEARCH**, over the past 12 months, do you, your spouse, domestic partner, or dependent children have or anticipate having any of the following:

F1. Any *activities* or *relationships* with an entity (excluding entities directly involved in the project), 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). 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.

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 (excluding entities directly involved in the project) 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.**

View: 01-1. Application Type
Section: 01. General Study Information

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 or when UM is a performance site in a multisite research project where UM is the lead site.
☐	**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.

View: 01-2. Standard Study Information
Section: 01. General Study Information

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**

View: 02. Sponsor/Support Information
Section: 02. Sponsor/Support Information

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**

View: VIEW000593_customAttributes._attribute239.customAttributes._attribute3_Internal Sponsor Detail
Section: 02. Sponsor/Support Information

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)	0.01

View: 03. UM Study Functions
Section: 03. Performance Sites

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.

View: 03-1. Performance Sites
Section: 03. Performance Sites

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

View: Performance Site Detail
Section: 03. Performance Sites

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	

View: Performance Site Detail
Section: 03. Performance Sites

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	

View: 05. Research Design
Section: 05. Research Design

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)

Right-handed 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"

View: 05-1. Research Design
Section: 05. Research Design

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 want to explore the cognitive process in code reviews and study the effect of author bias in the process. Results for this study can inform future research about efficient software engineering workforce training and improve the social environment in software engineering.

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 code comprehension and code source bias, we hypothesize that author bias may introduce distinct cognitive load and affect the decisions of code reviews.

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 reviewing activity. Especially with emerging automatic software repair tools, software developers do not quite understand what factors in code reviews affect the final decision. This study aims to uncover that information and learn if this information can improve the ways we train or evaluate engineers' both code writing and code review skills. For instance, it has been proposed that comments in code reviews are an important factor for the decisions and gender of the author of the pull request is related to the final decision of code reviews. We want to look into the cognitive process of code review to understand how the decisions are made.

To our knowledge, only three 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. 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.
Distilling Neural Representations of Data Structure Manipulation using fMRI and fNIRS was published in ICSE in 2019. This study investigated the relationship between manipulating program data structures and rotating 3D objects. It found out a similarity between those two tasks and suggested the applications of fNIRS and fMRI in software engineering.
One study explicitly explored pull requests in GitHub, the biggest open source software community, and found that when gender is not directly recognized, pull requests made by female developers are significantly more likely to be accepted than male developers. However, when gender is directly recognizable, female developers have more rejections than male developers.

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 and the University of Michigan. 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 have published peer-reviewed publications based upon such 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 and all the fMRI-specific data are de-identified.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.

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 conduct this study following the steps:

Step 1: recruitment
We will recruit participants from the undergraduate and graduate EECS student population. First, we will use mailing lists to email undergraduate and graduate CS majors about the study, benefits, risks, compensation, and skill level required. We will also recruit in undergraduate CS course via a 2-3 minute presentation about joining the study. PI Weimer's software engineering class is also considered. But PI Weimer will not involve in any recruitment. During the advertisement of PI Weimer's class, Research Fellow Leach or Graduate Student Huang will give the advertisement presentation and PI Weimer will leave the classroom until the advertisement is done. It will be made explicitly in the advertisement that the participation of this study will not affect the grades of the class. PI Weimer also does not have access to the recruitment information. We will also put flyers in public space on north campus of the University of Michigan. In all recruitment materials, we will make the requirements clear: participants must be right-handed, age between 18-65.

