

**NORFOLK STATE UNIVERSITY
700 PARK AVENUE
NORFOLK, VIRGINIA 23504**

Guidelines for Submitting Protocols

to the

Institutional Review Board (IRB)

**OFFICE FOR RESEARCH
Room 212, E. L. Hamm Bldg.
Phone: 823-8675**

December, 1999

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NORFOLK STATE UNIVERSITY

INSTITUTIONAL REVIEW BOARD (IRB)

POLICIES AND PROCEDURES

GENERAL COMMENTS

- A. The Institutional Review Board (IRB or Board) has jurisdiction regarding research on human subjects by the faculty, staff, and students on the campus of Norfolk State University (NSU) as well as any research on human subjects conducted by NSU faculty, staff, and students in conjunction with research investigators at other academic institutions and/or area hospitals, such as Children's Hospital of the King's Daughters (CHKD), Sentara Leigh Memorial Hospital (SLMH or Sentara), Sentara Norfolk General Hospital (SNGH or Sentara), Sentara Bayside Hospital (SBH or Sentara) and Depaul Medical Center. The NSU IRB has the authority to approve, require modification in, or disapprove all research activities that fall within its jurisdiction as specified by both federal regulations and NSU policy. Research projects that have been reviewed and approved by the IRB will be subject to review and disapproval by university officials (e.g., Office for Research and/or Office for the Vice President for Research and Technology). However, university officials may not approve research projects if they have been disapproved by the IRB

The Board is a committee body established by NSU to protect the rights and welfare of human research subjects recruited to participate in research activities on the NSU campus or in conjunction with other institutions. The IRB makes an independent determination whether to approve or disapprove research based upon whether or not human subjects are adequately protected. The IRB functions independently of but in coordination with other institutional committees. The administrative and maintenance costs of the IRB will be assessed, in part, via monetary funds received from the indirect cost of grant proposals.

- B. The principal investigator may be a faculty or staff member at NSU. Co-investigators may be faculty or staff members, or students. Principal investigators and co-investigators that are not faculty or staff members at NSU, but have NSU faculty and staff members participating in a research activity must have their research protocols reviewed by the IRB prior to submitting the grant proposal to a funding agency.
- C. All protocols must be reviewed for scientific validity before submission to the IRB. If the principal investigator is a faculty member of NSU, the responsibility for this lies with the dean of a particular school. If the Dean is submitting a protocol then the Director for Research will assign a reviewer and sign for approval. In cases where the principle investigator is a staff member at another academic institution or at one of the area

- E. No member will be allowed to serve on the IRB in which there is a conflict of interest or the perception of a conflict of interest, except to provide information requested by the IRB.
- F. The IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of research which require expertise beyond or in addition to that available on the IRB. These invited individuals may not vote with the IRB.

SUBMISSION OF RESEARCH PROTOCOLS AND RELATED MATERIALS

- A. Protocol Submission: Inclusive of the following information and collated as indicated on the IRB Checklist (page 16).
 - 1. A completed IRB Cover Sheet (see page 17)
 - 2. A signed Dean Approval Form (see page 18). Refer to "General Comment C", page 3, for information regarding signatures.
 - 3. A single copy of the research project budget. The budget should include sufficient explanation of any monies the principal investigator will receive from the sponsor (e.g., physician fees, reimbursements for tests, medications, subject participation, etc.). The budget will be reviewed by the IRB Chairperson for potential conflicts of interest. Budget submission to the IRB is not an approval process, rather a communication of the level of funding. Protocols submitted to external agencies for funding will not receive IRB approval until the budget is made available to the Chairperson for review. If conflicts of interest are found, a written communication of this fact will be sent to the principal investigator by the IRB. Studies funded by external agencies may include a onetime \$750 to \$1000 IRB administrative fee, if allowable.
 - 4. Protocol. A complete protocol encompasses sufficient information to permit the IRB to render judgment as to rationale, scientific merit and potential risk to the human research subject. Specifically, the IRB requires knowledge of: (a) the purpose of the research; (b) inherent risks; (c) whether the risks outweigh the potential benefits; (d) what the subject is being asked to do; (e) data analysis; and (f) alternate choices, including the option of no treatment if ethically acceptable. The following list should be used as a guideline:

MANDATORY INCLUSION- Information to be included in all protocols.

