Informed Consent Document Format Guide

This guide is designed to assist you as you develop consent documents. Please present all information clearly and in lay language. For information being distributed to the general public, a **6th grade language level** is recommended. **Consent documents should be written in second person.**

Project Title:

Investigators:

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

Purpose:

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

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

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;
- physical exercises;
- audio or video taping;
- any possible discomforts or inconveniences that the subject might experience;
- expected duration of the subject's participation including the number of individual interactions;
- any other activities that the subjects will be asked to complete.

Risks of Participation:

Inform subjects about any expected risks:

- emotional
- psychological
- physical
- inconveniences

Describe any steps that will be taken to reduce risks (i.e. counseling services).

If there are no risks specific 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 subjects and others that may be reasonably expected to come from the research. (Do not include payments or other types of direct compensation.) Inform subjects if there are no expected benefits.

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.

The records of this study will be kept private. Any written results will discuss group findings and will not include information that will identify you. Research records will be stored securely and only researchers and individuals responsible for research oversight will have access to the records. It is possible that the consent process and data collection will be observed by research oversight staff responsible for safeguarding the rights and wellbeing of people who participate in research.

This statement that follows may be necessary in certain situations.

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, pregnant women,

children, persons in mental hospitals or the military). If extra course credit is to be offered to students for participating in research, specific alternatives for earning extra credit must also be stated.

Contacts:

Fill in the contact information on the form for both the principal investigator and the research advisor. Do not remove the IRB chair's contact information.

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 by the researcher.

Signatures:

Do not remove signature information.

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 prospective participant sign it.

_____ _____

Signature of Researcher Date