Oak Ridge Sitewide Institutional Review Board (IRB#: IRB00000547)

April 3, 2025

Title of Study:	Science Undergraduate Laboratory Internship (SULI) Program Long-Term Follow-Up Study, FY 2014 – FY 2016
Investigator:	Tony Garcia
Type of Review:	Modification / Update
Exempt Category:	(2)(ii) Tests, surveys, interviews, or observation (low risk)
Submission ID:	ORAU001252
Funding Source:	DOE/Office of Science
Documents Reviewed:	• Invitation and Consent for Comparison Cohort • Invitation and Consent for SULI Alumni • Phone Script for Non-Alumni • Phone Script for SULI Alumni • Reminder for Comparison Cohort • Reminder for SULI Alumni • Study • SULI Alumni Survey Instrument - Integrated Introduction • SULI Comparison Cohort Survey Instrument - Integrated Introduction
Action:	Approved
Approval Date:	4/3/2025
Consent Waiver:	Waiver of Written Documentation of the Consent Process

Thank you for your submission of the **Modification Request** materials for this research study. The Oak Ridge Sitewide IRB has determined this study continues to be **Exempt** based on the applicable federal regulations, including DOE Order 443.1C, Chg. 1 (or current version) and has been approved.

Annual reporting is required for all studies no matter the review level. You will receive an email to provide either a continuing review (CR) to the IRB or annual update to the DOE Human Subjects Research Database. These updates must be provided least two

weeks before the expiration date or anniversary date of approval. You must report all study closure within 30 days of that event.

Please note that all principal investigators must **immediately** report to the IRB:

- **Upon finding of a suspected or confirmed data breach involving PII in printed or electronic form (see DOE Order 443.1C, Chg. 1 (or current version)).**
- **All unanticipated problems, adverse events, non-compliance issues, and complaints (see DOE Order 443.1C, Chg. 1 (or current version).**
- Any new information that might increase the risks or decrease the benefits to research subjects, or affect a subject's willingness to continue participation in the study.

All research records must be retained for a minimum of three years after the completion of the study.

Sincerely,

Kelli Bursey, MPH, CHES
IRB Chair
ORSIRB@orau.org
513-245-1286

Attachment:
Reminder: What are my obligations as a PI after IRB approval?

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1) Do not start Human Subjects Research activities until you have the final IRB approval letter.
2) Do not start Human Subjects Research activities until you have obtained all other required institutional approvals, including approvals of departments or divisions that require approval prior to commencing research that involves their resources.
3) Ensure that there are adequate resources to carry out the research safely. This includes, but is not limited to, sufficient investigator time, appropriately qualified research team members, equipment, and space.
4) Ensure that research staff are qualified (e.g., including, but not limited to, appropriate training, education, expertise, credentials, protocol requirements and, when relevant, privileges) to perform procedures and duties assigned to them during the study. Note that all members of the research team who have access to PII or who are responsible for subject interaction or intervention must complete training on the protection of human subjects research. DOE offers this training to researchers at DOE laboratories/sites and to DOE-funded researchers from institutions outside the DOE complex.
5) Update the IRB office with any changes to the list of study personnel.
6) Personally conduct or supervise the research.
    a) Conduct the research in accordance with the relevant current protocol as approved by the IRB.
    b) When required by the IRB, ensure that consent or permission is obtained in accordance with the relevant current protocol as approved by the IRB.
    c) Do not modify the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
    d) Protect the rights, safety, and welfare of subjects involved in the research.
7) Submit to the IRB:
    a) Proposed modifications.
    b) A continuing review application as requested in the approval letter.
    c) A continuing review application when the research is closed.
8) Report any of the new information items in a Reportable New Information (RNI) in the IRB Electronic System to the IRB immediately. In the case of loss of PII, for example, reporting to the IRB and other authorities is required immediately.
9) Submit an updated disclosure of financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.

10) Do not accept or provide payments to professionals in exchange for referrals of potential subjects (“finder’s fees.”)
11) Do not accept payments designed to accelerate recruitment that were tied to the rate or timing of enrollment (“bonus payments.”)
12) Ensure that you comply with the requirements of sponsoring organizations/agencies, which may be in addition to those that are required by the Federal Regulations and DOE. **You must comply with the more stringent requirements**. Consult with the IRB if you need clarification.