We will wait for participants to contact us via emails if they are interested in participating in this study. Upon receiving emails of potential participants showing their intention to participate and also meet our requirements of (1) right-handed (2) age between 18-65, we will email the consent forms (the consent form for this study and the blanket fMRI consent form under the blanket fMRI Master Protocol) and the fMRI safety screening form to them together with 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 (literature suggests they are relevant to human). The fMRI safety screening form is to check if the participant are eligible to take an fMRI scan (e.g., no metal implants, no head tattoos etc). The reason for collecting these surveys are because in psychology, studies have shown those factors are relevant to human decision making (see survey materials attachment section). Once they decide to participate the study, they sign the consent forms, safety screening form and also fill the surveys (the surveys will take about 20 minutes and no signatures are required on the surveys). They will email the signed consent forms and safety screening form to us (they will bring the surveys to their fMRI appointment in the future). Once we receive a participant's signed consent forms and safety screening form, we will check if they are eligible to take a fMRI scan. For participants that pass safety screening form, we randomly assign a participant ID to the participant. The ID ranges from 300 to 500. After this moment, we only use the ID to mark each participant's data. While we will need to interact with participants via email for scheduling an fMRI appointment and possibly contact a participant if we have incidental findings in their fMRI data, we will keep the email address and corresponding ID separately in an electronic file (the secured linking sheet) in our secured server,and delete this file 30 days after the study is finished. Only Research Fellow Leach and Graduate Huang have access to this secured linking sheet (PI Weimer has no access to this linking sheet).

Step 2: Scheduling fMRI scans
After receiving consent from the participants and assigning IDs to participants, we will schedule a 90-minute fMRI session with each participant through emails using the information on the secured linking sheet. We will email them candidate available fMRI slots and participants email us back their choice of the fMRI scan time. We will put the scan time for each participant on the secured linking sheet. One day before a participant's experiment, we will email him/her a reminder of the scan next day and also remind them of bring the surveys next day using the secured linking sheet.

Step 3: fMRI scan
Once the participant arrives for their scheduled fMRI scan, research Fellow Kevin Leach and/or graduate student Yu Huang and/or Co-investigator Zohreh Sharafi will sit with the subject and go through the preparation of the fMRI scan. The preparation includes: (i) print the signed consent forms and safety screening form sent by the participant and reaffirm the consent with the participant by explaining the experiment, the process of the study, their rights, risks, and benefits (all included in the consent forms). This reaffirm of consent is oral. (ii) If they reaffirm their consent, we will ask for their surveys that we sent them along with the consent forms before; (iii) we will give them the background questionnaire to collect their age, gender, sex, programming language, speaking languages, levels of experience and GPA; (iv) we will give them a simple test of C++ programming for sanity check of the participants since the participants are required to have basic knowledge of C++. We show them short snippets of C++ code and ask them what is the functionality of each code. If the participant cannot get all three tests correctly, they cannot proceed the study. This questionnaire will take roughly 5-10 minutes and will be completed with a pen and paper. (v) we and the fMRI lab technician will go through the safety screening form again orally with the participant to double check if the participant is qualified to take a fMRI scan. If the participant changed his answer of any item in the safety screening form that makes him/her ineligible to take the fMRI scan, he/she cannot proceed the study. (vi) 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; (vii) the participant will enter the fMRI and the study will begin. During the study, participants will be given an fMRI-safe button for giving their inputs while in the MRI tube. We will ask them to complete a series of tasks, each 40 seconds long. We will show them four 12-minute blocks. Each block contains 15 pull requests for the

participants to review. In each 40-second task, participants need to decide if they want to accept or reject the pull request. There will be a 5 second break between each 40 second task, as well as a 2 minute break between each 12-minute block. They will be told before the scan that they can stop the scan anytime in the middle (also listed in the consent forms). An MRI technician will conduct the scan on the subject. If the technician makes an incidental finding during the scan of the subject, we will immediately stop the scan and communicate the technician's findings to the subject, and suggest that they follow up with a physician to properly assess the incidental finding.

For any participant who cannot proceed the study in (iv), (v) or stops the fMRI scan in the middle as described in (vii), he/she will be instructed to leave and be compensated $25 voucher. For those participants, we will delete/destroy all the data and forms collected from him/her.

Step 4: After-scan
After completing the fMRI scan, we will let the participant finish two post-surveys. In the first post-survey, we ask three additional questions about a response they gave in each block of tasks (i.e., pull request generated by a female developer, pull request by a male developer, and pull request made by an automatic software repair tool). This post-survey is done by pen and paper. After they finish the post-survey, we will go through a debriefing form with the participants explaining the author information of the pull requests does not reflect actual author information and why we need to do that. Participants will sign this debriefing form to give us consent to include or exclude their data in this study. Participants will receive $75 compensation for their time no matter they decide to include or exclude their data in the debriefing form. Afterwards, the participant is free to leave.

