Section 1: Determination of Human vs. Non-human Participants

45 CFR 46.102 (f): Human participant means a living individual about whom an investigator obtains: (1) data through intervention or interaction with the individual or (2) identifiable private information.

(1) Intervention includes both physical procedures by which data are gathered (for example, venipuncture) or manipulations of the participant or the participant’s environment that are performed for research purposes. Interaction includes communication or interpersonal contact with a participant.

(2) Private information includes information about behavior occurring in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect would not be made public (for example, a medical record). Private information includes any of the bulleted items below. If there is access to or use of any of the following, the project involves individually identifiable information and the project must be submitted to the IRB for further review:

- Names
- Account numbers
- Certificate/license numbers
- Social Security numbers
- Device identifiers and serial numbers
- Health plan beneficiary numbers
- Full-face photographic or comparable images
- Vehicle identifiers and serial numbers, including license plate numbers
- All elements of dates directly related to an individual, except year (of birth, admission)
- Fax numbers
- Telephone numbers
- Electronic mail addresses
- Medical record numbers
- Web Universal Resource Locators (URLs)
- Biometric identifies, including finger and voiceprints
- Internet Protocol (IP) address numbers
- Any geographic subdivisions small than a state, except for the initial three digits of a ZIP code
- Any other unique identifying number, characteristic, or code
**Section 1 Questions:** All of the following must be “No” to qualify as “non-human” subject research.

[ ] Yes  [ ] No  
**Does the study involve intervention or interaction with a human subject?**

[ ] Yes  [ ] No  
**Does the study involve access to identifiable private information?**

[ ] Yes  [ ] No  
**Are data/specimens received by the Investigator with identifiable private information?**

[ ] Yes  [ ] No  
**Are the data/specimens coded such that a link exists that could allow the data/specimens to be re-identified?**

**STOP!**

If you answered “No” to all Section 1 questions, proceed to determination of Section 2 Research vs. Non-research.

If you answered “Yes” to any Section 1 question, your project appears to involve human participants and as such requires submission to the IRB for review and approval.

**Section 2. Determination of Research vs. Non-research**

45 CFR 46.102(d): *Research* is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

Activities meeting this definition constitute research, whether or not they are conducted or supported under a program which is considered research for other purposes.

**Section 2 Questions:** One of the following must be “No” to qualify as non-research.

[ ] Yes  [ ] No  
**Were the data/specimens obtained in a systematic manner?**

[ ] Yes  [ ] No  
**Was the intent of the data/specimen collection for the purpose of contributing to generalizable knowledge?**

**STOP!**

If you answered “No” to at least one of the Section 2 questions and you answered “No” to all Section 1 questions, you are not required to submit this project to the IRB for review. You may proceed with your project.

If you answered “Yes” to both of the Section 2 questions, your project appears to meet the criteria of research and as such you are required to submit the project to the IRB.