



DILLARD
UNIVERSITY

Institutional Review Board (IRB)
Application for Research Approval – Expedited/Full Board

RESEARCH INTEGRITY

Please save document as PDF and submit this protocol to IRB@dillard.edu in a single email; scanned signatures, [Adobe Digital ID](#) signatures, and DocuSign signatures are accepted.

Principal Investigator	
PI's Name:	Phone:
Email:	Department: <input type="text"/>
	College: Choose an item.
<input type="checkbox"/> Faculty <input type="checkbox"/> Doctoral <input type="checkbox"/> Specialist <input type="checkbox"/> Masters <input type="checkbox"/> Undergraduate <input type="checkbox"/> Other:	
Co-Investigator(s)	
Co-I's Name(s): <input type="text"/> (By each name indicate: F(Faculty), D(Doctoral), S(Specialist), M(Masters), U(Undergraduate), O(Other))	Email: <input type="text"/> (Note: Email addresses will be used for all correspondence.)
Personnel and/or Institutions Outside of Dillard University involved in this research:	
	<input type="checkbox"/> Training Attached <input type="checkbox"/> IRB Approval Attached <input type="checkbox"/> intent to rely on DU
	<input type="checkbox"/> Training Attached <input type="checkbox"/> IRB Approval Attached <input type="checkbox"/> intent to rely on DU
Project Information	
Title:	
Study Design:	
Research Interventions/Interactions:	
Study Specific Abbreviations/ Definitions	
Number of Subjects (Maximum): <input type="text"/>	
Will you be using monetary incentives (cash and/or gift cards)? <input type="checkbox"/> Yes <input type="checkbox"/> No	

Institutional Review Board (IRB)

Application for Research Approval – *Expedited/Full Board*

<input type="checkbox"/> Self-funded/non-funded <input type="checkbox"/> Internal Dillard University Internal Source:	<input type="checkbox"/> External Funding (<i>You are responsible for duplicate or additional approval submissions required by funders.</i>) Funding Source: <input type="checkbox"/> Federal <input type="checkbox"/> State <input type="checkbox"/> Private <input type="checkbox"/> Contract Funding Agency: <input style="width: 50px;" type="text"/> Status: <input type="checkbox"/> Pending Submission <input type="checkbox"/> Submitted <input type="checkbox"/> Funded Grant Number: 39G <input style="width: 50px;" type="text"/> Grant Title: <input type="checkbox"/> Same as above OR Enter here: <input type="checkbox"/> Funding application scope of work attached
---	--

Compliance Information

Do you or any investigator on this project have a financial interest in the subjects, study outcome, or project sponsor? (A disclosed conflict of interest will not preclude approval. An undisclosed conflict of interest will result in disciplinary action.). Yes No (If yes attach [disclosure form](#))

Certifications

I certify that the statements made in this request are accurate and complete, and if I receive IRB approval for this project, I agree to inform the IRB in writing of any emergent problems or proposed procedural changes. I agree not to proceed with the project until the problems have been resolved or the IRB has reviewed and approved the changes. It is the explicit responsibility of the researchers and supervising faculty/staff to ensure the well-being of human participants. At the conclusion of the project, I will submit a report. A report must be submitted no later than 12 months after project initiation.

Signature of Primary Investigator	Date
-----------------------------------	------

Signature of Co-Investigator(s)	Date
---------------------------------	------

By signing this cover page, I acknowledge that I have reviewed and approved this protocol for scientific merit, rationale, and significance. I further acknowledge that I approve the ethical basis for the study.

If faculty project, please have department chair sign.
If student project, please have the research advisor sign.

