Informed Consent Form Template
Miami Dade College Institutional Review Board
Based upon HHS.gov guidelines

Informed Consent

Title of Study

Purpose: Provide a statement that the study involves research and explain of the purpose of the research. Include a brief description about how the data will be used.

Procedure: Provide a description of the procedures to be followed and identify any procedures which are experimental. Provide an explanation of what participation in the study will entail and give the expected duration of the subject's participation. Provide a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

Risks: Provide a description of any reasonably foreseeable risks or discomforts to the subject. For research involving more than minimal risk, provide an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained. See **Appendix A** below for additional elements that are to be included in this section, if applicable.

Benefits: Provide a description of any benefits to the subject or to others which may reasonably be expected from the research.

Confidentiality: Provide a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.

Rights: Provide a clause stating that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may withdraw from the study at any time without penalty or loss of benefits to which the subject is otherwise entitled.

Contact information: Provide an explanation of whom to contact for answers to pertinent questions about the research and the subject's rights, and whom to contact in the event of a research-related injury to the subject. At minimum, this section must include the PI's contact information. If Miami Dade College is the PI's home institution, this section should also include the following statement: "Please contact Miami Dade College's IRB at IRB@mdc.edu if you have any questions, complaints, or concerns regarding your rights as a research participant."

Provide a statement of consent, such as "I have read and understood the information above, I voluntarily agree to participate in this study, and I certify that I am 18 years of age or older. All of my questions have been answered, and I have received a copy of this consent form."

_____ _____

Participant Name Date

_____

Participant Signature

_____

Participant Signature Authorizing Audio/Video Recording (if applicable)

Appendix A

Additional Elements of Informed Consent

When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

(2) A statement that anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

(3) A statement that any additional costs to the subject that may result from participation in the research;

(4) A statement that the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject

(6) A statement pf the approximate number of subjects involved in the study ; and

(7) A statement that indicates the recording devices that will be used and a statement of consent to being recorded.