NCURA 2002 – The Beginning of the “Envisioned Future”

By F. John Case

I want to thank the individual members of NCURA for the opportunity to serve you as President in 2002. It has been a dream of mine to work with the leadership of NCURA to direct the future of our organization and to turn the vision for our future into reality.

We experienced an exciting transition under the leadership of Regina White. The Board established an aggressive agenda for the future by revising its strategic plan to convey a solid vision for growth and quality professional development; in other words, they created an envisioned future. As your President, I will work with the Board of Directors to achieve the goals set forth and promote quality programming in an environment that encourages network building and lasting friendships.

Over the next year I will continue to build on the strengths of NCURA and create new opportunities to enhance professional development and achieve organizational goals. In 2002, the Board and I will focus on the following areas of excellence:

- **Innovative Programming** - Building on a successful past, we will continue to provide a foundation of excellence through programming including Fundamentals of Sponsored Projects Administration, Financial Research Administration, video conferencing, and the Annual Meeting. In an effort to meet the growing demands of our membership, we will introduce an additional Fundamentals team to increase the number of workshops offered throughout the year. Additionally, we are introducing an exciting new workshop to meet the needs of mid-level managers. Sponsored Project Administration: Level II is designed to expand the knowledge of research administrators by addressing complex issues including contract negotiation and cost sharing. Lastly, planning for a new summer conference to address the intricacies of university and industrial partnerships is underway.

- **Focused Board Activities** – The 2001 Board established a vision for the future of NCURA through the strategic planning process. We must now focus on implementation and formulation of activities to direct the future of the organization as envisioned. Of the ten issues identified by the Board as challenges, we will focus on two opportunities for growth. First,
Export control requirements are the law of the land. Therefore, the regulations which implement the law apply whether or not there is a specific reference in an award to the existence of and necessity to comply with the export control laws. There has been a tremendous amount of discussion by university and government officials recently with respect to the export control laws, discussion which has escalated since the tragedies of 9/11; this document will include a brief historical discussion of export control regulations, the current climate and regulatory framework, and provide some practical guidance to institutions on how to deal with this complex area.

A Brief History
Export control laws, federal laws enforced both by the Department of Commerce (Export Administration Regulations, EAR) and the Department of State (International Traffic in Arms Regulations, ITAR) have been in existence for more than twenty years. In the early 1980’s the higher education research community embarked on an interchange (an exchange or discussion) with the federal government about the extent to which the restrictions on export to foreign entities “defense articles” applied to research activities.

The outcome of these discussions in 1985, was the issuance of a National Security Decision Directive (NSDD 189). The directive clarified the definition of fundamental research (defined as “basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community…” ) and stated that fundamental research was not subject to the license requirements of the export control regulations. Of great significance in the issuance of NSDD 189 was the statement that:

Fundamental research is distinguished from research which results in information which is restricted for proprietary reasons or pursuant to specific U.S. government access and dissemination controls. University research will not be deemed to qualify as fundamental research if (1) the university or research institution accepts any restrictions on the publication of the information resulting from the research, other than limited prepublication reviews by research sponsors to prevent inadvertent divulging of proprietary information provided to the research by the sponsor or to insure that publication will not compromise patent rights of the sponsor; or (2) the research is federally funded and specific access and dissemination controls regarding the resulting information have been accepted by the university or the researcher.

NSDD affirmed that it is the U.S. Government and DoD’s policy to allow publication and public presentation of unclassified contracted fundamental research results. DoD’s mechanism for control of information generated under such research agreements is security classification and no other type of control is authorized unless required by law.

In practice, as long as an institution did not accept publication restrictions, then the only practical way to impose export restrictions was to classify the project. The situation remained static until the late 1990’s when control over commercial satellite technology was transferred to the State Department from the Commerce Department and the technology thus became subject to the ITARs rather than the EARs.

Definitions
A few definitions which are critical to an understanding of the export regulations are listed below.

- Export – the shipment of goods or items, including electronic or digital shipment, the release of specific technological data to any foreign national or the use by a foreign national of any covered technology.
- Deemed export – exists whenever a foreign national on U.S. soil may be able to access export controlled items. Deemed exports may require licenses and impose access restrictions.
- Export controls – federal laws which control defense articles (information and hardware) identified in either the EAR or the ITAR. References are 15 CFR 730-774 (EAR) and 22 CFR 120-127. The list of controlled items appear at 15 CFR 774, Supp. 1 (the Commerce Control List (CCL)) and 22 CFR 121 (the M units Control List (MCL)), respectively. Both the EARs and the ITARs are on line at http://www.access.gpo.gov/nara/cfr.
- Defense services – the furnishing of assistance to foreign nationals in the development, manufacture, repair, testing, modification, operation, etc. of defense articles or technical data controlled under the ITAR regulations.
- Fundamental research – basic or applied research in science or engineering at an accredited institution of higher learning in the U.S. where the resulting information is intended to be publicly available.
- Publicly available information – information that is published or generally accessible or available to the public and the scientific community. A sponsors review of the publication solely to ensure that the publication will not compromise patent rights nor inadvertently divulge proprietary information that the sponsor has furnished to you would not destroy the fundamental research exception. Any additional reviews or approvals would destroy an institution’s fundamental research exception.
- Commodity jurisdiction ruling – when an article is arguably covered by both the EAR and the ITAR, an institution can apply to the State Department for a commodity jurisdiction ruling to determine which agency will have jurisdiction over the export of the article.

Current Status
An export can occur whenever there is the transfer of a controlled item (as referenced on the CCL or the MCL) to an entity or individual outside the United States or to a foreign national, whether inside or outside the United States. As indicated above, the Departments of Commerce and State are responsible for the administration of the export control laws. In effect, the regulations prohibit the unlicensed export of specific technologies for reasons of national security or protection of trade, except when the fundamental research exemption is applicable. It is for this reason that colleges and universities must understand the importance of not accepting publication restrictions in contracts and grants.

One of the difficulties that the export regulations impose on institutions is that colleges and universities generally have policies that encourage open research and free interchange of information. The concept of openness generally requires that foreign faculty, students, and scholars not be singled out for restriction in their access to the institution’s educational and research activities.

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BIOTERRORISM AND UNIVERSITY RESEARCH

The threat of bioterrorism – which became all too real for us in Washington DC this fall by mail contaminated with anthrax – has prompted a flurry of reactions from the U.S. government. Some of those responses reach deep into the scientific community.

In an effort to track down the source of the attacks, the FBI stepped up a probe of research labs across the country. Congress also began discussing a slate of bills that will have significant implications for scientists.

FBI agents have been working for the past two months in a probe of U.S. research labs. The objective is to learn whether anthrax spores used in recent attacks could have come from the United States and whether other research organisms might be used as weapons. According to reports in Science magazine, some 250 laboratories are registered to handle dangerous organisms, and dozens have been contacted by the FBI. These inquiries request lists of employees, descriptions of the strains at the facility, and other details.

Congress is moving quickly to pass legislation that would require researchers to beef up lab security and register all collections of potential bioweapons with the Centers for Disease Control and Prevention (CDC) in Atlanta. One bill, the USA Patriot Act, has already passed, and additional separate bills have passed in the House and Senate, but most likely will not be reconciled until Congress reconvenes after January 1. COGR formed an ad hoc task force on this issue and what follows is some of the information developed so far by the task force to assist universities in assessing current risks.

The USA Patriot Act was signed by the President on October 26 (Public Law 107-56). This Act contains several provisions that impact universities. The provision with the most immediate implications for research is Section 817, Expansion of the Biological Weapons Statute. The Antiterrorism Act of 1996 mandated CDC registration of laboratories that transfer or receive select biological agents. The Patriot Act amends the Biological Weapons statute and criminalizes possession of such materials of a type or in a quantity not reasonably justified by bona fide research or peaceful purposes. In addition, it prohibits possession by “restricted persons” in a number of categories set forth in the Act.

Suggested Steps to Assess Current Risks:

1. Non-permanent residents from countries on the State Department list of countries that support terrorism are prohibited from transporting or possessing select biological agents. The seven countries currently on the State Department list are: Cuba, Iran, Iraq, Libya, North Korea, Sudan, and Syria. It would be prudent to determine if you have persons from any of those countries currently working with select agents. There are proposals in Congress to provide a waiver process for such individuals if it can be shown that they are not a threat, but at this time there are no exceptions to the prohibition.

2. Other “restricted persons” are also prohibited from transporting or possessing the select agents – this includes any individual who is:

   • under indictment or has been convicted for a crime punishable by imprisonment for a term exceeding one year;
   • a fugitive from justice;
   • a user of illegal drugs;
   • an alien illegally in the U.S.;
   • has been adjudicated as a mental defective or has been committed to any mental institution
   • has been dishonorably discharged from the US Armed Services.

While the prohibitions and penalties under the Act apply to the individual, it is reasonable to expect that the government will, either with regulations issued under this Act or in other legislation currently being considered, hold institutions at least partly responsible for any violations. Pending legislation in the Senate would place responsibility for background checks of individuals with the Justice Department, but other legislation being considered in the House would direct the DHHS Secretary to establish “personnel screening protocols.” For now it would be prudent to assess current risks by:

• Reviewing the adequacy of policies and procedures for handling select agents. This should include evaluating your:
  - inventory of biological materials- re-surveying faculty and laboratories to identify sites and individuals in possession of select agents
  - inventory tracking system
  - authority to acquire materials
  - authority to transfer materials
  - transfer tracking system
  - procedures for disposal
  - training for laboratory personnel

• Evaluating the current management of compliance with regulations, policies, and procedures, using existing committees such as Institutional Biosafety Committee and Environmental Health and Safety Committee. Consider establishing a special committee to include senior financial and administrative officers and legal counsel.

• Assessing the adequacy of physical security of laboratories, including protocols for handling unauthorized access to materials/laboratories, and coordination with federal, state and local officials. If you currently conduct personnel background checks, do such checks cover all the areas listed above under the Act? If not, or if you currently do not perform background checks, seek advice from law enforcement officials on how such checks might be accomplished.

As this COGR ad hoc task force develops more materials it will be posted to the web site at www.cogr.edu. In addition the Association of American Universities and the National Association of State Universities and Land Grant Colleges have set up a web page to enable research university officials to share information on the ways their campuses are addressing the challenges of the post-9-11 environment, and to provide them with a resource link to other useful materials and website addresses. This information can be accessed at www.aau.edu.

Tony DeCrappeo serves as the Associate Director for the Council on Governmental Relations (COGR).
Fuhgeddaboudit
by Suzanne Polmer

As I write this the snow has not yet begun to fall here in southern New England but, somehow, my office seems to be caught in a blizzard-like white out of paper labeled Contract, Subagreement, Material Transfer Agreement, Consortium Agreement, etc. Even the federal government, which still provides the vast majority of funding for basic research in this country, has agencies that still prefer the contract mechanism over the grant mechanism.

Within my office, we encourage the use of the negotiation strategy called “principled negotiation”. Described in “Getting to Yes” by Fisher and Ury, this method encourages the parties to decide issues on their merits. Where conflicts continue to exist, the authors recommend that the negotiation be based on fair standards independent of the will of either side. In spite of this office philosophy, I find myself in great sympathy with my staff who, frustrated with negotiating the same clauses over and over, would like to simply send the documents back with “Fuhgeddaboudit” stamped in red on the offending clauses.