- Introduction
- Research Objectives
- Background and Rationale
- Statement of Test Subject's Confidentiality
- Description of Subject Population
- Inclusion and Exclusion Criteria
- Research Methods and Study Procedures

Data Collection and Statistical Analysis
Literature Review
Consent Forms

OPTIONAL INCLUSION-Based on type of protocol.

Safety Information
Adverse Event Reporting
Record Management
Professional Qualifications/Curriculum Vitae

5. Subject Consent form: This is an integral part of the proposal and should be written in the first-person pronoun "I", "Me", "My", or "We" (as opposed to "You", "Your", etc.) All of the following items (written in 6th to 8th grade, non-technical language) as essential parts of each consent form:

- a. A uniformly typed document preferably customized to the NSU standards shown in the Model Consent Form (Appendix A). Pages must be numbered (page 1 of 4, page 2 of 4, etc.). **Standard forms from sponsors will not be accepted for review.**
- b. Place the title of the protocol, the investigators names and the study sponsor at the top of the first page.
- c. **Participation:** Include a statement indicating the study involves research and including the purpose and expected duration of the subjects participation. Discuss the procedures to be used identifying which procedures are experimental. Be as specific as possible. If blood samples are to be drawn, state how often and how much (e.g., 1 cc); if drugs are to be given, state the dosage and how often the drug is to be administered. Be sure to outline what is required of the subject for participation in the study (e.g., visits, diary keeping, etc).
- d. **Exclusion Criteria:** List only exclusion criteria for which the investigator will rely upon the participants knowledge of themselves and/or their medical or personal history. Example: not pregnant, drug or alcohol abuse, treatment for depression, etc.
- e. **Risks:** Discuss any reasonably foreseeable or serious risks, discomforts, inconveniences, or side effects that could be expected and what measures will be taken to minimize them. At the end of this section, always add the statement **"There may be other risks not yet identified"**.
- f. **Benefits:** Discuss possible benefits that may accrue to the subject as a result of participation in the research, including therapeutic benefits, if any or recognition.

Drugs or devices received by the subject are not considered benefits and should not be listed as such.

g. Alternative Treatment: Discuss or list any alternative courses of action open to the subject (e.g., generally another accepted course or therapy or diagnostic procedure) in lieu of participation in the study. This includes the option of "no treatment" when ethically acceptable.

h. Cost and Payments: Outline all cost to the subject above and beyond those associated with standard testing and/or medical care. If a subject is to be compensated, the amount and payment schedule should be included. Financial liabilities must be clearly stated in the informed consent. This includes cost for any tests, medications, trips, physician fees, etc. If possible, the investigator should give a dollar amount of the estimated costs.

i. Financial Disclosure: Include a statement indicating the source and purpose of financial support (e.g., administrative fees, payments to volunteers, as well as payments to the investigator) provided by the external funding agency.

j. AIDS Testing: To maintain conformity with Public Health Service (PHS) guidelines, a statement must be inserted into the subject consent form for a protocol that involves the testing of a subject's tissue sample, if used in the research, for the presence of HIV virus, whether it is "discarded tissue" or not. See the NSU Model Consent Form for boilerplate statement.

k. New Information: Include the following statement *"any new information obtained during the course of the research which may affect my willingness to continue participation in the study will be provided to me"*.

l. Confidentiality: Include a statement that medical and/or test records will be protected within the limits of the law (both state and federal). In addition, state the records may be examined by the sponsor, inspected by federal regulatory authorities, or reviewed by a representative from the Food and Drug (FDA) Administration. At the end of this section, add *"I also understand that non-personal information learned from this study could be used in reports, presentations at National Scientific meetings, and non-peer-reviewed (i.e., news magazines, news papers etc.) and peer-reviewed publications (i.e., scientific journals of the field), but I will not be personally identified"*. (When appropriate, specify the degree of confidentiality of records to be provided, whether the research subject has a right to a copy and if the records contain means of identifying the test subject. In some cases, the investigator may apply to the PHS Secretary for a "Certificate of Confidentiality", which overrides all other judicial authorities requiring disclosure of the data and/or conclusions of the study. For Further information contact the Office for Research at 823-9053.

m. **Withdrawal Privilege:** Include a statement that the subject's participation is voluntary and withdrawal or refusal to participate will not involve penalty or loss of benefits to which the test subject is otherwise entitled. Discuss the circumstances under which the test subject's participation in the study may be terminated without the test subject's consent.

n. **Compensation for Illness or Injury:** Include the following statements "*I understand if I suffer a physical injury or illness as a direct results of my participation in this 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*".

