

OLD DOMINION UNIVERSITY

Procedures for the Review of Human Subjects Research

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Office of Research

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Table of Contents

I. Introduction	3
II. Definitions	3
III. Researcher Procedures.....	5
IV. College Committee Procedures	9
V. Institutional Review Board Procedures.....	11
VI. Administrator Responsibilities.....	14
VII. College Dean Responsibilities	15
VIII. Footnotes	16

Forms for IRB Submission

Appendix A: Old Dominion University Research Foundation Proposal Transmittal Form.....	17
Appendix B: Application Form for Exempt Research.....	18
Appendix C: Human Subjects Research Review Application.....	22
Appendix D: Sample Informed Consent Document.....	29
Appendix E: Informed Consent Check List.....	31
Appendix F: Request for Waiver of Informed Consent.....	33
Appendix G: Drugs, Agents, and Devices Form.....	34
Appendix H: Biological Materials Form.....	35
Appendix I: Human Subjects Research Progress Report Form.....	36
Appendix J: Human Subjects Research Close Out Report.....	39
Appendix K: Adverse Event Reporting Form.....	41

I. INTRODUCTION

A. Overview: This procedure addresses the use of human subjects in research (hereinafter "human subjects research" or HSR). Both the state and federal governments control human subjects research conducted at Old Dominion University. For federally funded, aided, or "otherwise regulated" human subjects research, Old Dominion University must assure the federal government that it complies with the federal regulations.¹ The University does this on a case basis, using the "Federal-Wide Assurance" method.² If the federal government does not regulate the research, then Virginia law applies.

B. Scope: As a matter of policy, all Old Dominion University faculty, students, staff, and administrators are responsible for protecting the rights and well-being of human subjects of research. The following principles are the basis for Old Dominion University's human subjects research procedure:

(1) All research involving humans as subjects must protect the subjects' safety, privacy, health, and welfare;

(2) The benefit of the research must outweigh the risk to the subjects. For the University, only an authorized University committee may make this determination;

(3) The participation of humans as research subjects shall be voluntary. Voluntary means that the subject has given informed consent. Researchers must document informed consent except where the law explicitly waives such documentation;

(4) A human subject surrenders no rights by participating in research. In no case shall a human subject lose any benefit or entitlement by refusing to participate. In addition, subjects may withdraw from research at any time;

(5) Researchers shall protect private information about human subjects that is obtained in the course of research;

(6) All researchers, whether students, faculty members or staff, shall ensure that research complies with this procedure and all applicable laws, regardless of the location of the research.

C. Updating: In the event of a regulatory or statutory change, then this procedure should be construed to conform to that change. The researcher should bring any change to the attention of the reviewing committee and explain how the research project complies with the new law. All members concerned with HSR shall be familiar with the applicable laws.

II. DEFINITIONS

Caution: Institutions with US Department of Health and Human Services, HHS-approved assurances on file are to abide by provisions of title 45 CFR part 46 subparts A-D. This procedure is provided solely for general guidance and is not an acceptable substitute for the applicable law. Inasmuch as the federal law may define these terms, then that legal definition shall govern unless an applicable state law provides additional protections for human subjects.

A. "College Committee (CC)" means a committee that considers non-federally sponsored human subject research in order to identify and document research proposals that are exempt under the Federal statute.

B. "Exempt" research means that although the research is controlled or governed by an applicable law, the same law specifically exempts research of that type and a committee with jurisdiction over the research found the proposal to satisfy that legal exemption.³

C. "Human Subject Research (HSR)" generally means a systematic investigation designed to expand knowledge by obtaining data from a living individual, using:

(1) an intervention or interaction (i.e. interpersonal contact) between a researcher and another person as a subject; or
(2) the collection of identifiable private information, examples of which include physical procedures such as venipuncture, the observation of behavior while manipulating a person's environment, or a review of personal records.

D. "Institutional Review Board (IRB)" means a federally required committee that reviews research, using federal standards, for the protection of human subjects.⁶

E. "Institutional Review Board Approval" means that the appropriate committee has reviewed a research proposal under the applicable standard and has authorized the research from a human subjects perspective.⁷ Although no Human Subjects Research may proceed without such approval, it does not replace administrative approval of research. As in all cases of research compliance, Human Subjects Research review should follow administrative review.

F. "Jurisdiction" means the legal scope of a committee's authority. The jurisdiction of the IRB is federally sponsored research and all non-exempt research. The jurisdiction of the CC is that non-federally sponsored research exempt from the Federal statute.

G. "Minimal risk" means that the probability and magnitude of harm or discomfort in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. This definition may vary for vulnerable classes of human subjects.⁸

H. "Non-affiliated member" means an IRB member who is not affiliated with or employed by the University, nor part of the immediate family of a person who is affiliated or employed by the University.¹⁰

I. "Otherwise subject to regulation," as a federal term, refers to research that is not conducted or supported by the federal government, but still subject to human subject regulations for a different reason.¹¹ If the federal government has a specific responsibility to regulate a research activity regardless of whether it funds that research, and that research activity also includes HSR, then the HSR is "otherwise subject to regulation." This phrase promotes consistency in HSR whenever the federal government is involved. Examples include cases like the Food and Drug Administration's regulation of new drug investigations, or the Environmental Protection Agency's regulation of new chemicals; incidental regulation such as the Wage and Hour requirements of the Department of Labor does not make research "otherwise subject to regulation."

J. "Regulated research" or "research subject to a particular law" means simply that the law describes itself as applying to or governing research of that type. The federal regulations apply only to research "conducted, supported, or otherwise subject to regulation by any federal department or agency."¹²

K. "Responsible Project Investigator" (RPI) refers to an Old Dominion University faculty or staff member who serves as the project supervisor, assumes responsibility for the research proposal and for ensuring compliance with Federal, State, and University guidelines.

M. "Investigator" refers to individuals who are directly responsible for any of the following: the project's design, implementation, consent process, data collection, and/or data analysis. Investigators include faculty members, students, administrators, and staff.

N. "Researcher" refers to any individual affiliated with the research project, including the RPI and investigators.

O. "Support" means any involvement, including assistance such as the mere provision of data.

III. RESEARCHER PROCEDURES

A. Background: Responsible Project Investigators (RPI) bear the primary responsibility for compliance with all applicable laws and regulations. **All of the University's HSR is governed by the federal laws and regulations.**

The federal regulations are at 45 CFR §§ 46.101-409.¹³ A variety of federal agencies are authorized to issue their own HSR regulations, with perhaps the most prominent being the Food and Drug Administration's regulation of clinical investigations involving new drugs or food additives, 21 C.F.R. § 50 et seq. (under the Federal Food, Drug, and Cosmetic Act). However, many agencies have sought consistency in HSR regulation by adopting the "common rule" or "federal policy" that is described in the HHS regulations; these agencies are:

Central Intelligence Agency: Executive Order 12333

Consumer Product Safety Commission: 16 CFR § 1028

Department of Agriculture: 7 CFR § 1c

Department of Commerce: 15 CFR § 27

Department of Defense: 32 CFR § 219

Department of Education: 34 CFR §97

Department of Energy: 10 CFR § 745

Department of Housing and Urban Development: 24 CFR § 60

Department of Justice: 28 CFR § 46

Department of Transportation: 49 CFR § 11

Department of Veterans Affairs: 38 CFR § 16

Environmental Protection Agency: 40 CFR § 26

National Aeronautics and Space Administration: 14 CFR § 1230

National Science Foundation: 45 CFR § 690

Social Security Administration: Public Law 103-296

The RPI is strongly advised to be aware of any deviations between sponsoring federal agencies in order to fully comply with all requirements. For student research, the responsible project investigator bears a supervisory responsibility for the conduct of the HSR and compliance with this procedure.

B. Scope: This procedure applies to all Human Subject Research projects. Failure to comply may result in administrative review of the project and a suspension of IRB approval. In addition, failure to comply with federal regulations may jeopardize present and future funding.

C. Project Design Considerations: Researchers should consider human subjects issues during the design of research projects. Effort invested at this stage of the research will reap rewards during the review and execution stage. On the other hand, a research project designed without consideration of human subjects issues may be unnecessarily risky and face difficulties and delay in the review process. Even a project with minimal risk must have benefits that outweigh the low level risks identified and every precaution taken to ensure that participants will not feel pressured to participate.

For example, minimizing risk to human subjects is a basic objective; not only will this benefit the human subjects, but it can also simplify the research protocols and possibly the review process. Certain types of research that pose little risk to human subjects are deemed exempt by 45CFR46. Researchers will find that the review process is easiest if they are able to design their project so that it is likely to be found exempt by the responsible committee. At the same time, the risk to human subjects will be minimized. Even if an exemption is not available, attention to human subject issues in the design of research can expedite the IRB process. If the identity of subjects in a non-exempt project is not important, then anonymous data collection and coding of the data may protect the subjects from the risk of disclosure and avoid more complicated steps to ensure confidentiality.¹⁴ Note, however, that only the IRB is institutionally authorized to assess the risks and benefits of a particular non-exempt project.