The major issues in agreements with industry are familiar to you all - publication, intellectual property rights and confidentiality. In university-to-university agreements, the problems are different but no less contentious, and unfortunately the number of them appear to be even greater.

Let me give you a few examples:

The private educational institution I am employed at is covered byOMB Circulars A-110, A-21 and A-133. As a result of A-21, we are also covered by Cost Accounting Standards. We have an MPA (to be an FWA in the future), assurances on Animal Care, policies on Conflict of Interest and Scientific Misconduct, and even on Drug Free Workplace. I will certify to you that all of these policies are in place, and I will even send you copies. But if you ask that my faculty be covered by your state’s Conflict of Interest Policy – Fuhgeddaboudit!

We have a travel policy consistent with A-21, but asking us to agree to have our investigators adhere to your state travel policy is definitely a Fuhgeddaboudit.

I remember that academic institutions worked very hard to explain to our various audit agencies that sending copies of our A-133 audits all over the country was, among other things, ecologically unsound. We won that battle and now are only required to certify to each other that we have had an A-133 audit. No more is required, unless there are specific findings related to the specific contract. So my friends, why are your contracts still requiring full A-133 reports? Indeed, why are some of you threatening to withhold payment if you don’t get a full copy? Fuhgeddaboudit!

I understand that some state institutions can’t indemnify my institution. We can work out terms, sometimes using “hold harmless” language or other legalisms such as “to the extent permitted by the laws of”. But please make it mutual or Fuhgeddaboudit.

I’ll gladly give you a certificate indicating that my institution maintains certain levels of insurance, but if you ask us to name you as a co-insured - Fuhgeddaboudit!

Most federal grants will provide that equipment vests in the awardee at the time of purchase. I do not think it unreasonable to expect that clause to be flowed down in a subrecipient agreement. Protestations that you would not deny a request for title at the end of the project just underscore the denial of our fair flow down rights.

If a prime award is under “expanded authorities”, why ask that my PI request permission for activities usually covered under these authorities? With the exception of no-cost extensions, such requirements just add adminstrivia.

If a prime is a multi-year award, e.g., a NIH continuing grant, why send a new contract each year when a modification adding funds and time would be far simpler and consistent with the agency practice? The various steps a new contract involves are extra work not only for my office and my PI, but for yours as well. A new contract means: 1) I need to set-up a new account; 2) close-out the old account and, 3) since this is really a continuing award, request carry-forward of funds from one year to the next. Furthermore, since the anniversary date of the award may well have passed by the time your documents arrive at my institution, the department business office may have to transfer costs from the old award period to the new. I don’t know the process on your side, but surely you must at least have to close out and open a new award. More paper is not better management!

Authorship in scientific publications presumes significant input to the design and conduct of the study. The ethics of requiring that your PI receive authorship as a condition of providing experimental materials is questionable at best. An acknowledgment of the source of research material is one thing, requiring courtesy authorship is quite another. Fuhgeddaboudit.

There is no doubt that few of our offices have staff time to spare, and negotiating these clauses just wastes that precious resource, so what can we do? I suggest that you look at your “standard” subcontract and review it with the following question in mind - “Would I accept this for my institution?” If the answer is “Fuhgeddaboudit”, then you have some work to do. The recent FDP simplified sub-agreement is a very good start to simplifying and streamlining the subaward process. But until organizations start to adapt this model, please abide by the golden rule. “Do unto others as you would have them do unto you” should be the guiding principle in developing subrecipient agreements.

Suzanne K. Polmar serves as the Director, Grant & Contract Administration for Yale University.
If you are a research administrator at an academic institution, you most likely have had to deal with a research agreement or protocol related to the drug development process, most likely a clinical trial. What you might not be as familiar with is the breadth and scope of the drug development process and the scientific, economic, and regulatory factors which underlie it. Hopefully, this article will provide you with the basics and answer some of the questions that you might have.

By most accounts, the business of drug development in the U.S. pharmaceutical industry is lengthy, high risk, highly regulated and, potentially, very lucrative. It takes about 15 years, hundreds of researchers, thousands of human subjects, hundreds of thousands of pieces of documentation, and anywhere between $350 million and $500 million dollars to bring a successful drug to market. For every successful drug, somewhere between 5,000 and 10,000 starting compounds don’t make it. However, if a drug is highly successful, it can produce billions of dollars in revenue over its lifetime, impact the lives of millions of people, and, by the way, change the course of history.

Basic “Truths” Affecting Drug Development

The process of starting with a chemical compound or naturally occurring biological substance and bringing a safe, effective and commercially viable product to market, more commonly called drug development, is governed by certain truths:

- Not every chemical compound or biological substance has the potential to have an effective, specific, clinically measurable impact on a disease process.
- A compound that is effective in the test tube may not produce the desired effect in mice and what works in mice may not work in humans (i.e., a test tube or computer program is not a mouse, a mouse is not a dog, a dog is not a human.) There is no substitute for testing in volunteers.
- Even if a substance is highly effective, the short or long term adverse impact of it or one of its breakdown products may be too great.
- One pill does not fit all sizes, sexes, species, stages of development or situations. Not every potential drug that can be safely and effectively introduced into a mouse by an acceptable method of delivery (for example, orally by pill or liquid, by injection, or through the nose), in an acceptable dosage range (i.e., not too much or too little given the overall size and weight of the body or targeted organ) and has reasonable shelf stability will necessarily produce exactly the same results in humans.
- The dosage range where the drug produces its benefit without a significant adverse impact may be too narrow to justify the liability risk of marketing it. This is due to the variability mentioned above and the fact that patients and caregivers do not necessarily follow labeling information to the letter.
- Not every drug that is safe and effective to manufacture is either clinically better or commercially competitive with the methods of treatment that are currently available.
- Even if a drug is very safe, highly effective and will capture significant portions of the market, the potential market may be too small or market share may erode too quickly given anticipated scientific breakthroughs or competitive products to make it worth pursuing. (It is better to spend 15 years and $350 million to earn billions rather than millions.)

These truths have led to a drug development process that is broken into stages and substages at which scientific, economic, and regulatory decisions are made. The culling of unsuitable compounds starts early and continues throughout. This is accentuated by the fact that expenditure of development funds per compound is not linear over time. The later stages of drug development tend to be more expensive than the earlier ones. Strategically a pharmaceutical company is trying to develop a drug that affects a specific biochemical process within the body that disrupts the disease process. To have the greatest chance of success, the company should start out with the broadest range of high potential compounds that it can find or make and then reduce that number as quickly as possible. Obviously, the earlier that decision can be made, the less it costs the company in terms of expenditures and lost opportunity. Some smaller, specialty biopharmaceutical companies form mutually beneficial alliances with large multinational ones. The multinationals are in effect, cutting risk by “contracting out” some early drug development; the smaller company reduces the huge outlay for clinical trials and gains, by proxy, vast marketing and sales muscle.

The Regulation and Economics of Drug Development

Many strategic decisions are influenced by the regulatory process that overlays drug development. Any drug that reaches the market should have an impact for the public good. All potential drugs can have side effects: some minor, some devastating in both emotional and economic terms. A drug which is being considered for introduction can be a real star or a “me too” drug to increase market share or fill a niche. Obviously, the drug developer is conflicted. It is the role of the U.S. Food and Drug Administration to monitor the drug development process and ensure that the drug is suitable for testing in humans and later, whether it is permissible to market the drug and under what conditions. Obviously, the monitoring and decision-making processes have an impact on the profitability of a potential drug by increasing time to market. The experiments and paperwork needed to meet the regulatory requirements take significant amounts of time to produce and evaluate. A pharmaceutical company makes most of its profit from a drug during its period of exclusivity, i.e., when competition is low and a higher price can be charged. Most potential drugs are patented very early in the development process and have a patent life of twenty years. The longer it takes to reach market; the shorter the useful patent life and the less time available to recoup development costs and turn a profit. The advent of generic drugs practically guarantees that once a patent has expired, any highly successful drug will face generic drug competition resulting in a decline in market share and/or a price reduction. In addition, it is rare that a pharmaceutical company is the only one interested in a given disease. Competitors might have potential drugs in the pipeline. These may be targeting a different site or process, may require a shorter development period, and/or may be more effective or cheaper to produce due to inherent differences in the compounds or different efficiencies in scientific development and culling processes.

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Basics of Drug Development: A Primer for the Research Administrator (Continued)

Basic Research and Drug Discovery
The earliest scientific phase of drug development involves basic research and drug discovery in its broadest sense. Understanding the development and progression of the disease; determining which points in the underlying biochemical processes are key; and developing the best ways to attack these “target sites” is critical to success. It has been estimated that right now, there are currently about 500 useful targets for intervention. However, it is predicted that with advances in genomics and proteomics this number is likely to increase to around ten thousand.

Once a chemical compound or a biological material has been identified which seems to favorably impact the target, a discovery process begins. This involves synthesizing or identifying related compounds in order to maximize the chances that one will eventually have the requisite characteristics to enable it to reach market. This discovery or lead enhancement process can involve combinatorial chemistry (i.e., making multiple related variants of a compound), searching natural products libraries for similar materials, computer modeling of prospective compounds, large scale screening processes, and characterization of potentially useful compounds. The technologies that underlie preclinical efforts include bioanalytical chemistry, biotechnology, molecular biology, information systems, and computer technology. Somewhere toward the end of this stage, the company patents the compounds that it intends to continue to develop. From that point on, each day spent on studies and the concomitant paperwork necessary to obtain drug approval decreases the useful patent life and profitability of the drug.

Initial Safety and Metabolic Studies
The research then progresses to the initial experiments to understand the safety and metabolism of the compounds. Studies on the pharmacology, pharmacokinetics, toxicology, and metabolism of the compounds are conducted. These experiments provide information on the best mode of delivery, compound formulation (mixing the therapeutic agent with substances which enhance its effect, stability, handling ability, etc.), frequency of administration, duration of exposure, dose levels with optimal benefit to adverse effect ratios, targeted organs, how quickly the compound is broken down and excreted, and when the compound and its breakdown products lose their potency. These tests often involve the use of cell cultures, tissues, and animals of several different species. During the latter portion of this phase, the company ramps up production, refines its analytical techniques, and identifies manufacturing resources.

What has been done to date is the pre-clinical phase of drug development. On average, it takes about six years to reach this point. Of the five to ten thousand potential compounds developed during the lead enhancement stage only about 250 reach animal testing. Of these, about five continue into clinical testing. Between 35 and 40% of the cost of development of a marketable drug has been spent to date. The end of the pre-clinical phase is marked by the filing of an Investigational New Drug Application (IND) with the FDA. The IND contains the results of all conducted experiments and any other information that is known about the compound. It also contains a description of the clinical research plan for the product and the clinical protocol for the first phase of clinical evaluation. The FDA’s Center for Drug Evaluation and Research (CDER) conducts a safety review of the medical, pharmacological, toxicological and statistical data provided in the IND. Based upon its review, CDER can determine that more pre-clinical data is needed, that the clinical studies can go forward but identified data deficiencies have to be corrected, or that clinical studies are acceptable because the IND is satisfactory. The FDA has to complete its evaluation in 30 days or the company can start clinical testing. This serves to help minimize the loss of useful patent life during this stage of the regulatory process.

Clinical Trials
Pre-marketing clinical trials are conducted in three phases and are designed to minimize risk to the participants. Phase I trials are generally conducted on a small number of healthy volunteers. Phase II on slightly larger numbers but on patient volunteers. Phase III are full-fledged trials. CDER can stop these trials at any time for safety or design reasons.

