

APPENDIX A Request for Determination of Non-Human Subject or Non-Research

Federal regulations and OSU CHS policy require IRB review of all “research involving human subjects”. Some activities that may appear to be research involving human subjects do not meet the specific definitions of “research” and “human subjects” used in federal regulations and by the IRB, and thus may not be subject to IRB review. CHS policy charges the IRB with making this determination.

If, after reading the Explanation above, you believe that the planned activity is either not research or does not involve human subjects, then complete and submit Appendix A. If the IRB concurs, the activity will not be subject to review by the IRB. (If the activity meets the definition of “research involving human subjects”, do not submit Appendix A. Instead, submit application for IRB review.)

1. Principal Investigator Information

First Name:		Middle Initial:	Last Name:
Department/Division:		College:	
Campus Address:		Zip+4:	
Campus Phone:	Fax:	Email:	
Complete if PI does not have campus address:			
Address:		City:	
State:	Zip:	Phone:	

2. Faculty Advisor (complete if PI is a student, resident, or fellow) NA

Faculty Advisor's name:		Title:
Department/Division:		College:
Campus Address:		Zip+4:
Campus Phone:	Fax:	Email:

3. Study Information:

A. Title

B. Give a brief summary of the project. (See instructions for guidance)

- C. Describe the subject population/type of data/specimens to be studied. (See instructions for guidance)

4. Determination of “Research”.

45 CFR 46.102(d): *Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy whether or not they are conducted or supported under a program which is considered research for other purposes.

One of the following must be “no” to qualify as “non-research”:

- A. Will the data/specimen(s) be obtained in a systematic manner?
 No Yes
- B. Will the intent of the data/specimen collection be for the purpose of contributing to generalizable knowledge (disseminating the knowledge obtained outside of Oklahoma State University, e.g., presentation or publication)?
 No Yes

5. Determination of “Human Subject”.

45 CFR 46.102(f): *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual or (2) identifiable private information. Intervention includes both physical procedures by which data are gathered (for example venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. Private information includes information about behavior that occurs 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 will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

- A. Does the research involve obtaining information about living individuals?
 No Yes
If no, then research does not involve human subjects, no other information is required.
If yes, proceed to the following questions.

All of the following must be “no” to qualify as “non-human subject”:

- B. Does the study involve intervention or interaction with a “human subject”?
 No Yes
- C. Does the study involve access to identifiable private information?
 No Yes
- D. Are data/specimens received by the Investigator with identifiable private information?
 No Yes
- E. Are the data/specimen(s) coded such that a link exists that could allow the data/specimen(s) to be re-identified?
 No Yes

If "Yes," is there a written agreement that prohibits the PI and his/her staff access to the link? No Yes

6. Signatures

Signature of PI _____ **Date** _____

Signature of Faculty Advisor _____ **Date** _____
(If PI is a student)

Leave blank: To be completed by IRB

- Based on the information provided, the OSU CHS IRB has determined that this project **does not** qualify as human subject research as defined in 45 CFR 46.102(d) and (f) and **is not subject to oversight by the OSU IRB.**
- Based on the information provided, the OSU CHS IRB has determined that this research **does** qualify as human subject research and **submission of an application for review by the IRB is required.**

IRB Chairperson

Date