D. Research Practica: This involves classroom research activities designed to provide instruction or training in research methods. Faculty members often assign Research Practica as student projects in order to demonstrate research methods, techniques, and strategies. Research Practica can include student class projects conducted under faculty supervision or other “hands-on” classroom activities. Because of the participation of others and the collection of data, such activities are best treated as HSR. Even though the data gained may be used solely to demonstrate the ability to perform a particular research method, all researchers must still adhere to University procedure.

The “lead” faculty member is the responsible project investigator. Thus the faculty member must act as the lead researcher and ensure that all student researchers comply with applicable laws and this procedure. Where possible and appropriate, student projects should be designed to meet an exemption under the applicable law (e.g., surveys of anonymous human subjects with no linking identifier from data to the human subject, or limiting survey data to non-sensitive topics with no other risk [see IV.B.(2)(a)§(b)]). If an instructor agrees to award extra credit for student participation as human subjects of research, an alternate means of earning equivalent extra credit for an equivalent commitment of effort should be made available to students. Any faculty member who uses human subjects in a research practicum or student project must apply for review and approval by his/her College Committee or the IRB.

If a degree seeking student at ODU is employed through another agency such as EVMS and no faculty member is involved from ODU then the degree seeking student that is an employee at EVMS or any other agency that has an IRB should seek approval through that agency's IRB and not ODU's IRB.

If a degree seeking student at ODU works for EVMS and an ODU faculty member is involved from ODU for purposes of theses or dissertations then the student has the option to seek approval through either IRB, not limiting where he/she can get approval as long as it has been approved. However, the ODU IRB will need to provide the expedited approval if the study has already been approved outside ODU's IRB.

E. Applications: In order to ensure full compliance, the RPI shall direct the completion of the Human Subject Research Review Application Form (see Appendix C) and submit this application, an informed consent document (see Appendix D), and all protocols to the appropriate review board no later than one week prior to the next meeting. The RPI must document completion of NIH Training (<http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>). A copy of the RPI's NIH Certificate for Human Participant Protections Education for Research Teams **must** be included with the IRB application. RPIs must complete the NIH training within one year of each application submission. Incomplete applications may delay review.

In addition RPI's who propose studies with patient populations are required to document HIPPA training. RPIs **must** access the NIH booklet entitled “Protecting Personal Health Information in Research: Understanding the HIPPA Privacy Rule” at http://privacyruleandresearch.nih.gov/pr_02.asp, and must submit an attachment to the review application stating that the material has been read and will be adhered to in the proposed research. The attachment **must** include the date the material was read, which must be within the 12 months prior to the application.

For externally funded grants, researchers must complete an Old Dominion University Research Foundation Proposal Transmittal Form (Non-Standard Proposal), taking care to complete the form and choose the correct special review category. See Appendix A.

(1) Researchers who believe their study is not federally regulated and exempt from state law (see section IV below) shall complete an application for exempt research. See Appendix B for the Application Form for Exempt Research.

(2) All others must complete the Human Subject Research Review Application Form. See Appendix C.

- (a) The responsible project investigator, or a member of the research team familiar with the project, should attend review board meetings.
- (b) The responsible project investigator, or member of the research team, shall submit at least ten (10) copies of the entire proposal and at least ten (10) copies of the proposed informed consent document.

F. Informed Consent: Researchers shall give human subjects enough information in plain, easily understandable wording, to enable the subject to give informed consent. The standards of informed consent may vary depending on the applicable law. See 45 CFR 46.116. Studies involving special or vulnerable populations (e.g., children, pregnant women, fetuses, prisoners, disabled persons, etc.) must conform to the appropriate informed consent standards for that population.¹⁵ Some of the basic elements of informed consent are:

(1) A plain language, jargon-free description of the research project including:

- (a) a brief statement that the subject will be involved in research;
- (b) the purposes of the research;
- (c) the expected duration of the subject's participation;
- (d) the procedures to be followed and whether any of the procedures are experimental;
- (e) any generally accepted alternatives to experimental procedures;

(2) A clear explanation that the subject's participation is voluntary and that there will be no retaliation for refusal or withdrawal;

(3) A description of any direct benefits to the subject, but may include the general benefits of research if so noted. The potential advancement of knowledge should not be considered a direct benefit to the subject. If applicable, include any alternatives to the research by which the subject might gain the same benefit;

(4) A description of how the researcher will handle the data and, if applicable, what actual steps the researcher may take to keep records confidential; and

(5) For research involving more than minimal risk, a description of any compensation and whether the researcher is able to pay for medical care in the event of injury. In addition, the researcher should describe how to get more information about the HSR project and their rights as human subjects.¹⁶

Caution: This is a condensed explanation; researchers must be familiar with the applicable regulations. Researchers should refer to the sample informed consent documents and the specific statutory requirements. See Appendices D, E & F.

G. Informed Consent Exemptions: In certain cases, a researcher may ask the IRB for an exemption from the requirement of a signed informed consent document. This may be appropriate for research involving minimal risk and when the following conditions exist:

(1) The research comprises an anonymous (no means of identifying subjects) mailed questionnaire or randomly dialed telephone interviews; and

(2) The only record linking the subject and the research would be the signed consent document and the principal risk would be potential harm resulting from a breach of confidentiality.¹⁷

H. Request for Waiver of Informed Consent: Researchers requesting a waiver of informed consent or a waiver of the consent procedure requirement to include all or alter some or all of the elements of informed consent must complete the Request for Waiver of Informed Consent (See Appendix F). The IRB may consider a waiver or alteration of the informed consent requirement only if all four of the following are true:

(1) The research involves no more than minimal risk to the subjects;

(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;

(3) The research could not practicably be carried out without the waiver or alteration; and

(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

I. Drugs, Devices, and Agents: Research involving the use of drugs, chemicals, nonhuman biological agents, or devices, is subject to Food and Drug Administration (FDA) regulations. Researchers planning to use these agents or devices in human subjects research must complete the Drugs, Agents, and Devices Form (See Appendix G) and include it with the original IRB application, as applicable.

J. Biological Materials: Researchers planning to collect, analyze, or bank human cells, tissues, fluids, DNA or other human biological samples (existing or to be collected) as part of the research must complete the Biological Materials Form and include it with the IRB Application (See Appendix H).

K. Disapproved Projects: If a research project has been disapproved by any committee, and the RPI feels that the project complies with the applicable law, then the RPI may reapply to the disapproving committee, including a detailed, written explanation of how the research project does, in fact, comply. The committee's application of the governing law, however, is in no way limited by this process.

M. Continuing Review: Approvals expire after one year. Following initial approval, the RPI must seek review for projects that last longer than a year. Additionally, the RPI must ensure that progress reports are submitted more frequently if mandated by the IRB.¹⁸

(1)For projects that last longer than a year, the researcher shall forward 10 copies of a "Human Subjects Research Progress Report" (see Appendix I). This report should be submitted no later than two months prior to the anniversary of the initial approval. This allows the IRB to review the project well before it expires, thus avoiding an interruption in research. Failure to seek annual review may jeopardize present and future projects. If the study is active/open to subject

enrollment, researchers should submit one copy of the currently approved Informed Consent Document (but without the IRB stamp) with each report (two copies with the original). If any changes to the protocol or the consent form are being requested at the time of this continuing review, submit a cover letter indicating the requested changes, and submit the new informed consent document in place of the previously approved version.

(2) If a research proposal was authorized by expedited review [see V(E)], the researcher shall submit a research Progress Report and an approval (to continue the study) letter from the primary reviewing board no later than one month prior to the anniversary date of project approval.

(3) The researcher shall complete a Progress Report at more frequent intervals if mandated by the IRB.

N. Project Close Out: Upon completion of a project, the RPI shall provide the IRB with a Close out Report. A Close Out report should be submitted when **data collection and data analysis are complete**. See Appendix J. The report is due to the Office of Research no later than one month (30 days) after the project is complete.

O. Reporting of Adverse Events:

(1) Adverse events experienced by research subjects must be reported to the IRB in a timely manner. The procedures vary based on the nature of the event, whether serious, unexpected, both or neither.

An adverse event is any injury, trauma, or illness experienced by a subject that required medical or psychological treatment. If such events are brought to the attention of the researcher, even if they appear to be unrelated to the protocol, then the researcher will report them as outlined below.

A serious adverse event is an event that results in any of the following outcomes: death, a life threatening situation, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect.

An unexpected adverse event is any adverse event, the specificity or severity of which is not listed in the current informed consent.

(2) An adverse event that is serious must be reported to the IRB within 5 business days of the researcher becoming aware of it. Using the Adverse Event Reporting Form (Appendix K), the researcher describes the nature of the event, the medical treatment that the subject received, the likelihood that the event was related to the research protocol, and any changes in the protocol or informed consent that the researcher feels may be needed to protect other subjects. A consulting physician (the attending physician, or a physician provided through the Office of Research) must also comment on the severity of the event and the likelihood that it was related to the protocol.

