

### *Including required boilerplate statements*

#### **SUBJECT CONSENT FORM**

The attached is a "Model" Institutional Review Board Subject Consent Form that may be used as a "guideline" for consent forms to be considered by the IRB. It contains certain "boilerplate" statements that must be included in each consent form made by the principal investigator. Other portions depend upon the nature of the specific research. In each case, the subject should understand the reason for the research study, who is sponsoring the study, the nature or extent of any potential discomfort or adverse health effects as a result of participation, and the right to withdraw, or possibility of being withdrawn, from participation in the study at any time. The consent form should be written in "lay language" (6th to 8th grade reading level).

***NOTE:** Consent forms must be uniformly typed and customized to the NSU standards outlined in this Model Consent Form. Each section must be clearly subtitled (Exclusionary Criteria, Risks, etc.) and pages numbered (page 1 of 4, etc.).*

**Standard forms from a sponsor will not be accepted for review.**

Boilerplate statements are in **bold** and **must be included in the Subject Consent Form**. Statements that are in italics and/or in brackets [] should be adapted to the individual needs of a particular protocol.

#### **DISCLAIMER**

Because of the changing guidelines from the OPRR, FDA, and other federal agencies, adherence to this model Subject Consent Form does not guarantee IRB acceptance without further modification.

#### **EXPERIMENTAL PROTOCOL**

In addition to the subject consent form, IRB approval also depends upon the submission of a clear, well documented experimental protocol to assist the IRB in deciding if the risks and benefits are acceptable in relation to scientific merit.

Questions regarding the Institutional Review Board should be directed to [irb@nsu.edu](mailto:irb@nsu.edu).

### SUBJECT CONSENT FORM (sample)

"Descriptive Title for the Protocol"

**INVESTIGATORS:** List of all investigators who will be involved in the research protocol.

**SPONSOR:** Indicate source of funding for the project.

### DESCRIPTION

This section should include a full but brief description in lay terms of the research study to be performed. The description must specifically state the subject is being asked to **participate in a research project**. It should address why the subject is being asked to participate, what will be expected from the test subject as a result of participation (e.g., lift 40 pound for 50 minutes three time a week), and how long the subject will be expected to participate. This, and other sections must be written using the first-person pronoun "I", "Me", "My", or "We" (as opposed to "You", "Your", etc.). If the research will involve minors, there should be a statement at the opening that "I" refers to "my child". Other references to "I" being "my child" will then not be necessary

### EXCLUSIONARY CRITERIA

This section should address preexisting conditions, or other factors, that would preclude the participation of the individual in the study. List only the conditions subjects would be expected to know about themselves. Examples are drug or alcohol abuse, depression, etc.

If pregnancy is an exclusionary criteria or a risk, investigators should request that subjects employ acceptable methods of birth control during study participation. Allowable methods should be listed.

### RISKS

Potential adverse effects of participation in the protocol must be clearly stated. An example would be "I understand there is a chance of bruising, infection and pain at the site of blood drawing" for a protocol that involves blood drawing". All consent forms must include the statement **"There may be other risks not yet identified"**.

### **BENEFITS**

Discuss any potential benefits to the test subject as a result of participation in the study, including therapeutic benefits or recognition, and satisfaction from or contributions to social, science or medical research. If there are no benefits personally to the subject this should also be stated. For example, "I understand there are no specific benefits to me personally for my participation in this study" Drugs or devices received by the test subject are not benefits and should not be listed as such.

### **ALTERNATIVE TREATMENTS**

The test subject must be aware of any alternative treatment that might be available, including the possibility of no treatment at all, unless the investigator believes this option to be ethically acceptable to offer.

### **COSTS AND PAYMENTS**

Any additional cost to test subjects, above and beyond those associated with "standard medical or professional care" (e.g., audiologist), must be clearly indicated. This must include additional hospital cost, if the test subject is to be hospitalized, laboratory fees, device fees (if appropriate) and professional fees. If a research subject is to be compensated, the amount of compensation, schedule of payment and how payment would be prorated should the test subject withdraw or be withdrawn, should also be explained. If the participant is likely to encounter financial liabilities as a result of participating in the study, the investigator must give an estimate dollar amount of the cost.

