Virginia Commonwealth University
Office of Sponsored Programs

Internal Approval Form

PD/PT No.: _____
Date & Time: _____
Copy Received: Yes ☐ No ☐
Reviewer: _____

PRINCIPAL INVESTIGATOR INFORMATION

Principal Investigator _____ (PI Name as it exists in HRS)
Last Name First Name MI

E-mail: _____ PI Phone # _____ PI Fax # _____

PO Box _____ Department _____
Note: This department will receive credit for the award unless alternate department is listed below.

FA Name _____ FA E-mail _____ FA Phone # _____

Contact for Proposal Pickup _____ Contact E-mail _____ Contact Phone # _____

Is the department listed above also managing the project's fiscal responsibilities? Yes: ☐ No: ☐ If no, please list the department responsible for fiscal management which will receive credit for award.

Dept. for Fiscal Administration _____ FA Name _____

Fiscal FA E-mail _____ FA Phone # _____

Study Coordinator Name _____ E-mail _____

Study Coordinator Phone # _____ Fax # _____

Distribution List – Indicate email addresses to distribute documentation related to this proposal:

_____ _____ _____ _____ _____

_____ _____ _____ _____ _____

SPONSOR/AGENCY INFORMATION

Sponsor Name _____

Contact Name _____ **No Acronyms**

Phone # _____ E-mail: _____

Due Date: _____
Receipt Date ☐ Postmark ☐
E-Submission* ☐

Research ☐ **[i]Clinical Trial** ☐ **Fellowship** ☐ _____ **Training** ☐ **Other** ☐ _____
[i]See last page for key definition

Does the project involve Federal Funds? Yes: ☐ No: ☐ _____
(Originating sponsor, if applicable)

Solicitation/RFA/RFP/Award Number: _____

*For proposals requiring Electronic Submission, the complete proposal needs to be in the OSP office no later than **FIVE** days before the due date.

PROPOSAL INFORMATION

Proposal Title: _____ **No Acronyms**

_____

☐ Continuation of OSP# _____ ☐ Supplement of OSP# _____

Project Period	Begin:	End:
Budget Period	Begin:	End:

F&A Rate:	%
Nature:	CR ☐ TFP ☐ FUP ☐

Budget Information

	Year One	Year Two	Year Three	Year Four	Year Five	Project Total
Direct	$	$	$	$	$	$0
Indirect	$	$	$	$	$	$0
Subtotal Sponsor	$0	$0	$0	$0	$0	$0
Cost Share *	$	$	$	$	$	$0
Total	$0	$0	$0	$0	$0	$0

*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.

PI: _____ Title: _____ Sponsor: _____

-Is this project being conducted through a Center or Institute? Yes: ☐ No: ☐
If "YES", please indicate the Center or Institute: _____
(The list of Centers and Institutes is available at www.research.vcu.edu/vpr/institutes.htm)

-Are there VCUHS employees involved in the performance of the project? Yes: ☐ No: ☐

-The proposed project will use the services of the following Service Areas or Core Facility*(attach a copy of approved pricing sheet from each area):

☐ Respiratory Care ☐ Radiology ☐ CCTR ☐ MCV Physicians ☐ Pathology
☐ In-Patient Beds ☐ Nursing Support ☐ Pulmonary/Bronchoscopy ☐ Investigational Pharmacy ☐ CRSO
☐ Health Information/Computing ☐ Survey Evaluation Research Lab ☐ Biostatistics ☐ Other: _____
☐ Core: _____

*** Core facility listing can be found at www.research.vcu.edu/vpr/core_laboratory.htm**

-All or part of this project will be conducted in the following buildings (check all that apply):

☐ BioTech One ☐ Engineering East ☐ Engineering West ☐ W. Grace South
☐ Kontos Med. Sci. Bldg. ☐ Massey Cancer Ctr. ☐ McGlothlin Med. Ed. Ctr ☐ MMRB ☐ Sanger Hall
☐ School of the Arts ☐ Snead Hall ☐ Sports Medicine ☐ Trani Ctr. for Life Sci.

PERCENT EFFORT AND PERCENT RESPONSIBILITY ON PROJECT

Key Personnel, Faculty, and "COI Investigator" Designations: Note - Do not include subrecipient COI Investigators

Key	COI Investigator[ii]	Name	Role on Project	CAL Mnths	ACAD Mnths	SUMR Mnths	% EFFORT	% RESP	
☒	☒		PD/PI						Sal Esc ☐
☐	☐								Sal Esc ☐
☐	☐								Sal Esc ☐
☐	☐								Sal Esc ☐
☐	☐								Sal Esc ☐

COMPLIANCE DATA

-If project is research or clinical trial, please indicate:
Basic[iii] ☐ Applied[iv] ☐ Developmental[v] ☐ **[ii-v]See last page for key definitions**

The proposal enclosed involves the following:

Yes	No	Maybe		Yes	No		Yes	No	
☐	☐		Human Subjects Research[1] (If yes, complete table on next page)	☐	☐	Radioactive Materials[4,5]	☐	☐	Clinical Trial[7]
☐	☐		Animal Use[2] (If yes, complete table on next page)	☐	☐	Recombinant DNA, Select Agents or other biohazards[4,5]	☐	☐	Clinical Research[7]
☐	☐	☐	Foreign Nationals	☐	☐	Company Confidential Information will be provided	☐	☐	Sponsor is foreign-owned company or foreign government
☐	☐		Restrictions on Publication or Intellectual Property Rights	☐	☐	International Program	☐	☐	Program Income
☐	☐		Retired faculty participation	☐	☐	Subcontracts or subrecipients[6] (external)	☐	☐	Wet lab space
☐	☐		Rented off campus facility	☐	☐	Subaccounts (internal)[6]	☐	☐	Additional/New space
☐	☐		Delivery of anything more than technical report	☐	☐	NSF Funds- RCR Training Required	☐	☐	NIH Funds- RCR Training Required
☐	☐		HIPAA Covered Data[3]						

1. For further information on human subjects research refer to: http://www.research.vcu.edu/irb/activities.htm
2. For further information on animal research refer to: http://www.research.vcu.edu/iacuc/index.htm
3. Contact VCUHS Compliance Services at http://www.vcuhealth.org/?id=865&sid=1 or 828-0500
4. For more information on environmental health requirements refer to http://www.vcu.edu/oehs/
5. For more information on chemical and biosafety requirements refer to http://www.vcu.edu/oehs/chemical/biosafe/IBChome.pdf
6. If Yes, complete Internal Approval Form Proposal Budget Detail, http://www.research.vcu.edu/forms/IAFProposalBudgetDetail.xls
7. If Yes, complete Clinical Research Compliance Documentation Checklist, http://www.research.vcu.edu/forms/ClinResearchCompliance.pdf

PI: _____ Title: _____ Sponsor: _____

PROTOCOLS*: Principal Investigator / Co PI(s)	IRB/IACUC No.	Approval Date

(*From previous page, list protocols if applicable)

PRINCIPAL INVESTIGATOR CERTIFICATIONS, DISCLOSURES AND ASSURANCES

By signing below I certify that I have read and understand the statements below and those contained in this *Internal Approval Form* and further certify that the statements contained herein are accurate and truthful to the best of my knowledge and belief:

Yes	No	
☐	☐	All applicable items contained in the **Compliance Data** section have been identified. Investigator agrees to abide by any obligations applicable under VCU policies or other legal requirements (e.g., obtaining protocol approvals, adhering to export control laws, maintaining confidentiality, etc.).
☐	☐	Investigator has read and understands VCU's Conflict of Interest and Conflict of Interests in Research policies, has designated and informed all "COI Investigators," has reported required financial interests in the Activity and Interest Reporting System (AIRS), and prior to the expenditure of any awarded funds, if applicable, shall have reached an agreement with VCU for conditions or restrictions to reduce, manage or eliminate any conflicts of interest under University policy.
☐	☐	The enclosed proposal is complete in technical content, adheres to norms of proper scholarship and responsible conduct of research, including proper citation and attribution for all text and graphics, complies with federal guidance on research integrity (e.g., see VCU policy on responsible conduct in research), and is in accordance with all specifications from the sponsoring agency.
☐	☐	The space/facilities and other VCU resources necessary to conduct the proposed project are currently available to the investigators and if not currently available, arrangements will be made with the Department/School/Division to make all necessary resources available in the event an award is made by the sponsor.
☐	☐	If the proposal enclosed is funded and accepted by VCU, Investigator agrees to conduct the project in accordance with all terms and conditions stipulated by the sponsoring agency and all applicable VCU policies and procedures; furthermore, Investigator agrees to be fully responsible in meeting the requirements of the award, including but not limited to, proper and ethical stewardship of funds, timely submission of all required technical reports and deliverables, proper disclosure of all inventions to VCU's Technology Transfer Office, and also adhering to all federal compliance requirements (e.g., Export Control, HIPAA, IRB, IACUC, other Human Research protections, etc.).
☐	☐	Investigator acknowledges that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.

PI Signature _____ **Date** _____

REQUIRED SIGNATURES

We, the undersigned, do certify to the best of our knowledge and behalf that 1) the designated faculty will be released for the effort indicated; 2) personnel costs are correctly estimated; 3) adequate and suitable space is/will be provided for completion of the project; 4) no named participant is debarred from this application; and 5) this project is consistent with the educational and research objectives of the University. If applicable, signature of the Dean verifies that all joint VCU/VA appointees have a current Memo of Understanding (MOU) on file in their Dean's office.
For additional signature areas, please see the Continuation Page (http://www.research.vcu.edu/forms/IAFContinuationPage.doc).

Principal Investigator/Date	☐ A copy of this proposal has been delivered to my 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)	Dean/Date
Co-Investigator/Date	☐ A copy of this proposal has been delivered to my Department Chair for review. (Check Box)	Dean/Date
Services Investigator/Date	**Appropriate approvals obtained (see above). Approved on behalf of the University:**	Dean/Date
Clin. Research Services Office/Date* (*Only if non-SOM/MCC)	University Official/Date	

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

Key Definitions:

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[i] 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