Over time, the number of procedures per subject has increased as has the typical number of trials that are conducted prior to bringing a new drug to market. The result has been a loss in useful patent life. This is mainly due to the need to provide more information about drug interactions and safety. An overview of the clinical phases of drug development can be found in the figure below.
long-term quality of life issues, and cost-effectiveness. These trials enable investigators to provide more extensive safety and efficacy documentation, refine the frequency and type of adverse events, and establish dosages. The information gained in these trials is also used to develop the labeling on drug packages. Obviously, great care must be taken to ensure that adequate statistical power (the ability to distinguish whether the difference between values is significant) is available to allow extrapolation of the results to the target population or populations (men vs. women, adults vs. children, etc.). Generally, the FDA requires at least two successful, well-designed phase III trials as part of a New Drug Application submission (NDA). Completion of these trials usually marks the end of the pre-marketing clinical phase.

The NDA, which typically runs about 100,000 pages, is supposed to tell the complete history of the drug, from preclinical testing through phase III. It also includes information on how the drug is formulated and how it is manufactured, processed and packaged. A sample of the drug and proposed labels must be included. By law, the FDA must approve or disapprove the application within 12 months. While 25% to 30% of the drugs entering the clinical stage complete phase III, only 20% survive the FDA review to reach market. The pre-marketing cost of drug development, including the costs of preparing the IND and the NDA (about 4% of the total) represents about 90% of the total cost. The remainder is mostly due to phase IV clinical trials.

Post-Marketing

Phase IV trials involve post-marketing surveillance and are sometimes required to meet FDA requirements. At other times, they are done to learn more about drug effectiveness and operation. Obviously, this allows the company to collect information from a much wider population. This data can often reveal new applications or indications for the drug, as well as side effects and adverse reactions that are just too infrequent or long term to observe in the clinical phase. The discovery of new indications increases utilization and profitability; the information on adverse effects can lead to drug withdrawal or use modification to reduce liability. These studies are also useful in marketing. They can be used to compare the drug with competitive products and therapies in terms of therapeutic effectiveness, side effects, long-term quality of life issues, and cost-effectiveness.

In summary, drug development is a highly risky, government monitored and regulated, research intensive process that holds out the promise of huge returns if successful. It requires large, up front, long-term investments before any revenues are generated. Aside from luck, success is determined in large part by a company’s ability to economically find or design large numbers of candidate drugs which impact key targets in the biochemical mechanisms underlying the development of a disease. It is then critical to have effective technologies and decision-making processes in place to expeditiously eliminate the weaker candidates as data is analyzed. This becomes even more crucial during the clinical phase, given the large cost per day of the studies.

The challenge for the future is whether the industry will be able to take the vast amount of information becoming available as a result of the genomic and proteomic revolutions and successfully make the jump into personalized medicine. As the term implies, this means using genetic testing to predict the risk of a disease in a given patient and then tailoring the course of treatment based upon that individual’s profile after taking into account the individual’s probability of having a severe side effect. In other words, taking “the one pill does not fit all” proposition to the nth degree. In effect, this would require a rethinking of the industry and movement, in some diseases, from the “blockbuster drug” to the “individually customizable drug”.

Richard Sohn serves as the Associate Dean for Research at Columbia University.

This article was developed with reference material, which can be found at the following internet sites:
Pharmquest, Inc.: http://www.pharmquest.com/source/ddg
Pharmaceutical Research & Manufacturers of America: http://www.phrma.org/publications
CenterWatch, Inc.: http://centerwatch.com
FDA, CDER: http://www.fda.gov/cder/about/whatwedo/testtube.pdf
NIH: http://www.nih.gov/clintrials/clintrial.htm

1 Genomics tries to look at all the genes as a dynamic system, over time, and determine how they interact and influence biological pathways and physiology. In contrast, genetics looks at single genes, one at a time, as a snapshot. (http://www.genomicglossaries.com)

2 Proteomics is the analysis of complete complements of proteins. It includes not only the identification and quantification of proteins, but also the determination of their localization, modification, interactions, activities, and, ultimately, their function. (http://www.proteomics.com)
Negotiating Research Agreements: What’s in the Background? Seeing the Whole Picture

by Carol T. Carr

The negotiation of a research agreement requires consideration of many diverse elements: the institution’s policies, laws relating to contracts and intellectual property, and the financial and administrative requirements of the institution. However, it is easy to fall into the trap of viewing a research agreement as addressing only those elements related to a specific research project, and to fail to see the broader picture that surrounds the subject of research. Just as the science that is being researched doesn’t exist in isolation, a research agreement exists within a constellation of special interests. Every researcher has a vested interest in maintaining the direction of his scientific research and not compromising personal research interests. In a similar manner, a research institution wants to protect its existing research initiatives and the technology that derives from it, including its patent portfolio. The sponsor is equally committed to protecting its own patent position, with an eye also on the technology in the field patented by others, as often the intellectual property rights of a sponsor to its technology are among the key assets of the business.

No institution wants to engage in a relationship with a sponsor that will ultimately result in it being unable to give to the sponsor rights to practice the technology that might be developed as a result of its sponsorship. As part of a good faith negotiation, there should be an attempt to ensure that there be no unilateral surprises. To the extent it can reasonably do so, it is incumbent on the institution (with the research administrator being the responsible party) to make sure that there is no background intellectual property that already exists or may be in development under another research program that will ultimately be required for this sponsor to be able to practice the technology to which it will receive rights under the terms of the research agreement. There will always be some risk that a “surprise” patent may be found later to which a sponsor may require rights in order to practice intellectual property resulting from work they have funded, but all parties can take steps to minimize their risk of a future “surprise.”

Identifying the background intellectual property is the first task. The first line of defense here is the researcher, the most likely person in the institution to be aware of other work that the researcher or the researcher’s colleagues has done in this specific area of research. The next is the administrative office responsible for managing the institution’s technology portfolio and for dealing with an institution’s technology transfer matters. This office should have at least one staff member able to identify any inventions or copyrightable materials that have been disclosed by the researchers and are likely to be related. The sponsor itself may also be aware of existing background intellectual property.

How to accommodate a sponsor’s needs is a business decision on the part of the institution. Once the background intellectual property has been identified, at a minimum it should be assessed by a technology transfer officer in consultation with the researcher regarding the extent to which it is needed for the practice of the likely technology to come out of research program. If it is necessary, it should be held available for the sponsor in some manner that is workable for the institution. An institution might simply encumber it, so that it will not be licensed to another party until the research can be completed and it can be clearly established whether or not the background intellectual property is necessary to the sponsor. On the other hand, this may be the appropriate time to approach the sponsor with the fact that this technology may be available for licensing. It is at this point that the research agreement may become a tool for establishing a potential licensing relationship with the sponsor, but it is important for the research administrator to maintain a clear distinction between the requirements of the research agreement and the elements of a license agreement, as terms and conditions that are appropriate for a license agreement are not necessarily appropriate in a research agreement.

In implementing the above procedures, the institution must first have a clear understanding and determination of the limits of the background intellectual property review it is willing to perform. Sponsors often want to know the preexisting background technology that an institution as a whole has in the area of research that is the subject of the research agreement. However, it would be a tremendous task for major institutions to know all the technology within its walls that might be on point, even if this review is limited to only those inventions disclosed to the technology transfer office; smaller institutions may have an easier time complying with this request. But each institution needs to determine whether it is reasonable to review the background intellectual property of only the researchers on the project, the researcher’s laboratory, or a larger domain. Be aware that problems can arise within the institution with respect to the collegiality of its researchers, if the intellectual property of a researcher that is not receiving any of the sponsor’s funding is affected by its relationship to the research being performed.

Taking the time to view the world beyond the laboratory within which a research project exists and to understand the business needs of a sponsor can reap many benefits for all the parties involved. It can also be a fascinating opportunity to see the entire picture surrounding the work that we do as research administrators that enables research agreements to develop the new technologies of the future.

Carol T. Carr serves as the Associate Intellectual Property Counsel, Office of Sponsored Programs, Massachusetts Institute of Technology.
In Pursuit of Prestige: Strategy and Competition in Higher Education
Dominic J. Brewer, Susan M. Gates and Charles A. Goldman,
Transaction Publishers, 2002

by Steven Smartt

The authors of this RAND publication have produced an academic treatment of two of the least tangible yet most desirable qualities pursued by virtually every college and university: reputation and prestige. Based on a methodological approach using structured interviews with presidents, administrators, faculty and students at 26 campuses, the report identifies strategic investments to improve institutional status.

The text is straightforward and accessible, with a style that is more like a dissertation or journal article in the social sciences than a book intended for the general public. The opening chapters present an informative overview using a market-driven model of institutional behaviors and tendencies. The authors offer a working definition of reputation as distinct from prestige and speak to the role of student quality, research and sports as “prestige generators.”

At times, the book reads like a primer, oversimplifying concepts that are generally well-known, even to research administrators. One passage asserts, “Attracting research funding requires major investments. An institution must have top-quality faculty and facilities in order to compete in national competitions for research sponsorship.”

In some other ways, however, the book is prone to gloss over or loosely define some concepts, most notably by talking about investment choices but failing to quantify or define thresholds for what constitutes a significant investment, or attempting to measure return on investment. (“Institutions need to make three basic types of investments in order to support research activities. First, they need to invest in research facilities, especially laboratories, libraries, computer facilities, and management. Second, they must attract research-oriented faculty to the institution. Finally, they need to provide graduate education through the Ph.D. degree.”)

The number and mix of cases examined in this study is useful for making comparisons across different institutional types; however, with only a few campuses of each type and scope it cannot make refined distinctions between various classes of research-oriented institutions. Still, the brief summaries of selected case studies make for interesting reading.

This book will be of interest to students of higher education as well as research administration professionals for its contribution of a framework for better understanding factors—one of which is research funding—in shaping institutional prestige.

Steven Smartt is a Past President of NCURA and serves as the Director, Division of Sponsored Research for Vanderbilt University.

2001 Catherine Core Minority Travel Award

NCURA was once again fortunate to receive a large pool of impressive applicants for the Catherine Core Minority Travel Award. The award is available to minority applicants who, because of financial constraints, could not otherwise attend NCURA’s Annual Meeting. The awardees receive up to $1,000 toward expenses associated with attending the Annual Meeting. The purpose of the award is not only to assist in the financial aspects of attending the meeting, it also offers a wide variety of services and opportunities for the awardees to interact with their peers and colleagues from other educational institutions around the country. In the ever-changing world of research administration, NCURA’s network of administrators offers a wealth of expertise that is just waiting to be utilized.

Letters of recommendation from the institutional official stated repeatedly the benefits of attending the National NCURA Meeting. In addition to the awardees personal and professional growth, the institution acknowledged it would also reap the benefits of networking opportunities, agency contacts and the overall knowledge of the NCURA membership. The 2001 Catherine Core Travel Award recipients were: Sharon Brooks, Karmanos Cancer Institute; Katherine Ho, University of California-San Francisco; and Alfredo Medina Jr., Siena College. The NCURA Nominating and Leadership Development Committee eagerly anticipate the participation and leadership that our winners will bring to future NCURA activities. The deadline for applications for the 2002 Catherine Core Minority Travel Award is June 1, 2002. The application form is available on the NCURA Web site at www.ncura.edu. The criteria for selection are as follows:

The applicant should:

• Be engaged in the administration of sponsored programs
• Represent one of the following minority classifications: African American, Hispanic, American Indian or Alaskan Native, Asian or Pacific Islander
• Never have attended an NCURA national meeting
• Agree to stay at the host hotel for the duration of the meeting and be responsible for making own room and travel reservations
• Include with the application a letter of support from an official at their institution which clearly delineates the benefits to the applicant and institution
• Agree to submit a report on his/her annual meeting experiences within thirty (30) days of the meeting.