"NSU provides no compensation plan or free medical care plan to compensate me for such injury. In the event I believe I have suffered an injury as a result of my participation in any research program, I may contact the Office for Research and Technology, which will review the matter with me".

o. **Voluntary Consent:** Include a section stating the research subject certifies that they have read the consent form, understand its contents, and freely agree to participate in the study. Include the name and phone number of the person they should contact with questions about the research or their rights as a research subject. Also, state that the subject will receive a copy of the signed consent form. At the end of this section provide signature lines with dates for the subject (or subjects guardian) and a witness.

p. **Investigators Statement:** "*I certify that I have explained to the above individual the nature and purpose of the study, potential benefits and possible risks associated with participation in this research 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*".

Provide signature and date lines for the investigator.

q. **Child Assent Form:** Include, if the research involves children under 18 years-old (see page 17). Age guidelines are as follows: (1) 0.-7 years of age are usually not capable of giving assent; (2) 7-14 years of age may be able to understand the information presented to them and assent should be attempted; and(3) 15 years of age or older should be able to give assent. The investigator should note that giving assent depends upon the subject's level of maturity and judgement should be made on a case by case basis.

6. **Addendum Consent form:** This consent form can be used to provide new information to subjects or to extend the subject's participation beyond the original protocol. This form

cannot be used for extensive revisions in the original protocol and/or procedures that require an approval from the IRB (e.g., changing subjects from a placebo-controlled trial to an open-label trial) See page 21.

7. Short Consent Form: Studies involving only a questionnaire and/or limited manipulation of the subject physical person or tissues (e.g., limited blood draws) can utilize the new short consent form (See pages 22 and 23).

8. Advertisements: Copies of advertisements or videos used in the recruitment of research or test subjects must be submitted for approval prior to publication or distribution. This includes advertisement that reference a full-time or adjunct faculty member's affiliation with NSU.

- B. The principal investigator, or co-investigator, is required to attend the IRB meeting to briefly review the study and to answer or ask relevant question pertaining to the research study. Any recommended changes in the protocol, procedures, or consent form will be stated while the investigator is present at the meeting. This step enhances immediate clarification of any concerns. After the meeting, the Chairperson will notify the principal investigator, in writing, of the action taken and any required changes. Investigators should wait for written correspondence before submitting any changes for final approval.
- C. After the meeting, changes to a protocol or consent form should be submitted in the following manner: Submit TWO COPIES of the revised consent form and/or protocol with ALL CHANGES HIGHLIGHTED on one copy. Approval will not be granted until the IRB is in receipt of the appropriate material and has approved the changes. Written approval will then be given for study. If the study is to be conducted at or in conjunction with a local hospital or academic institution, the investigator must receive the appropriate institutional committee approval before initiating the study.
- D. The IRB chairperson must be notified, in writing, of any action that a granting agency or any other entity takes with respect to the study.
- E. Do not submit incomplete materials through the IRB process, as they will be returned without review.

ADVERSE EVENTS

If during the course of the research study, there are any deaths, adverse reactions or medical or legal complications associated with the study at the NSU site, the principal investigator must notify the Office for Research, by phone (823-9053), within five working days. The events must also be put in writing for the "official" record" and sent to the Office of the Vice President for Research and Technology. For events occurring off-site in a cooperative research study, the investigator must forward all information to the IRB within five days of receipt of the adverse event notice.

AMENDMENTS

The IRB must be informed in writing of any proposed changes to the study protocol and/or procedures, consent form, advertisement or the study related materials during the course of the research. Two (2) copies of the revised materials should be submitted for the Board's review. Changes should be highlighted on one of these copies.

If the changes are "minor", approval may be expedited. If the changes are significant, the investigator may be asked to resubmit the protocol for full-Board review. Approval must be obtained from the IRB prior to initiation of any change.