Typed/Printed Name	Signature	Date
--------------------	-----------	------

Institutional Review Board (IRB)

Application for Research Approval – *Expedited/Full Board*

Compliance Information	
Please indicate if the following are included in the study (Check all that apply):	
<input type="checkbox"/> Recruitment delivered to dillard.edu email addresses <input type="checkbox"/> Deception <input type="checkbox"/> Prisoners <input type="checkbox"/> Children <input type="checkbox"/> Individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons	<input type="checkbox"/> Video or Audio Recordings <input type="checkbox"/> Human Subjects Incentives <input type="checkbox"/> Medical Procedures, including exercise, administering drugs/dietary supplements, and other procedures, or ingestion of any substance
Is your project a research study in which one or more human subjects are <u>prospectively</u> assigned to one or more <u>interventions</u> (which may include placebo or other control) to evaluate the effects of those interventions on <u>health-related biomedical or behavioral outcomes</u> . See NIH for help with definition of Clinical Trial above. <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, attach Good Clinical Practice (GCP) CITI training appropriate to the project.	

Instructions: Please respond to the following as clearly as possible. The application should include a step by step plan of how you will obtain your subjects, conduct the research, and analyze the data. Make sure the application clearly explains aspects of the methodology that provide protections for your human subjects. Your application should be written to be read and understood by a general audience who does not have prior knowledge of your research and by committee members who may not be expert in your specific field of research. Your reviewers will only have the information you provide in your application. Explain any technical terms, jargon or acronyms.

DO NOT REMOVE THE QUESTIONS/PROMPTS.

1.	Personnel
A.	<i>Please list ALL individuals who will be conducting research on this study. This includes the principal investigator, co-investigators, and any additional personnel. Please describe the level of involvement in the process and the access to information/data that each may have.</i> (Add your text)
B.	<i>Please detail the experience of each researcher. Please include any credentials, training, or education that directly relate to the procedures in this research. Specifically, address any experience or knowledge that will help mitigate any risks associated with this research.</i> (Add your text)

2.	Purpose
A.	Purpose of Study. <i>Briefly describe in one or two sentences the purpose of your research.</i> (Add your text)
B.	Objectives. <i>What questions are you trying to answer in this project? Please include your research questions, specific aims objectives, AND state hypothesis in this section. The jurisdiction of the IRB requires that we ensure the appropriateness of research. It is unethical to put participants at risk without the possibility of sound scientific result. For this reason, you should be very clear about how participants and others will benefit from knowledge gained in this project.</i> (Add your text)

Institutional Review Board (IRB)

Application for Research Approval – *Expedited/Full Board*

C. Background. Provide a brief description of how this study fits into the current literature. Have the research procedures been used before? How were similar risks controlled for and documented in the literature? Have your instruments been validated with this audience? Include citations in the description. Do not include dissertation or thesis chapters.
(Add your text)

D. Study Intervention/Design. Describe the study intervention that is being evaluated, and/or the nature of interactions proposed.
(Add your text)

E. Data Specimen Banking. If data or specimens will be banked for future use, describe where the specimens will be stored, how long they will be stored, how the specimens will be accessed, and who will have access to the specimens may require a separate repository-specific IRB submission). List the data to be stored or associated with each specimen. Describe the procedures to release data or specimens, including the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.
(Add your text)

3.

Outcome

A. Endpoints: Please state what results you expect to achieve. Who will benefit from this study? How will the participants benefit (if at all)? Remember that the participants do not necessarily have to benefit directly. The results of your study may have broadly stated outcomes for a large number of people or society in general.
(Add your text)

B. Sharing of Results with Participants: Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with participants or others (e.g., the subject's primary care physicians) and if so, describe how the results will be shared.
(Add your text)

4.

Describe Your Subjects

A. Maximum number of participants
(Add your text)

B. Briefly describe the study population.
(Add your text)

C. Applicable inclusion or exclusion requirements (ages, gender requirements, allergies, etc.)
(Add your text)

D. Describe the duration of an individual subject's participation in the study, the duration anticipated to enroll all study participants and the approximate total duration of overall study (Please include the total number of occasions, the estimated duration of each occasion, and the overall timeframe)
(Add your text)

Institutional Review Board (IRB)

Application for Research Approval – *Expedited/Full Board*

E. Inclusion and Exclusion Criteria

Inclusion Criteria: Describe generally the individuals that will be included in your study. Describe any subject populations that will be specifically targeted

Exclusion Criteria: Describe specifically any subject populations that will be excluded from your sample.

