HSR Protocol Cover Sheet

HSR Submission Number: 9802

Title: Understanding Code Review with Functional Magnetic Resonance Imaging

Committee Review Amount: Expedited

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Sub-Investigators:
- NONE

Sponsor(s): N/A

Funding Grant(s): 1.) Grant Number: 18171, National Science Foundation (NSF)

Five Year Update: NO

Location of Study: UVA

Multi-Site Study: NO

PRC Study: NO

GCRC Study: N/A

IND NO

IDE: NO

Auxiliary Documents Required for Submission:	• HSR Grant • ISPRO Approval
If applicable, submit one copy of any other you have such as:	• Questionnaires • Surveys • Manual of Operations • Package Inserts • COI Management Plan
Auxiliary Documents Required for Approval:	None
Other Documents:	NONE

Committee Conflict: NONE

Question/Answers for HSR Submission: 9802		
1.	Are you doing research with human subjects as an agent for UVa?	YES
2.	Will the IRB-HSR be the IRB of record for this protocol for the research to be done by UVa personnel?	YES
36.	Do you plan to do research with data previously collected as part of an Improvement Project (e.g. Performance Improvement, Practice Improvement, Quality Improvement) in which there was no interaction or intervention with an individual and the project only involved the use of information from UVa medical records?	NO
38.	Is there a protocol already in existence (e.g. sponsor's protocol, investigator initiated)?	NO
39.	Is this a 5 year update of a previously approved protocol?	NO
40.	Is this protocol funded by an external grant?	YES
41.	Is the Principal Investigator on the Grant Proposal a UVa faculty member?	YES
42.	Was the IRB-HSR the IRB of record for the grant funding this protocol?	NO
43.	Do you or will you have a contract with an outside entity to support this protocol OR to share data with anyone not listed on the protocol, other than sponsor or CRO, prior to publication?	NO
48.	Is there an entity inside of UVA supporting/sponsoring this study?	NO
49.	Will this study be submitted through the PI's current primary school and department appointment?	YES
50.	Is this a multi-site trial?	NO
51.	Will data from this study be combined with data from other sites conducting the same or similar study?	NO
54.	Will any of your data involve information about students governed by the federal FERPA regulations, such as information from Student Health, the Registrar’s Office, the Office of Assessment and Studies, or the Student Information System (SIS)?	NO
55.	Does this study meet the criteria for research only involving coded private information or biological specimens?	NO
56.	Does this study meet Exempt approval criteria?	NO
57.	Will data/specimens be collected at another institution such as another health system, a school or HealthSouth and sent to UVA?	NO
58.	Does this study meet the criteria of "non engaged" in human subject research?	NO
59.	Is there a conflict of interest in the protocol?	NO
61.	Does the study involve a patent owned by UVA?	NO
62.	Will UVa release any information outside of UVa (e.g. to sponsor) about a potential subject BEFORE that subject signs a consent form (e.g. screening log)?	NO
63.	Is there an outside funding/supply source, other than the sponsor, supporting this study?	NO

64.	Will this study be done outside of the US and led by a research team from UVa?	NO
65.	Are all personnel listed on this study UVA employees or students?	YES
67.	Will you do any of the following in this study? • Collect identifiable* data onto** an individual use device (e.g. desktop computer, smart phone app, tablet, laptop) • Collect or store identifiable* data via web based format (e.g. online consent, online surveys)via a non- UVa server. Only exception is sharing or storing of data by sponsor or CRO in which data will be sent and stored in an encrypted fashion (e.g. Secure FX. Secure FTP, HTTPS, PGP) • Store identifiable* data on the Cloud (e.g., UVa Box, UVa Collab , Question Pro, Drop Box, Google Drive, SkyDrive, Survey Monkey etc.) • Store identifiable* data onto a server managed by the PI's department or school (except School of Nursing SECUREnet via an IKEY) • Store identifiable* data onto a server managed by UVa ITS (except Cancer Center ONCORE system).	YES
68.	Will all of the UVA portions of this study be carried out exclusively at the UVA Health System and UVA affiliated sites such as the clinics at Orange?	YES
69.	To avoid conflict of interest, are any HSR board members/alternatives listed on the protocol or a 1572 form as study personnel?	NO
70.	Will this study involve taking a family history for research purposes?	NO
71.	Will you collect data from the Clinical Data Repository (CDR)?	NO
72.	Is the ONLY intent of this protocol to establish a research database (repository)?	NO
84.	Does this study involve ONLY doing analysis on data collected from medical records?	NO
87.	Does the TARGET population of this protocol include patients with known or suspected cancer?	NO
94.	Is a scientific review required prior to submission of the protocol to the IRB-HSR?	NO
95.	Does this study involve collection of information about subjects that is not already known by their health care provider and documented in their medical record AND that, if released, might be damaging to an individual's financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination? This could include sensitive information relating to sexual or gender preferences or practices; information relating to the misuse of alcohol, drugs, or other addictive products; information about illegal conduct; sensitive information pertaining to mental illness; information regarding HIV, AIDS or other STDs; or sensitive genetic information or tissue samples.	NO
96.	Will any data from UVA subjects be sent outside of UVA?	NO
97.	Will subjects be photographed, videotaped or audiotaped?	NO
98.	Will this study involve only qualitative research?	NO