In the steps described above (step 1 to step 4), all the forms and data are marked with the special ID we assign to the participant. No identifiable information is collected from the online survey at all. There is no direct identifiable information on the forms and data.

Step 5 (optional):
In the following analysis of the fMRI data, if we notice any incidental findings of a participant's data, PI Weimer, Research Fellow Leach or Graduate Student Huang will follow up with this participant via emails by looking up the corresponding email address of the ID on the secured linking sheet. We will suggest in the emails that they follow up with a physician to properly assess the incidental finding.

Step 6. After 30 days of the complete data collection of the study, we will delete the secured linking sheet from our secured server.

We will develop example pull requests from GitHub, the biggest open source software community. We will randomly assign the author of the pull requests to be female, male developers and automatic software repair tool. The author of a pull request is shown to the participants as a corresponding avatar on the screen. A blurred name area for the female/male developers will be shown too to mimic the real code review environment. We explained to the participants in the debriefing that the avatar pictures of the authors are not reflecting the actual author information and this is due to the purpose of the study: it needs to control the quality of the code to study the effect of author information.

We will apply established techniques for de-identifying 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 transform original fMRI data into a new format (up to 7 dimensions of image data) that does not have any direct information of the brain shape: https://afni.nimh.nih.gov/pub/dist/doc/program_help/nifti_tool.html.

We plan to retain the de-identified fMRI and 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 email addresses. The email address of each participant will be saved in a secured linking sheet and used to scheduling time in the MRI and potentially future contacts for incidental fMRI findings. However, these are separate from the study and will not be retained as part of the research data. We will retain the subject's email address for 30 days after completion of the data collection to notify them of any incidental findings made during their scan.

Begin Ame00091189
This amendment includes the following updates: we add an electronic survey in Step4:after-scan. This electronic survey is based on the Harvard Implicit Association Test on Gender and Science. The survey is implemented on our secured server. It shows several words about male (e.g., man, boy, uncle) and female (e.g., woman, girl, aunt) as well as science words (e.g., Mathematics, English, Astronomy, History) and ask the participants to relate between gender words and science words to test their implicit association between gender and science. Participants conduct this survey on our research laptop through a html linking to the same secured server we save the rest of the data. The laptop is secured by a password only Graduate Huang knows. This survey will only ask about the Participant ID at the beginning and records no other personal information. All the inputs from the participants are stored with the Participant ID in our secured server. The data includes the time participants take to make a relation between a gender word and/or a science word and the categorical test results of the implicit association, such as "Your data suggest a slight automatic association for male with Science and Female with Liberal Arts". This test lasts 5-10 minutes.
End Ame00091189

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, speaking languages, levels of experience and GPA 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.

View: 06. Benefits and Risks
Section: 06. Benefits and Risks

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. It will also help the software engineering community to build a more inclusive working environment.

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	HUM00161095	No more than minimal risk	no

View: Benefits and Risks Detail
Section: 06. Benefits and Risks

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.)

HUM00161095

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 in this study. 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 deidentified, so that it cannot be used to learn the identity of individual participants, even if the data is decrypted. The only secured linking sheet that records the email address and de-identifiable ID of the participants will be stored on an encrypted volume on a server kept in a locked office and deleted 30 days after data collection.

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.

View: 07. Special Considerations
Section: 07. Special Considerations

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**

View: 07-1. Special Considerations - Continued
Section: 07. Special Considerations

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

View: 07-2. Special Consideration - Continued
Section: 07. Special Considerations

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**

View: 08. Subject Participation
Section: 08. Subject Detail

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

View: 08-1. Subject Recruitment
Section: 08. Subject Detail

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.

