OKLAHOMA PANHANDLE STATE UNIVERSITY

APPROVAL OF USE OF HUMAN SUBJECTS IN RESEARCH

FORMS and INSTRUCTIONS

June 20, 2011

IRB Guide

For Determining the Need for IRB Review

A study must be reviewed by the IRB if it involves human subjects and is considered research. Read the information below and answer the questions to determine if your study qualifies.

1. Determination of "Human Subject".

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 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 or a school record). Private information must be individually identifiable (i.e., the identity of the subject is or may be ascertained by the investigator or is associated with the information) in order for obtaining the information to constitute research involving human subjects.

2. Determination of "Research".

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 the IRB whether or not they are conducted or supported under a program which is considered research for other purposes.

Systematic investigation involves a predetermined method for studying a specific topic, answering a specific question(s), testing a specific hypothesis(es), or developing a theory. Examples of systematic investigations include, but are not limited to, observational studies, interview or survey studies, group comparison

studies, test development, program evaluation, and interventional research. Although 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.

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**. Theses or dissertation projects conducted to meet the requirements of a graduate degree are considered generalizable.

1. Determining if human subjects are involved.

A. Does the research involve obtaining information about living individuals?
☐ No ☐ Yes

If no, then study does not involve human subjects.

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

If you answered "yes" to any of questions 1B-E you must proceed to step 2 to determine if you are conducting "research" as defined by the IRB.

If you answered "no" to all of the above questions, you are not using human subjects and IRB review is not required. Do not proceed to step 2.

2. <u>One</u> 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
☐ No ☐ Yes

If you answered "no" to either of the above questions, you are not conducting research and IRB review is not required. However, you should submit this form to the IRB to document your responses and project. If you answered "yes" to both of the above questions, then IRB review is required, and you should complete and submit the request for IRB review and approval.

OKLAHOMA PANHANDLE STATE UNIVERSITY INSTITUTIONAL REVIEW BOARD APPLICATION FOR APPROVAL OF HUMAN SUBJECT RESEARCH

This application must be completed as a Word document. Handwritten applications will not be accepted.

Title of Project:

I agree to provide the proper surveillance of this project to ensure that the rights and welfare of the human participants are properly protected. Additions to or changes in the procedures affecting the participants after the project has been approved will be submitted to the committee for review.

Principal Investigators(s):

(If the PI is a student, please list faculty research advisor last)

_____	_____
Name	Signature
_____	_____
Name	Signature
_____	_____
Name	Signature
_____	_____
Name	Signature
_____	_____
Department	School
_____	_____
PI e-mail	PI phone
_____	_____
Advisor e-mail (if PI is student)	Advisor phone (if PI is student)

APPLICATION FOR APPROVAL OF RESEARCH PROJECTS INVOLVING HUMAN SUBJECTS

Instructions: Please complete in detail and submit one copy electronically and one hard copy to the chairman of the IRB at least 4 weeks before your proposed project. All students and non university personnel must have a faculty sponsor for the project.

1. Attach a copy of your proposal thoroughly describing the purpose of your project in detail.

2. Who will be the participants in this study, and how will they be solicited or contacted?

3. Participants must be informed about the nature of what is involved as a participant, including particularly a description of anything they might consider to be unpleasant or a risk. Please provide an outline or script of the information which will be provided to participants prior to their volunteering to participate. Include a copy of the written solicitation and/or statement of the oral solicitation.

4. Briefly describe each condition or manipulation to be included with the study.

5. What measures or observations will be taken in the study? Copies of any questionnaires, tests, or other written instruments that will be used must be included.

6. Will the participants encounter the possibility of stress or psychological, social, physical, or legal risks which are greater, in probability or magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests? Yes No. If Yes, please describe.

7. Will Medical clearance be necessary before participants can participate due to tissue or blood sampling or administration of substances such as food or drugs, or physical exercise conditioning? Yes No. If Yes, please describe.

8. Will the participants be deceived or mislead in any way? Yes No. If Yes, please describe.

9. Will there be a request for information which participants might consider to be personal or sensitive? Yes. No. If yes, please describe.

10. Will the participants be presented with materials which might be considered to be offensive, threatening, or degrading? Yes No. If yes, please describe.

11. Will any inducements be offered to the participants for their participation? Yes No. If yes, please describe. If extra course credit is offered, what alternative means of obtaining additional credit are available?

12. Will a written consent form be used? Yes No. If yes, attach the form; if not, indicate why not and how voluntary participation will be secured.

13. Will any aspect of the data be made part of any record that can be indentified or associated with the participant? Yes No. If yes, please explain.

14. Please describe in detail, the steps to be taken to ensure the confidentiality of the collected data.

15. Will the fact that a participant did or did not participate in a specific experiment or study be made a part of any record available to a supervisor, teacher, guardian, or employer? Yes No. If yes, please explain why and how the information will be used by the outside party.

16. Describe the benefits that might accrue to either the participants or society from this project.

Preparer's Checklist:
___Research proposal
___Written solicitation or script for solicitation of participants
___Review Application
___Informed consent form