 ALSO IN THIS ISSUE:

Building a Compliant Research Culture One Crisis at a Time
Success Built to Last and Research Management
CONTENTS

FEATURES

The Last Five Years and the Next Five Years  By Dan Nordquist .................................................... 1

Capitol View  By Carol Blum ................................................................................................................. 4

Surveying the Conflict of Interest Landscape at Research Universities  By Jodi R. Edelstein .................................................... 6

NIH Financial Conflict of Interest: The Final Rule  By Julie D. Gottlieb and Marianne L. Hockema........................ 10

Success Built to Last and Research Management  By James Casey .................................................... 14

ERA Success: Strategies for Successful Implementation  By Hope C. Grant .................................................... 16

Building a Compliant Research Culture One Crisis at a Time  By Joseph McNicholas .................................................... 18

Serving Many Masters: Managing Departmental Research Administrators’ Conflicts of Commitment  By Craig Reynolds .................................................... 20

NSF and Research.gov: If It Isn’t Broken Don’t Fix It  By Mary Santonastasso .................................................... 22

Attention Pre-Award Administrators: What You Need to Know About the Department of Health and Human Services Revised Financial Conflict of Interest Regulation  By Debra Thurley .................................................... 30

GUIRR February 2012 Meeting Update: Challenges and Opportunities of an Aging Population  By Katie Kalinowski .................................................... 35

The Seventh European Framework Programme Comes to an End: What Was it About and Why Should U.S. Researchers Cooperate Now?  By Elli Tzatzanis-Stepanovic .................................................... 36

IN THIS ISSUE

Pre-Award Research Administration Conference .................................................... 13
NCURAbly Pedantic ................................................................................................................................. 25
Financial Research Administration Conference .................................................... 26
SWOT – Not Just Another Acronym ......................................................................................................... 29
Annual Meeting Update ............................................................................................................................. 32
Collaborate NCURA ................................................................................................................................. 34
On Campus Profile ................................................................................................................................. 40
Regional Corner .......................................................................................................................................... 42
NCURATV 2012 DVD Workshop Series ..................................................................................................... 48
Calendar .................................................................................................................................................... 50
Back Cover
The Last Five Years and the Next Five Years

By Dan Nordquist, NCURA President

By Spring, most our New Year resolutions have been long since buried in guilt and we are realizing, once again, that it is one thing to set goals, but a whole different thing to achieve them. So what about NCURA? How are we doing?

The 2007 Officers and Board created a three to five-year planning horizon that provided NCURA a picture of what we wanted to be in 2012. Did we make it? Are we moving forward in alignment with their vision? Are we living up to the expectations encouraged by previous members?

Here’s our report card; what we said we would do, followed by what we have achieved.

“By 2012, NCURA will have:

✔ …an increased volunteer base.

• NCURA grew from 473 filled volunteer opportunities in 2007 to 754 by the end of 2011. Remarkably, this does not include all of the volunteer speakers and presenters. We are now looking for new and innovative ways to ensure we have the volunteer opportunities needed for our members for the next several years.

✔ …significantly advanced the field of research administration.

• NCURA advanced the profession by offering grants to universities to develop the first on-line Masters of Research Administration, thereby enabling those in the field to obtain a graduate degree in their profession.

• We have also continuously stayed abreast and provided programmatic training through all of the significant profession-changing events over the last 5 years: e.g. Grants.gov implementation; ARRA, FFATA and FAPIIS; the COMPETES Act; COI changes; the FDP Survey; Export Controls [continually]; all those troublesome clauses; proposed changes to the OMB Circulars; Hazardous Materials Shipping and Training; the huge growth in on-line activity (training, social media, etc.). NCURA has been the expert we turn to through it all.

✔ …become the widely-recognized voice of research administration.

• NCURA Magazine is read by more than 7,000 NCURA members and throughout the research community globally. NCURA’s on-line scholarly journal, Research Management Review is read by research managers around the world.

✔ …earned increased respect and recognition with academic leaders.

• NCURA’s Peer Review Program, publication record in our Research Management Review (RMR), and graduate degrees in research administration, as noted earlier, have paved the way for continued professional recognition.

✔ …become international.

• We created an international region and have interacted with countries all over the world. In 2014, NCURA is a co-sponsor for the International Network of Research Management Societies (INORMS) for its first North American Conference.

✔ …expanded its alliances and strategic partnerships.

• NCURA continues to work with U.S. sister organizations and also works with associations world-wide.

✔ …a better use of technology to adapt its programs to other cultures and languages.

• Social Media has been a huge boom for NCURA – Facebook, Twitter, YouTube Tuesdays, utilizing Skype and Google+. The opportunities and tools for participation grow daily – Collaborate NCURA is really on the move.

✔ …increased staff capacity and expertise.

• Having added a new position of Volunteer and Regional Assistance Coordinator in 2006, NCURA was able to move forward during the next five years and build significant infrastructure to its volunteer program and National/Regional interactions. In response to increased national con-
Conflicts of Interest  The Final Rule has changed the compliance environment at our institutions and this edition of NCURA Magazine brings definition and explanation to this Department of Health and Human Services edict. The Bayh-Dole Act of 1980 gave non-profit institutions and small businesses ownership of their intellectual property. Not many research administrators realized in 1980 that along with receiving intellectual property rights we were also accepting the responsibilities for managing our faculty and institutional interests and how complex those relationships could become.

Julie Gottlieb and Marianne Hockema dissect the DHHS Final Rule giving our readers insight into the new disclosure requirements, management plans and the other significant challenges that we will face when the final rule goes into effect on August 24, 2012. Jodi Edelstein examines the conflict of interest regulations for all Federal agencies in her article and very competently demonstrates how these regulations affect the compliance environment at our research institutions. These two articles provide our readers with a discerning look into the complex nature of financial conflicts of interest. This conflict of interest message is seamlessly connected to our pre-award and departmental research administrators through the articles authored by Debra Thurley and Craig Reynolds.

The On Campus Profile interview with my good friend Gunta Liders gives our readers a personal insight into a major research university’s response to the regulatory requirements of the Final Rule. Gunta outlines her development of a thoughtful implementation plan including communication, training and collaboration across all areas of the University of Rochester.

I am pleased to present this edition of NCURA Magazine to our readers and wish to thank all of the authors for their contribution to this edition including our Senior Editor Jim Casey, my fellow Co-Editors and the NCURA staff for their support.

Thomas Wilson
Co-Editor
"The Huron consultants were very knowledgeable about the industry itself and how it relates to our organization’s key issues and priorities."

Huron Education partners with institutions to provide strategic, operational, and technology solutions that enable clients to succeed and thrive in this new era of change. As a result, our clients consistently achieve market-leading levels of financial and operational performance. We focus on comprehensive performance improvement, freeing you to focus on your mission. Visit www.huronconsultinggroup.com.
By Carol Blum

An unconventional but increasingly troubling conflict in interests is the public’s interests in scientific advances and the security of the nation. On one hand, the public expects the research community to chase cures for the nation’s physical, economic, and intellectual woes. On the other hand, the public wants us to be alert to and protect it from threats to our well-being and security. But sometimes those desires for scientific advances and national security present conflicting interests.

The most recent challenge to these interests surfaced in the debate over the publication of two articles addressing the transmission of the avian flu (H5N1 influenza virus). Two separate groups of scientists working on the genetic basis of the transmissibility of H5N1 developed laboratory-modified H5N1 viruses capable of respiratory transmission between ferrets (ferrets are good respiratory models for humans) suggesting that with relatively few genetic changes, the H5N1 viruses could become more easily transmissible from person to person.

After articles describing the research findings were prepared for publication in Science and Nature but before publication, the papers were reviewed by the National Science Advisory Board for Biosecurity (NSABB) in the Fall of 2011 because of security concerns associated with the potential misuse of the research results. You may recall similar questions were raised over the 2005 publication of articles in Science and Nature describing the reconstruction of the influenza virus strain responsible for the 1918-1919 pandemic that killed an estimated 50 million people worldwide. At that time, the NSABB unanimously supported publication in order to make the findings available to other scientists to permit further research on the development of diagnostic tests, treatments, and preventive measures.

In this recent case concerning H5N1, the NSABB recommended that the research “not be fully communicated” to reduce the possibility that anyone seeking to misuse the knowledge could replicate the experiments with harmful intent, for example, vaporizing the deadly transmissible flu strain and threatening the general public health. Specifically, the NSABB recommended that details of the research methods used and the specific mutations be deleted from the papers. And yet, the value of the work for improving the public health and animal health seems as compelling as the information concerning the 1918-1919 pandemic. Understanding how the virus evolves is a critical component in improving public health surveillance, detecting potentially pandemic H5N1 strains, and aiding the development of vaccines and other countermeasures. Other scientists, and the public, can benefit from the knowledge.

In response, the virology community called for a 60-day moratorium on further research on H5N1, and the World Health Organization (WHO) convened a meeting in February 2012 to discuss the controversy and make recommendations on how the scientific community in cooperation with governments and agencies could address the challenges of what is called dual use research of concern (DURC). The WHO recommended that the papers be published in full but that publication be delayed to provide time to increase public awareness and understanding of this research, and to provide for the review of biosafety and biosecurity aspects raised by the new laboratory-modified H5N1 influenza virus.

Following the WHO recommendations, the NSABB reconvened in late March, 2012, and examined two revised manuscripts and recommended publication of the revisions. In announcing its decisions, the NSABB noted that, with the authors’ revisions, the risk/benefit calculation had changed. The NSABB believed that the data descriptions in the revised manuscripts would not immediately enable misuse, thus threatening public health, and evidence suggested that understanding specific mutations would aid in surveillance. The NSABB reiterated its strong support for the unrestricted publication of research information unless “that information could be directly misused to pose a significant and immediate risk to public health and safety” (NSABB, 2012).

The NSABB has been considering the oversight of DURC since the Board was established in 2005 and has issued a number of reports. Early in its deliberations the NSABB defined DURC as “life sciences research that can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security” (NSABB, 2007). The report in which the NSABB outlines a broad collaborative oversight mechanism including investigator and institutional responsibilities is entitled Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information and was published in 2007.

As the NSABB met to consider the revised manuscripts on A/H5N1, the Department of Health and Human Services’ (HHS) Office of Biotechnology Activities (OBA), acting for the Federal government, quietly posted the new US Government Policy for Oversight of Life Sciences Dual Use Research of Concern (DURC) on March 29, 2012. The undated document describes the
principles informing the policy, establishes the scope, and outlines the responsibilities of Federal departments and agencies.

The policy addresses research using 15 select agents and toxins and 7 experimental models or aims. It recognizes that the current Select Agent and Toxin Regulations as administered by the Centers for Disease Control and Prevention and US Department of Agriculture provide biosafety and biosecurity oversight. This policy is focused on mitigating or “minimizing the risk of misuse of the knowledge, information, products, or technologies provided by such research.” Federal agencies are directed to conduct a review of all current and proposed research and determine if any of the research falls within the scope (using the identified agents or toxins with the specific research aims) and meets the definition of DURC (research that, if directly misapplied, poses a significant threat). For those projects identified, the agency is required to assess the risks and, based on the assessment, “in collaboration with the institution or researcher, develop a risk mitigation plan.” New proposals and on-going projects may need to be modified to incorporate a plan.

The policy outlines a non-exhaustive list of possible risk mitigation measures that reflect the entire range of options from modifying the design or conduct of the research to termination of funding for the research. Some measures include regular institutional review of emerging research findings for DURC, determining the venue and mode of communicating research results or, for risks that cannot be adequately mitigated using less restrictive measures, classification.

Initially, Federal departments are asked to report on a series of metrics concerning the number of projects falling under the scope of policy (within 60 days) and summaries of the risk assessments and mitigation strategies in place (or proposed) to mitigate those risks (within 90 days). These reports are to be submitted to the Assistant to the President for Homeland Security and Counterterrorism. There is little detail in how the reviews will be conducted or how the mitigation plans will be developed with the institutions and/or investigators.

The policy directs agencies to the NSABB website for DURC educational tools for the extramural research institutions and to assist agencies in conducting risk assessments. Finally, the policy designates either the NSABB or the Countering Biological Threats Interagency Policy Committee as the final arbiters of review and guidance.

While it is not clear how or when this new policy will be applied, the agencies are conducting the initial review to identify projects that fall (or may fall) under the policy. Institutions or investigators (again the policy is not clear) will be contacted by the agency to determine the level of risk associated with the research and if a risk mitigation plan is appropriate. It is hoped that the development of the risk mitigation plan is done in collaboration with the investigator and the home institution. With a focus on current select agents and toxins, the scope of the policy at this juncture is relatively narrow. Institutions may want to conduct a review and assessment themselves to prepare for a discussion with Federal agencies. Balancing the public’s conflicting interests will be a challenge.

Associate Justice of the US Supreme Court Louis D. Brandeis once said, “In the frank expression of conflicting opinions lies the greatest promise of wisdom in governmental action.” We can only hope.

Carol J. Blum is Director for Research Compliance and Administration at the Council on Governmental Relations (COGR). Before joining COGR in 2001, Carol served Ohio University for ten years as associate vice president for research after three years at the Ohio Board of Regents as director of graduate and special programs. She holds a PhD in history from the University of Cincinnati. She has recently begun exercising the right side of her brain in art classes and continues to volunteer at the Washington Literacy Council and Washington Area (Reproductive Health) Clinic Defense Task Force.

References:


MAY/JUNE 2012
A conflict of interest (COI) exists when there is the risk that personal bias will unduly influence one’s institutional actions and choices. People are hard-wired with preferences and stereotypes, conscious and not, so the federal government has passed legislation aimed at preventing and managing the effects.

In the university environment, specifically, there are potential hot spots for COIs. As a result, the regulatory landscape for these interests is growing. To help the reader and university administrators, in particular, find these COIs, what follows below is a survey of the COI landscape as it affects research universities. Federally mandated COI regulations are first, and then COIs that commonly receive attention in university policies follow.

**FEDERAL LAW**

There are a number of federal regulations that address individual and organizational COIs either directly or through contract language under the Federal Acquisition Regulation (FAR).

Research

Public Health Service (PHS) Responsibility of Applicants for Promoting Objectivity in Research for which Public Health Service Funding is Sought and Responsible Prospective Contractors, 42 CFR, Part 50, Subpart F and 45 CFR, Part 94.

Originally passed in 1995, and recently revised on August 25, 2011, 42 CFR, Part 50, Subpart F and 45 CFR, Part 94 are the most expansive federal laws regarding COIs. Under them, institutions and contractors that receive research funding from one of eight of the federal agencies that comprise the U.S. Public Health Service must reasonably ensure that the “design, conduct, and reporting” of research is “free from bias resulting from Investigator financial conflicts of interest.” Regulatory implementation is due August 24, 2012, and institutions will comply by designating an official to gather and review Investigators’ significant financial interest disclosures relating to their Institutional responsibilities. The federal minimum for a significant financial interest is $5,000 or more in outside compensation (i.e., not one’s salary at the subject institution), intellectual property interests and publicly traded equity held by the Investigator, the Investigator’s spouse and dependent children in the twelve (12) months preceding the disclosure, and, any amount of equity held by the same individuals in a non-publicly traded entity, not including mutual funds. If significant financial interests are deemed financial conflicts of interest, appropriate management plans will be chosen and reported to the PHS Awarding Component using an online module, Electronic Research Administration (eRA) Commons. Management plans must be subject to ongoing monitoring, and annual reports on COI status are also required (42 C.F.R. Part 50, Subpart F and 45 C.F.R. Part 94, 2011).

National Science Foundation (NSF), Conflict of Interest Policy, Grants Policy Manual Section 510 (NSF, 2010).

The NSF’s policy is very similar to the PHS COI policy described above. It requires that the same research individuals disclose a smaller pool of significant financial interests, only including those that “would reasonably appear to be affected by the [NSF-funded] research or educational activities.” The minimum threshold is set at $10,000 or 5% equity ownership – also the standard under the old PHS policy, expiring this August. Similarly, a designated official must review the disclosed interests to determine whether there is a COI, but reports are sent to the...
NSF only if “the institution finds that it is unable to satisfactorily manage a conflict of interest” (NSF, 2009).

Both the PHS and NSF policies identify those that must disclose as “Investigators,” and define them as the project director or principal investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research, or proposed for such funding, which may include, for example, collaborators or consultants” (NSF, 2010, and 42 C.F.R. Part 50, Subpart F §50.603, 2011).

Membership on Safety Boards

U.S. Department of Health and Human Services (HHS), Common Rule, 45 CFR 46. Subpart A

Food and Drugs Administration (FDA), 21 CFR 56.107(e)

Employing identical language, both the U.S. Department of Health and Human Services and the Food and Drug Administration state that “no IRB may have a member participate in the IRB’s initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB” (Thompson, 2004). In other words, members of the institutional review board, or IRB, have an affirmative duty to recuse themselves from reviewing any project in which they are conflicted. Such conflicts need only reasonably affect one’s objectivity, and may be financial or not (Thompson, 2003).

Office of Laboratory Animal Welfare (OLAW), PHS Policy on Humane Care and Use of Laboratory Animals, Policy IV.C.2.