(Add your text)

F. Population

Indicate specifically whether you will include or exclude any of the following special populations: (You may not include members of these populations as participants in your research unless you include them in the description of your subject population.)

- Adults unable to consent
- Individuals who are not yet adults (infants, children, teenagers)
- Pregnant women
- Prisoners
- Cognitively impaired or Individuals with Impaired Decision-Making Capacity
- Individuals who are not able to clearly understand English
- Community Participation (if applicable)

For studies aimed at addressing issues that affect a certain community or group, how, if at all, will this study involve people from the target community in the design of the study? Conduct of the study? How will the results of the research be shared with the participants and/or the target community(ies)?

If your research questions involve race and/or ethnicity, please clarify the following:

(1) Describe the definition you are using for “Race” and/or “Ethnicity” in this study (examples here (link to [JAMA](#), [JHM](#), [AHA](#), and [Health Affairs](#) guidance). (2) State whether you are using racial and ethnic classification of patients for descriptive statistics or within an explanatory model (as a covariate). (3) If you are using race and/or ethnicity as a variable to explain differences between patients (as a covariate), please describe the proposed mechanism of action (what is race being used as a proxy for?).

5.

Recruitment

A. Recruitment Methods

- Describe when, where, and how potential participants will be recruited, who will make initial contact and how.
- Describe the source of participants.
- Describe the methods that will be used to identify potential participants.
- Describe materials that will be used to recruit participants. (Attach copies with the application)
- For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/videotape. You may submit the wording of the advertisement before taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/videotape.)
- How will eligibility be determined? Provide a detailed description of any eligibility screening done before enrolling the subject (including whether any identifiers will be recorded – note that IP address is an identifier)
- If using contests or raffles as incentive, you must offer entry to all potential participants, not just those who enroll in the study/complete study-related procedures, per Louisiana State Law.
- If recruiting online, describe how potential participants would be directed to your recruitment information and study description.

(Add your text)

Institutional Review Board (IRB)

Application for Research Approval – *Expedited/Full Board*

B. Withdrawal of Participants

Describe anticipated circumstances under which participants will be withdrawn from the research without their consent. Describe procedures that will be followed when participants withdraw from the research, including partial withdrawal from procedures with continued data collection.

(Add your text)

C. Economic Burden to Participants

Describe any costs that participants may be responsible for because of participation in the research.

(Add your text)

6. Incentives

A. *Are you compensating your subjects with money, course credit, extra credit, or other incentives?*

Yes No

B. *If yes, describe if/how subjects will be compensated for participation in this study. Indicate what method compensation will be delivered (e.g. cash, gift card, school credit). Describe the amount and timing of any payments to participants. How much? What kind? Is tax information required? (if so, must be reflected in the informed consent form). Will payments be pro-rated if a participant withdraws early?*

(Add your text)

C. *Describe if and how you will compensate subjects who withdraw from the project before it ends and any exclusion criteria from compensation.*

(Add your text)

7. Research Procedures

A. *Which statement best describes the procedures in this protocol (including recruitment, consent, interventions, etc.)?*

This data is being collected without ANY in person interactions with participants (i.e., online surveys, virtual interviews, etc.)

This data is being collected in person with participants (i.e., in person interviews, in person focus groups, etc.).

I certify that I will adhere to the following COVID safety guidelines:

1. I will monitor the current transmission risk assessment by state and county using the [COVID Data Tracker](#) provided by the CDC and increase COVID safety measures as appropriate.
2. I will follow the COVID safety guidelines of the organization whose facility I am using to conduct my research.
3. Any shared devices or equipment will be sanitized using standard sanitation methods.

