FOR EXAMPLE ONLY

IRB # _____
Project Title
Principal Investigator:

Department:
Telephone number:

INFORMED CONSENT FOR PARTICIPATION IN RESEARCH ACTIVITIES

I. **PURPOSE OF THIS RESEARCH STUDY:** **"**I have been asked to participate in this research study because…" "The purpose of this study is to …" "My participation in this study is expected to last …"

II. **WHAT WILL BE DONE/PROCEDURES**: State the protocol objectives, in lay language, and duration of the subject's participation.

III. **POSSIBLE BENEFITS** "I have been informed that my participation in this research may not benefit me…" OR "I have been informed that my participation in this research will not benefit me directly…"

IV. **POSSIBLE RISKS AND DISCOMFORTS**: I have been informed that the risks and discomforts of this study are {or "include"] ...

V. **CONFIDENTIALITY OF RECORDS**

Any information learned from this study in which I might be identified will remain confidential and will be disclosed only with my permission, to the extent allowed by law. All records **(and tapes - use if applicable)** will be stored in a locked file cabinet in a locked room. Only the investigator and members of the research team will have access to these records. If information learned from this study is published, I will not be identified by name. By signing this form, however, I allow the research study investigator to make my records available to the University of the District of Columbia (UDC) Institutional Review Board (IRB) Office and regulatory agencies as required by law. **(review consent form instructions for additional information regarding this section)**

VI. **OFFER TO ANSWER QUESTIONS AND RESEARCH INJURY NOTIFICATION**: The principal investigator, Dr./Mr./Ms. [**name of principal investigator**] or a colleague Dr./Mr./Ms. _____, responsible for this research study, has offered to and has answered any and all questions regarding my participation in this research study. If I have any further questions **or in the event of a research related injury**, I can contact Dr./Mr./Ms. [**name of principal investigator**] at (202) _____ [**principal investigator's telephone number**]. **(review consent form instructions for additional information regarding this section)**

VII. **SPONSOR OF THE RESEARCH** [Name of external sponsor] is the sponsor of (or "is funding"] this research study. [If there is no sponsor, delete this section and renumber.]

VIII. **COST TO THE SUBJECT / PAYMENT TO SUBJECT FOR PARTICIPATION** [Delete and renumber if not applicablel.]

IX. **EXPLANATION OF TREATMENT AND COMPENSATION FOR INJURY**:

(review consent form instructions for additional information regarding this section)

X. **VOLUNTARY PARTICIPATION WITH RIGHT OF REFUSAL:** I have been informed that my participation in this study is completely voluntary. I am free to withdraw my consent for participation in the study at any time

XI. **IRB REVIEW AND IMPARTIAL THIRD PARTY:** This study has been reviewed and approved by the UDC Institutional Review Board (IRB). A representative of that Board, from the IRB Office, is available to discuss the review process or my rights as a research subject. The telephone number of the IRB Office is (202) 274-5705.

XII. **SIGNATURE FOR CONSENT:** The above-named investigator has answered my questions and I agree to be a research subject in this study.

Participant's Name: _____ Date: _____

Participant's Signature: _____ Date: _____

Parent/Guardian Signature: _____ Date: _____
(for participants under the age of 18)
Investigator's Signature: _____ Date: _____

Translator's Signature: _____ Date: _____

I have translated this form into the _____ language.

§46.116 - Informed Consent Checklist - Basic and Additional Elements (PHS 398/2590 (Rev. 05/01)

	A statement that the study involves research
	An explanation of the purposes of the research
	The expected duration of the subject's participation
	A description of the procedures to be followed
	Identification of any procedures which are experimental
	A description of any reasonably foreseeable risks or discomforts to the subject
	A description of any benefits to subject or others which may reasonably be expected from the research
	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
	For research involving more than minimal risk, 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
( ) Research Qs ( ) Rights Qs ( ) Injury Qs	An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the subject
	A statement 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 discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled
Additional elements, as appropriate	
	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
	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent
	Any additional costs to the subject that may result from participation in the research
	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
	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
	The approximate number of participants involved in the study