Members of the Institutional Animal Care and Use Committee (IACUC) carry the same duty to remove themselves from reviewing projects where conflicted, except to provide requested information. For example, a committee member has a conflict of interest when “personally involved in the activity” under review (Pitts, 2002).

FDA Marketing Applications

Food and Drug Administration (FDA), Financial Disclosure by Clinical Investigators, 21 CFR Part 54 et seq.

The FDA evaluates clinical studies submitted in marketing applications, as required by law for new human drug and biological products, as well as re-classification petitions for medical devices. This review includes determining whether or not the data generated meet the statutory requirements. The regulations state that the “FDA may consider clinical studies inadequate and the data inadequate if, among other things, adequate steps have not been taken in the design, conduct, reporting, and analysis of the studies to minimize bias” (21 C.F.R., Part 54.1(b), 2011). The minimum thresholds set by FDA are higher than those for PHS and NSF, at $25,000 or more for grants, honoraria, and consulting fees; $50,000 or more in sponsor company equity; or, any interest in the patent, trademark, or licensing agreements for the product (Lutz, et al., 2010).

Physician-Industry Relationships

Centers for Medicare and Medicaid Services (CMS), Physician Payments Sunshine Act, Patient Protection and Affordable Care Act, Section 6002

Starting September 30, 2012, gifts, honoraria, compensation, equity, and investment interests given to physicians by manufacturers of drugs, devices, biologicals, and medical supplies will be posted online by the Centers for Medicare and Medicaid Services. They must be valued at $10 or more (or $100 aggregated annually) and covered by Medicare, Medicaid, or the Children’s Health Insurance Program (Policy and Medicine, 2012). Institutions need to be proactive in making sure their records accurately reflect the reported amount, and follow up with the CMS and physicians where there are differences. The reported interests are not conflicts per se, but they might form the basis of one.

Government Contracts

Secretary of Defense, Administrator of General Services, and National Aeronautics and Space Administration Administrator, Federal Acquisition Regulation (FAR), Subpart 9.5

Research universities are most often faced with “organizational COIs” under FAR 9.5 when the university is a prime or sub-grantee of an award.
In addition to regulatory requirements, most institutions have developed internal policies addressing potential COIs or conflicts of commitment affecting a variety of institutional activities. These policies may be in keeping with an underlying institutional mission or in uniformity with other legal requirements.

Conflict of Commitment
Conflicts of commitment arise when there are competing demands on a faculty member’s time and energy, such that the faculty member is not able to fulfill his or her contractually required duties (Steneck, 2006). Typically, a faculty member will be hired by an outside company to serve as an officer, consultant, speaker at a conference, or member of an advisory board.

Institutional COIs (ICOIs)
ICOIs are commonly identified and handled in a way that is similar to the Investigator COIs regulated by PHS and NSF regulations, described above. Though there are no federally-mandated regulations for ICOIs yet, in much the same way, they address the risk that institutional and senior official interests will bias research (Policy and Medicine, 2011). ICOIs arise out of equity, royalties, and gifts held by the institution, or equity, royalties, outside compensation, and outside professional roles held by senior officials.

ICOI policies are also required for Institutional Review Board (IRB) certification by the Association for the Accreditation of Human Research Protection Programs certification (AAHRPP 1.3.C) (Thompson, 2004). For this reason and in anticipation of future federal mandates, many research universities have developed and implemented ICOI policies similar to their Investigator-centered PHS-mandated policies (Levinson, 2011).

Licensing University Technology
ICOIs also arise where the university licenses its inventions to outside entities for research at the university, and in exchange, receives royalties and equity in the company (often a start-up). In this way, the success of the research will affect the amount of royalties and equity the university earns, thus creating potential bias and a COI.

Purchasing
Many institutions have developed policies that address purchasing practices where an institutional official (or the official’s family members) is involved with a company supplier. Under these

References:


policies, major purchases and non-routine supply contracts receive more scrutiny to ensure that the researcher, administrator, or official was not unduly biased in his or her decision (Rich and Wrighton 2008). Also noteworthy are situations where the university receives goods or services from a company that is providing some other benefit to the university such as a discount, donation, research sponsorship, or license for university technology, because the benefit may appear to unduly affect that purchasing choice (COGR, 2001).

**Activities Related to Family Members**

Hiring, supervising, or procuring contracts with family members through the university is often subject to scrutiny and may be prohibited under institutional policy. The familial relationship gives rise to an emotional conflict of interest. In most instances, the institution requires review by a designated official to determine if such recruitment may be permitted, and if so, establishes a reporting structure where a family member is not supervised by another family member.

**Interactions with Industry by Faculty and Clinicians**

Above and beyond the Physician Payments Sunshine Act, mentioned above, there has been a great deal of momentum behind preventing industry relations with faculty and clinicians for fear that such interactions unduly influence medical professionals in providing clinical care. These relations come in many forms, even when no money is exchanged, including:

- payment for attendance at and traveling to lectures and conferences;
- free Continuing Medical Education courses (CME);
- the provision of ghostwriting services;
- provision of pharmaceutical samples;
- grants for research projects; and
- payment for consulting relationships (Brennan, 2006).

**Conclusion**

The foregoing discussion of various regulatory and institutional policies regarding COI indicates that they may occur in a variety of situations, even while performing routine activities such as research, teaching and clinical practice. Though COIs are not inherently bad and can co-exist with the highest standards of conduct and integrity, it is important that they be identified, disclosed, and managed. Appearance of bias can weigh as heavily as the actual risk of it, and the failure to disclose and manage them can have long-standing consequences, including damage one’s to reputation. The best course is to gain an understanding of the institutional policies on COIs, including their relationship to each other, as highlighted above, and when in doubt – disclose. 

**Jodi R. Edelstein, J.D.,** is Compliance Manager for Research Conflicts of Interest at Boston University and Boston Medical Center. Prior to joining BU, Jodi practiced law; completed professional training in mediation, and taught English in Japan. She holds a Bachelor’s degree in Music from Vanderbilt University and a Juris Doctor degree from the University of Miami School of Law. Jodi’s responsibilities at BU and BMC include managing BU and BMC’s research conflict of interest program, including policy development, implementation, case and committee management, and community education.
Ask any colleague involved in conflict of interest identification and management at your institution about the most immediate challenge in this area ... and you may first see their eyes roll backward, but then you’ll hear something close to “the final rule.” Published in August 2011, the Final Rule has propelled COI administrators and their institutions into a year-long sprint to institute policies, processes and IT systems that meet new Department of Health and Human Services (DHHS) standards for disclosure, identification and management of COI by August 24, 2012.

What prompted the Final Rule

Ensuring research objectivity through management of COI is not a new subject for researchers and their institutions. Even before federal regulations regarding conflict of interest were first published in 1995, many professional societies and academic institutions placed absolute prohibitions on personal financial gain related to research and issued dire warnings about more subtle forms of conflict of interest, such as the desire for promotion and recognition by peers. However, with the passage of the Bayh-Dole Act in 1980, universities began taking ownership of intellectual property and licensing it for commercial development, which generated royalties for the institutions and the respective inventors. Interactions between universities and industry became more common, and relationships became much more complex. Academic medical centers urged their faculty to become more innovative and entrepreneurial, and companies encouraged continued research and development of new technologies with commercial potential. The ensuing growth in license fees, royalties, patents, consulting fees, equity and fiduciary roles led to a growing concern that financial incentives posed serious risks to researchers’ ability to remain objective in the conduct of their research projects.

During the 1980s and early 1990s, the academic research community explored various approaches to dealing with conflicts of interest. “Disclosure, disclosure, disclosure” was the easy first step in managing any conflict of interest, but it raised many more questions. What to disclose? To whom and when? Is consulting acceptable – even for a nominal fee? What about equity? Can conflict be managed by investigators placing stock in escrow accounts until the research is finished? Should the objectivity of research protocols be overseen by data safety monitoring boards?

In 1995, DHHS published a regulation titled “Objectivity in Research” which established “standards and procedures to be followed by institutions that apply for research funding from the PHS to ensure that the design, conduct or reporting of research funded under PHS grants, cooperative agreements of contracts will not be biased by any conflicting financial interest of those investigators responsible for the research.” While not expressly stated, the regulation also attempted to bring a degree of uniformity to the management of conflict of interest across biomedical research. Terms were defined, dollar thresholds listed, management options spelled out and reporting requirements enunciated. But despite the specificity provided in the regulations, institutions were left with considerable discretion in how to comply with its requirements.

Following the 1995 rulemaking, professional organizations including the Association of American Medical Colleges (AAMC), the Association of American Universities (AAU), the Council on Government Relations (COGR), the Federation of American Societies for Experimental Biology (FASEB), and NCURA attempted to add clarity and depth to the interpretation of the regulations. However, institutional approaches to comply with the regulation varied greatly. During this period, significant financial interests of some investigators in their research were not disclosed. As these came to light, Congress, the media and the public became increasingly worried that conflicts of interest were placing research objectivity at risk. Public scrutiny was not just reserved for academic research institutions. NIH, too, was criticized for inadequate attention to conflicts of interest in the intramural and extramural settings. At the urging of Senator Charles Grassley (R-IA), NIH revised and tightened the earlier DHHS regulations on objectivity in research, and a revised regulation – the Final Rule – was issued in August 2011.

Grantee institutions must be in compliance with the Final Rule by August 24, 2012. The structure
of the Final Rule is similar to that of the 1995 regulation, but its provisions are far more detailed than the earlier regulation. Institutions must solicit financial interest information from investigators, review the interests for conflicts of interest with PHS-funded research, and report to the awarding agency the existence of any Financial Conflicts of Interest (FCOI).

**The result: major changes under the new rule**

Under the Final Rule, institutions must make their conflict of interest policies publicly available, ideally on the Web. Revised policies are considered to be in effect as soon as they are made public.

The Final Rule defines an investigator as any individual, “regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding.” This may include collaborators, consultants, and in some cases trainees.

**Disclosure**

Investigators must disclose a broader range of financial interests to their institutions than under the 1995 regulation. A “significant financial interest” (SFI) exists when, with respect to the investigator and the investigator’s spouse and dependent children, (i) the value of any remuneration received from an entity within the 12 months preceding the disclosure and the value of any equity interests as of the date of the disclosure, when aggregated, exceed $5,000; (ii) any equity in a non-publicly-traded company; and (iii) intellectual property rights on receipt of income from those rights. The Final Rule still exempts income derived from intellectual property owned by the grantee institution if the investigator is employed by the institution. In addition to its lower monetary de minimus for disclosure, the Final Rule requires disclosure of all SFIs related to an investigator’s institutional responsibilities. For example, an investigator who is paid to consult for a pharmaceutical company because of the nature of her clinical practice, not because of the company’s interest in her research expertise, must nonetheless disclose her consulting income. All SFIs must be disclosed, whether or not the income is from a for-profit organization or a non-profit group. For instance, an investigator who is paid $10,000 to consult for a foundation must report that income to the institution. However, there are some important exceptions. Researchers do not have to disclose payments for seminars, lectures, teaching engagements, or service on advisory committees or review panels from federal, state, or local government agencies, U.S. institutions of higher education, academic teaching hospitals, medical centers, and research institutes affiliated with institutions of higher education.

**Travel**

The Final Rule requires that institutions collect and disclose information about investigators’ “sponsored or reimbursed travel” related to their institutional responsibilities, whether it is paid for by a for-profit or not-for-profit organization. The required information includes the name of the sponsor/organizer, purpose of the trip, length of the trip, and destination. This requirement is part of the SFI provision, but no de minimus is set forth in the regulation. For example, if a company pays for an investigator to travel to a professional society meeting, the payment or reimbursement must be disclosed. Similarly, if a professional society pays for travel to an annual meeting, the payment or reimbursement must be disclosed. Travel that is paid for or reimbursed by a research sponsor must be reported if the investigator is paid directly or reimbursed personally by the sponsor. However, if the grantee institution pays for an investigator’s travel from an institutional account, such as a sponsored project budget, the travel does not need to be reported.

Disclosures must be made within 30 days of travel. The NIH has suggested that researchers may report their travel prospectively. Researchers do not have to disclose payments for seminars, lectures or teaching engagements or service on advisory committees or review panels from federal, state, or local government agencies, U.S. institutions of higher education, academic teaching hospitals, medical centers, and research institutes affiliated with institutions of higher education.

**Reviewing Disclosures**

Disclosures of SFIs must be reviewed to determine whether they are related to an investigator’s PHS-sponsored research and, if related, to determine whether they create an FCOI with the research. What’s new under the Final Rule is that institutions must make these judgments. They may take into account information provided by investigators, but the institution is responsible for making and documenting its determinations. Under the Final Rule, an SFI is “related” if the research could affect the value of the SFI or the entity in which there is an SFI. An FCOI exists when an SFI “could directly and significantly affect the design, conduct, or reporting” of the research. Institutional officials making these determinations – whether individuals or a committee – must be given guidance by the institution.

**Management Plans**

If an FCOI is identified, the institution must develop and implement a “management plan” in order to minimize the risk of bias in the design, conduct and reporting of the research. A management plan may involve one or more steps. For example, a plan may require an investigator lower or eliminate a financial interest, disclose the financial interest in presentations, publications and human research consent forms, and/or limit his/her role in a research project. Additionally, a plan may require institutional oversight of the research. The institution must obtain documentation of the investigator’s agreement to comply with the management plan, and the institution must monitor the investigator’s compliance.

**Reporting**

Under the Final Rule, institutions have to provide the awarding agency with details of each FCOI, including the name of the individual with the FCOI, the name of the entity in which the investigator has the financial interest, the nature and magnitude (within ranges) of the interest, the basis for the FCOI determination, and the key elements of the management plan. The mechanism for reporting will continue to be eRA Commons, although the reporting portal is likely to be modified.

Under the Final Rule, certain details of each FCOI also must be made available to the public. This requirement applies only to FCOIs of senior/key personnel, not those of any other investigators or project personnel. The information may be posted on a publicly-accessible Web site or provided on a per-request basis to requestors within five business days.

**Special Challenges**

At the recent annual meeting of the AAMC-sponsored Forum on Conflict of Interest, there was consensus among the 225-plus attendees that the most challenging aspects of the Final Rule were provisions regarding travel (discussed above), sub-recipients and mitigation reports.

When a disclosure is received late or the review is delayed, and the financial interests are related to the research and constitute an FCOI, the institution must conduct a retrospective review to as-
Certain whether there has been bias in the design, conduct or reporting of the ongoing research. If bias is found, the institution must prepare a mitigation report and submit it to the awarding agency. The report must outline the actions that will be taken to eliminate or mitigate the effect of the bias.

**What’s Next?**

While the final rule presents many new challenges for research institutions, help is available. The NIH posts “Frequently Asked Questions” regarding the final rule on its website. It has also created a tutorial that institutions may consider as one way researchers can meet the training requirement. Other helpful resources are listed below.

**Resources**

**NIH**  
Regulations:  
Frequently Asked Questions (FAQs) about the final rule:  

**NSF**  

**AAMC**  
General website: https://www.aamc.org/  
The Association of American Medical Colleges (AAMC) Forum on Conflict of Interest in Academe (FOCI A)  
https://www.aamc.org/members/foci/

The overall purpose of the Final Rule is to reduce the potential for bias and preserve the public trust in research – goals that everyone can agree on. Robust conflict of interest policies and procedures will go far in supporting the credibility of researchers and their institutions.

**Julie Gottlieb, MA,** is Associate Dean for Policy Coordination at Johns Hopkins University School of Medicine. She is also a co-founder and the Past Chair of the Forum on Conflict of Interest in Academe, an affiliate of the Association of American Medical Colleges.

**Marianne L. Hockema, MA,** is Administrator in the Office of Conflict of Interest Review at Mayo Clinic. She is a co-founder of the Forum on Conflict of Interest in Academe, an affiliate of the Association of American Medical Colleges.

**Implementing the Final Rule on Financial Conflicts of Interest in Public Health Service Funded Research**  

**Task Force on Financial Conflicts of Interest in Clinical Research**  
Report on Institutions Financial Interest in Human Subjects Research  
(October 2002)  
Report on Individual Financial Interest in Human Subjects Research  
(December 2001)

**FDA**  
Regulations: http://www.fda.gov/RegulatoryInformation/Guidances/  

---

**NCURA Magazine Seeks Articles for Special “Green” Issue**

The *NCURA Magazine* seeks articles for a special, electronic-only issue, focusing on Human Capital. This includes investment in people, evaluation, organizational structure, relationships, stress management, and hiring. The issue will be published in August 2012 and will only contain feature articles. Individuals interested in submitting articles for this special issue should email their specific idea to:

Jim Casey, Senior Editor, *NCURA Magazine* at James.Casey@utsa.edu

**The deadline for submission of articles is June 29.**
The Networking Track:
Your Passport to Building and Growing Your Network

net·work·ing [net-wur-king]
noun: a supportive system of sharing information and services among individuals and groups having a common interest:

Well that doesn’t sound scary at all! But the thought of having to “network” can be scary. And we know that it is critical to continue to grow our peer network to strategy swap after the conference is over.

Even if you already know a lot of people…

* Every new person you meet knows someone that you do not know and every person you meet knows something that you do not know.