If portions of the study will be paid for from external sources that should be clearly stated. A statement indicating the source and extent of support being provided from an external funding agency should be included. An example of this is: "The cost of this study, including administrative fees, payment to volunteers, as well as payments to the investigator(s) for the visits and tests, are being paid by the (sponsor's name)".

**AIDS TESTING:** (This section is mandatory only if the protocol included AIDS testing)

I understand that my (tissue sample) will be tested for the HIV antibody (AIDS) because [state reason]. If the result of a positive test is confirmed by a second test (Western blot), the investigators of this research study will notify me of the positive result. The investigators will counsel me as to what further treatment or testing may be needed,

including providing referral to another qualified counselor. I also understand that I may inquire about and be given my HIV test results, and its full implication, at any time. My test results will be maintained in strictest confidence, consistent with current state and federal laws.

\_\_\_\_\_ I choose to be notified in person and can be reached at this phone number to schedule an appointment to meet with the investigator.

\_\_\_\_\_

\_\_\_\_\_ I choose to be notified by registered mail at this address.

\_\_\_\_\_

### **NEW INFORMATION**

Any new information obtained during the course of the research study that may affect my willingness to continue participation in the study will be provided to me.

### **CONFIDENTIALITY**

I understand all personal information learned about me during this research, will be kept strictly confidential and that my records will be protected within the limits of the law.

I also understand non-personal information learned from this study could be used in reports, presentations and publications but I will not be personally identified. It may be necessary for my records to be examined by the financial sponsor of this study or inspected by federal regulatory authorities such as a representative of the Food and Drug Administration.

### **WITHDRAWAL PRIVILEGE**

I understand that I may refuse to participate in or withdraw from this study at any time. I also understand that it may be necessary for [Principal Investigator] to withdraw me from the study. If I do withdraw, or am withdrawn, I agree to undergo all evaluations necessary for my safety and well-being as determined by [Principal Investigator].



# Institutional Review Board (IRB) Consent Form

## COMPENSATION FOR ILLNESS OR INJURY

"I understand that if I suffer a physical injury or illness as a direct result of my participation in this research study, immediate medical treatment will be made available to me [without charge, at an additional charge]. Financial compensation for a research related injury or illness, lost wages, disability, or discomfort is not available. However, I understand I do not waive any of my legal rights by signing this consent form".

Norfolk State University provides no compensation plan or free medical care plan to compensate me for such injuries. If I believe I have suffered an injury as a result of my participation in any research study at NSU, I may contact the Dean of the School of Graduate Studies and Research at [irb@nsu.edu](mailto:irb@nsu.edu).

## VOLUNTARY CONSENT

I certify that I read all of this consent form or it has been read to me and that I understand it. If I have any questions pertaining to the research study or my rights as a research test subject, I may contact [Principal Investigator] whose phone number(s) is \_\_\_\_\_ A copy of this consent form will be given to me. My signature below means that I freely agree to participate in this research study.

Signature of Participant \_\_\_\_\_ Date \_\_\_\_\_

Signature of Witness \_\_\_\_\_ Date \_\_\_\_\_

### INVESTIGATOR'S STATEMENT

I certify that I have explained to the above individual the nature and purpose of the research study, potential benefits, and possible risks associated with participation in this study. I have answered any questions that have been raised and have witnessed the above signature. I have explained the above to the volunteer on the date stated on this consent form.

Signature of Investigator \_\_\_\_\_ Date \_\_\_\_\_

### ADDITIONAL REQUIREMENTS

#### *Assent of the Child*

If the participant is under 18 years of age, the investigator must receive or waive the assent of the child to participate in the study. In either case, the investigator must include a completed "Assent of Child" form as part of the subject consent form. See the specific NSU form that must be submitted for each child.

#### *Employee/Students*

Consent forms must give NSU employees and students an opportunity to identify themselves as such and provide assurance that participation should not affect employment or student status.