RESEARCH QUARTERLY NEWSLETTER
April – June 2012

ENQUIRY

SPONSORED PROGRAMS

REMINDER: Mandatory Training – PIs and Administrators

Current PIs and sponsored project administration staff must complete the training program prior to May 31, 2012. After May 31, 2012, new awards will not be processed until the required training is completed. New PIs also will be required to complete the training before an award will be processed by the Office of Sponsored Programs. Proposals will continue to be processed without delay.

All individuals must score a minimum of 80% on each of the corresponding examinations to successfully complete the training program.

Training programs are available on Blackboard and should take approximately one hour to complete. Log in to Blackboard using your VCU eID, once in Blackboard, click on the "Courses" tab and select "Name of School – Required Training for PIs, Researchers and Administrators." Select the tab that best defines your role, i.e., "Investigator Training" or "Administrator Training."

If you encounter a problem registering for the course, contact Jose Alcaine at jgalcaine@vcu.edu or 828-2508.

FEDERAL REGULATORY CHANGES

Just-in-Time and Related Business Process Changes Beginning April 20, 2012

As of April 20, 2012, NIH is revising its business processes so applicants will have better information on when JIT submissions are required, and to *require* electronic submission of JIT information through the eRA Commons. Applicants are required to submit information using the JIT feature of the eRA Commons at least 60 days before the applicant's proposed project period start date (or sooner if requested). If the requested JIT information is not submitted, funding may be delayed. Applications receiving an impact score of 40 or less will receive a standard notice and request for submitting JIT information. E-mail notices will be sent from NIH eRA Commons to the Project Director/Principal Investigator(s) 2 weeks after release of the impact score. The eRA Commons JIT link will be opened and available for submission of JIT information with 24 hours after the impact score has been release. As a reminder, a notification request for JIT information is not a Notice of Award nor an indicator of possible funding by the NIH. For more information, read the revised policy at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-101.html

REPORT FRAUD OR ABUSE OR MISCONDUCT

Compliance Helpline:
1-888-242-6022

RIO
(804 827-2157

Report Online:
www.vcuhelpline.com

Research Performance Progress Report (RPPR)

In order to standardize recipient reporting on federally-funded research project, the Office of Management and Budget (along with The White House) has mandated that federal agencies implement a federal-wide research performance report for submission of required annual or other interim performance reporting on research grants and cooperative agreement awards.

NIH will pilot the program beginning in April 2012, with the intention of implementing the RPPR for all SNAP awards and individual fellowships in Calendar Year 2013. To read more about the project and the anticipated differences between RPPR and SNAP, go to http://grants.nih.gov/grants/rppr/

NEW RESEARCH POLICIES

There are six new and two revised administrative policies related to research which are now in effect or will become effective very soon. As required by VCU's Policy on Creating and Maintaining Policies and Procedures, these policies have been created/reviewed by the Committee on the Administration of Research (CAR), various components of the University (e.g, Faculty Senate, University Council) and have been made available for comment by the University community as a whole.

Minimum Effort for Key Personnel on Sponsored Programs Policy (new policy effective Sept. 2012):

This new administrative research policy describes the minimum effort required for PIs and other key personnel on sponsored programs projects as proscribed by a Presidential Review Directive and clarification memo (Clarification of OMB A-21 Treatment of Voluntary Uncommitted Cost Sharing and Tuition Reimbursement Costs) and OMB Circular A-110, as well as VCU's Cost Sharing Policy. PIs and Key Personnel must include some level of Committed Effort on most sponsored research activities. There are some exclusions to the minimum level of committed effort. The Policy describes the responsibilities of PIs and faculty, research administrators, chairs/division heads, and OSP. Read the policy at http://www.research.vcu.edu/osp/minimum_effort_key_personnel_on_sponsored_programs.pdf

Office of Sponsored Programs Responsibilities Policy (new policy effective Sept. 2012):

Have you ever wondered exactly what "Sponsored Programs" is responsible for? This new administrative policy describes the general responsibilities of the Office of Sponsored Programs. Very generally, OSP is responsible for communicating sponsor requirements to the University community and establishing controls necessary to ensure those requirements are met, as well as solicitation of grants, contracts and other agreements. Read the policy at http://www.research.vcu.edu/osp/osp_responsibilities_policy.pdf

Sponsored Agreement and Gift Policy (new policy effective Sept. 2012):

Is it a "grant" or a "gift?" This new administrative policy provides clarification regarding the difference between sponsored agreements and gifts. The term "grant" is defined differently by various funders and may cause some confusion. For that reason, VCU uses the term "sponsored agreement" in lieu of grant. Through a review of characteristics associated with each, this policy provides guidance for determining sponsored projects and gifts. Read the policy at http://www.research.vcu.edu/osp/sponsored_agreement_gift_policy.pdf

Sponsored Program Proposals: Definitions, Solicitation, Review, Approval and Submission Policy (new policy effective Sept. 2012):

This new administrative policy defines terms associated with sponsored programs and describes the solicitation, review, approval, submission process for proposals. The University is legally responsible for the program and for fulfilling the sponsoring agency requirements. All proposals for sponsored programs must be

made in the name of "Virginia Commonwealth University." Only certain VCU officials are deemed authorized to sign sponsored program solicitation documents in the name of VCU. All such signatories have delegated the primary signatory authority to the Associate Vice President for Research Administration and Compliance (or designee), who is generally referred to the "Authorized Official" for sponsor-related documents. This policy sets out the requirements that must be met by a PI, School, the Clinical Research Office and Sponsored Programs prior to submission to a funding agency. Read the policy at http://www.research.vcu.edu/osp/osp_proposals_definitions_solicitation_review_approval_submission.pdf

Sponsored Programs Proposal Submission Deadlines Policy (new policy effective Sept. 2012):

This new policy sets out the timelines applicable for review and submission of all requests for externally funded sponsored programs. Guidance is provided for the deadlines associated with both hard-copy and electronic submissions, as well as OSP Log-in and Queue Process. Read the policy at http://www.research.vcu.edu/osp/osp_proposal_submission_deadlines.pdf

Policy on Limited Submissions Programs (new policy effective Sept. 2012):

The Office of Research has maintained an informal limited submissions policy for several years. This new policy establishes this informal policy as a formal administrative policy. The policy aims to prevent potential disqualifications of submissions by funding agencies accepting only a limited number of submissions from one institution. Announcements of limited submission programs will be sent to VCU's Research Administration list-serve and to the Research Development Advisory Council (ReDAC). The policy sets out procedures for VCU researchers wishing to submit a proposal under a limited submission program. Read the policy at http://www.research.vcu.edu/osp/limited_submissions_programs.pdf

Policy on Misconduct in Research and Scholarly Activities (revised policy effective April 5, 2012):

Effective April 5, 2012, the VCU Policy on Misconduct in Research and Scholarly Activities was modified to clarify and streamline the process described in the policy. All members of the VCU community should read this policy at http://www.assurance.vcu.edu/Policy%20Library/Misconduct%20in%20Research%20and%20Scholarly%20Activities.pdf or at the Policy Library managed by the VCU Integrity and Compliance Office: http://www.assurance.vcu.edu/policylibrary.html

Research misconduct specifically refers to fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Importantly, research misconduct does not include honest error or differences of opinion or interpretation. Allegations of research misconduct may be directed to the appropriate chair, dean or vice president, to the Research Integrity Officer (RIO), Dr. Monika Markowitz, Director, Office of Research Integrity and Ethics, Office of the Vice President for Research (msmarkow@vcu.edu, 827-2157) or to the Fraud and Abuse hotline and website.

The VCU Research Misconduct policy has its origins in the regulations of the Office of Research Integrity, an agency of the Department of Health and Human Services - ORI (PDF). See the ORI home page at < http://ori.hhs.gov/ > for an interactive movie titled "The Lab: Avoiding Research Misconduct." Responsible conduct of research (RCR) is, of course, desired. To learn more about RCR see: VCU Policy on Responsible Conduct in Research and Scholarship. See also RCR Resources on the ORI website: http://ori.hhs.gov/.

Policy on Corporate-Sponsored Research Agreements (revised policy effective April 5, 2012):

This policy details requirements to appropriately execute research agreements with corporate sponsors. All university members involved in or contemplating corporate-sponsored research should read and comply with this policy. (Read the policy at: http://www.assurance.vcu.edu/Policy%20Library/Corporate-

Sponsored%20Research%20Agreements.pdf The revision to this policy sets out the increase in the period for confidentiality disclosure agreements related to corporate sponsors of clinical trials:

> Corporate Sponsors of Clinical Trials may require the University to enter into confidentiality disclosure agreements for the express purpose of disclosing proprietary or confidential information to the proposed principal investigator to determine their interest in participating in a study. Information disclosed for this purpose may be received under a promise of confidentiality for a period of time not to exceed ten (10) years. Subsequent Clinical Trial Agreements shall be negotiated using the preferred confidentiality terms not to exceed (5) years from the expiration/termination of the agreement or seven (7) years from the date of disclosure of confidential information as stipulated above.

OSP STAFFING UPDATES

The Office of Sponsored Programs welcomes Salina Mann-Ghee as the new Intake & Records Manager. Salina has many years of experience at VCU, most recently with the Department of Continuing Education.

On April 2, 2012, OSP's Blue Team welcomed Leslee Key as Blue Team Reviewer. Leslee has several years of VCU grants experience.

INTEGRITY AND ETHICS

Modified Conflict of Interest Regulations

The revised "Promoting Objectivity in Research" rule (**42 CFR Part 50 Subpart F**) for financial interest reporting and conflict of interest identification and management has a compliance date of August 24, 2012. Although the regulation focuses on Public Health Services sponsored research (especially NIH), many features of the new rule will apply to all research regardless of funding, as is currently the case. (VCU's policy is currently under revision). Differences between the current regulation and the new one include:

- Decreased *de minimus* threshold for a significant financial interest from $10,000 to $5,000; extent of financial interest reporting is increased
- Increased focus on COI identification among sub-recipients
- Investigator training requirement
- Increased emphasis on institution's management, including retrospective review and reporting for failure to disclose on a timely basis
- Rigorous institutional reporting of managed COI to PHS funding component, e.g. NIH
- Information about COI made accessible to the public

VCU is developing an electronic platform for financial interests reporting, utilizing Click Commerce (currently being used for animal research, and under development for human research). 'Investigators' will complete a financial interests report (FIR) on an annual basis and within 30 days of a change. In addition, a brief research-related interests report (RIR) will also be completed for each submission to OSP, IRB or IACUC. As the electronic system develops, investigators will be asked to assist in testing the system - in the next two months - before going live at VCU.

For further information about the federal COI rule see the following links:

- Summary of Major Changes (MS Word - 43 KB)
- FCOI FAQs
- 2011 FCOI tutorial

Post Approval Monitoring (PAM) of IACUC and IRB Approved Protocols

Post approval site visits are a Quality Assessment/Quality Improvement (QA/QI) activity of the Office of Research Integrity and Ethics. The site visits are designed to inform the IACUC and IRB in their work of protocol review and approval by giving the committees feedback on how the research is being conducted. In addition, the site visits are a major educational resource for the research team.

PAM - IACUC

Post approval monitoring is an explicit requirement of federal regulation for animal research. The animal research community is familiar with Ms. Patty Gerber, Research Liaison Specialist for Animal Research, performing protocol inspections on a semi-annual, annual, or every three year basis. Ms. Gerber's findings are reported to the IACUC and are regularly analyzed for quality improvement trends. During her inspections, Ms. Gerber provides education and guidance to researchers and notes knowledge deficits and other issues to be addressed by the Animal Care and Use Program. A summary of PAM findings is presented in the Animal Care and Use Program Updates session offered to experienced investigators and research staff. The next session is on June 6th from 1- 2 PM.

PAM - IRB

Post approval monitoring for IRB protocols occurs by way of IRB continuing review, in addition to site visits performed by Dr. Enid Virago, Research Liaison Specialist for Human Research Protection. Protocols eligible for site visits by Dr. Virago include one or more of the following elements: greater than minimal risk, involving vulnerable subjects, high level of complexity, history of disorganized or incomplete submissions to the IRB, suspended full board protocols, determinations of non-compliance, new PI, or even request by the PI. Dr. Virago also conducts educational visits requested by the PI or IRB. For more information about the Post Approval Monitoring and Education (PAME) Program scroll to 'Post Approval Monitoring' on the IRB Policies see the IRB Policies and Guidance page at http://www.research.vcu.edu/irb/guidance.htm

Policy on Misconduct in Research and Scholarly Activities (revised policy effective April 5, 2012):

As reported above, the VCU Policy on Misconduct in Research and Scholarly Activities has recently been modified, with an approval date of April 5, 2012. All members of the VCU community should read this policy at: http://www.assurance.vcu.edu/Policy%20Library/Misconduct%20in%20Research%20and%20Scholarly%20Activities.pdf or at the Policy Library managed by the VCU Integrity and Compliance Office: http://www.assurance.vcu.edu/policylibrary.html An article appearing in the May issue of Nature, discusses the apparent rise in cases reporting scientific wrongdoing. The article advises that "[T]he first step … is to understand what is and what is not scientific misconduct. Misconduct is not simply bad behaviour (sic); it is the falsification, fabrication or plagiarism of results. Honest errors, differences in the interpretation of results, authorship disputes … are issues of concern, but are not misconduct. At the core of misconduct is intent." (Nature, Vol 485, 3 May 2012, p. 137-139)

RESEARCH SUBJECTS PROTECTION

Human Subjects Research

New Informed Consent Element Required for Clinical Trials

As of March 7, 2012, the FDA now requires a new informed consent element for research studies that are applicable clinical trials. Applicable clinical trials are typically controlled interventional studies of drugs, biologics, or devices that are subject to FDA regulation.

The new element is required language designed to inform research participants that data from a study will be submitted to ClinicalTrials.gov. All clinical trials submitted for initial IRB approval must include the following language in the consent documents:

> "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

This language is available in the Biomedical Informed Consent template on the IRB website located at http://www.research.vcu.edu/forms/vcuirb.htm. The language must be used verbatim.

The requirement only applies to studies receiving initial approval on or after March 7, 2012. Previously approved consent forms do not need to be amended and previously enrolled research participants do not need to be re-consented.

For more information about ClinicalTrials.gov requirements, please refer to http://clinicaltrials.gov/ct2/invest.

Pre-Review of Full Board Initial Submissions Resumes May 1

Pre-review of full board initial submissions to the IRB by the ORSP Protocol Analyst resumed beginning May 1, 2012. The goal of the pre-review process is to have many of the administrative, regulatory issues addressed early on in the submission process, allowing IRB members to focus greater effort on ensuring human participants are adequately protected.

An electronic copy of all submission materials for initial full board applications should be submitted to IRBIntake@vcu.edu. Submissions with attachments too large to send via standard email should be uploaded to FileDrop. To use FileDrop, visit https://filedrop.vcu.edu/ and click on Send a File.

PI and Department Chair signatures are NOT required on the electronic copy submitted for pre-review, but are required once paper copies are requested.

The Protocol Analyst will correspond with the PI and/or study coordinator regarding any issues that should be resolved prior to IRB review. In some cases, the Protocol Analyst may send comments embedded in the electronic application documents. Once the pre-review process is complete, the PI will be instructed to submit 25 paper copies of the application to the ORSP office. When the 25 copies are submitted, the study will be assigned to an IRB panel for full review.

Questions about the pre-review process or completing an application may be directed to Nichole Haywood, Protocol Analyst, at 827-2272 or nsrichar@vcu.edu.

Criteria for Closing Human Participant Studies with the IRB

Investigators are reminded to officially close studies with the IRB when they meet the closure criteria. Closing studies prevents unnecessary study expirations requiring follow-up by the IRB to determine the status of research participants and any data being maintained. Studies may be closed by the investigator when the following criteria are met:

1. The research must be permanently closed to enrollment with no further interaction/intervention with subjects (or access to a subject's personally identifiable information) for the purpose of research data collection, AND

2. (a) All data analysis involving the research site(s), under the VCU IRB approval, is complete (with data and/or samples de-identified and will remain de-identified), OR

(b) Data has been de-identified, with no codes or keys that would allow for the potential of identifying individuals in the future. NOTE: This typically applies to multi-center research where de-identified data is provided to the sponsor and the sponsor authorizes VCU IRB closure.

To close a study, submit the study closure form (http://www.research.vcu.edu/forms/vcuirb.htm) to ORSP.

ANIMAL SUBJECTS RESEARCH

New Requirement for Reporting Adverse Events to the IACUC

To ensure VCU is meeting new requirements of the 8th Edition of the Guide for the Care and Use of Laboratory Animals, investigators are now required to report Adverse Events (AE) to the IACUC within 10 days of occurrence. An Adverse Event is defined as the occurrence of any unforeseen event that negatively impacts the welfare of research animal(s), usually involving pain, distress, and/or death of an animal that was not described and identified as potential risks or outcomes in the approved IACUC protocol.

When an AE occurs, investigators should first take steps to ensure animal welfare, contacting a DAR veterinarian or facility manager as necessary. Once the situation is under control and resolved, work with a veterinarian to complete the Adverse Event/Unanticipated Problem reporting form. The form is available on the ACUP website at https://www.vcu.edu/research/acup/guides_policies_resources.htm under the heading VCU Animal Research Policies. Submit the form by emailing to IACUC@vcu.edu.

Further information about this new requirement and examples of events that should be reported are available in the Reporting Adverse Events Policy located at https://www.vcu.edu/research/acup/guides_policies_resources.htm.

DAR Incident Reporting Process - Update

DAR management and staff would like to express our appreciation to those in the VCU research community that have utilized our recently introduced Incident Reporting system. As detailed in recent communications, this system is intended to enhance communication between the research community and the Animal Care and Use Program (ACUP). We are also utilizing this system to ensure that more thorough investigation, follow-up and documentation are generated to maximize remediation efforts for both the immediate issue and for longer term solutions.

Please note that the Incident Reporting program is now available for all animal users in all vivaria.

We encourage researchers and DAR personnel to continue utilizing the Incident Reporting mechanism to notify us of your concerns. Please feel free to review a more detailed description of the Incident Reporting process, including a chart to help determine which items may be submitted, a communications map for DAR and IACUC personnel that may be of assistance, and an investigation flowchart to illustrate the process utilized once an incident report has been received. This information is available by clicking or copy/pasting this link into your web browser: https://www.vcu.edu/dar/incident_reporting.htm

With your timely submissions and through close partnership between the ACUP and the VCU research community, we will ensure the best possible care for the animals under our stewardship and contribute to VCU's overall Quest for Distinction to evolve our university into a top-tier institution and flagship for research methodology.

TRAINING OPPORTUNITIES

Animal Care & Use Program – Upcoming Training Events

Please mark your calendar to attend one of the upcoming educational events to keep your knowledge of animal research topics current.

- Overview of the New Policy on Adverse Event Reporting
  Animal Lab Tech lunch & learn
  May 18, 12 – 1pm, Sanger Hall 1-006

- Animal Care and Use Program Updates Seminar
  June 6, 1 – 2pm, Location TBA

- OLAW Webinar: Grants Policy and Congruence
  June 7, 1 – 2pm, Location TBA

- NABR Webinar: Consolidated Inspection Guide (USDA)
  July 10, 12:30 – 1:30pm, Location TBA

- "New COI policy and processes: Getting a handle on reporting financial interests and research relatedness"
  5th Thursday for Research Ethics - open to all researchers and research staff
  May 31, 1 - 2:30pm, Biotech I, Ball Conference Room

- Expectations of Research Coordinators by the Health System
  Research Coordinator lunch & learn
  June 22, 12 – 1pm, Children's Pavilion 2015

Human Research Protection Program – Upcoming Training Events

Please mark your calendar to attend one of the upcoming educational events to keep your knowledge of human participant research topics current.

- Expectations of Research Coordinators by the Health System
  Research Coordinator lunch & learn
  June 22, 12 – 1pm, Location TBA

OSP

Research Administration and Compliance Meeting (RACM)

The next meeting is scheduled for May 23 in the Larrick Student Center on the MCV Campus. Come join the staff of OSP at 12:00 for pizza (while supplies last) and the chance to put a face with a name for the Green, Blue, Gold, Red, Intake & Records and Post Award Teams. The regular RACM meeting will follow at 1:00 p.m.

INTEGRITY AND ETHICS – Upcoming Training Events

"New COI policy and processes: Getting a handle on reporting financial interests and research relatedness"
5th Thursday for Research Ethics - open to all researchers and research staff
May 31, 1 - 2:30pm, Biotech I, Ball Conference Room

Expectations of Research Coordinators by the Health System
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