Research Administration and Compliance Meeting
Wednesday, January 23, 2013, 1:00 – 3:00 p.m.
Larrick Hall, Court End Ballroom A

Agenda

General Items/Updates

- New Policies
  - Compliance with the Federal Funding Accountability and Transparency Act
  - Cost Sharing
  - Establishment of Sponsored Project Subcontracts and Subawards
  - Subrecipient Monitoring Policy
  - Facilities and Administrative Cost Recovery
  - Post Award Changes – Rebudgeting, Prior Approvals and University Expanded Authority Approval
  - Sponsored Programs Award Review, Negotiation, Acceptance and Notification

Grants & Contracts Updates

- Effort Reporting – ECRT Upgrade Resources & New Staff Member Introduction – P. Fleming
- G&C Updates – M. Roberts

OSP Updates

- Electronic Submission Process for Multi-Project Applications & ASSIST – A. Publow
- Research Performance Progress Report (RPPR) – A. Publow
  - Research.gov for NSF Reporting – A. Publow
- "In Closeout" Records – A. Publow
- Intellectual Property Assignment in Sponsored Agreements – M. Wiggins
- Advance PT/SC Number Request Form

ORIE Updates

- FIR Update in AIRS – Monika Markowitz
- Research Integrity Officer – Monika Markowitz

ORSP Updates

- AAALAC Visit – March 26-28, 2013
  - AAALAC Preparation sessions scheduled – February 5 @ 10 a.m., February 25 @ 3 p.m. Both held in KMSB 104/105

New Business
Sponsored Project Certification Program Certificate Presentation

Future Meeting Dates, 1-3 p.m.

- May 22, 2013 – Larrick Hall – Court End Ballroom A

VIRGINIA COMMONWEALTH UNIVERSITY

OSP Updates

Melanie Wiggins
Director, OSP-Industry and Clinical Trials

January 23, 2013

OSP Update Topics

Intellectual Property (IP) Assignment in Sponsored Agreements

Revisions to Advance PT Request Form

Intellectual Property Assignment in Sponsored Agreements

• Recent trend: Many for profit companies (GlaxoSmithKline, Novartis & Ocera) as well as some government/non-profit funding agencies (Dept of Education) are requiring VCU to agree to present tense intellectual property (IP) assignment language in certain sponsored agreements.

• Terms such as "hereby assigns" in sponsored agreements are used:

(1) to verify assignment of IP from University personnel to VCU exists (e.g, "Principal Investigator hereby assigns all right, title and interest to University")

AND/OR

(2) to confer assignment of IP from VCU to the Sponsor (especially with respect to industry-sponsored clinical trials). (e.g, "VCU hereby assigns….. To Novartis")

• Under Sponsored Agreements, Sponsors want assurances that VCU (and not the individual inventor) owns the IP to avoid lawsuits for patent infringement. (e.g, Stanford vs. Roche)

Intellectual Property (IP) Assignment in Sponsored Agreements

• Present tense assignment language in sponsored agreements is problematic since it requires that VCU holds the right, title and interest to intellectual property at the time of execution of the agreement/contract which is most often prior to the creation of IP. This is contrary to our current IP policy and employment contracts.

• VCU IP assignment follows VCU Intellectual Property Policy and Commonwealth of Virginia statutes (Virginia Code § 23-4.3 and § 23-4.4.A).

Code of Virginia § 23-4.3. Adoption of intellectual property policies; employees to be bound by such policies.

- § 23-4.3. Adoption of intellectual property policies; employees to be bound by such policies.

A. The boards of visitors of state-supported institutions of higher education and the State Board for Community Colleges shall adopt policies regarding the ownership, protection, assignment, and use of intellectual property.

B. All employees of state-supported institutions of higher education, including the Virginia Community College System, as a condition of employment, shall be bound by the intellectual property policies of the institution employing them.

C. Upon adoption, the boards of visitors of state-supported institutions of higher education, including the State Board for Community Colleges, shall provide a copy of their intellectual property policies to the Governor and the Joint Commission on Technology and Science.

D. For purposes of this section, "intellectual property" means (i) a potentially patentable machine, article of manufacture, composition of matter, process, or improvement in any of those; (ii) an issued patent; (iii) a legal right that inheres in a patent; or (iv) anything that is copyrightable.

Code of Virginia § 23-4.4. Authorization to transfer interest

§ 23-4.4. Authorization to transfer interest; Governor's approval required under certain circumstances.

A. The boards of visitors, the State Board for Community Colleges, or their designees **are authorized to assign any interest they possess in intellectual property or in materials in which the institution claims an interest, provided such assignment is in accordance with the terms of the institution's intellectual property policies adopted pursuant to subsection A of § 23-4.3**. However, the Governor's prior written approval shall be required for transfers of such property developed wholly or predominately through the use of state general funds, exclusive of capital assets, and either (i) such property was developed by an employee of the institution acting within the scope of his assigned duties, or (ii) such property is to be transferred to an entity other than the Innovation and Entrepreneurship Investment Authority, an entity whose purpose is to manage intellectual properties on behalf of nonprofit organizations, colleges and universities, or an entity whose purpose is to benefit the respective institutions. The Governor may attach conditions to these transfers as he deems necessary. In the event the Governor does not approve such transfer, the materials shall remain the property of the respective institutions and may be used and developed in any manner permitted by law.

VCU's Intellectual Property (IP) Policy and Affect on Sponsored Agreements

http://www.assurance.vcu.edu/Policy%20Library/Intellectual%20Property%20Policy.pdf

- University employees are under an obligation to abide by University policies.
- As currently defined, intellectual property includes, an "Invention, issued patent, Copyrighted Work, a legal right inherent in a patent, copyright, trademark , know-how or trade secrets, or tangible research property; including, but are not limited to, compositions, biologicals, materials, illustrations and drawings, prototypes, devices, and equipment".

- Under the current policy, intellectual property created by a University employee under a Sponsored Agreement generally vests in the University; however, University procedures require **the inventor to submit an invention disclosure form to report inventions to Tech Transfer and to sign an assignment document assigning right, title and interest in the IP to VCU.**

VCU's Intellectual Property Policy Sponsored Agreements

- Sponsored Agreements for industry initiated clinical trials typically include a drug or device and generally define IP as any inventions , data, know how, etc., arising from conduct of the study and/or using the drug/device provided by the Sponsor and/or any Sponsor confidential information.
- In order for VCU to be able to agree to the "hereby assign" language in Sponsored Agreements, the IP policy is being revised to capture assignment upfront.
- Coordination with human resources is needed to revise faculty contract templates and classified employee obligations to include a present tense assignment to VCU at the time of employment rather than just capturing the obligation to assign.
- Further discussion with the Health System is needed to address IP issues for Health System employees working on sponsored projects since they are outside of University policies.

IP Assignment in Sponsored AgreementS

- The Office of Sponsored Programs (OSP) met with Tech Transfer and patent counsel for advice on assignment language.
- Based on that meeting, until the IP policy is revised and approved and human resource issues are resolved, OSP will require an assignment document prior to execution of those Sponsored Agreements requiring a present tense assignment.
- The assignment document is internal in nature and stipulates assignment of intellectual property arising from the conduct of the study.
- It will be signed by the Principal Investigator and any other personnel (including health system personnel involved in the conduct of the study) as required by the terms of the agreement/contract.
- OSP reviewers will forward the document to the PI as applicable, and the PI will be responsible for ensuring that all appropriate personnel have signed the assignment document.
- The PI will also sign verifying that any additional personnel will sign the document prior to their involvement in the study.
- OSP will keep the signed assignment document with the contract.

Virginia Commonwealth University
Intellectual Property Assignment

As indicated by my signature below and in order to participate in the **[enter type of study, e.g, clinical trial, research, etc.]** project entitled "**[enter title of study]**" sponsored by **[enter name of Sponsor]** at Virginia Commonwealth University ("Institution"), I hereby assign all right, title and interest in any and all intellectual property; including but not limited to discoveries, inventions, patent rights, copyrights, know how, data and work product, arising from the conduct of the study **[for clinical trials add: and/or arising from my treatment of participants enrolled in the study with the study drug/device]** to Virginia Commonwealth University

Principal Investigator:

Printed Name	Signature	Date

Other Personnel:

Printed Name	Signature	Date
Printed Name	Signature	Date

PI Certification: I hereby certify that all personnel currently involved in the conduct of the study have signed this assignment document. I understand that it is my obligation to obtain signatures of any additional personnel prior to their involvement in the study.

Printed Name	Signature	Date

Revisions to Advance PT Request Form

•OSP is expanding the Advance PT Request Form to capture the creation of SC numbers for Task Orders under Master Agreements.

• The form will be renamed the Advance PT/SC Number Request form.

• When requesting an advance number, you will be asked to specify if it is a PT number or an SC number that you are requesting.

• If you are requesting an SC number, you will be asked to supply the PT number for the Master Agreement.

• OSP will post a list of Master Agreements with the associated PT numbers on the OSP website.

Revisions to Advance PT Request Form

The electronic form will be revised to read:

“Please use this electronic form to request:

(1) an advance "PT" number for new proposals meeting the following criteria: NIH applications (P, U and C series) and applications for all other sponsors except where a Master Agreement exists

(2) an advance “SC” number (primarily for Task Orders under Master Agreements). For a list of existing Master Agreements, click here.”

Revisions to Advance PT Request Form

Additional Changes as follows:

"Electronic Form – Advance PT/SC Number Request*

Request for: PT Number ☐ SC Number ☐ If SC, what is existing Master Agreement PT Number? ☐ ☐ ☐ ☐ ☐ ☐

Complete the remaining fields for the PT or SC Number being requested."

• The fields themselves have not changed (e.g., Name of Requestor, Email, PI Name, etc).

Revisions to Advance PT Request Form

- Once the revised form and the listing of Master Agreements have been posted, an email will be sent to the research administrators list serve.

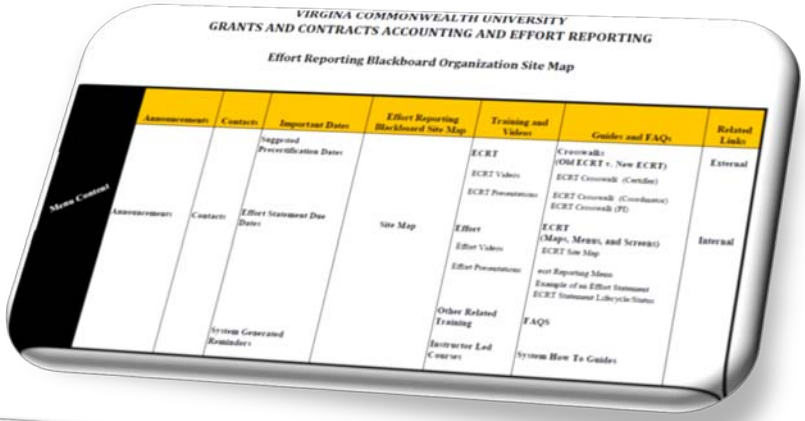
- Any questions, please contact OSP at 828-6772.

Effort Reporting and ECRT Updates

RACM January 2013

Training

- On-line
  - Effort Reporting Blackboard Organization
- Instructor-Led Courses
  - ECRT
  - Basic
  - Intermediate

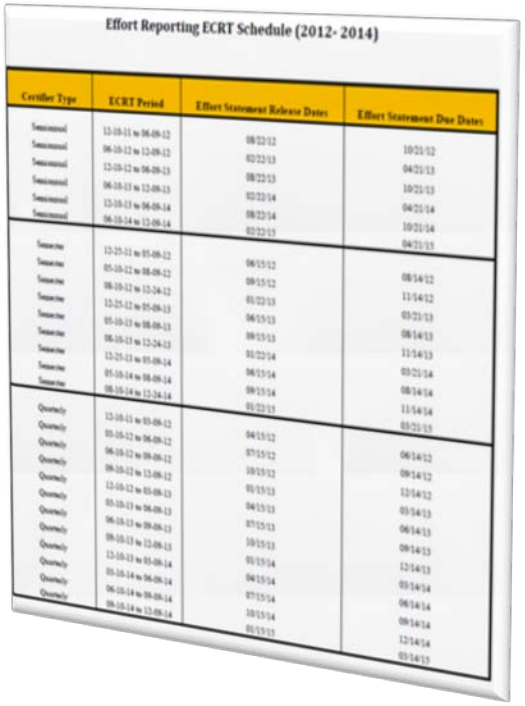


ECRT Updates

- Home page
- Reports
  - Now grouped by function
  - New reports
- Communication
  - ECRT now sends system generated memos to principal investigators
    - Principal Investigator's memo will include:
      - Principal Investigator's effort statement status
      - Lists the quarterly certifier with uncertified effort statement associated to his or her awards by org code
- Other

Effort Reporting Updates

- New Team Member
- Effort Period Reminders
  - Quarterly Certifiers (09-10-12 to 12-09-12)
    - Released 01-15-13 and due by 03-14-13
  - Semester Certifiers (08-10-12 to 12-24-12)
    - Released 01-22-13 and due by 03-21-13
  - Semiannual Certifiers (06-10-12 to 12-09-12)
    - Release 02-22-13 and due by 04-21-13
- Thank you!
  - Quarterly period (47% certified as of 01-22-13*)



Effort Reporting ECRT Schedule (2012- 2014)

Certifier Type	ECRT Period	Effort Statement Release Dates	Effort Statement Due Dates
Semiannual	11-10-11 to 06-09-12	08/22/12	10/21/12
Semiannual	06-10-12 to 12-09-12	02/22/13	04/21/13
Semiannual	12-10-12 to 06-09-13	08/22/13	10/21/13
Semiannual	06-10-13 to 12-09-13	02/22/14	04/21/14
Semiannual	12-10-13 to 06-09-14	08/22/14	10/21/14
Semiannual	06-10-14 to 12-09-14	02/22/15	04/21/15
Semester	12-25-11 to 05-09-12	06/15/12	08/14/12
Semester	05-10-12 to 08-09-12	09/15/12	11/14/12
Semester	08-10-12 to 12-24-12	01/22/13	03/21/13
Semester	12-25-12 to 05-09-13	06/15/13	08/14/13
Semester	05-10-13 to 08-09-13	09/15/13	11/14/13
Semester	08-10-13 to 12-24-13	01/22/14	03/21/14
Semester	12-25-13 to 05-09-14	06/15/14	08/14/14
Semester	05-10-14 to 08-09-14	09/15/14	11/14/14
Semester	08-10-14 to 12-24-14	01/22/15	03/21/15
Quarterly	12-10-11 to 03-09-12	04/15/12	06/14/12
Quarterly	03-10-12 to 06-09-12	07/15/12	09/14/12
Quarterly	06-10-12 to 09-09-12	10/15/12	12/14/12
Quarterly	09-10-12 to 12-09-12	01/15/13	03/14/13
Quarterly	12-10-12 to 03-09-13	04/15/13	06/14/13
Quarterly	03-10-13 to 06-09-13	07/15/13	09/14/13
Quarterly	06-10-13 to 09-09-13	10/15/13	12/14/13
Quarterly	09-10-13 to 12-09-13	01/15/14	03/14/14
Quarterly	12-10-13 to 03-09-14	04/15/14	06/14/14
Quarterly	03-10-14 to 06-09-14	07/15/14	09/14/14
Quarterly	06-10-14 to 09-09-14	10/15/14	12/14/14
Quarterly	09-10-14 to 12-09-14	01/15/15	03/14/15

Research Administration & Compliance Meeting

January 23, 2013

Annie Publow, Director, OSP,
Government/NonProfit

Office of Sponsored Programs (OSP) Government/Nonprofit Updates

- Application Submission System & Interface for Submission Tracking (ASSIST)
- Research Performance Progress Report (RPPR)
- Closeout of sponsored project records

ASSIST: What and Why?

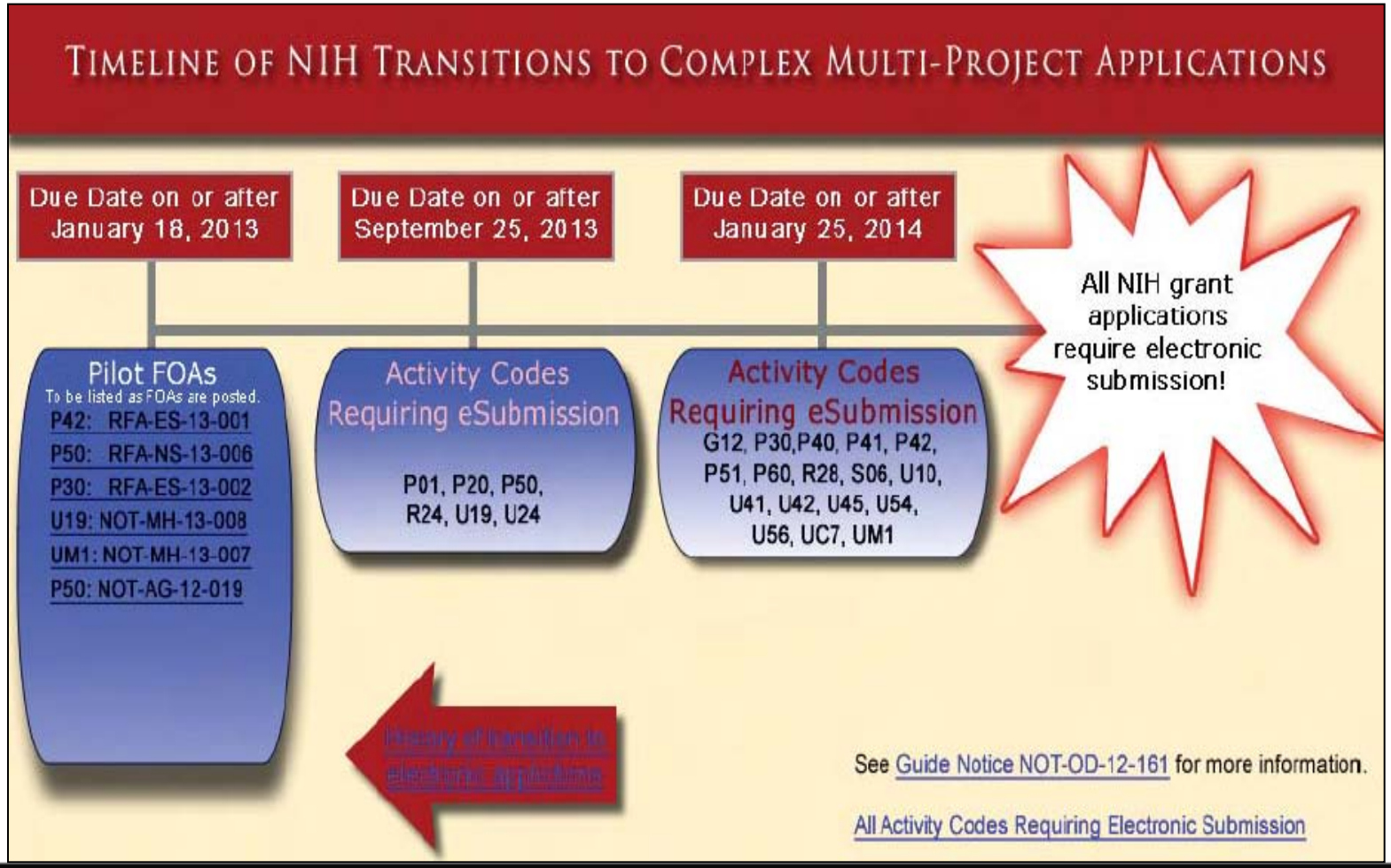
The What: ASSIST (Application Submission System & Interface for Submission Tracking) is a web-based system that NIH has created for multi-project proposal preparation, submission and tracking

The Why: To allow for electronic submission of multi-project proposal submissions (which have not been possible up until now)

- N.B. “Single-project” proposal submissions are currently submitted (through VCUeRA for VCU) to Grants.gov and will continue to be submitted this way

The How: **Agency specific web system**

NIH is Piloting ASSIST



What registrations are needed to utilize ASSIST?

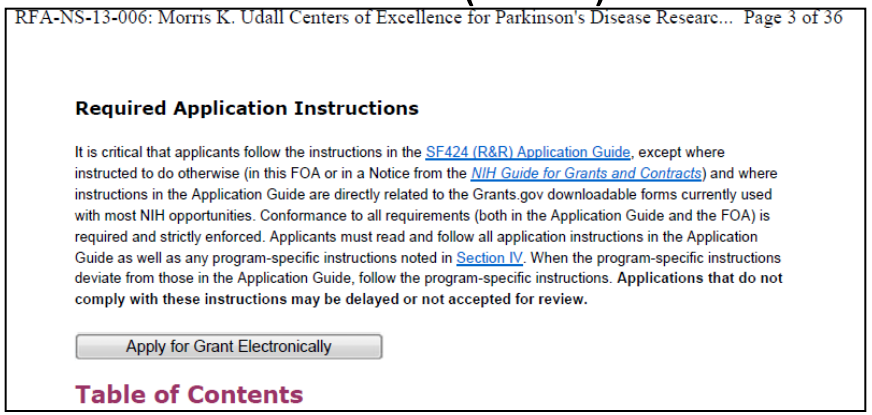
- **Grants.gov** institutional registration →VCU √
- **eRA Commons** (aka NIH website) institutional registration →VCU √
- eRA Commons individual registration, aka "Commons ID" → New PI's will need. Existing NIH PI's already have√
- Central Contractor Registry (CCR) has been replaced by **System for Awards Management** (SAM) →VCU √

Limited List of Important Considerations (when using ASSIST)-VCU specific

- These multi-project NIH submissions will not be prepared or submitted through VCUeRA. (VCUeRA still only for single-project submissions.)
- All multi-project NIH submissions prepared and submitted through ASSIST require an advance PT number, Internal Approval Form, COI reporting through AIRS, etc.
- Any proposed subawardees must still provide “mini-package” and completed and signed VCU Subrecipient Commitment Form

Limited List of Important Considerations (when using ASSIST)

- The application package will utilize the SF424 formset (what we use in VCUeRA)
- Proposed subawardees do not have to be registered in SAM or Grants.gov. DUNS is also requested but optional (use 000000000 if no DUNS available.)
- Download application package from Funding Opportunity Announcement (FOA)-not using Code of Federal Domestic Assistance (CFDA) number


RFA-NS-13-006: Morris K. Udall Centers of Excellence for Parkinson's Disease Researc... Page 3 of 36

Required Application Instructions

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide, except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts*) and where instructions in the Application Guide are directly related to the Grants.gov downloadable forms currently used with most NIH opportunities. Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

Apply for Grant Electronically

Table of Contents

GRANTS & FUNDING

Electronic Grants
Applying Electronically
Applying Electronically to Multi-project Applications
- Prepare to Apply & Register
- Find an Opportunity & Initiate Application
- Prepare & Submit an Application
- Track & View Application

Avoiding Common Errors
Frequently Asked Questions
Training
Resources
Finding Help
Site Map
eRA Commons
Intranet Link (NIH Staff Only)

Grants Basics

Submitting a Multi-project Application

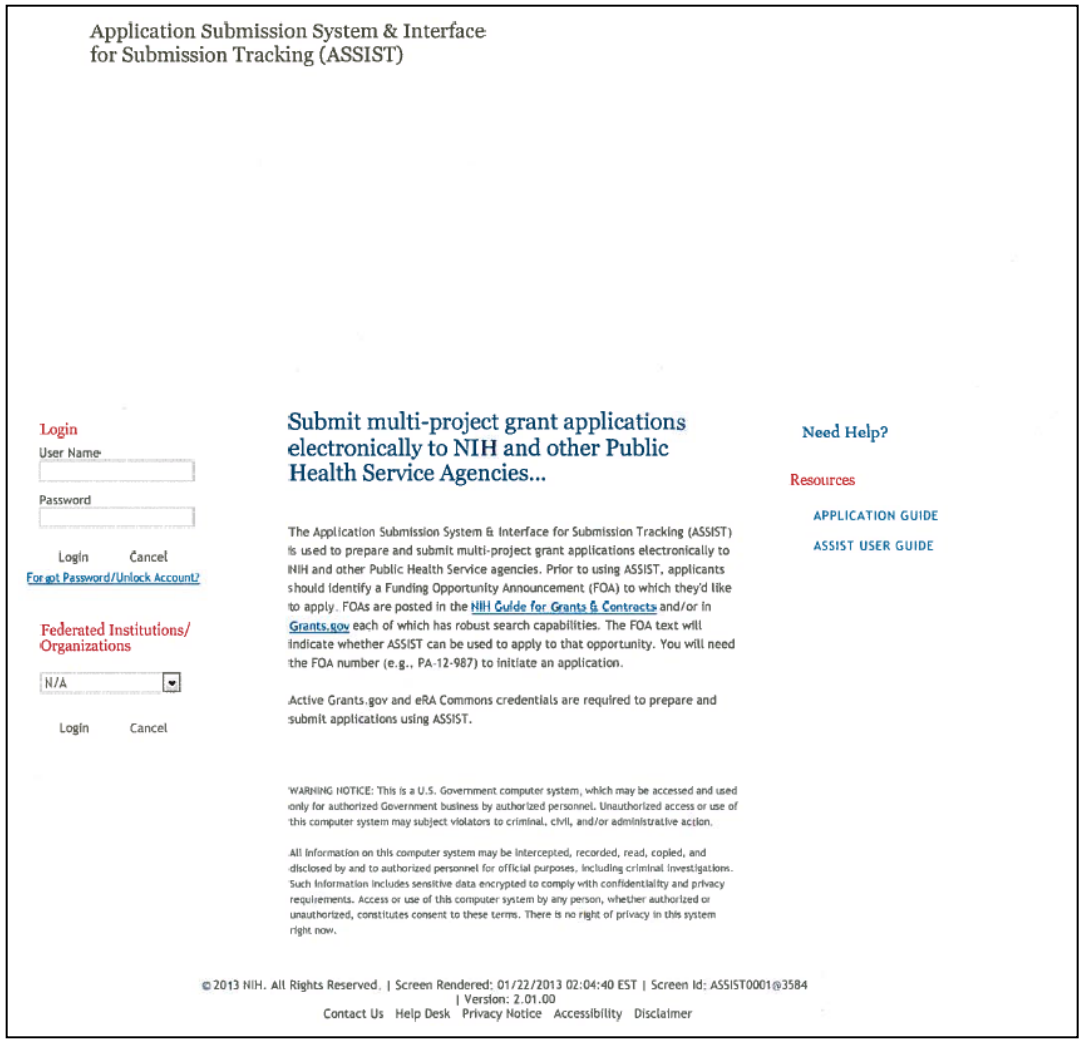
By Jan 2014 NIH's multi-project applications will transition to electronic submission through a new on-line application system called ASSIST. Between now and Sept 2013 NIH will be piloting the system with a handful of funding opportunity announcements.

Learn more about the transition timeline and the ASSIST system.

Electronic Application Process

Make Sure To...

- **Use ASSIST only if required by the FOA.**
- **Register early!** Organizational registration in DUNS, SAM, Grants.gov and eRA Commons is required, can take 6 weeks or more and MUST be completed before the application due date. Learn more about registration requirements.
  - SAM requires annual renewal to maintain an active registration.
  - PIs must be registered and affiliated with the applicant organization in eRA Commons.
  - ASSIST users must be eRA Commons registered.
- **Carefully follow the requirements** found in the application guide and funding opportunity announcement. Instructions in the FOA supersede those found in the application guide.
- **Submit early.** Reduce stress by submitting well ahead of the due date.



- ASSIST is a different system than eraCommons
- ASSIST uses eraCommons log in credentials
- Role in eraCommons will be your role in ASSIST

Limited List of Important Considerations (when using ASSIST)

- Attachments must be PDF (generated outside of ASSIST system.)
- Research Plan must comply with page limitations: create all elements of research plan as a single document and split into section pdf's when final, then upload.
- Reference letters are only permitted when specifically requested in the FOA
- The PI prepares the application and the SO (Signing Official), aka OSP reviews and submits.

Limited List of Important Considerations (when using ASSIST)

- There is a common application format for all multi-project applications to include:
  - A single Overall Component (summary)
  - Additional Components (e.g. Admin Core, Project Cores #1, #2, etc., FOA-specific cores, etc.)
- Components of the same type will appear in the order they are created, i.e. first project core entered will be #1, second #2, etc. –Plan ahead!!

Limited List of Important Considerations (when using ASSIST)

- ASSIST checks applications against both federal-wide and NIH business rules
  - ASSIST checks applications data as it is entered against the rules defined by Grants.gov for each form
  - ASSIST provides the option to “Validate” the application against NIH’s agency-specific business rules prior to submission
  - ASSIST checks for the most frequent Grants.gov rejection errors prior to submission

Limited List of Important Considerations (when using ASSIST)

- On-time submission is no later than 5:00pm on the deadline date.
- Submitted proposals can be tracked through Grants.gov and then, once accepted by NIH, in eRA Commons (just like with VCUeRA submissions now.)
- Once uploaded to eRA Commons, the PI will be able to view the transmission for two days during which time the proposal may be rejected by the SO. The proposal may be corrected and resubmitted only so long as the deadline has not passed.

Helpful links for Multi-Project Applications using ASSIST

(and identification of sources)

- NIH- Submitting a Multi-Project Application: http://grants.nih.gov/grants/ElectronicReceipt/com_index.htm
- ASSIST FAQs: http://grants.nih.gov/grants/ElectronicReceipt/faq_full.htm#prepare

RPPR: What and Why?

The What: RPPR (**Research Performance Progress Report**)

- A federal initiative that defines common reporting categories for interim performance reports from awardees
- Implemented by all federal agencies in their own web system

The Why: **Consistency**

- Standardize types of information requested across all federal agencies that administer research awards
- Streamline the ability to compare outputs and outcomes of research programs across the government
- Reduce costs through use of uniform criteria

The How: **Agency specific web interface**

- Research.gov for NSF, eraCommons for NIH, etc.

RPPR Standard Cover Page Elements

COVER PAGE DATA ELEMENTS

- Federal Agency and Organization Element to Which Report is Submitted
- Federal Grant or Other Identifying Number Assigned by Agency
- Project Title
- PD/PI Name, Title and Contact Information (e-mail address and phone number)
- Name of Submitting Official, Title, and Contact Information (e-mail address and phone number), if other than PD/PI
- Submission Date
- DUNS and EIN Numbers
- Recipient Organization (Name and Address)
- Recipient Identifying Number or Account Number, if any
- Project/Grant Period (Start Date, End Date)
- Reporting Period End Date
- Report Term or Frequency (annual, semi-annual, quarterly, other)
- Signature of Submitting Official (signature shall be submitted in accordance with agency-specific instructions)

The standard cover page data elements, as well as mandatory and optional components comprise the complete research performance progress report format. If an agency has an electronic reporting system that can identify the award and recipient, it is not required to collect the standard institutional information included in the cover page data elements.

RPPR Standard Reporting Categories:
Accomplishments

Accomplishments is a ***mandatory*** category for ***all*** federal agencies

- Category answers the questions: What was done? What was learned?
  - ☐What are the major goals and objectives of the project?
  - ☐What was accomplished under these goals?
  - ☐What opportunities for training and professional development has the project provided?
  - ☐How have the results been disseminated to communities of interest?
  - ☐What do you plan to do during the next reporting period to accomplish the goals and objectives?
- Allows the agency to assess whether satisfactory progress has been made during the reporting period

RPPR Standard Reporting Categories:
Products

Products is an ***optional*** category that will be used by some agencies for some projects

- Category answers the question: What has the project produced?
  - ☐Publications, conference papers, and presentations;
  - ☐Website(s) or other Internet site(s);
  - ☐Technologies or techniques;
  - ☐Inventions, patent applications, and/or licenses; and
  - ☐Other products, such as data or databases, physical collections, audio or video products, software or NetWare, models, educational aids or curricula, instruments, or equipment
- Allows the agency to evaluate what the publications demonstrate about the excellence and significance of the research and the efficacy with which the results are being communicated to colleagues, potential users, and the public. Products beyond publications allow an agency to assess and report to Congress, communities of interest, and the public.

RPPR Standard Reporting Categories:
Participants & Other Collaborating Organizations

Participants & Other Collaborating Organizations is an ***optional*** category that will be used by some agencies for some projects

- Category answers the question: Who has been involved?
  - What individuals have worked on the project?
  - What other organizations have been involved as partners?
  - Have other collaborators or contacts been involved?
- Allows an agency to know who has worked on the project to gauge and report performance in promoting partnerships and collaborations.

RPPR Standard Reporting Categories:
Impact

Impact is an ***optional*** category (that will be used by some agencies for some projects)

- **Category answers the questions: What is the impact of the project? How has it contributed?**

Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

- ☐the development of the principal discipline(s) of the project;
- ☐other disciplines;
- ☐the development of human resources;
- ☐physical, institutional, and information resources that form infrastructure;
- ☐technology transfer (include transfer of results to entities in government or industry, adoption of new practices, or instances where research has led to the initiation of a startup company); or
- ☐society beyond science and technology. Allows an agency to know who has worked on the project to gauge and report performance in promoting partnerships and collaborations.

- Allows agency to provide the taxpaying public and its representatives with an assessment of how the investments they make benefit the nation. Over time, this base of knowledge, techniques, people, and infrastructure is drawn upon repeatedly for application to commercial technology and the economy, to health and safety, to cost-efficient environmental protection, to the solution of social problems, to numerous other aspects of the public welfare, and to other fields of endeavor. Through this reporting format, and especially this section, recipients provide that assessment and make the case for Federal funding of research and education.

RPPR Standard Reporting Categories:
Changes/Problems

Changes/Problems is an ***optional*** category (that will be used by some agencies for some projects)

- Category answers the question: How is it going?
  - ☐Changes in approach and reasons for change.
  - ☐Actual or anticipated problems or delays and actions or plans to resolve them.
  - ☐Changes that have a significant impact on expenditures.
  - ☐Significant changes in use or care of animals, human subjects, and/or biohazards.
- Allows for agency understanding and involvement during course of project. Reminder grantee is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.

RPPR Standard Reporting Categories:
Special Reporting Requirements

Special Reporting Requirements is an ***optional*** category (that will be used by some agencies for some projects)

- Category answers agency- and/or project-specific questions
  - Will vary…..
- Allows the agency to assess progress toward or outcome of defined concerns

RPPR Standard Reporting Categories:
Budgetary Information

Budgetary Information is an ***optional*** category (that will be used by some agencies for some projects)

Category will be used to collect budgetary data from the recipient organization to be used in conducting periodic administrative/budgetary reviews. One of the standard budgetary formats, as identified by the agency, will be used to submit this information.

Note: These budgetary forms are identical to those included in the SF 424 R&R forms family, as implemented by Grants.gov. As these forms are updated in Grants.gov, these budget forms will change accordingly.

RPPR Standard Reporting Categories:

Demographic Information for Significant Contributors

Demographic Information for Significant Contributors is an ***optional*** category (that will be used by some agencies for some projects)

Agencies may require that recipients provide demographic data about significant contributors for a variety of purposes, including:

- ☐Gauge whether our programs and other opportunities are fairly reaching and benefiting everyone regardless of demographic category;
- ☐Ensure that those in under-represented groups have the same knowledge of and access to programs, meetings, vacancies, and other research and educational opportunities as everyone else;
- ☐Gauge and report performance in promoting partnerships and collaborations;
- ☐Assess involvement of international investigators or students in work we support;
- ☐Track the evolution of changing science, technology, engineering and mathematics (STEM) fields at different points in the pipeline (e.g., medicine and law demographics have recently changed dramatically);
- ☐Raise investigator and agency staff awareness of the involvement of under-represented groups in research;
- ☐Encourage the development of creative approaches for tapping into the full spectrum of talent of the STEM workforce;
- ☐Respond to external requests for data of this nature from a variety of sources, including NAS, Congress, etc.; and
- ☐Respond to legislatively-required analysis of workforce dynamics. Legislation requires at least one agency to routinely estimate scientific workforce needs. This analysis is accomplished through reviewing demographic data submitted for the existing workforce.

RPPR Implementation Plans by Agency

- Every agency will direct recipients to report on the one mandatory component →**Accomplishments**
- An agency may direct a recipient to report on optional components, as appropriate.
- Within a component, agencies may direct recipients to complete only specific questions, as not all questions within a given component may be relevant to all agencies.

Agency RPPR Implementation Plans

- DHHS/NIH (and Other PHS Agencies)
  - January 2012 update
- DHS
- DOC
- DOD
- DOE
- DoEd/Institute of Education Sciences
- DOJ
  - Office of Justice Programs
  - National Institute of Justice/Office of Justice Programs
- EPA
- NASA
- NEH
- NSF
- USDA
  - Forest Services
  - NIFA

OSTP/OMB Policy Letter

RPPR Format

- RPPR Format as approved by OMB/OSTP
- RPPR Format associated with the second Federal Register Notice
- RPPR Draft Format

RPPR Data Dictionary

- RPPR Data Dictionary
- RPPR Data Dictionary Guide

Federal Register Notices on Research Performance Progress Reporting

- Final Notice of a Uniform RPPR Format
- Request for Public Comment on Standardized RPPR Format

RPPR Implementation Plans by Agency

- Agencies may develop an agency- or program-specific component, if necessary, to meet programmatic requirements, although agencies should minimize the degree to which they supplement the standard components. **Such agency- or program- specific requirements will require review and clearance by OMB**.
- Agencies also may use other OMB approved reporting formats, such as the Performance Progress Report (PPR), if those formats are better suited to the agency's reporting requirements, for example, for research centers/institutes, clinical trials, or fellowship/training awards or in connection to reporting on program performance.

Agency RPPR Implementation Plans

- DHHS/NIH (and Other PHS Agencies)
  - January 2012 update
- DHS
- DOC
- DOD
- DOE
- DoEd/Institute of Education Sciences
- DOJ
  - Office of Justice Programs
  - National Institute of Justice/Office of Justice Programs
- EPA
- NASA
- NEH
- NSF
- USDA
  - Forest Services
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Research.gov & NSF Implementation of RPPR

Research.gov…

- Is the National Science Foundation's (NSF) grants management system
- Is the modernization of FastLane
- Replaces Fastlane for grants management functions
- Is not how grants will be submitted to NSF, i.e. we will continue to submit NSF applications to Grants.gov and/or Fastlane as required by NSF
- Login to Research.gov is using Fastlane User ID and password.
- Access privileges are defined through "Roles."

RPPR Implementation

NSF Implementation of RPPR

What do I Need to Know Now?

NSF awardees must stop submitting project reports in FastLane starting on February 1, 2013. On March 18, 2013, NSF will transfer its current project reporting service from FastLane to Research.gov. Principal Investigators should pay particular attention to reports previously submitted and returned by their NSF Program Officer. Returned reports should be revised and resubmitted prior to February 1. To assist the research community with this transition, the overdue date will be extended for all project reports that are currently scheduled to become overdue between January 31 and April 30, 2013.

Starting in January 2013, ACM$ will be implemented for 38 research organizations. These organizations will begin using ACM$ after the submission of their final Federal Financial Report to NSF. **ACM$ will be implemented for use by all NSF awardee organizations in April 2013.**

Note: The Office of Sponsored Programs does not review and submit NSF Progress Reports as we do NIH Progress Reports.

Other NSF Reports in Research.gov

Scope of Research.gov to include the following grants management services:

Reporting Services:

- Project Outcomes Report
- Annual, Final and Interim Reports

Financial Services:

- Federal Financial Report
- Access to financial services
- Award Cash Management Service

Application Services:

- Grants Application Status
- Application Submission Web Services

At right, report from Research.gov on overdue final reports

Report Type	Status	Days Until Overdue	Report Overdue Date
Final	Due	OVERDUE	01/31/2010
Outcomes	Due	OVERDUE	10/30/2011
Final	Due	OVERDUE	12/30/2011
Outcomes	Due	OVERDUE	11/30/2012
Final	Due	OVERDUE	11/30/2012
Final	Due	OVERDUE	11/30/2012
Final	Due	OVERDUE	11/30/2012
Final	Under Review	OVERDUE	11/30/2012
Final	Under Review	OVERDUE	11/30/2012
Final	Under Review	OVERDUE	11/30/2012

NIH Implementation of RPPR

- All NIH grantees will have the option to use the RPPR for Streamlined Non-competing Award Process (SNAP) and Fellowship progress reports beginning 10/19/2012.
- Use of the RPPR will not be mandatory at this time and grantees may continue to use eSNAP or paper submissions as appropriate.
- However….once grantees have had experience with the RPPR NIH expects to make it mandatory to use the RPPR format for all SNAP and Fellowship awards. (It will be announced in the NIH Guide when RPPR becomes requirement.)
- NIH also anticipates piloting the RPPR for non-SNAP awards during calendar year 2013.

NIH Implementation of RPPR

SNAP-eligible progress reports will continue to be prepared by the PI in eraCommons and released to OSP for review and submission to NIH.

Non-Fellowship, SNAP-eligible Awards:

- PI has option of submitting progress report in SNAP or RPPR format.
- Will be prompted to choose one or the other when logs in to process report. Once started, the only way to change the progress report format is with the assistance of the eRA Help Desk at Commons Support (1-866-504-9552 or commons@od.nih.gov).
- SNAP RPPRs are due the 15th of the month preceding the month in which the budget period ends.

Fellowship Award:

- Fellow has option of submitting progress report in RPPR electronic format or in paper.
- Fellowship progress reports are due two months before the beginning date of the next budget period.

Login to eraCommons is using the NIH Username and password

Access is by Role

SNAP vs. RPPR

The RPPR and eSNAP modules have a number of ***similarities***:

- The substance of the report is similar; the grantee will be asked to describe progress, study results, the significance of the findings, and any significant changes.
- Where possible, information is pre-populated from NIH systems for the grantee, including PD/PI information, grant number, project title and period, performance sites, and personnel.
- Publications in PD/PI's MyNCBI account will be displayed for easy association with the progress report.
- No need to submit a detailed budget.
- Information required by NIH policies will continue to be requested from grantees. For example, the RPPR will address policies covering such areas as human subjects education, inclusion enrollment reporting, and use of human embryonic stem cells.

The RPPR and eSNAP have a number of ***differences***:

- RPPR has separate screens for each of the following reporting components: Cover Page, Accomplishments, Products, Participants, Impact, Changes, Special [agency specific] Reporting Requirements, and Budget [applicable only for non-SNAP awards]
- When implemented for non-SNAP awards the Budget component will be a SF424(R&R) Budget.
- The format of the report will be new.
- Users will answer questions by using a checkbox, entering text or uploading a PDF, or selecting "Nothing to Report."
- New information to be provided by grantees through the RPPR includes:
    - Foreign component information
    - Dollars spent in foreign country(ies) [through first-tier subawards]
    - Organizational affiliation of personnel at foreign sites
- Effort on All Personnel report will be rounded to nearest whole person month.
- Other features of the RPPR include:
    - Specific location to report on competitive revisions/administrative supplements associated with the award.
    - Public Access compliance status will be displayed
    - Other support will only be required if there has been a change
    - Notice of Award link
    - Streamlined reporting of ClinicalTrials.gov information

Helpful links for understanding RPPR

(and identification of sources)

- Overview on NSF website: http://www.nsf.gov/bfa/dias/policy/rppr/index.jsp
- Overview on NIH website: http://grants.nih.gov/grants/rppr/
- RPPR Format as approved by OMB/OSTP: http://www.nsf.gov/bfa/dias/policy/rppr/format_ombostp.pdf

RPPR resulted from an initiative of the Research Business Models (RBM) Subcommittee of the Committee on Science (CoS), a committee of the National Science and Technology Council (NSTC)

NIH Public Access Policy

NIH Public Access Policy Details

The NIH Public Access Policy implements Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008). The law states:

The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided*, That the NIH shall implement the public access policy in a manner consistent with copyright law.*

NIH Guide Notice for Public Access (January 11, 2008)

Reminder Concerning Grantee Compliance with the Public Access Policy and Related NIH Monitoring Activities (September 23, 2008)

The Omnibus Appropriations Act of 2009 Makes the NIH Public Access Policy Permanent (March 19, 2009)

Clarification on the Use of an NIHMSID to Indicate Compliance with the NIH Public Access Policy (August 12, 2009)

Until further notice, only papers written in Latin script will be collected via the NIH Manuscript Submission System for the NIH Public Access Policy (October 30, 2009)

My NCBI Tool to Replace eRA Commons for Bibliography Management (June 10, 2010)

Upcoming Changes to Public Access Policy Reporting Requirements and Related NIH Efforts to Enhance Compliance (November 16, 2012)

Public Access Compliance Monitor: A New Resource for Institutions to Track Public Access Compliance (January 9, 2013)

eRA Commons Users Can Now Generate a Publications Report for the PHS 2590 with My NCBI (January 10, 2013)

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.

The Difference Between a PMCID and a PMID

The PubMed Central reference number (PMCID) is different from the PubMed reference number (PMID). PubMed Central is an index of full-text papers, while PubMed is an index of abstracts. The PMCID links to full-text papers in PubMed Central, while the PMID links to abstracts in PubMed. **PMIDs have nothing to do with the NIH Public Access Policy.**

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 explanation of that. **A PMCID is the only way to demonstrate compliance.**

Sample Email to PI from Program Officer when Publications reporting is delinquent

Delays issuance of continuing award

Dear [Principal Investigator name here],

I'm writing as the program officer of your R01 "Title here". While processing your progress report I noticed that the now-required PMCID numbers for your publications were not included. The text below is standard information sent to grantees to request the information and to provide more information regarding the policy. What is asked of you is simply to send the PMCID numbers for the publications I listed below by replying all to this email. Thanks very much,

The NIH Public Access Policy ensures that the public has access to peer-reviewed publications arising from NIH funded research. The full text of these publications is to be made freely available in the PubMed Central database in a manner consistent with copyright law.

The following citations in your recent progress report do not include **PubMed Central IDs (PMCIDs),** which are required for you to demonstrate compliance with the policy:

- Author #1, Author #2, Name of Publication, Journal Name, Dates.
- Author #1, Author #2, Name of Publication, Journal Name, Dates.

To comply with the policy, reply to all on this email and provide the PMCID at the end of each citation listed above. Here's help on locating the PMCID. Note that a PMCID is not the same as a PubMed ID (PMID).

- The PMCID is the *only* way to show compliance for a paper that was published more than three months ago.
- If a PMCID is not available because the paper is *in press* or was published within the last three months:
  - Indicate **"PMC Journal - In Process"** at the end of the citation if the journal will be submitting directly to PMC. (Check this list of journals or confirm your arrangements with these publishers to be sure.)
  - OR, provide an **NIHMSID** for a manuscript that is still in process in the NIH Manuscript Submission (NIHMS) system. (Be sure to complete the submission process promptly to obtain the PMCID!)
- If you believe the paper does not fall under the Policy, please provide a brief explanation.

Reporting to the NIH just got easier! The "*My Bibliography*" feature of My NCBI is now integrated with the eRA Commons. *Link your Commons account to a My NCBI account* for 1) easy linking of citations to NIH grants, 2) automatic prescreening and support for NIH Public Access Policy compliance, 3) auto-uploading of citations into NIH eSNAP Progress Reports with PMCIDs and NIHMSIDs displayed. And much more!

Compliance with the NIH Public Access Policy is a legal requirement and a term and condition of all NIH awards. NIH awardees are responsible for ensuring that evidence of compliance is included in all NIH applications, proposals and reports. If you have questions about the Policy, please check the NIH Public Access Website or send a note to PublicAccess@nih.gov.

^^

National Institute on Drug Abuse

Closeout of Sponsored Projects

- ~1150 Government/NonProfit awarded projects are in “Award in Closeout” status
- ~600 Industry awarded projects are in “Award in Closeout” status
- ~350 records that ended in 2012 need to be updated to reflect “Award in Closeout” status
- OSP will send Status Summaries to departments and schools: 1st Quarter 2013
- OSP will send Individual emails to PIs: 2nd Quarter 2013
- Consequences: External and Internal

FIR updates in the AIRS and A Brief Introduction to the RIO

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

RACM 1/2013

Updating the FIR

You are required to update your FIR **within 30 days** for the following reasons:

- If you discover or acquire financial interests with a new entity not previously reported in the FIR.
- If you discover or acquire new or additional interests in a previously reported entity and the financial interests are now >$5000 in aggregate.
- Travel must be updated ONLY if a new entity not previously reported is reimbursing directly or paying on your behalf

Update for changes to *research relatedness* within 30 days

- If you update your FIR, make sure to update research-relatedness, if applicable.

- You may need to update research relatedness of your reported financial interests based on a new proposal or protocol even if your reported financial interests did not change.

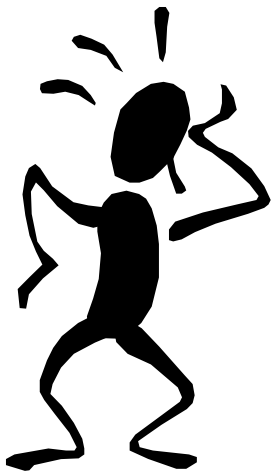
Updating financial interests and research relatedness within 30 days is required by VCU policy

Possible implications if FI is not reported and COI not identified :

- *retrospective review for bias*
- *mitigation report for noncompliance*
- *report to sponsor/agency*
- *corrective action, other sanctions*

Research misconduct:

- Diminishes the public trust in science and research
- Diminishes the scientific value of research
- Diminishes the professionalism of scientists and researchers
- Squanders public funds on research that cannot be replicated and research practices that are suspect



Federal regulatory requirement for a research misconduct process

- Office of Science and Technology published Federal Research Misconduct Policy - 2000

  All federal agencies supporting intramural/ extramural research must have policy

- 42 CFR 93.102 - for institutions applying for or receiving PHS support for research, research training, or research related activities

  >>>>> Office of Research Integrity, DHHS

  http://ori.hhs.gov/

Research misconduct is the:

- **fabrication,**
- **falsification, or**
- **plagiarism in**

  - proposing,
  - performing,
  - reviewing research, or in
  - reporting research results.

**Research misconduct does not include honest error or differences of opinion.

3 requirements to find RM
42 CFR 93.104

- Significant departure from accepted practices of the relevant research community
- Committed intentionally, knowingly, or recklessly
- Proven by a preponderance of the evidence
  - Misconduct is more likely to be true than not

VIRGINIA COMMONWEALTH UNIVERSITY

VCU

Misconduct in Research and Scholarly Activities

Policy Type: Administrative
Responsible Office: Office of Research
Initial Policy Approved: 05/18/1990
Current Revision Approved: 04/05/2012
Policy

http://www.assurance.vcu.edu/Policy%20Library/Misconduct%20in%20Research%20and%20Scholarly%20Activities.pdf

VCU Policy Library

Research misconduct concerns reported to RIO

Anyone who becomes aware of a possible incident of research misconduct by a member of the university shall immediately report the information to the Research Integrity Officer (RIO). (VCU policy)

VCU Research Integrity Officer, Office of Research:

Monika Markowitz, PhD – 827-2157,msmarkow@vcu.edu

Or report to any of the contacts below. If the concern involves research, it is referred to the RIO.

VCU Office of Compliance and Integrity: (804) 828-2336 or ucompliance@vcu.edu

VCU Helpline – confidential, anonymous:

1-888-242-6022 or www.vcuhelpline.com

VCU Ombudsperson, Office of the Provost:

Frank Baskind, PhD – 828-1040, ombuds@vcu.edu

Very abbreviated RM process

Allegation arrives about faculty or staff

(align with definition? credible? enough evidence?)

If YES: → 1) Inquiry – warrant an Investigation?

YES: → 2) Investigation – did research misconduct occur and who did it?

YES:
- Appeals process
- Sanctions

See ORI website for publicly reported adjudicated cases
http://ori.hhs.gov/case_summary