NCURA is bringing you over 100 educational and strategy swap opportunities and building in opportunities to grow your network. The PRA Conference Networking Track aims to take an active and purposeful approach to create the opportunities to help you build, or continue to build, these important relationships.

Some things you can look forward to:

- Sign up to be partnered with or be a Meeting Mentor
- Speed networking session
- Early Bird and Jetlag group Sessions
- The Eat Across Organizations Challenge
- Scavenger Hunt
- Walking Tour of Vancouver
- Taste of Vancouver Dine Arounds
- Tweet Up!
- Community Sessions
- Info session how to get involved in NCURA and more!

We’ll be using NCURA’s Professional Networking Platform, Collaborate, to begin the conversation and share information. Registered participants will be getting an invitation to join the PRA 6 Conference Community in June so we can begin networking, getting some early looks at some of the material being presented, and to open volunteer opportunities so you can get involved!

Register today to gain new knowledge, perspectives, and networks!

* from the online article: How Can I Network if it’s Really Scary to Walk up to Strangers and Start a Conversation? Pam Stoker - Assistant Director, Graduate Career Service Center, Neeley School of Business, Texas Christian University
As research managers, we should be in the business of building long term, successful research operations at our institutions and a respected profession. But what does success mean? What does long term success mean? Building upon the general concepts in the book Success Built to Last, by Jerry Porras, Stewart Emery, and Mark Thompson (Penguin Group 2007), this article seeks to stimulate thought about how we can make research management more successful, both on campus and profession-wide.

Porras, Emery, and Thompson interviewed 200 endurably successful people (“Builders”) between 1996-2006, including such individuals as Madeline Albright, David Barry, Bono, Bill Clinton, Sally Field, Rudy Giuliani, Peter Jennings, Carl Lewis, Condoleezza Rice, Charles Schwab, Barbara Walters, and Dieter Zetsche (pp. 263-270). The authors then analyzed the interviews to find the most frequent patterns of behavior and thinking.

From my perspective, and in light of our recent Leadership UTSA presentation, I want to focus on the following aspects of Builders:

**Integrity.** Merriam-Webster defines integrity as the firm adherence to a code of especially moral or artistic values (Merriam-Webster online dictionary, March 20, 2012). Based upon the interviews, the authors say that Builders are those who exhibit integrity over the long term, in their professional and personal lives (p. 69). People who lack integrity may have short term or isolated success, but not enduring success.

Integrity is a critical component of research administration in particular and higher education in general. All university employees, whether faculty, staff, or students, must exhibit integrity on a daily basis. In the area of research, funding by the American taxpayer of discretionary R&D projects is based upon the public perception that faculty research projects are objective and hence have integrity. If the American people perceive federal research projects as lacking objectivity and/or integrity, then the political underpinnings of such funding is eroded.

This issue of NCURA Magazine, focusing on conflicts of interest, is a natural fit with the concept of integrity since it is possible that a conflict of interest can also be illustrative of the lack of integrity. These are serious matters and all employees in the research enterprise should aim for the highest integrity possible.

For research managers, what does integrity mean in the workplace? I can name several examples: 1) Respect and civility towards colleagues; 2) Following through on what you promised; and 3) Keeping your word. These characteristics define research managers as professionals. And as the authors say in their book, acting with integrity in all aspects of your life is a hallmark of a Builder.

**Passion.** Another trait of Builders, which is the topic of Chapter 3, is that they possess a “portfolio of passions” that they build their futures around. These are passions that bleed the lines of what is the professional and what is the personal. We see this sort of passion in medical faculty, who became an expert in a field because they wanted to cure a disease. This portfolio need not be large, but it is one that you are drawn to, that taps into your inner being. And, as we all...
know, if we are passionate about our work, it does not seem like work.

**Alignment.** As discussed in Chapter 11, Builders align *meaning, thought, and action*, both professionally and personally, into a lasting engagement (p. 204). If you want success built to last, create a life that matters to you. How can research managers align meaning, thought, and action in the workplace? Balance between the personal and professional is part of the puzzle, but balance is not *The One Thing*. Alignment is more important. Builders create lives which go beyond the traditional societal indicators of power, money, and status.

**Failure.** Builders are not afraid to trip or fail. The key is to rise above tripping or failure and use the experience in a constructive manner toward accomplishment of your passions and goals (p. 129). And when you do fail, don’t deny your emotions. The authors quote Archbishop Desmond Tutu on page 130 of the book: “Emotions are a storm that sweeps through your life.”

**Personal Weaknesses.** Builders embrace their weaknesses and use them in a positive manner, e.g., don’t let them rule/ruin their lives (pp. 146-47). Builders claim that it is your choice whether to be a victim or beneficiary of what there is to harvest from difficult circumstances (p. 159). For research managers, it seems that the message is this: We all have weaknesses in the management of research—but use them in a positive manner so that research is facilitated at your institution. No one in the university environment is perfect—we have to manage our weaknesses in a responsible way and with integrity.

**Luck and Hard Work.** Builders work hard in their professional and personal lives, and their hard work creates serendipity. All endurably successful people have worked hard for the luck that came their way, according to the authors (pp. 168-69). To the authors, goals and plans are necessary to Builders because those goals and plans put Builders into a serendipitous position (p. 169). As we all know, people cannot be lucky all the time, and in general they will not succeed if they do not work hard. In other words, work hard and Lady Luck will find you.

**Naked Conversations.** Naked Conversations are brutally honest conversations, often difficult, that Builders seek out—also called “Creative Contention” in the book by Mike McGavick, former Chairman and CEO of Safeco (p. 188). Naked conversations must be focused on issues, not people, so that people do not become defensive and unwilling to engage in the conversation(s) (p. 192). How can this be applied in the research management context? One clear example is having staff meetings where new and exciting ideas come from such contentious discussions. Would this work in your environment? Would staff accept contentious meetings without becoming defensive?

These themes—integrity, passion, alignment, failure, personal weaknesses, luck and hard work, and naked conversations—are critical ingredients in building enduring success in our professional and personal lives. As research managers, how can we more fully build these themes into our daily work, thus becoming endurably successful research managers?

---

**Appendix A: Success Built to Last Chapters**

Chapter 1: From Great to Lasting—Redefining Success
Chapter 2: Love it or Lose—Passions and the Quest for Meaning
Chapter 3: Portfolio of Passions—It’s Not About Balance
Chapter 4: Why Successful People Stay Successful—Integrity to Meaning
Chapter 5: The Silent Scream—Why It’s So Damn Hard to Do What Matters
Chapter 6: The Cause has Charisma—You Don’t Have to Be Charismatic to Be Successful
Chapter 7: The Tripping Point—Always Make New Mistakes
Chapter 8: Wounds to Wisdom—Trusting Your Weaknesses and Using Your Core Incompetencies
Chapter 9: Earning Your Luck—Preparing for Serendipity by Using Big Hairy Audacious Goals
Chapter 10: Naked Conversations—Harvesting Contention
Chapter 11: Creating Alignment—The Environment Always Wins

---

James Casey is Executive Director of the Office of Grants, Contracts, and Industrial Agreements at The University of Texas at San Antonio (UTSA) and Senior Editor of NCURA Magazine. He is a member of the NCURA Board of Directors and the UIDP Board of Directors. Success Built to Last was originally used as part of the Leadership UTSA Program during the 2011-12 academic year. Dr. Harry Millwater, Chair of the UTSA Department of Mechanical Engineering, and the author reviewed and presented this book to their cohort on March 23, 2012.
Strategies for Successful Implementation

By Hope C. Grant

Any system implementation, including a Conflict of Interest (COI) management system, a financial grants management system, or one of the many others organizations use to manage our research administration enterprise is a very intricate process that can be quite tedious and intimidating to most organizations. An old proverb affirms, “He who fails to plan, plans to fail.” Therefore, the most important phase of implementation begins before you purchase the software. Planning involves strategic planning initiatives as well as a clear understanding of what outcomes are expected from an Electronic Research Administration system (ERA).

As noted in my previous article, Choosing the Best Electronic Research Administration System for your Organization, there is a logical method to distinguish between the perceived and actual benefits of any new system. Organizations should be careful to recognize and carefully evaluate these perceived advantages at the onset. Sorting out the actual benefits from the perceived benefits in the planning phase will be the key to success. Project objectives should be established in this planning stage along with the task of defining the scope of the ERA implementation. In this early stage of planning organizations should map business processes and decide which to keep, as well as, which need to be altered as they move to a new system. Additionally, after researching all alternatives and determining the total costs of the project, organizations should be sure the ERA system selected meets specific goals outlined by executives in the strategic planning process and employs cost efficient practices. If all stakeholders are represented and technical integration is evaluated in the selection phase, it will alleviate unforeseen impediments to ERA implementation success. An initial plan for implementation should be originated during the selection process which can be expanded to include detailed activities and decrease the time dedicated to the action plan discussed below.

Data Management

The data management aspect of implementation can be the most time consuming phase. ERA Software providers can facilitate the upload of data. However, if the data your organization currently maintains is incomplete or inaccurate, it will continue to be incomplete or inaccurate once the data is converted to the new ERA system which will result in 1.) a lack of data integrity, 2.) limited user acceptance of the system and 3.) a long list of cleanup projects to be completed following go-live. It is critical to ensure that the level of the integrity of your data is a high priority prior to conversion. It is also critical to consider how the new system will process your data differently and address those processing issues.

Resources

Financial: With any software implementation, there will be a variety of costs beyond the basic software costs such as maintenance, subscriptions and technological upgrades. Most organizations are working with a small budget to keep costs at a minimum. However, it is important to ensure that the plans include what is needed to support the system.

Technical: Organizations should be aware of the technical capabilities necessary to run the ERA software and assure that these can be met. It is important that operating systems and supporting software applications are current. An organization also needs to ensure that they have the appropriate servers to support the new system. Many software providers require a minimum level of advanced technological hardware before they can begin implementation. It is also important to determine whether other vital software systems can be integrated with the new ERA system (and what will be necessary to accomplish this).

Human: It is often difficult for organizations to determine the appropriate level of human resources to allocate to a system implementation planning and development project because the number of hours and knowledge needed for various roles is difficult to define. Human resources is a critical area. Choose people who are the most knowledgeable about the current business processes and systems. These people should be highly trusted and respected within the organization so that the others involved in the implementation will be comfortable sharing information. It is important to carefully plan the correct level of resources to dedicate. Information to assist in making these human resource decisions can be obtained from outside consultants, the software vendor and/or by talking to other organizations that have completed similar implementations.

Action Plan

The organization needs to determine who will serve as project manager(s) for the planning and implementation of the new system. The project manager can be an employee of the organization or a consultant from the software provider. A team of project managers including one external member and one internal member could be ideal...
providing both an objective view from the external consultant and existing process/organizational knowledge from the internal manager. Additionally, the project team should include representation from all areas of research administration that will interact with the software. The team’s purpose will need to be well defined and communicated to the group including a clear timeline and expectations for each team member. Each member of the project team needs to understand that their role is to ensure that the system can efficiently meet their organization’s needs and that their role is not to rebuild a system that allows them to handle business the same way as they always have.

**Strategic Measures**

Define concrete measurable goals expected from the ERA System using the SMART method (Specific Measurable Attainable Realistic and Timely) and align these goals with strategic priorities. Identify the desired outcomes and quantify what success will look like for your organization. Identify existing problems in the current system and determine how the new ERA system will provide a resolution to these problems. A carefully laid out plan needs to be developed for implementation of the new system. The plan needs to include a timeline with milestones to evaluate progress. The plan needs to address the management of all critical issues including communication, team building and organizational communication. An executive leadership team should be designated for all system implementations to provide high level oversight. The project manager(s) will report back regularly to this executive leadership team. The executive team should meet regularly reviewing project status and ensuring that the project team remains focused on the timeline and all parts of the implementation plan.

**User Oriented**

Begin the implementation process with brainstorming sessions to gather information from end users and educate them of the potential process improvements and/or changes. This form of bilateral communication builds rapport and allows project team members to be involved creating a sense of ownership for each participant. This team building environment will ensure a successful system implementation. Permitting a broad group of users to test the database before going live also confirms that all processes are working properly and the data is accurate as well as advancing user acceptance of the new system. This is also a good time to test the integration with other organizational software to verify that these interdepartmental functions work properly. Prior to going live, training must be provided to all users allowing them to be prepared for the change. For many systems, particularly more complex systems, training should be mandatory prior to allowing a user access to the system. Guides and manuals should also be available for new users.

**Customization**

ERA providers generally have some configuration options available to organizations. Customization is expected to a certain extent but major modifications should be avoided as much as necessary. Modifying the source code is costly, extends the timeline and can cause challenges with future upgrades. Customizations are sometimes done for convenience or to avoid changing old business processes. In order to avoid expensive or inefficient customizations, all customizations should be carefully evaluated to ensure they are necessary, warrant the cost and are the best choice for an efficient new world.

**Change Management**

An open and candid discussion of how process improvements can benefit the organization will ease the transition to the new ERA system. It is important to communicate everyone’s role and responsibilities in the implementation. How will they be involved in planning? What training are they responsible to complete? Positive attitudes go a long way to embrace change within organizations. Focus on the benefits of the new ERA system while realistically noting that change can create challenges and encouraging reciprocal communication throughout the process. Carefully prepare users for the change ensuring that they are well aware of what to expect and when. Change is not easy and this is frequently the area where organizations experience the largest challenge.

**Evaluation**

There should be defined criteria for “go live readiness” prior to going live with the system. After going live with ERA software, evaluation tools should be employed to determine if objectives and goals were met. If goals were properly defined, there should be key measures that can be utilized to confirm success for the ERA System Implementation. If the goals are not achieved, the issues should be revisited to develop a new course of action.

**Summary**

For most system implementations that a research administration organization takes on, other organizations have implemented the same or similar systems. Prior to selecting a software package, talk to other organizations about their experience. Learn from their experience. This can assist you more than any other step with selection, implementation and management of post go-live challenges. Research Administration is a broad field and there is much to be learned from other organization’s experience.

**Hope C. Grant** is a Research Administrator at Clark Atlanta University. Hope has seven years of experience in research administration including pre award, post award and financial compliance. She has been fundamental in electronic research administration matters throughout her career supervising data conversions, system modifications, process assessments as well as training end users. Additionally, Hope is interested in policy development and process improvement. Her current responsibilities include electronic documentation and data management, preaward services, proposal development and organizational strategic planning.

**Bibliography**


Every member of NCURA is in a position to provide leadership at one point or another. Whether we occupy formal positions of leadership by virtue of our title or whether we influence the unfolding of events through our technical knowledge, we will all encounter the feeling that other people are looking to us for direction. And they are looking to us for direction. Your ability to provide that guidance is particularly important when the stakes are high; when the dollars amounts large, when the legal liability is great, when the reputation of your university, your colleagues, and yourself hangs in the balance. And few topics arouse anxiety around these issues like conflict of interest (COI).

Perhaps the researcher sitting before you wants to issue a subcontract to a company in which she is a partner. Or maybe the dean has discovered that a faculty member wants to be paid through a non-profit organization to avoid overhead on a grant. Or perhaps you’ve just gotten a phone call from a company executive who is following up on a memorandum of understanding to conduct research on drug efficacy—oh, and it restricts the faculty from publishing negative results. There are hundreds of possible situations that involve COIs or the perception of a COI.

Throughout this issue of NCURA Magazine you will find good advice for dealing with such conflicts. For the Leadership corner, I’ve opted to devote some time to addressing what you, as a leader, may want to think about regarding this topic and how you may want to communicate. Leadership is primarily about people: our emotions, our thoughts, and our connections to the organizations in which we work.

Emotions

Unfortunately, many of the things we do just to catch people’s attention are aimed at stimulating fear, not allaying it. Consider the classic thought experiment regarding COI: the “front-page test.” We ask each other and ourselves, “What would this situation look like if it on the front page of next week’s Chronicle?” We then reframe the action under consideration in the worst possible light and imagine if it were publicly aired. This is a helpful litmus test for situations in which people are not paying attention to an ethical predicament. However, when people are already thoughtfully engaged with a potential ethical dilemma, the front-page test is likely to send some of your colleagues home to a sleepless night of fretful worry.
So when discussing a topic as sensitive as COI, we should remember that we may trigger the fears and anxieties of other people. When people are scared, they behave in strange ways: they may lose trust in one another, conceal their activities, or become litigious, defensive, arrogant, or otherwise hostile. As a leader, you want to help reduce the level of fear in the individuals around you to a useful level: one where people will pay attention and take appropriate action. So, take the temperature of the situation and adjust your own engagement to help ensure the group is being productive, not just reactive. Your leadership role calls upon you to engage others in converting emotions into helpful activity.

**Thoughts**

Even when rationality isn’t completely thrown out the window, we may still find that people have many misconceptions about COI. They may have formed their opinions through years of careful legal and ethical training or through watching *The Apprentice* last night. They may rely too heavily on their personal experience. And, of course, we all have a tendency to get comfortable with “that’s what everyone does.” But sometimes, what “everyone does” isn’t the right thing to do, as the executives at News Corp have found out with regard to the phone hacking scandal (it makes you wonder if those journalists performed the front-page test, doesn’t it?). But I digress.

