IRB Number: _____

DILLARD UNIVERSITY INSTITUTIONAL REVIEW BOARD
for the Protection of Human Subjects

Application for Initial Review

Principal Investigator: Department: Agency (*Non-Dillard Faculty or Agent)*: Title: Phone: E-mail Address: Mailing Address:

Co-Investigator: Department: Agency (*Non-Dillard Faculty or Agent)*: Title: Phone: E-mail Address: Mailing Address:

Additional Co-Investigators, if any	Department or Institution

Is this student research? *If yes, complete responsible party information below:*	Yes: ☐	No: ☐
Responsible Faculty: Title: Phone: E-mail Address:		

Title and Purpose of Research Project
Title of Project: Purpose: *(one or two sentences)*:

IRB Number: _____

Will this research project be submitted to another-other IRB for approval?
Yes ☐ No ☐ If "Yes" supply the information below:

Name of Agency-University:

Is this project funded by a grant or commercial support?
If yes, provide the information below: Yes: ☐ No: ☐

Funding Agency:
Title of Grant:
Grant Number:
Contact (name, address, phone, email):

Estimated duration of total project:
Estimated total number of subjects-participants (*including control subjects)*:
Age range of subjects-participants:
Sex of subjects-participants: Male: ☐ Female: ☐
Where will study be conducted?
Source of subjects?

Type of Research *(place an "X" in the appropriate area)*

The Research Involves:

- ☐ Interview (oral or digital)
- ☐ Survey – Questionnaire
- ☐ Behavioral Observation
- ☐ Intervention – Experiment
- ☐ Deception
- ☐ Existing Data (e.g. files, databases)
- ☐ Human Biological Specimen(s)
- ☐ Venipuncture
- ☐ Development of Commercial Product from Human Biological Material
- ☐ Clinical HIV-AIDS
- ☐ Clinical Studies
- ☐ Investigational Drugs
- ☐ Investigational Devices
- ☐ Radiation
- ☐ Controlled Substances
- ☐ Genetic Research

Other *(explain)*:

Subjects-Participants for this Study are: (*place an "X" for all that apply)*]

☐ Dillard University Faculty/Staff/Students	☐ Non-English Speaking
☐ Terminally ill	☐ Fetuses
☐ Adults (Non-Elderly)	☐ Comatose
☐ Elderly	☐ Institutional Residents
☐ Pregnant Teens or Women**	☐ Prisoners or Parolees**
☐ Cognitively-Mentally Impaired**	☐ Exclusion of Minors
☐ Children (anyone under 18 years of age)**	☐ Economically disadvantaged**
☐ Incarcerated-detained minors**	☐ Educationally disadvantaged**

Other *(describe*):

If you indicated any of the subjects-participants above (**), in the space below please describe what additional safeguards will be in place to protect these populations from coercion or undue influence to participate.

Identify individuals who will be excluded from the study and provide the rationale for this exclusion:

Recruitment: Describe how the subjects-participants will be recruited and how informed consent will be sought from subjects-participants or from the subjects-participants' legally authorized representative. If children are subjects-participants, discuss whether their assent will be sought and how the permission of their parents will be obtained.

Risks: Indicate what you consider to be the risks to subjects and indicate the precautions to be taken to minimize or eliminate these risks. If any data monitoring procedures are needed to ensure the safety of subjects-participants, describe them.

Compensation: Will subjects-participants receive any compensation for participation in cash or in kind? Yes ☐ No ☐ *(if " Yes", describe in the space provided below)*

Sensitive Information: Describe the provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Consent Elements: Identify the basic and additional consent elements you have in your assent and or consent form.

Basic

☐ 1. Research Statement
☐ 2. Reasonably foreseeable risks or discomforts
☐ 3. Possible benefits to subjects-participants or others
☐ 4. Available alternative courses of treatment(s) or procedure(s)
☐ 5. Available medical treatment for adverse experiences (greater than minimal risk)
☐ 6. Extent of confidentiality and anonymity for subjects - participants
☐ 7. Contact Information
☐ 8. Voluntary participation statement
☐ 9. Receipt of signed copy of assent and or consent form(s)

Additional

☐ 10. Unforeseeable risks to subjects-participants, embryos, or fetuses
☐ 11. Termination by principle investigator(s)
☐ 12. Additional costs to subjects-participants
☐ 13. Early withdrawal-procedures for termination
☐ 14. Number of subjects involved in study
☐ 15. Significant new findings impacting willingness to continue

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Waiver of Assent-Consent Elements: If you indicated above that you are not including Basic or Additional Consent Elements in your assent-consent forms, identify the element(s) by number(s) and provide the rationale(s) for a request for waiving the element(s).

Element Number	Rationale for Waiver Request

Attachments: Please attach the following items in order for the University IRB to review your research. In Addition, provide the original plus 7 copies of all materials for a *FULL REVIEW (ONLY)*. Provide the original plus 2 copies of all materials for *EXEMPT* or *EXPEDITED* reviews.

Remit application and hardcopies to: Lawrence Weber, Administrative Assistant, Office of Academic Affairs, Dillard University, New Orleans, LA 70122; Phone: (504) 816-4171; Email: lweber@dillard.edu

- ☐ Form IRB-A (always required)
- ☐ Request for Expedited Review (fForm IRB-B) and/or Request for Exemption (Form IRB-C)
- ☐ Conflict of Interest Forms for all Investigators
- ☐ Certificate of completion of education in the protection of human subjects research (required)
- ☐ Informed Consent Document
- ☐ Recruitment Notices or Advertisements
- ☐ Any Survey Instruments, psychological tests, interview forms, or scripts to be used in research
- ☐ Principal Investigator's qualifications (CV or biosketch)
- ☐ Research Proposal (maximum 10 pages)

IRB Number: _____

☐ I certify that the information furnished concerning the procedures to be taken for the protection of human subjects is correct. I will seek and obtain prior approval for any modification in the protocol or informed consent and will report promptly any unexpected or otherwise significant adverse effects encountered in the course of this study.

☐ I certify that all individuals named as consultants or co-investigators have agreed to participate in this study.

☐ I assure that the protected health information identified on the "Medical Records Release and General Authorization to Use and Disclose Health Information for Research" and the persons and entities that may use, give and receive protected health information is accurate and reflective of the known use and disclosure for this human clinical study.

_____ _____

Printed/Typed Name of Investigator Signature of Investigator

_____

Date

_____

Signature of Department Chair – Faculty Mentor

If more than one department, division, or administrative unit is participating in the research and/or if the facilities or support of another unit, e.g. nursing, pharmacy, or radiation therapy, are needed, then the chair or administrative official of each unit must also sign this application.

_____ _____

Authorized Signature Title & Department

_____

Date

_____ _____

Authorized Signature Title & Department

_____

Date