We will recruit participants from the undergraduate and graduate EECS student population. First, we will use mailing lists to email undergraduate and graduate CS majors about the study, benefits, risks, compensation, and skill level required. We will also recruit in undergraduate CS course via a 2-3 minute presentation about joining the study. PI Weimer's software engineering class is also considered. But PI Weimer will not involve in any recruitment. During the advertisement of PI Weimer's class, Research Fellow Leach or Graduate Student Huang will give the advertisement presentation and PI Weimer will leave the classroom until the advertisement is done. It will be made explicitly in the advertisement that the participation of this study will not affect the grades of the class. PI Weimer also does not have access to the recruitment information. We will also put flyers in public space on north campus of the University of Michigan.

We will wait for participants to contact us via emails if they are interested in participating in this study. Upon receiving emails of potential participants showing their intention to participate, we will email the consent forms (the consent form for this study and the blanket fMRI consent form under the blanket fMRI Master Protocol) to them together with 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 (literature suggests they are relevant to human). The reason for collecting these surveys are because in psychology, studies have shown those factors are relevant to human decision making (see survey materials attachment section). Once they decide to participate the study, they sign the consent form and also fill the surveys (the surveys will take about 20 minutes and no signatures are required on the surveys). They will email the signed consent form to us (they will bring the surveys to their fMRI appointment in the future). Once we receive a participant's signed consent forms, we randomly assign a participant ID to the participant. The ID ranges from 300 to 500. After this moment, we only use the ID to mark each participant's data. While we will need to interact with participants via email for scheduling an fMRI appointment and possibly contact a participant if we have incidental findings in their fMRI data, we will keep the email address and corresponding ID separately in an electronic file (the secured linking sheet) in our secured server,and delete this file 30 days after the study is finished. Only Research Fellow Leach and Graduate Huang have access to this secured linking sheet (PI Weimer has no access to this linking sheet).

In summary, 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 Huang's email address as a point of contact. Students interested in participating will be encouraged to email Huang to establish an appointment to meet for the fMRI study.
2) Students will not be given extra credit for taking this study.
3) PI Weimer has no access to the secured linking sheet that records participants' email addresses.

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?

We will recruit participants from the undergraduate and graduate EECS student population. First, we will use mailing lists to email undergraduate and graduate CS majors about the study, benefits, risks, compensation, and skill level required. We will also recruit in undergraduate CS course via a 2-3 minute presentation about joining the study. PI Weimer's software engineering class is also considered. But PI Weimer will not involve in any recruitment. During the advertisement of PI Weimer's class, Research Fellow Leach or Graduate Student Huang will give the advertisement presentation and PI Weimer will leave the classroom until the advertisement is done. It will be made explicitly in the advertisement that the participation of this study will not affect the grades of the class. PI Weimer also does not have access to the recruitment information. We will also put flyers in public space on north campus of the University of Michigan. In all recruitment materials, we will make the requirements clear: participants must be right-handed, age between 18-65.

We will wait for participants to contact us via emails if they are interested in participating in this study. Upon receiving emails of potential participants showing their intention to participate and also meet our requirements of (1) right-handed (2) age between 18-65, we will email the consent forms (the consent form for this study and the blanket fMRI consent form under the blanket fMRI Master Protocol) and the fMRI safety screening form to them together with 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 (literature suggests they are relevant to human). The fMRI safety screening form is to check if the participant are eligible to take an fMRI scan (e.g., no metal implants, no head tattoos etc). The reason for collecting these surveys are because in psychology, studies have shown those factors are relevant to human decision making (see survey materials attachment section). Once they decide to participate the study, they sign the consent forms, safety screening form and also fill the surveys (the surveys will take about 20 minutes and no signatures are required on the

surveys). They will email the signed consent forms and safety screening form to us (they will bring the surveys to their fMRI appointment in the future). Once we receive a participant's signed consent forms and safety screening form, we will check if they are eligible to take a fMRI scan. For participants that pass safety screening form, we randomly assign a participant ID to the participant. The ID ranges from 300 to 500. After this moment, we only use the ID to mark each participant's data. While we will need to interact with participants via email for scheduling an fMRI appointment and possibly contact a participant if we have incidental findings in their fMRI data, we will keep the email address and corresponding ID separately in an electronic file (the secured linking sheet) in our secured server,and delete this file 30 days after the study is finished. Only Research Fellow Leach and Graduate Huang have access to this secured linking sheet (PI Weimer has no access to this linking sheet).