CLOSE-OUT REPORTS

A Close-out Report is required at the conclusion of the study and should follow the guidelines specified under "Continuing Review".

CONTINUING REVIEW

Progress reports and administrative termination

Federal Regulations [45 CFR 46, 46.109 (e)] require the IRB to conduct continuing review of research at intervals appropriate to the degree of risk but not less than once per year. In order to fulfill this requirement, the NSU IRB will require the Principal Investigator to submit an annual (unless otherwise specified) progress report of all approved protocols, including exempt studies. At this time, an updated consent form for the study is requested. The consent form must comply with the current IRB Guidelines. Progress reports should be submitted on The Request for Reapproval and Continuation or Termination Form (see page 22). Continuing approvals will not exceed one year.

The federal regulations (45 CFR 46, 46.113) also stipulates that the IRB has the authority to suspend or terminate approval that is not being conducted in accordance with the IRB's guidelines. Therefore, in the event an investigator does not comply with the continuing review guidelines by providing a written report when requested, the following will be instituted as a mechanism for compliance.

1. On the anniversary date, a summary progress report should be submitted on a Request for Reapproval and Continuation or Termination Form (See Appendix). This form is designed to assist the investigator in providing the necessary information to determine re-approval or termination. The progress information is reviewed for completeness and if sufficient an approval letter will be forwarded to the investigator. If the information is not sufficient, a request will be sent for further information and a response expected within thirty (30) days of that request.

2. If the progress is not received within one month of the original request, a second notice will be sent to the investigator notifying him/her that failure to provide a report in (30) days will result in administrative withdrawal of IRB approval of the research study. This letter is copied and sent to the investigator's Dean and Department Chairperson.
3. If the progress report continues to be delinquent, a third notice will be sent to the investigator notifying him/her that **failure to comply with the previous two requests has resulted in administrative withdrawal of IRB approval for the research study and a close-out report must be submitted. In addition, until all delinquent reports have been submitted, the investigator will not be permitted to bring new protocols before the IRB**

The administrative termination of approval will be provided in writing and shall include a statement of the reason(s) for the IRB's action. This action will be reported promptly to the investigator, the Department Chairperson, Dean, the Office of the Director for Research, the Office of the Vice President for Research and Technology, any affiliated hospital or academic institution, the Food and Drug Administration (FDA), and any appropriate sponsoring agency.

EMPLOYEES AND/OR STUDENTS AS SUBJECTS

Investigators planning to recruit NSU employees or students as research subjects must inform the IRB of this population and attach an "**Employee/Student Consent Form**" to the full consent form. Employees or students should be recruited only by advertisement, such as a flyer on a bulletin board. Investigators should be particularly careful to ensure that no coercion is used in the recruitment of this subject population.

EXEMPT STUDIES

The Code of Federal Regulations (45 CFR 46) by which the IRB operates lists several possibilities in which a study may be exempt. The list provided below is only a brief synopsis of these possibilities to help the investigator determine how many copies of the study to submit to the IRB for review.

1. Research conducted in established or commonly accepted educational settings;
2. Research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior;
3. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens;
4. Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads;

5. Taste and food quality evaluation and consumer acceptance studies.

All items listed above must meet other criteria to qualify as exempt. It is the responsibility of the IRB to determine whether a study is exempt. Investigators should not presume a study to be exempt without receiving confirmation from the IRB.

Studies involving special populations, such as children, prisoners, or pregnant women, can not be considered for exempt status and must be given full-Board review in accordance with federal guidelines.

Investigators who believe they have an exempt study must submit two copies of the research protocol, including the Department chairperson and Dean form with all signatures. The research study will be reviewed administratively by the IRB chairperson or chairperson's designee. If the study is considered exempt, the investigator will receive a letter verifying that status. If the study is not exempt, the investigator will be advised to submit a protocol and informed consent for full-IRB review.

Studies which are believed to be exempt may be submitted at any time to the Office of the Vice President for Research and Technology. Review of the material will be performed in an expedited manner.

FINDER'S FEES FOR RESEARCH SUBJECTS

Finder's fees (i.e., cash or non-monetary payment) for the referral of test subjects to investigators is considered, in most situations, unethical. This practice has the potential to violate the test subject's trust in the referring entity, the investigator and in the process of research. Appropriate justification from the principal investigator as to the reason for offering a finder's fee should be submitted with the protocol. Studies which include a finder's fee will be closely examined by the IRB and decisions for approval made on a case by case basis.