100.	Will this study involve biomedical research?	YES
101.	Will this study involve an MRI with Gadolinium, in a site other than the brain, for research purposes?	NO
102.	Does this study involve the use of medical imaging for research purposes?	YES
103.	Does this study involve Magnetic Resonance Imaging (MRI) for research purposes?	YES
104.	Does this study involve tomography for research purposes?	NO
105.	Does this study involve nuclear medicine (radionuclide) imaging for research purposes?	NO
106.	Does this study involve x-rays including CAT scans, fluoroscopy, or mammography for research purposes?	NO
108.	Does this study involve the use of radiation therapy for research purposes?	NO
110.	Will you be working with any specimens from a human?	NO
117.	Does this study involve the use of recombinant DNA, biological vectors or infectious agents?	NO
118.	Does this study involve a medical device that will be used at the UVa Health System that is not currently used at the UVa Health System?	NO
119.	Are you evaluating the safety and/or efficacy of a medical device in this study?	NO
123.	Are you only USING a device in an unapproved manner in this study, but NOT EVALUATING it for safety and efficacy?	NO
124.	Are you including results from DNA or RNA testing that were performed for clinical purposes using clinically validated diagnostic tests?	NO
125.	Will you store and maintain any specimen for unspecified future use after this study is completed (specimen banking) AND/OR do any sequence analysis or other testing of the DNA or RNA as part of this research study (genetic research)?	NO
135.	Is there any possibility that data from this study may someday be used for a Genome-Wide Association Study (GWAS)?	NO
136.	Does this protocol involve RESEARCH of a drug, device or biologic already approved by the FDA for the indication, dose and route to be used in this protocol?	NO
137.	Does this study meet Expedited approval criteria?	YES
138.	Does this protocol **USE** or **INVOLVE THE RESEARCH** of a drug or biologic **not approved** by the FDA for the indication, dose and route to be used in this protocol?	NO
145.	Will this study be monitored by a Data and Safety Monitoring Board?	NO
146.	Does this protocol involve specimen banking and/or genetic research?	NO
168.	Do you plan on getting ONLY verbal consent (Waiver of Documentation of Consent) for the entire study?	NO
	Do you plan on getting verbal consent for part of this study (Waiver of Documentation of Consent) and	

189.	performing another part of the study without consent of the subject (Waiver of Consent)?	NO
210.	Are you requesting that NO CONSENT (verbal or written) be obtained from the subject for the entire study (Waiver of Consent)?	NO
211.	Do you plan on getting no consent for part of the study (Waiver of Consent) and a written consent for another part of the study?	NO
212.	Do you plan on getting VERBAL CONSENT for ONLY a PART of this study (waiver of documentation of consent) and will obtain a signature on a consent form for the main part of the study?	YES
214.	Will you be collecting health information?	YES
215.	Will this study require separate consent forms for different parts of the protocol (e.g. the screening vs. treatment portion of the protocol, or for patient vs. control)?	NO
216.	Does the study enroll adult subjects (age 18 and older)?	YES
217.	Will this study enroll subjects who would be age 65 or older?	NO
218.	Does the study enroll subjects under the age of 18?	NO
225.	Will a potential subject who is a prisoner be allowed to enroll in this study?	NO
226.	Will you enroll a woman if she is pregnant?	NO
227.	If a woman is pregnant or becomes pregnant while in this study would the study pose a risk to a fetus?	NO
228.	Would participation in this study pose risks to a fetus if a male subject were to father a child?	NO
229.	Will this protocol involve fetuses or human in vitro fertilization?	NO
230.	Will cognitively impaired subjects be allowed to enroll in this study?	NO
232.	Do you expect to enroll subjects who will not be able to read or speak English?	NO
235.	Will the subjects receive compensation or reimbursement for expenses for participating in this study?	YES
236.	Will this study enroll ONLY healthy subjects?	NO
237.	Will this study involve RESEARCH of a drug, device, biologic or involve any other intervention that might significantly affect the care of a patient?	NO

TEMPLATE	SECTIONS	
CONSENT	1.	Header (Adult)
	2.	Header (Participant Name)
	3.	Purpose
	4.	Introduction
	5.	Procedures (Expedited)
	6.	Procedures (Visits Duration)
	7.	Procedures (Caveat)
	8.	Risks
	9.	Risks (Other Side Effects)
	10.	Benefits
	11.	Options (Abnormal Volunteers)
	12.	Compensation
	13.	Costs
	14.	Injury Expedited
	15.	Withdrawal
	16.	Use of Information
	17.	Study Contact Information
	18.	HSR Contact Information
	19.	Conclusion
	20.	Signature (Participant)
	21.	Signature (Person Obtaining Consent)
	22.	Signature Impartial Witness
PROTOCOL	1.	Investigator Agreement
	2.	Signature Protocol
	3.	Table of Contents
	4.	Brief Summary Abstract

5.	Background
6.	Hypothesis to be Tested
7.	Study Design (Biomedical)
8.	Human Participants
9.	Inclusion Exclusion Criteria
10.	Study Design (Biomedical Statistical Analysis)
11.	Done To Participants (Biomedical)
12.	Data & Safety Monitoring Plan (Expedited)
13.	Payment
14.	Risk Benefit Analysis
15.	Bibliography
16.	Legal Regulatory
17.	Recruitment
18.	Waiver Documentation Consent
19.	HIPAA Criteria (without consent)
20.	HIPAA Criteria (with consent)

DOCUMENT SUBMISSION FORM