UNIVERSITY OF CENTRAL OKLAHOMA
INSTITUTIONAL REVIEW BOARD

# INFORMED CONSENT FORM GUIDELINES

Informed consent is an essential part of the design of every research project involving human subjects. Researchers who involve human subjects in their research have both an ethical and legal obligation to secure the informed consent of the potential research subjects prior to initiation of the research. This guideline is intended to assist researchers in complying with the requirements of informed consent for research involving human subjects. You may compose your own consent form but it should contain all of the elements contained in the template.

For research involving legal minors, separate age-appropriate Assent forms for minors and Consent forms for parents/guardians are required and a template is available on our webpage.

## I. General Elements of Informed Consent

The basic elements of effective informed consent are:

A. the full disclosure of the nature of the research, any risks and benefits, and a description of what the subjects will experience;

B. adequate information for the potential subjects to make an informed choice about participating in the research;

C. disclosure of measures to protect privacy and confidentiality;

D. affirmation of the subject's voluntary choice to participate.

## II. Specific Elements of an Informed Consent Document

In order to assure that these general elements are included, an appropriate informed consent document should include the following written to and in understandable language for potential subjects:

A. A general description of the study and its purpose or goal. (Similar to Item 1 in the IRB Application)

B. A description of the procedures and measures or observations (Item 4) involved in the study (tell them what they will experience).

C. A statement indicating how much time participation in the study is expected to take.

D. A description of any benefits which may be reasonably expected for both the potential research subject and society. If there is no direct benefit for subjects, that should be stated. (Items 13 and 14)

E. A description of any foreseeable risks or discomforts to the potential research subject. (Item 6) This section should include information from your IRB application regarding possible stress or risks for the research subjects, information regarding personal or sensitive questions, and disclosure if any of the materials to be presented might be considered offensive, threatening or degrading.

F. An explanation as to what medical and/or mental health care services are available and contact information (the name, location, and phone number of the UCO Student Counseling Services or Mercy Health Clinic) in cases where research involves more than minimal risk.

G. Phone and email contact information for questions or concerns about the research (for each Principal Investigator and Co-PI).

H. **C**ontact information for UCO IRB for questions about research participation.

I. A description of how the confidentiality of records identifying the subject will be maintained. This section should include information from your IRB application (Items 10 &11). We strongly urge that, where possible, data be stored on campus in a secure office file. You must specify the location of all documents related to the study and the person responsible for them in case these records need inspection. Federal guidelines require that signed consent forms be kept at least 3 years following the end of the study. Contact the ORC to discuss storage issues. Completely de-identified data records may be kept as long as needed.

J. A statement that participation in the research is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits.

**III. Informed Consent Modifications & Waivers**

In special situations, evaluated on a case-by-case basis, the UCO IRB may approve a consent procedure which modifies or waives the requirement to obtain written informed consent under one or more the following conditions:

A. The research cannot practicably be carried out without the waiver; e.g., research that must, due to the requisites of its design, purposefully mislead/deceive research subjects.

B. It is research that involves no more than minimal risk to the research subjects;

C. Subsequent to the research, the research subjects will be provided a statement (information sheet) containing the basic elements of the consent form which describe the research project.