Howard University Institutional Review Board
Application (Protocol) for IRB Review (A-1)
Funded and/or Drugs and/or Devices and/or Greater than Minimal Risk Research

Section One: Application Information

Principal Investigator:	
Department:	
Title:	
Phone/Pager:	
Fax:	
E-mail address:	
% Time/Effort:	

Co-Investigator:	
Department:	
Title:	
Phone/Pager:	
Fax:	
E-mail address:	
% Time/Effort:	
Co-Investigator:	
Department:	
Title:	
Phone/Pager:	
Fax:	
E-mail address:	
% Time/Effort:	

Responsible Participant (member of faculty or official or administrative unit)	
Title:	
Phone/Pager:	
E-mail address:	
Research Nurse Assigned:	
Phone/Pager:	
E-mail address:	
Study or Data Coordinator:	
Phone/Pager:	
E-mail address:	
Biostatistician (If study is Institutional)	
Phone:	

Title of Project	Purpose of Project (one or two sentences)

Additional Co-Investigators/Consultants, if any	Department or Institution

Estimated duration of total project	
Estimated total number of participants (including control participants)	
Age range of participants	
Gender of participants	
Where will study be conducted?	
Source of participants	
Experience of Principal Investigator: Brief summary (also attach a CV, biographical sketch)	

(IRB APPROVAL FOR MULTI-SITE and OTHER SITE STUDIES REQUIRES ADDITIONAL INFORMATION)

Source of Funding/Grant Support for Project (if any) Please attach two copies of the Grant Application	**Commercial Support (if any) for Project**

Investigational New Drug (IND)	**Investigational Device Exemptions (IDE)**
☐ None ☐ IND: FDA #_____ ☐ Drug Name: _____ ☐ Drug Sponsor: _____ ☐ Significant (SR) ☐ Non-Significant Risk (NSR)	☐ None ☐ IDE: FDA No. _____ ☐ Device Name: _____ ☐ Device Sponsor: _____ ☐ Significant (SR) ☐ Non-Significant Risk (NSR)
If this project involves an FDA regulated drug or device, you must file an FDA form 3455. Please submit any communications from the FDA regarding IND, IDE, or humanitarian use applications related to this submission.	
Phase: I ☐ II ☐ III ☐ IV ☐ Pilot ☐	

Section Two: Additional Howard University Regulatory Information

1. Does this project involve the use of biohazardous materials, recombinant DNA and/or gene therapy? If so, Institutional Biosafety Committee (IBC) approval must be obtained. Contact Mrs. Carol D. Winston, Coordinator, IBC (202) 806-5340 for assistance.

☐ Yes ☐ No

Has the Institutional Biosafety Committee approved the protocol?

☐ **Approved**	**Date Approved**:
☐ **Application Pending**	**Date Submitted**:

2. Does this project include the use of byproduct materials? If so, all protocols must be submitted to the Office of Radiation Safety. Contact Ms. Diana M. Roach, Program Coordinator, Office of Radiation Safety (202) 806-7216 for assistance.

☐ Yes ☐ No

Has the Radiation Safety Committee approved your application to use byproduct materials at Howard University?

☐ **Approved**	**Date Approved**:
☐ **Application Pending**	**Date Submitted**:

3. Does this project involve the use of fetal tissue?

☐ Yes ☐ No

4. Do any investigators or co-investigators have a conflict of interest as defined in the Howard University Faculty handbook?

☐ Yes ☐ No

A copy of the current Conflicts of Interest Disclosure Form for each Investigator and Co-Investigator involved with this study must be attached to this application.

Section Three: Information for Protocol Review

Please answer each specific question and use additional sheets as needed. A response of "See attached protocol or grant application" is not sufficient.

5. Study Description (summarize the protocol in no more than 2 pages using the following format)

Study Design (for example, hypothesis, research question, standard and experimental procedures, special or unusual equipment or procedures) **:**
Rationale and justification for study (for example, pertinent scientific or scholarly literature, historical background, investigator's professional research interests and experience,):
Primary study endpoint:
Primary objective:
Secondary objectives:
Treatment plan:
Statistical Considerations (justification for sample size or "n", power or degree of change):
Relative importance/value of the trial, considering "standard" therapy and competing trials:
Feasibility of study, including projections for accrual of participants (Total and Howard University) and timeline for accrual: Anticipated Accrual for local site? _____ Overall Target Accrual? _____ How Long Will Study Be Open to Accrual?_____ month(s) Duration of Study?_____ month(s)

6. Risks: Indicate what you consider e the risks to participants to be, and indicate the precautions to be taken to minimize or eliminate these risks. Justify the need for a placebo control group if one is included in this study. Where appropriate, describe the monitoring procedures that will be employed to ensure the safety of participants. Use additional sheets as needed.

