

Virginia Commonwealth University **Office of Sponsored Programs**

Internal Approval Form

PD/PT No.:
Date & Time: No Reviewer:

	PRINCIP	AL INVESTIGATOR	R INFORMAT	ION	
Principal Investigator				(PI Name	e as it exists in HRS)
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^{*}For Proposals with Cost Sharing, complete the Cost Share form at http://www.vcu.edu/finance/costsharingauthorization.pdf
*For Industry-Sponsored agreements, cost sharing of Principal Investigator's salary is not permitted without the approval of the V.P. for Research.

Is this project being conducted through a Center or Institute? Yes: No: If "YES": please indicate the Center or Institute: If "YES": please indicate the Center or Institute: If "YES": please indicate the Center or Institute If "YES": please indicate If yet please If yet please If yet	Set this project being conducted through a Center or Institute? Yes No	Page	2											
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	Investigator acknowledges that any fa administrative penalties.	alse, fictitious, or fraudulent	statements or cla	nims may subject me to	o criminal, civil, or
	PI Signature			Date	
	11 Signature	REQUIRED SI	GNATURES	2	
personnel debarred fi of the Dea	ndersigned, do certify to the best of our knows are correctly estimated; 3) adequate from this application; and 5) this project is noverifies that all joint VCU/VA appointed and signature areas, please see the Continuation.	and suitable space is/will be consistent with the educatio ses have a current Memo of U	provided for comp nal and research ob Inderstanding (MO	pletion of the project; 4) bjectives of the Universi bU) on file in their Dean	no named participant is ty. If applicable, signature "s office.
Principal		A copy of this proposal has be Department Chair for review (Check Box)		Dean/Date	
Co-Invest	tigator/Date	A copy of this proposal has b Department Chair for review (Check Box)		Dean/Date	
Co Investigator/Date		A copy of this proposal has been delivered to my Department Chair for review. (Check Box)		y Dean/Date	
Services 1	Investigator/Date	Appropriate approvals obta Approved on behalf of the U		Dean/Date	
	earch Services Office/Date* on-SOM/MCC)	University Official/Date			

Page 4

NOTE: This page is for information only and does not need to be printed and/or submitted to OSP

Key Definitions:

¹ Clinical Trial: A clinical trial is an interventional or observational prospective research study involving human subjects that is designed to answer specific questions about biomedical (e.g., drugs, treatments, devices) or behavioral interventions (e.g., diet modifications, physical activity) through the compliant collection and analysis of safety and efficacy data as measurement for health outcomes. In an interventional clinical trial, research subjects are assigned to a treatment or other intervention and their outcomes are measured. In an observational clinical trial, interventions given during the course of clinical care are observed and outcomes are measured by the researchers. Preclinical laboratory studies or studies in animals are not considered clinical trials.

ⁱⁱ Conflict of Interest Investigator (COI Investigator): Investigator describes any individual, regardless of title, role or position, who is responsible for the design, conduct, or reporting of research. Individuals with such research responsibilities may be, but are not limited to, senior/key personnel, sub/co-investigator or subrecipient investigator, medical investigator, collaborator, consultant, student, trainee, or research coordinator. Exceptions include students or other personnel whose research activities are directly supervised. By considering an individual's degree of independence relative to the research, the Principal Investigator on the proposal or protocol designates those who meet the definition of "Investigator."

iii Basic research: Research undertaken primarily to acquire new knowledge without any particular application or use in mind

iv Applied research: Research conducted to gain the knowledge or understanding to meet a specific, recognized need

^v Developmental Research – The systematic use of the knowledge or understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including the design and development of prototypes and processes