Where can we begin guiding and shaping the thought process about potential conflicts of interest? I continue to be amazed at the helpful, productive power of simply invoking your institutional policy and making sure that everyone involved has a copy. Actually reading it and understanding it will put you in an elite group at your university. By steering the thoughts of your faculty and staff colleagues toward written institutional policy, you will have already done much to help them lay aside their fears and begin solving their problems. Most institutions will have mechanisms for identifying and disclosing COIs. Many will have guidance for decision-makers about the kinds of activities that will require additional oversight and scrutiny, and about which activities your organization will and will not engage in. By directing attention toward policy, you also position yourself as a responsible, informed, and fair leader, and you reduce the likelihood of being perceived as the “bad guy” ruining an otherwise great business deal.

But as a leader, you want to help people put their thoughts in a larger context than just your organization’s policies. Help others think through their issues in a national frame of reference by drawing their attention to the policies of the funder themselves. You may refer researchers to the COI policy of the appropriate agency such as the National Science Foundation’s *Grant Policy Manual*, 510 (1); the National Institutes of Health’s *Promoting Objectivity in Research* at Title 42, Code of Federal Regulations, Part 50, Subpart F (2); or the Food and Drug Administration’s *Financial Disclosure by Clinical Investigators* (3). Remind colleagues that their professional organizations may offer training and guidance on ethics and on interpreting such regulations as well. Similarly, you may refer staff and other administrators to NCURA’s training sessions and conferences as reliable sources of current information. The topic of COI, while often new to the PI or other colleagues, aren’t really that new; there is plenty of guidance out there.

**The Organization**

One of the most important aspects of providing leadership is to remind others (and ourselves, at times) that we don’t work in a vacuum; we work within an organization. Too often, particularly at large organizations, individuals feel powerless to effectively address complex issues such as those surrounding ethical issues. In your role, you can help connect individuals with the solutions they seek. You can remind them that within your organization are many talented people who can help identify, manage, and solve problems created by a potential COI.

Sending this message is no small achievement. By helping others to see their organization in the light of competence, compliance, and effectiveness, you will empower others to do their best as well. Look for opportunities to bring people together in a collaborative, productive way. For example, help the chairperson view your internal auditor as a partner in ensuring institutional compliance. Help your faculty view university counsel as an experienced and trained expert on the legal implications of various courses of action. And, equally important, remind the various administrators on campus of the importance, the prestige, the sheer “gee-whiz-ness” of the faculty's research and contribution to their fields. Through your leadership, you can help create a relationship of trust between colleagues and foster an organizational culture of compliance.

When people look to you for leadership, they aren’t always looking for the quick answer or even the best opinion (though that would help). More likely, they want your experience, your knowledge, and your ability to help a group of people work together to solve a problem. This quality is even more important on difficult topics such as COI. So use your skills at managing emotions, helping the best thoughts come to light, and working within the organizational culture to foster a healthy research culture. Remember, your measure as a leader isn’t what you do alone, but what you do together with the whole community.

---

**Resources**

The National Science Foundation’s *Grant Policy Manual*, 510:


The Food and Drug Administration’s *Financial Disclosure by Clinical Investigators*:

http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm119145.htm

---

**Joseph McNicholas, Ph.D., M.B.A., C.R.A.,** serves as the Director of the Office for Research and Sponsored Projects at Loyola Marymount University in Los Angeles. Joseph has worked at Predominately Undergraduate Institutions since he began his career in research administration in 2001. Active in NCURA, he has presented at national and regional conferences and served Region VI in a range of capacities including as Secretary in 2011. He is a proud husband and father of a two-year-old.
Serving Many Masters: Managing Departmental Research Administrators’ Conflicts of Commitment

By Craig Reynolds

Research administrators serve many masters. We are responsible to our faculty, staff, students, institutions, sponsors and the tax-paying public. In a perfect world, the commitments we assume by serving each of these groups would always be in harmony. Unfortunately, but inevitably, having many masters sometimes leads to conflicts of commitment wherein we find ourselves wondering which is the best course of action amongst several seemingly incompatible options. These conflicts are especially acute for the Departmental Research Administrator (DRA), who sits side-by-side with his PI and reports to a Chair who has concerns and interests that extend beyond the research mission of the department.

What’s a DRA to do? Don’t tell anyone in central administration, but the dirty little secret of departmental research administration is that not everything goes “according to Hoyle.” We do our best, no question, but any DRA who claims every funded project in his department is conducted in absolute compliance with all applicable rules and regulations is probably not being entirely forthcoming. Moreover, while it seems that every DRA job posting these days includes a required ability to handle multiple conflicting priorities, no one ever suggests how one might actually accomplish such a juggling act. For the confused, conflicted and job seeking DRA’s of the world, then, I offer a few suggestions on what to do when conflicts of commitment arise.

Suppose, for example, that you overhear a faculty member in your department talking excitedly about the preliminary data her postdoc is collecting in preparation for a new proposal to the National Science Foundation (NSF). You know, however, that the postdoc is actually funded 100% on her National Institutes of Health (NIH) grant. It would appear that the postdoc’s effort is being improperly allocated. There are a number of conflicts of commitment at play here. Above all, you have a commitment to all your “masters” to ensure compliance. At the same time, however, you have a commitment to your PI to enable her research and a commitment to your department to manage and grow funded research activity. What do you do? Look the other way? Call the NIH Program Officer?

The first order of business is to make sure you fully understand what is actually happening. Get the details. Conduct your due diligence, and don’t automatically assume there is in fact a compliance risk to be resolved. Perhaps you misheard your PI or are mistaken about how the postdoc’s effort is currently allocated. In which case, you can happily go about your day — until your next conflict of commitment arises, that is.

If it turns out there is a compliance issue, try to resolve the matter at the local level. Work directly with your PI to set things right and be mindful of her intentions and grant management savvy. Does she even know that anything is amiss? Many times what may seem at first blush to be a flagrant violation is in reality an innocent lack of understanding. Use these opportunities as “teachable moments.” This is your opportunity to engage your PI in a conversation both about the science (it may be the NIH specific aim is showing promise of a spin off into a fundable NSF project) and about effort allocation. Alternatively, you might find that the problem lies not with your PI, but with your department’s or institution’s policies. If so, work to fix them. In either case, you may be surprised at how easily such conflicts can be managed by merely bringing them to the surface.

It’s possible, though, that your PI is still determined to have her way even after the “teachable moment” has occurred. In this scenario, the next order of business is to offer creative alternatives that achieve the same desired outcome. Don’t forget that the DRA’s primary functions are to support the faculty in achieving the goals of their sponsored projects while helping them navigate a complex and frequently unfamiliar (to them) regulatory landscape, and simultaneously helping to maintain institutional eligibility to receive research funding. More often than not, with your administrative expertise you will be able to suggest novel ways to get the same result while remaining compliant. In the example above, perhaps your PI has discretionary funds...
that can be used to support a modest percentage of the postdoc’s effort. If a share of the Facilities and Administrative costs (F&A) is returned to your PI, investigate whether your department is willing to provide some postdoc salary support now in exchange for a share of the PI’s F&A later. Perhaps your university has seed money available to fund pilot projects. The solutions available to you will be as unique as your situation; the key is to leverage your creativity and knowledge of the options for the benefit of your PI, department and institution.

If creative alternatives are not to be found and your PI is intransigent, you must next decide whether to escalate the problem that has given rise to your conflict to a higher authority. Here is where things get complicated fast. Discretion and sound judgment are key, because there are no hard and fast rules, algorithms or decision trees that lead unalterably to the best solution. Nevertheless, there are a few handy principles you can consider.

First, be clear on the relevant departmental, institutional and sponsor policies. They should define what constitutes correct practice and may provide guidance on how to resolve instances of non-compliance. That is to say, determine the regulatory environment in which you are living.

Second, recognize your limits of responsibility and authority. Know that some matters aren’t yours to resolve, that some priorities aren’t yours to set. Don’t make decisions “above your pay grade,” as the saying goes. Otherwise, when you make such decisions and things go wrong, you’ll find that you can be held as responsible as your PI.

Third, seek counsel from trusted DRA’s and colleagues. They may have valuable perspectives or relevant experiences that can help inform your decision. On particularly sensitive matters, they may even be able to serve as an intermediary to call upon a wider network of professionals for advice while maintaining your anonymity. You might also consider having a conversation with a trusted regulatory specialist in central administration regarding a “hypothetical situation.” The specialist can likely share a number of different ways similar problems have been handled in the past and how they turned out.

Fourth, consider what course of action is most fair to your PI. Your decision to escalate should be one of last resort, so give her every opportunity to mend her ways and be explicit about what is at stake if she fails to comply. You may wish to share examples of U.S. Department of Justice fines under the False Claims Act to impress upon your PI the seriousness of the matter and dispel any notion that “it will never happen to me.” And let her know you would be doing her a disservice if you did not bring the situation to her attention. Many an academic career has been derailed by failure to take compliance seriously.

Fifth, finally, and most controversially, consider the cost/benefit of escalation. Weigh the true consequences that failure to act may have for your department and institution. Are you dealing with a package of Post-It notes charged as research supplies or unauthorized use of recombinant DNA molecules in human subjects? Consider the bigger picture.Audit findings can be extrapolated across the university and result in significant fines. Non-compliance can result in revocation of institutional accreditations. Tread carefully here! If you are unsure or uncomfortable with making the call yourself, err on the side of caution, as all good DRA’s do, and escalate the problem.

After mulling over these considerations, inform your PI of your decision. (Note, however, there are some instances when you should not share the decision, e.g., chain of custody concerns in a case of alleged scientific misconduct.) When all is said and done you must still maintain a working relationship with your PI, so strive for open communication regarding your rationale, responsibilities and the conflict you are facing. If you decide the problem does not warrant escalation, lack of communication with your PI only increases the likelihood of the same problem happening again. Nobody wants that. On the other hand, if you do decide to escalate the matter, the first notice your PI receives that there is a problem in his research program should not come in the form of a surprise visit from the Assistant Vice President for Research!

Next, if warranted, escalate your concerns to the appropriate level. Recognize there are matters of degree. Not every problem warrants immediate sponsor notification. Nor can every problem be handled within the department. Your response should be reasoned, appropriate to the regulatory context, made in good faith, and proportionate to the severity of the infraction. Bar any established protocols to the contrary, you should almost always begin with a conversation with your direct supervisor. If you are dealing with a very serious breach of responsible conduct in research and are concerned about potential personal consequences of escalating the conflict, keep in mind that your institution may have a compliance office or hotline through which you can work anonymously.

Simple escalation, however, does not necessarily absolve you from any further responsibility. Seek agreement from the person you entrusted with the information, whether your chair or an institutional official, to report back to you on how the matter was ultimately resolved if they can. You might not be directly involved in the resolution process, but you nevertheless have a duty to all your “masters” to see that the problem from which the conflict arose is addressed and does not happen again. It would be a shame if nothing good ever came from these administrative contortions!

The grim reality of departmental research administration is that we walk a fine line every day, constantly balancing multiple priorities and commitments with the need to get things done, to make things happen, to grease the skids for our PI’s research. Any hope for sanity lies in the DRA’s ability to live comfortably with complexity and ambiguity. Know that some conflicts of commitment can indeed be managed, some can’t be resolved at all, and others require greater institutional resources than can be brought to bear at the departmental level. Take advantage of these resources. And finally, take comfort in the knowledge that “compliance” is not a state of being; it is a process, hopefully ever improving, never fully attainable, but always worth pursuing. [ ]

Craig Reynolds is Chief Administrator of the Department of Biological Chemistry at the University of Michigan Medical School and has been a member of NCURA since 1997. He is a Contributing Editor for NCURA Magazine and has never let a lack of expertise prevent him from pontificating on any number of topics. In this particular instance, he wishes it to be known that the opinions expressed in this article do not reflect those of the University of Michigan or the Department of Biological Chemistry. In fact, if pressed he will deny any knowledge of this article whatsoever.
If it isn’t broken, don’t fix it. This is the way FastLane users may feel when they learn that the National Science Foundation (NSF) is transitioning to Research.gov. After all, FastLane is a popular tool with research administrators, principal investigators, and others who use it to conduct business with NSF.

Since FastLane’s (NSF, 2012) launch in 1994, it has faithfully followed the principle that user feedback and overall benefit to the research community should drive any changes made to the system. Resulting in a site that handily processes more than 50,000 grant proposals every year, and supports many other tasks on behalf of NSF and the projects it funds.
What’s the conflict?

Why the move then to Research.gov (NSF, Research.gov, 2012), the multipurpose website NSF established in 2008? The reasons are numerous and all lead back to the “customer is always right” philosophy. For one thing, FastLane was developed more than 17 years ago — in an age when the features and functionality that we take for granted today did not exist. FastLane itself was a groundbreaking site, and it has worked hard to stay ahead of its users’ needs. Many of the modifications made over the years grew from its users’ changing expectations as to how the site should function and appear. FastLane has kept up with these expectations, but its system architecture is outdated. That means that making changes to it is more expensive and difficult to maintain than the newer technologies and architectures. So, NSF has been faced with a conflict between maintaining the status quo that customers like and changing to a newer system to better meet the customers’ needs.

Research.gov is the solution

NSF needed a new “house” for its modernized grants processing system — one that has flexible system architecture, with the ability to meet users’ changing needs, while handling emerging government requirements. NSF is gradually moving its FastLane functions to Research.gov, allowing time to incorporate user feedback and lessons learned. Eventually, Research.gov will replace FastLane as NSF’s end-to-end award management system.

Research.gov promises the best of both worlds. When the transition is complete, users will perform essential tasks by following virtually the same steps as they do now in FastLane. Financial users, for example, discovered this when they recently began submitting their Federal Financial Reports (FFR) through Research.gov. Although the business processes are the same, Research.gov includes some enhancements that should make the tasks easier. At the same time, Research.gov has the ability to change and grow — and build on the FastLane experience. Some examples include:

Flexible access control. InCommon (InCommon Governance, 2012) participants can request the ability to access Research.gov using passwords issued by their institutions. Single sign-on makes it possible for the user to access FastLane from Research.gov without having to sign in again.

Seamless recognition of your permissions, avoiding the need to login repeatedly. If you have multiple permissions on FastLane and you need to transition from using Sponsored Projects Office (SPO) functions to Financial User functions, you must login again. Not so with Research.gov.

Good “bones” to grow into a site that reflects the ever-changing trends in web use. Research.gov users in the future will be able to customize the site to their specific needs, similar to sites such as Yahoo and Amazon. This adds the ability to adapt more quickly to users’ expectations.

2012: The year of financial functions

Financial users — staff at grantee institutions who handle financial functions as part of grants management — were the first major group to access sponsored projects office (SPO) functions to Financial User functions, you must login again.

Another endeavor that involves financial users is another endeavor that involves financial users is currently under way — the Award Cash Management Service (ACM$). This new payment system will include the grant-by-grant method of handling award payments and associated post-award financial processes. ACM$ will address increased demands from Congress and the Office of Management and Budget (OMB), for more up-to-date and accurate financial information. Deployment of ACM$ is scheduled to occur in 2013.

Clearly, financial users need to stay on top of Research.gov’s developments. Banners at the top of each Research.gov page will deliver the latest news. The NSF Division of Financial Management has already started sending communications about the launch of ACM$ and will continue their campaign until the site is launched.

Project Reports Moving to Research.gov

Even if you are not a financial user, you will still want to keep up with the Research.gov changes coming in 2013 because all final, annual, and interim reporting services on FastLane will transition to Research.gov. Part of this transition includes the implementation of a new reporting format for research and research-related projects, the Research Performance Progress Report (RPPR) (NSF, 2012).

RPPR is the result of a policy-led effort to create greater consistency in administration of federal research awards, an initiative led by the Research Business Models (RBM) Subcommittee of the Committee on Science, a committee of the National Science and Technology Council. One of the RBM Subcommittee’s priority areas is to create greater consistency in the administration of federal research awards through streamlining and standardization of forms and reporting formats. The new reporting format on Research.gov will incorporate more structured collection of the project reports data and include upgraded features such as an option to use rich data text and special characters in report submission.
Do you use Research.gov?  
Making the transition at your institution

Are you still having trouble seeing the need to dive into Research.gov? It is easy to keep using FastLane when you are not required to make the move. But the transition of financial services makes it clear that Research.gov is here to stay.

Do not delay any longer. Here are some pointers to get you started on Research.gov:

**Try it – early and often.** The first step is to bookmark Research.gov and make it your entryway to FastLane. With single sign on, you can access FastLane functionality from Research.gov without logging in twice. Here are a few quick tips for you:

- If you and your organization are already registered in NSF’s FastLane system, you are automatically registered in Research.gov and can log in with your NSF FastLane ID and password. Just select “NSF User” under “Login As” in the upper left corner of any Research.gov page.
- If your organization is already registered in FastLane or Research.gov and you are not, you will need to register as a user. Notify your organization’s Institution Administrator, who can add you as a FastLane user.
- If your organization is not registered in FastLane, the Institution Administrator can register at https://www.fastlane.nsf.gov/a0/about/registration.htm. The Institution Administrator should register as the FastLane Contact. Your institution’s registration information will be available on Research.gov the next day.