In summary, 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 Huang's email address as a point of contact. Students interested in participating will be encouraged to email Huang to establish an appointment to meet for the fMRI study.
2) Students will not be given extra credit for taking this study.
3) PI Weimer has no access to the secured linking sheet that records participants' email addresses.

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 between 18-65, right handed and passing the fMRI safety screening form can participate in this study provided they demonstrate the required programming expertise for completing the C++ programming tasks. Every candidate participant will be assessed for minimal expertise using the same three C++ 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).

The recruitment will be done in CS relevant classes and through CS undergrad and graduate mailing list. The recruitment will also be done through a flyer in the public space on the north campus of the University of Michigan.

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 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 email lists to which the undergraduate and graduate CS majors are subscribed.

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)	0.04
mri-ad-flyer.docx(0.02)	0.02
recruitment-script.docx(0.03)	0.03
safety-screening.pdf(0.02)	0.02

☐ **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

View: 09. Survey Populations
Section: 09. Subject Populations

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**

View: 09-1. Subject Populations
Section: 09. Subject Populations

09-1. Subject Populations

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

Select all that apply

- [x] **Normal, healthy subjects**
- [x] **Adults** *age 18 and older*
- [ ] **Minors able to consent** *to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted (e.g. emancipated minors or minors seeking treatment for certain conditions.)*
- [ ] **Children and/or Viable Neonates** *(i.e. persons who have not yet reached the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted) [Require Sections 33 and 41]*
- [ ] **Neonates of uncertain viability and/or nonviable neonates** (do not check this box if the research is solely retrospective. For retrospective research regarding neonates of uncertain viability, check the box for 'Children'. See Help for additional information.) [Require Section 34]
- [ ] **Individuals and/or products involving human in vitro fertilization**
- [ ] **Pregnant women and/or fetuses** [Require Sections 35 and 41]
- [ ] **Lactating women** [Require Section 36]
- [x] **Women of child-bearing potential** [Require Section 37]
- [ ] **Prisoners** (If the research includes a study population that is likely to become incarcerated during the conduct of the research, also select this category) [Require Section 38 and 41]
- [ ] **Cognitively impaired adults** [Require Sections 39 and 41]
- [x] **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**

View: 10. Informed Consent - Adults
Section: 10. Informed Consent

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.

We will recruit participants from the undergraduate and graduate EECS student population. First, we will use mailing lists to email undergraduate and graduate CS majors about the study, benefits, risks, compensation, and skill level required. We will also recruit in undergraduate CS course via a 2-3 minute presentation about joining the study. PI Weimer's software engineering class is also considered. But PI Weimer will not involve in any recruitment. During the advertisement of PI Weimer's class, Research Fellow Leach or Graduate Student Huang will give the advertisement presentation and PI Weimer will leave the classroom until the advertisement is done. It will be made explicitly in the advertisement that the participation of this study will not affect the grades of the class. PI Weimer also does not have access to the recruitment information. We will also put flyers in public space on north campus of the University of Michigan. In all recruitment materials, we will make the requirements clear: participants must be right-handed, age between 18-65.

We will wait for participants to contact us via emails if they are interested in participating in this study. Upon receiving emails of potential participants showing their intention to participate and also meet our requirements of (1) right-handed (2) age between 18-65, we will email the consent forms (the consent form for this study and the blanket fMRI consent form under the blanket fMRI Master Protocol). Once they decide to participate the study, they sign the consent form and email the signed consent form to us.

Additionally, once the participant arrives for their scheduled fMRI scan, research Fellow Kevin Leach and/or graduate student Yu Huang and/or Co-investigator Zohreh Sharafi will sit with the subject, print the signed consent forms sent by the participant and reaffirm the consent with the participant by explaining the experiment, the process of the study, their rights, risks, and benefits (all included in the consent forms). This reaffirm of consent will be done orally.