7. Does a Data Safety and Monitoring Board exist?

☐ Yes ☐ No

[A Data Safety and Monitoring Board, an independent group of experts, will review the data from this research throughout the study. Patients will be told about new information from this or other studies that may affect their health, welfare, or willingness to stay in this study.]

8. Does this study include a Placebo?

☐ Yes ☐ No

9. Website Summary: If this is an open clinical trial, recruitment material for clinical trials and information for sponsors about the type of research we do will be posted on the Clinical Trials website. Please create a brief summary of this protocol, of 200 words or less, outlining the salient features that may be useful to public and health care professionals. Write in Layman Terms (8th grade reading level).

10. Data Safety and Monitoring Plan

10.1 Assignment of Risk Levels – Please select the risk level for your study and check the boxes that apply.

10.1.A Research entails minimal risk *only* if at least one of the following applies:

☐	Anthropomorphic evaluations	☐	DEXA scans
☐	Electrocardiograms (EKGs)	☐	Exercise testing
☐		☐	Intravenous catheter insertion
☐	Magnetic resonance imaging (MRI) scans	☐	Observational studies
☐	Oral glucose tolerance tests	☐	Pathology slide review
☐	Special/prescribed diets	☐	Venipuncture
☐	Other non-therapeutic tests or studies. Please list:		

Note: In the assignment of risk levels, a survey or interview instrument may be considered of more than minimal risk to participants if it requests sensitive information.

10.2 Plans for Reporting of Adverse Events Including the Death of a Participant.

Adverse events from this protocol will need to be reported to the HUIRB **within 72 hours** of its occurrence. Should a serious adverse event(s) occur that was not included in the risk statement in the protocol, it must be immediately reported verbally and in writing. All serious adverse events, both related and unrelated to the research, should be reported. In the section below, please list other individuals and/or entities to whom adverse events will be reported.

Individual/Entity		
☐	Investigator	
☐	National Institutes of Health and/or	
☐	Food and Drug Administration (FDA)	
☐	Other agency or sponsor	Please specify:

10.2.1 Who is the individual/entity primarily responsible for reporting AEs, and to whom do they primarily report.

	Who Reports:	**Reports to:**
Name		
Position		

10.3 Plans for Monitoring the Progress of Trials and the Safety of Participants

10.3.1 Safety tests. In the section below, please indicate the summary of safety tests, particularly those that screen out ineligible research participants, and those that monitor for toxicity and other adverse outcomes.

10.3.2 Safety Contact Information. In the section below, please include a description of who will manage the patients and be responsible for assessing participants' response,s including potential adverse events during their participation in the protocol. Please provide 24-hour contact information for the PI or the responsible member of the study team.

Name	**Role on the Project**	**Can be contacted 24X7?**	**Contact Information**
			Phone:
			Pager:
			E-mail:
			Phone:
			Pager:
			E-mail:

			Phone:
			Pager:
			E-mail:
			Phone:
			Pager:
			E-mail:
			Phone:
			Pager:
			E-mail:

10.4.3 Description of Individuals/Entities in Charge of Dispensing Drugs. In the section below, please identify the individuals and/or entities in charge of dispensing the drugs.

Name	**Role on the Project**	**Contact Information**
		Phone:
		Pager:
		E-mail:
		Phone:
		Pager:
		E-mail:
		Phone:
		Pager:
		E-mail:

10.4.4 Safety Monitoring Methods and Intervals In the section below, please check all that apply.

Data to be Evaluated	**Interval/Frequency of Evaluation***
☐ Age specific intervention(s)	
☐ Clinical test(s)	
☐ Participant interview and/or contact	
☐ Participant's physical exam	
☐ Participant's symptoms or performance status	
☐ Participant's vital signs	
☐ Other study parameters. Please list:	

10.4.5 Decision-Making Criteria and Stopping Rules

In the section below, please describe data safety monitoring criteria for decision-making regarding continuation, modification, or termination of the clinical study.

10.4.6 Monitoring of the Study

In the section below, indicate who will monitor the study, and the person or entity to which the study will report. Describe the frequency of the monitoring. If a DSMB is required, describe the composition of the board, its role, and the frequency of meetings and methods of communications.

10.4.7 Participant Withdrawals/Dropouts

In the section below, please describe how participant withdrawals/dropouts prior to study completion will be reported. Include examples of reasons that may prompt participant withdrawals/dropout.

Section Four: Selection of Participants and the Informed Consent Process

11. Indicate whether this project involves any of the following vulnerable populations?

- ☐ Children (Children are defined by local law as anyone under the age of 18.)
- ☐ Prisoners
- ☐ Pregnant women
- ☐ Cognitively impaired or mentally disabled participants
- ☐ Economically or educationally disadvantaged participants

If you indicated any of the above, in the space below please describe what additional safeguards will be implemented to protect these populations from coercion or undue influence to participate. (Use additional sheets as needed.)