B. *Outline step-by-step what will happen to participants in this study (including what kind of experimental manipulations you will use, what kinds of questions or recording of behavior you will use, the location of these interactions). Focus on the interactions you will have with the human subjects. Specify tasks given as attachments to this document.*

(Add your text)

Institutional Review Board (IRB)

Application for Research Approval – *Expedited/Full Board*

C. Identify any activity included in the research description that will occur without modification regardless of the research effort. (E.g., A class exercise that is part of the normal course activities that is not altered for the research about which you will collect data or a team warm-up exercise session that is not altered for the study about which you will collect data.) Answer “N/A” if this does not apply.

(Add your text)

D. Describe how legally effective informed consent will be obtained. (Also, attach a copy of the consent form(s))

(Add your text)

E. If minors are to be used describe procedures used to gain consent of their parent (s), guardian (s), or legal representative (s), and gain assent of the minor.

N/A or Explain:

F. Describe all study instruments and whether they are validated. Attach copies of questionnaires, surveys, and/or interview questions used, labeled accordingly.

G. Describe how you will protect the privacy of study participants.

8.

Data Analysis, Management, and Confidentiality

A. Describe the data analysis plan, including any statistical procedures or power analysis.

Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission. Describe any procedures that will be used for quality control of collected data.

(Add your text)

B. What will you do with the results of your study (e.g. contributing to generalizable knowledge, publishing sharing at a conference, etc.)?

(Add your text)

C. Include an explanation of how will the data be maintained after the study is complete. Specify where and how it will be stored (room number, password-protected file, etc.). How data or specimens will be transported? Who will have access to the data or specimens?

(Add your text)

D. If this research is externally funded (funded by non-Dillard University funds), student researchers must specify which faculty or staff member will be responsible for records after you have left the university. The person listed below must be included in the personnel section of this application.

Responsible Party:

N/A

Institutional Review Board (IRB)

Application for Research Approval – *Expedited/Full Board*

E. Anticipated destruction date or method used to render data anonymous for future use. Please make sure this is consistent with your informed consent.

- Destroyed 3 Years after conclusion of research (minimum required for all PIs)
- Other timeframe (min 3 years): [REDACTED]
- Maintained for future use in a de-identified fashion.

Method used to render it anonymous for future use:

- Originally collected as de-identified
- Other: [REDACTED]

Note: Your data may be subject to other retention regulations (e.g. American Psychology Association.)

Special Conditions

9.	Risk
Even minor discomfort in answering questions on a survey may pose some risk to subjects. Carefully consider how the subjects will react and address ANY potential risks.	
A.	Is there greater than minimal risk from physical, mental, or social discomfort?
<input type="checkbox"/> No	
If no, <u>Do not simply state that no risk exists.</u> If risk is no greater than risk associated with daily life experiences, state risk in these terms.	
<input type="checkbox"/> Yes	
If yes, describe the risks and the steps taken to minimize them. Justify the risk undertaken by outlining any benefits that might result from the study, both on a participant and societal level.	
[REDACTED]	
B.	Will you be carrying out procedures or asking questions that might disturb your subjects emotionally or produce stress or anxiety? If yes, describe your plans for providing appropriate resources for subjects.
[REDACTED]	

10.	Research Involving Minors
A.	Will minors be involved in your research? <input type="checkbox"/> Yes <input type="checkbox"/> No
B.	If yes, describe how the details of your study will be communicated to parents/guardians. Please provide both <u>parental consent</u> letters and <u>child assent</u> letters (or processes for children too young to read). Describe the criteria that will be used to determine whether a prospective participant has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (E.g., individuals under the age of 18 years.) (Add your text)
[REDACTED]	
C.	Will the research take part in a school (elementary, middle, or high school)? <input type="checkbox"/> Yes <input type="checkbox"/> No
D.	If yes, describe how permission will be obtained from school officials/teachers, and indicate whether the study will be a part of the normal curriculum/school process.
[REDACTED]	

Institutional Review Board (IRB)

Application for Research Approval – *Expedited/Full Board*

- Part of the normal curriculum/school process
- Not part of the normal curriculum/school process

Describe:

11.