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

○ Yes ● **No**

View: 10-1. Informed Consent
Section: 10. Informed Consent

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
Debriefing_form(0.01)	0.01
IRB-consent-code-review(0.10)	0.10

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

10-1.8.1* Provide a justification for this requirement. If the information is included in the attached protocol, please indicate section.

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. Thus, as part of our consent form, participants are required to agree to retention of their de-identified data as a condition of participating in the research.

The steps of sharing de-identified data in this study are as follows:
PI Weimer will write a note on our project website once it is public. The note is “please contact me via emails if your research team is interested in using this dataset to reproduce the research results, apply new data analysis or other research purpose activities”. Then PI weimer will share the de-identified dataset with researchers who requires it in emails.

For the consent of retention of the de-identified data, please check the IRB-HSBS_fMRI_consent_code_review consent form.

View: 11. Confidentiality/Security/Privacy
Section: 11. Confidentiality, Security and Privacy

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.

Upon receiving emails of potential participants showing their intention to participate and confirming they are between 18-65 and right-handed, we will email the consent forms (the consent form for this study and the blanket fMRI consent form under the blanket fMRI Master Protocol) and fMRI safety screening form to them together with four surveys. Once they decide to participate the study, they sign the consent form, the fMRI safety screening form and also fill the surveys (the surveys will take about 20 minutes and no signatures are required on the surveys). They will email the signed consent forms and safety screening form to us (they will bring the surveys to their fMRI appointment in the future). Once we receive a participant's signed consent forms and safety screening form, we will check if they are eligible to take a fMRI scan. For participants that pass safety screening form, we randomly assign a participant ID to the participant. The ID ranges from 300 to 500. After this moment, we only use the ID to mark each participant's data. While we will need to interact with participants via email for scheduling an fMRI appointment and possibly contact a participant if we have incidental findings in their fMRI data, we will keep the email address and corresponding ID separately in an electronic file (the secured linking sheet) in our secured server,and delete this file 30 days after the study is finished. Only Research Fellow Leach and Graduate Huang have access to this secured linking sheet (PI Weimer has no access to this linking sheet).

We will sit with participants to go through preparations of the fMRI scan in private before the scan.

All the forms and data are marked with the special ID we assign to the participant. There is no direct identifiable information on forms and data after consent if achieved.

fMRI anatomical data will be de-identified to prevent facial reconstruction in the event of a data breach.

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

View: 11-1. Identifiable Data
Section: 11. Confidentiality, Security and Privacy

11-1. Identifiable Data

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

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

Select all that apply:

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

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

In the recruitment, potential participants contact us through emails. Then we will contact them for consent, fMRI safety screening form and distributing surveys and scheduling experiments through emails. In addition, we will also need their emails for future contact if we have any incidental fMRI findings about any participant in our data analysis. The link between the emails and participant IDs is stored in a secured file in a secured server. We will not store their emails in any other format or for any other usage. For more details of this link file, please check section 5-1.5.

11-1.3* How long will the identifiers be retained?

We will delete the identifiers (the link between email addresses and participant ID) 30 days after the data collection is done.

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

○ Yes ● **No**

View: 11-3. End of Subject Participation
Section: 11. Confidentiality, Security and Privacy

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 C++ programming task 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 voucher) and their participation will end at that point.

We ask participants to take a safety screening check required by the fMRI Master Protocol. If the participant does not pass the safety screening check (e.g., have metal implants in their body), he/she cannot proceed the study.

During the fMRI scan, participants will be given an fMRI-safe button for giving their inputs while in the MRI tube. They will be told before the scan that they can stop the scan anytime in the middle (also listed in the consent forms). An MRI technician will conduct the scan on the subject. If the technician makes an incidental finding during the scan of the subject, we will immediately stop the scan and communicate the technician's findings to the subject, and suggest that they follow up with a physician to properly assess the incidental finding.

