Research Administration and Compliance Meeting
Wednesday, February 19, 2014, 1:00 – 3:00 p.m.
Larrick Hall, Court End Ballroom A

Agenda

Integrity and Ethics Updates (ORIE)

- PI designation for Industry-sponsored training grants in School of Medicine

Subjects Protection Updates (ORSP)

- RAMS-IRB conversion reminder for study coordinators
- Update to VCU and VCUHS Federalwide Assurance
- IRB Policy update: PI qualifications
- Animal Care and Use Program researcher survey

Clinical Research Services Updates (CRS)

- VCU Health System Standardized Fee Scheduled for Ancillary Services for VCU Clinical Trials

Sponsored Programs Updates (OSP)

- IAF Supplement for Clinical Research and Clinical Trial Billing
- OMB Circular A-81
- NSF Chronically Late Reports
- Request for Closeout Information
- ARRA Reporting Requirements Repealed

Grants & Contracts Updates (G&C)

- FY2013 Commonwealth of VA Single Audit Report
- G&C/Effort Reporting Updates

Research Administration and Compliance (ORAC)

- Clinical Research Compliance Officer
- Research Compliance Matrix

Future Meeting Dates, 1-3 p.m.

- April 24, 2014, Larrick Court End A

PI designation for:
Industry-sponsored fellowship support of School of Medicine ACGME programs

Basic AIRS troubleshooting

Monika Markowitz, PhD
COIC Chair
Director, Office of Research Integrity and Ethics

2/19/2014 RACM

PI designation for industry-sponsored fellowship support for SoM ACGME programs

Purpose:

- to mitigate potential COI a faculty PI may have with the industry sponsor.
- to minimize industry's reporting of payment to the faculty as per Physician's Sunshine/ Open Payment Act.
- to ensure appropriate disbursement of training grant support.

Industry sponsored SoM fellowship support – prospective process

- Designated PI – Dr. Mary Alice O'Donnell – Director of Graduate Medical Education on application
- Send her a notification about pending application, will need to sign as PI
- Program director – physician – remains the same
- Submit and process through OSP, award to G & C

Industry sponsored SoM fellowship support – 'fix'

Funding support arrives (!), but there was no prospective application sent to OSP:

- Contact OSP or COI Program -airs@vcu.edu
- Re- or new designation of PI to Dr. Mary Alice O'Donnell – Director of Graduate Medical Education
- Both Dr. MAO and physician "PI" to be notified about PI change.
- IAF to be submitted – Physician PI sign over to Dr. MAO; Dr. MAO signs on as PI

Alternate PI designation **does not** apply when:

- Training support is from non-industry sources
- In the unlikely event that the resident/fellowship training program is non-accredited

Basic AIRS troubleshooting

- My investigator is trying to get into the AIRS and website is not working…

Most frequent remedies:

- Do not use Google Chrome – use another browser.
- If using Chrome, delete the ‘s’ from https:
- If outside of VCU, use the VPN – see VCU eRA page for: Click here for VCU's VPN.
- Send notice to erahelp@vcu.edu

Office of Research Subjects Protection Updates

February 19, 2014

RAMS-IRB Conversion Tips

- Create conversion amendment within existing study shell in RAMS-IRB
- Conversion process & continuing review:
  1. Conversion amendment occurs 4-5 months before expiration. Should be complete prior to starting continuing review.
  2. Continuing review submission still required prior to expiration.

VCU and VCUHS FWA Update

- Federalwide Assurance with DHHS has been updated
  - Federal regulations only applied to federally sponsored research
  - In practice
    - Unanticipated problems & serious/continuing noncompliance will only be reported if federally funded
    - no other changes at present time
    - Presents opportunities to increase flexibility for non-federally funded research

IRB Policy Update

- ORSP is actively reviewing and updating all WPPs
- New: WPP IX-3 – Personnel Qualifications
  - Personnel involved in clinical research must be appropriately licensed and credentialed
  - PI and/or Medically Responsible Investigator will be verified by ORSP staff
  - PI responsible for assuring current credentials of all other clinical personnel

ACUP Survey

- Animal Care and Use Program (ACUP) researcher survey anticipated March 3
- Opportunity for researchers to provide feedback to IACUC and DAR

Office of Sponsored Programs (OSP) Updates:

Melanie Wiggins

Director, OSP-Industry and Clinical Trials

February 19, 2014

OSP Update

Presentation Topics:

- IAF Supplement for Clinical Research and Clinical Trial Billing
- OMB Circular A-81
- NSF: Chronically Late Reports
- (OSP's December 2013) Request for Closeout Information
- ARRA Reporting Requirements Repealed
- OSP Staffing Update

Background: Changes to Clinical Research and Clinical Trial Billing Procedures

- There is a new requirement (as Jan. 1, 2014) from the Centers for Medicare & Medicaid Services (CMS) for inclusion of the 8-digit National Clinical Trial Number (NCT #) on claims associated with clinical trial participation. Claims submitted to CMS for clinical trial services must include the NCT# or they will be returned.
- The Office of Sponsored Programs (OSP) is working with the School of Medicine, Clinical Research Services (CRS) and VCU Health System (VCUHS) billing to improve compliance with clinical research and clinical trial billing requirements by providing billing information to VCUHS for clinical research studies and clinical trials at the time of award distribution for sponsored programs.
- Billing forms are required for all clinical research and clinical trials enrolling or with the potential to enroll Medicare recipients and having potential VCUHS billing either to participant insurance or to the study.
- As a mechanism to facilitate the billing process for externally funded studies with potential clinical billing, OSP will ensure the following information is received at the time of proposal submission (as appropriate) and prior to award dissemination: (1) IAF Supplement for Clinical Research and Clinical Trial Billing form, (2) signed cost coverage analysis document, (3) billing grid and (4) clinical research/clinical trial billing account set up information

	Clinical Research**without** any potential VCUHS billing	Clinical Research*with* potential VCUHS billing	Clinical Trial Device Study	Clinical Trial Non-Device Study
Clinical Research Cost Coverage Analysis		X		
Clinical Trial Device Cost Coverage Analysis			X	
Clinical Trial Non Device Cost Coverage Analysis				X
Billing Grid		X	X	X
CR and CT Billing Setup (formerly called Grant and Clinical Trial Agreement Institutional Billing Form) with all ancillary prices		X	X	X

Changes to Internal Approval (IAF) Form

- For tracking purposes, changes to the paper and electronic IAF was necessary as well as implementation of a new IAF supplement form. The January 2014 version of the IAF should be used for all proposals.
- Page 2 of the hard copy version of the IAF was changed to incorporate "clinical research" as an additional category under Compliance Data.
- This change allows you to identify if your project is a "clinical trial" or includes a clinical trial component and/or is considered "clinical research".
- If you check either clinical research or clinical trial on the IAF form, you are required to fill out the IAF Supplement for Clinical Research and Clinical Trial Billing and attach the supplement to the IAF with your proposal.

COMPLIANCE DATA

-If project is research or clinical trial, please indicate:

Basic[i] ☐ Applied[ii] ☐ Developmental[iii] ☐ [i-v]**See last page for key definitions**

The proposal enclosed involves the following:

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

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

IAF Supplement for Clinical Research and Clinical Trial Billing

- The IAF supplement form is an assessment to ensure that the appropriate information is captured regarding whether the study is clinical research, a clinical trial or clinical research with a clinical trial and how billing will be performed. Information will be entered into the VCUeRA database.
- Indicate the Project Type and the Billing Category in the appropriate section
- For those studies where clinical services are being performed and the VCUHS is not responsible for billing (either to insurance or the study), please indicate who is responsible for billing and who is providing payment.
- For clinical trials, be sure to include whether the clinical trial is sponsor or investigator initiated and include the NCT # (if known).
- A table of associated billing forms and the definitions of clinical research and clinical trial have been included at the bottom of the supplement form. The link to the CCTR and CRS website with additional instructions is included.

IAF Supplement for Clinical Research and Clinical Trial Billing

(Submit only if human subjects receive clinical services in the course of the project)

PI: _____ PT/PD/SC#: _____ Title: _____ Sponsor: _____

PROJECT TYPE DESCRIPTION

Select the best answer describing your project:

☐ Clinical Research Only	☐ Clinical Trial Only	☐ Clinical Research with Clinical Trial Component

COMPLETE IF PROJECT IS CLINICAL RESEARCH ONLY

The appropriate billing category for this project is:

	Billing Category
☐	**Clinical Research with no potential VCUHS billing.** Identify who is responsible for billing, i.e. G&C Accounting? _____ Identify who is providing payment, i.e. sponsor?) _____
☐	**Clinical Research with potential VCUHS billing at project outset.** (Complete required billing forms per table below and submit with this form to OSP.)
☐	**Clinical Research with potential VCUHS billing not at project outset.** (Required billing forms to be completed at a later time.)