12. Recruitment: Describe how participants will be recruited, and how informed consent will be sought from participants or from the participants' legally authorized representative. If children are the participants, discuss whether their assent will be sought, and how the permission of their parents will be obtained. Use additional sheets as needed. Include information pertinent to the inclusion criteria and the exclusion criteria to be used.

13. Does the review of this protocol include an evaluation of the patient population to ensure that women and minorities are included, if appropriate?

☐ Yes. This study is open to both men and women, and to all racial/ethnic groups. Since there are no prior reasons to expect different effects of therapy in male and female patients, and in different racial/ethnic groups, this study will not have separate accrual targets for these groups. Subgroup analyses will be conducted to determine gender and race/ethnicity treatment effects and will document any interactions between treatment and these factors.

☐ No

Explain the rationale for excluding these populations in the space below.

14. Other Exclusions: Please check the corresponding box if any of the following populations is excluded.

☐ **HIV**

☐ **Pediatric**

☐ **Other** _____

Explain the rationale for excluding any sub-population populations in the space below.

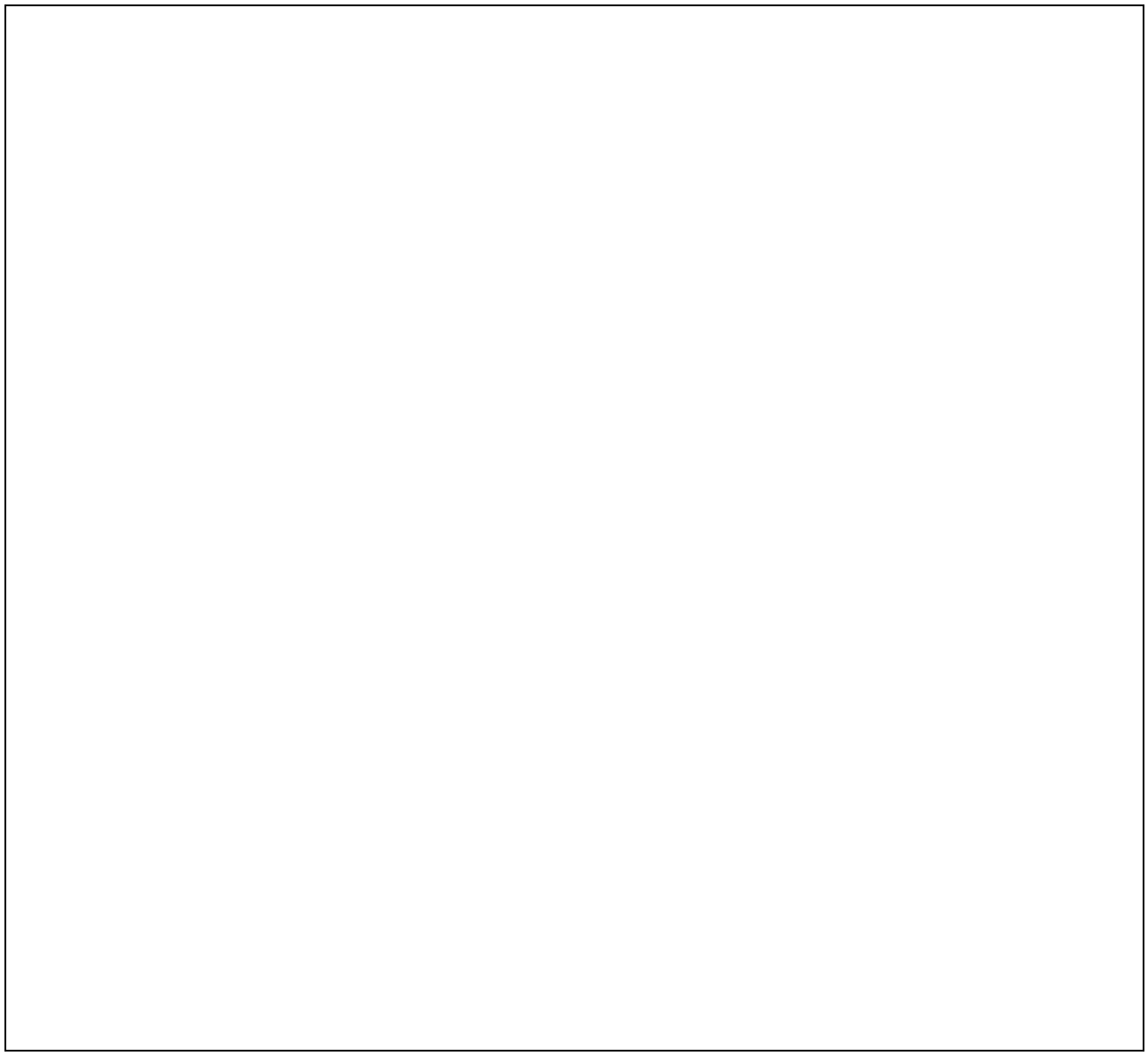
15. Will participants receive any compensation for participation in cash or in kind?