(3) Unexpected adverse events must also be reported to the IRB within 5 business days of the researcher becoming aware of them, using the Adverse Event Reporting Form. However, if the event is not serious, a consulting physician is not required.

(4) Adverse events that are neither serious nor unexpected in the view of the researcher must be reported to the IRB using the Adverse Event Reporting Form within one month of the researcher becoming aware of them. A consulting physician is not required.

(5) All adverse events, whether serious, unexpected or neither, must be reported at the time of continuing review, using the Human Subjects Research Progress Report Form.

IV. COLLEGE COMMITTEE PROCEDURE

A. Introduction: The role of the College Committee (CC) is to determine whether research that is not federally regulated is "exempt" under the Federal law. In general, exempt HSR poses little risk.

B. Jurisdiction: The CC shall not review proposals that are federally regulated. CC jurisdiction is further limited to proposals that fit into one of the following exempt categories under the Federal law:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt, if: (i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of [federal] department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Special Note: These exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization, subparts B and C. The exemption at 45CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Caution: CC members shall rely on current versions of the Federal statute. The above exemptions were current at the time of issuance of this procedure.

C. Composition: The Dean of the College appoints the members and Chairperson of the CC in accordance with section VII of this procedure. CC's shall have at least three (3) members. Members shall be familiar with, and have copies of, the relevant federal regulations.

D. Responsibilities: The responsibilities of the CC include:

(1) Each member of the CC is charged with the responsibility to be reasonably knowledgeable about the applicable laws and to be reasonably diligent in investigating and reviewing HS Research under the CC's jurisdiction.

(2) The CC shall meet at least once an academic year, although the CC may meet more frequently. The CC shall publicize the date, time and place of its scheduled meetings. At this meeting, the CC shall consider, among other things, its execution of these responsibilities over the past year.

(3) The CC shall maintain a standard application form: Application For Exempt Research (See Appendix B) by which the Researcher provides a written statement about the research. This form shall identify the exempt categories and provide space for the researcher to describe the study.

(4) The CC shall evaluate the entire research proposal, including surveys, questionnaires, and any other related documents.

(5) The CC shall explicitly identify the appropriate exemption. It shall pay close attention to guarantees of anonymity, security of potentially damaging information, and other risks.

(6) The CC shall promptly notify the Researcher of its decision or requirements for modifications.

(a) Negative decisions should explain why the proposal was considered not exempt;

(b) The CC shall forward a final written notification to the Researcher.

(c) The CC shall refer researchers with non-exempt projects to the appropriate committee.

(7) The CC shall reevaluate any proposal in which one of the following conditions occur:

(a) Substantial changes in the protocol;

(b) Emergence of problems or unexpected deviations in the HS Research that would alter the exempt status; or

(c) Development of hazardous conditions for the subjects.

(8) College Committees shall keep the following records in a secure location, accessible by the Dean of the College, for at least three (3) years:

(a) The names and occupations of committee members;

(b) The names of the reviewing members;

(c) One copy of each proposal reviewed.

(d) A description of the proposal, the decision of the CC and an explanation of why the research was found unregulated or exempt.

(9) A summary of proposals reviewed shall be forwarded to the Dean of the College and the IRB Chair annually. The summary shall include at least such information as the name of the RPI, the research title, whether the research was found exempt (and under which category), and the research end date.

(10) The CC shall grant an exemption only upon a unanimous vote of its members (no fewer than three members reviewing). The CC shall resolve any uncertainty about a proposal in favor of denying the exemption and submitting the proposal to the IRB Chair.

V. INSTITUTIONAL REVIEW BOARD PROCEDURES

A. Introduction: The role of the Institutional Review Board (IRB) is to review all non-exempt research and exempt research that is federally supported. In addition, the IRB reviews exempt research when there is no College Committee (CC) to consider it.

B. Jurisdiction:

(1) Federal regulations apply "to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency."²⁶

(2) Except for those categories specifically exempted or waived under 45 CFR §§ 46.101(b)(1-6) or 101(i) all federally supported, funded, or otherwise regulated research shall be reviewed and approved by the IRB. HSR shall not be permitted until the IRB has reviewed and approved the research protocol and Informed Consent Document has been obtained from the subject or the subject's legal representative.²⁷ Exempt research must be appropriately documented as such.

(3) The IRB review shall comply with applicable federal regulations and the provisions of this procedure for each project.

C. Composition:

(1) The IRB shall have at least five (5) members appointed by the Vice President for Research in accordance with section VII B(4). No member directly involved in a particular HSR project or the administrative approval of an HSR project can participate in the review of that project. The IRB shall have members of varying backgrounds to promote complete and adequate review of research activities. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.

(2) The IRB shall meet not less than quarterly, and may meet more frequently as required. Official meetings shall not begin until at least a majority of members, including at least one member whose primary concerns are in nonscientific areas and at least one whose primary concerns are in scientific areas are present. The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. In some cases, the sponsoring federal agency may permit the IRB to review HSR involving vulnerable subjects such as the handicapped, pregnant, prisoners, children, or mentally disabled persons only when the IRB membership is supplemented by at least "one person primarily concerned" with the welfare of such persons.²⁹

D. Scope of Review: The IRB shall review the HS Research proposal and give proper consideration to:

(1)The potential for satisfaction of a regulatory exemption;

(2) The risks to the subjects;

(3) The anticipated benefits to the subjects and others;

(4) The importance of the knowledge that may reasonably be expected; and

(5) The informed consent process.

E. Responsibilities: The responsibilities of the IRB include:

(1) Each member of the IRB is charged with the responsibility to be reasonably knowledgeable about the applicable laws and to be reasonably diligent in investigating and reviewing HS Research under the IRB's jurisdiction. Each member shall document completion of NIH training. IRB members are encouraged to read the IRB Guidebook.³⁰

(2) The IRB shall review, and have the authority to approve, require modification in, or disapprove all research activities under its jurisdiction, including proposed changes in previously approved human subject research. For approved research, the IRB shall determine which activities require continuing review more frequently than every twelve months or need verification that no changes have occurred if there was a previous IRB review and approval.

(3) The IRB shall provide written notice of its decisions and requirements for modifications to the researcher. Written notification of decisions to disapprove shall be accompanied by reasons for the decision. Certification of IRB review and approval for all federally sponsored research involving human subjects will be forwarded to the appropriate federal department or agency by IRB coordination with the Office of Research grant manager or the Old Dominion University

Research Foundation Contracting Officer, as appropriate. Compliance shall occur within the time and in the manner prescribed for forwarding certification of IRB review to HHS or other applicable federal agency.

(4) IRB review of non-exempt projects shall include the following:

(a) The IRB shall ensure that legally effective informed consent will be obtained and documented in a manner that satisfies federal regulations. The IRB may observe or have a third party observe the consent process.³¹

(b) The IRB shall evaluate whether the protections for human research subjects are adequate, in accordance with the criteria found at 45 CFR 46.111.

(c) Where appropriate, the IRB shall determine that adequate additional protections are ensured for fetuses, pregnant women, prisoners, and children, as required by Subparts B, C, and D of 45CFR46. The IRB shall notify the Office of Protection from Research Risks promptly when IRB membership is modified to satisfy 45 CFR 46.304 (studies involving prisoners.)

F. Expedited Review: The Chair (or one or more experienced reviewers designated by the Chairperson) may engage in expedited review procedures for certain kinds of research involving no more than minimal risk and for minor changes in approved research in accordance with 45CFR 46.110.

G. Continuing Review: The IRB shall require periodic reports from approved projects to ensure that the project is in compliance. At a minimum, continuing review shall comprise an evaluation of a Close out Report (CR) or any Human Subjects Research Progress Reports (RPR) required during the initial review, including any available study-wide findings.³²

IRB approval authority extends for only one year. The frequency of continuing review shall be no less than annual. The Human Protections Administrator (HPA) will send the Responsible Project Investigator (RPI) a written notice of a required continuing review at least two months prior to the date of expiration. However, notwithstanding the notice attempt, timely Continuing Reviews and IRB approvals are the responsibility of the RPI

(1) Continuing Reviews shall be commensurate with the overall risk to the subjects. For example, a brief HSR project involving more than minimal risk, but few subjects might merit less burdensome continuing review than a long HSR project involving more than minimal risk and many subjects. Thus, the factors of consideration in determining the overall risk to the subjects may include project duration, size and nature of the subject population, intrusiveness, deviation from minimal risk, experience of the researcher, location, and general level of acceptance of the research practices. Any member of the IRB may call for the emergent review of a project upon learning of any HSR non-compliance or injury to a human subject under the IRB's jurisdiction.

(2) The IRB shall terminate a project if neither an RPR nor a CR is received by the anniversary of approval.

(3) If an RPR is late, the IRB shall notify the researcher that failure to comply with the reporting requirement prompted a withdrawal of IRB approval for the project and a termination of the research project. The IRB may require the RPI to submit either a CR and/or all missing RPR(s). In addition, the IRB may suspend any other HSR or pending applications associated with that researcher.