COMPLETE IF PROJECT IS CLINICAL TRIAL or CLINICAL TRIAL COMPONENT (of Clinical Research)

The appropriate billing category for this project is:

	Billing Category
☐	**Clinical Trial Device Study with VCUHS billing** (Complete required billing forms per table below and submit with this form to OSP.)
☐	**Clinical Trial Non Device Study with VCUHS billing** (Complete required billing forms per table below and submit with this form to OSP.)
☐	**Clinical Trial Component (of Clinical Research)--VCUHS billing not at project outset.**(Required billing forms to be completed at a later time.)
☐	**Clinical Trial Study –no VCUHS billing** Identify who is responsible for billing, i.e. G&C Accounting? _____ Identify who is providing payment, i.e. sponsor? _____

Provide the 8 digit clinical trials registration number, if known. Contact Melanie Wiggins at mwiggins@vcu.edu for additional information:

	Clinical Trial Registration:	NCT#
☐	Investigator-initiated Clinical Trial	
☐	Sponsor-initiated Clinical Trial	

INSTITUTIONAL CLINICAL RESEARCH/CLINICAL TRIAL BILLING FORMS

This table identifies cost coverage forms required for this project based on the appropriate billing category.

These forms can be found on the CCTR website under Clinical Research Services. http://www.cctr.vcu.edu/clinicalresearch/index.html Click on VCU-VCUHS joint clinical research/trial institutional billing procedure on the left menu and enter your eID to access forms.

	Clinical Research **without** any potential VCUHS billing (no forms are required)	Clinical Research **With** potential VCUHS billing	Clinical Trial Device Study	Clinical Trial Non Device Study	OSP Use Only
Clinical Research Cost Coverage Analysis (Also called Non Clinical Trial)		√			☐
Clinical Trial Device Cost Coverage Analysis			√		☐
Clinical Trial Non Device Cost Coverage Analysis				√	☐
Billing Grid		√	√	√	☐
CR and CT Billing Setup (Formerly called Grant and Clinical Trial Agreement Institutional Billing Form with all ancillary prices		√	√	√	☐

MISCELLANEOUS

Clinical Research is research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator directly interacts with human subjects. Examples include mechanism of human disease, observational studies involving therapeutic interventions (where participant may receive intervention but investigator does not assign participants to intervention), epidemiological and behavioral studies, outcomes research and health services research.

Clinical Trial: An interventional or observational prospective research study involving human subjects that is designed to answer specific questions about biomedical or behavioral treatments 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 treatment and outcomes are measured. In an observational clinical trial, interventions given during clinical care are observed and outcomes are measured.

At award distribution time, VCUHS Billing and CRS Admin will receive a copy of this form and billing forms from OSP Post Award for all projects that indicated use of VCUHS billing.

IAF Supplement for Clinical Research and Clinical Trial Billing

(Submit only if human subjects receive clinical services in the course of the project)

PI: Schmidt PT/PD/SC#: Title: VX09-809-102 Sponsor: Vertex

PROJECT TYPE DESCRIPTION

Select the best answer describing your project:

☐ Clinical Research Only	☑ Clinical Trial Only	☐ Clinical Research with Clinical Trial Component

COMPLETE IF PROJECT IS CLINICAL RESEARCH ONLY

The appropriate billing category for this project is:

	Billing Category
☐	**Clinical Research with no potential VCUHS billing.** Identify who is responsible for billing, i.e. G&C Accounting? _____ Identify who is providing payment, i.e. sponsor?) _____
☐	**Clinical Research with potential VCUHS billing at project outset.** (Complete required billing forms per table below and submit with this form to OSP.)
☐	**Clinical Research with potential VCUHS billing not at project outset.** (Required billing forms to be completed at a later time.)

COMPLETE IF PROJECT IS CLINICAL TRIAL or CLINICAL TRIAL COMPONENT (of Clinical Research)

The appropriate billing category for this project is:

	Billing Category
☐	**Clinical Trial Device Study with VCUHS billing** (Complete required billing forms per table below and submit with this form to OSP.)
☑	**Clinical Trial Non Device Study with VCUHS billing** (Complete required billing forms per table below and submit with this form to OSP.)
☐	**Clinical Trial Component (of Clinical Research)--VCUHS billing not at project outset.**(Required billing forms to be completed at a later time.)
☐	**Clinical Trial Study –no VCUHS billing** Identify who is responsible for billing, i.e. G&C Accounting? _____ Identify who is providing payment, i.e. sponsor? _____

Provide the 8 digit clinical trials registration number, if known. Contact Melanie Wiggins at mwiggins@vcu.edu for additional information:

	Clinical Trial Registration:	NCT#
☐	Investigator-initiated Clinical Trial	
☑	Sponsor-initiated Clinical Trial	01225211

Clinical Trial (Industry)

Activity Description

Instr. Type: Contract

Award No.