For any participant who cannot proceed the study or stops the fMRI scan in the middle, he/she will be instructed to leave and be compensated $25 voucher. For those participants, we will delete/destroy all the data and forms collected from him/her.

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.

View: 11-4. Retention of Data and/or Specimens Detail
Section: 11. Confidentiality, Security and Privacy

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.

The steps of sharing de-identified data in this study are as follows:
PI Weimer will write a note on our project website once it is public. The note is “please contact me via emails if your research team is interested in using this dataset to reproduce the research results, apply new data analysis or other research purpose activities”. Then PI weimer will share the de-identified dataset with researchers who requires it in emails.

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 have a secure locker to store all the hard copies (consent forms etc) in the office. Only Research Fellow Leach has the key of the locker.

We store the secured linking sheet and all electronic data on a secured volume on our server. Only Research Fellow Leach and Graduate Student Huang have the access (secured passphrase) to the volume of server.

View: 13. Subject Payments Or Other Incentives
Section: 13. Subject Payments Or Other Incentives

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:

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:

None

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 right after each fMRI scan. If a participant is found ineligible during the fMRI safety screening or skills assessment or cannot finish the fMRI scan, they will receive $25 voucher.

The payment will be given to the participant as a voucher. Participants can bring this voucher to the University of Michigan Hospital Cashier or Student's office in the Central campus to redeem it. There is no information of the study on the voucher.

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 $25 (voucher). If they are excluded based on the skills assessment or fMRI safety screening or decide to stop the experiment in the middle, they will receive $25 (voucher).

View: 27. Deception or Concealment Research
Section: 27. Deception or Concealment Research

27. Deception or Concealment Research

Completion of this section is required based on the response provided to question 7-1.3.

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27.1* Indicate why deception or concealment is the only feasible means of conducting this research.

This study is about how programmers are thinking and making decisions in code reviews, where they read others' code and the associated information of the author of the code. One hypothesis of this study is to look at whether the bias of the code provenance (the author of the code) will affect decision making. To test this study, we need to control the variables (the characteristics of the code). Thus, for the same piece of code, we altered the author of the code to participants. In other words, the only difference of the same piece of code to different participants is the author shown with the code.

27.2* Provide a detailed explanation of the nature of the deception or concealment including the use of any "confederates."

In our study, there is no confederate. The deception part of out study is only on the avatar associated in code reviews. The avatar pictures indicate the code snippet in a code review is written by a female programmer, a male programmer or generated by a automatic computer program. There is no other information about authors are shown. Instead of showing the actual indication of the author, we randomly assign the avatar pictures to a code review. Then for each code review, we change the avatar picture and show it to a different participant. Thus, we can compare the effect of author information in code review decision by controlling the quality of the code itself.

27.3* Is the research likely to produce psychological discomfort or negative feelings in the subjects?

◯ Yes ● **No**

27.4* If you are obtaining informed consent from the subjects, is the informed consent document or process a part of the deception or concealment?

Yes - alteration of informed consent has been requested in Section 10.

27.4.1* Please explain the specific elements of deception or concealment that are incorporated into the informed consent document or process:

In the consent form, we informed the participants that they will complete code review tasks. We do not claim anything about the avatar pictures of the authors of code reviews (we do not explicitly tell the participants the avatar pictures are assigned randomly so that they do not reflect the actual indication of the authors of code reviews).

27.5* Do you plan to debrief subjects at the conclusion of the study?

● **Yes** ◯ No

27.5.1* Please upload the debriefing document here.

Name	Version
Debriefing_form(0.01)	0.01

View: 29. Survey Research
Section: 29. Survey Research

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	7	5 minutes	no	no
Implicit Association Test on Gender and Science	About 40	less than 10 minutes	no	no
knowledge assessment (c++ expertise)	3	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**

View: VIEW000619_customAttributes._attribute234.customAttributes._attribute8_Survey Detail
Section: 29. Survey Research

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
Austism Spectrum Quotient(0.01)	0.01

View: VIEW000619_customAttributes._attribute234.customAttributes._attribute8_Survey Detail
Section: 29. Survey Research

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?