We look forward to many outstanding applications in 2002!

HANSEN, KEOGH TO LEAD NCURA STANDING COMMITTEES

The NCURA Board of Directors has appointed Stephen Hansen, Dean of Graduate Studies and Research at Southern Illinois University at Edwardsville, as Chair of NCURA’s Nominating and Leadership Development Committee. The Board also has appointed Richard Keogh, Director of Research and Grant Administration at Rhode Island College, Chair of the NCURA Professional Development Committee. These two standing committees previously have been led by NCURA officers, but time constraints have made it impractical for these individuals to serve simultaneously as standing committee chairs. Consequently, the NCURA Board has shifted responsibility for leadership of these two standing committees to two NCURA members with significant experience in coordinating organizational activities. Hansen is a former president of NCURA. Keogh has been a member of the Board of Directors for the past two years, was co-chair of NCURA’s 41st Annual Meeting, and currently serves as co-editor of the NCURA Newsletter. The appointments of Hansen and Keogh will begin January 1, 2002. The Financial Management Committee, NCURA’s third standing committee, will continue to be led by NCURA’s Treasurer.
Greetings all.

If I only had the power to slow things down for a short period I am convinced that all would be well in my life. It seems that it was only last week that I was writing the September version of this column and was speaking about the upcoming RADG season and NCURA Annual meeting. We are now well into the RADG season and the Annual meeting is only a memory, but a great memory. For those of you who could not attend this year’s Annual meeting was one of the best, if not the best. The recent events of September 11th have changed us as individuals and that was very evident at the Annual meeting. There was a noticeable increase in smiles and community. I think “camaraderie” was the word of the day and that coupled with a great program created an inclusive environment not seen in some time and still being talked about. I would like to acknowledge our Bernard M. Lane Travel Award winners to the Annual meeting. They were Anne Pascucci, Rhode Island College; and Sheila Sullivan-Jardim, Bridgewater State College.

Our RADG season has gotten off to a very auspicious beginning with a presentation by Gary Thompson at our October meeting. It was standing room only. Melody Lin, OPRS spoke at our December 14th holiday meeting. We have opportunities open for our January, March and May meetings so if you have a topic you would like to have addressed at one of the meetings give Louise Griffin, UM ass Lowell a call.

Region I went to the polls in September and October to elect a Chair, Treasurer, and Board representative and on October 29th the results were announced and certified by N CURA National. And those results were: Louise Griffin, UM ass Lowell, Chair; Bruce Elliott, PIDMC, Treasurer; and Vivian Holmes, HSM, Region I elected Board member. Congratulations to the winners and especially to those who were also on the ballot – Ted Liszczak, M athew M eyer, and Kathaleen Mercier. It is increasingly difficult each year to find Region I members who are willing to step up to the plate and serve the region. These six individuals came forward and deserve our applause.

The Spring meeting program committee is hard at work putting the final touches on the program. They have worked hard over the holiday season to get the program together and up on the website in January. The Region I Spring meeting will be in Newport, Rhode Island from April 28 through May 1. Mark those dates on your calendar.

This is my final newsletter as Chair of Region I. On January 1, I will turn this responsibility over to Louise. The past two years as Chair of Region I have been a remarkable experience for me. It provided an opportunity to meet a lot of region I members as well as members from other regions, participate as a member of the Board of Directors, and gain a much better understanding of N CURA, its purpose, mission and goals. Thank you for allowing me to serve you.

William Corbett serves as the Region I Chair and Director of Research Administration, Dana-Farber Cancer Institute.

REGION II
Mid-Atlantic

Regional members noticed that there was much more hugging than usual at the Annual Meeting this year. Over 350 of our members benefited from the extraordinary professional development programs, but more than ever from the camaraderie and outpouring of concern we experienced from our colleagues who joined us in Washington, DC in November.

During the Annual NCURA Business Meeting, Barbara Bralver of Lehman College of the City University of New York voiced the gratitude of all members of Region 2 for the support we have received from the NCURA family. From the generous contribution made by NCURA National to the September 11 relief effort, to the gifts of classroom furnishings made by our sister institutions around the country to aid Borough of Manhattan Community College in its recovery efforts, the kindness of our NCURA family and colleagues who joined us in Washington, DC in November.

We are looking forward to our joint meeting with Region V at the St. Anthony Hotel in San Antonio from May 4-8, 2002. The hotel is accepting reservations now (210-227-4392), so come early and stay late. At the business meeting on November 13, Program Committee Chair Tim Conlon presented a preview of the program that promises a great opportunity for professional development. We are looking forward to a report on the progress made by Ada Sue Selwitz (Kentucky) with a special charge by the Region in the area of professional development. Ada Sue and NCURA Vice-President/President Elect John Case (UNC-Chapel Hill) will be reporting.
The Site Selection Committee, Chair Mary Watson (Valdosta State), Johnny Compton (University of Kentucky), Andrea Dixon (University of Alabama-Huntsville), and Jenny Bradley (Roanoke College), identified three very attractive sites for our Spring 2004 Meeting. The three possibilities are: Wild Dunes Resort, Isle of Palms, South Carolina; Park Vista Resort Hotel, Gatlinburg, Tennessee; and the El Conquistador Hotel, Puerto Rico. Region III members are encouraged to vote for their favorite site when they vote for regional officers after the first of the year. Watch for ballots on the regional web site at: http://www.orga.cofc.edu/ncura3/.

Thanks to the efforts of Hospitality Chair Greg Thompson (Florida State) and committee members Michael Addix (Virginia Commonwealth), Donna Strenke (Florida Gulf Coast) and Tim Atkinson (Arkansas Children’s Hospital Research Institute), some of the most popular and best attended sessions took place in the Region III Hospitality Room. A big “Thank you!” is in order for Tim Conlon who provided the sound system for the Hospitality Room.

Chair Carl Frantz (Louisiana-Lafayette) and his Professional Development Committee consisting of Jerry Fife (Vanderbilt) and Pam Whitlock (UNC-Wilmington) were putting together an innovative senior leadership professional development program. Watch the Region III web site for more information.

Region III Chair Phil Myers (Western Kentucky) would like to thank the officers from all of NCURA’s regions for helping with the two Newcomers’ Sessions at the annual meeting. Over 150 of new NCURA members attended.

Finally, the last item in this report but at the top in importance, thanks to the NCURA National Staff and the Sole Source and No-Cost Extensions for a great annual meeting! It went only too quickly.

Rosemary H. Ruff serves as the Associate Director, Office of Review and Compliance at Auburn University.

REGION IV Mid-America

For those of you not fortunate enough to attend the 43rd Annual Meeting in November, I’m sorry to have to tell you that you missed another great meeting! As usual, our Program Committee and National Office put on a meeting that not only had excellent content but also was great fun.

This past year I had the opportunity to be involved in our Spring Meeting in Minneapolis from beginning to end. I learned first hand about the endless little details needing attention that most people are not even aware of. Keep in mind this was for a meeting with attendance of about 120. I can only imagine how many of these little details had to be dealt with for a meeting with attendance in the range of 1300. To make all of these details transparent to the attendees is truly an amazing accomplishment. I realize this is the “Regional Corner” but after having just returned from the Annual Meeting I wanted to take this opportunity to recognize the tremendous effort contributed by our colleagues in putting on this meeting. Thanks!

So how about some Region IV news? We had over 60 new Region IV members in attendance. To the new members reading this now let me once again say welcome to Region IV. I enjoyed getting a chance to meet many of you. I’d encourage all of you to make an effort to keep in contact with the people you met. NCURA is much more than just meetings. Our colleagues are a year round resource.

Debi Galloway and her Program Committee are working hard on plans for the Spring Meeting. The theme of this year’s meeting is “Ethics in Research” and it’s shaping up to be a very strong program. Although it’s apparently still a closely guarded secret we were told the Monday night event was something we had never done before and should not be missed! So be sure to mark your calendars and plan to join us in Madison, Wisconsin April 27 – 30, 2002 for our Spring Meeting.

Jim Maus serves as the Region IV Chair and Division Administrator School of Medicine, Washington University.

REGION V Southwestern

“Coming Together in 2002” will be the theme of the spring meeting in San Antonio that Region V will hold jointly with Region III. The conference will take place May 5-8, 2002 at the St. Anthony Hotel, near the River Walk. There will be six workshops presented: two of them will be all-day and four will be half-day sessions.

Beginning January 1, 2002, Allen Soltow, University of Tulsa, will begin his term as representative from Region V on the national Board of Directors. Laura Wade, University of Texas Medical Branch in Galveston, will start her service as Treasurer-Elect.

Fifty-six members attended the Region V business meeting held during NCURA’s Annual Meeting in Washington, D.C. in November. At that time members reaffirmed their interest in having Las Vegas as the site of the annual meeting in 2003. Joan Howeth, our vice-chair/chair-elect, has subsequently negotiated a contract with the Imperial Palace hotel for April 27-30, 2003.

Sondra Fersl serves as Chair of Region V and Associate Dean for Research, Texas Woman’s University.

REGION VI Western

This year’s NCURA annual meeting was a rousing success with a record number of 1343 attendees! 139 were from the Western Region! Needless to say, all who attended had a wonderful time and learned a great deal from the many very informative sessions and workshops.

At our region’s business meeting our two Travel Award Winners were recognized. This year travel awards were given to Amy Hibbard, Grants Administrator, Keck Graduate Institute of Applied Life Sciences and Kevin Ishida, Administrative Officer, University of Hawai‘i - Hawai‘i Natural Energy Institute. Each indicated that they really enjoyed the opportunity to attend a national meeting and that they hoped to be able to attend many more regional and national meetings. Special thanks to Lucy Molina (California Institute of Technology), who chaired the Travel Awards Committee and to the other members of the committee - Tamara Combs (UCLA), Lillian Rivera (Southern Cal), and Gayle Yamasaki (Oregon Institute of Technology) for all their hard work.

We also held a drawing among first time attendees for a free registration to our regional meeting in Kona next spring. Bill Hunt (California State University, Fresno) was the lucky winner.

Pat Hawk (University of Oregon), our incoming Chair, led a discussion on long-range planning for future regional meeting sites. Leesa Brown (Seattle University), who has had over a dozen years of meeting planning experience volunteered to put a proposal together for the next four years of regional meetings. In considering future sites, the major criteria for the proposal will be reasonable room rates, adequate meeting space, and accessible location. We also decided that we would meet in Hawaii in 2006. Thanks to Leesa for taking on this assignment.

Pat Hawk will become Chair for our region as of January 1 and Cece M annochezhi (California Institute of Technology) will become Secretary-Treasurer. Both Pat and Cece are committed to regional activities and I look forward to helping support them in all of their successes.

(continued on page 20)
With registration numbers down just slightly from last year, NCURA’s 43rd Annual Meeting proceeded as planned and those who attended received one of NCURA’s finest meetings to date. Over 1,300 NCURA members, who refused to let anything stand in their way, traveled to Washington, D.C. to attend One Step Ahead and at the end of four days left knowing they had received the information necessary to keep them in the lead.

