Research Administration and Compliance Meeting Wednesday, August 15, 2012 1:00 – 3:00 p.m. Larrick Hall, Court End B

Agenda

Welcome

General Items/Updates

- VCU Interim Policy Conflicts of Interest in Research Monika Markowitz
- VCUeRA AIRS Demonstration Jim Ward
- Office of Sponsored Programs and Grants & Contracts Accounting Move September 6-7
- New F&A Rates

OSP Updates

- Request for Advance PT Number and Use of Transaction Routing Form
- Revised Internal Approval Form August 2012
 - "COI Investigator" column
 - VCUHS employee involvement
 - o Building identification tax exempt bond tracking
- VCU Subrecipient Commitment Form
- VCU Sponsored Project Administration Certification Program

G&C/Effort Reporting Updates

Update

Future Meeting Dates, 1-3 p.m.

- October 3, 2012 Larrick Hall, Court End Ballroom A
- January 23, 2013 Larrick Hall Jackson Ward Conference Room (Pending)
- May 22, 2013 Larrick Hall Court End Ballroom A

Demonstration of the Activity and Interest Reporting System (AIRS) for Financial Interests Reporting

Monika S. Markowitz, PhD
Director, Office of Research Integrity and Ethics
Chair, Conflict of Interests Committee

Susan E. Robb, CRA
Associate Vice President for Research Administration and Compliance

James Ward, MS, MBA Executive Director Research Information Systems

As of 8/13/2102

What is driving the changing COI policy and process?

Public Health Service (PHS) Final Rule: Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought ...

Published in Federal Register August 25, 2011 Implementation by August 24, 2012

➤ <u>Virginia State and Local Government Conflict of</u>
Interests Act Section 2.2-3100.

Specifically: restricts the ability of employees to have personal interests in certain contracts with their own or other governmental agencies (prohibited dual contracts)

> Increased public demand for transparency

What is a Financial Conflict of Interests?

Financial Conflicts of Interest in research occur when the Investigator, or any member of that person's immediate family (spouse, or domestic partner, and any other person residing in the same household as the researcher, who is a dependent of the researcher or of whom the researcher is a dependent), possesses a Significant Financial Interest (SFI) that is in conflict with his or her institutional responsibilities, such as the design, conduct, or reporting of research.

From VCU policy: Research Conflict of Interests

Who is affected by the changing COI policy and process?

The changing VCU COI policy and process applies to 'investigators' on <u>all</u> research, *including*:

- PHS (NIH) funded research
- NIH and other funded research for which VCU is sub-recipient
- research funded by a non-NIH federal entity
- research funded by industry/business
- research funded by any non-profit entity
- research that is not funded at all

Who is an 'investigator?'

<u>Investigator</u> 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 sub-recipient 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 the individuals who meet the definition of 'Investigator.'

'Investigators' report Financial Interests, regardless of research funding, into the AIRS

Each Investigator is responsible for reporting requested Financial Interests held by him or herself, or any member of his or her immediate family (spouse, or domestic partner, and any other person residing in the same household as the researcher, who is a dependent of the researcher or of whom the researcher is a dependent), with the exception of travel compensation.

'Investigator' reporting in the AIRS

Initial/annual — Report for 'now' and last 12months:

- Financial Interests (FI) for self and immediate family
- Travel <u>only</u> for self based on institutional responsibilities (if not paid through VCU or grant/contract processed through OSP)
- Research relatedness, if any, to all proposed or ongoing research
- Annually affirm accuracy of reported FIs for 'now' and last 12 months.

Investigator reporting in the AIRS Update – Report:

- FI reported within 30 days if a new entity OR if same entity and new interests are >\$5000 in aggregate.
- Travel for self ONLY if new entity is paying
- If update FI, update research-relatedness, if applicable
- May need to update research relatedness for new proposal/protocol based on existing FIs

Nothing to update? No relatedness? If entered/updated in last 12 months, no need to re-enter AIRS for specific proposal/protocol submission!

FIs that are reported in AIRS

- salary or other payments for services from an entity other than VCU (e.g., consulting fees, honoraria, or payments for serving on a corporate Board of Directors, Scientific Advisory Board, or holding a position in a company);
- income from seminars, lectures, service or teaching engagements sponsored by for-profit entities, federal, state, or local agencies or public or non-profit entities (includes study sections);
- ownership interests). (*Does not include mutual funds or other investment vehicles which are not controlled by 'investigator' or immediate family member);

FIs that are reported in AIRS (2)

- Income related to intellectual property rights held at VCU or other institution (e.g., patents, copyrights, and royalties from such rights,); and
- by a third party related to an Investigator's
 Institutional Responsibilities (includes travel that is
 directly paid to the Investigator and travel paid on behalf of
 the Investigator so that the exact monetary value may not
 be readily available; an estimate may be necessary)

Financial Interest <u>does not</u> include salary or reimbursement originating from VCU, <u>with the exception of royalties</u>/ payments from VCU IP Foundation.

What information about travel will be reported in the AIRS?

- Payer name
- Activity type: consulting, speaking, service, leadership activity
- Type of payer: government, non-profit, for profit, foreign, individual
- Type and amount of payment: travel reimbursement; third party payment (may be an estimate)
- Destination
- Duration: number of days for business
- Related VCU research project in progress or pending?

School of Medicine plans to utilize travel reporting for CP-2 purposes!

Questions?

For more information:

See the VCU COI website:
 http://www.research.vcu.edu/p and g/coi2.htm
 The presentation is continually updated and re-posted on website.