7

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

29.12* Upload the survey instrument here.

Name	Version
Background questionnare(0.02)	0.02

View: VIEW000619_customAttributes._attribute234.customAttributes._attribute8_Survey Detail
Section: 29. Survey Research

Survey Detail

29.2* Survey or interview name:

Implicit Association Test on Gender and Science

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.*

It will be an electronic survey and participants will finish it right at the end of the experiment on a computer from the research team. No identifiable information is collected.

29.5* What is the predicted response rate?

100 %

29.6* What is the total number of questions?

About 40

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

less than 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.

This is a public survey designed by Harvard to test the implicit association between science of gender. We implemented this survey on our secured server. It has been wildly used by many researchers.

29.12* Upload the survey instrument here.

Name	Version
Implicit Association Test: Gender vs. Science(0.02)	0.02

View: VIEW000619_customAttributes._attribute234.customAttributes._attribute8_Survey Detail
Section: 29. Survey Research

Survey Detail

29.2* Survey or interview name:

knowledge assessment (c++ expertise)

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.*

We will give this survey before the fMRI scan.

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

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

Such tests are widely used in IT interviews to assess programmers' basic knowledge of programing.

29.12* Upload the survey instrument here.

Name	Version
knowledge-assessment.docx(0.01)	0.01

View: VIEW000619_customAttributes._attribute234.customAttributes._attribute8_Survey Detail
Section: 29. Survey Research

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, J. T., Petty, R. E., & Kao, C. F. (1984). The efficient assessment of need for cognition. Journal of Personality Assessment, 48(3), 306-307

29.12* Upload the survey instrument here.

Name	Version
need for cognition(0.01)	0.01

View: VIEW000619_customAttributes._attribute234.customAttributes._attribute8_Survey Detail
Section: 29. Survey Research

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 emailed to the participant after we receive the consent from the participant.

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.

z-2-BRACE scoring instrument for spatial ability.

29.12* Upload the survey instrument here.

Name	Version
Paper Folding Test(0.01)	0.01

View: VIEW000619_customAttributes._attribute234.customAttributes._attribute8_Survey Detail
Section: 29. Survey Research

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
positive affect/negative affect score(0.01)	0.01

View: VIEW000619_customAttributes._attribute234.customAttributes._attribute8_Survey Detail
Section: 29. Survey Research

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(0.01)	0.01

View: VIEW000619_customAttributes._attribute234.customAttributes._attribute8_Survey Detail
Section: 29. Survey Research

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
socioeconomic(0.01)	0.01

View: 31. Watching/Listening to Audiovisual Materials
Section: 31. Watching/Listening to Audiovisual Materials

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-slidesset.pdf(0.01)	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**

View: 32. Data Safety And Monitoring Plan
Section: 32. Data Safety Monitoring Plan

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
HUM00161095	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.

View: 32-1. Data and Safety Monitoring Plan - AE Reporting
Section: 32. Data Safety Monitoring Plan

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)

View: 32-2. Data Safety and Monitoring Plan - Monitoring the Study
Section: 32. Data Safety Monitoring Plan

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:

View: 37. Women of Child Bearing Potential
Section: 37. Women of Child Bearing Potential

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.

View: 41. Subjects Vulnerable to Coercion
Section: 41. Subjects Vulnerable to Coercion

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).

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 data will be de-identified for analysis. We will record a secured linking sheet of participants' email addresses and IDs for scheduling fMRI scans and potential follow-ups if there is any incidental fMRI findings for a participant. Only Research Fellow Leach and Graduate Student Huang have access to this sheet and will delete this sheet 30 days after the data collection.

View: 44. Additional Supporting Documents
Section: 44 Additional Supporting Documents

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
Ame00091189-tracked-changes-for-consent-form(0.03)	0.03
Ame00091189-tracked-date-security-protocol(0.01)	0.01
data-security-protocol(0.02)	0.02
fMRI-umbrella-consent(approved)(0.01)	0.01

View: 45. End Of Application
Section: 45. End of Application

45. End of Application

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