DREXEL UNIVERSITY College of Medicine
Office of the Vice Dean for Research

INVESTIGATOR INITIATED RESEARCH ASSESSMENT

To: Kenny J. Simansky, Ph.D **Date:**
Vice Dean for Research
From: IISA Committee

General Research Information (please complete)			
Protocol Title:			
Principal Investigator:			
Other Investigators:			
Study Coordinator: Contact information			
Project No. (if applicable)			
Type of Study:	☐ Drug ☐ Device ☐ Specimen ☐ Behavioral	☐ Safety/Efficacy ☐ Registry ☐ Observational ☐ Phenomenological	☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ New Indication
Trial Costs	Per patient trial costs - excluding standard of care _____(please attach excel spreadsheet)		
Project Financial Support:	1. Total project budget: $_____ 2. Source of support (drug or device manufacturer; other company; agency or foundation; DUCOM department: _____ 3. Chair or departmental administrator signature: _____ Date: _____		
Location of study:	☐ DrexelMed ☐ HUH ☐ SCHC ☐ Inpatient ☐ Outpatient **(If HUH checked, email Daryl Spruill for hospital approval)** Daryl.spruill@americanacademic.com		
Number of Subjects to be Enrolled:	_____		
Additional comments			

Sponsor Responsibilities (please complete)	
Is the investigator required to obtain an IND or IDE to conduct this research?	☐ **Yes** ☐ **No** **Name of Sponsor:** **IND No.** **IDE No.** _____ **501 (k) No.** _____
Does the study involve off-label use?	☐ **Yes** ☐ **No**
Does the study involve administration of drug in combination with other drugs that is not considered SOC?	☐ **Yes** ☐ **No**
What aspect of the study is considered a deviation from SOC?	
Radiation Exposure & Biosafety (please complete)	
Does the protocol involve exposure to radiation?	SOC ☐ **Yes** ☐ **No** Research Procedure ☐ **Yes** ☐ **No**
Should the protocol be submitted for Radiation Safety Committee review?	☐ **Yes** ☐ **No**
Does the protocol involve use of biohazards or recombinant material?	☐ **Yes** ☐ **No**
Should the protocol be submitted for Biosafety Committee review?	☐ **Yes** ☐ **No**
Comment:	

Legal (do not complete)	
Is there a contract between Institution and any third parties regarding this research study?	☐ **Yes** ☐ **No**
If so, does the third party provide any indemnification? Describe.	☐ **Yes** ☐ **No**
If so, is the Institution required to provide any indemnification? Describe.	☐ **Yes** ☐ **No**
Comments:	
Conflict of Interest / Intellectual Property (do not complete)	
Conflict of Interest Assessment:	Reviewed by:
Was the conflict of interest documentation completed?	☐ **Yes** ☐ **No** **Comment:**
Is there any potential intellectual property?	☐ **Yes** ☐ **No** **Comment:**
Risk Management (do not complete)	
Risk Management Assessment:	Reviewed by:
Is there any experimental procedures? Include in Clinical Trials Insurance Policy:	☐ **Yes** ☐ **No** ☐ **Yes** ☐ **No** **Comment:**

Clinical Research Support (do not complete)	
Should the investigator involve additional investigators?	☐ **Yes** ☐ **No**
Does the investigator need clinical research support staff to manage the study?	☐ **Yes** ☐ **No**
If yes, what type of support staff and on what basis? Also, on a part-time or full-time status?	

IISA Committee Recommendation
Approve ☐ Disapprove ☐ Further review required for: IP ☐ Conflict ☐ Design ☐ Funding ☐ Risk management ☐ Review to be done by WIRB ☐
Additional Comments

Approvals

Signature of the approvers` signifies agreement that the IISA Committee approves this protocol for signature by the vice dean for research.

Name	Author's Title	Signature	Date

Name	Title	Signature	Date