

Appendix B

Informed Consent Guidelines

INFORMED CONSENT DOCUMENT FORMAT GUIDE

This guide is intended to be used as a model for consent forms for adults and parents or guardians of older children. Please present all information clearly and in lay language.

Project Title:

Investigators:

List all investigators and key personnel, including their degrees, responsible for obtaining informed consent or that will have contact with participants.

Purpose:

A brief general description of the purpose of the study that includes:

- *a statement that study involves research;*
- *why they are being asked to participate;*
- *the type of information sought.*

Procedures:

Clearly, and in lay language, explain what the subjects will be asked to do, including:

- *the topic areas of any instruments or tests;*
- *interviews;*
- *medical procedures;*
- *physical exercises;*
- *any other activities that the subjects will be asked to complete;*
- *audio or video taping;*
- *identification of any procedures or products that are experimental;*
- *any possible discomforts or inconveniences that the subject might experience;*
- *expected duration of the subject's participation including the number of individual interactions.*

Risks of Participation:

Inform subjects about any expected risks:

- *emotional*
- *psychological*
- *legal*
- *pain*
- *inconveniences*

Describe any procedures that will be made available to reduce risks (i.e. counseling services, CPR trained personnel, informational contacts, etc.) For research that involves physical activity, a liability statement may be needed.

If there are no risks identifiable to the research, please include the following statement, (modify if necessary);

There are no known risks associated with this project which are greater than those ordinarily encountered in daily life.

Benefits:

Describe any benefits to the participants and others which may be reasonably expected from the research. (Do not include payments or other types of direct

compensation.) Inform the subject if there is no expected benefit.

Confidentiality:

Provide a full explanation of confidentiality protections the investigator plans to use, including:

- where the data will be stored;
- who will have access to the stored data;
- how long the data will be kept;
- how the data will be reported.

Describe any foreseeable risks to maintaining confidentiality and how these will be minimized.

Researchers are not prevented from voluntarily disclosing certain information about research participants, such as evidence of child abuse or a participant's threatened violence to self or others. However, if a researcher intends to make such disclosures, it should be clearly indicated in the consent form.

Compensation:

Describe any compensation to be offered for participation, when it will be given and any conditions of full or partial payment. (It is considered coercive to make completion of the study the basis for compensation).

Appropriate alternatives to participating in the research must be clearly stated. This is particularly important when there is a dependent relationship where coercion could be perceived. (i.e., student/professor, prisoners, persons in mental hospitals or the military). If extra course credit is to be offered for participation, specific alternatives for earning extra credit must also be stated.

Contacts:

Provide subjects with information about whom to contact with questions about both the research and the subject's rights. **The points of contact should include, at a minimum, the investigator's name and phone number and the following statement for the IRB contact:**

If you have questions about the research and your rights as a research volunteer, you may contact Dr. Yvonne Montgomery, IRB Chair, 109 Moore Hall, Langston University, Langston OK 73050, 405-466-3242 or ykmontgomery@lunet.edu.

Participant Rights:

Include a statement emphasizing that participation is voluntary and that subjects can discontinue the research activity at any time without reprisal or penalty. Any risks to subjects that might occur due to withdrawal must be made clear. Explain any reason the subject's participation may be terminated.

Signatures:

Preface the signature lines with the following statement (expand if appropriate):

I have read and fully understand the consent form. I sign it freely and voluntarily. A copy of this form has been given to me.

Signature of Participant

Date

I certify that I have personally explained this document before requesting that the participant sign it.

Signature of Researcher

Date

Use the following signature block only if the consent form is for an older child and parental/guardian permission is required.

Parental Signature for Minor

I have read and fully understand the consent form. As parent or guardian I authorize _____ (print name) to participate in the described research.

Parent/Guardian Name (printed)

Date

Signature of Parent/Guardian

Date

I certify that I have personally explained this document before requesting that the participant sign it.

Signature of Researcher

Date