**Encourage others to use Research.gov.** You can play a valuable role in preparing your institution for using Research.gov. At this point, everyone involved in grants at your institution – ranging from principal investigators (PI) to administrators – could benefit from using Research.gov. Here are a few reasons why:

- The launch of ACMS could require new business processes and new roles for your accounting department staff.
- PIs will find expanded access to better and more timely financial data.
- Research.gov is the only way to submit a Project Outcomes Report, a reporting requirement that describes how project findings address intellectual merit and its broader impacts as defined in the NSF merit review criteria. PIs must use Research.gov to prepare and submit these reports.
- Another feature available through Research.gov is “Grants Application Status”; it is a website that allows Sponsored Research Offices and PIs to check the status of their NSF grant applications that have been submitted thru FastLane or Grants.gov.
- Also available is “Research Spending & Results,” which provides information on grants funded by NSF and the National Aeronautics and Space Administration (NASA).

**Webinars**

You can take advantage of NSF’s current series of webinars for grantees interested in learning more about Research.gov. Each webinar will review current and upcoming services and tools for the research community. Additionally, NSF offers individual webinars for institutions interested in learning more about Research.gov and its services. Presentations can be customized to the needs of individual institutions and highlight both the public information available through Research.gov, as well as the services available to grantees. Send your request to webinars@research.gov or visit the site for more information.

**Send feedback to Research.gov.** Your input will influence the planned enhancements and prioritized improvements for future releases. There are three ways in which you can provide feedback:

1. Select “Tell Us What You Think” from the left navigation bar and complete the online form.
2. Complete the ForeSee survey, if a pop-up appears while visiting the site. Visitors are randomly selected to participate in a customer satisfaction survey. Your results will be used to improve your website experience.
3. Email your feedback to feedback@research.gov.

---

Mary Santonastasso joined the National Science Foundation in April 2001 as the Director, Division of Grants and Agreements and has been the Director, Division of Institution and Award Support, in the Foundation’s Office of Budget, Finance, and Award Management (BEA), since its establishment in July 2004. Her organizational responsibilities extend to the NSF Policy Office, the Awards System Office, and the Cost Analysis, Audit Resolution, and Post-award Monitoring and Oversight Branch. She is responsible for NSF’s expanded program of post-award, on-site monitoring, and the risk identification and mitigation strategy that is the foundation of this program. In 2007, Ms. Santonastasso received a Presidential Rank Award in recognition of her distinguished executive service.

**Author Note** Correspondence concerning this article should be addressed to:
Katie Simon, Division of Information Systems, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230; email: ksimon@nsf.gov

---

**References**


---

24  
NCURA Magazine
The federal government has long recognized the need to promote objectivity in science when researchers have significant financial interests. Examples abound over the course of history of governmental interventions that have saved the tax-paying public from fates worse than death or multiple viewings of Jersey Shore.

Consider Benjamin Franklin: scientist, founding father, and CEO of American Lightning Rod, Inc. Had the Continental Congress not regulated Franklin’s research, he might never have invented electricity or, worse yet, kept it all to himself for running his printing presses. Then where would we be? Sitting in the dark, listening to crickets chirp, and stubbing our toes every time we got up for a drink—that’s where. Federal regulators were regulating then and haven’t stopped since.

Recent evidence of this zeal to protect the public comes in the form of the August 2011 revision of 42 CFR Part 50 and 45 CFR Part 94. The rationale for this revision of the existing conflict of interest regulations is simple: faculty can’t be trusted. More to the point, according to Cyrus T. Thumbstwiddle, Director of Regulatory Burden Creep of an unnamed federal agency, faculty can’t be trusted as much now as they could be back in 1995 when the original rules were published.

Is this true? Are faculty devious, ill-tempered scoundrels known to happily take candy from babies—especially when the candy is made in factories spun off by the Office of Technology Transfer using their intellectual property? Yes, they may refuse to put their dirty laundry in the hamper and frequently forget to call their mothers on their birthdays, even though there is a phone right there on their desks. Indeed, over the last 17 years it is the rare research administrator who has not witnessed at least one formerly angelic faculty member become a profit-mad scientist bent on world domination and market penetration. Like Donald Trump, except smarter and with better hair.

So what are research administrators to do when torn between remaining true to the regs or becoming conspiratorial henchmen? The answer should be obvious to anyone familiar with the regs (or the fate of every henchman ever filmed). Follow the regulations! Make sure Dr. Evil reports all of his significant financial interests! Remember his consultancy agreements with Big Pharm and the seat his wife holds on the board of his spin-off company of which his son is COO. Don’t forget his numerous business trips to Grand Cayman, Bali, Tahiti, and Switzerland.

And if in your efforts to spoil Dr. Evil’s nefarious plot he should threaten you with his moon-destroying death ray? You have the power to make him regret ever giving you his FastLane username and password. Chances are pretty good they will also work for his anonymous Swiss bank account. Then it will be your turn to disclose some significant financial interests.
It was only fitting that the 13th annual Financial Research Administration (FRA) Conference took place in the middle of Mickey’s magical world in Orlando, Florida this year at the Swan and Dolphin Resort. FRA 13 turned out to be a wonderful experience for all. With almost 900 attendees present and institutions from across the US as well as several foreign countries represented, there was plenty of connecting and networking taking place. The location and weather was great and the conversations were timely and pertinent to the field of financial research administration. Our formula for the conference did indeed achieve success!

The conference kicked off with a successful day of workshops on Monday, March 26th with an opening “Silver Reception” in the evening co-sponsored by one of NCURA’s contributing sponsors, IT Works, who is celebrating their 25th anniversary this year. Then on Tuesday, the attendees got revved up and “switched on” to take in all the concurrent sessions by a lively and energetic keynote speaker, Chip Eichelberger. What followed then were two days of wonderful and informative concurrent sessions and discussion groups. They covered everything from effort reporting and service centers to the proposed reforms to the OMB A-21 circular. The attendees couldn’t get enough of audits, F&A proposal development or cost transfers and subrecipient monitoring. If the topic is vital to financial research administration, FRA 13 delivered a platform for it to be covered.
By Michelle Vazin and Brenda Kavanaugh

As is true for all successful events, it takes many people to make them happen. FRA 13 was possible due to all the hard work and commitment of the FRA 13 Program Committee, the workshop faculty, the concurrent session speakers, the discussion group facilitators, the volunteers and last but not least the wonderful NCURA staff. All of these individuals came together and worked hard to make FRA 13 the outstanding success that it was.

We hope everyone returned to their institutions better informed and equipped to deal with daily challenges and with an expanded network of colleagues to call on for support. Thank you to all who attended and be sure to keep an eye out for upcoming information on FRA 14. You will definitely want to attend to find out what’s hot in financial research administration in 2013! See you there!
Prepare to lead.

Start your research administration career at one of the nation’s leading academic medical centers. Our online Master of Science in Research Administration program will prepare you for leadership roles in all areas of research administration.

Our MSRA program provides:

- Leadership training in specific research administration specialty areas
- Core competencies needed for practice as a research manager
- Tools to understand and excel in key principal areas of research compliance, budgeting, grant management and contract administration
- Experience through investigational research projects suitable for publication in an academic journal

Find your rush. Learn more about Rush University’s Master of Science in Research Administration degree program. Learn more at www.rushu.rush.edu/msra.

The Faculty:
John M. Carfora, Ed.D.
Marianne Rinaldo Woods, Ph.D., J.D.
Kerry Peluso, MBA
Thomas J. Roberts, Ed.D.
Matthew J. Raymond, Ph.D.
Susan Wyatt Sedwick, Ph.D.
As research administrators, we’ve become accustomed to acronyms. So when the Board of Directors gathered in San Antonio, Texas on February 3rd and 4th, it’s not surprising that we embraced a new acronym – SWOT (Strengths, Weaknesses, Opportunities and Threats) – during an in-depth assessment of our organization.

**STRENGTHS**

NCURA’s strength comes from its members and their willingness to volunteer their time and effort to help one another. If you’re new to NCURA, you may already know that our membership is comprised of a community of friends that voluntarily share their knowledge and resources. If you’ve been connected with NCURA for decades, you know that it is regarded as an organization that provides the best value and return on investment in the training and development of research administrators. This would not be possible without NCURA’s member-based governance structure, which enables our organization to remain flexible and adaptive in the face of new challenges and expanding competition.

Another strength is the community culture that permeates the organization. In fact, NCURA is recognized for being a community of communities – we embrace the full breadth of research administration. This enables our members to engage in smaller groups while remaining actively connected to the whole organization. However, one of our greatest strengths is the solid organizational foundation created by the experience, knowledge and stability of the dedicated and creative professional staff in the National Office. Upon this foundation rests the strong leadership within the regions, the national officers and NCURA’s fully-engaged Board of Directors.

**WEAKNESSES AND OPPORTUNITIES**

One of NCURA’s most valued strengths – the volunteer culture created by its members – also represents a potential weakness. As NCURA’s member continues to grow, sustaining our culture of volunteerism will become more difficult. It is essential that we continue to find ways to increase volunteer opportunities to keep the membership engaged for their benefit and the betterment of NCURA. We will be exploring many ideas to strengthen the organization in this respect, including evaluating the creation of pathways that will guide volunteers to the opportunities that are most attractive to them (e.g., presenting, leadership, meeting/activity organizing, etc.).

Technology is an ever-present weakness in organizations; too much or too little can seriously hamper the effectiveness of an organization. Striking the appropriate balance is critical, especially as NCURA continues to grow and making “personal” connections becomes more challenging for our members. We have increased our social media presence – NCURA YouTube Tuesdays are heavily viewed – but we need to advance further into the social space to effectively connect with our membership. We have adopted a renewed approach to technology by actively identifying those tools that will help us “get the job done” and discovering how best to utilize them. NCURA Web and NCURA Collaborate are two new tools that will soon be available to the membership and will play a critical role in building connections and enriching organization-to-member and member-to-member communication at the member, institutional, regional, national and international levels.

**THREATS**

The economy and its impact on members, including shrinking institutional budgets, increasing workloads and less time for professional development is the most immediate threat to NCURA – especially now as NCURA is challenged with sustaining and growing its pool of organizational leaders. Fortunately, NCURA continued to grow during the recession and our growth rate is almost back to the pre-recession rate.

Complacency was recognized as a threat; however, competition from other non-profit and for-profit organizations actually keeps NCURA from becoming complacent and ensures that we stay on the cutting edge of research administration training and professional development. Of course, some threats are associated with competition, such as loss of volunteer capacity to other professional organizations. Likewise, technology was identified as a threat in the context of competition for the attention of NCURA’s volunteers and members. With technology becoming more ubiquitous every day, our training and professional development programs and meetings compete in the same space (physical and electronic) for our members’ attention. This form of competition is also recognized as a challenge and if met in a strategic way can help propel NCURA toward the future.

**SWOT and the Future**

The NCURA community embraces research, research administrators and their institutions. As our organization continues to grow, NCURA and its community-based culture will benefit from continual, objective SWOT analyses over time. Doing so is not just an activity in which only the Board should participate; SWOT analyses should be conducted at all levels of the organization. While the Board represents the broad interests of NCURA and its members, we welcome and encourage input from the membership at SWOT@ncura.edu for those who would like to share their SWOT analysis with the Board.
As a pre-award administrator, your focus right now is likely not on the Department of Health and Human Services (DHHS) revised financial conflict of interest (FCOI) regulations (Promoting Objectivity in Research, 2011). You may feel quite comfortable because there are other administrators or staff at your institution who are taking the lead on the policy and process changes that must be implemented no later than August 24, 2012. But don’t breathe a sigh of relief yet. As with the 1995 FCOI regulations, there are new and newly clarified requirements that will have an impact on pre-award administration. Compliance with the DHHS’s FCOI regulations has always required a certain level of collaboration between the pre-award operations and the FCOI compliance operations; however, with the expanded definition of financial interests that must be disclosed and the addition of other new burdens on applicants and awardees of funds from Public Health Service ("PHS") agencies, it is important for pre-award administrators to understand how the new regulations may impact their role and how they can help ensure compliance with the new regulations.

One of the first things pre-award administrators should be aware of is whether your institution will be applying the new FCOI regulations to all sponsored research, in the same manner, regardless of sponsor. Typically in the research compliance world, there is one FCOI policy modeled after the DHHS’s FCOI regulations (the strictest federal FCOI regulations in existence), applied to all sponsored research (and even all unsponsored research), and your policy would not make distinctions in the disclosure requirements or the processing of financial disclosures based upon sponsor. However, with the increased burdens placed on investigators for disclosing more financial information than previously required (e.g., lowered thresholds, the addition of sponsored/reimbursed travel at a $0 de minimis) and the increased burdens placed on institutions (e.g., sub-recipient compliance and monitoring, retrospective reviews and mitigation plans), many institutions are looking at whether the one policy model still works for them. Some institutions are looking at having multiple FCOI policies that vary depending on sponsor, some institutions are considering one FCOI policy with different thresholds and disclosure requirements depending on sponsor, and yet others think having one FCOI policy but different procedures and processes for PHS-sponsored research is best (my institution falls here). It will be important for pre-award administrators to know their institution’s decision on this point because they will need to know whether the disclosure requirements at proposal time, and all of the other newly expanded upon requirements, apply to every proposal and every contract/award negotiation and whether there will be differences in requirements, processes, or procedures based upon the proposed sponsor.

The revised FCOI regulations, as well as the 1995 regulations, require that all “investigators” who are planning to participate in proposed PHS-sponsored research disclose their significant financial interests to the institution at the time of proposal submission. It has always been an institution’s responsibility at pre-award time to require financial disclosures from all people meeting the definition of “investigator.” The revised FCOI regulations, however, expand upon the definition of “investi-
2 Under the revised FCOI regulation for any financial interest to meet the definition of a “significant financial interest” it must also be related to the investigator’s institutional responsibilities (e.g. research, teaching, service, etc.). There are also several important exclusions to the definition of a significant financial interest, and thus there are financial interests that may meet the threshold values but do not need to be disclosed (e.g., any remuneration or sponsored or reimbursed travel paid by a US Institution of Higher Education or by a US governmental agency).

The FCOI regulations make it clear that, by agreeing to abide by the prime institution’s FCOI policy, the sub-recipient investigators, if they are identified at proposal time, are treated like all other “investigators” and must submit disclosures of significant financial interests to the applicant institution prior to proposal submission. For pre-award administrators, these revisions could mean ensuring not only that your institution’s investigators have disclosed their significant financial interests to the institution prior to proposal submission, but also that sub-recipient investigators, collaborators, and consultants have disclosed their significant financial interests to your institution prior to proposal submission. This will undoubtedly require close contact with sub-recipient investigators, collaborators, and consultants and your institution’s COI staff to ensure that all proper disclosures have been made. Informing your own investigators that you will need to contact those participants outside of your institution to confirm disclosure at proposal time is also a good idea in order to maintain the collaborative working arrangements between your institutional investigators and their research colleagues.

Another major change to the FCOI regulations of concern at pre-award time involves the greatly expanded federal definition of the financial interests that require disclosure as “significant financial interests.” The threshold values that are considered “significant” enough to require disclosure have been lowered for both remuneration and for equity, and there has been a new category, sponsored or reimbursed travel, added to the definition of significant financial interests. Remuneration greater than $5,000 from an entity and equity (e.g., stock) in a publicly traded entity valued at greater than $5,000 requires disclosure as significant (previously the thresholds were $10,000 and/or 5%). And, any amount of equity or ownership ($0 de minimis) in a non-publicly traded entity (e.g. “faculty start-ups,” LLC’s, sole proprietorships, partnerships) requires disclosure as significant. Additionally, for the first time, sponsored travel (travel costs paid directly to the provider) and reimbursed travel of any amount ($0 de minimis) paid by an outside entity must be disclosed as a significant financial interest.2

These expansions on the definition of what is considered a significant financial interest will increase the number and kinds of financial interests that are required to be disclosed to your institution at pre-award time. This, in turn, will increase the burden on your investigators, both inside and outside the institution, in terms of the time and effort they must put into making a financial disclosure at pre-award time. It probably goes without saying, but any additional steps or burdens added to your investigators at proposal time is likely to also increase investigator frustration. While you cannot ease the federally required disclosure requirements for your investigators, being aware of the increased amount of financial interest that is required to be disclosed could help you try to address these new requirements with your investigators early on in the proposal process, so as to help keep frustrations and last-minute disclosures to a minimum.

The revised FCOI regulations have changed in many important respects from the 1995 regulatory requirements. Some of these changes, as I’ve outlined above, will impact pre-award administration. Hopefully you’ll now have a better understanding of them, and, as pre-award administrators, can effectively be part of ensuring institutional compliance with the new regulations.