☐ Yes ☐ No

If participants receive any compensation, please describe amount or kind of compensation in the space below.

Section Five: Privacy and Confidentiality of Data and Records

16. Will identifiable, private, or sensitive information be obtained about the participants or other living individuals? Whether or not such information is obtained from a covered entity (HUH), describe the provisions to protect the anonymity and/or privacy of participants, and to maintain the confidentiality of the data they provide. If the information does come from a covered entity, please attach a copy of the completed appropriate HIPAA General Authorization Form or Request for Waiver. Use additional sheets as needed. For HIPAA compliant forms, please refer to the Chief Compliance Officer, Howard University Hospital at (202) 865-5266.



☐ I certify that the information furnished concerning the procedures to be taken for the protection of human participants is correct. I will seek and obtain prior approval for any modification in the protocol or informed consent document 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	_____ Telephone number _____ Date
_____ Printed/Typed Name _____ Signature of Department Chair	Signature of the Dean ☐ Approved ☐ Disapproved _____ Telephone Number _____ Date

If more than one department 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 and Department	☐ Approved ☐ Disapproved _____ Date
_____ Authorized Signature and Title _____ Title and Department	☐ Approved ☐ Disapproved _____ Date
_____ Authorized Signature and Title _____ Title and Department	☐ Approved ☐ Disapproved _____ Date

Section Six: Attachments

Please attach the following items in order for the HUIRB to review your research.

3 Copies of the Following for Full Board review:

- ☐ IRB Application form (Form A-1)
- ☐ Informed Consent Document(s)
- ☐ Signed copy of The Principal Investigator's Assurance Form
- ☐ Any recruitment notices or advertisements
- ☐ Any research survey instruments, psychological tests, interview forms, or scripts to be used
- ☐ HIPAA Authorization or Request for Waiver*
- ☐ Any communications from the FDA regarding IND, IDE, or humanitarian use applications related to this submission.

3 Copies of the following, when applicable:

- ☐ Request for Expedited Review. Typed letter on letterhead signed by the PI.
- ☐ Request for Exemption (Form D-1)

2 Copies of the Following for Full Board review:

- ☐ Investigator's Brochure from the sponsor, if applicable**
- ☐ Research protocol and sample consent document from the sponsor or Cooperative Group, if applicable

3 Copies of the following, if applicable

- ☐ Grant application

One Copy of the following forms for Principal Investigator and **ALL** Co-Investigators

- ☐ Certificate of Completion for HIPAA training and HIPAA forms.*
- ☐ Conflict of Interest or Financial Disclosure Form
- ☐ Certificate of Completion of Education in the Protection of Human Research Participants (NIH or CITI)***
- ☐ Investigator's qualifications (CV or biographical sketch)
- ☐ If this project involves an FDA regulated drug or device, FDA form 3455

* HIPAA Training

All persons listed on the IRB application, Co-Investigators Page, Investigator's Agreement or 1572 of any research protocol will need to have completed the HIPAA training module for Researchers in order to secure HUIRB approval. Additionally, Investigators will need to assure that all key personnel involved in the research, especially personnel with data access and patient contact, have completed the HIPAA training module for Researchers. For more information and to download forms, please refer to Meredith Harrison, J.D., Chief Compliance Officer, Howard University Hospital at (202) 865-5266.

** Investigator's Brochure (where applicable)

The Investigator's Brochure must contain the following information. If it does not contain the information, then please attach a separate sheet of paper to address the item.

- Name of drug under study.
- Source of the drug.
- Experience with the drug in humans, including doses tested, toxicity observed, minimal toxic dose, pharmacokinetic data (absorption, elimination, metabolism, etc.).
- Description of toxicity in humans.

- Procedures for minimizing adverse reactions and dealing with those that might occur.

*** Information on Human Participants Protection in Research Training: www.howard.edu/orrc

Applications/Protocols are to be delivered to the Office of Regulatory Research Compliance, located in the HU Research Building-1, 1840 Seventh Street, N.W., Suite #309, Howard University, Washington, DC 20001.

The Office of Regulatory Research Compliance does not accept electronic submissions at this time, should you have any questions, you may e-mail: theorrc@howard.edu or call the ORRC at (202) 865-8597.