Registration opened on Saturday evening and, those who arrived early and attended our Night of Networking reception noticed NCURA sharing space with the Marine Corps Ball and Vice President of the United States, Dick Cheney. Yes, on that one night we all knew where Dick Cheney was! On Sunday, 435 members attended one or more of the 23 workshops in the Workshop 2001 series. The Annual Meeting began that evening with the traditional banquet, which was opened by Hilton Hotels Vice President and General Manager of the Hilton Washington and Towers, William Edwards. Edwards, who thanked those in attendance for “Coming home” then treated everyone to a tremendous, laser light show. After dinner speaker, Dave Barry, was as hilarious as predicted and the audience had a wonderful opportunity to relieve stress as many laughed and cried at the same time.

Monday morning at 8:30 am, Keynote Speaker George Stephanopoulos, brought to us his thoughts on the impact of the events of September 11th on our government and society and the world. From his own personal moments at Ground Zero to his thoughts on where we are headed in the fight against terrorism, his speech made a powerful impact on all. Throughout the day and on Tuesday and Wednesday members were able to choose from over 120 concurrent sessions, discussion groups, primers and real-life experience sessions designed by Annual Meeting Co-chairs Denise Clark, Cornell University, and Alice Tangredi-Hannon, Thomas Jefferson University and their program committee.

Tuesday evening, members decked out in red, white and blue, joined NCURA’s band, Soul Source and No-cost Extensions for an impromptu sing-along of “America the Beautiful” and then danced, visited, danced, ate, and…danced until midnight.

NCURA members are a formidable group of individuals who do not sit back and let life pass them by. Over 1,300 of them chose to move forward because, if ever a time for community was needed, this meeting was it. They attended their educational sessions and, in between, took time to give hugs of reassurance and acknowledge that they had come through September 11th and would continue to come through whatever was thrown their way.

Member reviews of sessions along with the official photo gallery are now available on the NCURA web site.
Members enjoy this year’s Communication Pavilion, sponsored by Oracle and Apple Computer.

Getting down to important issues during Discussion Groups.

Members who visited the Exhibit Hall had the chance to “Ask Bob” (Robert Kiloreen, Pennsylvania State University, Editor of NCURA’s “Research Management Review” and Vice-President/President-elect) everything they needed to know about submitting journal articles.

Members visit some of NCURA’s Neighborhoods.

Workshop Faculty, Peggy Lowry and Barbara Gray list some of the important ingredients necessary for Team Building.

Workshop 2001 Deputy Coordinator, Marianne Rinaldo Woods, University of Texas at Arlington and Workshop 2001 Coordinator, Jean Humphries, Arizona State University East.

John Case, University of North Carolina at Chapel Hill, NCURA 2002 President with 43rd Annual Meeting Co-Chairs: Alice Tangredi-Hannon, Thomas Jefferson University and Denise Clark, Cornell University.
NCURA COMMUNITY COMES TOGETHER

Mareda Weiss, University of Wisconsin-Madison, is presented with NCURA's Outstanding Achievement in Research Administration Award by American Council on Education President and former Chancellor of the University of Wisconsin, David Ward.

Keynote Speaker George Stephanopoulos

Mareda address Recognition Luncheon Audience

Kathleen Larmett, NCURA Executive Director, receives Officers' Pin from Regina White, National Institutes of Health, NCURA 2001 President

NCURA Past Presidents Seated L-R: Nancy Wilkinson, University of Wisconsin-Madison; Mary Ellen Sheridan, University of Chicago; Mary Husemoller, University of Nevada-Reno, Emeritus; Julie Norris, Massachusetts Institute of Technology; Standing, L-R: Dennis Barnes, e-Numerate Solutions, Inc; Steve Erickson, Boston College; Eric Rude, University of Wisconsin-Madison (Emeritus); Steve Hansen, Southern Illinois University at Edwardsville; Ardis Savory, University of South Carolina (Emeritus); Cheryl-Lee Howard, The Johns Hopkins University; Kim Moreland, Fred Hutchinson Cancer Research Center; Dick Seligman, California Institute of Technology; Last Row, L-R; Jane Youngers, University of Texas Health Science Center at San Antonio; Steve Smartt, Vanderbilt University

NCURA members begin an evening of community by signing "America the Beautiful" with the Soul Source.
What Universities and Research Administrators Should Know About Export Controls (Continued)

Because the consequences of violation of the export control laws are potentially so severe – both to the individual who violates the regulation and to the institution (including both substantial fines and criminal penalties, including jail time) it is vitally important to clearly understand the circumstances under which the fundamental research exclusion can be asserted. It is relatively easy to understand the publication restriction issue as well as the access of foreign nationals, but difficulties often occur when an institution of higher education is accepting research funding from a corporate entity. Remember that the fundamental research exemption does not extend to the for-profit sector and such an entity might try to impose export controls on a university as a subrecipient because the prime awardee is required to accept those controls. This is often one of the more challenging areas of negotiation and it may take significant skill (and sometimes some luck) to negotiate institutionally acceptable terms.

It is often a challenge to work with faculty and researchers to identify whether any specific technology is controlled and, if so, under what control list. Further, the lists can be impacted by the government’s identification of embargoed entities (nations, organizations, individuals) for which the restrictions are greater than for the export regulations; such lists change from time to time. Any institution which has individuals working on research projects whose technology is identified on one of the control lists needs to consider how to approach the issue of export controls – who will be involved, who will be identified as the institution’s “empowered official”, whether and to what extent to seek outside legal help in determining whether any specific item is subject to controls and, equally important, whether outside expert counsel’s advice help should be identified to help prepare the license request. Of equal importance is the need to communicate with faculty and researchers their roles in identifying whether their research is impacted by the controls or requirements contained in the export regulations.

Securing a License

Securing an export license is an interesting experience interfacing with government bureaucracy. The documentation that is required to be submitted is substantial and relies in great measure on the writing of the technical specifications and utilization of the technology. Generally, this must be done by the investigator. From an administrative perspective, the license application must be submitted by the college or university by an individual authorized to do so. Certifications by the authorized institutional official are part of the license application and indicate that the institution is cognizant of its responsibilities and will adhere to any restrictions that may be imposed by the license.

The normal processing time now for export licenses is approximately 4-6 months although, with support from a governmental research sponsor, consideration for a license may be expedited, which can cut processing time to approximately 2 months.

Other Issues to Consider

ITAR Compliance Program

Some universities have reported that they have been required to have an ITAR compliance program in effect, particularly when they accept funding from an industrial concern that has accepted ITAR restrictions in its award. It is unclear whether there is formal guidance in regulation for what such a program would entail, but (based upon audits of installations which have prepared and submitted license applications to the State Department) it appears that such a program would include responses to the following questions:

• Can you trace with precision who is working on the project?
• How do you know with whom they can share the work? How do you track/ensure this?
• Do you have appropriate physical precautions in place
  - To prevent unauthorized access?
  - To restrict to authorized individual computer passwords/authentication for access to project data?
• Is there a compliance person at a sufficiently high level in the organization who can answer questions with respect to ITAR regulations, controls, and processes?

To be fully in compliance with the requirements of an ITAR compliance program may require in some institutions the creation of veritable “Chinese walls” between laboratories or researchers that is in conflict with the collegiality and open sharing of research results that fuel a vibrant and productive academic community.

Award Language

Universities often struggle with what they feel is appropriate language related to export regulations in awards they are negotiating. Each institution needs to make a determination for itself what language is acceptable and should do so before any specific award arrives at the institution. Although specific situations may vary, it is clear that language which requires an institution to comply with export regulations is certainly acceptable because it is required to whether or not it is a specific requirement in the contract. Generally, language which restricts the access of certain foreign nationals from participating on an unclassified research project is normally not acceptable. Institutions may wish to incorporate termination for convenience clauses in the event that ITAR restrictions during the course of the research would impact the course of the research.

Educational Resources

One of the difficulties with the export regulations related to what educational materials are available to inform both the researcher and the institution. The Commerce Department regulations contain an extensive Q & A, Supplement 1 to 15 CFR Part 734 which is extremely useful with regard to when licenses are not required under the EARs. There is no parallel Q & A for the State Department, but NASA has recently published on its web site a Q&A related to export controls, which provides some guidance (see http://gaia.hq.nasa.gov/rcu_webcast/ ecfqa.html). In addition, there are other publications available which provide some ITAR guidance. One such source is the Society for International Affairs publications such as its pocket ITAR, exemption handbook, and licensing handbook.

The Issue of Security Classification

Classification is one of the ways DoD has instructed its personnel to impose publication restrictions. There continue to be instances where agency personnel as well as industrial negotiators try to impose publication restrictions on non-classified projects. Further, some universities have seen instances where agency contracting officers indicate that NSDD 189 is no longer effective. However, that is not the case. On November 1, 2001, the Assistant to the President for National Security Affairs, Condoleezza Rice, reaffirmed in a letter that "this Administration will review and update as appropriate the export control policies that affect basic research in the United States. In the interim, the policy on the transfer of scientific, technical, and engineering information set forth in NSDD-189 shall remain in effect...."

The Future

It isn’t clear exactly how the export control policies will change as a result of 9/11. Even before that date there were indications that both the CCL and the MCL would be expanded (for example, with additional biological agents covered under the regulations). Clearly, research has become more global since the issuance of NSDD-189 and recognition of that is essential. At the same time, the U.S. needs to encourage cutting edge research in a variety of areas such as biotechnology and nanotechnology and to do so in an environment that is as open and collegial as possible, where restrictions and controls are reserved for only the most pressing national security concerns.

Julie T. Norris is a Past President of NCURA and serves as the Director, Office of Sponsored Programs for the Massachusetts Institute of Technology.
NCURA 2002 – The Beginning of the “Envisioned Future”

should we broaden our membership base to be more inclusive? Second, how do we maintain or enhance our level of excellence in the face of competing demands placed on member’s time, talent, and financial resources? These questions must be answered in order to gather insight into NCURA’s future and shape the organization to better serve the membership. In addition to implementing the strategic plan, the 2002 Board must review the bylaws for simplification where possible.

While the annual meetings have been a very successful part of NCURA’s programming, we must assess whether the existing meeting structure is best for the current membership. A Task Force will review this question and make recommendations for the Board’s review and consideration. Lastly, we will focus on building relationships with our regions. The changes in the governance structure that took place in 1999 created questions, concerns and communication issues. We need to understand the issues and address them to make NCURA a stronger organization at both the regional and national levels.

• Powerful Professional Connections – NCURA must collaborate with various organizations to better serve its constituents. We need to strengthen relationships with the Federal Demonstration Partnership (FDP) and the Council on Governmental Relations (COGR). We need to identify strategic opportunities to work with the Association of University Technology Managers (AUTM), the National Association of College and University Attorneys (NACUA), and the National Association of College and University Business Officers (NACUBO).

In addition we must create a closer working relationship with our sister organization, the Society of Research Administrators (SRA). While each of these organizations share similar goals and objectives, we must work together to create better opportunities for interaction and education.

NCURA continues its 43-year history of excellence through the tireless efforts of its volunteers, and we continue to encourage involvement at all levels. I want to express my gratitude to all of those who balance professional and personal commitments to serve this organization.