References:

Debra Thurley, J.D., is an Assistant Director in the Office for Research Protections at The Pennsylvania State University, where she manages the COI Program. Prior to joining Penn State in 2004, Debra practiced administrative and regulatory law in Connecticut and general civil and criminal law in Pennsylvania. She has presented nationally and internationally on the Department of Health and Human Services revised FCOI regulations.
By the time you read this, we will be less than six months away from NCURA’s 54th Annual Meeting, “Honoring Old Traditions and New Beginnings.” The Program Committee has been hard at work putting together a slate of sessions that will meet the professional development needs of NCURA’s diverse constituency. We wanted to share with you highlights from some of the tracks:

New to the annual meeting is the Nonprofit Track, which will be focused on raising awareness of some key strategic issues and challenges facing nonprofits as they engage in partnerships and collaborations with foundations, and other nonprofit and for-profit organizations. As the nonprofit sector grows, the challenges that it faces are also growing. Sessions within this track will explore ideas on promoting sustainability of business relationships and improved effectiveness in partnering. Sessions will also identify the profound cultural differences among various organization types, including analyzing transactional patterns and structures, best practices for effectively partnering with nonprofits and other business entities, and strategies for approaching research agreement negotiations. Sessions will also explore the variety of business goals impacting these relationships.

The Senior Track is primarily intended for those administrators who have policy level authority, or are directly involved in creating or disseminating policy at their institution. The track is comprised of 22 sessions: three Senior Forum sessions, eight concurrent sessions and eleven discussion groups. The Senior Forum sessions (free, advanced registration required) are designed to be highly interactive, with senior administrators sharing views on three topics: new ideas for mining funding opportunities out of the mainstream, maintaining PI relationships, creating a positive work environment, better negotiation techniques, and clinical trial management systems.

and providing administrative support across campus units. Other Senior Track sessions will encompass a wide variety of topics at an “advanced” level, including managing international projects, living non-federal in a federal world, creating effective and innovative teams, and risk/reward at the institutional level.

The Clinical Track is primarily intended for those who work directly with clinical research. Clinical research is extremely important to patients who seek better ways of fighting disease, coping with side effects and to bring quality back into their lives. As administrators, it is our role to partner with physicians and scientists to more quickly identify novel diagnostics, therapeutics and devices and expedite administrative processes in bringing benefits to patients. Topics will include best practices in clinical trials offices, maintaining PI relationships, creating a positive work environment, better negotiation techniques, and clinical trial management systems.
Most researchers are aware of the compliance issues that affect their research directly, and only dimly aware of any others. And this is probably as it should be. After all, it would be a rare project indeed that implicated all of the following: animal subjects, human subjects, stem cells, select agents, radioisotopes, foreign national restrictions, and financial conflicts of interest. Yet while few researchers are affected by all compliance areas, almost all researchers are affected by one or more of them. Compliance is an area that spans both pre-award and post-award. An understanding of these issues is critical to our ability to protect our researchers, our subjects, and our institutional reputations, and the goal of the Compliance Track will be to ensure that you have the tools necessary to address these needs.

The Human Capital Track will offer concurrent and discussion sessions looking at a wide range of issues from successful mentoring to effective use of social media. Sessions will examine the challenges of working full time while pursuing a master’s degree; how both our workplaces and workforce are changing; how to write for NCURA publications; and team building. This year will also feature something new — the NCURA Book Club. If interested, your summer reading assignments are: The Five Dysfunctions of a Team: A Leadership Fable by Patrick Lencioni (concurrent session) and/or Drive: The Surprising Truth about What Motivates Us by Daniel H. Pink, NCURA’s 2010 keynote speaker (discussion group).

The Pre-Award Track is continuing with many of the traditional topics such as A-21, subawards, and funding for the humanities, however, with a little twist. For example, instead of Post-Award for Pre-Award, a session will be added to address Department Administration for Pre- and Post-Award. This session will provide an overview of research administration from the department perspective, giving central administrators a view from the very beginning of the process. An additional offering will specifically relate to industry contracting; another will session will focus on how to Review a Proposal Budget for those new to the profession. This is only a sneak peek, so stay tuned for more offerings for both the very new and the more experienced Pre-Award research administrators.

The Post-award Track will continue to cover the necessary topics surrounding post award activities but will also take folks in new directions covering areas such as the following three session titles: NCURA meets HBR – Discussion groups focused on research administration case studies; Implementing Best Practices – Tools, Policies and Processes; and How do we make that happen? - Getting your system to do what you need it to do.

Embracing the AM54 theme, the Departmental Track is designed to honor old traditions while embracing new ones. Recognizing the balancing act all Departmental Administrators must manage, the topic areas are designed to provide practical tips and up-to-the-minute views on time honored issues and concerns of the Departmental Administrator. With everything from a primer on budgeting, to a Town Hall on coping with faculty personalities, to a discussion group on managing both sponsored and non-sponsored funds, the Departmental track highlights the unique role that the Departmental Administrator plays within research administration.

The Predominately Undergraduate Institution (PUI) Track is designed for those working in colleges and universities that focus primarily on educating undergraduate and master’s students. Research administrators at PUIs tend to wear many hats and encounter challenges unique to less research-intensive environments. Topics will include managing compliance without a compliance officer, starting a sponsored programs office, developing staff, effort-reporting at PUIs, post-award issues at PUIs, and strategies for strengthening faculty competitiveness.

We are very excited about this year’s International Track. As in the past, we will we be offering sessions that cater to U.S. members’ needs for ever-increasing information on the complexity of international issues. And, in keeping with NCURA’s expanding international presence, we will be including more sessions targeted for and led by international members. For example, planned sessions include International Subcontracting, Risk Management and International Research, International Research Funding Sources and NIH for the International Research Institution.

The Federal Track is back and better than ever. In addition to traditional highly valued offerings such as the NIH Update and the NSF Update, we will be offering an in-depth look at the status and plans for reform of the OMB Circulars; the status of the DATA Act; the latest deployment plans for the Research Performance Progress Report; and STAR Metrics. In addition, we’ll expand agency-focused sessions this year to include updates from USDA, DOD, and Homeland Security.

These are but a few of the 54th Annual Meeting offerings that are designed to help any attendee, new or seasoned in the field of research administration, bring back new-found knowledge and skills immediately upon their return to their institutions. Please look for registration to begin in mid June.
How Collaborate.NCURA Network Works for You

What’s in it for me?

- Stay up-to-date in your areas of interest by joining topical Collaborate Communities. The 7 Communities are Pre Award, Compliance, Predominantly Undergraduate, Financial, eRA, International and Departmental Administration.
- Find colleagues quickly in the directory and start a conversation.
- Locate NCURA members with common interests in the networks section.

How will Collaborate help us support research together?

- Share your institution’s best practices and resources with other members.
- Stay ahead of the curve in by collaborating and conversing with members.
- Tap into new resources or create connections between your institution and others.
- Through resource sharing and collaboration, we support research together!

Get Connected Today!!

1. Login at http://Collaborate.NCURA.edu/Home, using your NCURA member ID and password. NCURA membership is required to access the network.

2. Complete your profile. Your colleagues will want to know a little bit about you. Share something about yourself and upload your photo.

3. Join a Collaborate Community. Keep up with conversations on the topics of your choice. Go to Communities, then All Communities. Select the communities you want to join.

4. Post a message. Got a question? Your colleagues have the answer! Go to Discussions, then Post a Message to send a message to your colleagues in your communities.

5. Collaborate. When you find something useful on the site, we hope you will share something of your own! You might even ask colleagues for feedback on your work. To share a document, go to Resources, then Add Document.

Have a Question?

Contact: Stephanie Moore, Community Curator
Email: moore@NCURA.edu
Phone: (202) 466-3894
Twitter: @NCURA
Facebook: www.facebook.com/ncura1959
Video tutorials available at: www.youtube.com/ncura1959
Estimates show that by 2035, one in five Americans will be age 65 or older—but is society ready to meet the needs and desires of this aging population? This phenomenon is occurring in the U.S., Europe, Japan, and other parts of world, leading the National Academies' Government-University-Industry Research Roundtable (GUIRR) to devote its most recent meeting to exploring the challenges and opportunities presented by aging populations.

As people live longer, the incidence of diseases associated with aging is increasing, including chronic diseases that require continuing care. Overall demand on health and other care services is increasing, potentially outpacing providers unless measures are taken to address the additional need. Aging can also mean changes in physical abilities, making it challenging for seniors to do even ordinary tasks. As mobility declines with aging, GUIRR members discussed how robots, infrastructure improvements like handicap-accessible sidewalks, and other tools can be designed to allow seniors to retain their independence for a greater amount of time. Finding ways to motivate people to take measures to maintain better health will be crucial to keeping medical costs down as the population ages.

In the U.S. specifically, the pace of aging brings significant fiscal challenges as federal retirement and health benefits will nearly double as baby boomers retire. Measures like increasing the eligibility age or reducing benefits may be needed, but such steps are liable to face resistance from an aging electorate. Further, slowing growth in the working age population will likely translate into slower economic growth.

On the other hand, there are seniors who have the energy and drive to continue making contributions to society through work, volunteering, and family time. This trend prompted dialogue about considering changes to institutions that would give people more work schedule flexibility, allowing more seniors to engage in part-time work but also for employees to work an alternative schedule so they can provide care to the elderly in their families. Many seniors also have financial resources that they can use to invest in opportunities for travel, education, and other endeavors that bolster the economy.

Despite acknowledgment of the aging population, there has not been much dialogue about how to address this development on a global level. GUIRR members talked about how the aging issues raised during this meeting need to be taken up by decision makers in other conversations. All three GUIRR sectors stand to play a role in addressing the challenges and opportunities presented, be it from policy development to conducting research to product development.

For a more expansive written recap of the February 28-29, 2012 GUIRR meeting and access to the various guest presentations, visit the GUIRR website at www.nas.edu/guirr under “Past Meetings.” All online presentations are posted with the speakers’ permission.

Katie Kalinowski is a Senior Program Associate supporting the Government-University-Industry Research Roundtable (GUIRR) and the University-Industry Demonstration Partnership (UIDP) at the National Academies. Prior to joining the Academies in 2012, Ms. Kalinowski analyzed green power and climate change issues for the Renewable Northwest Project and she facilitated the National Wind Coordinating Collaborative, a national forum on wind power development, at RESOLVE. She served as a U.S. Peace Corps volunteer in Macedonia from 2009-2011. She holds a master’s degree in Economics from North Carolina State University and a B.S. in Natural Resource and Environmental Economics from the University of Nebraska-Lincoln.
Competition has been shown to be useful up to a certain point and no further, but cooperation, which is the thing we must strive for today, begins where competition leaves off.

Franklin D. Roosevelt

International relations between the U.S. and Europe have a long history and are backed by several Declarations and Agreements. After years of competition the U.S. is more than willing to cooperate with the rest of the world, especially with Europe. Half of the world’s GDP and one third of world’s trade are created by EU-US transatlantic cooperation. In order to tackle global societal challenges transatlantic S&T cooperation has to play a stronger role. The Seventh European Framework Programme (FP7), which will be replaced by ‘Horizon 2020’ in 2014, is encouraging transatlantic S&T teams to submit joint research proposals. European project consortia with U.S. participation have higher success rates and U.S. partners are provided partial funding for such proposals.

EU–U.S.: Competition or Cooperation?
The first formal cooperation between the EU and the U.S. in the area of S&T cooperation took place in 1990 with the Transatlantic Declaration. In 1995 the New Transatlantic Agenda provided the foundation for this relationship.

Cooperation in competition matters has been taking place for 20 years, regulated by the EU/US Competition Cooperation Agreement of 1991, which foresees, among other aspects, regular exchange of information on current enforcement activities and priorities, on policy regulations and other matters of mutual interest. The EU/U.S. Positive Comity Agreement followed in 1998 and the Administrative Arrangement on Attendance in 1999. In 2002 the EU and the United States agreed on best practices on cooperation in merger cases which were updated and revised in 2011.

As recognition that science and technology contribute significantly to economic growth and quality of life, the EU and the U.S. concluded a Science and Technology Cooperation Agreement in 1998 which was renewed in 2004 underlying the importance of the on-going transatlantic research dialogue. Transatlantic research cooperation is one piece of many within the Seventh Framework Programme for Research and Technological Development, the European Union’s main instrument for funding research. It is nevertheless an important one. Although FP7 will come to an end in 2013, the last round of Calls to be opened in July 2012 is said to become the most significant for bridging the gap to the next Framework Programme for Research and Technological Development, Horizon 2020, which will start in 2014 and end in 2020.

The ‘Cooperation’ Programme in FP7

The European Framework Programme represents only a small portion of total R&D investment in Europe, but it is a key element in providing a basis for strategic coordination and cooperation and therefore better utilization of resources. FP7 is structured into four so-called Specific Programmes which reflect the four major areas that...
are being funded by FP7. Cooperation among researchers is funded within the ‘Cooperation’ Programme and excellent ideas are funded in the ‘Ideas’ Programme from the European Research Council. Carrier development and mobility of researchers is funded in the ‘People’ Programme and the building of different research capacities is funded in the ‘Capacities’ Programme.

With more resources than in the previous Framework Programme (FP6) and more open to international cooperation, FP7 was and is open for U.S. partners throughout all research topics of the Specific Programme ‘Cooperation,’ supporting all types of research activities carried out by different research bodies in trans-national cooperation. The ‘Cooperation’ Programme is sub-divided into ten distinct themes, reflecting the most important fields of knowledge and technology where research excellence is particularly important to improve the ability to address social, economic, public health, environmental and industrial challenges of the future.

The ‘Cooperation’ Programme, together with the ‘People’ Programme, so far has been the most attractive for U.S. organisations joining research activities within FP7. U.S. participation in the Cooperation Programme was dominated by higher education Institutions, totalling 61.4% of all proposals. From January 2007 to December 2010 a total number of 1,118 U.S. organisations have been included in the submission of 868 proposals, with a success rate of 19.2% involving 215 U.S. participants.

The thematic distribution of U.S. participation in FP7 shows that almost one third of EU-U.S. cooperation in FP7 takes place in health research. Since 2008, the U.S. National Institutes of Health (NIH) and FP7 have offered reciprocal opportunities for participation and funding aimed at fostering transatlantic research cooperation in health and smarter competition in science. Setting an example for research cooperation in other areas of research, pursuing mutual interests in S&T cooperation needs a strategic orientation and pragmatic steps.

**Transatlantic S&T Cooperation Wanted Now**

Although the international dimension of FP7 laid the groundwork for increasing U.S. participation, it is still low and there is a huge potential for improvement. An important structural difference that could be an obstacle to a complete understanding of Framework Programmes and their importance is that in the U.S. research is directed mainly by a principal investigator (PI). Cooperation is usually not a required component in U.S. funding, meaning that funding is mainly given to individuals and not to teams. This is very different compared to the Framework Programmes. Additional efforts are needed to create greater awareness in the U.S. of opportunities for EU-U.S. S&T cooperation within FP7.

There are many reasons why U.S. researchers should participate in the last round of FP7 Calls to be open as of July 2012, but the following seven would persuade most researchers:

1. **Funding Budget is High** The last round of FP7 Calls will become the largest ever with respect to available funds. In general, the EU budget for U.S. researchers is accessible if certain conditions are met.

2. **Transatlantic Cooperation is Stimulated** Collaborative research is encouraged within FP7 aiming at establishing excellent research projects and networks able to attract researchers and investments. Tackling global challenges and addressing more ambitious problems become easier through international cooperation where mutual interest exists. Clear provisions foreseeing the integration of entities established in the U.S. may be included in the work programme/call for proposals, such as the upcoming work programme in Health or Socio-economic Sciences and Humanities.

3. **Participation in FP7 is Simple** Participation for U.S. partners in FP7 research consortia is simple. The role of European research project coordinators is to guide partners, support them during the project proposal phase, and to manage
the project during project life cycle. In addition, the Participant Portal has become the European Commission’s single authoritative website for the publication of FP7 calls, organisation registration, all project related services and all FP7 related legal and guidance documents.

**4. Timing is Good** Now is the best time to reactivate research networks, reshape research ideas and get started: the last round of FP7 Calls opens in July 2012. It offers a good opportunity for U.S. researchers to secure partial funding of their research by FP7. The new Science, Technology and Innovation Programme, Horizon 2020, will start in January 2014 creating a gap between the two research funding programmes.

**5. Re-submission is Encouraged** It is common that most research project proposals become successful when being submitted the second or third time! Re-submission of proposals is encouraged by the European Commission giving the research consortium enough time to complete, review and adapt the research project proposal to the current work programme. It is fact that project consortia with U.S. participation have a higher success rate!

**6. Established European Networks are available** During the lifetime of FP7, numerous European Networks have been established and a number of research consortia have been dealing with research on European scale and several teams have been successful. Finding an existing research consortium is easier than ever! The European Commission also offers online partner search services.

**7. BILAT-USA and Link2US are supportive** The projects BILAT-USA and Link2US, funded by the EC under FP7, support the enhancement and development of transatlantic S&T partnerships. All relevant services and information offered can be found under [www.EuUsScienceTechnology.eu](http://www.EuUsScienceTechnology.eu)

One does not have to believe that transatlantic cooperation under FP7 per se is easy. One cannot deny the distance, and cooperation needs team spirit. One has to become very familiar with the participation rules and administrative procedures of FP7. Here the European research consortium plays an important role which gives support and guidance to U.S. partners. When asking U.S. partners in FP7 research consortia what the main reasons for their transatlantic cooperation are, they mostly cite the establishment of a wider cooperation network, access to specific expertise, and improvement of scientific excellence. This sounds worth an experiment!