For questions once AIRS is live:

- <u>eRAHELP@vcu.edu</u> for system questions
- AIRS@vcu.edu for content questions

Financial Interest Report (FIR) for Alexander Bell

Question	Responses	Relatedness
List Immediate Family Members	Christa Markle (Wife) Alexis Bell (Daughter) Christopher Bell (Son)	
Officers and Directorships	No	
Investments and Securities	Stock – Roche Diabetics, \$52,000 Stock – Facebook - \$10,000	Yes –My NIH grant is also related to insulin delivery.
Payment for Consulting, Talks, Meetings and Publications	Bristol-Myers-Squibb: Honoraria for speaking, \$3000 on 6/8/12 and travel reimbursement for \$1000 on 6/8/12; Consulting Fee for \$5000 on 2/5/12 American Diabetes Association: Third party payment of travel \$1000	Yes, Presentation to Bristol-Myers- Squibb included information from basic science research being conducted under American Diabetes and NIH grants.
Salary and Wages other than VCU	Christa – Wife – Biovail – greater than \$10,000 Alexis – Daughter –Macy's – Between \$5,000 & \$10,000	No
Business Interests	No	
Grants, Gifts, In-Kind Materials	No	
Intellectual Property	No	

THEN Start a Company named MedDevice		
Business Interests	Co-Own MedDevice with my wife (50/50): MedDevice, Richmond, VA, Medical device company, Gross Income, \$10,000, Amount of financial investment \$150,000, Percent Equity 100%; Owned by You and Immediate Family member	Yes – Proposed clinical trial with Roche Diabetics to test insulin delivery device developed by MedDevice. I have stock ownership in Roche Diabetics and coown MedDevice with my wife Christa. My NIH grant is also related to insulin delivery.
Intellectual Property	Inventor on IP owned by VCU IP Foundation – licensed to MedDevice – no income to date	Yes – Proposed clinical trial with Roche Diabetics to test insulin delivery device developed by MedDevice. I have stock ownership in Roche Diabetics and coown MedDevice with my wife Christa. My NIH grant is also related to insulin delivery.
Salary and Wages other than VCU	Christa – Wife – Now works for MedDevice – greater than \$10,000 Christopher – Son – now works for MedDevice – greater than \$10,000 Alexis – stays the same	

OFFICE OF SPONSORED PROGRAMS

PLEASE NOTE: The VCU Office of Research will be relocating to the 3rd floor of Biotech One in early September, 2012. This move includes the Office of Sponsored Programs (OSP). Please review the important information below.

The Office of Sponsored Programs begins its move late in the day (3:00 p.m.) on Thursday, September 6 and continues through Friday, September 7.

IMPACT - Proposals: Proposals will be accepted at our intake desk until 3:00 p.m. on Thursday, September 6. No proposals will be accepted at the intake desk from 3:00 p.m. Thursday, September 6 through 10:00 a.m. Monday, September 10. Electronic proposals can continue to be submitted; however, the ability to acknowledge receipt and review proposals will be greatly diminished during this time as staff transition to the new space. Please plan accordingly for proposals due September 6 through September 12.

Proposals will be accepted at our new intake desk on the third floor beginning at 10:00 a.m. on Monday, September 10.

IMPACT – Awards and Subawards: The ability to review awards and issue subawards will be greatly diminished from 3:00 p.m. Thursday, September 6, through 10:00 a.m., Monday, September 10. Please plan accordingly.

All phone numbers will remain the same; however, substantial down time of phone lines and email is anticipated on Thursday and Friday, September 6-7.

OFFICE OF RESEARCH SUBJECTS PROTECTION

PLEASE NOTE: The VCU Office of Research will be relocating to the 3rd floor of Biotech One in early September, 2012. This move includes the Office of Research Subjects Protection (ORSP). Please review the important information outlined below.

The anticipated moving date for ORSP is on or around Friday, September 7, 2012.

IACUC Impact: IACUC submissions and processing should not be impacted by the move.

IRB Impact: To ensure an orderly move (including the relocation of all IRB study files, records, and submissions), it will be necessary to postpone the submission process for IRB documents (other than Prompt Reports or other urgent submissions*) for several days before and after this period. Thus, we will not be accepting IRB submissions at our Intake desk during the period of September 5-10, 2012. We are looking forward to receiving submissions at our new location beginning Tuesday, September 11, 2012. For continuing review submissions that are due on or around the above period, please make every effort to submit your materials by August 31, 2012.

*Submission of Prompt Reports for the reporting of unanticipated problems involving risk or harm to subjects or others WILL BE ACCEPTED during the period noted above. For guidance on what constitutes an unanticipated problem involving risk or harm to subjects or others, refer to the VCU IRB Prompt Reporting Form available at

http://www.research.vcu.edu/forms/vcuirb.htm. Please contact our office if you need assistance with a Prompt Report submission or have another urgent issue during this period.

GRANTS AND CONTRACTS ACCOUNTING

PLEASE NOTE: Effective September 10, 2012 VCU's Grants and Contracts Accounting Office new physical location will be 800 East Leigh Street, Suite 3100. Due to our relocation which will commence on Thursday September 6, 2012 at 3:00 p.m., there will be periods of service interruption through September 10, 2012 for telephone, fax, and email communication. All voice messages and emails will be responded to promptly on September 10th. We apologize for any inconvenience that this may cause. Please review the important information below.

IMPACT - Check and document delivery: Checks may continue to be brought to the Theater Row office location until 12:00 on Friday 9/7/2012. After that time all checks and documents will need to be delivered to 800 East Leigh Street Suite 3100.

All phone numbers will remain the same; however, substantial down time of phone lines and e-mail is anticipated on Thursday and Friday, September 6-7. If unable to reach a G&C staff member, please leave a voicemail and the staff member will promptly return the call as soon as service is restored.

IMPACT - New Banner Index Creates: We will not be able to accommodate request to create new awards during the period of September 6-10, 2012. It is our expectation that we will be able to resume normal operations beginning Tuesday, September 11, 2012.

Current Rates

Fringe Benefits Rates: 07/01/2012-06/30/2013

Non-Sponsored and Sponsored

Faculty and Classified Staff	32.3%
Hourly	8.2%
Full-Time VCU Student	0.0%

Facilities & Administration (F&A) Rates 07/01/2012-Until amended

Research

52.0%
52.5%
26.0%

Instruction

On-Campus	40.0%
Off-Campus	26.0%

Other Sponsored Activities

On-Campus	35.0%
Off-Campus	26.0%

OFFICE OF SPONSORED PROGRAMS MELANIE WIGGINS

OSP Update:

Advance Proposal Tracking Numbers

REQUIREMENT FOR ISSUANCE OF AN ADVANCE PROPOSAL TRACKING (PT) NUMBER

- In order to comply with the new financial conflict of interest reporting requirements, advance assignment of PT (or SC) numbers are required for all new proposals.
- Proposal Tracking numbers are required for upload to the Activity and Interest System(AIRS). Numbers assigned through VCUeRA will require an overnight update before they are available in AIRS.
- The Office of Sponsored Programs (OSP) will assign tracking (PT or SC) numbers based on the information provided in the Advance PT Number Request Form available on our website.
- An email containing the tracking number will be generated and sent to the person indicated on the request form. This tracking number must be included with the proposal package of materials delivered to OSP for review and/or submission.
- OSP will use AIRS to associate COI Investigators indicated on the internal approval form with a research project at proposal time using the tracking number provided with the proposal. This will enable a request for review to be submitted.

