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

INVESTIGATOR INITIATED RESEARCH ASSESSMENT

Date:

IISA Committee

General Research Information (please complete)			
Protocol Title:			
Principal Investigator:	Name: Title: Email: Phone: Fax:		
Other Investigators:	Name: Title: Email: Office: Phone: Fax:		
Study Coordinator: Contact information	Name: Title: Email: Phone: Fax:		
Project No. (if applicable)			
Type of Study:	☐ Drug ☐ Device ☐ Specimen ☐ Behavioral ☐ Treatment	☐ Safety/Efficacy ☐ Registry ☐ Observational ☐ Phenomenological	☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ New Indication
Trial Costs			
Project Financial Support:	1. Total project budget: 2. Source of support (drug or device manufacturer; other company; agency or foundation; 3. Chair or departmental administrator signature: Signature Date:		

Location of study:	☐ Drexel Med ☐ Tower Health ☐ SCHC ☐ Inpatient ☐ Outpatient **Additional Study Locations:**
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**

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