University of the District of Columbia
Institutional Review Board
APPLICATION FOR APPROVAL TO USE HUMAN PARTICIPANTS

IRB No: _____ Date Received: _____

Instructions to the applicant:

1. Please review the UDC IRB *Guidelines* udc.edu/irb and complete this application form.
2. Attach a copy of the informed consent form, project description including methodology and, recruitment strategy, any recruitment notices, research survey instruments, psychological tests, interview forms, or scripts to be used. (The attached Sample Informed Consent Form and Checklist are useful guides.) Include a statement of how the researcher will accommodate persons with disabilities.
3. Attach a certificate of completion of training in the protection of human research subjects, completed within the last three years, from http://phrp.nihtraining.com/users/login.php or other appropriate source for the PI and all Co-PIs.
4. If your application has been approved by another IRB, kindly attach a copy.
5. Submit completed application documents electronically in a single file to IRBNet.org
6. Sign this application form (electronically in irbnet.org submission.

A. Administration

Principal Investigator:_____ Faculty Rank:_____

Department: _____ Office Phone:_____ Email: _____

Co-Investigator: _____ Faculty Rank: _____

Department: _____ Office Phone: _____ Email: _____

Project Title: _____

Source of funding: _____

Dates of Proposed Project From: _____ To:_____

Type of application: ( ) New ( ) Renewal ( ) Revision

Date of Submission to IRB: _____

B. Project Information

1. Is this proposal qualified as exempt research? Yes ( ) No ( )

If yes, please check the following items to indicate why this proposal qualifies for Exemption.
If no, please complete items 2 to 9

a. Does the research involve normal educational practice? Yes ( ) No ( )
b. Does the research involve the use of educational tests, surveys, interviews, and observations of public behavior? Yes ( ) No ( )

If yes:

Can information be linked to the subject? Yes ( ) No ( )
Will disclosure of information place subjects at some risk? Yes ( ) No ( )

c. Does the research involve the use of educational tests, surveys, interviews or observations of public behavior not exempt under (b) above, where participants are elected or appointment of public officials or candidates for public office? Yes ( ) No ( )
d. Does the research involve only the collection of existing data, documents, records or pathological specimens? Yes ( ) No ( )

If yes:

Are these sources publically available? Yes ( ) No ( )

Can information be linked to the subject? Yes ( ) No ( )

e. Is research conducted by or subject to approval of Federal agencies? Yes ( ) No ( )
f. Is research an evaluation of taste, food quality, and consumer acceptance? Yes ( ) No ( )

g. Does the procedure meet government safety regulations? Yes ( ) No ( )

2. Human Participant Pool (Please mark the appropriate space(s).)

Children: _____ Age Range: _____

College Students:_____

Prisoners: _____

Pregnant women: _____

AIDS patients: _____

Persons with disabilities: _____

Other (please specify): _____

3. Does the study involve:

University public records?	Yes ( )	No ( )
University non-public records?	Yes ( )	No ( )

4. Does the study potentially involve:

Physical risks to the participants?	Yes ( )	No ( )
Social risks to the participants?	Yes ( )	No ( )
Psychological risks to the participants?	Yes ( )	No ( )
Discomfort to participants?	Yes ( )	No ( )
Invasion of privacy?	Yes ( )	No ( )
Disclosure of information possibly damaging to participant(s) or others?	Yes ( )	No ( )

5. Are participants clearly informed about:

The nature and purposes of the study?	Yes ( )	No ( )
The procedures to be followed including alternatives?	Yes ( )	No ( )
Any risks and/or discomfort?	Yes ( )	No ( )
Any sensitive questions?	Yes ( )	No ( )
Any benefit to be derived?	Yes ( )	No ( )
The right to refuse or withdraw from the study?	Yes ( )	No ( )
The confidential handling of data?	Yes ( )	No ( )
The compensation policy (for more than minimal risk)?	Yes ( )	No ( )
Whom to contact?	Yes ( )	No ( )

6. Will a signed or oral consent be obtained? Yes ( ) No ( )

If yes,

From participants?	Yes ( )	No ( )
From parent or guardian?	Yes ( )	No ( )

7. Will a copy of the disclosure consent form be given to the participant/guardian? Yes ( ) No ( )

8. Will precautions be taken to safeguard confidentiality and protect the anonymity of participants? Yes ( ) No ( )

9. Will proposal involve collaboration with an institution, agency, or individual etc.? Yes ( ) No ( )

   If yes, please specify below:

C. Project Description
   a. Please attach, insert or append a description of the project's purpose, hypothesis, research design and methodology
   b. Please attach, insert or append a statement describing the involvement of human participants, including how you will accomplish the items answered "Yes" above.

