IRB #2004128 C

Project number	2004128
Project title	Quick responses to faces and objects
Project status	
Principal investigator	Scherer, Laura Danielle
Expiration date	

IRB Application #209964

Submission date: **10/30/2015**

1. Investigators

1. **Project title (do not use all capitals)**

   Provide the full title of the project.

   Quick responses to faces and objects

2. **Study Staff (students, fellows & residents must have a faculty member as a co-investigator)**

User	Role	Department	IRB training date	Primary contact	Consent personnel role	Veterans personnel
Scherer, Laura Danielle	Principal Investigator	Psychological Sciences	04/24/2014	☐	Non-Consenting Personnel	☐
Baker, Samuel Glenn	Student Investigator	Psychological Sciences	08/28/2013	☐	Authorized to Obtain Consent	☐
Volpert, Hannah Inyong	Student Investigator	Life Sciences Center	08/14/2014	☑	Authorized to Obtain Consent	☐

3. **Contact Information**

Principal investigator

Scherer, Laura Danielle

Job title	PROF, AST
Department	Psychological Sciences
Division	Arts & Science
Business unit	University of MO-Columbia

Primary contact

Volpert, Hannah Inyong

Job title	GRAD RESRCH AST
Department	Life Sciences Center
Division	Office of Research
Business unit	University of MO-Columbia

4. **Is this application submitted by an outside entity utilizing MU IRB as their IRB of record?**

   The answer is YES if MU has entered into a formal collaborative agreement with the outside entity to be their IRB of Record. If you are unsure, please contact the IRB office at 573-882-3181.

   No

5. **Conflicts of Interest**

   A. **Describe any Conflicts of Interest with this study.**

   Example: Financial, Personal, Institutional, or Other, for any study team member. If none please indicate N/A.

   N/A

   B. **Do all study team members have a current, up-to-date MU Conflict of Interest Disclosure on file with the Office of Research?**

   for more information click the link to the COI website http://research.missouri.edu/complia/coi_new2.htm

   Yes

   C. **Has it been updated to include the conflict with this study?**

   N/A

6. **Will the team include external investigators not affiliated with the University of Missouri-Columbia?**

   Yes

7. **If yes, identify the investigator(s) and their institution and describe their role in the study.**

   Specify if the external investigator(s) will interact or intervene with the participants in the study or have access to their private identifiable information. Also, clarify whether they will obtain informed consent from participants.

   Joseph Hilgard will be involved, a former student at Mizzou, who is now a post doc at UPenn. He will have no contact with participants in the study, will not have access to their private identifiable information, and will not obtain consent from participants. His role on the project will only involve management and analysis of anonymous data.

2. Protocol, Clinical Trials, CIDB, and IC Document (Only Applicable to Health Sciences IRB Submissions - Skip if Campus)

1. **Protocol Information**

   All applications must submit a protocol in addition to the grant application with the application materials. The information provided below will be reflected in your approval letter.

A. **Protocol Number**

Please upload a copy of the protocol to this application.

B. **Protocol Version Number**

C. **Protocol Version Date**

2. **Clinical Trials Information**

A. **Is this a clinical trial?**

Note: To determine if this is a clinical trial requiring registration, please follow the flow chart at http://irb.missouri.edu/eirb/documents/clinical-trials-flowchart.pdf

B. **Please provide the clinicaltrials.gov number, if applicable.**

If the clinicaltrials.gov number is not available prior to IRB approval, please update this information using the Identification Form.

C. **Phase of Trial**

3. **CIDB (Clinical Investigation Drug Brochure)**

The information provided below will be reflected in your approval letter.

A. **CIDB Number**

B. **CIDB Version Number**

C. **CIDB Version Date**

4. **Informed Consent**

The information provided below will be reflected in your approval letter.

A. **Informed Consent Version Number**

Leave blank unless you have a sponsor provided version number in the footer of your consent.

B. **Informed Consent Version Date**

Leave blank unless you have a sponsor provided version date in the footer of your consent.