H. Review of Adverse Event Reports:

(1) Adverse events that are serious or unexpected will be reported to the IRB chair by the researcher within 5 business days of the researcher becoming aware of them. If the chair judges that such serious adverse events may be related, or are likely related, to the research protocol, then the chair will report the event to the full board at its next meeting or, if there is reason to suspect increased risk to other subjects prior to the next regularly scheduled meeting, call an emergency meeting of the board. The board will review the risks and benefits of the research protocol and consider changes in the protocol, changes in the informed consent and possible suspension or termination of the research. The findings of the board will be forwarded to the Human Protections Administrator, the federal Office of Human Research Protections and, if applicable, the sponsor.

(2) If the chair judges that a serious or unexpected adverse event is unlikely related to the protocol, then the event will be reported to the full board at its next meeting and the researcher's report along with the chair's finding will be forwarded to the Human Protections Administrator and be filed.

(3) Adverse events that are neither serious nor unexpected will be reported to the IRB chair by the researcher within one month of the researcher becoming aware of them. Such reports will be forwarded to the Human Protections Administrator and be filed.

(4) In addition to the prompt submittal of the required Adverse Event Report Form (Appendix K), adverse events must also be reported by the researcher as part of the continuing review, using the Progress Report Form. The Human Subjects Research Progress Report form will summarize all adverse events of any nature that had occurred in the reporting period. This report will be reviewed by the full board at the time of continuing review so that the board may review the risks and benefits of the research protocol and consider changes in the protocol, changes in the informed consent and possible suspension or termination of the research.

(5) IRB approval shall become effective when the appropriate federal department or agency receives assurance of the IRB review.³³

Caution: IRB members shall rely on current versions of the federal regulations. The above requirements were current at the time of issuance of this procedure.

VI. ADMINISTRATOR RESPONSIBILITIES

RESEARCH ADMINISTRATOR (RA)

A. Introduction: The Old Dominion University Research Administrator (RA) serves as the administrator responsible for oversight of the humans subjects review process. The Vice President for Research shall serve as the RA. The RA shall maintain records regarding research compliance issues. The RA serves as the Signatory Official for the IRB with legal authority to represent the University. The RA is the institutional official responsible for ensuring compliance with all Human Subject Research regulations and statutes.

B. Responsibilities:

- (1) The Vice President for Research shall supervise the overall execution of this procedure.
- (2) The RA is responsible for ensuring constructive communication among administrators, deans, researchers, human subjects, and regulators as a means safeguarding of the rights and welfare of human subjects. The RA sets the tone for the University's culture of respect for human subjects and facilitates participation in human subject education activities.
- (3) The RA shall periodically review federal and state regulations and maintain this procedure accordingly.
- (4) The RA shall ensure adequate IRB membership. The RA shall appoint the members of the IRB, with the assistance of the Deans, in compliance with federal requirements.³⁶
- (5) For all federally regulated research, the RA shall report promptly to the IRB, the Provost, the Deans, the National Institutes for Health, Office for Human Research Protections (OHRP), or other sponsoring federal entity:
 - (a) any injuries to human subjects or other unanticipated problems involving risks to subjects or others,
 - (b) any serious or continuing noncompliance with the regulations or requirements of the IRB, and
 - (c) any suspension or termination of IRB approval for research.
- (6) At a minimum, the RA shall maintain federal research records for at least three years after completion of the research activity.
- (7) The RA shall make reports required by VA. CODE § 27-9.2:3.3. A copy of this report shall be forwarded to the State Council of Higher Education.
- (8) The RA may initiate the promulgation of implementing regulations supporting this procedure in accordance with VA. CODE § 32.1-162.20.
- (9) The Vice President for Research may initiate the process of establishing an MPA.

HUMAN PROTECTIONS ADMINISTRATOR (HPA)

The Human Protections Administrator assists the RA on a day-to-day basis and has a comprehensive knowledge of all aspects of the University's systematic protections for human subjects. The HPA is responsible for ensuring appropriate oversight the HSR program.

VII. COLLEGE DEAN RESPONSIBILITIES

A. Introduction: The Deans are responsible for ensuring that research conducted in their College complies with federal and state laws governing HSR.

B. Responsibilities: The Deans shall have the following responsibilities:

(1) Determining whether or not, according to the amount of HS Research the college conducts, their college requires a College Committee. If the Dean desires not to empanel a CC, then the Dean shall arrange beforehand to send exempt proposals to another college's CC and notify the RA and the IRB Chair in writing;

(2) Appointing the members and chair of the CC. Supervise the proper operation of the CC and the documentation of its findings;

(3) Providing adequate administrative support, meeting space, and sufficient staff for the CC and/or IRB;

(4) The Deans of Colleges shall each year prior to July 1, nominate a faculty member to the Vice President for Research to become a member of the University's IRB and/or CC.

(5) Given the current CC and IRB memberships, each Dean shall identify IRB and CC nominees in accordance with the Federal statute:

(a) Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas...[e]very nondiscriminatory effort shall be made to ensure that no IRB consists entirely of men or entirely of women...[n]o IRB may consist entirely of members of one profession....³⁴

(b) The IRB and CC shall be composed of representatives from varying backgrounds to ensure the competent, complete, and professional review of human research activities conducted or proposed to be conducted or authorized by the institution or agency.³⁵ Thus, nominees shall come from varying backgrounds and have experience and expertise sufficient to understand the ethical standards, legal requirements, institutional constraints, and any other factors, which may contribute to a determination of the risks and benefits to subjects.

VIII. FOOTNOTES

- 1 45 C.F.R § 46.101(a).
- 2 45 C.F.R. § 46.103(a).
- 3 45 C.F.R. § 46.101(b); VA. CODE § 32.1-162.17.
- 4 45 C.F.R. § 46.102 (d),(f); VA. CODE § 32.1-162.16.
- 5 VA. CODE § 32.1-162.19.
- 6 45 C.F.R. § 46.102 (g).
- 7 45 C.F.R. § 46.102 (h); VA. CODE § 32.1-162.19(b).
- 8 45 C.F.R. § 46.102(i); VA. CODE § 32.1-162.16.
- 9 45 C.F.R. § 46.103.
- 10 45 C.F.R. § 46.107(d).
- 11 45 C.F.R. § 46.102(e).
- 12 45 C.F.R. § 46.102(e); VA. CODE § 32.1-162.20. As stated in the sample MPA offered by HHS, "MPA institutions generally elect to comply with all Subparts of 45 CFR 46 for any research conducted under their auspices (i.e., regardless of the source of support). When an institution has elected to abide by 45 CFR 46, regardless of the source of support, all Subparts of 45 CFR 46 are applicable to research even if it is not federally sponsored or sponsored by Federal departments or agencies other than DHHS."
- 13 Both laws were available on the Internet upon issuance of this procedure. The Virginia Code was available at the General Assembly pages <http://leg1.state.va.us/000/src.htm> and the Code of Federal Regulations was available at <http://www.gpo.ucop.edu:80/search/cfr.html>.
- 14 Note that satisfying an HSR exemption does not remove all regulatory requirements. For example, the U.S. Dep't of Education mandates prior consent and access to instructional material for certain experimental teaching methods. 37 C.F.R. § 98.1-98.10.
- 15 45 C.F.R. § 46.207 (pregnant women); 45 C.F.R. § 46.208- 210 (fetuses); 45 C.F.R. § 46.304-306 (prisoners); 45 C.F.R § 403-409 (children).
- 16 45 C.F.R. § 46.116; VA. CODE § 32.1-162.18.A.
- 17 45 CFR § 46.116 (c); VA. CODE § 32.1-162.18.C.
- 18 45 C.F.R. § 46.109(e); VA. CODE § 32.1-162.19.B.
- 19 VA. CODE § 32.1-162.17.
- 20 Upon issuance of this procedure, the Virginia Code was available on the internet at <http://leg1.state.va.us/000/src.htm>.
21 Id.
- 22 VA. CODE § 32.1-162.19.A.
- 23 VA. CODE § 32.1-162.19.B.
- 24 VA. CODE § 32.1-162.19.C.
- 25 VA. CODE § 32.1-162.19.B.
- 26 45 C.F.R. § 46.101.
- 27 45 C.F.R. §§46.111, 46.116, and 46.117.
- 28 45 C.F.R. § 46.108(b).
- 29 45 C.F.R. § 46.107. IRB Membership.
- 30 Protecting Human Research Subjects, Dep't Of Health And Human Services, Office For Protection From Research Risks (1993).
- 31 45 C.F.R. § §46.116 -117.
- 32 45 C.F.R. § 46.109(e).
- 33 45 C.F.R. § 46.119.
- 34 45 C.F.R. § 46.107(a-f).
- 35 VA.CODE § 32.1-162.19.A.
- 36 See supra, notes 34 and 35.