This year’s leadership created an envisioned future - NCURA will be acknowledged as the premier source of professional development, knowledge and leadership for research administration. In support of this vision, I look forward to meeting the challenges established for 2002. Again, I appreciate the opportunity you have given me to serve the membership, and work with the Board, the various committees, the task forces, and the national office staff in 2002.

F. John Case is the 2002 NCURA President and serves as Executive Director, Office of Contracts and Grants for University of North Carolina at Chapel Hill.
December 7, 2001

To the Editors:

At the close of the business meeting during NCURA’s 43rd annual meeting, Regina H. White, NCURA President and new Director of the NIH Office of Policy for Extramural Research Administration, announced that the Board of Directors had determined that because of her new status as a federal employee, she could not serve her NCURA 2002 officership of Immediate Past President. This determination is a disservice to NCURA and to the NCURA membership that elected Regina.

The Board’s action was based on an interpretation of NCURA administrative policy differentiating regular members (those who are university affiliated and can become officers) from associate members (those who are not university affiliated and cannot become officers). Ironically, the Board has fully supported Regina, but it has not fully supported this membership differentiation, and this year will seek to eliminate it.

But, as many Board members agree, we did not have to change the policy to avoid this distressing outcome. Despite some spin and rhetoric about how this case proves that the regular/associate member distinction should be abolished, the Board could have interpreted the existing policy so that Regina could have served the Immediate Past President term for which the membership intended her. NCURA has had fine moments in its 43-year history, but this narrow and contentious interpretation is not one of them.

Cheryl Howard has fortunately agreed to fill the resulting Immediate Past President vacancy. Best wishes to her and to all the officers and Board members in the year ahead for only wise action that will represent the best of the NCURA tradition and spirit.

Sincerely,

Merrily D. Sterns
Director, Federal Programs, American Museum of Natural History
Member, NCURA 2001 Board of Directors

Coping with the Cost of Compliance
by Pat Fitzgerald

The ever-increasing accumulation of regulations governing the conduct of Federal sponsored research poses major challenges for our institutions. While few would argue with the need for rules designed to ensure the safety of human subjects or the proper operation of animal care facilities, implementing these and other regulations is causing severe financial pressures for our institutions. How do we pay the bill for expanded compliance programs in an environment where institutional subsidies of Federal research are already substantial and the reimbursement of compliance costs are limited by the 26% administrative cap? The RAND Corporation estimates that the Federal government does not reimburse universities between $0.7 billion and $1.5 billion in F&A costs allocated to Federal projects, or between 10% and 30% of the total negotiated amount for F&A costs. The under-recovery is much larger when you include administrative costs in excess of the administrative cap and the substantial university subsidization of faculty time. Absent changes in Federal regulations or agency policies, the burden of paying the costs of increased compliance requirements will fall solely on the research universities. Indeed, the “unfunded mandate” appears to be a fact of life for colleges and universities.

Efforts are underway by federal agencies, especially the National Institutes of Health (NIH), institutional associations and professional societies to find ways to help alleviate the burden on institutions. Potential solutions include lifting the 26% cap, the creation of a pool of compliance costs within the F&A rate not subject to the administrative cap, the direct charging of certain compliance activities such as IRB review, and grant funding to institutions to pay for compliance costs. While each of these options is worthy of consideration, all will require additional Federal funding. In the post 9.11.01 world, as funding priorities change and competition for government resources intensifies, the likelihood that additional funds will be made available to universities to pay for compliance diminishes. Moreover, universities can expect additional Federal regulations designed to protect the safety of our personnel, materials, and facilities. Finding ways to cope with the cost of compliance will become more difficult and more urgent.

As institutions explore ways to pay for compliance, their focus must broaden to include an assessment of regulations that have been in force for some time as well as new or proposed requirements. In a collaborative effort, Federal agencies and universities should undertake a re-examination of existing regulations to evaluate changes that could make institutional compliance simpler and less costly. Such an assessment should differentiate scientific compliance regulations that add value to the research enterprise from administrative requirements that have little to do with the proper conduct of research. All compliance regulations should not be viewed with the same lens or treated as equal in value-added or importance. For example, the risk of institutional non-compliance with time and effort reporting regulations is minimal when compared to the risk of non-compliance with regulations governing human subjects. From a risk assessment perspective, is it logical for an institution to devote the same or greater resources to effort reporting as it does to the protection of humans involved in research?

In evaluating ways to streamline, simplify or eliminate administrative compliance regulations, we should acknowledge that some regulations no longer serve a useful purpose, especially when the cost of compliance outweighs the benefit. If the risk associated with non-compliance is minimal and the cost of compliance is substantial, can we justify the regulation? If administrative regulations can’t be justified, shouldn’t they be changed or eliminated? Rules and regulations that are overly prescriptive, process oriented, and administratively burdensome should be examined to see if there is a more efficient way of accomplishing the same results. We can’t sacrifice accountability in order to achieve cost savings, but we can become more efficient. Minimizing the burden of regulations that have no substantive benefit and involve minimal risk will free-up institutional resources that can be re-directed to pay for scientific compliance activities that are more mission critical. Surely we should look for ways to increase Federal payments for compliance costs. But parallel efforts should be directed towards finding ways to minimize the burden of administrative compliance requirements that are ineffectual, unnecessary or can be accomplished in ways that are more cost effective.

(Continued on the next page)
What are some examples of existing compliance regulations that may be candidates for simplification or elimination? We could start with an examination of OMB Circular A-21. Requirements in A-21 that could be simplified and made less costly include effort reporting, space inventory, Cost Accounting Standards and the administrative cap.

The Federal Demonstration Partnership (FDP) has identified the payroll distribution (i.e. effort reporting) requirements in A-21 as a no value-added process that should be substantially changed. The FDP argues that effort reporting has little to do with scientific outcomes or effective accountability for the use of Federal funds. The rules are complicated and excessively prescriptive and have resulted in interpretations by auditors and negotiators that have forced universities to account for salaries of faculty that are not paid by Federal sponsors. Effort reporting offers great potential for simplification and cost reduction.

The process of performing a space inventory has become more complicated, and more costly, since the elimination from A-21 in 1991 of the concept of “predominant use” of space. Predominant use represented a simplified method to assign building or room usage to the primary functions (e.g. Instruction, Research, Public Service, etc.) performed in a facility. Eliminating this methodology caused universities to implement costly systems and processes to more precisely determine the functional use of facilities. Often utilizing consultants, institutions typically perform room-by-room surveys that attempt to accurately identify room occupants and the specific sponsored projects performed in each room. Conducting a space inventory and maintaining a detailed space database can cost hundreds of thousands of dollars per year and the process is highly subjective, prone to error, and a major source of contention in the negotiation of F&A rates. Simpler methods could be developed that would achieve comparable results at far less cost to universities and the government.

Cost Accounting Standards (CAS) have greatly increased the cost of compliance since these rules were first applied to universities in 1995. The Council on Governmental Relations (COGR) argued that the essence of CAS was embodied in A-21 prior to the incorporation of CAS into the Circular. Since the requirements were not new, CAS has not had a significant impact on university costing practices. However, there has been a substantial increase in administrative costs due primarily to the disclosure statement requirements. Institutions receiving $25 million in Federal sponsored agreements must complete a detailed disclosure statement i.e., DS-2. Completion of the DS-2 has proven to be a costly and time-consuming process frequently involving many institutional departments and external consultants. While there is some benefit to the institution in compiling a document that describes its cost accounting practices, the benefits are not commensurate with the costs. And what benefit has the government realized from CAS? Judging by the lack of resources devoted to the review of DS-2s, it seems obvious that CAS is not a high priority for the government and little benefit has been realized.

A study of 144 COGR member institutions shows that more than 80% of these schools have administrative costs in excess of the cap. Yet for these schools the accountability requirements are no different from those applying to the cap. Clearly, OMB limited the reimbursement of administrative costs but didn’t make concomitant changes to enable institutions to reduce administrative costs. Changing the cap to an allowance, similar to the 3.6% allowance for faculty administrative effort, would provide institutions with some relief. There would be no increased cost to the government for the 80% of research institutions with administrative costs that exceed the cap.

These are only a few examples of the types of changes to A-21 that could yield significant savings to research institutions and the government. A careful review of OMB Circulars A-110 and A-133 would certainly uncover additional opportunities to reduce the compliance burden. An effort to re-evaluate the OMB Circulars could be done by a partnership of universities and Federal agencies initiated by the FDP, COGR or both. Similar efforts, such as those examining electronic research administration activities, are underway as a result of Public Law 106-107. The time is right for collaboration.

Pat Fitzgerald serves as the Director of Cost Analysis for the Massachusetts Institute of Technology.
Institutions have long required their investigators to certify, annually, as to whether they have any financial conflicts of interest. The National Science Foundation (NSF) and the National Institutes of Health (NIH), on July 14, 1995 issued “Objectivity in Research” regulations that became effective October 1, 1995. Under the rules, investigators are required to disclose to an institutional official a listing of Significant Financial Interests (as well as those of his/her spouse and dependent children) that would reasonably appear to be affected by the research proposed for funding. Designated institutional officials review those disclosures and determine whether any of the reported financial interests could directly and significantly affect the design, conduct, or reporting of the research.

According to the definition of Conflict of Interest developed by the Association of American Medical Colleges in 1990, “the term individual financial conflict of interest in science refers to situations in which financial considerations may compromise, or have the appearance of compromising, an investigator’s professional judgement in conducting or reporting research. The bias such conflicts may conceivably impart not only affects collection, analysis, and interpretation of data, but also the hiring of staff, procurement of materials, sharing of results, choice of protocol, involvement of human participants, and the use of statistical methods.”

Columbia University began to consider these issues, about a year ago, from a different perspective - if we were asking our faculty and researchers to disclose their financial conflicts of interest, was it not proper that we establish safeguards to protect the institution from institutional conflicts of interest? As our relationships with outside companies became more and more complex, we realized the need for a clear statement of principles and specific guidelines for handling institutional conflicts (whether real or apparent). Conflicts of interest must concern universities if they have a significant potential to compromise the university’s mission.

The Association of American Universities’ Task Force on Research Accountability recently published their “Report on Individual and Institutional Financial Conflict of Interest” (found at http://www.aau.edu/research/conflict.html). This report succinctly defines key values that universities must protect from financial conflicts of interest. These include our commitment to educating students, to academic freedom, to advancing the range and depth of knowledge and understanding of the natural world; to the care and safety of patients; and to protection of both the appearance and the actual integrity and objectivity of research, instruction and public service.

The Bayh-Dole Act encourages institutions to retain title to inventions developed by its faculty and to transfer the technology to the private sector. Universities use royalty payments from technology transfer transactions and, increasingly, may retain equity interests, particularly in start-up companies, as part of such transactions. As equity and royalties increase so too does the potential for conflicts.

We are considering a policy that defines a financial interest as any equity interest, royalties, or other payment received from a company under a license or other technology transfer by the University. Potential conflicts are deemed to arise when a company in which the University has an existing financial interest proposes to provide funding for research. Specific situations that would require review for actual or apparent conflicts include:

• A company proposes to provide research funding to the University for further development of a technology previously licensed by the University to the company and from which the University's financial interest is derived;

• A company in which the University has an equity interest (as opposed to royalties or other cash payments) proposes to fund any type of research (i.e., where the proposed research or clinical trial is not related to the technology that was previously licensed to the company and from which equity is derived); and

• A company proposes to provide funding for a clinical trial of a product or device that was developed by the company with the use of University-owned technology previously licensed to the company and from which the financial interest is derived.