3. Funding Information

1. **How is this project funded? ***

Internal Funding

- ● Departmental Funding
- ○ Personal funds
- ○ Internal Grant (ex. Research council, etc)

External Funding

- ○ HHS funded (The Department of Health and Human Services)
- ○ External Grant (ex. Federal funding, foundation funding)
- ○ In-kind (donation of equipment or services)
- ○ Industry Sponsor (ex. Pharmaceutical company, device company, etc) * IRB fees apply

2. **Sponsor or Funding Source Information**

3. **If this study is sponsored please provide the MU Sponsored Program Grant Proposal Number (OSPA)**

   If you receive funding after IRB approval, please update this information using the Identification Form.

4. Location of Research

1. **Is this a multi-center study?**

   A multi-site study is defined as a research study being conducted at multiple sites. Studies being conducted at more than one MU facility are not considered multi-site.

   No

2. **If this is a multi-center study, is MU functioning as the lead site?**

   If yes, a subform will automatically generate for your completion at the end of the application.

   N/A

3. **Does another institution(s)/organization(s) IRB want to Rely on MU IRB Approval?**

   If yes, a subform will automatically generate for your completion at the end of the application.

   No

5. Project Information

1. **List all committees (other than the MU IRB) that have and/or will review this project.**

   - ☐ **Radiation Safety**
   - ☐ **Investigational Pharmacy**
   - ☐ **VA Research and Development**
   - ☐ **Institutional Biosafety**
   - ☐ **Other**

   A. **If other, please list:**

2. **Objectives: Research Question(s): What are you hoping to learn?**

   The current research seeks to improve our understanding of what a commonly used behavioral task, the Weapons Identification Task, measures and what inferences can be made from performance on this task. Instead of a pure measure of prejudice or racial bias, we suggest the WIT may reflect the operation of cognitive

processes, such as response mapping.

3. **Rationale/Justification for the study: What is the scientific reason for this study?**

   Provide a brief background on subject population, procedures etc., as rationale for conducting the study.

   Measures of implicit bias such as the Weapons Identification Task are commonly used in psychological research as a way of assessing "automatic", "unintentional" and "unconscious" forms of bias. However, since the introduction of these tasks, what exact processes and constructs that these types of tasks measure have been called into question. Clarification of what constructs and processes the WIT measures (which has theoretical implications for other behavioral measures of implicit bias that rely on the mapping of two categorizations on two responses keys) is essential in determining the inferences we can make about people's performance on these tasks. A pure measure of implicit racial bias that is immune to socially desirable responding and cognitive control is highly desirable in the research of bias and how it influences our behavior, but the current research seeks to establish the possibility that the WIT is not a process-pure measure of bias and instead reflects the cognitive process of response mapping.

4. **Provide a project summary for non-medical and community members on the IRB.**

   The IRB includes members without a scientific or medical background. Using lay language, provide a brief, but thorough, summary of the project.

   Implicit racial bias is thought to be unintentional, unconscious, and automatic, and can influence our behavior in a number of ways. To investigate the relationship between implicit bias and explicit attitudes and behavior, behavioral tasks have been developed, including the Weapons Identification Task, that were thought to tap into those unconscious attitudes. The current study investigates the possibility that the WIT may be measuring something else-- response mapping-- in addition to implicit bias.

5. **Describe the subject's participation:**

   What will be expected of the participants? This should include all items listed in Question #6 below.

   Participants who have been recruited to participate in IRB #2003469 (an unrelated study) will be asked once they're done that study if they would like to additionally participate in the current study. Once informed consent has been obtained, participants will complete a Weapons Identification Task, where they will see faces followed quickly by objects. Half the participants will see and be asked to identify guns and tools. The other half will see and be asked to identify guns and non-guns.

6. **Procedures/Tests/Surveys**

   List all tests, procedures, and surveys that will be performed during the study. These tests should include tests done for medical purposes ONLY IF the data will be collected for the research.

   Procedures/Tests/Survey WIT

   A. **Name of test/procedure**

      WIT

   B. **Brief description**

      In the Weapons Identification Task, participants see pictures of African-American and European-American male faces followed quickly by objects that they are asked to identify using two keys on a keyboard. In one version of the task, given to half the participants, the objects are either guns or household tools (such as a wrench or a hand drill). In the other version of the task, given to the other half of the participants, the objects are either guns or non-guns (such as a giraffe or a banana). Participants are asked to categorize the objects as quickly and accurately as possible.

C. Relationship

○ Routine care where the information/data will be collected for the research study

● Research Only

D. Indicate the study visit(s) at which this will occur

This will occur during the experimental session.