INQUIRES BY REGULATORY AGENCIES

Principal investigators must notify the IRB when there is to be a review of their study by any regulatory agency. This does not include the routine "site visits" often conducted by sponsors. A copy of all correspondence relating to the investigation must be submitted to the IRB.

NON-COMPLIANCE WITH INSTITUTIONAL AND/OR FEDERAL GUIDELINES

The federal regulations (45 CFR 46. 113) stipulates that the IRB has the authority to suspend or terminate approval when research is not being conducted in accordance with federal and/or institutional policies (e.g., Animal Care & Use (ACU), Intellectual, Biohazards and Chemical Use policies). Therefore, in the event an investigator does not comply with established policies, all active protocols may be closed and IRB approval withdrawn. An investigator may also have privileges for the submission of new protocols for consideration by the IRB denied.

Any action taken will be reported promptly to the investigator, the Department Chairperson, Dean, the Office of the Director of Research, the Vice President for Research and Technology.

DOCUMENTATION AND RECORD RETENTION RESPONSIBILITIES

The IRB Responsibilities: IRB, assisted by the staff in the Office of the Vice President for Research and Technology, will maintain the following records, which will be accessible for inspection and copying by authorized representatives of federal agencies (e.g., NIH or FDA) at reasonable times and in a reasonable manner

a. **Copies** of all research proposals involving human subject research, scientific evaluations and sponsor information, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by research investigators, and reports of adverse experiences to test subjects.

b. **Minutes** of all IRB meetings which will be insufficient detail to show the names of the attendees at the meeting; actions taken by the IRB; the vote on these actions, including the number of members voting for against, and abstaining; the basis for requiring changes in or disapproving research proposal; a written summary of the discussion of controvert issues and their resolution; and dissenting reports and opinions. If a member in attendance has a conflicting interest regarding any research project, minutes will show that this member did not participate in the review, except to provide information requested by the IRB

c. **Records** of continuing review activities.

d. **Copies** of all correspondence between the IRB and: (1) the principal investigator (PI) or other investigators; (2) federal agencies (e.g., HHS, FDA); and (3) the sponsor

e. **A statement** of the principles and procedures governing the IRB in the discharge of their responsibilities to protect the rights and welfare of human test subjects of research covered by federal and institutional guidelines and policies.

f. **Statements** of significant new findings provided to human subjects pursuant to federal regulations (45 CFR 46.113).

h. **All records** relating to a specific research protocol, including all informed consent documents. These will be kept on file for at least three (3) years after termination of the last IRB approval period for the activity

The PI Responsibilities: The PI will maintain the following records, which will be accessible for inspection and copying by the IRB and authorized representatives of federal agencies (e.g., HHS and FDA) at a reasonable time and in a reasonable manner:

a. **All records** relating to a specific research protocol, including all informed consent forms and case report forms, which will be kept for

(1) at least three(3) years following completion of the research or,

(2) in the case of research involving minors, seven (7) years after the minor reaches the age of 18, or

(3) at least seven (7) after any child born to the test subject during the research project reaches the age of 18.

b. **All correspondence** with (1) the sponsor; (b) federal agencies (e.g., HHS and FDA), (3) other individuals at NSU or elsewhere participating in the research project.

STUDIES CONDUCTED AT AREA HOSPITALS AND/OR ACADEMIC INSTITUTIONS

If a study is to be conduct at one of the local hospitals or academic institution, the NSU investigator must be certain to receive the appropriate approval form the hospital(s) or other academic institution(s) before initiating the study. If a hospital or other academic institution committee makes a change in a consent form or protocol, that change must be sent to the IRB for review and approval

Sentara hospitals require investigators to submit a statement describing the total impact of the study on the hospital, in addition to, a copy of the protocol, to the Vice President of Medical Affairs. This statement should also be included in the materials submitted to the IRB and will be reviewed only for consistency with the protocol.

For more information on a particular hospital please contact the medical staff offices listed below:

Children's Hospital of the Kings Daughters.....668-7038
DePaul Medical Center.....889-5309
All Sentara Hospitals.....668-3481

For more information on a particular academic institution, contact the research office of the particular academic institution directly.