ADVANCE PT REQUEST FORM

• A web form to request your advance number has been developed and can be accessed at the following website:

http://www.research.vcu.edu/forms/osp.htm



Our Offices

- » Vice President for Research
- Undergraduate Resources
- » Postdoctoral Services
- » Research Subject Protection
- Technology Transfer
- Animal Resources
- Sponsored Programs
- Compliance and Education



Each university member is expected to report actual or suspected violations of laws, regulations, VCU policies and procedures or other misconduct. Management has a special duty to recognize and report violations.

Research Resources

- Research Incubator
- Research Compliance Matrix
- » Proposal Preparation Tools
- Find Funding
- » More Research Resources
- » Policies and Guidelines

Research A to Z

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

Advance PT Number Request

The Office of Sponsored Programs records proposals in its database using a unique institutional number, either a "PD" or "PT" number depending on whether it is submitted from the VCUeRA database or not.

Please use this electronic form to request an advance "PT" number for new proposals meeting the following criteria: NIH applications submitted in paper format (P and U series) and all applications for <u>all other sponsors</u>.

Do not use this electronic form for applications submitted electronically through VCUeRA (NIH applications with R, T, and F series)—the identifying number for these proposals is a "PD" which is available when the PI creates the application.

Do not use this electronic form for Clinical Trials if a Confidentiality Disclosure Agreement (CDA) has been executed for your proposed Study. Use the same PT number assigned to your CDA when submitting your proposal.

OSP will make every effort to respond to your request for a PT number within 24 hours of receipt. The PT number we assign to your proposal must be included with the proposal package of materials you deliver to the Office of Sponsored Programs for review and/or submission.

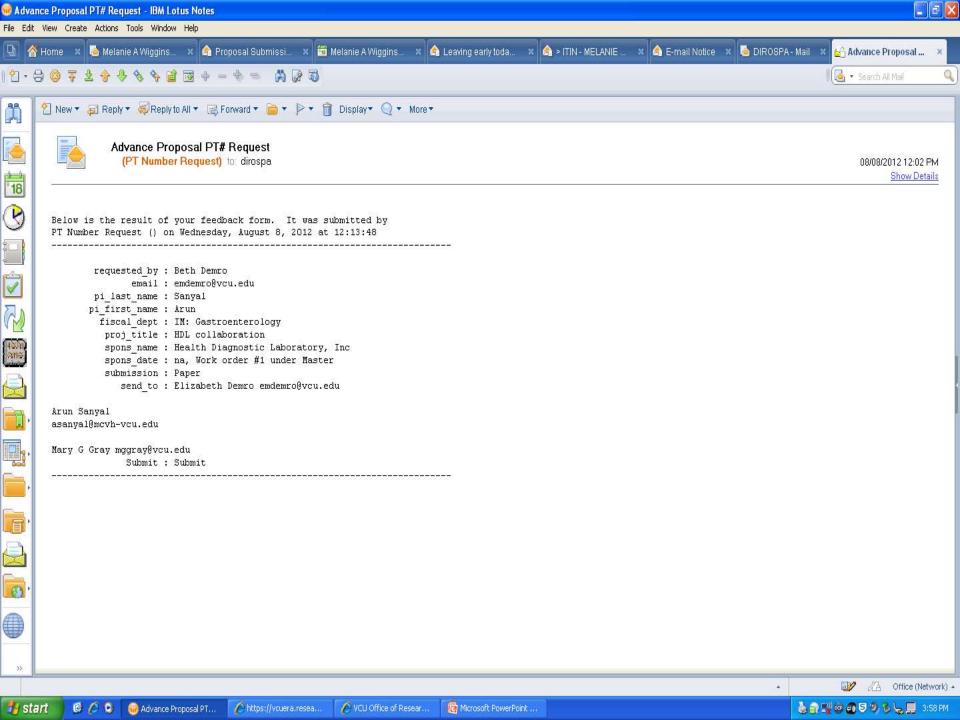
ubmission.
lame (of requester):
mail (of requester):
I Last Name:
I First Name:
roposed Fiscal Managing Department:
roject Title:
ponsor Name:
ponsor Published Due Date:
ponsor's Solicitation/RFA/RFP/Award Number:
leans of Submission:
O Electronic
O Paper

Indicate all VCU individuals by name and email address to whom the PT number should be sent:

Hybrid (Electronic and Paper Combination)

WHEN TO USE THE WEB FORM

 Please use this electronic form to request an advance "PT" number for new proposals meeting the following criteria: NIH applications submitted in paper format (P and U series) and all applications for <u>all</u> <u>other sponsors</u>.



u.edu/shared/popUpViewDocument.asp?DocVersionId=AEBD797C-4474-4240-A0 - Windows Internet Explorer

hared/popUpViewDocument.asp?DocVersionId=AEBD797C-4474-4240-A0E9-7C6C5476156F







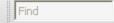




🚵 Collaborate 🕶









Thank you for requesting an advance PT number from the Office of Sponsored Programs (OSP) for your upcoming proposal submission.

A proposal tracking record and number has been created in VCUeRA as follows:

OSP Proposal Development/Tracking number assigned: SC104336

Principal Investigator: Sanyal, Arun J

Project Title: Subproject for Institution # PT108314

Sponsor: Health Diagnostic Lab, Inc.

Sponsor-published due date you have indicated:

Email us at dirospa@vcu.edu if any corrections to this information are needed.

Please remember to forward your proposal to OSP five (5) business days prior to deadline to ensure adequate time for university-level review. For all proposals forwarded to OSP after August 24, 2012, please ensure that all VCU personnel designated on the Internal Approval Form (IAF) as a "COI Investigator" have completed a Financial Interests Report (FIR) in the Activity & Interest Reporting System (AIRS).