E. Where will this test take place?

207 Psychology Building

Procedures/Tests/Survey Demographic questions

A. Name of test/procedure

Demographic questions

B. Brief description

Demographic questions administered at the beginning of the experiment. Exact items are uploaded as a separate document.

C. Relationship

○ Routine care where the information/data will be collected for the research study

● Research Only

D. Indicate the study visit(s) at which this will occur

During the experimental session.

E. Where will this test take place?

207 Psychology Building

7. Subject Participation

A. Length of time of the subject's participation.

15 minutes

B. How long is the subject on active treatment or actively participating in the research?

15 minutes

C. If applicable, how long will the subject be in follow up?

N/A

8. Visit Information (For Campus investigators, this would translate to number of interactions with subjects)

A. Number of total visits:

1

B. Frequency of visits:

1

C. Length of visits:

15 minutes

9. What is routine care for this condition for non-study participants?

This may not be applicable to non-medical research studies.

10. Will the participant be withdrawn from the care listed in the answer above?

This may not be applicable to non-medical research studies.

11. Inclusion criteria:

If the study has a protocol, these must match what is stated in the protocol.

None.

12. Exclusion criteria:

If the study has a protocol, these must match what is stated in the protocol.

None.

13. Powertrials

Complete the next two questions if this study is a clinical trial. Select the appropriate box:

☐ **Required** to be entered into Powertrials (This is a medical intervention, uses drugs or devices, OR includes other interventions that might impact the healthcare of the subject. If you are unsure whether it's required, please call the MU Clinical Research Center at 882-4894.)

☐ **Recommended** to be entered into Powertrials (This is a clinical trial AND utilizes subjects from MU Healthcare. If you are unsure whether it's recommended, please call the MU Clinical Research Center at 882-4894.)

14. Review requested

Expedited

6. Subject Recruitment

1. Explain how you will have access to a population that will allow recruitment of the required number of subjects in the proposed recruitment time.

(For example, will you be going to a particular location, are they potential patients in the clinic, etc.)

Participants will be recruited from the Psych 1000 participants that participate in IRB# 2003469. 225 subjects are anticipated to participate in that study, and so we expect to be able to recruit enough subjects for the current study from that.

2. Will you access/screen the medical record prior to obtaining consent?

This includes, but not limited to, EMR, powerchart, or i2b2. If YES, you must apply for a waiver of consent and waiver of HIPAA.

N/A

3. Target accrual

   A. For all MU sites, how many people do you expect to complete the study?

      100

   B. How many people will be enrolled (sign the consent) to reach the number listed in the previous question?

      For some studies this number may be the same, for other studies there may be a high rate of screen failures.

      100

   C. If this is a multi-center (multi-site) study, what is the study wide target accrual?

4. What methods will be used to identify and recruit subjects?

   Check all that apply. *Please note, if you are recruiting with a flyer, you may need a waiver of documentation of consent if you are screening subjects before they sign a consent.*

   - ☐ Advertisements
   - ☐ Flyers
   - ☐ Letters
   - ☐ Patients of the PI/Co-I
   - ☐ other

   A. If other, please explain.

5. What methods will be used to avoid inadvertent coercion in the recruitment process?

   Students have alternative options for fulling their class requirements. No additional compensation besides research participation will be offered.

6. Retaining Information

   A. Do you plan to retain any information on recruitees not ultimately enrolled in the study?

      No

   B. List the information that will be kept.

7. Consent Process

This section should only be completed for studies using WRITTEN consent or WAIVER OF DOCUMENTATION (signature).

1. **Describe the consent process.**

   Describe in detail how the consent process will be presented to the subject, how subject comprehension of the study is determined, where and when consent is performed, and how questions from the subject are answered.

   Once they finish the study they have been initially recruited for, participants will be asked if they would like to participate in an additional experiment for additional compensation. Participants will be given all the details of the experiment in the written consent form and then be given a chance to discuss their questions with the experimenter before agreeing to participate. Participants will be explicitly asked if they understand that they can discontinue participation at anytime without penalty. The experimenter keeps a copy of the consent form and the participant is offered a copy for their records if they would like it.

2. **How long will participants be given between the time they are approached to participate and signing the consent for participation.**

   The regulations require investigators to seek consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate minimizing the possibility of coercion or undue influence.