Note: All questions concerning the research subjects' rights, IRB policy and procedures, and the submission of any information to the Board, should be directed to the Office for Research and at 823-9053.

NORFOLK STATE UNIVERSITY (NSU)

INSTITUTIONAL REVIEW BOARD FORMS

The following forms are provided for use when submitting a new protocol to the IRB for review and for assistance in continuing review of ongoing research studies.

Except for sample or model consent forms, the forms should be utilized as shown and not retyped. Page numbers in the bottom right corner can be omitted.

Please make additional copies as needed.

IRB CHECKLIST FOR SUBMITTING PROTOCOLS

The investigator should submit a total of _____ sets collated in the order below. Each individual set must be bound in some manner such as staples or binder clips.

_____ Sets (certain number of copies plus an original) containing the following materials in the order listed:

- Cover Sheet
- Department Chairperson and Dean Approval Form
- Proposed Advertisements
- Test Subject Consent Form*
- Hospital Impact Statement (for Sentara studies only)
- Complete Protocol (See page 2, item 4)

* (If a waiver of consent is requested, _____ complete sets must be submitted for review)

AND

_____ Sets containing the following materials:

- Cover sheet
- Proposed Advertisement
- Test Subject Consent Form

AND

- Detailed Budget (_____ copies)

All materials must be received by the Office of the Vice-President for Research and Technology before 5:00 p.m. on the _____ day of the month. If complete sets are submitted before the deadline and the information is deemed acceptable by the Office of the Vice President for Research and Technology, the protocol will be included on the agenda for the meeting on the _____ of that month.

PLEASE NOTE: *If materials are to be sent by mail, the package should be mailed several days in advance so that it can be received by the deadline. Packages received after the deadline will not be reviewed until the next months meeting.*

Mailing Address: Office of Research, NSU
Attention: IRB, 210 E. L. Hamm Bldg.
Norfolk, VA 23504

Telephone: (757)-823-9053 **Office Hours:** 9 a.m. to 5 p.m.

Hand Delivery Address:
Same

COVER SHEET

Title of Study: _____

Principal Investigator(s): _____

Department & School: _____

Position _____ Full-Time at NSU? Yes _____ No _____

SSN: _____ Phone: _____

Address: _____

Co-Investigator(s) _____

Coordinator/Contact Person: _____ Phone _____

Site where study will be conducted (if different from address):

Source of Financial Support: _____

Source of Study Subjects: _____

Number of Test Subjects Expected in Study: Local _____ Multisite total _____

Age of Subjects: _____

Duration of Study: Starting Date _____ Ending Date _____

IDE/IND Information: Number _____ Date _____

Is the article FDA approved for this indication? Yes _____ No _____

Department Chairperson and Dean Approval of Research Protocol

Principal Investigator(s): _____

Co-Investigator(s): _____

Study Title: _____

I certify the research protocol, including budgetary information, I am submitting to the Office of the Vice President for Research and technology for Institutional Review Board consideration is a true and accurate representation of my research goals and financial support. I further certify that I, or any of my co-investigators, do not have a financial interest in the described work which is not clearly and completely indicated within the submitted materials. I agree to follow the established guidelines for submission of reports, adverse events, regulatory review, and other related materials in a timely manner.

_____ Date _____ Principal Investigator

I certify _____ I have reviewed the research protocol or _____ it has been reviewed by a member of this Department and School and approve of the procedures outlined for this study. I further certify I believe the investigators named above to be capable of conducting scientific sound research and that they will insure the proper safeguards for the human subjects involved in this study.

I understand if this research protocol is approved by the Institutional Review Board, a report will be required of the principal investigator no later than one year following this approval. The exact time will be determined by the IRB at the time the protocol is reviewed. I further understand when this study is finished or if this principal investigator terminates his/her affiliation with Norfolk State University, it is my responsibility to insure the Institutional Review Board is notified immediately.