Sponsor Ind.: No

Originating Sponsor

Vertex Pharmaceuticals, Inc | Change | Remove | Load Sponsor Profile | - Select -

Funding Source: Non Federal

% Federal: 0.000

Special Requirements

Sponsor Contact Set	Project Officer Set	Grant/Contract Officer Set	Billing Officer Set

Additional Sponsor Information

CRO Set Clear

Expanded Authorities

NIH SNAP/RPPR Eligible

NIH RPPR-Fellowship Only

FFATA Applies

E-Verify Applies

File Destruction Date

Retention Qualifier

Clinical Research And Clinical Trial Billing

Human Subjects Involvement: Clinical Trial Only

Clinical Research Billing Category: Not Applicable

Clinical Trial Billing Category: Clinical Trial Non Device Study with VCUHS billing

Clinical Trials Registration

Clinical Trial Initiated By: Sponsor

NCT #: NCT01225211

Summary of OSP Review Criteria

New proposals which include human subjects should be assessed to determine whether clinical services are involved. If clinical services are involved, an IAF supplement form along with the appropriate billing information is required at the time of proposal review.

For current studies: Prior to processing your award, if your study includes human subjects, Post Award will request identification of whether your study includes potential clinical services or if your interaction is non-clinical. The IAF supplement form and all appropriate billing information is required prior to award distribution for studies involving clinical services.

Use of the latest forms is encouraged. Cost coverage forms received without School level signature will be forwarded to the appropriate official for signature (e.g. Margie Halverson for SOM, Bob Houlihan for Massey).

A Clinical Research/Clinical Trial Billing packet consisting of the IAF supplement form, the cost coverage analysis, a billing grid and the account set up form will be distributed to Margaret Johnson (hospital) and Alice Fowler (practice), with copies to the CRS and the Dean's office at the time of award distribution.

Questions

For information about OSP review contact:

Office of Sponsored Programs:

dirospa@vcu.edu

Annie Publow

828-6772

mwiggins@vcu.edu

Melanie Wiggins

827-4992

For information about billing forms contact CRS website:

http://www.cctr.vcu.edu/clinicalresearch/billing/index.html

Rudi Ross

628-2942

Research Administration & Compliance Meeting

February 19, 2014

Annie Publow, Director, OSP,
Government/NonProfit

OMB Circular A-81

Also known as….

- 2 CFR Chapter I, Chapter II, Part 200, et al.
- Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards; Final Rule
- The “Omni” or “Super” Circular

OMB Circular A-81

Uniform implementation date for all federal agencies:

December 26, 2014

Date applies to all requirements except audit. The audit regulations become effective the first fiscal year after implementation, so July 2015 given our July-June fiscal year.

“Omni Circular” will replace:

A-21, A-50, A-87, A-89, A-102, A-110, A-122, A-133

OMB Circular A-21: Cost Principles for Educational Institutions (5/10/2004)

OMB Circular A-110: Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations (09/30/1999)

OMB Circular A-133: Audits of States, Local Governments, and Non-Profit Organizations (06/26/2007)

OMB Circular A-87: Cost Principles for State, Local, and Indian Tribal Government (05/10/2004)
OMB Circular A-102: Grants and Cooperative Agreements with State and Local Governments (10/07/1994)
OMB Circular A-122: Cost Principles for Non-Profit Organizations (05/10/2004)
OMB Circular A-50: Audit Followup (09/29/1982)
OMB Circular A-89: Catalog of Federal Domestic Assistance (08/17/1984)

Organizational Overview of A-81:

Sources:
*Reorganization
*Revision of existing language
*New language

Section In OMB Uniform Guidance: Cost Principles, Audit, and Administrative Requirements for Federal Awards
Subpart A - Acronyms and Definitions
Subpart B - General Provisions
Subpart C – Pre-Federal Award Requirements and Contents of Federal Awards
Subpart D – Post Federal Award Requirements
Standards for Financial and Program Management
Property Standards
Procurement Standards
Performance and Financial Monitoring and Reporting
Subrecipient Monitoring and Management
Record Retention and Access
Remedies for Noncompliance
Closeout
Post-Closeout Adjustments and Continuing Responsibilities
Collection of Amounts Due
Subpart E – Cost Principles
General Provisions
Basic Considerations
Direct and Indirect (F&A) Costs
Special Considerations for States, Local Governments and Indian Tribes
Special Considerations for Institutions of Higher Education
General Provision for Selected Items of Cost
Subpart F – Audit Requirements
Audits
Auditees
Federal Agencies
Auditors
Management Decision
Appendices