   It will take the amount of time to explain the current experiment and answer any questions they may have, so probably less than ten minutes.

3. **Please indicate how the language level of the consent matched to the comprehension level of your prospective participants?**

   Note: The regulations require the information be understandable to the subject or the representative so please consider the subject population and type of study.

   The consent form is written to be understandable to freshmen in college with a high school education, since that is the subject population we're recruiting from.

4. **What measures will be taken to ensure the prospective participant/representative understands the consent?**

   Participants will have the opportunity to ask any clarifying questions they may need to ask.

5. **Informed Consent**

   A. **Who will be approached for informed consent?**

      Mark all that apply

      ☐ **Subject`s parent or legal guardian**

      ☐ **Other**

      ☑ **Subject**

   B. **If other, please explain.**

6. **Will the study be documented in the medical record?**

   No

7. **Subject Privacy**

   Note: Privacy refers to a person, not the confidentiality of their data.

A. If subjects have an expectation of privacy, please describe your plan to protect their privacy during and after the course of the data collection?

Participants will perform all experimental tasks in a private room, where the only person who can see them and interact with them is the experimenter. All computerized data is maintained on a password-protected server.

B. What are the consequences to subjects if a loss of privacy were to occur (e.g. risks to reputation, insurability, embarrassment, other social risks)?

Consequences to participants of a loss of privacy would include the possibility of information about their performance on a computer task commonly used to measure implicit racial bias being known by individuals other than the researchers. However, because there are no names associated with questionnaire data or electronic data, even if data privacy were to be compromised, there would be no way to link this data to an individual.

8. Confidentiality and Security

1. Confidentiality

Confidentiality concerns data, specifically the researchers plan to handle, manage, and disseminate the participant's identifiable private information.

PLEASE INDICATE ALL IDENTIFIERS THAT MAY BE INCLUDED IN THE RESEARCH RECORDS FOR THE STUDY. CHECK ALL THAT APPLY.

- ☐ Names
- ☐ Dates
- ☐ Postal Address
- ☐ Phone Numbers
- ☐ Fax Numbers
- ☐ Email Addresses
- ☐ Social Security Number
- ☐ Medical Record Numbers
- ☐ Health Plan Numbers
- ☐ Account Numbers
- ☐ License or Certificate Numbers
- ☐ Vehicle ID Numbers
- ☐ Device Identifiers or Serial Numbers
- ☐ Web URLs
- ☐ IP Address Numbers
- ☐ Biometric Identifiers

- ☐ Facial Photos or Images
- ☐ Any Other Unique Identifier
- ☐ None of the 18 Identifiers Listed Above

2. Data Security

   A. Will any web applications be utilized for such purposes as recruiting subjects, completing questionnaires or processing data?

      No

   B. If you are administering an anonymous online survey, have you checked the appropriate boxes on the survey tool to ensure that the data collected will be anonymous?

   C. If you are hiring Qualtrics or another survey tool to recruit and administer a survey, do you have a business associate agreement or have you contacted Business Services at MU to enter into a contract?

   D. Will you be utilizing REDCap (Research Electronic Data Capture)?

      For more information, go to http://icats.missouri.edu/portal/redcap.php

   E. List all web applications that will be used in the study.

   F. Describe the security features for the web application(s).

3. Will the data be collected and stored as:

   - ☐ Hard Copy
   - ☑ Electronic (Hard Drive - best practice is to encrypt the PC)
   - ☐ Electronic Portable (mobile) device
   - ☐ Hard Copy and Electronic

4. Check the appropriate box below:

   - ☐ Data are coded; data key is destroyed at the end of the study
   - ☐ Data are coded; data key is kept separately and securely
   - ☐ Data are kept in locked file cabinet
   - ☑ Electronic data are protected with a password
   - ☐ Electronic data are encrypted
   - ☑ Data are kept in locked office or suite
   - ☑ Data are stored on a secure MU network
   - ☐ Data are stored on a secure VA network

   A. If data are coded and the data key will be destroyed, please provide the anticipated date of destruction:

5. If you plan to disclose any of the identifiers listed above as part of the study process, check all that apply:

   ☐ No identifying information will be disclosed.

