

## **APPENDIX L Request for Determination of Non-Human Subject or Non-Research**

### **Explanation of Appendix L**

*Federal regulations and OSU-CHS policy require IRB review of all research involving human subjects. The IRB reviews only activities that are research and involve human subjects, as defined in federal regulations and used by the CHS-IRB.*

*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 CHS-IRB, and thus may not be subject to IRB review. CHS policy charges the CHS-IRB with making this determination.*

*The CHS-IRB has developed an administrative procedure to assist in making this determination. Please read the definitions below of “research” and “human subject”. **If the planned activity is either not research or does not involve human subjects (according to the definitions below), then complete and submit Appendix L.** If the IRB concurs that the activity is not research involving human subjects, 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 L.)*

#### **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.*

- A. A systematic investigation is one that involves a predetermined method for studying a specific topic, answering specific questions, testing specific hypotheses, or developing theory.
- i. Examples of systematic investigations include, but are not limited to, observational studies, interview (including those that are open-ended) or survey studies, group comparison studies, test development, program evaluation, and interventional research.
  - ii. Examples of activities that would not normally be considered systematic investigations include, but are not limited to, training activities (e.g., human subjects being trained to perform a certain technique or therapy such as art therapy or psychoanalysis), classroom exercises involving human subjects or human subject data where the objective of the activity is to teach proficiency in performing certain tasks or using specific tools or methods.
  - iii. Although, continuous quality improvement (CQI) and quality assurance (QA) activities often follow a systematic method of gathering information the findings are generally utilized for internal program improvements and do not meet the definition of “research.” However, at any point if the CQI or QA activities are intended to be extended beyond a single individual or an internal program, e.g., publications or presentations, they would be considered “research” and an IRB determination would be required.
- B. To develop or contribute to generalizable knowledge requires that the results (or conclusions) of the activity are intended to be extended beyond a single individual or an internal program, e.g., publications or presentations. Examples of activities that are typically not generalizable include biographies and service or course evaluations, unless they can be generalized to other individuals, services, courses or concepts, and there is an intention to do so. In addition, classroom exercises solely to fulfill course requirements or to train students in the use of particular methods or devices

would also not typically be considered generalizable. However, theses or dissertation projects conducted to meet the requirements of a graduate degree are usually considered generalizable.

### **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. A study does not qualify as “non-human subject” research if data or information is obtained about living individuals.
- B. The study does not qualify as “non-human subject” research if data is obtained through intervention and interaction with an individual. Interaction or intervention involves direct human contact with individuals or manipulation of an individual’s environment. Examples of intervention and interaction include the performance of physical exams, obtaining blood samples, performing x-rays, altering light, temperature, or student course materials, etc.
- C. To qualify as “non-human subject” the data cannot contain any of the following 18 identifiers:
1. Names;
  2. Geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent zip codes, except for the initial three digits of a zip code;
  3. All elements of dates (except year) for dates directly related to an individual (e.g., date of birth, admission);
  4. Telephone numbers;
  5. Fax numbers;
  6. Electronic mail addresses;
  7. Social security numbers;
  8. Medical record numbers;
  9. Health plan beneficiary numbers;
  10. Account numbers;
  11. Certificate/license numbers;
  12. Vehicle identifiers and serial numbers, including license plate numbers;
  13. Device identifiers and serial numbers;
  14. Web Universal Resource Locators (URLs);
  15. Internet Protocol (IP) address numbers;
  16. Biometric identifiers, including finger and voiceprints;
  17. Full-face photographic images and any comparable images; and
  18. Any other unique identifying number, characteristic, or code.

- D. To qualify as “non-human subject”, the Investigator must receive the data or specimens without any of the 18 unique identifiers described above.
  - E. To qualify as “non-human subject”, a code or link cannot exist that could allow the Investigator to establish identity.
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## **Instructions for Completing Appendix L**

1. **Principal Investigator Information:** Provide all information regarding the Principal Investigator. Provide off campus address only if the PI does not have a reliable campus address.
2. **Faculty Advisor:** If the Principal Investigator is graduate student OSU-CHS IRB requires that a Faculty Advisor be appointed to oversee the conduct of human research. Provide all information regarding the appointed Faculty Advisor.
3. **Study information:**
  - A. Provide the title of the research.
  - B. Give a summary of the proposed research to include: the research question; a brief description of the methodology; and a description of any interventions.
  - C. Describe the subject population that will be studied or reviewed. This should include the age and number of the subjects and how they will be recruited. It is important to identify who your research subjects will be, as the IRB must follow specific guidance and regulations for certain populations. Also indicate the type of data or specimens. Describe the methods in which this data or specimens will be collected, stored, and how confidentiality will be maintained.
4. **Determination of “Research”:**  
Indicate whether the data/specimen(s) will be obtained in a systematic manner and if the intent of collection is to contribute to generalizable knowledge.
5. **Determination of “Human Subject”:**  
Indicate whether the activity involves obtaining information about living individuals, intervention or interaction with a human subject, or access to identifiable private information.
6. **Signatures:**
  - A. The PI must sign the form.
  - B. The Faculty Advisor must sign the form if the PI is a student.
7. **Submit to the IRB:**  
Submit the original form and one copy to:

Teri Bycroft, Assistant Director of Human  
Subjects Research  
1111 West 17<sup>th</sup> Street  
Tulsa, OK 72107

**Questions? Please contact the IRB office at 918-586-4609 or [teri.bycroft@okstate.edu](mailto:teri.bycroft@okstate.edu)**

## APPENDIX L: 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 CHS-IRB, and thus may not be subject to IRB review. CHS policy charges the CHS-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 L. 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 L. 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:		
<b>Complete if PI does not have campus address:</b>				
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)

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**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.**

\_\_\_\_\_  
Dr. Stephen Eddy, IRB Chair

\_\_\_\_\_  
Date