As with faculty, when an institution reviews a situation to determine where there is an institutional conflict of interest, we should operate on the principle that potential conflicts must always be disclosed; conflicts must be managed, and the activity prohibited if it is determined that this is necessary to protect the integrity of the university. We propose to establish an Institutional Review Committee, appointed by the President, consisting of faculty members, administrators and at least 2 members from outside the University who have expertise in the particular area.

We have identified some significant factors that the Committee should take into account in determining whether a real or apparent conflict of interest exists and, if so, how it should be dealt with. These include:

• Is the research clinical or non-clinical? Research involving human subjects must be held to a higher standard and subject to greater scrutiny.

• Does the University's financial interest include equity? What is the value? An equity interest may be more likely to raise a potential conflict as the institution's financial interest is tied more directly to the overall success of the company.

• What is the size of the company in which we have an equity interest? How diverse is the company?

• If the research is a clinical trial - is it a multi-site trial? Are we gathering and/or monitoring the data from all the sites? Is it a double-blind study? What Phase is the trial in? What is the role of the institution's principal investigator? What public benefit may be derived from the research? Can the research go forward without our participation?

We believe establishing a sound Institutional Conflict of Interest policy is the right thing to do. Universities must do whatever is necessary to ensure the public has confidence in the integrity of our research universities - in both our faculty and in our institutions. Are we finished once a policy is put in place? Not at all. The principles and practices we, and all institutions develop must evolve, must be refined. Ultimately, we are held accountable for the research we conduct and the decisions we make. Let's make sure these decisions are the right ones.

Beth H. Israel is the Executive Director, Office of Projects and Grants for Columbia University.
Regional Corner continued

Also on January 1, as a result of our regional election, Terry Manns (California State University, Sacramento) will become Chair-elect, Geri Walker (Western Washington University) will become Secretary-Treasurer-elect, and Linda Patton (University of San Diego) will become a member of the Regional Advisory Committee. Terry and Geri will serve for one year as Chair-elect and Secretary-Treasurer-elect and then on January 1, 2003 will become Chair and Secretary-Treasurer respectively. Linda serves a two-year term beginning January 1, 2002.

The Program Committee for our joint region VI-VII spring meeting, chaired by Region VII’s Judy Fredenberg, met and is well into the planning for the April 14th-17th Hawaii meeting at the Keauhou Beach Resort in Kailua-Kona. Hotel and area information is on our region’s web site so you can make your travel plans now. Remember that the great room rate of $109/night is good for 5 days before and 5 days after the meeting.

I have enjoyed my service to the Region as Chair and strongly encourage each of you to volunteer and get involved with NCURA activities – I know that I have benefited greatly and will continue to benefit from being involved. Pat and Cece, I am quite sure, would appreciate all the assistance you can give them.

Finally I want to express my appreciation for the support and encouragement I received from Terry Manns our Secretary/Treasurer, Pat Hawk, Cece Manoochehri, the Regional Advisory Committee, and all those involved with the ad-hoc committees, Site-Selection, Nominating, and Travel Awards. Happy New Year and may this be the best year ever! Aloha!!

Dan Nordquist serves as Region VI Chair, and Interim Director, Washington State University.

REGION VII
Rocky Mountain

Three awards were presented in conjunction with our recent Annual Meeting in Washington to members of Region VII. Two meritorious individuals received travel awards of $1,000 to help defray their expenses associated with the national meeting: Rubert Herrick, College of Engineering, Colorado State University; and, Jacque Bernard, University of Utah. Moving from merit to luck, Jacque also won the new member drawing to waive her registration fee for the 2002 Region VI/VII Spring meeting that will be held in April in Kona, Hawaii.

Speaking of the regional meeting, program development efforts are well underway. The program committee, consisting of representatives of both Region VI and VII, met during the Annual Meeting and, not only will we be meeting in a site of unmatched beauty and allure, the professional development opportunities are abundant and robust. There will be six half-day workshops on Sunday, April 14, in addition to the 27 sessions held Monday through Wednesday, April 15-17. Stay tuned for details, which will be provided to you as early as possible!

Aloha!

Judy L. Fredenberg serves as the Region VII Chair and Executive Assistant to the Vice President for Research & Development and Director of Federal Relations for The University of Montana.

Clifford Shisler, Director of Research, Grants and Contracts at Northern Kentucky University will be retiring on February 1, 2002. Cliff has been a member all of NCURA since 1978 and a frequent panelist and contributor at NCURA annual meetings over the years.

David Mayo, Director of the Office of Research Information Systems and Associate Director of Sponsored Projects at the University of California-Santa Barbara has accepted a new position at the California Institute of Technology, where he will become the new Associate Director of Sponsored Research on February 11, 2002.

Good Luck to both of you!
A “One-Stop Shop” Approach to Sponsored Awards Administration

by Barbara Cole and Joseph Barabino

The following article is a historical review of the many changes of a sponsored program operation from 1997 to present from the perspective of two Directors who have been responsible for its management. It is our hope that this historical accounting will offer helpful perspective and insight to those sponsored programs managers embarking upon or considering a redesign of office services.

In 1996, a cross-section of faculty and administrators at the Boston University Medical Campus, comprised of a Medical School, Dental School and School of Public Health, embarked on a mission to provide a conceptual redesign and action plan for implementation of a new research administration process that would accommodate its increasing award base in the years 2000 and beyond.

This core group, dubbed the BUSM 2000 team, of approximately 20 individuals spent an intense six-month period collecting background information, reviewing current processes, devising general principles and cataloging recommendations to emerge with an action plan presented to the Provost of the Medical Campus. The findings were not uncommon among Universities, which had grown their research base at a rapid rate. There was extensive fragmentation, limited communication, and minimal training with a lack of shared goals and rewards. Administrative support for P.I.’s varied in type, accessibility and quality. Overall, it was articulated that there was an absence of a single point of contact for research administration coupled with limited use of new technology that contributed to slow, inadequate and inefficient service.

In a 100+ page report, the team made five major recommendations for Redesign with the theme of service coordination paramount. It was recommended that a central office comprised of pre-award, post-award and research committees be placed under one director. Responsibility and authority for the administrative and financial management of proposal and grant accounts were to be flowed down to appropriate qualified unit managers. A position to market faculty research, as well as build relationships for new sources of support was encouraged. The use of cross training made our employees more marketable and we lost staff to other Universities (Boston is a very competitive city for research administrators). We couldn't compete with other salary offers and began to hire less experienced persons who needed to be trained from the ground up. There were vacancies for long periods of time. Everyday activities like FSR’s fell behind. It was also noticeable that most heretofore pre-award people had a slightly longer learning curve for the accounting than vice versa. When application deadlines occurred, almost everything else stopped.

From the period of 1997 through 2001, our award base had grown from $72.5 M to $141.2 M and was, of course, managed with the same number of staff!! ORA changed its strategy slightly to allow for each TEAM member to be stronger in one arena than another, with the proviso that, to the client it was presented as a seamless operation. Each TEAM member was still required to do pre, post and accounting work, but it was decided among the team members which member concentrated on what.

The office did weather all the adversities that occurred in 1999 and 2000. In FY 2001, a Business Systems team was added to the group to help provide better reporting tools to alleviate workload issues. In FY 2002 ORA got the green light for two additional positions and with the economy on a downturn, the good news is that we've been able to hire again!

Is a comprehensive “one-stop shop” sponsored programs office a good deal? Is there too much to know, perhaps? The majority of the BUSM 2000 issues have been addressed positively. The faculty appreciates not being bunged around. The service orientation is there. The cross training is invaluable. To be sure, there’s no more passing the buck on blame. There is an inherent understanding and appreciation for pre-award folks. FAR clauses were, “excuse me, what??” to the accountants. The charge was given to each team to organize and cross-train themselves, over the ensuing 18 months, with the help of extensive weekly staff training sessions.

Luckily, during those first crucial months, there was absolutely no staff turnover. The enthusiasm was high, the expectations great and the spirit of camaraderie was tremendous. The reality of one office also began to sink in with the faculty. They were a bit hesitant because their apple cart had also been upended. They would call wanting person X or person Y and what they got was the TEAM. Discussion groups were formed at the administrator meetings with the TEAM S. Individual faculty and administrator mini-workshops were conducted with the TEAM S.

Most importantly, however, was the concept of TEAM management, which was introduced in July 1997. The recommendation of the BUSM 2000 Redesign Team to consolidate the ORA pre and post award management became reality. ORA organized into teams servicing specific departments. Each team was formed from the “old” departments to provide staff expertise in pre and post award management. The concept was to provide a “one-stop shopping service” for investigators as well as administrators.

Reorganization came at a price. It was apparent that a great deal of knowledge had to be learned quickly. Accounting was “greek” to the pre-award folks. FAR clauses were, “excuse me, what??” to the accountants. The charge was given to each team to organize and cross-train themselves, over the ensuing 18 months, with the help of extensive weekly staff training sessions.

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Barbara Cole serves as the Assistant Vice President for Financial Affairs and Joseph Barabino as the Director of the Office of Research Administration, Boston Medical Campus, Boston University.
The next NCURA Video Conference Airs
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11:30 am-3:30 pm, Eastern Time

Compliance Issues for Clinical Trials

Clinical trials are highly regulated and monitored activities. At the same time, universities and affiliated medical centers are under tremendous pressure to move quickly in order for sponsors to capitalize on intellectual property protection, obtain FDA approval, and deliver a safe and effective product to the public. This broadcast will examine major compliance issues affecting clinical trials and the partnership that exists among Federal agencies, drug manufacturers, clinical research organizations, academic health centers and private research organizations for maintaining compliance. Viewers will be able to ask questions of the panel.

Faculty: Christina K. Hansen, Assistant Vice Chancellor, Office of Research Administration, University of California-Irvine; Joseph Sherwin, Director, Office of Regulatory Affairs, University of Pennsylvania; Michael A. Carome, Director, Division of Compliance Oversight, Office for Human Research Protections, DHHS; Cynthia Dunn, Director, Clinical Research Institute, University of Rochester; David Lepay, Senior Advisor for Clinical Science, Director, Office for Human Research Trials, FDA

The cost of the full series (all four workshops) is $2,800.00 per campus. To purchase a “ticket” to an individual session the cost is $950.00 per campus. All Video Conferences will be aired from 11:30 am-3:30 pm, Eastern Time. NCURA will transmit a test signal one hour (10:30-11:30 am, Eastern Time) prior to air time!

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CONCURRENT SESSIONS
Please indicate below which sessions you would like to attend. These choices will not commit you to attend specific sessions, but will help us in our pre-meeting planning.