Deception

A. Will you use deception in your research?

- No Deception
- Passive Deception
- Active Deception

B. If yes, describe the deception and how the subject will be debriefed. Include a copy of any debriefing materials. Make sure the debriefing process is listed in your timeline in the Procedures section.

C. Address the rationale for using deception.

Be sure to review the deception disclaimer language required in the informed consent. Note: All research in which active deception will be used is required to be reviewed by the full Institutional Review Board. Passive deception may receive expedited review.

12.

Medical Procedures

A. Does your research procedures involve any of the following procedures:

- Low expenditures of physical effort unlikely to lead to physical injury
- High expenditures of physical effort that could lead to physical injury
- Ingesting, injecting, or absorbing any substances into the body or through the skin
- Inserting any objects into bodies through orifices or otherwise
- Handling of blood or other bodily fluids
- Other Medical Procedures
- No Medical Procedures Involved

B. Describe your procedures, including safeguards. If appropriate, briefly describe the necessity for employing a medical procedure in this study. Be sure to review the medical disclaimer language required in the informed consent.

C. Describe a medical emergency plan if the research involves any physical risk beyond the most minimal kind. The medical research plan should include, but not necessarily be limited to: emergency equipment appropriate for the risks involved, first rescuer actions to address the most likely physical risk of the protocol, further actions necessary for the likely risks.

13.

Informed Consent for Vulnerable Populations (not including minors)

A. **Cognitively Impaired Adults** Describe the process to determine whether an individual is capable of consent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require children to sign assent documents.

(Add your text)

Institutional Review Board (IRB)

Application for Research Approval – *Expedited/Full Board*

B. Adults Unable to Consent. List the individuals from whom permission will be obtained in the order of priority. (E.g., durable power of attorney for health care, a court-appointed guardian for health care decisions, spouse, and adult child.)

Describe the process for the assent of the participants. Indicate whether:

- Assent will be required of all, some, or none of the participants. If some, indicated, which participants will be required to provide assent and which will not.
- If assent will not be obtained from some or all participants, an explanation of why not.
- Describe whether the assent of the participants will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require participants to sign assent documents.

(Add your text)

14. HIPPA

A. If you are recording identifiers from the medical record from subjects who are still living, and it is not practicable to obtain their HIPAA authorization for your study, you will need to request a HIPAA waiver.

Please address how your request meets the following criteria:

- The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
- An adequate plan to protect the identifiers from improper use and disclosure;
- An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law; and
- Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, or for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by this subpart.
- The research could not practicably be conducted without the waiver or alteration.
- The research could not practicably be conducted without access to and use of the protected health information.

(Add your text)

15. FERPA

A. If your study involves collecting data of college student records, certain additional protections for students and parents are provided by federal regulations. FERPA restricts researchers' access to student records without written permission from parents of minors, or permission from students over the age of 18. Use of educational records for research purposes requires consent.

Consent form must:

- Specify the records to be disclosed;
- State the purpose of the disclosure;
- Identify the party to whom the disclosure is to be made;
- Include a dated student signature

(Add your text)

Institutional Review Board (IRB)

Application for Research Approval – *Expedited/Full Board*

16. Multi-Site Research When Dillard is the Lead Site

Study -Wide Number of Participants

If this is a multicenter study, indicate the total number of participants to be accrued across all sites.

Study-Wide Recruitment Methods

- If this is a multicenter study and participants will be recruited by methods, not under the control of the local site (e.g., call centers, national advertisements) describe those methods. Local recruitment methods are described later in the protocol.
- Describe when, where, and how potential participants will be recruited.
- Describe the methods that will be used to identify potential participants.
- Describe materials that will be used to recruit participants. (Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/videotape. You may submit the wording of the advertisement before taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/videotape.)
- Describe the processes to ensure communication among sites. All sites have the most current version of the protocol, consent document, and HIPAA authorization. All required approvals (initial, continuing review, and modifications) have been obtained at each site (including approval by the site's IRB of record).
- All modifications have been communicated to sites and approved (including approval by the site's IRB of record) before the modification is implemented.
- All engaged participating sites will safeguard data, including the secure transmission of data, as required by local information security policies. All local site investigators conduct the study following applicable federal regulations and local laws.
- All non-compliance with the study protocol or applicable requirements will be reported following local policy

Describe the method for communicating to engaged participating sites:

- Problems (inclusive of reportable events).
- Interim results.
- The closure of a study

If this is a multicenter study where you are a participating site/investigator, describe the local procedures for maintenance of confidentiality.