---

**Elli Tzatzanis-Stepanovic** is an FP7 Senior Expert in International Cooperation at the Austrian Research Promotion Agency (FFG). She is Project Manager of the FP7 project BILAT-USA, which together with the complementary project Link2US aims to raise awareness towards EU-US S&T cooperation.

---

**References:**


BILAT-USA Analysis of Existing Instruments, Regulations and Obstacles for U.S. participation in FP7 (2011).


---

1 Based on contracts signed.

2 KBBE=Knowledge Based Bio Economy, ICT=Information and Communications Technology, NMP=Nanotechnologies, Materials and new Production Technologies, SSH=Socio-economic Sciences and Humanities.
Is your institution BETTER by having an NCURA Peer Review?

When you have an NCURA Peer Review,
- you are not hiring just anyone to review your sponsored program operation
- you are not receiving a report that recommends high priced costs for training and process improvement
- you are not relying on a single individual with a single perspective

With an NCURA Peer Review,
- you ARE engaging with a program created by senior research administrators that will review your sponsored program operations through an integrated package of National Standards for research administration, expertise, and consistency in approach
- you ARE working with nationally recognized research administrators who serve as reviewers and who know best practices and multiple models for organizing sponsored program operations and creating effective services
- you ARE benefitting from a Team, both on- and off-site, that works collectively to explore and review your programmatic areas and to present you with solid, practical, and useful information
- you ARE making an investment in your research administration by working with a national program that will provide you with a roadmap for strengthening and benchmarking your operations

YES!

E-mail or call for a price quote to have a peer review at your institution or for questions or further information. Contact peerreview@ncura.edu or call: (503) 364-1847. www.ncura.edu/content/peer_to_peer_review/
The revised National Institutes of Health (NIH) Financial Conflict of Interest (FCOI) regulation modifies the requirements of the earlier 1995 FCOI regulation in a number of important areas. All organizations receiving NIH funding must have an implementation plan in place to comply with the new requirements no later than August 24, 2012. It is an issue that is surely top-of-mind for research administrators.

Recently, the NCURA Pre-Award Neighborhood (PAN) Committee “sat down” with Gunta Liders, the Associate Vice President for Research Administration at the University of Rochester. We wanted to learn more about her institution’s experience in developing their FCOI implementation plan.

NCURA: Implementing an NIH FCOI compliance program is certainly a complicated process. What offices have you involved in the review and implementation of the NIH FCOI regulation? Have you used outside consultants?

GL: Wow, who haven’t we involved! At UR, the Deans of the various schools and colleges are responsible for the administration of our FCOI policy. Thus far, we have involved the Dean’s offices, the COI Committees, IT staff, faculty groups, departmental research administrator groups, central research administration and others. With all the folks we’ve involved, we have a great base of in-house expertise, so we have not used consultants.

NCURA: So, getting down to business, have you updated your existing FCOI policy or developed a separate policy for the NIH FCOI?

GL: We have updated our current policy which applies to financial interests and significant financial interests regardless of funding source. However, we have designated a couple “carve-outs” for PHS investigators (e.g., disclosure of sponsored or reimbursed travel).

NCURA: Sounds like you’re ready for prime time. Have you already released this, or when do you plan to implement this?

GL: We are still in the approval stages of our revised policy, and do not plan to implement until August 2012.

NCURA: Putting together a plan will tap a lot of folks, but the finished product will need to be communicated to an even broader audience. How do you plan to get the word out?

GL: We began to communicate the changes in the PHS FCOI regulations in November 2011 – starting with our COI Committees. Since then, we have communicated both the changes and our possible implementation plans to faculty groups, administrative and study coordinator groups.
NCURA: What about training? Have you developed your training plan yet, or can you share any details on how you plan to address the training requirement?

GL: We will roll out the educational program to PHS investigators first. We will probably require FCOI training for all investigators, but this still needs vetting and approval.

NCURA: It will be a big job. Have you looked into a comprehensive IT or systems solution to handle training, or will it be handled by in-person training?

GL: We will be providing education on BlackBoard which is a web-based (with audio) tool. We also plan on providing CME credit for our physicians that are required to take the course.

NCURA: Since training will be required prior to engaging in PHS funded research and every four years thereafter, how does your institution plan to track compliance?

GL: The nice thing about BlackBoard is that it tracks required education in the HR system.

NCURA: Even with systems support, the monitoring component for training is significant. At Rochester, will there be an individual responsible for monitoring training compliance, initial and every-4-year renewal? Will they be responsible for following up with individuals who do not complete training on schedule?

GL: I envision that we will determine whether an investigator has complied with the training requirements as we do now with our educational programs for human subjects research – validated and confirmed at time of proposal and/or award by sponsored programs staff. Research may not be initiated until the training requirements are satisfied. I envision that all our investigators will take the training in a timely basis!

NCURA: What about access? How does your institution plan to address the public accessibility requirement for both the institution’s FCOI policy and for individual investigators’ disclosures?

GL: At this point, we do not plan on implementing a publicly accessible web site. As a shorter-term solution, we will provide the required information on request. We may investigate other options in the future, such as a web application to receive and process information requests.

NCURA: Complying with FCOI is a major undertaking which will require a large commitment of staff time to complete. Will the expanded reporting requirements (and the potential need to respond to requests from the public) require your institution to hire additional personnel specifically for Conflict of Interest?

GL: Our COI administration is a collaborative effort among the Dean’s offices, legal counsel, sponsored programs, IRB and hospital staff (for the identification and management of COIs related to clinical care). At this point, it is unclear whether we will be able to hire an additional FTE. (I hope so!). This new FTE, if approved, will assist in all aspects of COI administration, not just related to research.

NCURA: Compliance with FCOI will impact current grant processes. Will the annual disclosure requirement for investigators require procedural changes at your institution? Will you perform additional certification steps at the proposal stage? If so, how will they differ from your current processes?

GL: Of course, the disclosure questions will need to be modified, however we are fortunate because our schools/colleges that receive PHS funding have implemented electronic systems. We hope that we can use our electronic systems to update annual disclosures of outside interests (versus completing the full-blown electronic form).

NCURA: How is your institution adapting or updating practices and processes to accommodate flow-down requirements for subrecipients at pre-award and/or post-award stages?

GL: This is a difficult issue to work through. We already require our subrecipients to certify that they have a FCOI policy that conforms to the PHS regulations or to adopt our policy. However, now that PHS has clarified the requirements of prime awardees for those sub-recipients that do not have a compliant FCOI policy, the reality is really daunting. I worry (especially) about how our foreign research collaborations will be impacted by this requirement. My hope is that we can work with the Federal Demonstration Partnership and NIH to explore solutions that won’t negatively impact collaborative and international research endeavors.

NCURA: Do you know how you will manage the travel aspect of the regulation?

GL: We will implement this requirement for PHS investigators only. The travel disclosures will be collected in a separate “form” in our electronic systems. We will probably take advantage of the information noted in the NIH FAQ’s and determine that disclosure of travel sponsored or reimbursed by certain entities will require not further institutional review (e.g., professional societies, university associations, voluntary health associations, etc.).

NCURA: If there were anything you could do differently with your own institution’s response what would it be?

GL: We have a very collaborative environment at the UR, and I am confident that we will implement a policy and processes that are compliant to the PHS regulations, yet are sensitive to the significant regulator burden that will need to undertaken by our investigators, research staff, Dean’s offices and COI committees.

NCURA: Do you have any parting advice for institutions that are still working their way through this issue?

GL: We are all in this together. My best advice is to network with other universities and colleges that are “like you” and brainstorm on solutions to implementing the PHS regulations. There is no one “right” way, and you need to find a solution that works for your university, your processes and your culture.

NCURA: Thanks so much for sharing your thoughts and experience. This information will be a great help for the research administration community.

GL: You’re most welcome!
“Steering a Course for Success”

Region I (New England) is gearing up for our Spring Meeting, which will be held on May 6-9 at the Marriott Hotel, located on the waterfront in beautiful Newport, Rhode Island. The preliminary program was released and early bird registration was opened on March 27th. We start with four workshops on Sunday, May 6 and we offer more than 40 sessions on Monday through Wednesday, including five sessions led by Federal agency representatives from NIH, NSF and ONR. In addition to highly informative sessions, we will have a variety of networking opportunities, including a Tuesday night dinner celebration at the Newport Yachting Center. Chair-Elect Karen Woodward Massey (Harvard U) and her Program Committee Co-Chairs, Michelle Auerbach (Suffolk U) and Kris Monahan (Providence College), have done an exceptional job planning an extraordinary meeting in a wonderful location. I hope to see you all in Newport!

Research Administrators Discussion Group (RADG) Update

The March RADG meeting was very successful and attracted nearly 150 attendees with a presentation on “Managing International Projects.” An experienced panel consisting of Norm Hebert (Brown U), Connie Galanis (Consultant), and Jennifer Donais (University of Massachusetts Amherst), provided information on the perils of international research and gave practical advice to reduce risk. The June 20th RADG meeting will focus on “Finding non-Federal Funding from Foundations and Philanthropies,” a timely topic considering the uncertainties we are facing with respect to future federal funding for research. Plans are underway for the September 26th RADG meeting on “Service Centers” and the December 11th meeting with a “Federal Update” and end-of-the-year gala. Please save these dates for 2012 RADG meetings.

Nominating Committee Update

This year Region I will be electing a new Secretary along with the Chair-Elect and Treasurer-Elect. The Nominating Committee, Chaired by Susan Zipkin (Brigham and Women’s Hospital), has been meeting to discuss potential nominee’s for these positions, and members of the Committee will be reaching out to nominated individuals in the coming weeks to confirm their interest in running for office. I strongly encourage you to nominate a fellow NCURA colleague for an Officer position, or to consider a self-nomination. The Nominating Committee plans to have the ballot out in early June in order to enable our members to cast their votes prior to their summer vacations. We hope to announce our new Officers by August 1st.

Congratulations!

Lincoln Lawrence from Dana Farber Cancer Institute was the recipient of a Region I Travel Award to the NCURA FRA Conference in Orlando Florida in March.

Arlenis Perez Dushku from Children’s Hospital Boston has been selected for a NCURA National Catherine Core Minority Travel Award to attend the 2012 NCURA Annual Meeting in Washington DC in November.

Finally, it is my great pleasure to congratulate my close friend and valued colleague, Franc Lemire, who has been chosen as a recipient of NCURA’s prestigious Distinguished Service Award. A former Region I Chair and Treasurer, Franc has been active in NCURA at the national and regional levels for more than twenty five years and has made substantial contributions to our professional development programming, as well as participating in NCURA governance and committee work. Franc will receive this well deserved honor at the Annual Meeting in November. I hope you will extend your personal thank you and congratulations to Franc for his exemplary service to NCURA.

Patrick (Pat) Fitzgerald is the Chair of Region I and serves as the Associate Dean for Research Administration for the Faculty of Arts and Sciences (FAS), Harvard University.
teers for the region; I would like to congratulate them on receiving this wonderful recognition award. Another significant highlight was our mentoring program which paired some “new bees” with our “veterans” to gain firsthand experience as to how our spring meeting operates, as well as a variety of sponsored programs insight. Thanks to those who took part in this year’s program.

There is a lot of buzz in the air for upcoming summer plans, as we are preparing for our second One Day Traveling Workshop. Date and location will be determined soon, so make sure that you’re on the lookout for the e-blast, as well as to check the Region II website http://ncuraregionii.org/home/ for announcements and updates. We are very excited to host this workshop based on how well our first workshop in February was received. We were expecting it to be a home run; however, it was a grand slam! You won’t want to miss it.

Aside from our Region II website we are also on Facebook; so look for NCURA Region II and “Like” the page.

Until next time…

Jared Littman is Chair of Region II and serves as the Director of the Office of Grants and Sponsored Research at St. John’s University.

REGION III
Southeast

www.ncuraregioniii.com

https://www.facebook.com/groups/192985387430137

By the time you are reading this, we hope you have already thoroughly enjoyed, or regret not attending, the Region III Spring 2012 meeting in Panama City Beach, Florida. At the time this article was being written, plans were in place to again offer a valuable opportunity for our members to increase their Knowledge, KnowHow and KnowWho (our meeting theme). The successful development of our excellent program is all due to the hard work of this year’s program committee: Pat Green, Vanderbilt University; April Heyward, University of South Carolina; Laura Leibetter, Kennesaw State University; Tanta Myles, The University of Alabama; Velera Pate, Georgia Institute of Technology; Cathy Snyder, Vanderbilt University; Jill Frazier Tinch, University of Miami; Cindy White, Belmont University (retired); and Pam Whitlock, University of North Carolina Wilmington (retired). The program committee, in turn, could not have been so successful if it were not for the workshop faculty, session presenters and discussion facilitators who agreed to share their knowledge and expertise. We would also be unable to manage this large event without our generous volunteers, led again this year by Robyn Remotigue, Mississippi State University. Special thanks is also due to Erica Gambrell, The University of Alabama, who not only had to manage the duties of Treasurer (which are not insubstantial) but also, generously, took charge of every job, large and small, that came to her attention. A big “Thank You” to everyone who contributed to make this one of the biggest and best (and that is saying a lot!) Region III meetings ever!

Region III Travel Award Winners

Congratulations to Karen Fletcher, Coastal Carolina University, and Rachel Wurth, Bellarmine University for receiving $1,000 travel awards to the spring meeting in Panama City Beach.

Catherine Core Minority Travel Award Winner

Congratulations to Latica Jones, University of Memphis, for receiving one of the Catherine Core Minority Travel Awards. This award is in support of her participation in NCURA’s 54th Annual Meeting, November 4-7, 2012, in Washington, DC.

Dhanonjoy C. Saha, Ph.D. and Bill Lambert serve as Region III’s regional corner contributors. Dr. Saha is Assistant V.P. of Research Administration & Operations at Carolinas Medical Center. Bill is the Assistant Dean for Research Administration at Emory University.

REGION IV
Mid-America

www.ncuraregioniv.com

Spring has sprung earlier than normal in many of our Midwest States. I trust you all are enjoying the warmer outdoor weather, bright sunshine, flowers blooming, etc...

Many Region IV activities have also sprung earlier than normal. Our 2012 Spring meeting will be held on April 14-18, 2012 in St. Louis, MO. This is a joint meeting with the folks from Region V (Texas/Oklahoma). The St. Louis Ballpark Hilton is the conference hotel. This is a great venue and we have an exciting program that aligns the research administration and professional development needs of both Region IV and Region V. More information can be found at: http://www.ncuraregioniv.com/conferences.html

The Program Committee has been working very hard on the 2012 Joint Spring Meeting. Jeff Ritchie, Region IV Chair Elect, is responsible for organizing and planning the meeting for us. He’s been working with our Region V counterparts. If you have any questions, please contact Jeff at: jeffrey.ritchie@yahoo.com

Please also visit us at: http://www.ncuraregioniv.com/ for more information on the Region happenings. The Region has been working on some other exciting initiatives. You may have seen email blasts about these: 2014 Spring Meeting Site Selection, 2012 Regional Awards, 2012 Regional Nominations and 2012 Joint Spring Meeting.

Also, at the conclusion of the Spring Meeting, there will be openings for Committee Chair positions. If you are interested in these, please contact Jeff at: jeffrey.ritchie@yahoo.com or contact the current list of Committee Chairs for more information.

Awards Committee Chair: Elena Cruse, University of Kansas Medical Center
Communications Chair: Sue Kelch, University of Michigan
Membership Committee Chair: Sheila Lischwe, Saint Louis University
Nominations Committee Chair: Christa Johnson, Johnson, Washington University
Site Selection Chair: Michelle Ginavan-Hayes, University of Kansas Center for Research
Site Selection Member: Natalie Goodwin-Frank, Washington University
Volunteer Coordinator: Debbie Meltzer, University of Wisconsin-Madison

See you in St. Louis!

David Ngo is the Chair if Region IV and serves as Managing Officer at the University of Wisconsin-Madison.

**Election Results:** The Region V election results are in and I am pleased to announce the following results:

Vice-Chair/Chair Elect (term began immediately following the regional meeting in St. Louis): Scott Davis, University of Oklahoma Health Sciences Center.
Treasurer (term begins January 1, 2013): Brenda Garner, University of Texas Medical Branch at Galveston
Ad Hoc Members (term begins January 1, 2013): Shelly Berry-Hebb, Texas A&M University System, Susan Wyatt Sedwick, University of Texas at Austin

Congratulations to our newly elected officers.

**2013 Spring Meeting:** The Spring 2013 meeting will be at the Sheraton Hotel in Oklahoma City starting Sunday April 21st and ending Wednesday April 24th 2013. We were successful in negotiating the State room rate of $81 per night! Please plan ahead and be sure to have this meeting in your institution’s travel budgets. This will be Scott Davis’s meeting to organize and plan, if you have any questions about the area, the hotel or the meeting, please contact him.

**Awards:** The following awards were announced at the spring meeting in St. Louis:

2012 Distinguished Service Award: Gail Davis, Lamar University. We thank Gail for all of the many and outstanding things she has accomplished for our region. She has worked tirelessly over the years to help Region V grow and prosper.
Quinten S. Mathews Regional Travel Award Winners: Ardenna Harris, Langston University and Kimberly Henderson, Lamar University.