   ☐ The subject's medical record

   ☐ The study sponsor

   ☐ Foreign Country or Countries

   ☐ The US Food & Drug Administration (FDA)

   ☐ Other

   A. If other, please specify.

6. How and where will the data be stored after the study is completed?

   Computerized data will be maintained on a password-protected secure server.

☑ Check this box to confirm you will retain all research records for a period of seven years following the completion of the study, in accordance with MU Policy.

7. Certificates of Confidentiality

   For more information on Certificates of Confidentiality, please go to http://grants.nih.gov/grants/policy/coc/

   A. Will this research collect any information that may require a Certificate of Confidentiality?

      Certificates of Confidentiality are issued to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

      No

   B. If YES, has a Certificate of Confidentiality been applied for?

9. Risks and Benefits

1. Pregnancy

   A. Please list all drugs or procedures used in this study that may affect (known/unknown) an unborn child.

   B. If applicable, how will pregnancy be determined:

   ☐ Verbal confirmation

   ☐ Serum

   ☐ Urine

2. If participants with reproductive potential are involved, what contraceptive measures will be taken for both females and males during the active phase of the study?

3. **Please check the applicable categories of risk below which apply for participation in the study:**

   If checked, please be sure the information is in the protocol or the consent.

   - ☐ Any surgical procedure
   - ☐ Use of approved/unapproved devices
   - ☐ Use of approved/unapproved drugs or biologics
   - ☐ Administration of placebos
   - ☐ Administration of controlled substance(s)
   - ☐ Administration of physical stimuli
   - ☐ Major changes in diet, exercise or sleep
   - ☐ Use of private records including medical or educational records
   - ☐ Possible invasion of privacy of the subject or family
   - ☐ Any probing for personal or sensitive information in surveys or interviews
   - ☐ Use of audio or video for data collection
   - ☐ Physical risk
   - ☑ Psychological risk
   - ☐ Social risk
   - ☐ Economic risk
   - ☐ Legal risk
   - ☐ Other risks (Please list below)

   A. Other risks

4. **What procedures will be used to prevent and/or minimize any potential risks and discomfort?**

   You must address each item marked in question #3 above.

   Mild risks include boredom or frustration. To mitigate this, the length of the task is limited to ten minutes.

5. **What are the potential direct benefits to the subject?**

   If there are no direct benefits, state none.

   In addition to compensation, subjects will benefit by gaining an educational experience and learning how psychologists conduct research.

6. **What are the potential benefits to the community and/or society?**

   Measures of implicit bias such as the Weapons Identification Task are commonly used in psychological research as a way of assessing "automatic", "unintentional" and "unconscious" forms of bias. However, since the introduction of these tasks, what exact processes and constructs that these types of tasks measure have been called into question. The current research seeks to improve our understanding of what the WIT measures and inferences that can be made from performance on this task. This knowledge is essential to understanding racial bias and how it impacts our behavior on an interpersonal level as well as a societal level.

7. **Are there any other options for participants?**

   Please list any other treatment alternatives for the condition under study besides participating in this study (may include standard therapy, palliative care, other research protocols, etc.).

   There are many other alternative studies for students to participate in to fulfill their research credit. Alternatively, there is are other acceptable options for students who do not wish to participate, as outlined in the class syllabus.

8. **Describe the data and safety monitoring plan developed to ensure the safety of participants as well as validity and integrity of research data.**

   This needs to include, when something needs to be reported, the frequency of the monitoring, such as points in time or after a specific number of participants are enrolled; who will conduct the monitoring, such as a data monitoring committee, data and safety monitoring board, medical monitor, investigator, independent physician, the specific data to be monitored; procedures for analysis and interpretation of the data; actions to be taken upon specific events or end points; and procedures for communication from the data monitor to this site.

   The data will be discussed during weekly meetings between the experimenters and the PI, Dr. Scherer. At this time any problems with the research will be brought forward for discussion. In addition, should an adverse event occur Dr. Scherer will be notified immediately by email and/or telephone.