Organizational Overview of A-81: Appendices

Appendices
Appendix I – Full Text of Notice of Funding Opportunity
Appendix II – Contract Provisions for Non-Federal Entity Contracts Under Federal Awards
Appendix III – Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Institutions of Higher Education (IHEs)
Appendix IV – Indirect (F&A) Costs Identification and Assignment, and Rate Determination for Nonprofit Organizations
Appendix V – State/Local Government and Indian Tribe – Wide Central Service Cost Allocation Plans
Appendix VI – Public Assistance Cost Allocation Plans
Appendix VII – States and Local Government and Indian Tribe Indirect Cost Proposals
Appendix VIII - Nonprofit Organizations Exempted from Subpart E: Cost Principles
Appendix IX – Hospital Cost Principles
Appendix X – Data Collection Form (Form SF-Sac)
Appendix XI – Compliance Supplement

Council on Financial Assistance Reform "COFAR"

COFAR website: https://cfo.gov/cofar/

- Excellent source of information, webinars, FAQs, and "crosswalk" documents for understanding the changes

Why is there a new circular?

When and why did we begin this process?

- This uniform guidance was developed in response to the November 23, 2009 Executive Order 13520 on *Reducing Improper Payments* and the February 28, 2011 Presidential Memorandum on *Administrative Flexibility, Lower Costs, and Better Results for State, Local, and Tribal Governments*.
- In those documents, the **President directed OMB** to work with Executive Branch agencies; state, local, and tribal governments; and other key stakeholders to evaluate potential reforms to Federal grants policies.
- The **Council on Financial Assistance Reform (COFAR)** was established in October 2011 and has led several efforts to improve delivery, management, coordination, and accountability of Federal grants and cooperative agreements, which includes the development of the uniform guidance.

From: https://cfo.gov/wp-content/uploads/2013/01/2-C.F.R.-200-FAQs-2-12-2014.pdf

How has COFAR engaged stakeholders?

How have we engaged stakeholders over the past two years?

- This reform follows OMB's February 1, 2013 **Notice of Proposed Guidance (NPG)** and February 28, 2012 **Advance Notice of Proposed Guidance (ANPG) published in the Federal Register**.
- The **COFAR also hosted a public webcast** on the NPG (available at cfo.gov/COFAR) and **participated in public discussions** of the proposed reforms when invited by interested stakeholders.
- The ANPG and NPG each received more than **300 public comments**, which are available to the public on www.regulations.gov
- **The process has been led by the COFAR, an interagency council of OMB, the eight largest Federal grant-making agencies and one rotating small grant-making agency**. Other Federal grant making agencies have provided input as well.

From: https://cfo.gov/wp-content/uploads/2013/01/2-C.F.R.-200-FAQs-2-12-2014.pdf

VCU's follow up

Committee on the Administration of Research subcommittee appointed to evaluate A-81 and make recommendations for implementation at VCU

- Led by Annie Publow and Mark Roberts
- CAR member participation by Stacey Garnett (SoN), Robert Houlihan (Massey), Brigette Pfister (College of Humanities & Sciences), Margaret Poland (School of Dentistry)

Some Key Changes

- Emphasis on accountability through performance measures over compliance (increased need for agencies and recipients to relate financial data to performance requirements)
- Emphasis on delivering results and outcomes (from program announcement through to closeout)
- Emphasis on establishment and monitoring of internal controls
- Focus on reducing waste, fraud and abuse-greater scrutiny and follow up on audit findings (obligation sponsor to prime, and prime to subrecipient)

Some Key Changes

- Family-friendly policies encouraged
- Establishment of “de minimis” 10% Indirect Cost rate (for entities with no negotiated rate)
- Single Audit threshold increased from $500K to $750K
- Ability to charge administrative/clerical costs as direct costs (with justification and agency approval) –but such costs may not also be recovered as F&A
- Funding announcements must be available for at least 60 days