Intake Specialist - Office of Sponsored Programs Virginia Commonwealth University T: 804.828.6772; F: 804.828.2521 Email: dirospa@vcu.edu

WHEN NOT USE THE WEB FORM

- Do not use this electronic form for applications submitted electronically through VCUeRA (NIH applications with R, T, and F series)—the identifying number for these proposals is a "PD" which is available when the PI creates the application.
- PD numbers will continue to be assigned through the electronic system as proposals are developed
- Do not use this electronic form for Clinical Trials if a Confidentiality Disclosure Agreement (CDA) has been executed for your proposed Study. Use the same PT number assigned to your CDA when submitting your proposal.

QUESTIONS

- Give us a call (828-6772) if you are not sure about whether a new PT number is required.
- This will help ensure duplicate numbers are not created.



Virginia Commonwealth University **Office of Sponsored Programs**

Internal Approval Form

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

	PR	INCIPAL IN	VESTIGATOR	INFORMAT	ION	
Principal Investigator					(PI Name	as it exists in HRS)
1 0	Last Na	ame	First Name	MI	[
E-mail:		Pl	[Phone #	PI Fax	#	
					·	
	Department _		partment will receive credit f		nate denartment is listed be	low
FA Name	·	FA E	-mail	<u> </u>	FA Phone	#
Contact for Proposal Pi	ickup		Contact E-mail		Contact Pho	one #
Is the department listed fiscal management which			eal responsibilities? Y	es: No: If	f no, please list the de	partment responsible fo
Dept. for Fiscal Admin	nistration			FA Name		
Fiscal FA E-mail				FA Phone #		
Study Coordinator Nan				E-mail		
Study Coordinator Pho				Fax #		
Distribution List – Indica		o distribute docum				
						<u> </u>
		SPONSOR	AGENCY INFO	ORMATION		
		or ondor	AGENCTINI	JAMATION		
Sponsor Name				<u></u>	Due Date:	
G · · · · · · · · · · ·				No Acronyms	Receipt Date	Postmark
Phone #	E-mail:	.		-	E-Submission*	П
I none "	<i>L</i> man.			_		
Research	ical Trial 🗌	Fellowship		Trainin	g 🗌 Othe	er 🗌
ⁱ See las	st page for key definitio	n				
Does the project invol	lvo Fodoral Funds'	,	Yes: ☐ No: ☐			
Does the project invol	ive rederal runus.	•	res	(O	riginating sponsor,	if applicable)
Solicitation/RFA/RFP/	Award Number:			`		11 /
*For proposals requiring Elec					days before the due date	
		PROP	OSAL INFORM	IATION		
Proposal Title:						- No Acronyms
						110 reconyms
☐ New ☐ Prepro	oposal Comp	eting Renewal of	OSP#	☐ Cont	inuation of OSP#	
Task Order of OSP	#	Revision of C	OSP#	Suppl	ement of OSP#	
Project Period Beg	gin:	End:		F&A Rate:		%
•	gin:	End:		Nature:	CR TFP	FUP
Budget Information				11,000101	011	
	Year One	Year Two	Year Three	Year Four	Year Five	Project Total
Direct						\$0.00
Indirect			-			\$0.00
Subtotal Sponsor	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
Cost Share *	<u>.</u>	<u>.</u>				\$0.00
Total	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00

^{*}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.

Page	2											
PI:		Title:				_ Spons	or:					
If "Y	ZES", please inc	ng conducted through a Center or In dicate the Center or Institute: rs and Institutes is available at www				og htm)						
		s employees involved in the performa			-							
☐ R	espiratory Car		TR		☐ M	CV Phys	icians		•	Patho	ology	area):
	-Patient Beds ealth Informat	— v 11 —			choscopy		onal Phar iostatisti		· —	CRSC)	
□ n		inon companing Sur	.,0, 1	, araaci	on rescuren Eus		ostatisti	Co				
* Cor	e facility listing	g can be found at <u>www.research.vcu.</u>	edu/vp	r/core	laboratory.htm							
☐ Bi	ioTech One	project will be conducted in the follo	eering	West	☐ Kontos Mo	edical Sci			_	Massey Car		
∐ M	IcGlothlin Me			l of the			Sport				Ctr. for Li	ife Sci.
Kev I	Personnel, Fa	PERCENT EFFORT A culty, and "COI Investigator" Description of the control of the										
	COI					CAL	ACAL)	SUMR	%	%	
Key	Investigator ⁱⁱ	Name		Ro	le on Project	Mnths	Mnths	3	Mnths	EFFORT	RESP	Sal Es
												Sal Es
												Sal Es
												Sal Es
												Sal Es
			CO)MPI	IANCE DAT	A						
-If pr	oject is resea	rch or clinical trial, please indicaed iv Developmental Developmental		naga for	key definitions							
		sed involves the following:	see iasi	page 101	key definitions							
Yes	No Maybe	Human Subjects Research ¹	Yes	No			_	Yes	No			
		(If yes, complete table on next page)			Radioactive Mate	rials ^{4,5}				Clinical Trial		
		Animal Use ² (If yes, complete table on next page)			Recombinant DN. or other biohazard	A, Select <i>A</i> Is ^{4,5}	Agents			Research is so	-	
		Foreign Nationals			Company Confidential Information will be provided					Sponsor is for owned compa foreign gover	any or	
		Restrictions on Publication or Intellectual Property Rights			International Prog	ram				Program Inco	me	
		Retired faculty participation			Subcontracts or subrecipients ⁶ (external)					Wet lab space	;	
		Rented off campus facility			Subaccounts (internal) ⁶					Additional/N	ew space	
		Delivery of anything more than technical report			NSF Funds- RCR Training Required					NIH Funds- I Training Req		
		HIPAA Covered Data ³										
1. For	r further infor	mation on human subjects research	refer t	o: <u>http</u> :	://www.research.v	cu.edu/ir	b/activit	ies.h	<u>tm</u>			

- 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

age 3				
PI:	Title:		Sponsor:	
PROTOC	COLS*: Principal Investigator / Co PI(s)	IRB/IACUC No.	Approval Date
*From p	revious page, list protocols if applica	able)		
F	PRINCIPAL INVESTIG		ONS, DISCLOSURES AN	ND ASSURANCES
	g below I certify that I have read an t the statements contained herein a			
es No	All applicable items contained in	the Compliance Data section h	ava baan idantified. Investigator	agrees to shide by any
	obligations applicable under VCU control laws, maintaining confidenti	policies or other legal requireme		
	Investigator has read and understand informed all "COI Investigators," h applicable, shall have reached an ag of interest under University policy.	as reported required financial inte	erests, and prior to the expenditure	of any awarded funds, if
	The enclosed proposal is complete research, including proper citation a (e.g., see VCU policy on responsi agency.	and attribution for all text and gra	phics, complies with federal guida	nce on research integrity
	The space/facilities and other VCU and if not currently available, arran available in the event an award is m	gements will be made with the D		
	If the proposal enclosed is funded a and conditions stipulated by the spagrees to be fully responsible in stewardship of funds, timely submi VCU's Technology Transfer Office IACUC, other Human Research pro	consoring agency and all applicab meeting the requirements of the ssion of all required technical rep, and also adhering to all federal c	e award, including but not limite ports and deliverables, proper discl	furthermore, Investigator d to, proper and ethical osure of all inventions to
	Investigator acknowledges that any administrative penalties.	y false, fictitious, or fraudulent s	tatements or claims may subject	me to criminal, civil, or
	PI Signature	REQUIRED SIG	Date Date	
ersonnel lebarred f of the Dea	ndersigned, do certify to the best of our costs are correctly estimated; 3) adequation this application; and 5) this project in verifies that all joint VCU/VA appoint on a signature areas, please see the Correction to the contract of the correction of the correcti	r knowledge and behalf that 1) the ate and suitable space is/will be pre- it is consistent with the educational intees have a current Memo of Under intinuation Page (http://www.resear	designated faculty will be released rovided for completion of the project and research objectives of the Understanding (MOU) on file in their rch.vcu.edu/forms/ContinuationPag	ct; 4) no named participant is iversity. If applicable, signature Dean's office.
Principal	Investigator/Date	A copy of this proposal has bee Department Chair for review. (Check Box)	en delivered to my Dean/	Date
Co-Inves	tigator/Date	A copy of this proposal has bee Department Chair for review. (Check Box)	n delivered to my Dean/	Date
		A copy of this proposal has bee	n delivered to my	
Co-Inves	tigator/Date	Department Chair for review. (Check Box)	Dean/	Date
Services	Investigator/Date	Appropriate approvals obtaine Approved on behalf of the Uni		Date
	search Services Office/Date*	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



Virginia Commonwealth University

VCU Tax-Exempt Debt Compliance Policy

Policy Type: Board of Visitors

Responsible Office: Office of the Associate Vice President for Business Services and Treasurer

Department of Treasury and Foundation Services

Initial Policy Approved: 02/09/2012

Current Revision Approved:

Policy Statement and Purpose -

This policy provides a framework for complying with federal laws relating to the issuance and post-issuance monitoring of tax-exempt bonds. The purpose of this policy is to identify the compliance areas of tax-exempt bond financing and define the University's policy for fulfilling all requirements in these areas during both pre- and post-issuance processes. This policy provides guidance to University units involved in tax-exempt financings so that they understand and are able to carry out their roles in these processes.

The University relies heavily on the tax-exempt bond market to finance a significant portion of the University's capital projects. The consequences of violating federal laws can be severe and can include the retroactive loss of tax-exempt status, significant liability to the IRS or bondholders, reputational damage, and the inability to access the tax-exempt bond market in the future.

Accordingly, the policy provides guidance in the following areas:

- Identification of applicable Internal Revenue Code provisions and Treasury rules and regulations relating to tax-exempt debt compliance (collectively, the "Tax Rules");
- Definition of the University's policy for complying with applicable rules and regulations to safeguard against violations that may result in penalty or the loss of the tax-exempt status of its bonds;
- Assignment of responsibility for tax-exempt bond compliance to specific departments to maintain continuity and ensure that sufficient information is routinely identified, maintained and shared as appropriate between departments; and,
- Identification of the University's continuing disclosure requirements and establish procedures for providing annual disclosure, "event disclosure" and voluntary disclosure through the EMMA system¹.

Approved: 02/09/2012

_

¹ These requirements relate, not to federal tax exemption, but to the federal securities law, as discussed below

The principal purpose of the policy is to ensure that (1) the proceeds of tax exempt bonds are spent as required by both the bond documents and the Tax Rules and (2) the buildings and equipment financed by tax-exempt bonds do not have impermissible amounts of "bad use." In simplest terms "good use" is use exclusively by the University or other governmental entity (like the VCU Health System) or, in the case of 501(c)(3) bonds, by a private charitable organization in connection with its charitable activities, while "bad use" is use by or for benefit of private, for-profit entities or the Federal Government. There are special rules relating to sponsored research.

Management and development contracts with private parties also can create bad use. There are also requirements requiring the timely expenditure of bond proceeds (usually within three years) and on the payment of investment "arbitrage" arising from the investment of bond proceeds prior to their expenditure.

The University recognizes compliance with IRS and Treasury Regulations is fluid. Accordingly, the Policy requires on-going monitoring and will be reviewed periodically and modified as necessary.

Oversight:

The Director of Treasury and Foundation Services is responsible for administering and overseeing the day-to-day aspects of the program as well as supporting the Bond Compliance Committee. At a minimum, the committee shall consist of the individuals from the following departments: Treasury and Foundation Services ("Treasury Services"), Facilities Management Division, the Controller's Office, the Office of the General Counsel, and the Office of Research. The Bond Compliance Committee reviews compliance procedures and systems on a periodic basis, not less than annually.

Each individual department is responsible for maintaining a written set of procedures to ensure compliance with this policy.

Table of Contents ————

Who Should Know This Policy	3
Definitions	3
Contacts	3
Procedures	3
Forms	9
Related Documents	9
Revision History	9
FAQs	9

Approved: 02/09/2012

Who Should Know This Policy —————

- Vice Presidents and other Senior Executives
- Vice Provosts, Deans, Directors, and Department Heads

Definitions —		
DCIIIIIIIIII —		

There are no definitions associated with this policy and procedures.

Contacts —

The Department of Treasury and Foundation Services within the Office of the Associate Vice President for Business Services and Treasurer officially interprets this policy. The Department of Treasury and Foundation Services is responsible for obtaining approval for any revisions as required by the policy Creating and Maintaining Policies and Procedures through the appropriate governance structures. Please direct policy questions to the Department of Treasury and Foundation Services. The Office of the Vice President for Finance and Administration is responsible for responding to inquiries by investors, rating agencies and other outside parties relating to the status of projects, the financial condition of the University and any other events that may affect investors. All such inquiries should be referred to the Office of the Vice President for Finance and Administration.

Procedures -	
1 Toccuui cs	

Pre-Issuance:

Tax-exempt debt compliance begins with the proper planning for debt issuances. While capital projects can be proposed and approved at any time, it is expected that the majority will be identified during the biennial updates to the University's six-year capital plan which is approved by the Board of Visitor's.

For projects that require debt as part of the financing, Treasury Services will complete a project initiation form which can be accessed at http://www.vcu.edu/treasury/.

Upon receipt of a project initiation form or in coordination with biennial updates to the six-year capital plan, Treasury Services will assemble a group of key stakeholders and coordinate the completion of a financial feasibility study. Such a study is required for "double barrel" bonds under section 9(c) of Article X of the Virginia Constitution.

Final approval of the financial feasibility study will be given by Senior Management, and at a minimum, will include approval by the University's Vice President for Finance and Administration and the Dean/Vice President of the sponsoring department.

Approved: 02/09/2012

Once a financial feasibility study is complete and the project is approved by senior management, the following authorizations are generally required to be in place prior to any debt issuance:

<u>Authorization of Debt</u> — All indebtedness incurred by the University, whether tax-exempt or taxable, must be authorized by the Board of Visitors.

<u>Declaration of Intent To Borrow and Reimbursement Resolution</u> — While the Tax Rules restrict the ability of the University to use bond proceeds to reimburse itself for costs incurred prior to the issuance of the Bonds, the University can in many circumstances preserve the right to reimburse itself for current expenditures with the proceeds of future bonds by passing a qualifying "reimbursement resolution" or adopting a qualifying expression of intent to reimburse. The Board of Visitors has authorized the Vice President for Finance and Administration to take such action. Reimbursement resolutions and expressions of intent should be regularly reviewed to see if they need to be updated to cover project changes. In general bond proceeds can be used for reimbursement for prior costs within 18 months after the project is "placed in service" but in no event later than three years after the date of the expenditures. There are exceptions for certain preliminary costs, such as architects' and engineering fees.

<u>State Authorization</u> – Legislative approval is required as well as approval by the Treasury Board in accordance with § <u>2.2-2416</u> of the Code of Virginia for any debt issued through a State authority.

<u>Legal Opinions</u> – Legal counsel is required to opine on debt authorizations and the effect on the tax-exempt status of the debt being issued. For new bond issues, bond counsel opines on the validity and tax exempt status of the bonds, while University counsel opines on due authorization of the bonds and compliance with existing bond documents and similar restrictions.

<u>Tax Certificate</u> – also known as an Arbitrage Certificate is required to properly document the validity (and tax-exempt status) of the financing and to evidence compliance with applicable laws and regulatory requirements during the time of issuance. The Arbitrage Certificate sets forth the University's expectations as to the use of bond proceeds and should be reviewed by an official familiar with the project being financed, its cost components and its schedule. For bonds issued by another entity for the benefit of the University (such as The Treasury Board for 9(c) Bonds or the Virginia College Building Authority), similar certificates are required.

Treasury Services will manage the pre-issuance process including the drafting, review, and development of any needed resolutions, write-ups, Financial Feasibility Studies or other materials.

Post Issuance:

For bonds to continue to qualify for tax-exempt status, the applicable detailed provisions in the Tax Rules must be satisfied. Accordingly, post issuance debt compliance generally falls into the following categories:

- Expenditure and allocation of bond proceeds
- Investment of bond proceeds and payment of rebates to the U.S. Government
- Use of bond financed project (private use) and compliance with remedial action in case of a "change in use"

Approved: 02/09/2012

Disclosure and other filing requirements

- Record retention
- Training

If the potential to fail to comply with post issuance compliance activities is identified, the Director of Treasury Services will notify the Controller and the Vice President for Finance and Administration and seek the advice of qualified bond counsel in order to assess the need to take remedial actions described under section 1.141-12 of the Income Tax Regulations or enter into a closing agreement under the Tax-Exempt Bonds Voluntary Closing Agreement Program described in Notice 2008-31

Expenditure and Allocation of Bond Proceeds

Bond proceeds can only be used for eligible project costs in accordance with applicable federal law and the restrictions of the bond documents. The spending of bond proceeds and related investment earnings toward eligible project costs must be tracked to ensure they are used for qualified purposes. Bond proceeds shall only be disbursed for the following expenditures:

- Project Costs
- Capitalized Interest
- Bond Issuance Costs

The Director of Facilities Management Division Financial Services is responsible for verifying that bond proceeds are spent on qualified purposes and maintaining related payment records. At the conclusion of a project, a final accounting should be compiled, documenting the use of all bond proceeds and related investment earnings and arrangements made to having the accounting documentation made part of the permanent records for the particular bond transaction. There are rules that permit a reallocation of use of bond proceeds if action is taken not later than 18 months after the later of the date of the expenditure or the date the project is placed in service. Bond counsel should be consulted regarding any planned reallocations.

Spending Requirements and Arbitrage Rebate

There also are restrictions on the timing of the expenditure of bond proceeds. Generally proceeds must be spent within three years of bond issuance. If it appears that all proceeds will not be spent within the three year period, bond counsel should be consulted.

The Tax Rules also generally require borrowers to calculate and pay or "rebate" to the U.S. Government any "arbitrage profit" earned on the investment of bond proceeds prior to their expenditure. Arbitrage is the investment gain made by investing the proceeds of tax exempt bonds in taxable investments. Arbitrage compliance is governed by arcane provisions of the Tax Rules. There are several "rebate exceptions" if bond proceeds are spent promptly.