10. Costs Associated with the Research

1. **Are there costs associated with the research, including subject/sponsor costs?**

   No

2. **Will the subjects bear any costs associated with the research?**

   No

3. **If the subjects will be responsible for any costs, please list all procedures, etc. that the subject will cover.**

4. **Please list all test procedures that will be paid for by the sponsor.**

5. **If there are other costs incurred in the research for ancillary resources, such as medical treatment, psychological counseling, emergency services, or concomitant medications, how will the cost be covered?**

11. Sub-forms

1. **Select the items that are included as part of your study. For items marked, a sub-form will be generated for your completion at the end of this application.**

☐ Collection of **blood, fluid, or tissue**

☐ **Infectious and zoonotic agents** (viruses, bacteria, etc), **biological toxins, or Recombinant DNA or Synthetic DNA products** ((Excluding human blood, serum, and other potentially infectious materials of human origin)

☐ Administration of a **drug or biologic** (This can include investigational drugs that have an IND, FDA approved drugs, FDA approved drugs that are being used "off-label," herbal extract, or a biologic (a preparation, such as a drug, a vaccine, or an antitoxin, that is synthesized from living organisms or their products and used medically as a diagnostic, preventive, or therapeutic agent). Hospital Policy defines "investigational drug" as

"a drug undergoing clinical study within an investigational protocol and either has not yet been approved by the Food and Drug Administration (FDA) for marketing, or, is FDA-approved and is being studied for a non-FDA-approved indication or dosage regimen.")

☐ Administration of a **supplement** (vitamin, mineral, etc.)

☐ **Cold Isotopes** (non-radioactive isotopes)

☐ **Device, including Humanitarian Use Devices in a clinical investigation** (This is for any device used in this study that is FDA regulated if the device is being used for the study and not as standard treatment. Do not list items such as a treadmill for a stress test.)

☐ **Radiation emitting devices, radioactive drugs, lasers or MRIs** (If the study involves a test solely for research purposes and the test involves the use a contrast dye, please complete the drug form as well.)

☐ Requesting a **waiver of documentation of consent** (no signature) -(Some studies may have a waiver of documentation and a written consent.)

☐ Requesting a **waiver of consent or an alteration of consent** (select for HIPAA waivers, altering required elements of consent)

☐ Access to Health Information (HIPAA)

☐ Participants with **impaired decision-making capacities** (Some subjects maybe temporarily incompetent due to circumstances or medication. Please check this box if the subject population for this study meet these criteria.)

☐ **Pregnant women or fetuses** (This item is for studies that will enroll pregnant women. Do not check for survey research.)

☐ Children (under 18)

☐ Non-viable neonates or neonates of uncertain viability

☐ Non-English speaking subjects

☐ Prisoners

☐ VA participants, VA resources, and/or time of VA personnel

☐ Sub-study included

☑ Subject Compensation

☐ Use of audiotapes, videotapes, and/or photographs

☐ Use of Deception

☐ International Study

☐ Access to Student Records (FERPA Regulations)

☐ Involves an Exception from Informed Consent for Planned Emergency Research

2. The research is sponsored and/or supported by:

☐ US Department of Education

☐ Department of Energy

☐ Department of Defense

- ☐ Department of Justice
- ☐ Environmental Protection Agency

Compensation Subform

1. Compensation

1. **Does this study involve subject compensation (this includes monetary payment, educational credits, etc.)?**

   Yes

2. **Describe the amount, method, and timing of disbursement.**

   The amount of payment and the proposed method and timing of disbursement neither is coercive nor presents undue influence and is reflective of the degree of risk, inconvenience, or discomfort associated with participation.

   Participants will be compensated for their time with course credit at the rate agreed upon for all studies. The same exchange rate of credit will be offered for this study that will be offered for all other studies where course credit serves as compensation.

3. **Were all sponsored payments (internal or external support) including cash and non-cash items approved by the Accounting Services Department at the University of Missouri?**

   You must UPLOAD this approval. IRB approval will be held until the approval from accounting services is uploaded. Send this form to Lynn Herdzina in Accounting Services: accounting form (click here).

   N/A

4. **If you are offering extra credit or course credit for student participation, describe the alternative assignment for students who may decline. The alternative assignment must be comparable in effort and time commitment.**

   Students in Psychology 1000 courses may choose to write a research report that would take the equivalent amount of time as an experiment and would teach them similar information on the research process as an experiment.

5. **In your opinion, will the subject be influenced by the compensation offered?**

   No

6. **If yes, please explain.**

7. **If the study is not funded with internal funds or external grant funds, how is the cost of compensation being covered?**