APPENDIX A
OLD DOMINION UNIVERSITY
RESEARCH FOUNDATION PROPOSAL TRANSMITTAL FORM

**The most updated version of this form can be downloaded from the
Old Dominion University Research Foundation:**

<http://www.researchfoundation.odu.edu/forms.htm>

APPENDIX B
OLD DOMINION UNIVERSITY
APPLICATION FOR EXEMPT RESEARCH

Note: For research projects regulated by or supported by the Federal Government, submit 10 copies of this application to the Institutional Review Board. Otherwise, submit to your college human subjects committee.

Responsible Project Investigator (RPI)

The RPI must be a member of ODU faculty or staff who will serve as the project supervisor and be held accountable for all aspects of the project. Students cannot be listed as RPIs.

First Name:	Middle Initial:	Last Name:
Telephone:	Fax Number:	E-mail:
Office Address:		
City:	State:	Zip:
Department:	College:	
Complete Title of Research Project:		Code Name (One word):

Investigators

Individuals who are directly responsible for any of the following: the project's design, implementation, consent process, data collection, and data analysis. If more investigators exist than lines provided, please attach a separate list.

First Name:	Middle Initial:	Last Name:
Telephone:	Fax Number:	Email:
Office Address:		
City:	State:	Zip:
Affiliation:	<input type="checkbox"/> Faculty <input type="checkbox"/> Graduate Student <input type="checkbox"/> Undergraduate Student <input type="checkbox"/> Staff <input type="checkbox"/> Other	
First Name:	Middle Initial:	Last Name:
Telephone:	Fax Number:	Email:
Office Address:		
City:	State:	Zip:
Affiliation:	<input type="checkbox"/> Faculty <input type="checkbox"/> Graduate Student <input type="checkbox"/> Undergraduate Student <input type="checkbox"/> Staff <input type="checkbox"/> Other	

List additional investigators on attachment and check here:

Type of Research

1. This study is being conducted as part of (check all that apply):

- | | |
|--|--|
| <input type="checkbox"/> Faculty Research | <input type="checkbox"/> Non-Thesis Graduate Student Research |
| <input type="checkbox"/> Doctoral Dissertation | <input type="checkbox"/> Honors or Individual Problems Project |
| <input type="checkbox"/> Masters Thesis | <input type="checkbox"/> Other _____ |

Funding

2. Is this research project externally funded or contracted for by an agency or institution which is independent of the university? Remember, if the project receives ANY federal support, then the project CANNOT be reviewed by a College Committee and MUST be reviewed by the University's Institutional Review Board (IRB).

- Yes (If yes, indicate the granting or contracting agency and provide identifying information.)
- No

Agency Name:

Mailing Address:

Point of Contact:

Telephone:

Research Dates

3a. Date you wish to start research (MM/DD/YY) _____ / _____ / _____
3b. Date you wish to end research (MM/DD/YY) _____ / _____ / _____

Human Subjects Review

4. Has this project been reviewed by any other committee (university, governmental, private sector) for the protection of human research participants?

- Yes
- No

4a. If yes, is ODU conducting the primary review?

- Yes
- No (If no go to 4b)

4b. Who is conducting the primary review?

5. Attach a description of the following items:

- Description of the Proposed Study
- Research Protocol
- References
- Any Letters, Flyers, Questionnaires, etc. which will be distributed to the study subjects or other study participants
- If the research is part of a research proposal submitted for federal, state or external funding, submit a copy of the FULL proposal

Note: The description should be in sufficient detail to allow the Human Subjects Review Committee to determine if the study can be classified as EXEMPT under Federal Regulations 45CFR46.101(b).

Exemption categories

6. Identify which of the 6 federal exemption categories below applies to your research proposal and explain why the proposed research meets the category. Federal law 45 CFR 46.101(b) identifies the following EXEMPT categories. Check all that apply and provide comments.

SPECIAL NOTE: The exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

(6.1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Comments:

(6.2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

Comments:

(6.3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) The human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Comments:

(6.4) Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Comments:

(6.5) not applicable

(6.6) Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Comments:

PLEASE NOTE:

1. You may begin research when the College Committee or Institutional Review Board gives notice of its approval.
2. You MUST inform the College Committee or Institutional Review Board of ANY changes in method or procedure that may conceivably alter the exempt status of the project.

Responsible Project Investigator ([Must be original signature](#))

Date

APPENDIX C
OLD DOMINION UNIVERSITY
HUMAN SUBJECT RESEARCH REVIEW APPLICATION FORM

Responsible Project Investigator (RPI)

Responsible Project Investigator: The RPI must be a member of ODU faculty or staff who will serve as the project supervisor and be held accountable for all aspects of the project. Students cannot be listed as RPIs.

First Name:	Middle Initial:	Last Name:
Telephone:	Fax Number:	E-mail:
Office Address:		
City:	State:	Zip:
Department:	College:	
Complete Title of Research Project:		Code Name (one word):

Investigators

If more investigators exist than lines provide, please attach a separate list.

Investigator(s): Individuals who are directly responsible for any of the following: the project's design, implementation, consent process, data collection, and/or data analysis.

First Name:	Middle Initial:	Last Name:
Telephone:	Fax Number:	Email:
Office Address:		
City:	State:	Zip:
Department:	College:	

Affiliation: Faculty Graduate Student Undergraduate Student
 Staff Other _____

First Name:	Middle Initial:	Last Name:
Telephone:	Fax Number:	Email:
Office Address:		
City:	State:	Zip:
Department:	College:	

Affiliation: Faculty Graduate Student Undergraduate Student
 Staff Other _____

List all information for additional investigators on attachment and check here:

Type of Research

1. This study is being conducted as part of (check all that apply):

- | | |
|--|--|
| <input type="checkbox"/> Faculty Research | <input type="checkbox"/> Non-Thesis Graduate Student Research |
| <input type="checkbox"/> Doctoral Dissertation | <input type="checkbox"/> Honors or Individual Problems Project |
| <input type="checkbox"/> Masters Thesis | <input type="checkbox"/> Other _____ |

Funding

2. How is the research project funded?

- Research is not funded (**go to 3**)
- Research is funded (**go to 2a**)
- Funding decision is pending (funding decision has not been made) (**go to 2a**)

2a. What is the type of funding source? (Check all that apply)

- Federal Grant or Contract

Agency Proposal Number _____

Grant Start Date (MM/DD/YY) _____ Grant End Date (MM/DD/YY) _____

- State or Municipal Grant or Contract

- Private Foundation

- Corporate contract

- Other (specify): _____

2b. Who is the point of contact at the funding source?

Name:

Mailing Address:

Telephone:

Email:

Research Dates

3a. Date you wish to start research (MM/DD/YY): ____ / ____ / ____

3b. Date you plan to end research (MM/DD/YY): ____ / ____ / ____ (End date for data collection and analysis)

Note: Protocols are approved for a maximum of 1 year. If a proposed project is intended to last beyond the approval period, continuing review and reapproval are necessary.

Research Location

4. Where will the experiment be conducted? (Check all that apply)

- On Campus (Building and Room Number)
- Off-Campus (Street Address)

Human Subjects Review

5. Has this project been reviewed by any other committee (university, governmental, private sector) for the protection of human research subjects?

- Yes
- No (**If no, go to 6**)

5a. If yes, is ODU conducting the "primary" review?

- Yes
- No (**If no, go to 5b**)

5b. Who is conducting the primary review?

Study Purpose**6. Describe the rationale for the research project.****Subjects****7. What will be the maximum number of subjects in the study?**

7a. Indicate the expected number of: Males _____ Females _____

7b. What is the age of subjects? (Check all that apply)

- Children (1-17 years old) Adults (18-65 years old)
 Elderly (65-years and older)

7c. Will students be enrolled in the study? (Check all that apply)

- Undergraduate students(dept)* _____ Advanced students (dept)_____

*If students are under 18 years old, parental consent must be obtained

7d. Provide rationale for the choice of subjects. Enumerate any additional defining characteristics, including age, of the subject population. (e.g., symptomatology, history, socio-economic status).**Vulnerable Subjects****8. Are research subjects being used whose ability to give informed voluntary consent may be in question? (e.g., children, persons with AIDS, mentally disabled, psychiatric patients, prisoners.)**

- Yes (If yes, explain the procedures to be employed to enroll them and to ensure their protection).
 No

8b. What type of vulnerable subjects are being enrolled? (check all that apply)

- Critically Ill Patients Mentally Disabled or Cognitively Impaired Individuals
 Prisoners Physically Handicapped
 Pregnant Women Children
 Other _____

Recruitment**9. How will participants be recruited? (Please submit a copy of the sign-up sheet, newspaper advertisement, or any other protocol or procedure which will be used to recruit subjects.)**

- Internet
 Newspaper/radio/television advertising
 Posters/brochures/letters
 Other _____

Comments:

Inclusion and Exclusion Criteria

10. Are subjects equitably chosen for participation in the study? (no one group is excluded without justification)

- Yes
- No (If no, specify criteria and justify in detail below.)

10a. Does the study require special evaluation and screening of potential subjects to determine their appropriateness for inclusion in the study?