- Where and how data or specimens will be stored locally?
- How long the data or specimens will be stored locally?
- Who will have access to the data or specimens locally?
- Who is responsible for receipt or transmission of the data or specimens locally?
- How data and specimens will be transported locally?

(Add your text)

Reminder: No research can be undertaken until your proposal has been approved by the IRB.

Institutional Review Board (IRB)

Application for Research Approval – Expedited/Full Board

CERTIFICATION OF INVESTIGATOR RESPONSIBILITIES

By signing the cover page, I agree/certify that:

1. I have reviewed this protocol submission in its entirety and I state that I am fully cognizant of, and in agreement with, all submitted statements and that all statements are truthful.
2. This application, if funded by an extramural source, accurately reflects all procedures involving human participants described in the proposal to the funding agency previously noted.
3. I will conduct this research study in strict accordance with all submitted statements except where a change may be necessary to eliminate an apparent immediate hazard to a given research subject.
 - a. I will notify the IRB promptly of any change in the research procedures necessitated in the interest of the safety of a given research subject.
 - b. I will request and obtain IRB approval of any proposed modification to the research protocol or informed consent document(s) prior to implementing such modifications.
4. I will ensure that all co-investigators, and other personnel assisting in the conduct of this research study have been provided a copy of the entire current version of the research protocol and are fully informed of the current (a) study procedures (including procedure modifications); (b) informed consent requirements and process; (c) anonymity and/or confidentiality assurances promised when securing informed consent (d) potential risks associated with the study participation and the steps to be taken to prevent or minimize these potential risks; (e) adverse event reporting requirements; (f) data and record-keeping requirements; and (g) the current IRB approval status of the research study.
5. I will not enroll any individual into this research study: (a) until such time that the conduct of the study has been approved in writing by the IRB; (b) during any period wherein IRB renewal approval of this research study has lapsed; (c) during any period wherein IRB approval of the research study or research study enrollment has been suspended, or wherein the sponsor has suspended research study enrollment; or (d) following termination of IRB approval of the research study or following sponsor/principal investigator termination of research study enrollment.
6. I will respond promptly to all requests for information or materials solicited by the IRB or IRB Office.
7. I will submit the research study in a timely manner for IRB renewal approval.
8. I will not enroll any individual into this research study until such time that I obtain his/her written informed consent, or, if applicable, the written informed consent of his/her authorized representative (i.e., unless the IRB has granted a waiver of the requirement to obtain written informed consent).
9. I will employ and oversee an informed consent process that ensures that potential research subjects understand fully the purpose of the research study, the nature of the research procedures they are being asked to undergo, the potential risks of these research procedures, and their rights as a research study volunteer.
10. I will ensure that research subjects are kept fully informed of any new information that may affect their willingness to continue to participate in the research study.
11. I will maintain adequate, current, and accurate records of research data, outcomes, and adverse events to permit an ongoing assessment of the risks/benefit ratio of research study participation.
12. I am cognizant of, and will comply with, current federal regulations and IRB requirements governing human subject research including adverse event reporting requirements.
13. I will notify the IRB within 24 hours regarding any unexpected study results or adverse events that injure or cause harm to human participants.
14. I will make a reasonable effort to ensure that subjects who have suffered an adverse event associated with research participation receive adequate care to correct or alleviate the consequences of the adverse event to the extent possible.
15. I will notify the IRB prior to any change made to this protocol or consent form (if applicable).
16. I will notify the IRB office within 30 days of a change in the PI or the closure of the study.

***Faculty signature on the first page indicates that he/she has reviewed the application and attests to its completeness and accuracy**