_____ Date _____ Chairperson

Typed Name _____ Department _____

_____ Date _____ Dean of School

Typed Name _____ School _____

ASSENT OF THE CHILD

Study Title: _____

Child's Name: _____

I. The person doing this experiment has explained to me what will happen if I take part in this activity. I know that no one will get mad at me if I say no. I agree to be in this experiment. this

Signature of Child Date

Signature of Witness Date

WAIVER OF ASSENT OF THE CHILD

I. I have determined that this child does not have the capacity to give assent because of the following:

Age Maturity Psychological state of the child

Signature of the investigator Date

II. Despite the fact that this child does not wish to participate in this study, it has been determined by both parents and the investigator that it is in the child's best interest to participate in this study.

Signature of the investigator Date

Signature of parent(s) or guardian Date

Signature of parent(s) Date

EMPLOYEE/STUDENT CONSENT FORM ADDENDUM

Study Title _____

Subject _____ Investigator _____

I understand that I am being asked to participate in the above research study which is being conducted at Norfolk State University, where I am an employee or student. The research study has been described to me, in writing, on the attached consent form. I have also had the opportunity to ask the investigators conducting this study any questions that I may have regarding participation in this study.

The purpose of this addendum consent form is to inform me that I have the right to choose not to participate in this research study. If I choose not to participate, or to withdraw at any time, it will not affect my standing as an employee or student.

If I am an employee, I understand that participation will not place me in good favor with the investigator, my supervisor, or NSU (e.g., increase in salary, promotion, extra vacation, or the like). I also understand that not participating will not adversely affect my employment with NSU. In particular, the position I currently hold.

If I am a student, I understand that participating will not place me in good favor with the investigator or other faculty members (e.g., receiving better grades, recommendations, employment). Also, I understand that not participating in this study will not adversely affect my relationship with the investigator or other NSU faculty.

I understand if I suffer a physical injury or illness as a result of participating in this research study I will not receive a financial payment. Treatment for such injury or illness is not covered under Workmen's Compensation. Any immediate emergency medical treatment I may need as a result of participating in this study will be provided as outlined in the attached consent form.

Norfolk State University provides no compensation plan or free medical care plan to compensate me for such injuries. If I believe that I have suffered an injury as a result of my participation in any research program I may contact _____, who will be glad to review the matter with me. I can also discuss any other concerns I may have as a result of participating in this study. Any discussions with _____ will be kept confidential.

My signature below means that I have read the attached subject consent form, as well as this addendum, and freely agree to participate in this study.

Signature of employee/student

Date

I have answered any questions that have been raised and have witnessed the above signature. I also certify that if this employee/student chooses not to participate or withdrawal from this study it will not adversely affect their relationship with the investigators.

Signature of investigator

Date

ADDENDUM CONSENT FORM

Title of Project:

Investigators

Sponsor:

Name of Study Subject: _____

DESCRIPTION: I am currently participating in the above named research study. I am being asked to sign this addendum to the original informed consent because [*insert reason here-including a statement of significant new findings, or additional procedures, potential risks and additional cost/payment*]

All other information provided in the original consent I previously signed will apply to this addendum.

VOLUNTARY CONSENT: I certify that I have read the preceding or it has been read to me and that I understand its contents. If I have any questions pertaining to the research or my rights as a research subject, I may contact the investigators whose names, phone number(s) are listed at the beginning of this addendum. A copy of this form will be given to me. My signature below means that I have freely agreed to continue my participation in this research study.

Signature of participant

Date

Signature of witness

Date

INVESTIGATORS STATEMENT: I certify that I have explained to the above individual the nature and purpose of the study, the potential benefits and possible risks associated with continued participation in this research 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 addendum.

Signature of investigator

Date

SAMPLE CONSENT FORM FOR QUESTIONNAIRE USE

Title:
Investigator:
Sponsor:

I am being asked to participate in a research project involving the collection of information in the form of a questionnaire. The purpose of the research project is to *[fill in a brief description of the project]*. Completion of the questionnaire will approximately _____ minutes/hours of my time.

I understand there are no specific risks related to my participation but there may be other risk not yet identified.

I understand I will (or will not) be reimbursed in the amount of *[insert amount]* for my participation.

Although the results of this research may not benefit me directly, they may be made available upon request. Data collected during the research will be confidential and any publication resulting from this research will not personally identify me. Additionally, I understand I may terminate my participation at any time.