As a general rule, the University will seek to finance projects when proceeds will be spent within two years, and thus, attempt to meet the two year spending rebate exception. The two year spending exception requires that proceeds be spent as follows:

- 10% within 6 months of issue date
- 45% within 12 months of issue date
- 75% within 18 months of issue date
- 100% (less "reasonable retainage") within 24 months of issue date

Approved: 02/09/2012

Expenditures should be reviewed 30 days prior to the end of each six month period to minimize the chance of forfeiting the rebate exception. The two year exception applies only to transactions primarily for construction. In addition, there is an 18 month exception available for bonds with the following spending thresholds:

- 15% within 6 months of issue
- 60% within 12 months of issue
- 100% within 18 months of issue

Investment Proceeds

All bond proceeds will be invested in the Virginia State Non-Arbitrage Program ("SNAP"), unless approved in writing by the University's Vice President for Finance and Administration. The Virginia Treasury Board sponsors the SNAP to provide comprehensive investment management, accounting and arbitrage calculation services for the proceeds of tax-exempt financings of Virginia governments.

The Director of Treasury Services will monitor compliance with periodic spending exceptions and the investment of bond proceeds. In cases when a rebate is owed (as calculated by the Arbitrage Rebate Consultant), any resulting liability will be paid and properly reported on the applicable IRS form(s).

Private Business Use

The Tax Rules generally limit the amount of Private Business Use or the amount of private payment or "security." The University generally complies with these provisions by limiting Private Business Use rather than private payment or security.

Private Business Use is use (directly or indirectly) in a trade or business carried on by any person other than a governmental unit. Pursuant to the Private Business Use test, the tax-exempt status of a bond issuance is jeopardized if more than 10% of the proceeds are used for Private Business Use. Improper use of the bond financed facility is considered bad use of the proceeds of the bonds that financed the facility.² Generally, most Private Business Use in a tax-exempt financed facility arises from the following types of arrangements:

- Ownership: A sale or transfer of ownership to a Non-Governmental Person (as defined by applicable tax law) of tax-exempt financed property. For 501(c)(3) bonds, no portion of the bond financed property can be owned by a private, for-profit entity.
- <u>Leases:</u> Any arrangement where the University leases a tax-exempt financed property to a Non-Governmental Person. Transactions that are not called lease transactions may be treated as a lease based on the level of control given to the Non-Governmental Person and whether the Non-Governmental Person bears the risk of loss.
- Management Contracts: A management contract is any arrangement whereby a Non-Governmental Person actively manages the operations of a facility. Management contracts include, for example, contracts for dining services (food courts), retail services, facility

Approved: 02/09/2012

 $^{^2}$ In the case of bonds that are "501(c)(3) bonds" rather than "governmental bonds," the maximum amount is 5% rather than 10%. While most bonds issued by the University are governmental bonds, bonds involving related foundations may be 501(c)(3) bonds.

management, or vivarium services (management of an animal facility). The basic rules for permitted management contracts are set forth in IRS Revenue Procedure 97- 13. As a general principle, the contract should not give the private party any of kind of profit sharing or "investment" in the undertaking, and the term of the contract is limited based on the type of compensation to the Non-Governmental Entity. All management contracts for bond-financed space should be reviewed.

- Sponsored Research Agreements: Any research that is sponsored by a Non-Governmental Person (including the federal government and its agencies). The basic rules for determining when sponsored research is not considered "bad use" are set forth in IRS Revenue Procedure 2007-47. Generally, qualifying research agreements must be for "basic research" and the rights of the sponsor to the results of the research must comply with the stated rules.
- Other Actual or Beneficial Use: Any other arrangement that conveys special legal entitlements to a Non-Governmental Person for beneficial use of tax-exempt financed property, such as an arrangement that conveys priority rights to use a tax-exempt financed facility, will result in Private Business Use. Examples of such "special legal entitlements" include summer camps having the exclusive right to use an athletic facility, specially designed courses open only to one company, or use of a parking garage for a private event.

The Controller will be responsible for monitoring private use and will maintain and distribute a Private Use Questionnaire to responsible Department Managers prior to debt issuance and annually thereafter. The Controller with the assistance of Treasury Services will analyze questionnaire responses to: (i) determine whether taxable financing is appropriate for a particular capital project; (ii) identify impermissible Private Business Use in existing facilities so that corrective action can be taken; and (iii) collect information necessary for reporting purposes. If potentially impermissible Private Business Use is identified, the Controller will notify the Vice President of Finance and Administration and seek the advice of qualified bond counsel.

In addition, any change in a project's use or contemplated change in a project's use that includes Private Business Use must be reported to the Controller's Office and Treasury Services prior to the implementation of the proposed change in use to ensure compliance with applicable regulations.

Tax and State Filings

The University is required to provide the following filings:

- Tax Forms Tax-exempt debt obligation issuers are required to file the 8038 series of IRS forms (8038, 8038-G, 8038-T, and 8038-R) in accordance with applicable federal law.
- Statistics and filings required to be sent to the State for any debt issued through a State authority for the benefit of the University.
- Arbitrage Certificates Within five years of the anniversary of the debt issue to close out the
 issue, the University, must calculate any arbitrage on the debt in a final accounting, and make
 any required rebate payment.

Approved: 02/09/2012

The Director of Treasury Services is responsible for ensuring that such filings are made.

Continuing Disclosure

In connection with the issuance of the Bonds the University has signed several, substantially identical continuing disclosure agreements ("CDAs"). These are required, not by the Tax Rules, but by a rule of the United States Securities and Exchange Commission that requires the University's bond underwriters to require the execution of a CDA in connection with sale of bonds to the public. The CDAs require the University to file certain annual financial and operating information with the Electronic Municipal Market Access System ("EMMA.") maintained by the Municipal Securities Rulemaking Board. EMMA permits investors to access the information to assess the University's financial position. The CDAs also require the University to disclose through EMMA certain specified events ("event disclosure") such as bond defaults. Future bond issues for special university credits may require CDAs that require the filing of additional different information.

The Director of Treasury Services is responsible for making all filings required by CDAs, and any events affecting such filings should be reported to Treasury Services. The Office of the Vice President for Finance and Administration is responsible for responding to inquiries by investors, rating agencies and other outside parties relating to the status of projects, the financial condition of the University and any other events that may affect investors. All such inquiries should be referred to the Office of the Vice President for Finance and Administration.

Record Retention

It is the University's policy to retain all records relating to tax-exempt bond financings for the entire term of the bond issue plus three years. This policy supersedes any other documented retention policies at the University or the Commonwealth.

Generally, records refer to all documents, reports, accounts and certifications relating to the:

- Issuance of tax-exempt bonds
- Investment of bond proceeds
- Expenditure and allocation of bond proceeds
- Use of debt-financed property
- Disclosure and other filing requirements

Due to the decentralized nature of the University, specific departments are responsible for the following:

<u>Treasury and Foundation Services</u> – is responsible for maintaining records relating to the issuance of the University's tax-exempt bonds, the investment of bond proceeds and the University's annual continuing disclosure.

<u>The Facilities Management Division</u> – is responsible for maintaining records on the expenditure and allocation of bond proceeds including construction contracts, vendor invoices, payments and requisitions.

<u>The Office of the Controller</u> – is responsible for maintaining records on private use including responses to the annual private use questionnaire, service contracts, leases, and other pertinent contracts. The Controller's Office will also retain the audited financial statements and reports of any prior IRS examinations of VCU or bond financings.

Approved: 02/09/2012

<u>The Office of Research</u> – is responsible for maintaining records relating to research contracts. **Training** The Controller's Office will develop training materials, hold classes for employees in departments that are impacted by this policy, and post the training to the web site for reference. There are no forms associated with this policy and procedures. Related Documents — 1. VCU Debt Management Policy 2. Treasury Board of the Commonwealth of Virginia: Post Issuance Compliance Policy for Tax-**Exempt Qualified Obligations** 3. US Code: Title 26, Section 141 **4.** IRS Revenue Procedure 97-13 (management contracts) **5.** IRS Revenue Procedure 2007-47 (research agreements) 6. Tax-Exempt Governmental Bonds Compliance Guide 7. VCU Private Use Questionnaire Revision History — This policy supersedes the following archived policies: None – New Policy FAOs —

There are no FAQs associated with this policy and procedures.

Approved: 02/09/2012

Virginia Commonwealth University Subrecipient Commitment Form

For VCU Use Only: PT/PD#:	
SC#:	

Subrecipi	ent Legal Name:			
Subrecipi	ent PI Name:			
	Address:		City:	State:
Address v	where research will be performed:		City:	State:
Proposal	Title:			
Performa	nce Period Begin Date:		End Date:	
VCU's PI				
Prime Spo	onsor:			
SECTIO	N A – Proposal Documents			
	wing documents are included in our proposal STATEMENT OF WORK (required) BUDGET AND BUDGET JUSTIFICATION F&A Rate Agreement - including fringe ben Small/Small Disadvantaged Business Subc Biosketches of all Key Personnel, in agency Other: Other:	including any cost-s efit information (requ ontracting Plan, in a y-required format	sharing (required) uired)	es below (check as applicable):
SECTIO	N B - Certifications and Assurances			
1. 2. 3.	Animal Subjects	No IA NSF, or other spor eing funded by NIH, NS is that it has an active a for Promoting Objectivi nat, to the best of Institu- eement, and required b ed in accordance with s onflicts and resultant mants. r enforced conflict of int es.nationalacademies.or ired. r enforced conflict of int c://www.assurance.vcu.	SF, or other sponsor that has adopted the and enforced conflict of interest policy that ty in Research." Subrecipient is intion's knowledge, (1) all financial disclosery its conflict of interest policy; (2) all identification in the subrecipient's conflict of interest policy proposed in the subrecipient's conflict of interest policy and is opting to create and the subrecipient's policy and agrees to abide by Virgitation in the subrecipient in the subrecipient in the subrecipient is subrecipient.	equired at just-in-time ral financial disclosure requirements) e federal financial disclosure requirements at is consistent with the provision of 42 CFR Part is not registered on the FDP Institutional sures have been made related to the activities that attified conflicts of interest have or will have been rior to the expenditures of any funds under any U's Office of Sponsored Programs to enable implement its own policy. A sample model policy by the Authorized Official below indicates policy is jinia Commonwealth University's policy, Conflict of
APPROVED FOR SUBRECIPIENT The information, certifications and assurances above have been read, signed and made by an authorized official of the Subrecipient named herein. The appropriate programmatic and administrative personnel involved in this application are aware of agency policy in regard to subawards and are prepared to establish the necessary inter-institutional agreements consistent with those policies. Any work begun and/or expenses incurred prior to execution of a subaward agreement are at the Subrecipient's own risk. Signature of Subrecipient's Authorized Official Date Federal Employer Identification Number (EIN)				
	d Title of Authorized Official		Address	
Email			City, State, Zip	
Subrecipi	ient's Congressional District		DUNS or DUNS+4 number	

VCU Activities and Interests Reporting for Subrecipients

VCU's Policy entitled "Conflicts of Interest in Research" will be incorporated into the subrecipient agreement at the time of award. Please review the Policy at

http://www.assurance.vcu.edu/Policy%20Library/Researcher%20Conflict%20of%20Interests%20Policy.pdf.

Following review, the subrecipient PI should complete the following:	
Subrecipient Legal Name	
Subrecipient PI Name	
Project Title:	
VCU PI Name:	
Subrecipient PI Designation of "COI Investigators"* for this project:	
COI Investigator Full Name	
Contact name, phone and e-mail to obtain following data on "COI Investigator(s)" fo Birth, SS#, Home Address, Phone and e-mail:	
I certify that I, and all COI Investigators identified above, have read and understand Research Policy, will make all required reports, and prior to expenditure of any awar reached an agreement with VCU for conditions or restrictions to reduce, manage, or under the policy.	rded funds, if applicable, shall have
Subrecipient PI Signature	Date
Instructions for VCU PI and PI Department: Each of the individuals named above, includir into the VCU Affiliate database. Once the names have been entered and a VCU eID is issue instructed to log in to the VCUeRA Activities and Interests Reporting System (AIRS) to complinterests. Proposal submission will not occur until all financial interest reports are completed.	d for each, the individuals should be lete training and enter their financial
I certify that each individual identified above has been entered into the VCU Affiliate and each individual has been instructed to enter their data in the VCUeRA AIRS.	database, an eID has been created,
VCU PI Signature	Date

*COI 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.'