D. Brief Biographical Sketch of the Principal Investigator:
   a. Name: _____
      Rank:_____
   b. Education:

Highest Degree	Institution	Year Completed	Field of Study

   c. Research and/or Professional Experience: Please list in chronological order: previous employment, experience and honors. Please also list in chronological order the titles of all publications during the past three years pertinent to this application.

E. Commitment to Human Subjects Protection

I, the Principal Investigator, declare that the information provided in this application is correct and complete to the best of my knowledge. I agree to abide by the rules and regulations governing the rights and welfare of human participants in research as set forth by the Institutional Review Board (IRB) of the University of the District of Columbia. I will Not conduct the project involving human subjects unless and until it is approved by the IRB. I also agree to submit documents/information pertinent to this project as requested by the IRB. I will retain properly executed consent forms as part of my record of this project and I will immediately notify the Chairperson of the IRB of any adverse reactions encountered and corrective measures taken. I will also provide Notice to the Board of any changes to be instituted in the protocol and seek approval from the Board during this investigation.

Principal Investigator's Signature:_____ Date:_____

Address:_____
Telephone: (O):_____ (H):_____Fax:_____
Email:_____

For Official Use Only

( ) Exempt

( ) Expedited Review

( ) Full Review

IRB Recommendation: (if disapprove, give reasons)

( ) Approve ( ) Need modification ( ) Disapprove

Reason (s)/modification (s):

_____

_____

_____

Signature:

Chairperson: _____ Date:_____

Member:_____ Date:_____

_____ Date:_____

_____ Date:_____

_____ Date:_____

_____ Date:_____

Vice President for the Academic Affairs or designee: ( ) Approve ( ) Disapprove

Signature: _____ Date:_____

SAMPLE INFORMED CONSENT FORM

INFORMED CONSENT FOR PARTICIPATION IN RESEARCH ACTIVITIES

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

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

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

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

V. **CONFIDENTIALITY OF RECORDS**

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

VI. **OFFER TO ANSWER QUESTIONS AND RESEARCH INJURY NOTIFICATION**:

The principal investigator, Dr./Mr./Ms. [**insert name of principal investigator**] or a colleague Dr./Mr./Ms. _____, responsible for this research study, has offered to and has answered any and all questions regarding my participation in this research study. If I have any further questions **or in the event of a research related injury**, I can contact Dr./Mr./Ms. [**name of principal investigator**] at (202) _____ [**principal investigator's telephone number**].

VII. **SPONSOR OF THE RESEARCH** [Name of external sponsor] is the sponsor of (or "is funding"] this research study. [If there is No sponsor, indicate by N/A.]

VIII. **COST TO THE SUBJECT / PAYMENT TO SUBJECT FOR PARTICIPATION** **[If Not applicable, indicate by N/A.]**

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

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

XI. **IRB REVIEW AND IMPARTIAL THIRD PARTY:** This study has been reviewed and approved by the UDC Institutional Review Board (IRB). A representative of that Board, from the IRB Office, is available to discuss the review process or my rights as a research subject. The telephone number of the IRB Office is (202) 274-5973.

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

Participant's Name: _____ Date:

Participant's Signature: _____ Date:

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

Translator's Signature: _____ Date:

I have translated this form into the _____ language.

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

	A statement that the study involves research
	An explanation of the purposes of the research
	The expected duration of the subject's participation
	A description of the procedures to be followed
	Identification of any procedures which are experimental
	A description of any reasonably foreseeable risks or discomforts to the subject
	A description of any benefits to subject or others which may reasonably be expected from the research
	A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
	A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
	For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained
( ) Research Qs	An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the subject
( ) Rights Qs	
( ) Injury Qs	
	A statement that participation is voluntary, refusal to participate will involve No penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled
Additional elements, as appropriate	
	A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant), which are currently unforeseeable
	Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent

	Any additional costs to the subject that may result from participation in the research
	The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject
	A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject
	The approximate number of participants involved in the study