

Research Administration and Compliance Meeting
Wednesday, May 22, 2013, 1:00 – 3:00 p.m.
Lerrick Hall, Court End Ballroom A

Agenda

General Items/Updates

- Special Guest - Daniel Jason, Benefits Administrator, HR – “Separation and Retirement”
- Special Guest - Betsy Ripley, Executive Director, Clinical Research Services – “Medicare Cost Analysis Form”

ORIE Updates

- AIRS: Annual Update for the FIR - July 1st
- Final Research COI Policy Approval

ORSP Updates

- RAMS-IRB Update
- IACUC JIT Congruence
- Controlled Substances Update

ORAC Updates

- Routine and Non-Routine Government Reporting
- Data Use Agreement Form
- SPIN Contract ending 6/30/13

OSP Updates

- PACR Update
- Staffing Update
- E-Closeout Forms

Grants & Contracts Updates

- NCURA FRA Training
- June 3 Brown Bag – Closeout – 12:00 pm – 1:00 pm – Lerrick Hall
- Effort Reporting Training

Future Meeting Dates, 1-3 p.m.

- August 20, 2013, Lerrick Court End B
- October 30, 2013, Lerrick Court End B
- February 19, 2014, Lerrick Court End A
- April 24, 2014, Lerrick Court End A



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Separation and Retirement

VCU Human Resources
2013

What is a Separation?

A separation from employment (TERME) occurs when an employee leaves employment with the university for any reason.

A separation from a job (TERMJ)occurs when an employee leaves a job with the university but continues employment in another capacity.



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What is a Retirement?

Retirement is defined as:

- A complete separation from employment with the university (TERME), and
- A complete separation from all employment with the Commonwealth, and
- Beginning to draw a benefit from a Commonwealth funded retirement plan (VRS or ORP).



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Bona Fide Separation

VRS and the ORP are IRS-qualified retirement plans. In order to draw a benefit from such a plan, the IRS requires a bona fide separation from service:

- A **complete severance** of the employer/employee relationship. “Employer” means the Commonwealth, not just VCU.
- No pre-arranged agreement to return to employment



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VRS Retirement Application Language

What the employee certifies:

28. Member Certification

I hereby certify: 1) All information I provide in this document is true and I understand that any willful falsification of facts presented may result in prosecution as provided by law, 2) I have read and understand the service retirement information in the *Handbook for Members*, 3) I will terminate all full-time positions prior to my retirement, and 4) I will not return to work in a part-time position with my current employer following my retirement date for at least one full calendar month during which I would normally work.

Additionally, I agree that, in the event that VRS pays retirement benefits in excess of those to which I am entitled, I or my estate will repay the excess to VRS. By signing this form, I hereby assign to VRS any VRS group life insurance benefits that may be payable as a result of my death to secure repayment of any such retirement benefit overpayment.

Member Signature

Date



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VRS Application Language

What VCU certifies:

-
15. Authorization I certify: 1) the member will cease any non-covered part-time position with this employer prior to the retirement date and will be fully removed from the payroll, 2) the member will not return to work in a part-time position with this employer following the retirement date for at least one full calendar month during which the member would normally work and 3) there are no prearrangements with the member to return to a part-time position.

Human Resources Signature

Date

Payroll Signature

Date



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ORP Retirement Language

What the employee certifies:

Employee Certification of Employment Status (Please read the following statements carefully and choose one. Enter the employer and employment type when required.)

- I am terminating, or have terminated, employment with the Commonwealth of Virginia and have no agreement to return to employment with any public employer in Virginia.



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The Law and the Penalties

Code of Virginia 51.1-124.9:

B. The Board is authorized to recover any overpayments, from an employer found to be responsible for such overpayments, to a member or beneficiary (i) whose average final compensation exceeds the limitation in § 51.1-152, (ii) who receives in-service distributions because the member or beneficiary is rehired by the employer without either a bona fide break in service, as determined by the Board, following retirement, or the break in service required under subdivision B 3 (a) of § 51.1-155, or (iii) who the Board determines was in service as an employee covered for retirement purposes as prohibited by subdivision B 1 of § 51.1-155.



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Consequences for the VCU ORP

If the VCU ORP makes distributions improperly, when there has been no bona fide separation, the IRS-qualified status of the entire plan can be jeopardized.



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IRS “Good Faith” Compliance with the Bona Fide Separation Requirement

- Completely sever the employment relationship.
- Do not allow the employee to continue to perform any duties of the former job in any capacity (even unpaid) until the requirement is satisfied.



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IRS “Good Faith” Compliance with the Bona Fide Separation Requirement

- Do not initiate any conversations about re-employment until the break is over.
- When the break begins, remove employees from grants coming through the university.
- Do not allow a faculty member’s name to be published in a future course bulletin prior to retirement.



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IRS “Good Faith” Compliance with the Bona Fide Separation Requirement

- Re-employment that begins exactly one calendar month after retirement does not demonstrate a good faith effort to comply.
- Re-employment discussions during the break do not demonstrate a complete severance of the relationship.



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Risks for the Employee

- Revocation of retirement
- Loss of retiree health coverage
- Loss of retiree life insurance
- Required repayment of ORP distributions



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Reminders.....

- Re-employment of retirees requires VP approval. Refer to Guidelines on HR web site
- Adjunct and hourly employment is limited to 29 hours per week, on average over a 12-month period.



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FTIP

- FTIP allows your faculty member to reduce effort over a period of 1-3 years in exchange for a formal agreement to retire.
- Benefits eligibility is preserved
- Can achieve similar research continuation goals as Adjunct re-employment. No hour limit.
- Management initiated. Consult with your Dean's office.



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Remember.....

- Your compliance responsibilities.....
- The law....
- The VCU Code of Ethics and Code of Conduct...

*Take precedence over the personal desires
and work preferences of your employee*



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Questions About Retirement Rules?

VCU Benefits

827-1723



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Annual Update of the FIR in AIRS

Due July 1

Office of Research Integrity and Ethics
COI Program

Annual Update requirement

- PHS Final Rule for COI
- VCU Policy on Research COI

Implementation in August 2012;
2013 is transition year for updating

Research FIR users

Pathway chosen on Introduction page of FIR

1.0 * Which of the following forms were you asked to create or complete? You may select one or both:

Research Financial Interest Report

Statement of Economic Interest

All those who checked the Research FIR box receive a communication from AIRS about the Annual Update

Who does the Annual Update in the AIRS?

- All Research FIR users

Enter AIRS to update FIR **regardless** of last entry date

For example:

- initial entry on 9/19/2012, updated on 3/24/2013 – Annual Update due
- initial entry on 4/26/2013 – Annual Update due

Communications to Research FIR users and investigator community

- Email from AIRS starting May 20th to all Research FIR users
- Email from VPR on May 20th to investigators and research administrators
- Email from AIRS to non-completers of Annual Update: 6/3, 6/17, 6/24, 7/1, and weekly through end of July

Update Instructions for Research FIR users

If you were **NOT** required by the VCU Office of Integrity and Compliance to submit the Statement of Economic Interests in January:

- **Uncheck** the ‘Statement of Economic Interests’ box on the Introduction page.
- If you can update a former ‘yes’ response to a ‘no’, first remove all interests listed under the question BEFORE changing your response to “no”.

Instructions for Research FIR users (continued)

- Update your FIR to reflect only the last 12 months of financial interests. That means you can remove Financial Interests if dates are over a year from the date on which you are updating. For example, if you received payment on March 16th last year for consulting, you may now delete that payment.

Instructions for Research FIR and SoEI users

If you **were required** by the VCU Office of Integrity and Compliance to submit the Statement of Economic Interests in January:

- Do not uncheck the ‘Statement’ box
- Do not remove financial interests reported for the past calendar year.
- Only add to update; do not delete FIs

Instructions for ONLY SoEI Users

If you are not a designated ‘COI Investigator’ for any research:

- the Annual Update does not apply to you!
- if you are receiving annoying Annual Update reminders from AIRS, consider going in to uncheck the Research FIR box

Ongoing requirement to update FIR for Research FIR users

Within 30 days under the following circumstances:

- Obtaining a financial interest in a new entity not previously reported
- Obtaining a financial interest in a previously reported entity where the aggregate amount is now over \$5,000
- A change in Financial Interest relatedness to research because of new interests or new research

AIRS email sent upon successful update



Monika S Markowitz <msmarkow@vcu.edu>

AIRS Informational: Successful Update of FIR in AIRS

1 message

AIRS@vcu.edu <AIRS@vcu.edu>

Tue, May 21, 2013 at 11:44 AM

Reply-To: AIRS@vcu.edu

To: msmarkow@vcu.edu

Financial Interest Report: DC00000132 Financial Interest Report for Monika Markowitz

Submitted on: 5/21/2013 11:44 AM

Thank you for updating your Financial Interests Report (FIR) in the Activity and Interests Reporting System (AIRS). Your FIR is now in an 'Active' state.

As a reminder, an update to your FIR is required within 30 days of acquiring or discovering a new financial interest with an entity not previously reported or when financial interests with a previously reported entity now exceed \$5,000.

*For additional technical information on how to use the VCU Activity and Interest Reporting System, please visit
<https://www.vcu.edu/vcuer/airs.htm>*

VCU Office of Research

Resources for help

- ‘AIRS How-To Guide’

<https://www.vcu.edu/vcuera/airs.htm>

- Contact AIRS@vcu.edu

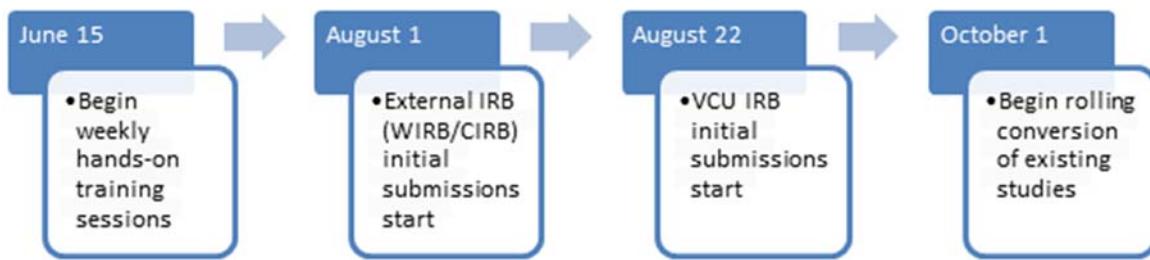
- COI website at:

http://www.research.vcu.edu/p_and_g/coi2.htm



RAMS-IRB Implementation

Timeline



Conversion of Currently Approved Studies – Full Board and Expedited

	Full Board Review (days prior to expiration)	Expedited Review (days prior to expiration)
Conversion Email	210	180
Conversion Amendment Due	165	135
Conversion Reminders	Every 14 days until submit	Every 14 days until submit
Continuing Review Email	90, 75, 45	60, 50, 40
Continuing Review Due	70	35

Conversion of Currently Approved Studies – Exempt

Exempt Studies Approved >12 Months Ago

- Investigators of exempt studies approved more than 12 months ago will receive an email from ORSP prior to August 1 inquiring whether the study is still active.
- If the study is completed, the PI does not need to take any action.
- If the study is ongoing, the PI must respond to the email indicating that the study should remain under IRB oversight and transition to RAMS-IRB. A study shell will be created in RAMS-IRB, but no action be required unless an amendment must be made to the study (per IRB requirements) prior to its completion.

Exempt Studies Approved <12 Months Ago

- Exempt studies approved less than 12 months ago will have a study shell created in RAMS-IRB.
- No action in RAMS-IRB will be required unless an amendment must be made to the study (per IRB requirements) prior to its completion.



RAMS-IRB Training

Use of RAMS-IRB is very intuitive. However, attending training and thorough review of online resources is highly recommended to ease the transition and help users become familiar with all of the functions of the system.

Training to use the system will be offered using a variety of methods including:

- online resources such as videos and tip sheets
- hand-on training in computer labs
- group training scheduled on request.

Hands-on, group training sessions will be available beginning in mid-late June and will be scheduled weekly for the first several months. A current list of RAMS-IRB training can be found at http://www.research.vcu.edu/irb/rams_irb_training.htm. Units can request individual training sessions of 5 or more people by contacting Shivi Stanley at sstanley3@vcu.edu.

RAMS-IRB Liaisons

Departments and divisions also have the opportunity to identify an individual who will serve as a liaison to the IRB and RAMS-IRB. Liaisons will receive focused, one-on-one training on the RAMS-IRB system. Liaisons will be identified as the first line of contact for members of a department or division to help respond to user questions related to use of RAMS-IRB. Liaisons do not need to be information technology staff, but they do need to have strong computer skills. To sign up as a liaison, email Shivi Stanley at sstanley3@vcu.edu.

How You Can Help / Next Steps:

- Identify liaisons from your units
- Communicate with other within your unit about the coming transition
- Encourage closing any IRB studies that are no longer active

Additional information can be found at http://www.research.vcu.edu/irb/rams_irb.htm. Specific questions can be forwarded to Shivi Stanley at sstanley3@vcu.edu.



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Controlled Substances Update

May 2013

RACM Meeting – 5/22/13

Controlled Substances

Any substance listed in the Controlled Substances Act, 21 CFR part 1300 to end), first enacted in 1970, and Title 54.1, Section 3400 of the Code of Virginia.

- Lists change regularly
- Classified into Schedules I through V



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Schedule I

- Schedule I – have no currently accepted medical use in the US, a lack of accepted safety for use under medical supervision, and a high potential for abuse
- Heroin, LSD, Marijuana, Peyote, Ecstasy



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Schedule II

- Schedule II – have a high potential for abuse which may lead to severe psychological or physical dependence
- Examples: oxycodone, methadone, morphine, opium, codeine, amphetamine, methamphetamine



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Schedule III

- Schedule III – Have a potential for abuse less than substances in Schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence
- Examples: ketamine and anabolic steroids



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Schedules IV & V

- Schedule IV – Have a low potential for abuse relative to substances in Schedule III
- Examples: Xanax, Valium, Ativan, Halcion
- Schedule V – Have a low potential for abuse relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics
- Examples: Robitussin AC, Phenergan with Codeine



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Background

- Concerns raised by faculty members
- Internal Inventory conducted
- Access issues
- Recordkeeping issues
- Storage issues
- Training issues
- Expired/unused substances have not been disposed of



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Remediation Plan

- Survey – All PIs on proposals and protocols
- Interim Policy – Using Controlled Substances for Research – expect in June 2013
- Training Requirement for users
- Manual for users
- Office of Research Subjects Protection Oversight (Monitoring Visits)



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Use of Controlled Substances

- Individual is responsible as the registrant – if fined, VCU will not reimburse; if criminal action, VCU will not defend
- Vice President for Research has authority to suspend, revoke, or deny any researcher registration application



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Recordkeeping and Storage Requirements

- Inventory – Initial, Annual, Biennial, and Continuous
- Authorized Users
- Usage Logs
- Disposal Logs
- Inventory stored in a substantially constructed, securely locked safe
- Schedule I, Schedule II and Schedule III-V must each be stored separately
- Authorized Users permitted weekly usage amounts – stored in an individual (by person) lockbox stored inside a locked cabinet



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Next Steps

- Survey respondents – All registrants and users invited to attend an educational presentation by DEA in early June (required for pending applicants)
- Working closely with DEA to clean up records/undocumented substances
- Interim policy implementation – primarily education as well as ensuring appropriate storage, etc.
- Policy will go through standard review process beginning late summer



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Routine and Non-Routine Government Review Reporting

May 2013

Routine and Non-Routine Government Review Reporting

- Inquiries, inspections, audits, investigations, unannounced visits and other information-gathering activities conducted, directly or indirectly, by federal, state, or local Government regulators, however they are made, including, without limitation, those made by email, letter, telephone, fax, personal visit, or by any other method, and whether made on campus, during regular business hours, or “off- hours” and “off-site.”
- Government reviews of affiliated entities that affect or pertain to University operations or personnel are also considered Government Reviews.



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What's Not Included

For purposes of this exercise, Government Reviews do not include:

- external audits conducted by auditors or consultants hired by the University,
- accreditation visits or monitoring activities conducted by accrediting bodies,
- regularly scheduled clinical trial monitoring visits conducted by industry sponsors or other non-Governmental agencies,
- peer reviews and other programmatic site visits conducted in relation to competitive grant awards or renewals, or
- routine facilities visits by the Commonwealth Health Department or any local Fire Marshal.



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Data Points to be Reported

Initial Report to CAC Member

- Inquiry Type
- Begin and End Date
- Area/Unit
- Agency Type
- Agency Name
- Routine/Non-Routine

Final Report to CAC Member

- Findings
- Response Due
- Response Due Date Met
- Agency Contact Name
- Agency Contact Info
- Notes



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University Integrity and Compliance Officer, Integrity and
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Department of Assurance Services
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Department of Assurance Services
- **Frank R. Baskind**
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- **John A. Venuti**
Chief of Police
VCU Police
- **VACANT**
Assistant Athletic Director for Compliance and Student
Services
VCU Athletics



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Data Use Agreement Submission Form

Data Use Agreements

Agreements we enter into when our faculty want access to data from another organization

Hard copy and electronic systems

- Data Use Agreement
- Data Transfer Agreement
- Restricted Use Data Agreement
- Data Use Certification (NIH)



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Data Use Agreements

- Often need to be negotiated to remove state-related issues, i.e., governing law, indemnification, etc.
- Information is required to assist in review and negotiation
- Introducing.....the Data Use Agreement Submission Form!!!!
- Posted at
http://www.research.vcu.edu/forms/dua_form.docx



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Data Use Submission Form

VIRGINIA COMMONWEALTH UNIVERSITY DATA USE AGREEMENT SUBMISSION FORM

Submit this completed form and supporting documents for University review and signature to: sarobb@vcu.edu

University PI Name/Department: Click here to enter text.	Name of Company/Institution: Click here to enter text.
PI's Departmental Administrative Contact Click here to enter text.	Company/Institution Contact for Agreement Issues: Click here to enter text.
Describe Data being provided under this DUA: Click here to enter text.	Company/Institution PI Name: Click here to enter text.

General Questions:

Is this human data? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, provide IRB approval letter, exemption letter or determination of no human subject involvement	Is the data confidential under HIPAA? <input type="checkbox"/> Yes <input type="checkbox"/> No	Is this a limited data set? <input type="checkbox"/> Yes <input type="checkbox"/> No
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If VCU is receiving data, answer the following questions:

Will you make a derivative or modification of the data set you receive? <input type="checkbox"/> Yes <input type="checkbox"/> No	Do you intend to share the results of your research/project back with the provider? <input type="checkbox"/> Yes <input type="checkbox"/> No
Is this a collaboration with the provider? <input type="checkbox"/> Yes <input type="checkbox"/> No	Is this data needed for a proposal under development or consideration for funding? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, indicate name of funding agency and provide institution numbers, project numbers of details: Click here to enter text.
If there are physical storage requirements, please provide details re: locking procedure, workstation to be used, or office security measures: Click here to enter text.	If there are electronic security standards, please identify your Department IT representative: Name: Click here to enter text. Phone/E-mail: Click here to enter text.
What is the source of funds to do the research with this data? Index Number: Click here to enter text.	List all other agreements related to this DUA: Click here to enter text.



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Data Use Submission Form

If VCU is providing data, answer the following questions:

Is the data de-identified? <input type="checkbox"/> Yes <input type="checkbox"/> No	Is this a collaboration with the recipient? <input type="checkbox"/> Yes <input type="checkbox"/> No
Do you require the recipient PI to share results with you? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Was this data collected with the use of federal funds? <input type="checkbox"/> Yes <input type="checkbox"/> No. If yes, provide institution number: Click here to enter text.
Are you aware of any restrictions or confidentiality obligations that would impact sharing this data? <input type="checkbox"/> Yes <input type="checkbox"/> No. If Yes – specify: Click here to enter text.	Is the data under review by Tech Transfer? <input type="checkbox"/> Yes <input type="checkbox"/> No
Is there a cost for you to provide the data? Costs charged must total exact costs spent to provide data: <input type="checkbox"/> Yes – explain: <input type="checkbox"/> Shipping Only-via Recipient entity; FedEx Account <input type="checkbox"/> No	Do you have any other requirements for the exchange? <input type="checkbox"/> Yes-specify Click here to enter text. <input type="checkbox"/> No

To the best of my knowledge, the answers to the questions are true, complete and accurate. I have read the reference DUA and agree to provide the data as outlined, adhering to VCU's policies and procedures. I am a VCU faculty member authorized to oversee the transfer of the data named above:

Principal Investigator: _____ Date: _____

DUA 5-13-13



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Research Administration & Compliance Meeting

May 22, 2013

Annie Publow, Director, OSP,
Government/NonProfit

OSP Update

Presentation Topics:

- OSP Staffing Update
- Non-financial Closeout of Awards
- Compliance with NIH Public Access Policy
- Sponsored Project Administration Certification Program



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VCU OFFICE OF SPONSORED PROGRAMS

Director, Office of Sponsored Programs –
Government/Non-Profit
Andrea Publow

Director, Office of Sponsored Programs –
Industry and Clinical Trials
Melanie Wiggins

Gold Team
Leader
Don Howe
Senior Contract &
Grants Administrator

Green Team
Leader
Kathleen
Gabriel
Senior Contract &
Grant Administrator

Blue Team
Leader/ARRA
Reporting
Manager
Jason Withers
Senior Contract & Grant
Administrator

Post-Award
Manager
Amy Lutero
Senior Contract & Grant
Administrator

Red Team
Leader
Juanita
Lawrence
Senior Contract &
Grant Administrator

Contract &
Grant
Administrator
Alex Craig

Contract &
Grant
Administrator
Brandi Becerra

Contract &
Grant
Administrator
Leslee Key

Intake &
Records
Manager
Salina Mann-
Ghee

Contract &
Grant
Administrator
Alanda Perry

Contract &
Grant
Administrator
Amanda Hill

Post Award
Administrator
Joshua
Dickerson

Post Award
Administrator
Christy Morris

Intake & Records
Assistant
Cecily Hickman

Intake & Records
Assistant
t.b.d.

Post Award
Assistant
Nina Goodman

Non-financial Closeout of Sponsored Projects

- ~1100 Government/NonProfit awarded projects are in “Award in Closeout” status
- ~630 Industry awarded projects are in “Award in Closeout” status
- To help you (and your PIs) to initiate the non-financial closeout process, we have created **three** electronic or “E-forms, all available on our website
- OSP will send individual, project-specific emails to PIs this summer. The link to the E-forms will be provided in the email.



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OSP Non-financial Closeout

- Use E-Closeout forms to initiate close out:
<http://www.research.vcu.edu/forms/osp.htm>
 - E-Closeout Form-General
 - Use for non-industry, non-clinical trial projects
 - E-Closeout Form-Industry
 - Use for industry-sponsored projects
 - E-Closeout Form-Clinical Research
 - Use for clinical trials close out, whether federally or industry sponsored
- When you complete and submit the form, it is emailed to ospaward@vcu.edu, the OSP Post Award Team.



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Office of Research

Forms

- » Sponsored Programs
- » Technology Transfer
- » Institutional Review Board (IRB)
- » Institutional Animal Care and Use Committee (IACUC)



Forms



Sponsored Programs Forms

- Proposal Forms
- Budget Worksheets
- Administration Forms
- Federal Forms

Award Forms

[COI Investigator Form](#) [COI Investigator Form](#) [Banner Account Request Form](#) [Subaward Request Form](#) [Subaward Modification Request Form](#) [No-Cost Extension Request Form](#) [No-Cost Extension Requests Instructions](#) [Grant Transfer Between Institutions Form](#) [E-Closeout Form-General](#)[E-Closeout Form-Industry Research](#)[E-Closeout Form-Clinical Research](#)

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E-Closeout Form

Non-financial close out of each sponsored project is the responsibility of the Office of Sponsored Programs (OSP) with direct input from the Principal Investigator. By completing this form, a PI can initiate the close out process with OSP.

Name (of person completing this form):
Email (of person completing this form):
PI Last Name:
PI First Name:
Department:
VCUeRA PT, PD or SC#:
Project Title:
Sponsor Name:
Sponsor Award Number (if known):

Standard Closeout Questions:

Section I: Final Technical ReportWas a final report required by the sponsor? Yes/No If yes, was the final report provided to sponsor? Yes/ Not Applicable (N/A) Were all deliverables provided to sponsor? Yes/ Not Applicable (N/A)

Date report was transmitted to sponsor:

Month-day-year (xx-xx-xxxx)

Section 2: Final Invention StatementWere inventions created in the course of this project? Yes/No

If yes, were inventions reported to the Office of Technology Transfer? Yes/Not Applicable

(N/A)

If yes, what was invention title, inventor name and date reported to sponsor?

Section 3: Subaward CloseoutWere subawards or subcontracts issued by VCU in the course of this project? Yes/No If yes, have all final technical reports been received? Yes/Not Applicable (N/A) Have all subaward invoices been received and paid? Yes/Not Applicable (N/A) Comments:

(Maximum characters: 100)

By clicking "Submit", this email will be sent to ospaward@vcu.edu, which is the Office of Sponsored Programs Post Award Team email. You will be contacted by Post Award staff if we have any further questions.

Your answers
to the
questions
should be
mindful of the
terms of the
executed
agreement or
the requirements
specified in
the notice of
award.

E-Closeout Form - Industry Research

Non-financial close out of each sponsored project is the responsibility of the Office of Sponsored Programs (OSP) with direct input from the Principal Investigator. By completing this form, a PI can initiate the close out process with OSP.

Name (of person completing this form):

Email (of person completing this form):

PI Last Name:

PI First Name:

Department:

VCUeRA PT, PD or SC#:

Project Title:

Sponsor Name:

Sponsor Award Number (if known):

Standard Closeout Questions:

Section I: Final Data or Deliverables Reported

Have you provided the sponsor with all required data, deliverables and/or technical report?

Yes/ Not Applicable (N/A)

Date report was transmitted to sponsor:

Month-day-year (xx-xx-xxxx all numbers format)

Were any other non-financial reports required by the sponsor. If yes, list reports and confirm you have submitted them:

(Maximum characters: 100)

Section 2: Final Inventions Reported

Were inventions created in the course of this project? Yes/No

If yes, confirm that inventions were reported to the VCU Office of Technology Transfer?

Yes/Not Applicable (N/A)

If yes, what was invention title, inventor name and date reported?

Section 3: Final Payment Received

Confirm that all payments have been received for the work performed

Yes

Section 4: Research Subjects Closeout

Were human subjects involved in the project? Yes/Not Applicable (N/A)

If yes, please confirm the study has been closed with the governing IRB (WIRB) Yes/Not Applicable (N/A)

Were animal subjects involved in the project? Yes/Not Applicable (N/A)

If yes and if applicable, confirm the IACUC protocol has been closed with ORSP. Yes/Not Applicable (N/A)

Section 5: Subaward Closeout

Were subawards or subcontracts issued by VCU in the course of this project? Yes/ No

If yes, have all final technical reports been received from all subawardees? Yes/Not Applicable (N/A)

Have all subaward invoices been received and paid? Yes/Not Applicable (N/A)

Section 6: Confidential Information

PI confirms that all confidential information provided by the sponsor and needing to be returned to the sponsor has been returned? Yes/Not Applicable (N/A)

PI confirms that all confidential information provided by the sponsor and needing to be destroyed has been destroyed? Yes/Not Applicable (N/A)

PI affirms his/her awareness of obligations to maintain confidentiality of designated information for period of time specified by the terms of the agreement Yes/Not Applicable (N/A)

By clicking "Submit", this email will be sent to ospaward@vcu.edu, which is the Office of Sponsored Programs Post Award Team email. You will be contacted by Post Award staff if we have any further questions.



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The Clinical Trail closeout form is the most detailed of the E-forms. There are ClinicalTrials.gov reporting requirements and IRB/WIRB closure that necessitate the questions.



E-Closeout Form-Clinical Trial

Non-financial close out of each sponsored project is the responsibility of the Office of Sponsored Programs (OSP) with direct input from the Principal Investigator. By completing this form, a PI can initiate the close out process with OSP.

Name (of person completing this form):

Email (of person completing this form):

PI Last Name:

PI First Name:

Department:

VCUeRA PT, PD or SC#:

Project Title:

Sponsor Name:

Sponsor Award Number (if known):

Standard Closeout Questions:

Section I: Final Data Reported

Have you provided the sponsor with all required data (case report forms)? Yes/ Not Applicable (N/A)

In accordance with signed agreement, PI affirms understanding of and confirms agreement to abide by all Code of Federal Regulations requirements in connection with data retention.
 PI confirms

Section 2: Final Inventions Reported

Were inventions created in the course of this project? Yes/No

If yes, confirm that inventions were reported to the VCU Office of Technology Transfer?
Yes/Not Applicable (N/A)

If yes, what was invention title, inventor name and date reported?

Section 3: Final Payment Received

Confirm that all payments have been received for the work performed
 PI Confirms

Confirm that final site visit has occurred

PI Confirms

What was VCU's final project end date (date on which all payments received and site visit(s) completed)?

Month-day-year (xx-xx-xxxx all numbers format)

Section 4: Human Subjects Closeout

Please confirm the study has been closed with the governing IRB (VCU IRB or WIRB)
 PI Confirms

Section 5: Subaward Closeout

Were subawards or subcontracts issued by VCU in the course of this project? Yes/ Not Applicable (N/A)

If yes, have all final technical reports been received? Yes/Not Applicable (N/A)

Have all subaward invoices been received and paid? Yes/Not Applicable (N/A)

Section 6: Confidential Information

PI confirms that all confidential information provided by the sponsor and needing to be returned to the sponsor has been returned? Yes/Not Applicable (N/A)

PI confirms that all confidential information provided by the sponsor and needing to be destroyed has been destroyed? Yes/Not Applicable (N/A)

PI affirms his/her awareness of obligations to maintain confidentiality of designated information for period of time specified by the terms of the agreement Yes/Not Applicable (N/A)

Section 7: ClinicalTrials.gov Registry

Was this a Phase II, III, or IV interventional clinical trial that was initiated on or after September 27, 2007 or still ongoing as of December 26, 2007? Yes/No

Section 8: ClinicalTrials.gov Registry Update (Sponsor-Initiated)

Was this a sponsor-initiated clinical trial? Yes/Not Applicable (N/A)

Section 9: ClinicalTrials.gov Registry Update (Investigator-Initiated)

Was this an investigator-initiated clinical trial? Yes/Not Applicable (N/A)

Please, provide NCT tracking number (from ClinicalTrials.gov database) or check appropriate box :

NCT Not Registered N/A

PI confirms that the ClinicalTrials.gov database has been updated to reflect a terminating status for the study (withdrawn, terminated, or completed.)
 PI Confirms N/A

Results reporting is required within 12 (twelve) months of the primary completion date, i.e. date when the last participant received an intervention. What was the primary completion date?

Month-day-year (xx-xx-xxxx all numbers format)

At a minimum, results reporting is required for Phase II, III, or IV interventional clinical trials. If required, has results reporting been completed in ClinicalTrials.gov database for this study? Yes/ Not Applicable (N/A)

By clicking "Submit", this email will be sent to ospaward@vcu.edu, which is the Office of Sponsored Programs Post Award Team email. You will be contacted by Post Award staff if we have any further questions.

What if I were to tell you that your investigator's awards could be delayed by NIH as of July 1, 2013 if they haven't included PMCID numbers on all peer-reviewed manuscripts arising from NIH funding?



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Changes to Public Access Policy Compliance Efforts Apply to All Awards with Anticipated Start Dates on or after July 1, 2013

Notice Number: NOT-OD-13-042

Key Dates

Release Date: February 14, 2013

Related Notices

[NOT-OD-13-035](#) NIH Requires Use of RPPR for All SNAP and Fellowship Progress Reports, and Expands RPPR Functionality

[NOT-OD-12-160](#) Upcoming Changes to Public Access Policy Reporting Requirements and Related NIH Efforts to Enhance Compliance

Issued by

National Institutes of Health ([NIH](#))

Purpose

For non-competing continuation grant awards with a start date of July 1, 2013 or beyond:

- 1) NIH will delay processing of an award if publications arising from it are not in compliance with the [NIH public access policy](#).
- 2) Investigators will need to use [My NCBI](#) to enter papers onto progress reports. Papers can be associated electronically using the RPPR, or included in the PHS 2590 using the My NCBI generated [PDF report](#).

Please see [NOT-OD-12-160](#) for more details.

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NIH Public Access Policy and Compliance

Overview (<http://publicaccess.nih.gov/>)

The [NIH Public Access Policy](#) ensures that the public has access to the published results of NIH funded research. It requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive [PubMed Central](#) *upon acceptance for publication*. To help advance science and improve human health, the Policy requires that these papers are accessible to the public on PubMed Central no later than 12 months after publication. **A PMCID is the only way to demonstrate compliance.**

Unique Article Identifiers	PMID (PubMed Reference Number)	PMCID (PubMed Central ID)	NIHMSID (ID in NIH Manuscript System)
Corresponding Repository/System	PubMed (an index of abstracts)	PubMed Central (PMC) (an index of full-text papers)	NIHMS (National Institutes of Health Manuscript System)
Does it fulfill the NIH Public Access Policy?	No	Yes	Yes

Progress Report Requirements

Your progress report must include the PMC reference number (PMCID) when citing applicable papers that you author or that arise from your NIH-funded research. Here is a clear explanation of the rules: Link: http://publicaccess.nih.gov/citation_methods.htm. The bottom line is that you must have a PMCID number (not a PMID number) for any publication that was published more than 3 months ago. For new pubs or "in press" pubs, they have two options, see link above for further explanation.



NIH Public Access Compliance Monitor

- We have the ability to run a report on the compliance status of all journal articles associated to VCU.
- Director, OSP will be sending the “noncompliant” report to all CAR members on a quarterly basis. The first report went out last week.
- The difficulty in achieving compliance is that uploading the publication can’t be easily delegated by the PI. Only those with copyright permission can legally upload publications to PubMed Central.
- Please help to educate your PIs on this requirement. Forward the email sent 5/21/13 to ResAdmin List serve



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What do your Principal Investigators Need to Know? (more than will fit on this slide!)

From [http://publicaccess.nih.gov/...](http://publicaccess.nih.gov/)

Preparation is Key to Avoiding Delays in Funding. Some suggestions:

- Use [My NCBI](#)'s My Bibliography feature to monitor Public Access compliance for **all the applicable papers that you author or arise from your NIH award**. Create an account using your eRA Commons ID, or [link](#) your current account with your eRA Commons account.
- As you plan a paper or support one with your NIH award, discuss with the authors how the paper and the NIH awards that support it will comply with the Public Access Policy.

How to Comply

All of your papers that fall under the NIH Public Access Policy, whether in press or in print, must include [evidence of compliance](#) in all of your NIH applications and reports.

1. [Determine Applicability](#)

Does the NIH Public Access Policy apply to your paper?

2. [Address Copyright](#)

Ensure your publishing agreement allows the paper to be posted to PubMed Central in accordance with the NIH Public Access Policy.

3. [Submit paper to PMC](#)

Submit papers to PubMed Central (PMC) and approve public release. Enter your journal name into the box on the right side of the screen to determine how your paper will be posted to PMC.

4. [Include PMCID in Citations](#)

Include the PMCID at the end of the full citation in your application or report.



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Overview of Submission Methods

Submission Methods:

http://publicaccess.nih.gov/submit_process.htm

There are four methods to ensure that an applicable paper is submitted to PubMed Central (PMC) in compliance with the NIH Public Access Policy. Authors may use whichever method is most appropriate for them and consistent with their publishing agreement. Click on the method in the table for details. Use the box on the left to help determine which submission method to use for your journal.



	Method A Journal deposits final published articles in PubMed Central without author involvement	Method B Author asks publisher to deposit specific final published article in PMC	Method C Author deposits final peer-reviewed manuscript in PMC via the NIHMS	Method D Author completes submission of final peer-reviewed manuscript deposited by publisher in the NIHMS
Version of Paper Submitted	Final Published Article	Final Published Article	Final Peer-Reviewed Manuscript	Final Peer-Reviewed Manuscript
Task 1: Who starts the deposit process?	Publisher	Publisher	Author or designee, via NIHMS, upon acceptance for publication	Publisher via NIHMS, upon acceptance for publication
Task 2: Who approves paper for processing?	Publisher	Publisher	Author, via NIHMS	Author, via NIHMS
Task 3: Who approves paper for Pub Med Central display?	Publisher	Publisher	Author, via NIHMS	Author, via NIHMS
Participating journal/publisher	Method A Journals	Make arrangements with these publishers	Check publishing agreement	Make arrangements with these publishers
Who is Responsible?	NIH Awardee	NIH Awardee	NIH Awardee	NIH Awardee
To cite papers, from acceptance for publication to 3 months post publication	PMCID or "PMC Journal- In Process"	PMCID or "PMC Journal- In Process"	PMCID or NIHMSID	PMCID or NIHMSID
To cite papers, 3 months post publication and beyond	PMCID	PMCID	PMCID	PMCID



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Are there publications identified by the NIH compliance monitor as “noncompliant” that are not subject to the NIH Public Access Policy?

Yes! There are **four** reasons why a paper identified as non-compliant may actually be exempt from the NIH Public Access Policy:

1. The paper was not peer-reviewed.
2. The paper was accepted for publication before April 7, 2008.
3. The paper was published in a script other than Latin (e.g., Russian, Japanese).
4. The paper was not directly supported by an NIH grant. Note: the compliance monitor captures NIH grant information that is found in the text (e.g., in the acknowledgements section) of articles. Sometimes authors acknowledge grants that did not directly fund the creation of their paper. Although the compliance monitor will identify such papers as non-compliant, they do not fall under the Public Access Policy.

If a PI determines that a non-compliant paper does not fall under the NIH Public Access Policy for one or more of the reasons given, can the PI remove the paper from the Public Access Compliance Monitor? Yes! To remove a paper from the compliance monitor, PIs can do the following:

1. Log in to your My NCBI account.
2. Go to My Bibliography and click on the “Manage My Bibliography” link.
3. Locate the non-compliant paper in your list of citations and click the “Edit Status” link.
4. Select the reason that this article is exempt from the submission requirements of the NIH Public Access Policy.
5. Save your changes but do NOT delete the citation from My Bibliography. When the compliance monitor is next updated it will capture your changes and the paper will be removed.



Compliance-related Statuses

Defining compliance status

The compliance status of an article in the compliance monitor is based on the following criteria.

Compliant

- The article has a PMCID (PubMed Central ID), indicating that it has been or is ready to be made public on PubMed Central,
- OR the article has been published in a Method A journal

In Process

- The article is NOT from a Method A journal ,
- AND it is less than 3 months past its final publication date,
- AND it is still somewhere in the NIHMS processing cycle, i.e., manuscript files have been deposited, but the cycle has not been completed and the article does not yet have a PMCID.

Non-Compliant

- The article is NOT from a Method A journal,
- AND it does not have a PMCID,
- AND it is not “in process” as defined above. (This includes articles less than 3 months past publication that have not yet begun the NIHMS submission process.)



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Summary of Systems and Terminology

Corresponding Repository/System	Unique Article Identifiers or Noted Features	Relationship to NIH Public Access Policy?
PubMed (an index of abstracts)	PMID (PubMed Reference Number)	None
PubMed Central (PMC) (an index of full-text papers)	PMCID (PubMed Central ID)	PMCID fulfills
NIHMS (National Institutes of Health Manuscript System)	NIHMSID (ID in NIH Manuscript System)	Yes
NIH Public Access Compliance Monitor	"PACR" Public Access Compliance Role	PACR designees can view summary reports for the institution
NIH eRA Commons	Grants Management Interface for PIs, NIH officials and university officials	<ul style="list-style-type: none">Reports funded projects subject to NIH Public Access PolicyPI can access "My Bibliography" tool using eRA Commons or My NCBI system
NIH's My NCBI	My Bibliography <ul style="list-style-type: none">Set up PubMed filters and iconsCustomize the search results displaySave and manage searchesCreate and manage collections	Use "My Bibliography" tool to save your citations (journal articles, books/chapters, patents, presentations and meetings) directly from PubMed or, if not found there, to manually enter citations using My Bibliography templates.



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Sponsored Project Administration Certification Program

- Program runs annually from September-November
- On-line registration will begin later in the summer-will be announced through Research Administration list serve
- Nominal fee charged to cover lunch expenses
- Program is geared toward research administrators with 3 years of experience, but beneficial for those just starting out as well as those experienced in the field
- Enrollment will be limited to ~32 students and priority given to those who have not completed the course



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