

# INSTITUTIONAL REVIEW BOARD

FOR RESEARCH WITH  
HUMAN SUBJECTS

POLICIES AND PROCEDURES

FWA #

VIRGINIA UNION UNIVERSITY  
OFFICE OF ACADEMIC AFFAIRS

DRAFT

Revised August 13, 2010

**Table of Contents**

| <b>Research Involving Human Subjects</b>                    | <b>Page</b> | <b>Forms</b>  | <b>Page</b> |
|---|-------------|---|-------------|
| Policy  | 3           | Application Checklist                               | 15          |
| Ethical Principles  | 3           | New Study Application Form                          | 16          |
| Review Process  | 4           | Continuation of an Approved Protocol Form           | 19          |
| Institutional Review Board Membership                       | 5           | Termination of an Approved Protocol Form            | 21          |
| Forms   | 5           | Informed Consent to Participate in a Research Study | 23          |
| Training for Researchers                                    | 6           | Report of an Adverse Event                          | 25          |
| Responsibilities of the Researcher Before IRB Consideration | 6           | Conflict of Interest                                | 26          |
| Conflict of Interest  | 6           |   |             |
| Informed Consent of Adults                                  | 6           |   |             |
| Assent of Minors  | 7           |   |             |
| Adverse Events  | 8           |   |             |
| Class/ Student Research Project                             | 8           |   |             |
| Research Using Electronic Methods                           | 8           |   |             |
| Violations  | 8           |   |             |
| Appeals   | 9           |   |             |
| Approval Categories   | 9           |   |             |
| Exempt Research   | 9           |   |             |
| Expedited Review  | 11          |   |             |
| Full Review   | 12          |   |             |
| Continuing Review   | 12          |   |             |
| Responsibilities After IRB Approval                         | 13          |   |             |
| Audit Policy  | 13          |   |             |

## **Members of the IRB**

Dr. Sandra Flynn, Social Work

Dr. Carleitta Paige, Natural Sciences

Dr. Wally Smith, MD, Virginia Commonwealth University

Dr. Peter Sutton, Philosophy

Dr. Michele Stacey, Criminology & Criminal Justice

Dr. Heidi Villanueva, Psychology, Chair

Dr. Mary Young, Theology

## **Alternate Members of the IRB**

Dr. Beverly Aurand, Social Work, Secretary

Dr. Julie Molloy, Criminology & Criminal Justice

Dr. Judith Powell, Business

Dr. Felecia Williams, Political Science

## Research Involving Human Subjects

### Policy

Virginia Union University (VUU) is responsible for safeguarding the rights and welfare of human subjects involved in research activities. Any project originating at VUU which uses human subjects, including self-experimentation, is subject to review and approval by the Institutional Review Board (IRB) for the Protection of Human Subjects. Studies may not begin until an IRB review process is fully executed and the protocol is approved by the members of the IRB. If a research project is to be done at an institution other than VUU, the Principal Investigator (PI) must follow that institution's IRB process.

Certification that the project is approved by the IRB will be given to the PI. Consent to participate will be documented by the use of a written consent form approved by the IRB and signed by the PI and/or his/her representative.

The IRB may impose additional conditions prior to, or at the time of, approval when, in the judgment of the IRB, additional conditions are necessary for the protection of the human subjects. (Code of Federal Regulations, Title 45 Public Welfare, Department of Health and Human Services, Part 46 Protection of Human Subjects, Subpart sections 46.101 - 46.409 <http://ohsr.od.nih.gov/guidelines/45cfr46.html>).

### **IRB REVIEW AND APPROVAL IS REQUIRED PRIOR TO INITIATING ANY RESEARCH INVOLVING HUMAN PARTICIPANTS!**

Virginia Union University assures that it will apply Title 45 Code of Federal Regulations Part 46 (<http://ohsr.od.nih.gov/guidelines/45cfr46.html>) and all of its subparts to all research involving human subjects:

- A: General adult population;
- B: Additional protections for pregnant women, human fetuses and neonates;
- C: Additional protections for prisoners;
- D: Additional protections for children.

VUU's IRB will report to the Vice-President of Academic Affairs.