- Yes (If yes, briefly elaborate on the screening process and attach the screening questionnaire.)
- No

Experimental Procedures

11. Describe the experimental procedures that will be followed. (Include a succinct, but comprehensive statement of the methodology relating to the human subjects. You are encouraged to include a discussion of statistical procedures used to determine the sample size.)

11a. Will any aversive or painful procedures be employed (e.g., shock, the threat of shock or punishment, experimentally induced stress?)

- Yes (If yes, specify and justify in detail below.)
- No

11b. Will the deliberate deception of research participants be involved as part of the experimental procedure?

- Yes (If yes, explain the nature of the deception, why it is necessary, any possible risks that may result from the deception, and the nature of the debriefing with specific reference to the deception.)
- No

Attach copies of the following items:

- Research Protocol(s)
- Questionnaire
- Copies of any instructions or debriefings given
- If the research is part of a research proposal submitted for federal, state or external funding, submit a copy of the FULL proposal

Compensation

12. How much time will be required of each subject?

12a. Will research subjects receive course credit for participating in the study?

- Yes (If yes, please explain in comments section.)
- No

Comments:

12b. Are there any other forms of compensation that may be used? (e.g. Money)

- Yes (If yes, please explain in comments section.)
- No

Comments:

12c. Are there any penalties for subjects who do not show up for a research session?

- Yes (If yes, please explain in comments section.)
- No

Comments:

Informed Consent

13. Do you intend to obtain informed consent from subjects?

- Yes (please answer question 13a)
- No (please complete Appendix F: Request for Waiver of Consent Form)

13a. Describe the procedures that will be used to obtain Informed Consent and attach the Informed Consent Document (follow the guidelines for preparation of the University Informed Consent Form).

Note: Subjects MUST be given a description of the procedures and rationale for the study to the extent possible. The benefits and ANY risks associated with participating in the study MUST be enumerated. The subjects MUST be informed of their right to terminate the experiment at any time. If there is no risk associated with the study and participants' signature on the informed consent sheet is the only identifying information about the name of the subject, then the subjects' signature may not be necessary.

Risks

14. What are potential risks of the research? (Check all that apply)

- physical harm
- psychological harm
- Release of confidential information
- Other _____

14a. Describe any potential risks to subjects for the activities proposed and describe the steps that will be taken to minimize the risks. Include any risks to the subject's physical well being, privacy, dignity, emotions, employability, and criminal and legal status. A detailed, comparative statement of the risk (harm or likelihood) must also be described in the consent form.

Please attach the following (if you have developed them)

- The script by the experimenter to disclose potential harm and likelihood (risk) prior to the subject's choice to participate.

Benefits

15. Assess the potential benefits that may accrue to the individual subject as well as to others as a result of the proposed study. Do the potential benefits justify the possible risks involved? Although you may mention general benefits to society, such speculative benefits should not be presented to a subject as a direct benefit for informed consent.

Protection of Anonymity

16. Describe in detail the procedures for protecting the anonymity (meaning that no one will ever be able to know the names) of the research subjects. If anonymity is impossible, then describe in detail the procedures for safeguarding data and confidential records. These procedures relate to how well you reduce the risk that a subject may be exposed or associated with the data.

Drugs or Devices

17. Will any drugs, devices, or chemical biological agents be used with the subjects?

- Yes (If yes, please attach Appendix G: Drugs, Agents, and Devices Form)
 No

Biological Materials

18. Will this research involve the collection, analysis, or banking of human biological materials (cells, tissues, fluids, DNA?)

- Yes (If yes, please attach Appendix H: Biological Materials Form)
 No

Training

19. Briefly explain the nature of the training and supervision of anyone who is involved in the actual data collection, research design, or in conducting the research. This information should be sufficient for the IRB to determine that the RPI and investigators possess the necessary skills or qualifications to conduct the study.

Human Subjects Training

20. The RPI must document completion of NIH Training. (Attach a copy of the RPI's NIH Certificate for Human Participants Protections Education for Research Teams.)

Date RPI completed NIH Training: _____

Responsible Project Investigator (Must be original signature)

Date

APPENDIX D
INFORMED CONSENT DOCUMENT
(SAMPLE)
OLD DOMINION UNIVERSITY

PROJECT TITLE: (Insert project title here.)

INTRODUCTION

The purposes of this form are to give you information that may affect your decision whether to say YES or NO to participation in this research, and to record the consent of those who say YES. (Include the Name or Title of the Research Project and room in which the proposed research will be conducted.)

RESEARCHERS

(Identify the following...Name, Title, Academic Degree of Responsible Principal Investigator, College, and Department...then investigators)

DESCRIPTION OF RESEARCH STUDY

Several studies have been conducted looking into the subject of (...plain language description of whatever you are researching....) None of them have explained the (...purpose of the research, e.g., the effects of independent variable on dependent variable...).

If you decide to participate, then you will join a study involving research of (... a non technical, plain language explanation of the testing protocol and exactly what is expected of the subject, including a description of which procedures are experimental and their accepted, non experimental alternatives...) If you say YES, then your participation will last for (...duration of participation...) at the (...location of participation...). Approximately (...number...) of (...similarly situated subjects...) will be participating in this study.

EXCLUSIONARY CRITERIA

You should have completed (...description of screening instrument or questionnaire(s)...). To the best of your knowledge, you should not have (...list of exclusionary criteria....) that would keep you from participating in this study.

RISKS AND BENEFITS

RISKS: If you decide to participate in this study, then you may face a risk of (... clear description of all foreseeable risks, discomforts, or undesirable outcomes....). The researcher tried to reduce these risks by (...e.g., providing padding, using a licensed nurse, removing all linking identifiers...). And, as with any research, there is some possibility that you may be subject to risks that have not yet been identified.

BENEFITS: The main benefit to you for participating in this study is (...example of benefit other than payment, e.g., a free eyesight exam...). Others may benefit by (...example...).

COSTS AND PAYMENTS

The researchers want your decision about participating in this study to be absolutely voluntary. Yet they recognize that your participation may pose some (...costs, inconvenience, etc., such as parking fees...). In order to (...e.g., help defray your costs) you will receive (...e.g., five dollars, or "no payment...") to help defray incidental expenses associated with participation.

[OR]

The researchers are unable to give you any payment for participating in this study.

NEW INFORMATION

If the researchers find new information during this study that would reasonably change your decision about participating, then they will give it to you.

CONFIDENTIALITY

All information obtained about you in this study is strictly confidential unless disclosure is required by law. The results of this study may be used in reports, presentations and publications, but the researcher will not identify you.

WITHDRAWAL PRIVILEGE

It is OK for you to say NO. Even if you say YES now, you are free to say NO later, and walk away or withdraw from the study -- at any time. [If applicable] Your decision will not affect your relationship with Old Dominion University, or

otherwise cause a loss of benefits to which you might otherwise be entitled. [Optional: The researchers reserve the right to withdraw your participation in this study, at any time, if they observe potential problems with your continued participation.]

COMPENSATION FOR ILLNESS AND INJURY

If you say YES, then your consent in this document does not waive any of your legal rights. However, in the event of (.harm, injury, or illness...) arising from this study, neither Old Dominion University nor the researchers are able to give you any money, insurance coverage, free medical care, or any other compensation for such injury. In the event that you suffer injury as a result of participation in any research project, you may contact (...the responsible principal investigator or investigators at the following phone numbers...) or Dr. David Swain the current IRB chair at 757-683-6028 at Old Dominion University, who will be glad to review the matter with you.

VOLUNTARY CONSENT

By signing this form, you are saying several things. You are saying that you have read this form or have had it read to you, that you are satisfied that you understand this form, the research study, and its risks and benefits. The researchers should have answered any questions you may have had about the research. If you have any questions later on, then the researchers should be able to answer them:

(...investigators and phone numbers....).

If at any time you feel pressured to participate, or if you have any questions about your rights or this form, then you should call Dr. David Swain, the current IRB chair, at 757-683-6028, or the Old Dominion University Office of Research, at 757-683-3460.

And importantly, by signing below, you are telling the researcher YES, that you agree to participate in this study. The researcher should give you a copy of this form for your records.

Subject's Printed Name & Signature	Date
Parent / Legally Authorized Representative's Printed Name & Signature (If applicable)	Date
Witness' Printed Name & Signature (if Applicable)	Date

INVESTIGATOR'S STATEMENT

I certify that I have explained to this subject the nature and purpose of this research, including benefits, risks, costs, and any experimental procedures. I have described the rights and protections afforded to human subjects and have done nothing to pressure, coerce, or falsely entice this subject into participating. I am aware of my obligations under state and federal laws, and promise compliance. I have answered the subject's questions and have encouraged him/her to ask additional questions at any time during the course of this study. I have witnessed the above signature(s) on this consent form.

Investigator's Printed Name & Signature	Date
--	-------------

APPENDIX E
INFORMED CONSENT CHECK LIST
OLD DOMINION UNIVERSITY

Note: This document is a reproduction of the Office of Human Research Protections Informed Consent Checklist.
The original may be found at: <http://www.hhs.gov/ohrp/humansubjects/assurance/consentcls.htm>

46.116 - Informed Consent Checklist - Basic and Additional Elements	
	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 the subject or to 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
	An explanation of whom to contact for answers to pertinent questions about the 1) research, 2) research subjects' rights, and 3) 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 subjects involved in the study
§46.117 Documentation of Informed Consent Checklist	
a.	Except as provided in the "waiver" section, informed consent shall be documented by the use of a written consent form approved by the IRB, and signed by the subject or the subject's legally authorized representative. A copy shall be given to the person signing the form. The consent form may be either of the following: WRITTEN A written consent document that embodies the elements of informed consent required by §46.116. This form may be read to the subject or the subject's legally authorized representative, but in any event, the investigator should give either the subject or the representative adequate opportunity to read it before it is signed.

DONE ORALLY

A short form written consent document, stating that the elements of informed consent required by §46.116 have been presented orally to the subject or the subject's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the subject or the representative. Only the short form itself is to be signed by the subject or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the representative, in addition to a copy of the short form.

WAIVER

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects, if it finds either:

1. That the only record linking the subject and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
2. That the research presents no more than minimal risk of harm to subjects, and involves no procedures for which written consent is normally required outside of the research context. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research

IRB Latitude to Approve a Consent Procedure that Alters or Waives some or all of the Elements of Consent

§ 46.116 - An IRB may approve a consent procedure, which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent, provided the IRB finds and documents that:

C: 1. The research or demonstration project is to be conducted by, or subject to the approval of, state or local government officials, and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

C: 2. The research could not practicably be carried out without the waiver or alteration.

D: 1. The research involves no more than minimal risk to the subjects;

D: 2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

D: 3. The research could not practicably be carried out without the waiver or alteration; and

D: 4. Whenever appropriate, the subjects will be provided with additional pertinent information participation.

Special Requirements - 45 CFR 46 Subpart D - Additional DHHS Protections for Children Involved as Subjects in Research

Assent/ Waiver	The IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted, or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children, and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances, in which consent may be waived in accord with §46.116 of Subpart A.
Parents	The IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405.
	Where research is covered by §46.406 and §46.407, and permission is to be obtained from parents, both parents must give their permission, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
	If the IRB determines that a research protocol is designed for conditions or for a subject population, for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in Subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, state or local law.

APPENDIX F
OLD DOMINION UNIVERSITY
REQUEST FOR WAIVER OF CONSENT

Instructions: If you are requesting a waiver of informed consent or a waiver of the consent procedure requirement to include all or alter some or all of the elements of informed consent [45CFR46.116(d)], you must document the responses to each of the statements, citing supporting sections of the study protocol.

Responsible Project Investigator (RPI)	
1) RPI First Name	RPI Last Name
2) Project Title	
3) The research in its entirety involves no greater than minimal risk. <input type="checkbox"/> Yes <input type="checkbox"/> No	
4) The waiver of informed consent will not adversely affect the rights and welfare of the subjects. <input type="checkbox"/> Yes <input type="checkbox"/> No	
5) It is not practicable to conduct the research without the waiver/alteration. <input type="checkbox"/> Yes <input type="checkbox"/> No	
6) Whenever appropriate, subjects will be provided with additional pertinent information after their participation. <input type="checkbox"/> Yes <input type="checkbox"/> No	
7) If you have selected the "yes" response to each of the four statements above, in order to receive the waiver, you must: <input type="checkbox"/> Describe the reason(s) why the waiver is necessary, and <input type="checkbox"/> Explain whether the entire informed consent is being waived or only certain required elements are being waived. (If so, list which ones)	
Note: If a waiver is granted under the above conditions, documentation of informed consent (i.e., signed consent form) is also waived. Even if the waiver is granted, the IRB may require other conditions. The IRB may require the researcher to provide subjects with an informed consent sheet (written summary/notification document) about the research.	

APPENDIX G
OLD DOMINION UNIVERSITY
DRUGS, AGENTS AND DEVICES FORM

Instructions: If this study involves the use of drugs, chemicals, nonhuman biological agents, or devices, the study is subject to Food and Drug Administration (FDA) regulations. Researchers planning to use these agents or devices in human subjects research must complete this form and include it with an original IRB application, as applicable.

Responsible Project Investigator (RPI)	
1) RPI First Name	RPI Last Name
2) Project Title	
3) Will drug(s) be administered as part of this study?	
<input type="checkbox"/> Yes <input type="checkbox"/> No (If no, go to 4)	
3a) Drug Name(s): Trade: _____ Generic: _____	
3b) If the drug is investigational provide the Investigational New Drug (IND) number: IND# _____	
3c) Who is the IND held by? (check one) <input type="checkbox"/> Sponsor (provide a copy of the Investigator's Brochure and the sponsor's protocol) <input type="checkbox"/> Investigator (provide a copy of the IND application submitted to the FDA and safety information)	
4) Will biologic(s) be used as part of this study? <input type="checkbox"/> Yes <input type="checkbox"/> No (If no, go to 5)	
4a) Biologic Name(s): _____	
5) Does the study involve the evaluation of investigational or marketed medical devices? <input type="checkbox"/> Yes <input type="checkbox"/> No	
5a) Device Name(s) and functions: _____	
5b) IDE# _____ Date: _____	
5c) Who is the IDE held by? (check one) <input type="checkbox"/> Sponsor (provide a copy of the Investigator's Brochure and the sponsor's protocol) <input type="checkbox"/> Investigator (provide a copy of the IDE application submitted to the FDA)	
5d) For a device with an IDE, check one of the appropriate categories: <input type="checkbox"/> 510 K Device (provide a copy of the FDA letter confirming the 510K status) <input type="checkbox"/> Non-significant risk device (provide justification of non-significant risk determination) <input type="checkbox"/> Marketed device	

APPENDIX H
OLD DOMINION UNIVERSITY
BIOLOGICAL MATERIALS FORM

Instructions: Researchers planning to collect, analyze, or bank human cells, tissues, fluids, DNA or other human biological samples (existing or to be collected) as part of the research must complete this form and include it with the IRB Application.

Responsible Project Investigator (RPI)	
1) RPI First Name	RPI Last Name
2) Project Title	
3) Describe the materials that will be collected, analyzed, or banked by the investigator(s).	
<p>4) What type of samples will be used? (Check one)</p> <p><input type="checkbox"/> Samples are unidentified (anonymous)-identifying information was not or will not be collected, or if collected by a repository was not maintained and cannot be retrieved by repository</p> <p><input type="checkbox"/> Samples are identified-links to personal information exist somewhere or will be collected and maintained (Go to 4b)</p>	
<p>4b) If samples are identified</p> <p><input type="checkbox"/> Samples are unlinked (“anonymized”)-samples are provided to investigator without identifiers or codes that can link to identifiers</p> <p><input type="checkbox"/> Samples are coded (“linked” or “identifiable”)-provided to investigator with codes that are linked to identifiers</p> <p><input type="checkbox"/> Samples are identified-provided to investigator with identifying personal information</p>	
<p>5) What is the intended use of the samples for purposes of the current protocol?</p>	
<p>5a) Where will the samples be stored?</p>	
<p>5b) In what manner will samples be stored?</p> <p><input type="checkbox"/> Frozen <input type="checkbox"/> Cell lines <input type="checkbox"/> Paraffin Blocks <input type="checkbox"/> Other _____</p>	
<p>5c) Who will have access to samples? (Check all that apply)</p> <p><input type="checkbox"/> Samples will be used by members of the research team <input type="checkbox"/> Samples will be shared with outside researchers <input type="checkbox"/> Other _____</p>	
<p>6) Will the samples be destroyed after this purpose is served?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No (go to 6a)</p>	
<p>6a) Will you utilize samples in the same manner?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No (If no, please describe)</p>	

APPENDIX I
OLD DOMINION UNIVERSITY
HUMAN SUBJECTS RESEARCH PROGRESS REPORT FORM
(Required for Continuing Approval)

Progress reports should be submitted when data collection and/or data analysis is ongoing.

Responsible Project Investigator (RPI)		
Responsible Project Investigator: The RPI must be a member of ODU faculty or staff who serves as the project supervisor and is held accountable for all aspects of the project. Students cannot be listed as RPIs.		
First Name:	Last Name	
Telephone:	Email:	
Department:	IRB Identifier:	Expiration Date:
Complete Title of Research Project:		Code Name (one word):
Indicate the dates for the period of time that this report covers. This must not exceed one year and must be retrospective. The following information is for the time interval of:		
Start Date (MM/DD/YY):	End Date (MM/DD/YY): (This is the date of the report.)	
1. How is the project funded? <ul style="list-style-type: none"> <input type="checkbox"/> Research is not funded (Go to question 2) <input type="checkbox"/> Research is funded 		
1a. What is the type of funding source? (Check all that apply) <ul style="list-style-type: none"> <input type="checkbox"/> Federal Grant or Contract <ul style="list-style-type: none"> Agency Proposal Number _____ Grant Start Date (MM/DD/YY) _____ Grant End Date (MM/DD/YY) _____ <input type="checkbox"/> State or Municipal Grant or Contract <input type="checkbox"/> Private Foundation <input type="checkbox"/> Corporate contract <input type="checkbox"/> Other (specify): _____ 		
1b. Who is the point of contact at the funding source? Name: _____ Mailing Address: _____ Telephone: _____ Email: _____		
2. Please indicate the status of the research project: <ul style="list-style-type: none"> <input type="checkbox"/> Active/Open to subject enrollment (Please attach ONE (1) copy of the current consent form with each progress report and TWO (2) copies of the consent form with the original progress report. Include consent forms that do not have the IRB stamp) <input type="checkbox"/> Active/Closed to subject entry <ul style="list-style-type: none"> Date of closure to subject entry (MM/DD/YY): _____ / _____ / _____ Closure is: _____ Permanent _____ Temporary (If closure is temporary, please attach ONE (1) copy of the current consent form with each progress report and TWO (2) copies of the consent form with the original progress report. Provide consent forms that do not have the IRB stamp.) 		
3. Has the protocol or consent form changed in any way since the last approval? <ul style="list-style-type: none"> <input type="checkbox"/> Yes (Please attach a copy of any amendment(s) not previously submitted.) <input type="checkbox"/> No 		

4. During the time interval described above (1 year time period this report covers), have you:

4a. Actively Enrolled Subjects Yes _____ No _____

4b. Collected Follow-up Data Yes _____ No _____

4c. Have any subjects withdrawn from the study?

- Yes
 - No

Note: The term WITHDRAWN means that the subject voluntarily withdrew or was removed from the study prior to study completion.

5. Enrollment numbers for the time interval described above (1 year time period this report covers) for the categories below:

Please fill in the table below. (This information is required for all studies that are NIH-sponsored. It is recommended, but not required, that other researchers provide this information.)

Sex	Ethnicity		
Male:	Black, Non-Hispanic:	Native American/Alaskan:	Caucasian, Non-Hispanic:
Female:	Hispanic:	Asian/Pacific Islander:	Other/Unknown:

6. Provide the following information for study population:

1. Total number of subjects ACTIVELY in the protocol: _____
 2. Total number of subjects WITHDRAWN since initiation of study: _____
 3. Total number of subjects COMPLETED and OFF the study: _____
 4. Total number of subjects enrolled SINCE INITIATION OF THIS STUDY: _____

Note: The total of 1, 2 and 3 should equal 4.

7. Were there any medical, legal, or practical difficulties that have been encountered in this time interval of the study aside from adverse events? For example, difficulties would include complaints of subjects, logistic problems of performance, or any difficulties that may pertain to the rights of subjects.

- Yes (If yes, please summarize below.)
 No

8. Were there any adverse events encountered during the study period?

Yes _____ (If yes, summarize below and provide a statement of trends e.g. more women affected)
Number
 No (go to 9)

8a. Have all adverse events been reported to the IRB?

- Yes
 No (If there are any events that have NOT been reported to the Old Dominion University Institutional Review Board, attach a letter of notification with an explanation. Serious adverse events MUST be reported to the Board within FIVE days of the investigator being notified.)

9. Has any new information become available during the course of the research which may affect the subject's willingness to continue participation in this study?

- Yes (If yes, explain)
 No

9a. Was the new information provided to the subjects?

- Yes (If yes, attach written documentation)
 No

10. Please provide, or attach, a brief overview of research/results/observations obtained to date. Include a copy of ANY publications that have resulted from this research. Note: This section MUST be completed.

11. The RPI must document completion of NIH Training within 1 year of submission of the progress report. (Attach a copy of the RPI's NIH Certificate for Human Participants Protections Education for Research Teams.)

Date RPI completed NIH Training: _____

Responsible Project Investigator (Must be original signature)

Date

APPENDIX J
OLD DOMINION UNIVERSITY
HUMAN SUBJECTS RESEARCH CLOSE OUT REPORT

A close out report should be submitted when data collection and data analysis are complete.

Responsible Project Investigator (RPI)			
First Name:		Last Name:	
Telephone:		Email:	
Department:	IRB Identifier:		Expiration Date:
Complete Title of Research Project:			Code Name (one word):
Data on Number of Subject's Studied			
1. Indicate the number of subjects studied in the space provided.			
1a. What is the total number of subjects enrolled since the last approval? _____			
1b. What is the total number of subjects to date? _____			
1c. What is the sex and ethnicity distribution of the subjects? Please fill in the table below. (This information is required for all studies that are NIH-sponsored. It is recommended, but not required, that other researchers provide this information.)			
Sex	Ethnicity		
Males	Black, Non-Hispanic:	Caucasian, Non-Hispanic:	Native American/Alaskan:
Females	Hispanic:	Asian/Pacific Islander:	Other/Unknown:
Summary of Results			
2. Please summarize results to date and any relevant information from other studies. Please also discuss any changes in procedures and anticipated risks or benefits. Please attach reprint(s), if available.			

3. Were there any medical, legal, or practical difficulties that have been encountered in this time interval of the study aside from adverse events? For example, difficulties would include complaints of subjects, logistic problems of performance, or any difficulties that may pertain to the rights of subjects.

- Yes **(If yes, please summarize below.)**
- No

4. Were there any adverse events encountered during the study?

- Yes _____ **(If yes, please summarize below.)**
Number
- No **(go to 5)**

4a. Have all adverse events been reported to the IRB?

- Yes
- No **(If no, attach a letter of notification with an explanation)**

5. Did you experience any problems with the consent process?

- Yes **(If yes, describe the problem(s) and how they were corrected in the space provided. Use additional sheets if necessary.)**
- No

6. Please identify the location of the project files in the space provided.

Responsible Project Investigator (Must be original signature)

Date

APPENDIX K
OLD DOMINION UNIVERSITY
ADVERSE EVENT REPORTING FORM

Protocol Information	
RPI First Name:	RPI Last Name:
Date: MM/DD/YY _____	Human Subject's Initials and/or Identifier:
Complete Title of Research Project:	
Research Sponsoring Agency (e.g. NIH, NSF):	
Description of Event	
Date of Event: ____ / ____ / ____	Time of Event: ____ : ____ AM? ____ PM? ____
Location:	Attending Physician:
Hospital or Site of Medical Care:	
Provide a brief description of the event. Attach any additional documentation that may be helpful (lab or x-ray reports):	
Medical Treatment Received:	
Describe the Subject's Prognosis and Outcome. Attach any follow-up reports if the outcome is indeterminable at the time of this report.	

Nature of the Event

Serious? A serious adverse event is any event occurring that results in any of the following outcomes. Check the outcome that applies:

- death
- life-threatening event
- in-patient hospitalization
- prolongation of existing hospitalization
- a persistent or significant disability/incapacity
- a congenital anomaly/ birth defect (pregnant subjects only)

An unexpected adverse event is any adverse event, the specificity or severity of which is not listed in the current informed consent.

Unexpected? Yes No

Probable (The adverse event is *likely related* to the study.) Probable? Yes No

Possible (The adverse event *may be related* to the study.) Possible? Yes No

Unlikely (The adverse event is *doubtfully related* to the study.) Unlikely? Yes No

Unknown?

Provide a brief rationale for your assessment. State whether the same adverse event has occurred previously and provide incidence data whenever relevant.

Was the study blind broken as a result of the event? Yes No

Impact on Study

Protocol Changes. In your judgment, is a change in the protocol necessary to reduce or eliminate the risk?

Yes. Attach a Protocol Amendment.

No. Provide a brief rationale in the space provided.

Informed Consent Document. Are any changes required in the informed consent document(s) to better inform and protect the rights of subjects enrolled hereafter?

Yes. Attach two (2) revised consent forms.

No. Provide a brief rationale in the space provided.

Impact for Existing Subjects. Should/will subjects and/or guardians who have already consented to participate in the study be informed of this new information?

Yes. Attach an information sheet or consent addendum form.

No. Provide a brief rationale in the space provided.

NOTE: This form must be completely filled out.

Incomplete forms will be returned to the RPI for the completion of missing information.

Signature of Responsible Project Investigator:	Date Signed: _____/_____/_____
--	-----------------------------------

Consulting Physician Report
(required for "Serious" Adverse Events whether expected or unexpected)

Please describe the severity of the event, the likelihood in your judgment that it was related to the research protocol, and any other information you feel would be important:

Signature of Consulting Physician (if required):	Date Signed: _____/_____/_____
--	-----------------------------------

*** FOR IRB USE ONLY ***
FINAL DISPOSITION

Review Category: <input type="checkbox"/> Expedited <input type="checkbox"/> Full	Action: <input type="checkbox"/> Approved <input type="checkbox"/> Disapproved
--	---

Recommendations:

Signed by IRB Chair:

Date Signed: ____ / ____ / ____

Continuing Review Deadline: ____ / ____ / ____