Jeremy Forsberg is Chair of Region V and serves as the Assistant Vice President for Research at the University of Texas at Arlington.

**REGION VI**
Western
www.ogrd.wsu.edu/r6ncura

A hui hou k kakou…
Until we meet again

**REGION VII**
Rocky Mountain
ncuraregionvii.asu.edu

Our Spring Meeting was held at the Hilton Waikoloa Village from April 15th to April 18th. The theme of the meeting was “Discover the Difference: Creating Connections Together”. The program included eight workshops and over 52 concurrent sessions. The program committee worked energetically to put together a wonderful program for the members of Regions VI and VII.

The program committee for both regions included: Workshops (Georgette Sakamoto, Josie Jimenez, and Keith Andre); Professional Development (Linda Patton, Lisa Mosley, Allison Weber); Sponsored Program Administration (Mich Pane, Csilla Csaplar, Mary Townsend and Jackie Hinton); Management and Operations (Bruce Morgan, Ralph Brown and Kathi Delehoy); Financial Management (Deb Chapman, Mona Weer and Bo Bogdanski); Compliance and Legal (Helene Orescan, Randall Draper, Adilia Koch and Kay Ellis); Sponsors and Agencies (Sara Judd, Winnie Ennenga, Jeri Muniz and Carol Beltran); IT Support (Steve Shapiro, Lance Akana, Jon Peterson, Allen Anderson, Tyler Wilson and Michael Morimoto); Sponsorships (Julie Guggino, Gene Larson and Sinh Simmons); Evaluations (Lynda Olin, Nettie Nelms and Jennifer Teixeira); Presentation/Website Coordinators (Jan Crane, Aiah Sankoh and Candyce Lindsay); Activities (Nozomi Kanoho) Volunteer Coordinators (Melissa Mullen and Sandra Logue).

A sampling of sessions offered at the meeting included: Multi Layered Complex Projects — Staying Ahead of the Lava Flow (Michele Dondanville, Deb Chapman, Andrew Gray and Susie Carson); Leadership Succession Planning: Developing a Strategy (Rosemary Madnick and Bruce Morgan); Conducting Surveys to Evaluate and Enhance Research (Kathi Delehoy); NIH Updates (David Curren, NIH/OPERA); Doing More with Less- A Success Story (Tamarra Deuser, Jeri Muniz); How to Develop, Implement and Manage Successful International Collaborations (David Mayo and Denise Wallen); You’re in Charge of Yourself- Self-Guided Professional Development (Lisa, Mosley, Sam Westcott and Josie Jimenez) and Getting Social: Applying Social Media to Research (Esther Pratt and Dan Nordquist);
Preparing for Change: How the Proposed Revisions to A-21 Impact You (Cheryl Birch, Andres Chan, Dava Casoni); Conduct of Research (RCR) Education Program (Tony Onofrietti); Clinical Trial Agreements and Research Agreements – How they Differ (Helene Orescan, Tam Tran); and Going Green...Bury the Paper Before It Buries You (Teri Hansen, Jan Crane). The listing of the presentations can be found on our meeting websites: http://www.ogr.wsu.edu/r6ncura/meetings.aspx and http://ncurarregionvii.asu.edu/meetings.

The meeting was kicked off by our keynote speaker, Maenette K.P. Benham, Dean of the Hawai‘i‘i kea School of Hawaiian Knowledge, University of Hawai‘i at Manoa. Her presentation used story to invite the audience members to reflect on their own cultural/lineage stories, to think deeply about their passions and dreams, and to consider re-imagining a collective, inclusive work environment.

The meeting hosted a record number of attendees: Region VI (285 attendees); Region VII (82 attendees) and other regions, 15 attendees.

Dan Norquist, President of NCURA, opened the lunch on Monday, April 16th. He presented Maggie Griscavage with the Region VI Helen Carrier Distinguish Award. Unfortunately, Maggie was unable to receive her actual award during the Annual Meeting last November; she accepted the award via Skype.

Tihati Productions, the Legends of the Pacific Luau dinner and show performed dramatic Polynesian dances and music of the Pacific Rim including the breath taking Fireknife Dancer. The number of people attending the luau was over 450.

Travel Awards from both regions were given to the following individuals: Charlene Hart (University of Nevada, Reno); Marci Copeland (University of California, Irvine); Jennifer Wang (Stanford University); Farhat Taqui (University of California, San Diego); Howard Bergman (Arizona State University); Elizabeth Sexton (University of Utah).

Special thanks to our sponsors, Key Solutions, Emmanuel College and Baker Tilly for their support.

In addition, please do not forget to complete your evaluations of the Kona Meeting. The evaluations are used to assist us with the planning of our future regional meetings.

Lastly, we want to give a SUPER special thanks to Gale Yamada (Secretary, Region VI), Wanda Bowen (Treasurer, Region VI) and Lisa Jordan (Secretary/Treasurer, Region VII). The dedication of these individuals was amazing and we truly appreciate their commitment to ensuring a smooth running meeting.

Mahalo nui loa

Rosemary Madnick is the Chair of Region VI and serves As the Assistant Vice President, Research Administration, at the Los Angeles Biomedical Research Institute.

Vicki Krell is the Chair of Region VII and serves as the Research Advancement Supervisor in the College of Liberal Arts and Sciences Dean’s Office, Research Advancement Office at Arizona State University.

As the NCURA International Region continues to grow, we are in need of volunteers to assist with developing the information for our webpage: http://www.ncura.edu/content/regions_and_neighborhoods/international.php

If you go to the general NCURA Regional web site page, you will be able to see some of the information our colleagues in the other regions are sharing with each other. http://www.ncura.edu/content/regions_and_neighborhoods/regions.php

Information, such as, Career Opportunities where members can post job openings; news about individual members; upcoming meetings and educational offerings are just a few areas that we might wish to post to our web page.

We also need help with writing the column you are currently reading. The International Region’s Regional Corner column is in five of the six editions of NCURA Magazine and, as you will see from the articles surrounding this one, there is a designated person who writes this information.

Other areas of growth in the coming months where we will need your expertise and time are:

Professional Development Committee: The PDC which will look to develop educational information and programs for the members of our region. Committee volunteers needed: Chair, Vice Chair and approximately 10 members.

Nominating Committee. This committee will put together a slate of candidates for Vice Chair; Secretary; Treasurer and Regional Board of Directors. Committee volunteers Needed: Chair, Vice Chair and approximately 8 members

Membership Committee. This committee will welcome new members to the region and also point potential members to NCURA. Committee volunteers needed: Chair, Vice Chair and approximately 5 members.

Volunteer Coordinator will work with the NCURA National Regional Volunteer Coordinator to help fill positions in our region.

This is an exciting time! I ask you to consider offering your talent and expertise to help design and build our region the way we wish to see it. A call for Volunteers will be sent to you within the next month. When you receive it, please step forward and answer the call.

José Mário Leite is the Chair of the International Region and serves as the Deputy Director of the Gulbenkian Institute of Science (Portugal).
ferences and traveling workshops, the professional meetings staff also increased by one in 2008 and, that same year, the membership department added the position of Assistant Membership Services Coordinator. At the end of 2011, in anticipation of NCURA’s new on-line communities and professional network platform, Collaborate NCURA added the new position of Community Curator.

✔ …an increased membership.

• During a time when the economy caused some organizations to close their doors, NCURA membership grew by 5%, from 6,700 members in 2007 to over 7,100 in 2012.

✔ …integrated technology into multi-forms of online sharing.

• The neighborhoods were born. We created on-line trainings; webinars; NCURA TV; podcasts; and now, we are moving into a whole new world of community through Collaborate NCURA (and a new website coming in 2012).

So what does it mean? It means that NCURA is a great goal-setting group AND a SUPER goal ACHIEVING group!! We are set up for solid and sustainable success with a national-level structure that provides for an experienced Executive Committee and Board of Directors; a stable National Staff; and the regular contribution of many seasoned research administrators. Our 2007 leaders successfully mapped out the needs and built an organization designed to weather the ever-shifting landscape in research administration. Our officers, boards, committees, task forces, and volunteers, from 2007 to 2012, have successfully navigated and responded to everything that came our way (e.g. Grants.gov, ARRA - my, oh my…were those doozies!). We stayed on top the most current topics; featuring issues at our national meetings (FRA, PRA, and the Annual Meeting), providing training in our traveling workshops and, if necessary, updating our online training and/or publications. It means that NCURA was there for you and will continue to be there for you!

So, thanks again Officers, Board, and Committees of 2007, we salute you for setting the vision with the 2007-12 goals and salute the rest of us who made it happen. The Officers, Boards, and Committees of 2008, 2009, 2010, and 2011 were as committed to continually improving the programs, technology, and relationships as all the boards before. We should all be proud of NCURA’s accomplishments. The 2012 group will continue this good work in the summer where we will start laying out the vision for the next five years. In 2017, when we look back, I expect that we will be as proud of NCURA’s accomplishments as we are today. There will be lots to do; supporting research…together for the next five years.

Dan Nordquist is Assistant Vice President and Director, Office of Grant and Research Development at Washington State University.
Expectation-based Efficiency and Quality Improvements in Research Administration: Multi-Institutional Case Studies
Transforming Research Management Systems at Mayo Clinic
Developing an Institution-wide Web-based Research Request and Preliminary Budget Development System
Managing Risk and Uncertainty in Large-Scale University Research Projects
Crafting a Sales Pitch for Your Grant Proposal
Behind Door #3: The Hard-to-Please Grant Reviewer
Media Review: NIH Peer Review Revealed

See the latest issue of the scholarly journal Research Management Review

Now Online at: http://www.ncura.edu/content/news/rmr/index.php
Available Now

IT TAKES A VILLAGE TO MANAGE AWARDS:
POST-AWARD ISSUES FOR PRE- AWARD
RESEARCH ADMINISTRATORS &
DEPARTMENTAL ADMINISTRATORS

Program Level: Overview

As research administrators, we are challenged with multiple compliance issues in supporting our researchers. Whether it’s assisting with proposal preparation, facilitating the submission process, award negotiation and acceptance, or managing the award through closeout, there are many aspects of research administration compliance that impact what we do as administrators. Communication is essential between departmental, pre-award and post-award offices to ensure that award compliance is managed effectively and efficiently. This program will examine such areas as best practices for good communication between departmental, pre-award and post-award offices at proposal stages, facilitating budget development and budget justifications which can be defensible in post-award audits, minimizing cost transfers, and managing cost sharing on sponsored projects.

Learning Objectives:
- Explore key compliance issues impacting departmental, pre-award and post-award functions;
- Identify best practices to facilitate efficient and effective award management.

Target Audience: Departmental Administrators, Pre-Award Administrators, Post-Award Administrators

Moderator: Samantha J. Westcott, Manager, Sponsored Projects Team, Children’s Hospital Los Angeles

Panelists: Kerry Peluso, Associate Vice President for Research Administration, Emory University; Jerry Pogatshnik, Associate Vice President for Research and Dean of the Graduate School, Eastern Kentucky University; Tamara Lucas, Specialist, Contracts and Grants, Departments of Pathology, Medical & Research Technology, University of Maryland, Baltimore

Available Now

TECHNOLOGY TRANSFER ISSUES FOR THE
RESEARCH ADMINISTRATOR

Program Level: Overview

Universities are involved in technology transfer activities related to the intellectual property generated by their faculty, staff and students. Research administrators need to understand the basics of these activities in order to obtain agreements that are compliant with federal law and promote research activities. This program will start with the policies and regulations which created most modern practices, like the Bayh-Dole Act, the Tax Reform Act of 1986, and federal government rights and regulations. It will also provide an understanding of intellectual property, starting with patents, copyrights, and trademarks. It will continue with the transfer mechanisms used to get the IP into the hands of the industrial collaborators with definitions of the different agreements, namely licenses and options as well as the impact of the America Invents Act. It will cover the terms used in those agreements like exclusivity, fields of use, timeframes, royalties, equity, and patent cost recoveries. Examples will be shared and analyzed.

Learning Objectives:
- Obtain a fundamental understanding of intellectual property;
- Understand industry collaborations and what they mean to the university;
- Understand the basics and beyond of agreement terms and conditions.

Target Audience: Pre-Award and Departmental Administrators

Moderator: Jilda Garton, Vice Provost for Research and General Manager of Georgia Tech Research Corporation, Georgia Institute of Technology

Panelists: Elaine Brock, Senior Associate Director, Office of Research and Sponsored Projects, University of Michigan; Cathy Innes, Director, Office of Technology Development, UNC-Chapel Hill; Alexandra McKeown, Associate Dean for Research Administration, Johns Hopkins University Bloomberg School of Public Health
**Release Date: July 16, 2012**

**EXPORT CONTROLS AND OTHER SECURITY CONCERNS**

**Program Level:** Overview

This program will cover export controls and national security concerns applicable to research at those universities that may not have a skilled or dedicated export control officer or export control compliance office. The session will take export control and national security (e.g., security plans, access to classified information) issues and their applicability in the everyday life of the pre-award research administrator (grant proposal preparation, award negotiations), department administrator (field research trips, foreign travel, shipments), and faculty members (conferences, meetings, sharing of data/etc.). The session will also include how to “start from the very basics” in building an internal export control management plan, training, etc.

The Obama Administration’s new export control reform initiatives and their affect on universities would be discussed. This session is not intended to review the licensing process, as its focus would be towards the organizations that perform fundamental research with no requirements for receipt of controlled information on their campus.

**Target Audience:** Departmental, Pre-Award, Research Compliance Administrators, Faculty

**Moderator:** Randall Draper, Director, Office of Contracts and Grants, University of Colorado at Boulder

**Panelists:** Elizabeth Peloso, Director, Export Compliance, University of Pennsylvania, Lisa Mosley, Director of Research Advancement, Arizona State University, Ajay Kuntamukkala, Partner, Hogan Lovells

Build a library of NCURA TV workshops that you can use to train all year long

**Release Date: October 17, 2012**

**HOW TO APPLY PROCESS IMPROVEMENT STRATEGIES TO RESEARCH ADMINISTRATION**

**Program Level:** Intermediate

This program will describe the framework for some of the best practices used in both pre- and post-award. We often solve sponsorship-related issues on a case-by-case basis considering the variety of factors impacting each award. As volume, sponsor [and customer] expectations, and complexity have increased, many institutions are pursuing systemic process improvement in order to increase stewardship, efficiency, and transparency while improving customer service with limited personnel and budgetary resources. Technology has advanced allowing for a range of simple and inexpensive solutions for low volume users and sophisticated electronic systems to address high volume activity.

The session will include: how to approach process improvement, strategies used in decision-making, obtaining resources, tools to define system requirements. Case studies of process improvement in the research administration area will be explored including system-to-system grant submissions, agency invoicing and reporting, electronic archiving, sophisticated reporting tools for key metrics, and responding to unintended consequences.

**Learning Objectives:**
- How to approach business process improvement in pre and post award processes;
- Identify best practices to improve processes and customer service through systemic solutions and collection of metrics;
- Identify streamlining techniques while addressing compliance concerns.

**Target Audience:** Departmental, Pre-Award, Post-Award and Research Compliance Administrators

**Moderator:** Robert Lowman, Associate Vice Chancellor for Research, UNC-Chapel Hill

**Panelists:** Kim Moreland, Associate Vice Chancellor for Research Administration, University of Wisconsin-Madison, Andrew Chase, Corporate Director, Research Management and Research Finance, Partners Healthcare

ORDER ONLINE ATwww.ncura.edu

DVDs are divided into chapter segments for your training convenience.
ONLINE TUTORIALS
A Primer on Clinical Trials - 8 week program
A Primer on Federal Contracting - 8 week program
A Primer on Subawards - 8 week program
Visit the website for Enrollment Periods

NATIONAL TRAVELING WORKSHOPS
DEPARTMENTAL RESEARCH ADMINISTRATION WORKSHOP
May 14-16, 2012 .................................................................Irvine, CA
FUNDAMENTALS OF SPONSORED PROJECT ADMINISTRATION WORKSHOP
June 18-20, 2012 .................................................................Cambridge (Boston), MA

NCURATV 2012 DVD WORKSHOPS
It Takes a Village to Manage Awards:
Post-Award Issues for Pre-Award and
Departmental Administrators.................................................Available February 15
Technology Transfer Issues for the Research Administrator............Available April 9
Export Controls and Other Security Concerns ............................Available July 16
How to Apply Process Improvement Strategies
to Research Administration..................................................Available October 17

NATIONAL CONFERENCES
6TH ANNUAL PRE-AWARD RESEARCH ADMINISTRATION
(PRA) CONFERENCE
Sheraton Wall Centre, Vancouver, British Columbia ....................July 18-20, 2012
54TH ANNUAL MEETING
Washington Hilton Hotel, Washington, DC............................November 4-7, 2012

DEADLINES FOR AUGUST 2012
Submission of Articles to Contributing Editors .........................June 29, 2012
Submission of Articles to Co-editors .....................................June 29, 2012
Submission of Advertisements .............................................June 29, 2012

Additional information for authors can be found at:
www.ncura.edu/content/news/newsletter/author_instructions.php

For further details and updates visit our events calendar at www.ncura.edu