### **Ethical Principles**

VUU assures that all research involving human subjects will be guided by the ethical principles in The Belmont Report (<http://ohsr.od.nih.gov/guidelines/belmont.html>) published by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The University will be guided by these ethical principles and use them as a foundation for all research conducted with human subjects. These principles include:

1. Respect for Persons: Individuals should be treated as autonomous agents. Persons with diminished autonomy are entitled to protection.
2. Beneficence: Human beings are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being.
3. Justice: The burdens and benefits of research shall be distributed equitably.

## Review Process

All investigators who conduct research involving human subjects must familiarize themselves with the IRB Policies and Procedures and submit an application to the IRB.

### What projects require IRB oversight?

All research involving human subjects that:

- (i) is conducted by VUU faculty, staff, or students;
- (ii) is conducted at VUU facilities; or that
- (iii) involves the private records of VUU.

#### 1. Is my work considered research?

The federal definition of research is “a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. (Federal Regulation 45 CFR section 46.102 <http://ohsr.od.nih.gov/guidelines/45cfr46.html>).

#### 2. What is a systematic investigation?

A systematic investigation is one that involves a predetermined method for studying a specific topic, answering a specific question (s), testing a specific hypothesis (es) or developing theory. This may include, but is not limited to: observational studies, open-ended interviews or survey studies, tests, program evaluation and interventional research.

#### 3. What is ‘contributing to generalizable knowledge’?

Federal Regulation 45 CFR does not provide a definition of ‘generalizable knowledge’; however, it is implied that contributing to generalizable knowledge is sharing the information/ data/ results and possible concerns obtained through research in a public setting such a publication, presentation at a conference, flyers, leaflets and so forth.

#### 4. What is a ‘human subject’?

A human subject is a living individual about whom an investigator conducting research obtains:

- (i) data through intervention or interaction with the individual; or
- (ii) identifiable private information.

#### 5. What is the process for IRB review?

(i) If desired, the researcher can contact the IRB chairperson for a consultation to assist in developing the research proposal, or completing the IRB review material. Then, the researcher will:

(ii) Print the forms that apply to the research project (new project, renewal, cover letter.

(iii) Complete the CITI (Collaborative Institutional Training Initiative) training program; print the *Certificate of Completion* to attach to the IRB application. If the PI has completed the CITI training program within two years, the most recent *Certificate* must be attached.

(iv) Determine the applicable review category (exempt, expedited or full) of the research, and complete the paperwork accordingly.

(v) Using the IRB checklist, assemble the needed material and submit it to the IRB chairperson.

(vi) The IRB chair will assign an IRB number to the application and will then assign a primary and secondary reviewer; the reviewers will make a recommendation to the chair as to whether the designation of exempt, expedited or full review is appropriate. The PI will be notified by the chair.

See flow chart.

#### 6. Why do modifications have to be made?

The goal of the IRB process is to make sure that the potential human subjects that you will be working with are aware of what they will be doing (risks and benefits) if they choose to participate in the project, that they will be treated fairly and with dignity, and that what you do is both legal and ethical.

If the IRB tells the PI to modify the protocol, it is to bring it into closer alignment with the goal as stated above. Many protocols will be modified before they are given full approval, and the process will provide the PI with the exact information about what needs to be changed.

#### 7. What happens if the project is not completed within 12 months?

Six weeks prior to the 12 month anniversary, if the research is ongoing, the PI will prepare the Continuation of an Approved Protocol form and submit it with the required material to the chair of the IRB committee.

#### 8. What happens when the project is completed?

When the project is completed, the PI will submit the Termination of an Approved Protocol form to the IRB before the expiration date of the study.

### **IRB Committee Membership**

In accordance with the Title 45 CFR Part 46, (<http://ohsr.od.nih.gov/guidelines/45cfr46.html>):

1. There will be a minimum of five (5) members (both men and women), including the committee chairperson.
2. Three of the members must have a scientific background.
3. Two of the members must have a non-scientific background.
4. One member of this committee must not be affiliated in any way with VUU.
5. One member will serve as the Chairperson.
6. There will be an alternate for each member, from the appropriate category, who will attend meetings and make decisions in the member's absence.

### **Forms**

All appropriate forms must be used in submitting information to the IRB. They include:

1. New Study Application Form;
2. Consent to Participate in a Research Study;

3. Continuation of an Approved Protocol Form.
4. Termination of an Approved Protocol Form.

These forms are included in the Manual, and are located online. [\(LINK\)](#)

### **Training for Researchers**

VUU requires all research personnel, including student researchers, to successfully complete the CITI course before submitting a new IRB application for review. **The training is valid for two (2) years and then the refresher course must be taken for the researcher to be recertified.** (<https://www.citiprogram.org> )

The *Certificate of Completion* of the training must be attached to the IRB application.

### **Responsibilities of the Researcher Before IRB Consideration**

1. All research investigators must obtain IRB approval for each research protocol involving human subjects prior to initiating the study.
2. The PI is required to prepare the New Study IRB Application form [\(LINK\)](#), and submit this along with the training certification, research proposal, informed consent form(s), study instruments, recruitment materials, and any other relevant documentation to the IRB.
3. The PI and/or faculty advisor may be asked to attend an IRB meeting when his/her protocol is under review.
4. Any research activities involving institutions or agencies outside of VUU must receive written approval from the institution or agency, which must be submitted with the IRB application.
5. All personnel involved in the research project must complete the required CITI training and a copy of their *Certificate of Completion* must be attached with the application.

### **Conflict of Interest**

All personnel involved in the research project must complete the Conflict of Interest Form [\(LINK\)](#) indicating any support, funding or affiliation with any outside agencies, institutions or entities which might have any interest or influence in the outcome of the research, or which might possibly benefit in any way from the outcome of the research project.

### **Informed Consent of Adults**

The researcher must obtain the legally effective informed consent of subject or the subject's legally authorized representative. Special care and consideration should be exercised when the subjects are legal minors (see section on Assent of Minors) or adults legally incapable of giving consent. 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.

In all other cases, consent shall be documented by the use of the Informed Consent form. By Federal Law, researchers are to keep the signed informed consent forms for three (3) years. (Federal Regulation 45 CFR section 46.116 <http://ohsr.od.nih.gov/guidelines/45cfr46.html> ).

The following guidelines should be followed when conveying informed consent:

1. Information should be expressed in understandable language;
2. Information must exclude language waiving legal rights;
3. Information should be stated in language that minimizes the possibility of coercion or undue influence.

### **Assent of Minors**

Research involving minors requires their assent: their agreement to willingly participate in the study, **in addition to** the parent's or legal guardian's informed consent for the minor to participate. Assent may only come from children capable of making this decision. The regulations at 45 CFR 46.408 (a) (<http://ohsr.od.nih.gov/guidelines/45cfr46.html> ) identify three types of circumstances where the IRB may determine that waiver of children's assent is appropriate:

1. if the capability of some or all of the children is so limited that they cannot reasonably be consulted;
2. if the intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research.
3. if the research meets the same conditions as those for waiver or alteration of informed consent in research involving adults, as specified in the regulations at either 45 CFR 46.116(c) or 45 CFR 46.116(d) ( <http://ohsr.od.nih.gov/guidelines/45cfr46.html> ).

Parental permission may suffice when a child is not capable of making this decision.

Investigators are required to provide a method of assent with their IRB proposals involving minors that may include, but is not limited to:

1. A letter of assent signed by the minor;
2. A statement of assent read or communicated to the minor;
3. A procedure whereby assent is implied by the child's active participation;
4. A statement explaining why assent is not necessary (for example, minors involved in classroom activities that are part of their required curriculum and instruction.)

**Minors may not be coerced either actively or passively, into participating in a study. Any statement, either written or verbal, must be communicated in ways that the child will understand.**

Answers to Frequently Asked Questions (FAQ) regarding the treatment of minors by the US Department of Health and Human Services (HHS), Office of Human Research Protections may be found at the following link: <http://www.hhs.gov/ohrp/researchfaq.html> .

## Adverse Event

An adverse event is defined as a negative consequence of the research. They may or may not be the fault of the PI. All adverse events will be reported to the IRB within three days after they occur, using form [\(LINK\)](#).

## Class/ Student Research Project

All research conducted by students that involves human subjects must be reviewed by the IRB. Students are expected to submit their research proposals through their Professor or Faculty Advisor, who will serve as the PI of the study. Students are listed as Co-Investigators (CI). Students will complete the Student section of the CITI training prior to submitting their proposals, and their *Certification of Completion* forms will be attached to their IRB applications.

It is **STRONGLY** recommended that ALL faculty **teaching scientifically based research courses** complete the CITI training.

A program evaluation with a survey IS NOT research with human subjects and does NOT need to be submitted to the IRB for approval.

## Research using Electronic Methods

Researchers will take added precautions to protect the identities of their research subjects when using electronic methods for obtaining and/or storing information and data. These may include, but are not limited to:

1. Using a Secure Site
2. Make sure that surveys conducted on line that are supposed to be anonymous can in no way be traced back to the computer account where the survey was completed.
3. Randomly assigned computer generated username/ password.

This applies to any research that:

1. is conducted on the internet, such as survey research;
2. uses e-mail addresses;
3. uses e-mail as a method of communication.

## Violations

Violations to the IRB policies and procedures will be handled on a case-by-case basis. In general, the PI of the alleged violation will be required to meet with the IRB to discuss the situation. The IRB will make every effort to assist the PI in finding a remedy to the violation.

There are many potential types of violations, which include:

- 1) an adverse event that results in harm to the subject, which may or may not be the fault of the PI;
- 2) research being carried out that did not have prior IRB approval;
- 3) failure to follow approved protocol;

4) failure to undergo continuing review process, such as continuing research beyond approval date, or failure to submit termination report prior to end of approval date.

The IRB would need to decide which type of potential violation has occurred and make an appropriate decision.

Failure of the PI to comply with the decision(s) of the IRB may result in one or more of the following:

- 1). PI will be required to cease all research activities;
- 2). Sanction from future IRB reviews for a stated period of time.

## Appeals

If the IRB does not approve a proposed research project, or gives a contingency approval, the PI may request an appeal hearing before the full IRB. Records and notice of action will be provided. No other University approval may be provided in opposition to IRB disapproval. However, an IRB approved project may be disapproved by other offices of the University.

## Approval Categories

Approval may be granted in one of three categories. Each of these is explained in detail in later sections.

1. Exempt: General characteristics of all exempt research include the following:

- (i) Private identifiable information **cannot** be recorded by the investigator or members of the research team if the possibility exists that release of that information could affect the individual's reputation, employability, or financial status;
- (ii) Research participants **do not** sign a consent form, but should be informed about the nature of the study via the use of an "introductory script";
- (iii) Prior scientific review by a School or Departmental review committee is **not** required.

2. Expedited: Research:

- (i) that involves minimal risk or discomfort to the subject; is not invasive
- (ii) in which the subject is identifiable through characteristics recorded by researcher, including name, address, phone number, etc.
- (iii) that does not involve special populations such as: prisoners, pregnant women, children, adults who are not able to provide informed consent

3. Full Review: Research that does not meet the criteria for either exempt or expedited research.

## Exempt Research

**Investigators who believe that their research fits an exempt category must submit a completed application to the IRB** (see submission requirements). This will be reviewed to determine whether it meets the federal criteria for an exemption, or meets the criteria for "no human subjects" or "not research". Applications that do not fall into any of those 3 categories will be recommended for either an expedited review, if they meet those specific requirements, or will be recommended for full review.

Please make selections carefully; if an exempt submission is determined by the IRB to require an expedited review, the investigators must submit a new “expedited review” application.

The following types of research are determined to be exempt: (Federal Regulation 45 CFR section 46.101(b) <http://ohsr.od.nih.gov/guidelines/45cfr46.html>).

1. Evaluation of educational strategies, curricula, or classroom management methods

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.

**This type of research is an area of exemption that may apply to minors when the researcher is the minor’s teacher, instructor, therapist, etc.**

2. Tests, surveys, interviews, or observations of public behavior

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 under section 2 (above) of this section, if:

- (i) the human subjects are elected or appointed 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. Existing data, or research records; not applicable for Medical Record Reviews; studies using in vitro diagnostic devices with specimens that are not individually identifiable; research with biological specimens

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. **This type of research is an area of exemption that may apply to minors.**

5. Retrospective medical record review

- (i) Medical record review with certified honest broker

- (ii) Medical record review by investigator who is part of the VUU/covered entity workforce
6. 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 benefits or services programs;
  - (ii) procedures for obtaining benefits or services under those programs;
  - (iii) possible changes in, or alternatives to, those programs or procedures;
  - (iv) possible changes in methods or levels of payment for benefits or services under those programs.
7. 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 (FDA) or approved by the Environmental Protection Agency (EPA), or the Food Safety and Inspection Service of the US Department of Agriculture (USDA).

### **Expedited Review**

Research in this category includes:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
  - (a) Research on drugs for which an investigational new drug application (21 CFR part 312 <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=312>) is not required.
  - (b) Research on medical devices for which:
    - (i) an investigational device exemption application (21 CFR Part 812 [http://www.access.gpo.gov/nara/cfr/waisidx\\_01/21cfr812\\_01.html](http://www.access.gpo.gov/nara/cfr/waisidx_01/21cfr812_01.html)) is not required; or
    - (ii) the medical device is cleared/ approved for marketing and the medical device is being used in accordance with its cleared/ approved labeling.
2. Collection of blood samples by finger stick, heel stick, ear stick or venipuncture.
3. Prospective collection of biological specimens for research purposes by noninvasive means.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed they must be cleared/ approved for marketing. Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices or new indications.

5. Collection of data from voice, video, digital, or image recordings made for research purposes.
6. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior), or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies.
7. Continuing review of research previously approved by the convened IRB as follows:
  - (i) where the research is permanently closed to the enrollment of new subjects;
  - (ii) all subjects have completed all research-related interventions;
  - (iii) the research remains active only for long-term follow-up of subjects;
  - (iv) where no subjects have been enrolled and no additional risks have been identified;
  - (v) where the remaining research activities are limited to data analysis.
8. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories (2) through (7) do not apply, but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

### **Full Review**

All proposed research deemed by the IRB chair to fit neither the exempt nor the expedited review must be reviewed by the full IRB committee. The IRB will conduct a full review for research that involves anything greater than minimal risk. The IRB will consider the following:

1. Risks are reasonable in relation to expected benefits and minimized by the use of the safest procedures consistent with standard research practice.
2. The selection of subjects is equitable, taking into account the purpose of the research.
3. Privacy of the subjects and confidentiality of data are protected.
4. Informed consent is obtained and documented.

### **Continuing Review**

The IRB is required to re-evaluate research projects at appropriate intervals of not less than once a year. For research involving no more than minimal risk, the approval period is generally one year from the date of the convened meeting at which the protocol was reviewed and approved. For research involving greater than minimal risk, the IRB will determine the appropriate approval period.

PIs are required to submit either the Continuation or the Termination form ([LINK](#)) to the IRB before the expiration date of the study.

Continuing review is required for continued analysis of identifiable information, but is not required if the data have been de-identified. An original protocol may have received an expedited review, but the continuing review may go either to exempt or to the full IRB committee for review, as deemed necessary by the IRB chair or designee.

## Responsibilities after IRB Approval

All PIs must adhere to the terms and conditions of the IR approved application and make sure that all researchers are aware and comply with it. In addition, the following criteria must be followed:

1. Researchers must provide a copy of the IRB Approved Informed Consent Form to each participant at the time of consent. All documentation must be stored in a secure location for a minimum of three (3) years after the completion of the study.
2. PIs must promptly report proposed modifications to approved studies to the IRB using the *Modification to a Previously Approved Protocol* form ([LINK](#)). No changes to the study should be initiated without prior IRB review and approval. Some modifications may require full IRB review. PIs must inform their co-investigators from cooperating institutions that any change in a previously approved protocol must be submitted to the appropriate IRB and approved before implementing the change.
3. If findings are developed during the course of the research that may have an effect on participant's willingness to continue in the study, PIs must report the findings both to the IRB and to the study participants.
4. PIs must report all adverse events and unanticipated problems that involve risks to study participants immediately to the IRB using the *Adverse Event Reporting* form ([LINK](#)).
5. The IRB will send a letter to the PI two (2) months before the expiration of the study as a reminder that the study will expire soon. PIs are required to submit either the *Continuation* or the *Termination* form ([LINK](#)) indicating whether they will continue or terminate the study. In general, the IRB grants approval for no more than one year. Some studies may be approved for a shorter time depending on the nature of the research. If an IRB approval has expired, research activities must cease.

## Audit Policy

The IRB will annually randomly audit 2% of all active projects to review for compliance with the approved protocol.

## **FORMS**

Application Checklist for IRB Approval

New Study Application Form

Continuation of an Approved Protocol Form

Termination of an Approved Protocol Form

Informed Consent to Participate in a Research Study

Report of an Adverse Event

Conflict of Interest Form



Institutional Review Board

Application Checklist

---

**Items to be included with the New Study Application Form**

- New Study IRB Application Form
- Informed Consent Form
- Assent Form (for minors)
- Parental Consent Form (if minors are subjects)
- Grant proposal, as submitted to potential sponsor/ funding agency, if applicable
- Recruitment material, such as (but not limited to) flyers, posters, letters, e-mail text, newspaper ad text, web site text
- Data collection instruments, such as surveys, questionnaires
- Focus group questions, if applicable
- Human subjects training certification for all research personnel
- Conflict of Interest Form, to be completed for each person working on the project

Rev. 3/26/10



Institutional Review Board

New Study Application Form rev. 3/26/10

|   |
|---|
| For IRB USE:<br>Date Received: _____<br>IRB # _____ |
|---|

Type or Print all information except where indicated otherwise.

**A. RESEARCH INVESTIGATOR INFORMATION**

Study Title:

Principal Investigator:

Title:

Department:

Campus Address:

Phone :

FAX:

E-mail:

Check all that apply:  Administrator  Faculty  Staff

Study Coordinator:

Title:

Phone:

FAX:

E-mail:

Will your research be a collaborative effort with another institution(s):  Yes  No

If so, Name of other institution(s):

*All study personnel associated with this project are required to complete human subjects training as described in the "Institutional Review Board Policies and Procedures Manual. Please identify all study personnel in the chart below. This would include the PI, co-investigator, faculty advisor, coordinator, research assistants and all others who will interact with research participants and/ or data. Please attach an additional sheet as needed.*

| <i>Name and Degrees</i> | <i>Role in Study</i>          | <i>VUU Affiliation? Yes or No</i> | <i>Training Certification Attached? Yes or No</i> | <i>Conflict of Interest Form Attached? Yes or No</i> |
|-------------------------|-------------------------------|-----------------------------------|---|--|
|                         | <i>Principal Investigator</i> |                                   |   |  |
|                         |                               |                                   |   |  |
|                         |                               |                                   |   |  |
|                         |                               |                                   |   |  |

**B. FUNDING**

Is this study funded? \_\_\_ Yes \_\_\_ No

If “yes”, attach a copy of the completed and approved *Authorization to Prepare a Sponsored Program Grant Application*.

Sponsor (s):

Grant Application #:

Anticipated Start Date:

**C. RESEARCH PROTOCOL**

*Check all that apply:*

- Minors (under the age of 18)
- Pregnant women
- Prisoners
- Persons with mental, emotional or physical disabilities
- Elderly (65 years and over)
- Students in a class taught by the PI
- Biological specimens (ie: saliva, blood)
- International research

*Please answer ALL of the following questions in narrative format, and attach to this form. If question is irrelevant to your study, indicate N/A.*

1. Describe your purpose, hypotheses and methodology.
2. Describe your participants, specifying inclusion/ exclusion criteria, age, range, gender and number of participants.
3. Describe your method of recruitment and attach your recruitment material.
4. Identify any existing data or data sets that will be used; include appropriate references.
5. Describe the anticipated risks, and how you plan to minimize them.
6. Describe any illegal activities that are involved.
7. Describe any deception that is involved.
8. Describe any anticipated benefits to the participant, to the community, to the larger society.
9. Describe your method for obtaining informed consent, and attach the informed consent document.
10. Describe your procedures for maintaining privacy and confidentiality.

**D. PRINCIPAL INVESTIGATOR ASSURANCE**

Your signature assures Virginia Union University that you have read the IRB *Policies and Procedures Manual*. It also assures the IRB that all procedures will be conducted as stated in this application and that any modifications to the application will be submitted to the IRB for approval prior to implementation.

\_\_\_\_\_  
Principal Investigator

\_\_\_\_\_  
Date

**E. SUBMISSION INFORMATION**

If requesting **Exempt status**, submit the original and 1 copy of the completed application, with all attachments.

If requesting **Expedited Review**, submit the original and 1 copy of the completed application, with all attachments.

If requesting **Full Review**, submit the original and 4 copies of the completed application, with all attachments.

**Applications are to be submitted to:**

Chair of IRB:  
PO Box \_\_\_\_\_  
VUU  
1500 N Lombardy St  
Richmond, VA 23220

**F. FOR IRB USE ONLY**

Assigned to Primary Reader: \_\_\_\_\_ Date: \_\_\_\_\_

Assigned to Secondary Reader: \_\_\_\_\_ Date: \_\_\_\_\_

Final review/ determination:  Exempt  Expedited Review  Full Review

Approved as submitted  Must be modified  Not approved

Comments:

\_\_\_\_\_  
IRB Chair Signature

\_\_\_\_\_  
Date



Institutional Review Board

Continuation of an Approved Protocol Form rev. 3/26/10

|   |
|---|
| For IRB USE:<br>Date Received: _____<br>IRB # _____ |
|---|

Use this form if you have an approved research study that is required to receive a continuation/ renewal for your study. All protocols that were deemed "Exempt" do not require a continuing review. All research protocols that received an "Expedited" or "Full Review" approval were given expiration dates. **If your research has expired, you are in violation of University and IRB guidelines if you continue data analysis or subject recruitment and/or intervention.**

Type or Print all information except where indicated otherwise.

**A. RESEARCH INVESTIGATOR INFORMATION**

Study title:

IRB #

Principal Investigator:

Title:

Department:

Campus Address:

Phone :

FAX:

E-mail:

**B. CONTINUATION/ RENEWAL OF RESEARCH**

Number of subjects recruited since last continuation/ renewal (or original approval, if not previously renewed):

Number of subjects you intend to recruit between now and the next continuation/ renewal:

Have you completed the recruitment phase of your study?  Yes  No

Are you requesting continuation only for data analysis?  Yes  No

Briefly summarize the research activities since the last renewal (or original approval, if not previously renewed):

**C. SIGNATURES**

\_\_\_\_\_  
Principal Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Faculty Advisor/ Professor (if applicable)

\_\_\_\_\_  
Date

**D. SUBMISSION INFORMATION**

Submit original and 1 copy of the application for Expedited projects and 4 copies for Full Review projects to:

Chair of IRB:

PO Box \_\_\_\_\_

VUU

1500 N Lombardy St

Richmond, VA 23220

**E. IRB USE ONLY**

Result of review:

\_\_\_ Approval extended until: \_\_\_\_\_

\_\_\_ Approval NOT extended.

Comment:

\_\_\_\_\_  
IRB Chair

\_\_\_\_\_  
Date



Institutional Review Board

Termination of an Approved Protocol Form rev. 9/8/09

|  |
|--|
| <p>For IRB USE:</p> <p>Date Received: _____</p> <p>IRB # _____</p> |
|--|

Use this form if you are terminating your approved research study. Protocols that were deemed “Exempt”, “Expedited” and “Full Review” all need to submit termination plans.

Type or Print all information except where indicated otherwise.

**A. RESEARCH INVESTIGATOR INFORMATION**

Study title:

IRB #

Principal Investigator:

Title:

Department:

Campus Address:

Phone :

FAX:

E-mail:

**B. TERMINATION OF RESEARCH**

Describe the reason(s) for terminating your research.

**C. SIGNATURES**

\_\_\_\_\_  
Principal Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Faculty Advisor/ Professor (if applicable)

\_\_\_\_\_  
Date

**D. SUBMISSION INFORMATION**

Submit original and 1 copy of the application for Exempt and Expedited projects and 4 copies for Full Review projects to:

Chair of IRB:

PO Box \_\_\_\_\_

VUU

1500 N Lombardy St

Richmond, VA 23220

**E. IRB USE ONLY**

Result of review:

\_\_\_\_ Termination Effective Date: \_\_\_\_\_

Comment:

\_\_\_\_\_  
IRB Chair

\_\_\_\_\_  
Date



Institutional Review Board

Informed Consent Form rev. 9/8/09

|   |
|---|
| For IRB USE:<br>Date Received: _____<br>IRB # _____ |
|---|

All questions/ requested information must be completed. If the answer is not applicable to the research study, please put "N/A".

Type or Print all information except where indicated otherwise.

**A. RESEARCH INVESTIGATOR INFORMATION**

Study Title:

Principal Investigator:

Co-Investigators:

Funding Agency:

The potential participants in your study must understand why they are being asked to participate in the study, what the potential risks and benefits will be, and the consequences to them if they choose to withdraw from your project. This information is conveyed through an Informed Consent document that must be presented for each participant to read and sign. The PI must write this document using the following format. The language of the consent form must be clear enough for your targeted participants to understand. Each page of the document must have a place for the participant to initial and the final page must have space for both the participant and the PI or the PI's representative to sign.

**B. INFORMED CONSENT DOCUMENT**

**Introduction:**

You are being asked to participate in a research study. Research studies are planned to collect new information and gain new knowledge that may potentially help people in the future.

Taking part in this research study is voluntary. You will not be penalized in any way if you choose not to participate. If you decide to participate you can stop at any time and will not be penalized in any way.

Review this form and ask the researchers all the questions you have so that you can make an informed choice as to whether you will take part in this research study.

**Details about the study:** *This section needs to provide answers to each of the following questions in a question/ answer format.*

**What is the purpose of the study?**

The purpose of this study is...

**How long will I be involved in this study?**

**What will happen if I decide to take part in this research?**

**What risks are involved in taking part in this study?**

**What benefits are involved in the study?**

**Are there any other alternate treatments or procedures that may benefit me?**

**How will my privacy be protected? How will my records be maintained to protect confidentiality?**

**Will I receive anything for being in this study?**

**Who do I contact if I have any questions about this study?**

Questions about your rights as a research volunteer can be directed to the Virginia Union University Institutional Review Board (IRB). The IRB reviews all research involving humans to ensure that all of your rights are protected. The office telephone number is \_\_\_\_\_. You may contact us without giving your name, if you prefer.

If you have questions about this project, please contact:

Principal Investigator:

E-mail:

Phone:

Faculty Advisor/ Professor:

E-mail:

Phone:

**CONSENT:**

I have read the above information, and have asked all the questions that I have at this time. I understand what I am being asked to do and I agree to take part in the study described above. I understand that I may refuse to take part or stop at any time and that I will not be penalized in any way for my decision.

Printed Name of Research Participant \_\_\_\_\_

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

Printed Name of Parent/ Legal Guardian/ Legal Representative \_\_\_\_\_

Indicate relationship to participant \_\_\_\_\_

Signature of Parent/ Legal Guardian/ Legal Representative \_\_\_\_\_ Date \_\_\_\_\_

Printed name of Researcher/ PI \_\_\_\_\_

Signature of Researcher/ PI \_\_\_\_\_ Date \_\_\_\_\_



Institutional Review Board

Adverse Event Form rev 3/1/10

|  |
|--|
| <p>For IRB USE:</p> <p>Date Received: _____</p> <p>IRB # _____</p> |
|--|

An adverse event is defined as a negative consequence of the research. They may or may not be the fault of the PI. All adverse events will be reported to the IRB within three days after they occur. Use this form to report any Adverse Event(s) that occurred during the course of the research project. Type or Print all information except where indicated otherwise.

**A. RESEARCH INVESTIGATOR INFORMATION**

Study title:

IRB #

Principal Investigator:

Title:

Department:

Campus Address:

Phone :

FAX:

E-mail:

**B. ADVERSE EVENT REPORT**

Attach separate pages that describe in detail, the Adverse Event(s) that occurred, specifying how each event was handled and potential consequences to the research project, personnel and subjects/ participants.

**C. SIGNATURES**

\_\_\_\_\_  
Principal Investigator

\_\_\_\_\_  
Date

**E. IRB USE ONLY**

Result of review:

Comment:

\_\_\_\_\_  
IRB Chair

\_\_\_\_\_  
Date



Institutional Review Board

Conflict of Interest Form rev 3/26/10

|   |
|---|
| For IRB USE:<br>Date Received: _____<br>IRB # _____ |
|---|

All personnel involved in the research project must complete this Conflict of Interest Form indicating any support, funding or affiliation with any outside agencies, institutions or entities which might have any interest or influence in the outcome of the research, or which might possibly benefit in any way from the outcome of the research project. Use this form to report any Conflicts of Interest for each of the personnel involved in the research project. Type or Print all information except where indicated otherwise.

**A. RESEARCH INVESTIGATOR INFORMATION**

Study title:

IRB #

Principal Investigator:

Title:

Department:

Campus Address:

Phone :

FAX:

E-mail:

**B. CONFLICT OF INTEREST STATEMENT**

Attach separate pages that describe in detail, the actual or potential conflict of interests that exist or may exist for each of the research personnel; each person must sign his or her own page.

**C. SIGNATURES Sign here only if there is no conflict.**

I certify that there is no such conflict.

---

|           |                  |      |
|-----------|------------------|------|
| Signature | Title in Project | Date |
|-----------|------------------|------|

---

|           |                  |      |
|-----------|------------------|------|
| Signature | Title in Project | Date |
|-----------|------------------|------|

---

Signature

Title in Project

Date

---

Signature

Title in Project

Date

**E. IRB USE ONLY**

Result of review:

Comment:

---

IRB Chair

---

Date