I also understand that in the event of injury resulting from this research procedure, immediate medical treatment will be available to me. I am aware that Norfolk State University provides no financial compensation plan or free medical care.

If I believe that I have suffered a research related injury as a result of my participation in any research project, I may contact _____ Phone _____, an employee of NSU, who will review the matter with me.

Signature of participant

Date

I certify that I have explained to the above individual that nature and purpose of the study, potential benefits, and possible risks associated with participation in the 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

NORFOLK STATE UNIVERSITY CONSENT FORM

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 the Office of the Vice President for Research and Technology at 823-8409.

SUBJECT CONSENT FORM

"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 unacceptable 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 (sponsors 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 future 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].

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 Office of the Vice President for Research and technology, 757-823-8409, who will review the matter with me.

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.

Date

Signature of Participant

Date

Signature of Witness

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 raise and have witnessed the above signature. I have explained the above to the volunteer on the date stated on this consent form.

Date

Signature of investigator

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 the attached form as part of the subject consent form. For age guidelines see page _____ of the NSU Guidelines for Submitting Protocols to the Institutional Review Board.

EMPLOYEE/STUDENTS:

If any participants will be employees or NSU students, then the investigator must attach an "EMPLOYEE/STUDENT CONSENT FORM" (see page _____ of the NSU Guidelines for Submitting Protocols to the Institution Review Board.)

**INSTITUTIONAL REVIEW BOARD
ANNUAL REPORT FORM**
(Required for Continuing Approval)

Principal Investigator: _____ Phone: _____

Financial Sponsor: _____ IRB Number: _____ - _____ - _____

Complete Title (Do Not Abbreviate): _____

The following information is provided for the period _____ to _____
 (Must not exceed 1 year and must be retrospective) MONTH/YEAR MONTH/YEAR

1. Is this research project ongoing at this site? Yes No : _____ / _____ / _____
 Termination Date

2. Do you wish to continue this research study?

Yes Two copies of current consent form must be attached unless study is closed to patient entry.

No This will be considered a closeout report and the file removed from the IRB's active files. (Closure of files must not be performed simply for closure to patient entry!)

3. Have you actively enrolled subjects or collected data for this time interval? Yes No

4. Please provide the following information for this site:

Number of subjects enrolled within the interval described above: _____

Provision of the enrollment numbers for the categories below is a federal requirement.

Gender: Male _____ Female _____

Ethnicity:

Black Non-Hispanic	American Indian/ Alaskan Native	Asian/Pacific Islander
Hispanic	White, non-Hispanic	Other or Unknown

Total number of subjects enrolled since initiation of this trial: _____

Number of subjects actively on protocol at the present time: _____

Number of subjects withdrawn from the study during this interval: _____

Total number of subjects withdrawn from the study since initiation: _____

5. TOTAL number of subjects enrolled across all sites to date: _____

6. Is the protocol closed to patient entry? Yes No

If yes, date of closure: ____/____/____ Closure is: Permanent Temporary

7. Please describe below any medical, legal or practical difficulties that have been encountered in this interval of the study aside from adverse events. Difficulties would include complaints of subjects, logistic problems of performance, or any difficulties that may pertain to the rights of these subjects.

8. Indicate numbers of adverse events encountered during this interval. Provide a brief description of trends (e.g. cardiac, CNS, renal, hepatic). Adverse events must be reported to the IRB within five days of the investigator being notified. If there are events that have not been reported to the IRB attach notification with a brief explanation.

Number of local adverse events: _____ Number of non-local adverse events: _____

9. Has the protocol or consent form changed in any way since the last approval? Yes No
If yes, attach a copy of any amendment(s) not previously submitted.

10. Has any new information become available during the course of the research which may affect the subject's willingness to continue participation in the study? Yes No

If yes, explain:

Was new information provided to subjects? Yes No Attach any written documentation.

11. Is there recent information, especially regarding risks associated with the research, that the IRB should be aware of in conducting the continuing review? Yes No If yes, please attach the pertinent information with a summary.

12. Please provide below, or attach, a brief overview of research results/observations obtained to date. If applicable, include local and multisite information. Include one copy of any publications that have resulted from this research. (THIS SECTION MUST BE COMPLETED)

PRINCIPAL or CO-INVESTIGATOR
(Must be original signature)

DATE

Return to: