



NEWSLETTER FROM THE OFFICE OF THE EXECUTIVE VICE PRESIDENT OF RESEARCH

Volume 1, Issue 2

July 2009

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Message from David Hirsh

Welcome to the second issue of our quarterly newsletter. We have all been focused on capturing the opportunities available from the American Recovery and Reinvestment Act (ARRA) stimulus package, a sizeable portion of which will flow to university research. Our Offices, especially Sponsored Projects Administration and Research Initiatives, are working to raise awareness of the ARRA RFA's through our website and weekly email notifications, to match expertise and needs with individual opportunities, to manage internal competitions for limited awards and to provide assistance in preparing applications. Thus far, Columbia researchers have submitted applications for more than \$500 million in grants. In anticipation of awards, SPA has been assisting Sponsored Projects Finance in the creation of reporting mechanisms to assist investigators and the University overall in meeting the new ARRA reporting requirements.

On June 27, the new upgraded RASCAL infrastructure went live. We are extremely grateful to the RASCAL development team of Halayn Hescok, Andy Thompson, Yueping Yu, Bill McCartin, Carpenter Ngo and Milind Despande, who have been working for seven months on updating the technical infrastructure in order to be able to provide you with the newest technologies and enhanced functionality. While these changes will not be immediately apparent to you, this is the starting point for the new functions, including advanced PDF capabilities, the new Radiation Safety module, a redesigned Conflict of Interest (COI) module, ARRA tracking, performance enhancements and more.

I have highlighted these two points, but I want you to note the following descriptions of the activities in our Offices that can impact your research. We hope that our efforts will enhance your scholarly endeavors and raise the standards of safety and compliance throughout the University.

Sponsored Projects Administration (SPA)

ARRA GRANT SUBMISSIONS

The funding opportunities presented by the American Recovery and Reinvestment Act (ARRA) have been unprecedented. SPA has spent the last quarter advising and assisting faculty and staff in submitting more than 700 applications for new and supplemental funding totaling more than \$500 million. In addition to reviewing each RFA closely, SPA has had to deal with relatively new electronic submissions systems, such as FedConnect, that are being used to supplement grants.gov.



SPA has also taken the lead on compiling all pertinent ARRA related information in a weekly Monday campus email to track upcoming deadlines, new funding opportunities and news on evolving administrative requirements.

Information related to the American Recovery and Reinvestment Act (ARRA, aka the Stimulus Package) as related to academic research can be found on the EVPR website at:

<http://evpr.columbia.edu/content/stimulus-arra>

Sponsored Projects Administration (SPA) cont.

RASCAL COMPLIANCE

With the tremendous increase in grant applications being reviewed by SPA, it is important that the RASCAL Proposal Tracking form be complete and accurate and submitted with all proposals five business days prior to the submission deadline of the sponsoring agency. Signatures from the Principal Investigator as well as all key personnel and the appropriate Chair/Dean are also required. **If the finalized RASCAL form with all appropriate signatures is not received, SPA will be unable to provide institutional approval to submit the grant application.** In order to help protect the investigators as well as the institution, certain compliance reviews require the finalized RASCAL form in order to proceed. Please note that complete, accurate and approved finalized RASCAL forms are required for non-competing continuation submissions as well.

SPA AS PRIMARY CONTACT

An additional area that is becoming increasingly important as the volume of activity increases is the coordination of contact with our sponsors. SPA is the department at the University that is authorized to conduct official business with sponsoring agencies. Although departments and investigators are of course encouraged to have dialogues with their funding agencies, please remember that if official approvals are being requested or other official university business conducted, SPA personnel are the authorized officials to conduct this business. If there is ever a question about whether or not to contact your sponsor, please contact your department's SPA Project Officer, a list of whom can be found at: <http://spa.columbia.edu/about-us/departments-assignments>

ADMINISTRATOR FORUMS

SPA began regular monthly departmental administrator forums during the last quarter and hosted three sessions at each campus.



These forums will not be held in July and August, but will resume on a monthly basis in September. SPA is utilizing these meetings to discuss updates on ARRA, share new procedures and focus on hot topic areas such as the account setup process, InfoEd updates, RASCAL compliance and the new Conflict of Interest process. Information on these Sponsored Project Administrator Forums can be found at: <http://spa.columbia.edu/forums-administrators>.

Clinical Trials Office (CTO)

MARILYN MORRIS APPOINTED NEW MEDICAL DIRECTOR

The CTO is pleased to announce the appointment of Marilyn Morris, MD, MPH as the Medical Director of the CTO. Dr. Morris is currently an Assistant Professor of Clinical Pediatrics at Columbia University College of Physicians & Surgeons and an Assistant Attending Physician in Pediatric Critical Care at The Morgan Stanley Children's Hospital of New York-Presbyterian Hospital. As Medical Director of the CTO, Dr. Morris will direct the proposed IND/IDE Assistance Program and will oversee regulatory affairs and compliance in the CTO.



PROCESS IMPROVEMENTS

In January 2009, CTO embarked on several process improvement initiatives to reduce contract/budget turnaround time, and provide improved services to our research community. Our most recent metrics indicate that we reduced the time to negotiation of clinical trial contracts from an average of 87 days to 34 days and reduced the budget turnaround time from an average of 61 to 37 days during the past six months.

In addition, the CTO successfully executed 13 additional Master Agreements with key sponsors during the past six months. The rollout of StudyManager© has continued on schedule. We currently have 275 trials and over 1,000 study participants entered into the system. StudyManager© has been implemented in over 80% of the divisions performing clinical trials. This enables the centralization of invoicing, collections and reconciliation of all industry study related payments within the CTO.

During the next six months the CTO will launch additional initiatives, including the implementation of an IDE/IND Assistance Program and mechanisms to boost subject recruitment for active clinical trials. We look forward to the continued challenges ahead and thank the CUMC and the New York-Presbyterian Hospital research community for their patience and support as we continue our revitalization of the CTO.

Environmental Health & Safety (EH&S)

PLANNING PLAYS OFF!

On May 18, a fire in a ConEd transformer vault resulted in a 3-day power outage at the Eye Institute, Eye Institute Annex and Service Building. The fire impacted emergency power systems to the buildings and extended to the tunnel system resulting in building evacuations. Fortunately, no one was injured, and thanks to the planning and team work among Facilities, ICM and EH&S, losses to the University were minimized. However, building systems



were without power, necessitating emergency deliveries of dry ice for refrigeration and back-up generators for the ani-

mal facility. Additional interventions to secure research materials and safeguard the mouse colony were taken: a temporary freezer farm was created on PH-4; a dozen low temperature freezers were leased; and an extra emergency generator was procured.

Our ability to respond effectively with back up plans and emergency power in this Eye Institute crisis was at least in part due to the lessons we learned from the black-outs of 1999 and 2003.

In April, CUMC hosted its annual Table Top Drill for first responders from the New York City Police and Fire Departments and the Department of Homeland Security (DHS). With Columbia Public Safety, EH&S, Facilities and the New York Presbyterian Hospital Emergency Department, they addressed a model scenario in which structural damage to a building resulted in possible contamination of laboratory workers, requiring an assessment of existing systems for intra-campus communication, emergency response management, and coordination with external (Police, Fire, DHS) responders. The exercise enabled internal groups to better understand their responsibilities in the overall structure of a scaled emergency response and the external groups came away with a clearer understanding of the possible incident types and the level of hazard that they may entail.

On June 6, EH&S hosted a semi-annual familiarization drill with the New York City Fire Department (FDNY) at the Mailman School. With the completion of the new NYSTAR Facility and a new auditorium coupled with the existing laboratories, the Radiation Safety receiving room, the Dental School's Pediatric Clinic, multiple administrative offices and a primary building entrance on the 10th floor, the FDNY wanted to become more

familiar with the building and the operations of these special areas. Local units and the Hazardous Materials Unit joined representatives of the NYSTAR Facility, Radiation Safety, EH&S, Facilities and Public Safety. The FDNY expressed its gratitude to CUMC for hosting these drills so that they could better understand the layout of our buildings and be able to "preplan" for possible incidents.

Office of Postdoctoral Affairs (OPA)

CUMC POSTDOC FELLOWS MINIMUM

In conjunction with the Vice Deans of Academic Affairs and Research at CUMC, OPA is happy to announce a new salary guideline for full-time Postdoctoral Research Fellows hired at CUMC. CUMC Postdoctoral Research Fellows must receive a stipend that matches the current zero-level NIH stipend of **\$37,368** in order to be appointed at CUMC. This amount reflects the increased NIH stipend level for NRSA that was implemented in Spring 2009. As a reminder, all FY 2009 awards issued using FY2008 stipend levels will be revised to increase the stipend category to the FY 2009 level. These stipend levels are to be used in the preparation of future competing and non-competing NRSA institutional training grant and individual fellowship applications.

Do you have new postdocs starting this summer?

In an effort to acclimate new postdocs to Columbia University, OPA offers a first look at the resources at the Morningside campus and CUMC that directly relate to the postdoctoral experience. Discussion includes a brief description of benefits according to the four postdoctoral titles, an initial look at an Independent Development Plan and how to plan for the future and the services available University-wide and through OPA.

Upcoming orientation dates are available on the OPA events calendar: <http://vesta.cumc.columbia.edu/postdoc/calendar/index.php>

Office of Research Compliance & Training (RCT)

NEW VISITOR POLICY

Summer is a common time for researchers to host visitors at Columbia. In many cases, visitors involved in research-related activities are appointed as officers of research or instruction or designated as visiting scholars or visiting scientists. In preparation for this summer's visitors, the University revised its Guidelines for Short-term Visitors in Research-Related Activities, first published in 2006. The revised Guidelines are posted on the EVPR website <http://evpr.columbia.edu/>.

TWO HIGHLIGHTS FROM THE REVISED GUIDELINES ARE:

- All short-term visitors must **register**.
- All short-term visitors must comply with the University's policies concerning safety, training, human subject protection, and other requirements.

Special provisions apply to minors (individuals less than eighteen years of age), performing (as opposed to being present during a tour for strictly observational purposes) research-related activities in University laboratories.

- No one under the age of **fourteen** is allowed in any University laboratory.
- No one under the age of eighteen may:
 - handle radioactive materials
 - work with animals
 - be alone in a laboratory
 - handle human blood, human cell lines, or any other material defined as "other potentially infectious materials" by OSHA (Bloodborne Pathogens Standards 29 CFR 1910.1030).

If you have questions about the revised Guidelines, contact Carolyn Merten at cm822@columbia.edu (for CUMC) or Pearl Spiro ps27@columbia.edu (for the rest of the University).

NEW FINANCIAL CONFLICTS OF INTEREST POLICY

On July 1, 2009, Columbia implemented a new, University-wide Policy on Financial Conflicts of Interest and Research. The new Policy was approved by a unanimous vote of the University Senate on April 3, 2009.

As David Hirsh wrote in a statement to the University research community announcing the Policy: "Conflict of interest in research is an issue that goes to the heart of the academic mission. The new Policy aligns us with many best practices recommended by professional associations such as the Association of American Universities and the Association of American Medical Colleges."

Among the new Policy's key points are

that it is a uniform, University-wide policy; that it is overseen by a single faculty committee with two sub-committees: one for CUMC and one for other campuses; that it codifies the review process; and that it embodies flexibility for a case-by-case approach to managing potential conflicts. The policy also includes some changes in standards for disclosure and review.

The new Policy applies to all individuals who conduct research at the University, whether or not the research is federally funded. The Policy does not cover conflicts of commitment or institutional conflicts of interest. Individuals covered under the Policy are required to file Financial Interest Reports in RASCAL

upon being hired by the University, annually thereafter, and when submitting a protocol to conduct human subjects research. The Financial Interest Report form has been revised to reflect the new Policy's requirements so researchers may notice a change the next time they file a Report in RASCAL.

A copy of the Policy, an appendix of examples and a list of Frequently Asked Questions are posted on the RCT website, at http://www.columbia.edu/cu/compliance/docs/conflict_interest/index.html. The Policy is also posted on the main Research homepage, under Selected Policies.

RCT recently distributed a Quick Guide for Principal Investigators. This printed tri-fold pamphlet is a companion to the Quick Guide to Research that was published last year. The Guide provides answers to common questions and excerpts from the important research policies and guidelines applicable to PIs. The Guide can be found on the RCT website at http://www.columbia.edu/cu/compliance/pdfs/PI_Quick_Guide.pdf. If you would like hard copies, please email Joel Roselin at jr2644@columbia.edu.

Institutional Review Board (IRB)

NEW ABBREVIATED IRB SUBMISSION PROCESS

The IRB developed a new abbreviated submission process for multi-center studies supported by industry or NIH cooperative groups (e.g., ACTG, HVTN, NCI oncology group studies, etc.). The new process will still require completion of all RASCAL fields that provide information regarding local implementation of the study. However, entering of the study summary into the Study Description field will no longer be required, as the IRB will now rely on the sponsor's protocol for review by IRB members.

The new process can be found at: <http://www.cumc.columbia.edu/dept/irb/documents/AbbreviatedIRBSubmission.061809.pdf>.



TRAINING WORKSHOPS

Starting this summer, the IRB will convene workshops for investigators and research staff to improve their skills in writing informed consent documents. The first such workshop, held on June 23, 2009, took place in a computer lab that allowed hands-on training. The workshop was oversubscribed and we plan to hold additional sessions this summer. By improving the quality of the informed consent documents submitted to the IRB, we will be able to further improve the turnaround time of IRB reviews.

Two other consent workshops or seminars will be designed to enhance the informed consent process as well as the consent form. You may find out about future consent form workshops or other training initiatives from the Columbia IRB by joining the IRB listserv (scroll down the IRB Home page <http://www.cumc.columbia.edu/dept/irb/> for the 'Join the Listserv' link).

USE OF WESTERN IRB

Effective July 15, 2009, the IRB office will no longer grant permission for review by the Western IRB (WIRB) of industry-supported multi-center clinical trials involving investigational drugs or devices. In addition, protocols for which the WIRB is currently the IRB of record will transition back to CUMC IRB review at the time of renewal, beginning with those with WIRB expiration dates on or after September 15, 2009.

IRB Conference - Save the Date!

The Columbia IRB is co-sponsoring an IRB Conference with the City University of New York (CUNY), State University of New York, Stony Brook, and the federal Office for Human Research Protections. The conference will be held on September 11, 2009 at the Graduate Center of CUNY. Details regarding the conference will be available on the IRB website <http://www.cumc.columbia.edu/dept/irb/>.

The following new policy will go into effect on September 1, 2009: if the IRB has not received a response from a Principal Investigator (PI) to any IRB comment letter that adequately articulates the IRB requests for revision within 90 days after delivery of the IRB comment letter to the PI, the PI will be required to withdraw the protocol and re-submit it under a new IRB number. The IRB and/or RASCAL will send periodic reminders to the PI to try to prevent such withdrawal.

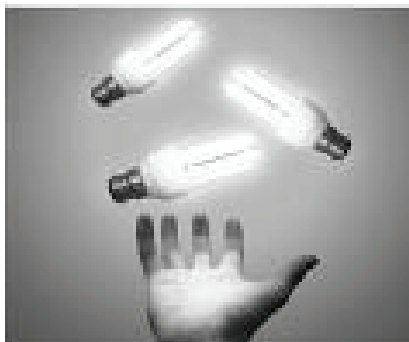
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Office of Research Initiatives (RI)

2009 RISE AWARDS



The Office of the EVPR grants annual Research Initiatives in Science and Engineering (RISE) awards to support early stage or innovative research that is not yet ready for conventional funding with the goal of enabling the grantees to advance their research and gather sufficient data to secure funding from more standard sources. Interdisciplinary and inter-campus activities are particularly encouraged. This year, five RISE grants were awarded out of 67 applications. The funded proposals came from the following departments: Biological Sciences, Biochemistry, Molecular Biophysics, Neuroscience, Psychiatry, Biomedical Engineering, Chemistry and Civil Engineering.

The topics included, "Beyond the Adaptor Hypothesis: The role of the amino acid in the regulation of protein synthesis", "Decoding the in vitro and in vivo target specificity of Hox proteins", "GLSI as a novel therapeutic target for the pharmacotherapy of schizophrenia", "ISPEM (Integrated Sustainable Policy Economic Model)" and "Re-Interpreting the Brain Imaging Signal".

A number of investigators who received RISE awards in the past several years have successfully secured further support. Eric Greene, who was awarded a RISE grant for his proposal "The Integrated Approach to Nanoscale Bioscience", received an NIH R01 grant in July 2008 and will begin receiving funds from the Howard Hughes Medical Institute in September 2009. Dr. David Waltz's proposal for "An 'Early Warning' Device to Allow Epilepsy Patients to Live a More Normal Life" just received funding from the NSF and the National Epilepsy Foundation. Additionally, Dr. Peter Kelemen, a RISE award recipient for his proposal "Natural Carbon Sequestration in Ophiolite Peridotites – Rates and Mechanism of Serpentinization and Carbonation", filed for a patent and received funding from Petroleum Development Oman. His group has also recently submitted a proposal to the Department of Energy's Advanced Research Projects Agency – Energy (ARPA – E) program under ARRA.

For more information regarding this year's RISE recipients and the RISE program, please visit our website at <http://researchinitiatives.columbia.edu/funding-resources/research-initiatives-science-and-engineering-rise>.

NYS MATCHING FUNDS

Governor Patterson introduced a plan to offer a 10% match on certain federally-funded stimulus grants. RI is working with a number of research teams to apply for these incremental funds. Dr. James Yardley will receive matching funds for his DOE Energy Frontiers Research Center and the State also pledged to provide 10% matching funds to the six proposals for NIH C06 research construction grants. Further information can be found on the EVPR Stimulus web-site at <http://evpr.columbia.edu/content/new-york-state-innovation-economy-matching-grants-program>.