**HRP 503c – TEMPLATE – HUMAN SUBJECTS RESEARCH DETERMINATION (HSR)**

**INSTRUCTIONS:**

* This form should be used when an investigator is unsure of whether their research activities constitute human subjects research, or when they anticipate that correspondence from the IRB will be required to satisfy funding agency requirements or for presentation and/or publication purposes. Please consult HRP 310 – WORKSHEET – Human Research Determination before completing this form.
* As you are completing this form, remove all instructions in orange italics so that they are not contained in the final version of your document (or use the version without instructions available on the IRB website or through Endeavor) and use this copy as a guide).
* If the research involves secondary use of data, please complete HRP-900 – APPENDIX – Secondary Use of Data.

**BASIC PROTOCOL INFORMATION:**

**Title:** *Include the full protocol title.*

**Version:** *Include the protocol version and date. Version numbers should go up sequentially (i.e., 1 then 2 then 3).*

**Version Date:** Click or tap to enter a date.

**Other IRBs associated with this project:** *List any IRBs associated with the current protocol. This may include previously approved studies, related studies, or IRBs at other institutions. If the latter, please include the IRB from the other institution in the Local Site Documents section of Endeavor.*

**FUNDING INFORMATION:**

*Check all that apply.*

|  |
| --- |
| Not funded by any source. |
| Internal funding. Provide the source/mechanism of internal support: |
| U.S. Federal government funding (i.e., DoD, NIH, NSF, etc.) via one or more direct awards or a sub-award. Provide the source of federal support: |
| Other sources of funding (please specify): |

**PRINCIPAL INVESTIGATOR:**

***Please Note:*** *Undergraduate and graduate students are not allowed to be the Principal Investigator on a research study. For further information on who is eligible to serve as a Principal Investigator, see HRP-103 – INVESTIGATOR MANUAL.* *Please be sure to list all key study personnel in the “Local Study Team Members” within Endeavor. If personnel are not auto populated, please contact taylomm@auburn.edu. All study team members must have appropriate CITI training as specified in HRP-103 – INVESTIGATOR MANUAL. All emails \*must\* be original AU emails, and not aliases (i.e., abc1234@auburn.edu, not uniqueid@auburn.edu).*

Name:

Department:

Telephone Number:

Email Address:

Department Head/Chair Name:

Department Head/Chair Email:

**\*\*ALL KEY STUDY PERSONNEL MUST BE ADDED THROUGH ‘LOCAL STUDY TEAM MEMBERS’ IN ENDEAVOR.\*\***

# Study Summary

Answer yes or no to determine whether the activity is human subjects’ research.

|  |  |  |
| --- | --- | --- |
| Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge? | **YES** (If selected, the activity is research) | **NO** (If selected, the activity is not research, and does not require IRB review) |
| Does the research involve obtaining information about living individuals? | **YES** | **NO** |
| Does the research involve intervention or interaction with individuals? | **YES** (If selected, the activity is research involving human subjects and requires submission of a protocol) | **NO** |
| Will the investigator have access to private or identifiable information? | **YES** (If selected, the research requires submission of a protocol) | **NO** |

# Project Description

* 1. Describe the purpose, specific aims, and objectives:. It is helpful to begin sentences with “The purpose of this study is…”, “The specific aims of this study are…”, and “The objective of this study is…”.
  2. Brief summary of the project: Include the research question(s) and a brief description of the methodology, including recruitment and how data will be collected. If data is publicly available, be sure to include the link. If data will be shared, describe access to the data and submit the appropriate data use/data sharing agreement(s). Describe any applicable permissions required to access data, if using a repository or other publicly available information/data. Upload permission documents under ‘Local Site Documents’ in Endeavor.
  3. State the hypotheses to be tested:
  4. Subject population:Describe, including age, gender/sex, any special population characteristics, whether any vulnerable populations will be involved, etc. If data is publicly available, include the link. If not publicly available, describe how you will get access to the data.
  5. Study Instruments:Upload a copy of any data collection instruments, surveys, interview questions, etc. as applicable under ‘Local Site Documents’ within Endeavor. Any data collection instruments should be in their final participant-facing form (i.e., if using something like Qualtrics, be sure to include the survey as the participant would see it using screenshots or another method).