Monday, Feb. 18, 2002: 8:30 - 10:30 am
☐ Financial Compliance Perspectives (Plenary Session)

Monday, Feb. 18, 2002: 10:45 am - noon
☐ Departmental Administration: How to Be Everything to Everyone (Departmental Administrator)
☐ Effective Sponsored Program Training Programs (Compliance/Regulatory)
☐ Effort Reporting (Transactional)
☐ Dealing with DARPA Agreements (Discussion Session)

Monday, Feb. 18, 2002: 1:00 - 2:15 pm
☐ A-21 for Departmental Administrators (Don't Shoot the Messenger) (Departmental Administrator)
☐ Financial Compliance from the NIH Perspective (Compliance/Regulatory)
☐ Maximizing Revenue from Sponsored Research Activities (Transactional)
☐ Dealing with Non-Federal Funds (Discussion Session)
☐ Faculty Perspectives on Financial Research Administration (Discussion Session)

Monday, Feb. 18, 2002: 2:30 - 4:00 pm
☐ PayWeb, AwardWeb, or AdminWeb: Everything You Need to Know (Transactional)
☐ The Critical Role of Central & Departmental Administrators in Compliance (Compliance/Regulatory)
☐ What do Departmental Administrators do to Monitor Sponsored Program Expenses (Departmental Administrator)
☐ Cost Sharing: Is It the Best Written Fairy Tale? (Discussion Session)
☐ Web-based Effort Reporting (Discussion Session)

Tuesday, Feb. 19, 2002: 8:15 - 9:15 am
☐ Washington Update (General Session)

Tuesday, Feb. 19, 2002: 9:15 - 10:30 am
☐ A-110 for Departmental Administrators (Departmental Administrator)
☐ Compliance: How to Tackle the Beast (Compliance/Regulatory)
☐ The F&A Space Study & How to Best Prepare for the Negotiations (Transactional)
☐ Land Grant Institutions and Formula Funds (Discussion Session)

Tuesday, Feb. 19, 2002: 10:45 am - noon
☐ Best Practices for Departmental Financial Management of Clinical Trials (Departmental Administrator)
☐ F&A: What Is It and How Does It Affect My Institution? (Compliance/Regulatory)
☐ Operating Service Centers: The Good, the Bad and the Ugly (Transactional)
☐ Regional Differences In Negotiating F&A Rates (Discussion Session)

Tuesday, Feb. 19, 2002: 1:00 - 2:15 pm
☐ Cash Management—A Best Practice Session (Transactional)
☐ Communications: Who You Gonna Call/How You Gonna Call? (Departmental Administrator)
☐ The Cost of Compliance (Compliance/Regulatory)
☐ How Will the Changes to the OASC-3 Guide for Hospitals Affect You? (Discussion Session)

Tuesday, Feb. 19, 2002: 2:30 - 3:45 pm
☐ Ask the Experts for Departmental Administrators (Departmental Administrator)
☐ Maintaining Compliance in an Electronic Environment (Compliance/Regulatory)
☐ The Interface Between Medicare Cost Report and Universities F&A Rates (Transactional)
☐ Ask the Experts for Research Administration (Discussion Session)
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Assistant Director (Health Sciences)
Office of Sponsored Programs
University of Vermont

The Office of Sponsored Programs (OSP) is seeking an experienced research administrator to oversee the pre-award unit, which assists faculty in the College of Medicine and Schools of Nursing and Allied Health Sciences and to provide senior level research administration support to faculty in these academic areas. The Assistant Director, reporting to the Director, will be part of the University-wide OSP management team, assisting with direction and management of the office and with policy and process development. The Assistant Director will also assist faculty with proposal and budget preparation, review proposals for institutional endorsement, and negotiate and accept awards and contracts for the University.

This position requires a minimum of five years' experience in research administration with progressively more responsibility and independence. Experience in all aspects of supervision of professional and support staff is essential. Demonstrated skills in financial analysis and a basic understanding of legal and contracting principles are also required. Effective interpersonal communication skills, scrupulous attention to detail, and strong computer proficiency, including a demonstrated working knowledge of the use of spreadsheets for financial analysis are all necessary basic requirements.

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The University of Vermont is an Equal Opportunity/Affirmative Action Employer. Applications from women and people from diverse racial, ethnic and cultural backgrounds are encouraged.
POSITION ANNOUNCEMENT
DIRECTOR - RESEARCH ADMINISTRATION

The University of Wisconsin-Milwaukee (UWM) seeks an experienced research administrator to lead and direct the Office of Research Services and Administration. The Office handles pre-award processing and post-award financial management for all UWM sponsored projects. The Director’s position involves interaction with University administrators, investigators, sponsors, and the UWM Foundation. The Director reports to the Associate Provost for Research and Dean of the Graduate School.

UW-Milwaukee has a record of research growth and a strong commitment to continued expansion of research and extramural funding. UWM is Wisconsin’s major public urban research university, located in an attractive neighborhood setting near the shores of Lake Michigan only minutes from the center of metropolitan Milwaukee. Offering a comprehensive liberal arts and professional education at the undergraduate and graduate levels to its 23,000 students, UWM is one of the two doctoral-granting campuses in the University of Wisconsin System.

Responsibilities: Working with a full-time staff of eleven, the Director’s responsibilities include assisting faculty, staff, graduate students, and administrators in obtaining sponsored projects from federal and non-federal sources; negotiating complex grants and contracts; accepting awards; monitoring compliance with federal, state, UW System, and UWM policies, procedures, and regulations; records maintenance; and report preparation as required.

Minimum Qualifications:
• A Master’s degree is required with a minimum of six years of progressively responsible experience in a leadership position in sponsored projects administration in a research university setting.
• Excellent communication skills, including listening, oral, and written communications; effective managerial and interpersonal skills; and the ability to present material in a concise, effective, and professional manner to a variety of groups and individuals.
• A demonstrated record of skill in analysis, negotiation, organization, training, supervision, teamwork, and budget development.
• Broad knowledge regarding grant and contract administration, including research agreements, material transfer agreements, and responsible conduct of research.
• General knowledge of federal regulations governing sponsored project administration including OMB Circulars A-21, A-110, and A-133; Federal Cost Accounting Standards; and Federal Acquisition Regulations.
• Ability to develop and deliver responsible service to project directors and unit administrators responsible for sponsored project activities.

Salary and Pay Basis: This is a full-time, annual basis (12-month) academic staff position. Salary commensurate with qualifications and experience; excellent fringe benefits. Anticipated start date is February 14, 2002 or as soon as possible.

Application Process and Deadline: Interested individuals should submit a (1) cover letter of application; (2) a resume or vita; and (3) names and contact information for three current references postmarked by January 22, 2002, to:

Marjorie Bjornstad, Assistant Dean, UWM Graduate School,
P.O. Box 340, Milwaukee, WI 53201

Learn more about the University of Wisconsin-Milwaukee and the Graduate School by visiting our home page at http://www.uwm.edu/

Interested applicants may request additional information from the Graduate School Human Resources and Budget Office at gshrb@uwm.edu

UWM is an AA/EO employer and educator. Applications from individuals who would enhance and diversify our workforce are encouraged.
THE UNIVERSITY OF PENNSYLVANIA HAS AN OPENING FOR THE POSITION OF DIRECTOR, POST AWARD FINANCIAL ADMINISTRATION, IN THE OFFICE OF RESEARCH SERVICES.

This is an excellent opportunity for a seasoned individual with over ten years experience, excellent technical knowledge of relevant federal cost principles and administrative circulars, and a strong work ethic to assume significant responsibility for sponsored programs fiscal administration at one of the nation’s premier research institutions. The position reports to the Associate VP for Finance and Executive Director of Research Services. The position has primary responsibility for managing and supervising the following functional areas: post-award accounting, preparation of financial status reports, billings and receivables, and federal cash management. The position also interacts with the University A-133 auditors; is responsible for managing the annual A-133 audit process, and for developing corrective action plans as necessary. Penn received approximately $540 M in sponsored program awards in FY2001 and maintains approximately 5000 sponsored program accounts.

The incumbent will supervise a staff of 15 individuals and will be key in the University’s implementation of its electronic research administration systems. The incumbent will also work closely with ORS pre-award and the cost accounting and effort reporting groups. Moreover ample opportunities exist for improving processes and procedures and for recommending and drafting operational policies for improved grants administration. Salary is competitive and commensurate with qualifications.

Screening of applicants will begin immediately and continue until the position is filled. Applications, including a letter of interest that addresses the qualifications being sought and a curriculum vitae, should be sent in confidence to:

Andrew B. Rudczynski, Ph.D.
Associate Vice President for Finance
Executive Director Research Services
Office of Research Services
University of Pennsylvania
3451 Walnut Street, Suite P-221
Philadelphia, PA 19104-6205
The National Council of University Research Administrators (NCURA), founded in 1959, is an organization of individuals with professional interest in problems and policies relating to the administration of research, education and training activities at colleges and universities.

Co-Editors:
Richard N. Keogh
Rhode Island College
Phone: (401) 456-8228
Fax: (401) 456-8209
E-mail: rkeogh@ric.edu

Gunta J. Liders
University of Rochester
Phone: (716) 275-5373
Fax: (716) 275-9492
E-mail: gliders@orpa.rochester.edu

Managing Editor:
Kathleen Larmett
E-mail: larmett@ncura.edu

Assistant Editor for Regional Activities:
Tara E. Bishop
E-mail: bishop@ncura.edu

Production:
Tara E. Bishop
E-mail: bishop@ncura.edu

The NCURA Newsletter accepts advertisements for products and services pertinent to university research administration. In addition, display advertisements (including those for position openings) only will be published. The minimum rate is $400. For additional information, please contact the NCURA office at:
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April 20-23, 2002
Region II Spring Meeting
Ithaca, NY

April 27-30, 2002
Region IV Spring Meeting
Madison, Wisconsin

April 28-May 1, 2002
Region I Spring Meeting
Newport, RI

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NEWSLETTER DEADLINES
February/March 2002 Issue
Submission of Articles: February 8, 2002
Space Reservation for Ads: February 15, 2002
Submission of Display Ads: February 15, 2002

NEXT EVENT:

See page 22 for details!
NCURA Award for Outstanding Achievement in Research Administration

Each year NCURA looks to recognize one individual, who has made significant contributions to the profession of Research Administration and has demonstrated noteworthy service to NCURA, by presenting its award for “Outstanding Achievement in Research Administration.” The award, presented during NCURA’s Annual Meeting, began in 1994 and has had eight recipients. Those receiving NCURA’s highest honor are: Julie Norris, Tony Merritt, Dennis Barnes, George Dummer, Eric Rude, Ardis Savory, Richard Seligman, and Mareda Weiss.

NCURA’s Nominating and Leadership Development Committee invites nominations for the 2002 award. Individuals considered for this award

• Must be current or past NCURA members.
• Have made noteworthy contributions to NCURA
• Have made significant contributions to the profession of Research Administration. This may be evidenced in ways such as, publications, presentations, teaching, mentoring, service to one’s home institution/organization, service to outside organizations.

If you would like to nominate someone for NCURA’s highest honor please:

• Submit a letter of nomination (300-400 words). This letter written by someone with personal knowledge of the nominee should state why the individual should be considered for this honor.
• Supply at least two supporting letters including at least one from the nominee’s institution/organization that comment this person’s role in research administration.
• Supply an abbreviated resume of the nominee including educational background and professional service.
• Confirm that the nominee would be available to personally accept the award at the 44th Annual Meeting in November 2002.

If you would like to re-nominate a previous candidate, please:

• Submit a revised letter of nomination.
• Supply copies of previous supporting letters and include any new letters of support.

DEADLINE FOR NOMINATIONS IS APRIL 1, 2002.

Please send nomination packet to: Kathleen Larmett, Executive Director, NCURA, One Dupont Circle, NW, Suite 220, Washington, DC 20036. The packet may be sent electronically to: larmett@ncura.edu

Inquiries regarding the award may be directed to Kathleen Larmett at (202) 466-3894 or NCURA 2002 President, John Case at (919)966-2542.