Some Key Changes

- Program income, “additive alternative” still default for IHEs (Institutions of Higher Education) but “royalties and license fees” for patents and copyrights are required to be tracked
- Voluntary committed cost sharing is not expected and cannot be used as a factor in merit reviews
- Federal agencies must accept negotiated rate agreements (unless the specific funding announcement identifies otherwise)
- Emphasis on Subrecipient Monitoring by the Pass-Through (prime) to include risk assessment, performance monitoring and audit deficiency monitoring

VCU Approach

- Plan utilize advisory/professional resources: Council on Government Relations (COGR), National Council of University Research Administrators (NCURA) and Society of Research Administrators (SRA)
- Document existing circular requirements with existing policies, procedures and responsible parties and identify the areas changing or staying the same
- Involve VCU stakeholders as needed
- Provide updates to CAR and RACM
- Update training materials and/or create new

NSF: Chronically Late Reports

Report on RESEARCH COMPLIANCE

Volume 11, Number 1 • January 2014

News and Analysis for Colleges, Universities and Teaching Hospitals

Contents

NSF OIG: Chronically Late Reports Are Grounds for Governmentwide Debarment

In its recent report to Congress, the National Science Foundation's (NSF) Office of Inspector General (OIG) has taken a more aggressive tone, promising to use every compliance and enforcement tool at its disposal even while it pursues new ones.

Covering the six-month period ending Sept. 30, 2013, the report also documents IG Allison Lerner's quest to expand debarment to include principal investigators (PIs) who are not current with final reports. And, for the first time, OIG has recommended that NSF make use of its authority under the Program Fraud Civil Remedies Act (PFCRA) to recover "up to twice the amount of a false claim, as well as a penalty for each false claim" — an action OIG said it is pondering for all confirmed cases of fraud.

NSF: Additional Recent Actions

VCU

Andrea J Publow < ajpublow@vcu.edu>

Overaged Overdue Reports for NSF Awards
1 message

Vieceli, Jeffery A. < jvieceli@nsf.gov> Tue, Feb 4, 2014 at 11:00 AM
To: "ajpublow@vcu.edu" <ajpublow@vcu.edu>

NSF Awardee Organization: Virginia Commonwealth University

NSF Organization ID: 0001347000

Awardee Contact: ajpublow@vcu.edu

Dear NSF Awardee—

You are receiving this communication because **NSF records indicate that Annual and/or Final Project Report(s) and/or the Project Outcomes Report for the General Public (POR) in connection with one or more of the awards made to your organization are more than 90 days overdue.** NSF has sent numerous reminders to the PI, co-PI(s) and the Sponsored Projects Office (SPO) of your organization regarding the requirement to file the reports. As of this notice, NSF has not received the required overdue Annual, Final and/or POR reports for the awards.

SPOs are strongly encouraged to contact the PI and co-PIs about the overdue reports. Overdue reports block any and all actions on the subject award and any other award(s) for which the PI and co-PIs are listed as active personnel.

(OSP's December 2013) Request for Closeout Information

- One-time email sent to PI with projects in "Award in Closeout" status with project end dates between January 1, 2009 and June 30, 2013
- ~900 emails generated
- OSP Post Award has received ~300 responses
- After we process these, we will re-send
- No need to wait for a prompt, use the e-closeout forms on OSP website

  …http://www.research.vcu.edu/forms/osp_closeout.htm

The project currently shows a status of Award In Closeout in VCUeRA (the Office of Sponsored Programs' (OSP) database) most likely because OSP has not been informed by you or your departmental administrator that the required non-financial closeout has been provided to the sponsor.

While you may have already processed final financial closeout with the Office of Grants and Contracts Accounting, you may not be aware that OSP is responsible for recording that non-financial closeout has occurred as required by the sponsor. A few examples of non-financial closeout are final technical report, final invention report, and property report. Please take the time to review your award document for specific final reporting requirements and stipulated due dates. Coordinate with your departmental administrator on any needed follow up.

Please use the new Electronic-forms that OSP has developed to inform the OSP Post Award Team that your project can be closed out. There are three versions of the E-form, available at http://www.research.vcu.edu/forms/index.htm#osp_forms.

Select the correct version of the form for your type of project:

(1) E-Closeout Form-General – Use for non-industry, non-clinical trial projects.
(2) E-Closeout Form-Industry Research – Use for industry-sponsored projects.
(3) 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.

Finally, please note that the Commonwealth of Virginia requires that supporting documentation and project data be retained for a period of 5 years from the end date for every sponsored project. For additional guidance and to understand your record retention obligations please refer to http://www.assurance.vcu.edu/Policy%20Library/Record%20Retention.pdf.

Thank you for your assistance and cooperation,

Office of Sponsored Programs
Post Award Team

RECOVERY ACCOUNTABILITY AND TRANSPARENCY BOARD

PRESS RELEASE

Nancy K. DiPaolo | Chief, Congressional & Intergovernmental Affairs
202.254.7900 | media@ratb.gov

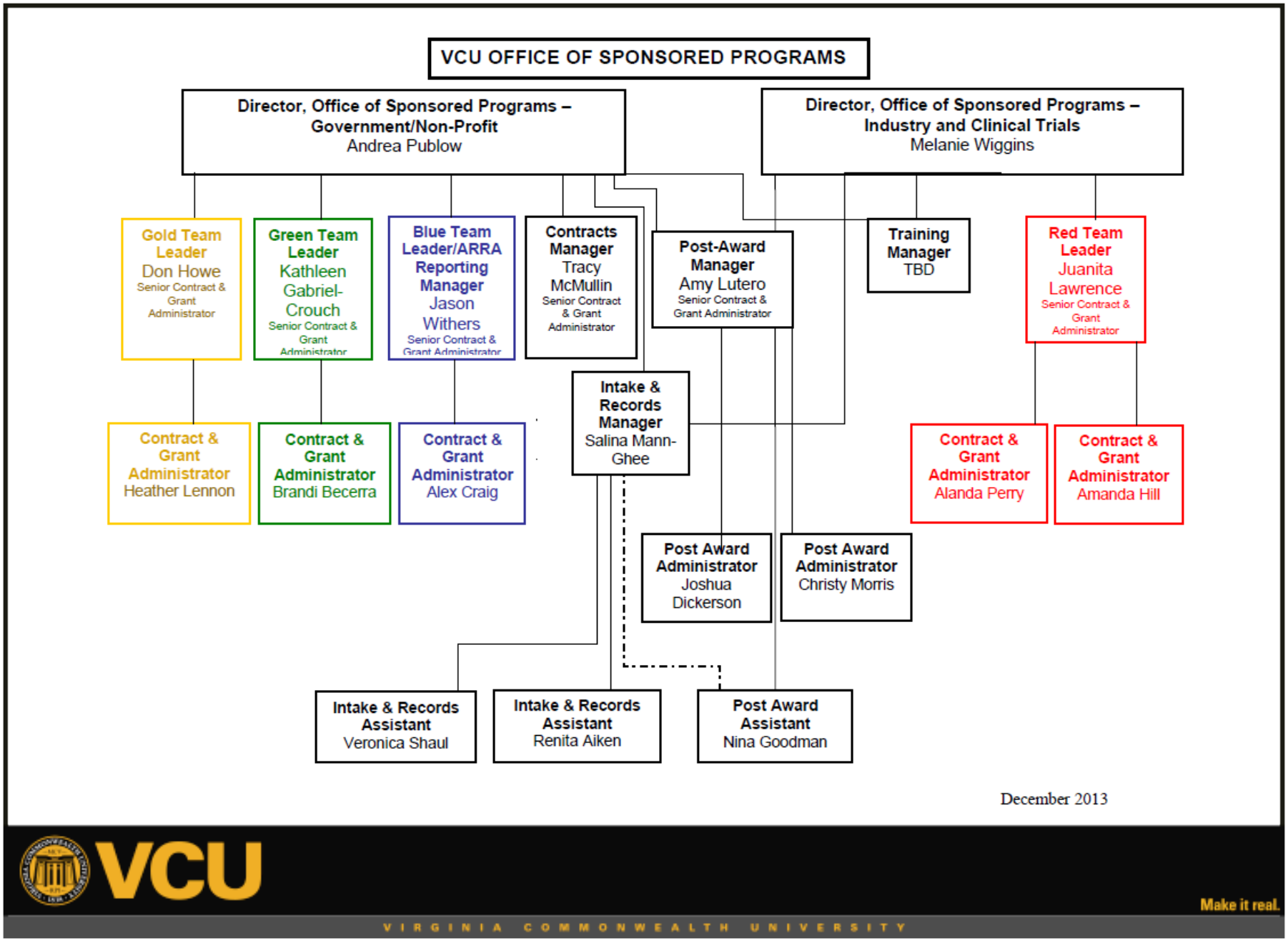
FOR IMMEDIATE RELEASE
JANUARY 17, 2014

ARRA Recipient Reporting to End on February 1, 2014

WASHINGTON – The enactment of the Federal Government's Fiscal Year 2014 Omnibus Spending bill brings an end to the "1512" Recipient Reporting requirements of the American Reinvestment and Recovery Act (ARRA). Section 627 of the Omnibus repeals the reporting as of February 1, 2014.

Recipients and agencies are currently finalizing recipient reports for Quarter 4, 2013. Data from these reports will be posted on Recovery.gov by the Recovery Accountability and Transparency Board (Recovery Board) on January 30th.

Quarterly reporting which began back in 2009 and was a condition of receipt of awards funded by the American Reinvestment and Recovery Act is no longer required.



VIRGINIA COMMONWEALTH UNIVERSITY

Make it real.

Research Administration and Compliance Meeting

G&C Accounting Updates; February 19, 2014

G&C/Effort Staffing

-Rebecca Bockus is out of the office for medical reasons. Until further advised please contact Christine Tanner-Walker or Shavonda Gravely (Gamma Team) in Rebecca's absence.

-Leon Brown is out of the office for medical reasons. Until further advised please contact Joyce Wimberly (Alpha Team) in Leon's absence.

Recent Federal Reforms

-Revision of OMB Uniform Guidance

-NIH Notice NOT-OD-13-120 (Transition to Subaccounts

-Annual NSF Program Income Reporting (Effective 3/1/2014)

COFAR Release FAQS

On Monday, February 12, 2014, COFAR released the first set of FAQs in support of 2 C.F.R 200 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.

https://cfo.gov/wp-content/uploads/2013/01/2-C.F.R.-200-FAQs-2-12-2014.pdf

NIH Notice NOT-OD-13-120

NIH transition to new HHS payment policy

Transition to subaccounts for continuations beginning 10/1/2014

New document number and project period end date change

Greater enforcement by HHS institutes of 90 day closeout and availability of funds for reimbursement to VCU

NSF Program Income Reporting

NSF Awardee organizations will be required to submit a Program Income Reporting Worksheet on Research.gov by October 31st each year to report the amount of program income earned and expended during the previous Federal fiscal year (October 1 – September 30).

G&C immediate priorities

-Office of Assurance Services 2014 Audit
-Program Income Org Code reviews
-Close-outs, required documents needed
-Policies and Procedures revisions

G&C Close-outs Update

GREAT NEWS REPORT

Information As of 2-19-2014

-Grants with end date Dec. 31, 2011 and earlier dates pending close-out: **7 Funds less than 4%**

-Grants with end date Jan. 1, 2012–Dec. 31, 2012 pending close-out: **9 Funds less than 5%**

-Grants with end date Jan. 1, 2013 - Oct. 31, 2013 pending close-out : **175 Funds**

Your continued assistance to respond to final documentation requests in a timely manner is greatly appreciated!

Effort Reporting Update

GREAT NEWS REPORT

Remaining Effort Statements *Information As of 2-17-2014*

Semester Period (8-10-2013 to 12-24-2013) Due 3/21/14

Has 195 (56.36%) of 346 statements remaining to be certified

Quarterly Period (9-10-2013 to 12-9-2013) Due 3/14/2014

Has 349 (27.24%) of 1281 statements remaining to be certified

Semi-Annual Period (12-10-2012 to 6-9-2013) Due 10/21/2013

Has 62 (4.79%) of 1252 statements remaining to be certified

Thank you for all of your efforts in having effort statements certified in a timely manner

Thanks…….

The staff in the Office of Grants and Contracts Accounting would like to thank you for your continued support towards research fiscal compliance!

Contact our Helpline at 804-828-8104 for assistance, or email GCAVCU@vcu.edu or effortreport@vcu.edu

VCU Clinical Research Compliance Officer

Betsy Ripley, MD, MS

- Betsy Ripley, MD, MS
  eripley@mcvh-vcu.edu
  804-828-1955
- Oversight of investigator compliance activities related to FDA regulated research including Investigative New Drugs (IND) and Investigative Device
- Education and training needs for IND and IDE compliance
- Oversee and report on inventory, including status profile, of all VCU Sponsor-Investigator Investigational New Drug and Investigational Device Exemptions.
- Collaborate with the VCU CCTR on Clinicaltrials.gov registration and reporting
- Develop and oversee an institution-wide tracking process for VCU investigator-held applications for FDA approval of IND and IDEs, approvals, SAE reporting, and annual reporting.
- Currently collecting information regarding faculty who hold INDs or IDEs
  - https://redcap.vcu.edu/rc/surveys/?s=CuNP79WmH6