Looking Forward...
by Regina H. White

It is a thrill and an honor for me to look ahead to the Year 2001 as NCURA’s President. To serve the membership of this organization, which has meant so much to me in my own professional development, is an opportunity for which I am grateful, and a responsibility I take very seriously.

Professional development has always been the hallmark of NCURA and the demand grows each year. The evidence for this is clear in the record breaking numbers we attract for all forms of professional development activities such as teleconferences, the Annual Meeting, and special conferences like FRA and ERA. As we all attempt to keep up with ever increasing workloads and compliance standards, we are finding it difficult to attend to our own needs and to provide proactive training and professional development for our staffs. Thus we look increasingly to NCURA for assistance, for guidance and for training.

As I said in running for this office, my priority is that “NCURA stay focussed on its mission of providing excellence in all forms of professional development activities and resources to its members”. The timing for this priority could not be better. We spent FY1998-1999 in strengthening the organization, through intense work around development of a strategic plan and consequent re-organization and by-laws revision. President Wilkinson’s theme for FY2000 of strengthening the community that exists within NCURA helped identify those ways in which we align with, learn from, and complement each other.

The priorities of the past few years - service to the Council (reorganization), and service to individual members (community) - result in our being better equipped to get back to what we’re all about in our everyday jobs: service to the faculty and to our institutions. This will be my focus.

A number of current issues, controversies, and federal developments cause our institutions grave concern: recent additional human subjects requirements, the new Responsible Conduct of Research guidelines, cost sharing and the costs of compliance. These are just a few that leap to mind. It is to the research administration office that our faculties and (Continued on page 10)

ERA Video Broadcast Set for January 23, 2001
by Nancy L. Wilkinson

NCURA is excited to present, in cooperation with the Federal Demonstration Partnership (FDP), its second video broadcast of the 2000-2001 series, entitled “Electronic Research Administration (ERA) – Where are We Today and What Can We Expect Tomorrow?” The live video presentation will be telecast to our subscribers on January 23.

The broadcast will examine current ERA events as well as consider what we might expect to occur in this arena in the near future. Included will be a detailed discussion of Public Law 106-107, a look at the ERA activities of several major federal agencies and committees, and the status of the development of the Federal Commons. Viewers will also have a chance to learn more about the exciting technology of digital signatures, complete with a demonstration.

To conclude the presentation, two panels will discuss ERA opportunities in the near future, one with an institutional perspective and the other from the federal agency viewpoint.

This broadcast has a terrific cast that includes, Jimmy Charney, Office of Management and Budget; Steve Dowdy, MIT; J.J. McGowan, NIH; Brad Stanford, ONR; Jerry Stuck, National Science Foundation; Sarah Wasserman, University of Illinois at Urbana-Champaign; Nancy Wilkinson, Emory University; and Pamela Webb, Northwestern University.

We hope that you’ll join us for the first ever ERA broadcast. If you’re not already a subscriber and would like to view this telecast, please visit the NCURA web site at www.ncura.edu for further details.

Nancy Wilkinson is 2000 NCURA President and Assistant Vice President for Research/Director of Sponsored Programs at Emory University.

(Continued on page 11)
On December 1, 2000, the Office of Research Integrity (ORI) released its long-awaited final PHS Policy for Instruction in the Responsible Conduct of Research. The policy expands existing regulations to mandate that research staff working on PHS-supported research or research training projects complete a basic program of instruction in the responsible conduct of research. Institutions are required to develop their programs of instruction by October 1, 2001; all existing research staff to whom the policy applies must be trained by October 1, 2003. The policy also provides guidance covering the training of research staff hired thereafter.

The policy reflects the importance that PHS places on fundamental and continuing education in conducting research responsibly, and it provides a basic foundation from which more detailed or focused programs may develop. The policy seeks to “increase knowledge of, and sensitivity to, issues surrounding the responsible conduct of research; improve the ability of participants to make ethical and legal choices in the face of conflicts involving scientific research; develop appreciation for the range of accepted scientific practices for conducting research; provide information about the regulations, policies, statutes, and guidelines that govern the conduct of PHS-funded research; and develop positive attitudes toward life-long learning in matters involving the responsible conduct of research.”

The final version of the policy incorporated many of the comments provided by the research community in response to the draft version released in July 2000. In the final rule, institutions are now afforded considerable flexibility in scope, coverage, format and timing for the training. ORI has also committed to offering institutions baseline training tools that can be utilized to meet the new requirements, as well as facilitating information sharing about tools that are developed by various institutions around the country.

The new policy applies to all research staff working on PHS-supported research or research training projects. “Research staff” has been defined to include “staff at the institution who have direct and substantive involvement in proposing, performing, reviewing or reporting research, or who receive research training.” The definition includes principal investigators and co-investigators who write the grant application, conduct the actual research, and report the research in abstracts, articles, and at scientific or lab meetings, whether or not they are receiving support from the PHS-funded project. The role of each individual, rather than the person’s title, is deemed to be key; for example, an experienced technician who actually conducts experiments may be covered while other less experienced technicians who do not perform such duties conceivably may not be. The training requirement also applies to internal and external collaborators, as well as consultants and subcontractors who meet the core definition of “research staff” above. The responsibility for determining who reasonably meets the definition of “research staff” rests with each institution. A notable change since the draft policy is the exclusion of departmental and sponsored research/administrative and support staff from the training requirements. While PHS continues to recommend that these staff receive training in those areas consistent with their roles, this will not be considered mandatory.

As indicated above, the final rule provides a great deal of flexibility for institutions to determine the appropriate scope and format of the training needed for each research staff member. Nine key core instructional areas have been established as the baseline universe for which training must be developed. These areas include:

- Data acquisition, management, sharing, and ownership
- Mentor/trainee responsibilities
- Publication practices and responsible authorship
- Peer review
- Collaborative science
- Human subjects
- Research involving animals
- Research misconduct
- Conflict of interest and commitment

Instruction in the core areas will be required to the extent that the core areas are applicable to the institution’s research programs and the particular research projects and staff involved. While PHS recommends that institutions consider whether to require at least introductory training covering all of these core areas (e.g., a 3-hour overview course), determination of the actual scope and format of the training has been left up to each institution.

The policy also defines what is intended by “a program of instruction.” Instruction in an area has been defined to mean completion of an educational activity, which could include reading a self-study guide; attending a lecture, formal course, workshop or seminar; making a presentation, working through a CD-ROM and Internet program, leading or participating in a discussion of case studies, or participating in any other educational activity consistent with the policy. Institutions are given flexibility to determine the exact content, length, level, method of instruction and documentation mechanism they wish to use to meet policy requirements. Those individuals asked by an institution to lead a training activity will be deemed to have met the training requirements in that area themselves. Research staff previously complying with NIH’s human subjects or responsible use of animals training requirements, or trainees having completed previous RCR training requirements in recent years, will be deemed to have already met the training requirements in these specific areas. Institutions may also decide whether to grant ‘credit’ for training previously received.

In the months ahead, institutions will prepare their plans for how to meet the new requirements. By October 1, 2001 each institution must have in place a program of instruction that complies with the policy, as well as a published written description documenting the program. The institution must also include in its plan the applicability of the RCR training to all research staff at the institution, as well as describing how the institution plans to document completion of RCR instruction by its research staff. After this date, ORI plans to select various institutions to request document completion of RCR instruction by its research staff.

Pamela Webb is NCURA Secretary and serves as the Director, Office of Research and Sponsored Programs, Chicago Campus of Northwestern University.

For additional information, please see:

The NIH Proactive Site Visit:  
A Perspective from Harvard University  
by Elizabeth Mora

When Harvard first learned of this series of NIH site visits in March 2000, several of us thought we would be selected as a university to be visited as we seemed to fit the profile of what the NIH was looking for:

- We are a large, decentralized research university with a medical school
- We are located in a part of the United States that was not represented in the first three NIH site visits
- We have a bit of history with NIH’s Office of Policy for Extramural Research (OPERA)—in the mid 1990s, we were in significant arrears with our federal reporting and were at risk of losing our Expanded Authorities.

The Planning

So, even not knowing with certainty that we would be selected, we began preparing by mobilizing a task force chaired by Harvard University’s Office of the General Counsel (OGC) and staffed by individuals in the following positions:

- Financial Deans of key research schools within Harvard (Arts and Sciences, Medical, and Public Health)
- Senior Research Administrators in those schools
- Financial Vice President
- Director of Technology, Trademark Licensing
- Director of Sponsored Research
- Director and Senior Members of Risk Management and Audit Services
- University Attorneys

This was serious! We met every Friday afternoon for two hours to inventory our research administration processes and identify areas of strength and weakness using information from the NIH focus areas at schools already visited. The areas of initial focus were:

- Roles and Responsibilities in Research Administration
- Training and Education
- Financial Conflict of Interest
- Human Subject/IRB Processes
- Animal Care Use Review Processes
- Gene Therapy Review Processes

The OGC appointed a member of the task force to head up each subject area and to work with others within the schools and central administration to review current policies and practices. Recall that we began preparation in March—in June we received official notification from NIH that indeed they would be coming for a day and a half in mid-July. This news was bittersweet.

While we had been preparing, the fact that this was now “real” added a new level of seriousness to our preparations. No more discussion about summer vacations in those meetings! By this point in time, three schools had already experienced the site visit—Johns Hopkins, University of Texas SW Medical Center, and the University of California, San Francisco (UCSF). We learned from UCSF that the NIH had requested materials on each subject matter to review in advance. As such, OGC hired a paralegal to work with each subgroup to compile materials that included website content, training materials, policies, sample reports, roles and responsibilities matrices, etc. One week before the visit, we learned that NIH had changed the focus areas. They added:

- Financial Management of Sponsored Projects
- Data Safety and Monitoring

And NIH subcontracted the review of:

- Animal Use Review Processes

Maybe this was to keep us on our toes!

The final week was very stressful for everyone involved. We knew that NIH wanted individual meetings with faculty members and the middle of July is not a good time to find faculty members on campus. Also, the NIH’s visit was coinciding with SAIL BOSTON - every hotel room within miles was booked!

The Process

A few days before they arrived, we learned of the format that NIH wanted during their visit. On Wednesday morning they asked for group sessions targeted to each focus area with a cross section of individuals from the schools and central administration in attendance. Then Wednesday afternoon, they requested either individual or small group meetings with Principal Investigators. Anticipating this approach, the Director of Risk Management and I had prepared a series of “mock questions” that we thought NIH might pose. This set of questions included topics such as effort reporting, costs transfers, roles and responsibilities, financial reporting, and unallowable costs. We distributed these in advance to those selected to participate in the sessions (and crossed our fingers). After the series of meetings on Wednesday, Gary Thompson, who was in charge of the visit from NIH, asked that the Harvard task force reconvene with the NIH team to receive some feedback. We joked nervously about this meeting all day Wednesday by referring to this late afternoon session as “The Sentencing.”

On Thursday morning, as part of the NIH’s transition from calling this a “not for cause” site visit to a “proactive” site visit, NIH had requested a joint presentation from Harvard and the NIH to be delivered to faculty members and administrators on each of the topic areas covered the day before. Mr. Thompson led the session off and then each NIH subject matter expert presented his/her area followed by each Harvard subgroup leader. This went on for three and a half hours. Somehow, we managed to collect about 130 university participants in the audience - about one half of these were faculty members.

And finally, back to “The Sentencing” ... what follows is a recap of NIH’s observations:

1) They noted some confusion in our regulations on the frequency of financial conflict of interest reporting
2) They noted that our cost transfer policy of allowing up to 120 days to transfer costs to and between federal awards was too long
3) They noted that there should be, at a minimum, mandatory faculty training for those faculty members involved in large program projects
4) They noted some confusion in our and their interpretation of certain gene therapy regulations
5) They noted that we had a heavy reliance on shadow systems at the department level.

None of these observations seemed earth shattering and Mr. Thompson and his team delivered the message in a very positive tone of partnership. He was even funny!

Afterthoughts

This experience was very positive for Harvard. Not only did we establish solid working relationships with members of OPERA, we also benefited by coming together internally to inventory our policies and evaluate our strengths and weaknesses. This visit also proved extremely helpful to those of us in research administration in delivering the message to faculty on the importance of training and education; we will leverage this site visit going forward. In summary, like many other challenges, this one was painful in the preparation and execution, but rewarding in the end. Some have compared the experience to that of a wedding!

Beth Mora is the Director, Sponsored Research Operations, at Harvard University.

See Gary Thompson’s article “Site Visits in the New Millennium: Partners and Stewards Together” on Page 12
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 seven recipients. Those receiving NCURA’s highest honor are: Julie Norris, Tony Merritt, Dennis Barnes, George Dummer, Eric Rude, Ardis Savory, and Richard Seligman.

NCURA’s Nominating and Leadership Development Committee invites nominations for the 2001 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 43rd Annual Meeting in November 2001.

Deadline for nominations is April 2, 2001. 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 President, Regina White, at (802) 656-3360.

What’s So New About The New Nominating and Leadership Development Committee?

by Cheryl-Lee Howard

“What is the new committee doing that the old Nominating Committee didn’t do just as well?” is the question most often asked of me as the first Chair of NCURA’s Nominating and Leadership Development Committee (N&LDC). And the answer? Absolutely amazing things!

First of all, let’s be perfectly clear that the changes were not necessitated because of any failings on the part of the “old” committee. The charge to the Nominating Committee consisted of issuing a call for nominations and selecting the best possible slate of candidates for whatever NCURA national offices were open each year. And each year, the committee members fulfilled that charge very well.

The problem was that the nomination process is only the tip of the leadership development “iceberg”. To be selected to run for office means that someone along the line an individual must have acquired skills as a leader, as well as knowledge of the organization and its members. That training is by far the biggest part of the process leading to election—and in NCURA it has traditionally been very informal and often even haphazard. The Nominating and Leadership Development Committee now carries a full range of charges for identifying potential leaders; mentoring, training, cultivating those identified; recommending and nominating them for leadership roles; and recognizing the efforts of those who contribute so much.

So, is it working? Yes! The excitement of this year’s committee has been contagious! Their creativity bubbled over into our annual meeting...and is already starting to empower next year’s committee. The most visible product was undoubtedly at our annual meeting with N&LDC’s successful Tuesday afternoon track of leadership-related concurrent sessions.

Less visible but equally strenuous, this year’s N&LDC inherited the task of transition. In addition to the nomination process, NCURA’s recognition activities have become part of the committee’s portfolio. These include the Catherine Core Travel Awards and selection of the Y2K recipient of NCURA’s award for Outstanding Achievement in Research Administration. At the same time, committee members were grappling with the entire new challenge of identification, mentoring, and developing a continuum of strong leaders and leadership activities. The result of these transitional activities is a road map for future committees—a strategic plan. Next year’s chair, Nancy Wilkinson, is already talking with this year’s committee, and especially the members who will carry over to next year, about priority tasks such as establishing pools of identified future leaders. Due to timing slips caused by the change in governance, the Y2K Committee got a late start and still accomplished so much. Next year, N&LDC will have a full year of activity, so stay tuned as the momentum builds.

(Members of N&LDC who have accomplished so much in such a short time include Steven Bernstein – Region I; Garrett Sanders – Region II; Kent Walker – Region III; Cordell Overby – Region IV; Gregory Foxworth – Region V; Linda Patton – Region VI; Judy Fredenberg – Region VII)

Cheryl-Lee Howard was the 2000 Chair of the N&LDC and serves as the Assistant Provost, University Research Projects Administration at the Johns Hopkins University.
As I sit in my office four blocks from the White House in mid-December, we still are uncertain who the next President of the United States will be. We do know that the next Congress will be about as evenly split as it can possibly be, with either a 50-50 or 51-49 split in the Senate, depending on the final Presidential election outcome. But we should not even talk about the next Congress yet, because we are in a lame duck session of the previous Congress that cannot agree on a budget for the federal government one fourth of the way through the fiscal year. The country seems as polarized as it has ever been ideologically, with seemingly little interest in bipartisanship. How can things be in such disarray, at a time of almost unprecedented internal prosperity and peaceful relationships with other countries? It’s as if we can’t stand the good times and are not satisfied without demons to be exorcised, but disagree on who or what demons to fight.

Similarly, at least at first glance, the conduct of science seems under attack. There is often a rush of new regulations at the end of an Administration, but the outsourcing (some have called it a “flushing”) of regulations and policies the past few weeks and months affecting the conduct of science is mind-numbing. A casual observer, seeing sweeping new and proposed rules on instruction in the responsible conduct of research, protection of human research subjects, research misconduct, protection of whistle blowers in research misconduct, and conflict of interest, would be justified in thinking that the entire research enterprise must be corrupt and in need of reform. Yet to come is the long-awaited final report from the Office of Science and Technology Policy which, among other things, will address the issue of cost sharing in research. Initiated by university presidents four years ago in an effort to re-invigorate the idea of a partnership between the federal government and universities in research, the report has been delayed by sometimes contentious debates over the language used in trying to precisely define different types of cost sharing. The reason for this debate can only be characterized as mistrust of the motives and actions on both sides.

Can things be that bad? A closer look gives some reasons to think otherwise. First, most of the regulations and policies have been in development for some time and have benefited from suggestions from the research community. One only has to look at the draft policy on responsible conduct of research compared to the final policy to see that the government in this case heard the message and made significant revisions, and from our perspective, improvements. The research community long ago asked for a government-wide definition of research misconduct, and after extensive consultation with science organizations has reached a mostly beneficial outcome. Regarding human subjects in research, most would agree that the system has suffered from lack of resources and coordination both in the government and in institutions, and this combined with rapid advances in science and concomitant new ethical challenges justifies the attention currently being devoted. New leadership on this issue is committed to working with the research community on the very best and most efficient ways to protect human subjects from harm while continuing the search for new knowledge. Investigator financial conflict of interest regulations have been on the books since 1995 and yet the federal government has never really looked closely at how institutions have implemented the regulations. And though it is part of the regulations, institutional conflict of interest has been off the radar screen until recent well-publicized occurrences of injury and death of human subjects in drug trials where the institution had financial interests that at least give an appearance of a conflict. It is probably appropriate to take a fresh look at this issue.

One of the few things Congress, the Administration, and the general public have agreed on in recent years is the importance of basic research. Funding increases for NIH in particular and more recent broader increases for NSF and other agencies has had bipartisan support, and just as importantly, strong public support. The analogy above of the political and scientific scenes is marked by one great difference - the public places great trust in science and scientists, while having a, shall we say, somewhat lower opinion of politicians and the political process. We have to keep reminding policy-makers and the public that these regulations are necessary but only to weed out the small fraction of violations that occur in an enterprise that is enormous beneficial to society and the economy.

As far as the tumult of recent regulations is concerned, research again may hold the answer. German theoretical physicists, turning their attention to traffic congestion, have concluded that traffic congestion can arise completely spontaneously under certain circumstances. No accidents, bottlenecks, or other external causes are necessary. Traffic can be flowing freely along at a density still well below what the road can handle, and then suddenly get into a slow moving ooze. They came to this by comparing traffic to moving gas molecules. American traffic engineers, of course, want to build more roads or lanes, or somehow reduce traffic. But the Germans’ analysis, based on the phenomena popularized as “chaos theory”, shows that in complex interacting systems, tiny fluctuations can grow in huge and unpredictable ways. Perhaps in this way these new interrelated research policies and regulations have been dumping along on their own path, suddenly converged and intermixed, and now pour freely forth. And as in the traffic jam, you are frustrated by the backup, but relieved when it clears and no one, including yourself, got seriously hurt.

Tony DeCrappeo is a Staff Associate for the Council on Governmental Relations (COGR).
Finally A Digital Signature or Cryptography 101
by Stephen Dowdy

This is the third installment on electronic and digital signatures. In the first article, we explored NSF's move to electronic (not digital) signatures by implementing a strong password scheme. In the second article, we looked at OMB's guidance to the agencies that enabled NSF to justify the use of passwords for official NSF business (non-cryptographic method of authenticating the identity of the individual) and introduced digital signatures (public/private key cryptography.) As explained in the previous article, OMB asserts that both methods are legitimate for conducting business.

A non-cryptographic method of authenticating a user's identity is basically using a password. The password is a "shared secret" because it is known both to the user and to the system. The system checks that password against a database to ensure its correctness and thereby "authenticates" the user. If, however, the authentication process is performed over an open network such as the Internet, it is essential that the shared secret be encrypted.

One way of encrypting the password, as it travels across the network, is to use Kerberos. Kerberos is a network authentication protocol developed at MIT and is designed to provide strong authentication for client/server applications by using cryptography. In fact, Microsoft Windows 2000 domain controllers use Kerberos for authentication. Unfortunately, Microsoft has changed the protocol slightly, but it is possible to configure existing Kerberos servers to work with Windows 2000. In conjunction with Brown University, University of Michigan, Carnegie Mellon University, and Cornell, MIT has developed and maintains a set of dynamic link libraries supporting Kerberos for use on Microsoft Windows 95, 98 and NT. (Go to http://web.mit.edu/kerberos/www/ or for Mac versions of Kerberos to http://web.mit.edu/macdev/www/kerberos.html) Now the really good news is that since Microsoft has embraced Kerberos as the native authentication scheme in Windows 2000, several companies are now beginning to provide commercial support for Kerberos. Therefore, one solution to encrypt the user's password as it travels across the open network is to use Kerberos.

So, what about digital signatures and how does it relate to authentication? Well, to get digital signatures, we will make use of what is known as public and private keys. The computer generates two mathematically linked keys -- a private signing key that is kept private, and a public validation key that is available to the public. Therefore, if I send you a signed e-mail message, it will be signed with my private key. You will use my public key to verify my signature. If the signature is "good", then you can be sure I was the original sender since only my private key could have generated the correct signature for you to use my public key for verification.

Now remember, my public key is public. Sally knows my public key and so does Billy. What do I do if I only want Sally to read my e-mail and I don't want Billy to intercept the e-mail and read it? I encrypt the message with Sally's public key! Instead of using my key to encrypt the message, I use Sally's public key and then only Sally's private key will be able to decrypt the message.

So, what does a public key look like? Depending on the key length, it will be a random string of 40 to 2048 characters. To save print space in this article, I am not going to reproduce my entire public key. But to show you how random a key is, here is the first 40 characters of my 2048 character public key:

mQGiBDon7Z8RBAjdDZn8lyFINyNh5w5e7C+OsNwK

I have posted my public key at http://web.mit.edu/osp/www/Dowdy.asc. I used Pretty Good Privacy, PGP, to generate my key pairs. A quick search of the web should locate the PGP software for your particular e-mail program and operating system.

Now you can imagine how difficult it would be if you needed to give someone your public key. And it isn't something that you can remember (unless you can remember a string of 2048 random characters). One of the biggest problems with public/private key pairs is how to deploy and manage them. Remember, you will need your public key if you want to verify my signature. I will need your public key to verify your signature and to send you an encrypted file that only you can open. Therefore, what we need is a way to deploy and manage the public key infrastructure. Digital certificates offer us a solution.

By now, you have probably been asked to accept a digital certificate from some site when browsing the web. This is known as a site certificate. It is used to verify the identity of the actual computer you are connecting to. Anyone can get a web address. How do you know that the web server you are connecting to is actually the correct web server you intended to connect with? Site certificates help identify the server as being legitimate. Why do you need this? Well, if you give your password to a server, you probably want to make sure it is the real server and that you haven't been re-directed to a different server by a "bad guy". The site certificate will authenticate the server. The personal certificate will authenticate the user.

The user's public key is made part of a digital certificate, which is a specialized electronic file digitally signed by the issuer of the certificate, binding the identity of the individual to his or her private key in an unalterable fashion. The whole system that implements digital signatures and allows them to be used with specific programs to offer secure communications is called a Public Key Infrastructure, or PKI. So, my public key is inside of my digital certificate. My digital certificate is signed with the private key of the issuing certificate authority (CA). MIT is a certificate authority. At MIT, personal certificates are issued to users and are signed by MIT. Now we have another problem. How does another university accept my digital certificate to authenticate me?
This is known as trust relationship. If your institution creates a certificate authority and begins to issue certificates, your site certificate will be incorporated into your browser. To see what certificates your browser accepts, follow these steps:

**For Netscape**
Select the “security” icon.
You will see a link on the left-hand screen for “signers”.
Click on signers.

**For Internet Explorer**
Select “Tools” from the menu.
Select “Internet Options”.
Select the “Content” tab.
Click the “Certificates” button.
Then select either “Intermediate” or “Trusted Root” Certificate Authorities tab.

Any digital certificate issued by one of the companies listed in the box will be verified by your browser. Notice that “MIT Certificates” is NOT listed in your box (unless you are an MIT reader of this article). If I present you with my digital signature, your browser will not be able to verify my identity since it won’t recognize a certificate signed by MIT. The browser manufactures want a lot of money to get your site’s certificate authority listed in their product. Then how do we establish the trust of your site’s certificates with my site and vice versa?

On November 17, 1999, the Corporation for Research and Educational Networking, CREN, a non-profit member organization of over 220 universities, colleges, and research organizations, deployed a top-level certificate authority service that provides authentication services to academic and research institutions (http://www.cren.net).

The idea is simple, CREN will issue MIT’s certificate and will verify it as being valid. CREN will issue you a certificate too. If you trust CREN and CREN verifies the MIT certificate as being valid, then you should be able to trust MIT when our certificate authority says you have a digital certificate for Steve Dowdy. MIT will sign my certificate as being a valid MIT issued certificate, CREN will sign the MIT certificate and will verify that you truly have the MIT certificate that was issued to MIT – not an imposter trying to claim to be the MIT certificate authority.

Using these technologies is becoming standard at many organizations. At MIT, our web-enabled applications make use of digital certificates. All other client/server applications rely on Kerberos to encrypt the password so that it doesn’t travel across the open network in the clear. Regardless of what technology your institution chooses, eRA systems are upon us. It is very important that you begin to plan and implement and security infrastructure that will give you confidence that you are authenticating users with the appropriate technology for the business risk associated with the transaction.

Steve Dowdy is the Manager of Network and Information Services in Office of Sponsored Programs at MIT. See Steve in NCURA’s January 23 live video broadcast, “ERA—Where are We Today and What Can We Expect Tomorrow?”

---

**2000 Catherine Core Minority Travel Award**

by Glenda Luecke

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 2000 Catherine Core Travel Award recipients were: Tyra Darville, University of Arkansas for Medical Sciences; L’Yana Batts, University of Arkansas at Little Rock; George R. Johnson, University of Colorado Health Science Center; and Shirleyae Williams Reed, University of California Berkeley. 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 2001 Catherine Core Minority Travel Award is August 15, 2001. Application forms are available upon request from the NCURA Office at (202) 466-3894 or e-mail at info@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 2001!

Glenda Luecke is Grants and Contracts Manager in the Research Office of Washington University.

---

See Page 22  For the Tech Transfer Community Corner.
It’s a cool day here in New England and although no snow for many of us yet the temperature yesterday and today is a reminder of what is yet to come. The Annual meeting is behind us now with a new attendance record set. The meeting was a huge success with a mixture of some old and some new. As always there were great workshops and thought provoking sessions. In addition, this year the Nominating and Leadership Development Committee coordinated the inauguration of leadership and development sessions on Tuesday afternoon that appeared to be very successful.

The 2000 – 2001 RADG season is up and running. The speaker for our meeting on December 13th was Charles Goldman, Ph.D. for the Rand Corporation. The January RADG meeting will be hosted by Beth Mora, Harvard University. Plans for our upcoming Spring meeting in Burlington are moving forward and the Program Committee along with its co-chairs Vivian Holmes and Louise Griffin are at work coming up with ideas for sessions as well as entertainment. Watch for upcoming announcements on the Region I webpage.

We recently completed the nomination and electronic balloting process for a new Secretary for Region I. Its my pleasure to announce that Tom Richardson, HMS, is the our new Secretary. I would also like to take this opportunity to thank our outgoing Secretary, Elayn Byron, for her support and dedication to the region over the past two years.

This past month saw the inaugural use of the Region I Listserv. Although off to a rocky start, the listserv will be a wonderful communication vehicle for the region. A reminder, however, that should you wish to forward listserv emails along to others it is better to copy and paste the text into a new email. Simply replying or in some cases even forwarding the email sends the message back though the listserv, as we found out.

In closing I would like to take this opportunity to acknowledge another Region I member who has volunteered to serve on the national level. Our own Alice Tangredi-Hannon, Brown University, has agreed to serve as Co-Chair of the 2001 Annual Program Committee. Congratulations, Alice.

Bill Corbett is Chair of Region I and is the Director of Research Administration, Dana-Farber Cancer Institute.

Members who attended the NCURA 42nd Annual meeting were treated to a wide variety of programs and activities. Highlights included the Sunday evening banquet, a spirited keynote session devoted to the U.S. Presidential election eve forecasts, and the always-popular Tuesday night party. Region II was impressively accounted for at the sessions–regional attendees totaled 342!

At the annual business meeting, the new Chair-elect for 2001-2002, Betty Farbman from Teachers College and Secretary-Treasurer-elect Ann Holmes from the University of Maryland were introduced. The electronic election slate for the inaugural regional representative to the National Board was also announced, consisting of Janice Anderson from Princeton University and Janet Simons from the University of Maryland-Baltimore. Appreciation was expressed to all those individuals who have held active roles in the region over the last two years. Special acknowledgement was expressed to Gunta Liiders, our outgoing Secretary-Treasurer, for all her efforts on behalf of the region.

An overview of key topics from July’s Regional Revitalization Workshop was also presented. A floor motion was approved to move forward with some of the provisional recommendations from that event.

As outgoing 1999-2000 Chair, I would like to express “thanks” to all of you, the membership of the region, for your participation and engagement over the last two years. We have a tremendous talent pool and experience base in the region. Your continuing professional involvement will help assure that new organizational milestones are achieved, both at regional and national levels.

The new Regional officers are looking forward to increased participation from new as well as veteran members. We are joined by our first Regional Representative, Jan Anderson of Princeton University. We are grateful for this opportunity to move the Region into the next century, and excited about prospects for the future. Warmest thanks to Mike and Gunta for all their efforts on behalf of our membership during their years of service.

Plan now to join your fellow Region II members in Hershey, PA from April 29 through May 1 for our annual spring meeting. The Program Committee, headed by Denise Clark of Cornell University, and Charlie Kaars of SUNY Buffalo, is hard at work. The meeting’s theme, “2001: A Research Odyssey: Navigating in a Changing Federal Universe” is coming to life. Keep posted on developments by visiting the meeting web site at http://www.osp.cornell.edu/regionii2001. The festivities will include extending a warm welcome to our new NCURA Vice-President/President Elect John Case as he visits his “region of origin”.

Mike Crouch served as Region II Chair and is the Director, Office of Research, University of Pittsburgh; Betty Farbman is the incoming Region II Chair and is Director of Sponsored Programs Office at Teacher College, Columbia University.

Plan now to join your fellow Region II members in Hershey, PA from April 29 through May 1 for our annual spring meeting. The Program Committee, headed by Denise Clark of Cornell University, and Charlie Kaars of SUNY Buffalo, is hard at work. The meeting’s theme, “2001: A Research Odyssey: Navigating in a Changing Federal Universe” is coming to life. Keep posted on developments by visiting the meeting web site at http://www.osp.cornell.edu/regionii2001. The festivities will include extending a warm welcome to our new NCURA Vice-President/President Elect John Case as he visits his “region of origin”.

Mike Crouch served as Region II Chair and is the Director, Office of Research, University of Pittsburgh; Betty Farbman is the incoming Region II Chair and is Director of Sponsored Programs Office at Teacher College, Columbia University.

Region IV members approved revisions to the regional bylaws at their business meeting in Washington, DC this fall. Most of the proposed changes aligned our bylaws with the governance of the national organization. “In drafting the proposed changes to our bylaws, the Region IV leadership has worked to support and continue the spirit of inclusiveness being instituted by our national organization,” said Kathy Taggart, Region IV Chair.

Regional leaders with a host of volunteers are preparing for the regional meeting in Minneapolis scheduled for April 29–May 8. As chair of the 2001 Program Committee, Jim Maus (Washington University) is seeking volunteers.

Region IV is proud of its contributions to the field of research administration and to our national organization. Region IV members contributing at the national level include:

- **Pamela Webb**, Secretary, Communication & Member Services, ERA V Program Committee, Member Profile Task Force and Newsletter Article Contributor (Northwestern University); 
- **Jamie Caldwell**, Board of Directors and Minority Task Force
The standing committees provide the infrastructure for Region IV professional development programs. Why does it work so well? Because of our volunteer members.

Awards Committee. Joanne Altieri, Chair (University of Kansas); Alicia Knoedler (University of Notre Dame); Pamela Krause (University of Notre Dame); Lillian Manning (Southern Illinois University at Edwardsville); Cordell Overby (Michigan State University).

Membership Committee. Susan Toler, Chair (Loyola University of Chicago); Tyece Little (University of Missouri-Columbia); Lucy Mayhugh (Loyola University of Chicago); Heather Offhaus (University of Michigan); Crystal Taylor-Nevis (University of Chicago).

Nominating Committee. Ellen Rogers, Chair (University of Notre Dame); Robert Aull (Indiana University Medical Center); Patricia Conway (University of Illinois, Chicago); Monya Schulenberg (University of Wisconsin-Extension); Sarah Starr (The Ohio State University Research Foundation).

Program Committee. James Maus, Chair (Washington University, School of Medicine); Robert Aull (Indiana University Medical Center); Don Boydston (Rush Medical College); Jamie Caldwell (Loyola University of Chicago); David Lynch (University of Minnesota); Dorothy Spurlock (Eastern Michigan University); Susan Toler (Loyola University of Chicago).

Communications Committee. Deborah Vetter, Chair (Wright State University); Bradley Fitch (University of Detroit Mercy); Dola Haessig (University of Missouri-Columbia); Marjorie Piechowski (DePaul University); Bill Sharp (University of Kansas).

Site Selection Committee. Glenda Luecke, Chair (Washington University); Deborah Galloway (University of Cincinnati); Ted Knous (University of Wisconsin-Stout).

For more news on Region IV, visit our Web site at www.udmercy.edu/ncura4/.

Deborah Vetter is Director of Faculty Development Operations, School of Medicine at Wright State University.

REGION V
Southwestern

Region V is in the process of voting on amended By-Laws. If the amended By-Laws are passed, we will be constituting a number of Regional committees: Nominating, Membership and Hospitality, Awards, Travel Scholarship, Publications and Communications, and Finance. It has been great to receive an overwhelming number of responses from our call for volunteer committee members. In fact, we have received a greater number of volunteers than positions on available Committees!

Sondra Frestl, Vice Chair of Region V, is busy planning the Spring 2001 meeting which will be held at the Westin Hotel in Oklahoma City, Oklahoma from Sunday, April 29 through Wednesday, May 2. Also, Region V is excited about our joint meeting in Spring 2002 with Region III. This meeting will be held at the St. Anthony Hotel in San Antonio, Texas from Sunday, May 5 through Wednesday, May 8.

At our business meeting in Washington, D.C., a committee was formed to make location recommendations for our 2003 meeting. Mary Catherine Spikerman has offered to chair this committee which consists of Jan Fox, Jan Madole, Wayne Kuenstler and Judy Cook. We will look forward to their report at our Spring business meeting.

Region V now has a Listserv! The address is: region5@lists.ncura.edu. If you send a message to this address, all members of Region V will receive your message. If you send a message to the Listserv and would like a response back to you, please be sure to include your email address.

Susan Krause is Chair of Region V and Director, Program Development, Texas Children’s Cancer Center and Hematology Service/Baylor College of Medicine.

REGION VI
Western

I would like to take this time to say good-bye to all my friends and colleagues in Region VI (and Region VII with whom we have our joint meetings). I have enjoyed our comraderie, discussions, golf tournaments, etc. over the past 8 years and hope to see you at future annual meetings. It was a difficult decision to move from the left coast to the right coast and I look forward to the challenges this move has to offer. I hope everyone has a terrific holiday season and a Happy New Year.

Hal Gollos is the outgoing Region VI Chair and the former Director, Research Development, Pacific Graduate School.

Region VI was well represented at the annual meeting. During the month of October, NCURA gained fifty new members from Region VI. Over 125 colleagues attended our region’s business luncheon. A special drawing was held at the luncheon for new members. Glenda Smith, UC, Berkeley won the prize – a free registration to our joint Region VI-VII meeting in Santa Fe in April. Congratulations Glenda!

First time attendees Carlette Thompson, Cal Tech and Lynne Prichard, UC, Santa Barbara were introduced as recipients of the Region VI Travel Awards. Welcome Carlette and Lynne to NCURA! We hope to see you at many more regional and national meetings.
Looking Forward...(Continued from cover)

administrations will turn for analysis and assistance, for which we must be prepared.

We must also not lose sight of NCURA’s traditional strengths in providing the fundamentals. The administration and support for research and scholarly activity on our campuses is becoming increasingly specialized and it behooves us to recognize the need to offer our members professional education in a variety of core specialties (funding information, grant and contract proposal development, negotiation, post-award administration, compliance) AND to provide basic foundations in such relevant areas as technology transfer, legal concepts, Federal government processes, and corporate/university relationships. The needs of department administrators and financial research administrators must also be addressed, as they become important members of the NCURA community.

In determining how well we are contributing to the ability of our members to serve their institutions, my first goal will be to examine exactly where we are now. I plan to launch a critical evaluation of our current programming - what we are presenting, and by what mechanism - to identify strengths, weaknesses and gaps. With that evaluation in hand we will be in a position to decide what steps need to be taken, and with what priority, for protecting our strengths, improving our weak areas, and whether gaps should be filled by NCURA or in collaboration with one of our colleague organizations (e.g., NACUA, AUTM, NACUBO).

NCURA is an extraordinary association, and it has reached a level of excellence due to the efforts of many, many volunteers throughout the organization. We still have much work to do, and as I look to the year ahead I intend to be cognizant of the needs of NCURA and how much we can reasonably expect to accomplish given the demands of our profession and our lives. NCURA is a community of colleagues with wide ranges of interests, activities, pursuits and accomplishments - our association benefits from recognizing that our volunteer effort is a precious commodity, and it must be valued and judiciously utilized.

The year 2001 holds great promise for NCURA in the programs already scheduled, tools in development, and initiatives under discussion. I look forward to working with the Board and the entire membership in continuing to assure NCURA’s primacy in the field of research administration.

Regina White is the 2001 NCURA President and serves as the Director, Office of Sponsored Programs at the University of Vermont.

PDF in eRA (Continued from page 21)

- The PDF file can be created and viewed, but cannot be successfully uploaded to FastLane. This has typically been related to font problems in Adobe Acrobat 4.0. Pdfzone.com4 describes this problem as follows:

As part of its installation process, Adobe Acrobat 4.0 places in its own folder/directory a set of standard PostScript (Type 1) fonts—the so-called “Base 14 Fonts”—that the program uses. There’s a difference, however, from the base fonts installed by previous versions.

Acrobat 4.0 does not include Helvetica and Times, which were part of the base fonts in version 3 and earlier. Instead, it includes two similar Type 1 fonts from Monotype—MT Arial and MT Times New Roman.

This can be the cause of problems, i.e. unexpected font behavior. While viewing a PDF with Helvetica and/or Times, where the fonts were not embedded in the document and are not located on the viewing system, Acrobat will substitute the respective Monotype fonts.

De-bugging PDF conversion problems is not for the faint of heart, nor for the technically unsophisticated. However, there are a number of resources, in addition to FastLane and pdfzone.com, available on the Internet that can help provide solutions—

For Adobe, www.adobe.com/support/

Sarah Wilson Wasserman is the Associate Director, Grants and Contracts Administration of the University of Illinois at Urbana-Champaign.

---

1 The 194 Transaction Set is an approved Electronic Data Interchange format for the submission of a grant proposal. It defines the data fields that constitute standards agreed upon by the major research funding agencies.
2 Even when PDF is not officially “required,” for all practical purposes it is the only way that information besides ASCII text can be transmitted electronically. Since ASCII text is not typically adequate for scientific purposes, PDF is a default requirement.
3 NSF provides extensive instructions for PDF production, including detailed instructions for embedding fonts, at www.fastlane.nsf.gov/a1/pdcreat.htm
4 www.pdfzone.com is a website providing “the most timely and useful information on PDF and Acrobat on the Internet.”
FRA II: Making Sense of Research $ (continued from cover)

Our conference theme, “Making Sense of Research $,” aptly describes what we are trying to accomplish with FRA II. Our goal is to encourage an exchange of ideas and information that will help all of us to become better informed about the principles, policies, and processes that encompass the financial framework of research administration.

General and concurrent sessions will explore what is happening on our campuses, as well as timely policy issues being discussed in Washington. Small group discussion sessions will enable participants to explore in greater detail some of the topics introduced in concurrent sessions. We will also be offering two excellent pre-conference workshops covering pre-award fundamentals for post-award administrators and post-award fundamentals for pre-award administrators. (Please note that these workshops require a separate registration and attendance will be limited, I encourage you to register early).

The FRA II program offers something for everybody involved in research administration, whether you are an experienced research administrator or you are new to research administration, a full-time administrator or an individual for whom research administration is only part of your job responsibilities. I hope that you will consider joining us in Orlando this winter for FRA II. It promises to be an outstanding conference and an excellent opportunity to interact with your colleagues from across the country.

Patrick Fitzgerald is the Chair of FRAII and serves as the Director of Cost Analysis at the Massachusetts Institute of Technology.

Regional Corner (Continued from page 9)

REGION VI
Western (continued)

We are very proud that one of our colleagues, Richard Seligman, Cal Tech was selected to receive NCURA’s Outstanding Achievement Research Administration Award. Dick has served faithfully in many roles within NCURA, both at the regional and national levels. In 1995 he served as President of NCURA. Congratulations Dick!

The Program Committee is well into the planning for our joint meeting with Region VII this spring in Santa Fe. Along with an outstanding (and seasoned) group of volunteers, Hal Gollos and Terry Manns are co-chairing the program committee. If you have any suggestions for a workshop or session please e-mail Terry at jtmanns@csus.edu. Mark your calendar and plan to attend. The meeting will be held at the El Dorado Hotel in Santa Fe, New Mexico, April 16-18, 2001.

Our Chair, Hal Gollos has moved to the University of Pittsburgh Medical Center. Our loss is Region II’s great gain. While we will surely miss Hal, we are pleased that he will still organize the golf tournament for our spring meeting.

Terry Manns is Region VI Secretary-Treasurer and Director, Research and Sponsored Projects, California State University, Sacramento.

REGION VII
Rocky Mountain

Region VII Grows by Leaps and Bounds!

Region VII (the Rocky Mountain Region) experienced unparalleled growth in our attendance at the NCURA Annual Meeting in Washington D.C. We met many new Region VII members and had the opportunity to discuss issues relevant to our geographic local and profession. What a great turnout for the national meeting!

We are expecting the same great response to the upcoming combined Region VI and VII meeting in beautiful Santa Fe, New Mexico. Mark your calendars for April 16-19, 2001, for this lively meeting nestled in the historically beautiful pueblo that is Santa Fe. There will be an opportunity for all to participate in the plenary presentation and a variety of panel discussions and workshops. From proposal development to training…from human subjects to compliance…from animals to cost sharing…from negotiating contracts to cost accounting standards…Santa Fe is the place to be! (Because the regional meeting falls on the day after the Easter holiday, we will be starting the meeting on the afternoon of Monday, April 15, 2001, to allow for morning travel. The meeting will close on Wednesday afternoon).

Region VII elections are coming up. Be sure to vote on-line!!

Carey Conover is the Associate Director for Special Projects Office of the Vice Provost for Research & Graduate Studies at Northern Arizona University.

Region III is on hiatus!
The NIH Proactive Grants Compliance Program
"Site Visits in the New Millennium: Partners and Stewards Together"
by Gary Thompson

INTRODUCTION
As the new millennium hit just its third month, the National Institutes of Health (NIH) began a most important initiative: The NIH Proactive Grants Compliance Program. A site visit team of five NIH professionals hopped in a vehicle from the NIH Car Pool and drove approximately 50-miles to conduct its first Proactive Compliance Site Visit at The Johns Hopkins University in Baltimore, Maryland. Over the next six months a cadre of eighteen NIH staff would travel to ten major institutions across the United States covering a distance in excess of 22,000 roundtrip miles.

I drove the vehicle that carried the site visit team to Baltimore and I chaired that first site visit at The Johns Hopkins University. I also had the responsibility of chairing the other nine site visits conducted during the spring and summer of 2000. From Baltimore, MD to Portland, OR --- from Boston, MA to Miami, FL and six other sites in between. Now, I’d like to take you along with me, and the other site visitors, as we re-visit those ten institutions and share with you what this was all about.

PERSPECTIVE
While compliance and oversight is not new, clearly, in recent years, there has been a growing emphasis on these important elements of the sponsored projects relationship between NIH and its grantees. The NIH, and therefore the enterprise of biomedical research, has been very fortunate over the past several years to experience dramatic budget gains. Not surprisingly, the increases in resources have also resulted in heightened scrutiny of how those dollars are expended and in the oversight required by both the recipient institution and the sponsoring agency. For instance, Congress has posed to NIH the following question:

- How much oversight does NIH conduct on its extramural spending, and how much of the oversight is left up to the institutions themselves?

NIH has responded, in part, by saying:

- NIH seeks to ensure integrity and accountability in its grant award and administrative processes by establishing a set of expectations for grantee operations that is reliant on a system of checks and balances.
- NIH expects grantee organizations to provide an appropriate level of day-to-day oversight of individual projects that uphold high ethical, health, and safety standards in both the conduct of research and the expenditure of public funds.
- The grantee is responsible for establishing and maintaining the necessary processes to monitor its compliance...
- NIH staff fulfills their responsibility for stewardship of Federal funds through the monitoring of grants and grantee organizations to identify potential problems and areas where technical assistance might be necessary. This active monitoring is accomplished through review of progress and financial reports, correspondence from the grantee, audit reports, site visits, and other information available to NIH.

KEY CONCEPT
A critical element of this new compliance program was that the site visits be conducted in a proactive mode. The site visits would not be audits, nor would they be investigations. Rather, they would be conducted in a non-crisis and non-adversarial manner... a manner that would enable the NIH site visit team to act as both a partner and steward as we engaged our partners in the biomedical research community.

BACKGROUND
The National Institutes of Health (NIH) is the principal Federal-funding agency responsible for the conduct of biomedical and behavioral research, and research training. We believe very strongly in the sponsor/recipient relationship and the partnership we enjoy with our grantees. This partnership is even more important when we consider that the overwhelming majority of our extramural program is funded by the assistance mechanism (grants and cooperative agreements). The grant relationship is largely predicated upon trust. We expect and we make assumptions that our grantees will properly administer the sponsored activity in accordance with applicable rules, regulations, and cost principles.

As a Federal granting agency, NIH is responsible to Congress and to the general public for carrying out its mission in a manner that not only facilitates the efficient and proper conduct of the research but also ensures compliance with applicable policies, rules, and regulations.

When the NIH commenced its Proactive Grants Compliance Program, early in calendar year 2000, with the initiative to conduct a series of site visits to major institutions across the country, many wondered and questioned: “Where did this come from; what will it be; and will my institution be one of those visited?”

A LOOK AT THE EXISTING CULTURE
- The NIH is the principal sponsor of biomedical and behavioral research and research training.
- The grantee institutions are the recipients.
- We’re partners in the biomedical research enterprise.
- It’s a big enterprise!
- It’s an enterprise that is important to the public welfare.
- It’s an enterprise that is put at risk through acts of noncompliance.
- Both partners have a legitimate stewardship role.
- The NIH budget for FY1999 was nearly $16B (as in billion).
  - The Extramural Budget was 81% of the NIH total or $12.8B.
  - Grants represented 92% of the Extramural total $11.8B.
- The NIH budget for FY2000 was approximately $17.8B.
- We made grant awards to nearly 2,500 recipient institutions in FY1999.
- The Top 100 institutions received nearly 75% of all extramural funds in FY1999.
- Medical Schools received approximately 51% of all extramural funds in FY1999.
- The Top 25 institutions received nearly 38% of all extramural funds in FY1999.

So, why the site visits... and why now? How much did specific events contribute to this initiative? Clearly, we learned a great deal from our intensive interaction with major recipient institutions such as the University of Minnesota and Thomas Jefferson University. Certainly, we could focus on the unfortunate death of 18-year old Jesse Gelsinger after participating in a gene-therapy experiment at the University of Pennsylvania. We can cite the 37% increase in grant related cases of noncompliance, from FY1999 to FY2000, handled by NIH’s Office of Management Assessment. All of these events have contributed significantly to the need for more effective compliance and oversight. Yet the real impetus for this initiative is the basic and fundamental need to restore confidence in the biomedical research enterprise and maintain and preserve the public trust.
These were good questions then and they’re still good questions, especially if you were not among those sites visited by NIH. This article will address these questions by exploring the background, planning, preparation, execution, and feedback process of this important initiative, as well as providing some insight for what it portends for the future.

WE LOOKED AT THE EXISTING CULTURE AND MADE SOME CONCLUSIONS

• If the biomedical research enterprise is put at risk, then the public welfare is put at risk.
• NIH truly is a granting agency.
• A relatively small number of grantee institutions receive an inordinately large portion of the total funds available.
• NIH would be well served to focus its compliance program on the institutions that receive the most support.

WE DECIDED TO DO TEN SITE VISITS

• All ten institutions site visited by NIH were in the Top 100 in FY1999.
• All ten institutions site visited by NIH had Medical Schools.
• The 10 institutions that were site visited received slightly less than 10% of all extramural awards made by the NIH in FY1999.
• The 10 institutions that were site visited received approximately 11% of all extramural dollars awarded by NIH in FY1999.
• We felt that what we would observe at the ten institutions would give us a reasonably good view of the broader grantee community.

PLANNING

As Congress expressed concern about NIH’s oversight of its extramural program, NIH assured Congress that it would be appropriately responsive. A number of areas were identified that would form the basis for NIH’s response. Included among these were issues around the reporting of adverse events, the conduct of gene therapy research, the identification and reporting of financial conflict of interest, and the reporting of inventions under the provisions of the Bayh-Dole Act. Subsequently, a determination was made to conduct three “not-for-cause” site visits. The not-for-cause mode would accommodate a proactive approach and format that would enable NIH to be both a partner and a steward. It would afford us the opportunity to focus on the most important issues, give us knowledge of how institutions implement our policies, and help identify difficulties institutions face in fulfilling Federal requirements.

Criteria for selecting the three institutions were determined and included:

• Level of support
• Nature of support (that it include gene therapy transfer research)
• Geographic diversity
• That the Office of Policy for Extramural Research Administration (OPERA) not be currently involved in a specific noncompliance case or issue with the selected institution

From a number of institutions that met the selection criteria, the three institutions selected for Phase I of the Proactive Compliance Site Visits were:

1. Johns Hopkins University (Baltimore, Maryland)
2. University of Texas Southwestern Medical Center, Dallas (Dallas, Texas)
3. University of California, San Francisco (San Francisco, California)

These three site visits were conducted in March 2000. Subsequently, seven additional site visits would be conducted between early July and late September 2000. These seven Proactive Compliance Site Visits became known as Phase II and comprised the following institutions:

1. The Harvard University (Cambridge, Massachusetts)
2. Medical University of South Carolina (Charleston, South Carolina)
3. University of Miami (Miami, Florida)
4. University of Arizona (Tucson, Arizona)
5. Indiana University (Indianapolis, Indiana)
6. Oregon Health Sciences University (Portland, Oregon)
7. Vanderbilt University (Nashville, Tennessee)

PREPARATION AT THE NIH

We discussed what would be the premise for the site visits, the purpose, goals, the subject areas that would form the basis of the site visits themselves; and the hoped for outcome. Our discussions led to the following:

• Premise: It is not always apparent that a culture of compliance and oversight is universally present in the biomedical research enterprise.
• Purpose: Assess level of understanding of certain NIH rules by discussing policies, procedures, and practices at recipient institutions to ensure compliance with NIH requirements.
• Goals: a) Increase educational outreach; b) enhance administrative oversight of sponsored research; c) renew institutional commitment to compliance; and d) receive feedback on obstacles to implementing Federal rules and NIH policies.

(Continued on next page)

### NIH Staff Comprising the Core Site Visit Team

- **Gary Thompson** (Chairman)
  Director, Division of Grants Compliance and Oversight
  Office of Policy for Extramural Research Administration (OPERA) Office of Extramural Research, NIH
- **Diane Dean** (Roles and Responsibilities and Training and Education)
  Division of Grants Compliance and Oversight Office of Policy for Extramural Research Administration (OPERA)
  Office of Extramural Research, NIH
- **Dennis Dixon, Ph.D.** (Clinical Trial Data Safety and Monitoring)
  Chief, Biostatistics Research Branch
  Division of Acquired Immunodeficiency Syndrome
  National Institute of Allergy and Infectious Diseases (NIAID)
- **Robert Jambou, Ph.D.** (Clinical Gene Transfer Research)
  Office of Biotechnology Activities
  Office of Science Policy
  Office of the Director, NIH
- **Shelley Mizzell/Greg Pryor** (Financial Management of Hazardous Waste Disposal)
  Division of Biomedical Research Activities
  Office of the Director, NIH
- **Mike Payne** (Financial Management of Sponsored Programs)
  Director, Division of Financial Advisory Services
  Office of Acquisition Management and Policy
  Office of the Director, NIH
- **George Stone, Ph.D.** (Bayh-Dole Act/Invention and Patent Reporting)
  Chief, Extramural Inventions and Technology Resources Branch
  Office of Policy for Extramural Research Administration
  Office of Extramural Research, NIH

Other site visitors who participated in more than one site visit were:

• Anthony Demsey, Ph.D., OER/OD (Hazardous Waste Disposal)
• Mary Groesch, Ph.D., OBA/ (Clinical Gene Transfer Research)
• Tom McCormack, DGP/OPERA/OER/OD* (Financial Conflict of Interest)

*Currently, Mr. McCormack is the Grants Policy Officer, PHS
Site Visits (continued from page 13)

- Subject Matter: a) Roles and responsibilities; b) training and education; c) financial conflict of interest; d) inventions and patents; e) data and safety monitoring; and f) clinical gene therapy research. These were the six areas upon which the first three Not-for-Cause Site Visits (Phase I) were based. For the Phase II site visits, we added: 1) Financial management of sponsored projects; 2) hazardous waste disposal (for several institutions); and 3) a one-half day education-outreach seminar for an expanded institutional audience of faculty and staff on the second day.

- Hoped for Outcome: To increase NIH’s level of confidence in grantee institutions ability to effectively manage NIH sponsored project funds. The overarching theme of the site visits would place an emphasis on institutional oversight.

Finally, we selected the NIH subject matter experts who would comprise the site visit team for the Phase I and Phase II site visits. We were extremely fortunate to identify and receive commitments from a core group of NIH professional staff, each of whom brought a wealth of experience and expertise to this important initiative.

PREPARING THE INSTITUTIONS TO BE SITE VISITED

We contacted each of the institutions by telephone and followed up with an electronic transmission that included subject matter attachments that were transmitted prior to the site visit. The ATTACHMENTS were intended to describe the nature of the subject matter discussions and provide information that would enable them to self-select the institutional experts with whom the NIH Site Visit Subject Matter Experts would meet with at the University.

GETTING STARTED

Each site visit began with an opening plenary session. The entire site visit team represented NIH. Institutional representation was self-determined. Our criterion was basic. We wanted to meet with officials who properly represented the institution and, in each case, the institution was properly represented. Typically, we would present the NIH overview and ask for an institutional overview with particular focus on institutional oversight of sponsored projects, an assessment of the current institutional culture of compliance, and the commitment of the institution to a compliant culture.

Immediately following the plenary session the NIH site visit team would meet in an executive session to determine if there was anything we heard that we should speak to or have addressed during the course of the day. We proceeded from there to breakout sessions, where the NIH subject matter experts would meet with our institutional peers. The morning sessions were directed to institutional officials and their appropriate staff, as well as certain central staff functions. These sessions might be characterized as learning more about those centralized activities that provide services to the faculty and staff at the departmental level. The afternoon sessions were directed primarily to principal investigators, department chairs, and departmental administrators… those activities that benefit from the centralized functions.

The discussions also helped us determine the congruity of our mutual understanding of certain administrative requirements. This had particular value because there were instances in which the institutions and NIH did not understand the nature of the requirements the same way.

Another important part of this process was to encourage institutional views and perspectives on ways to enhance coordination and communication between Federal and local oversight programs.

Again, we were trying to enhance the concept of “partners and stewards together”.

SHARING TIME

It’s important to reiterate that the site visits were not audits… that they were not investigations. Accordingly, we decided early in the process that specific, individual reports would not be prepared for any of the site visits. Rather, the closing plenary session on Day I would be used for providing feedback to institutional officials. This would be the only direct institution-specific feedback provided by the site visit team. We indicated that a compendium of non-institution-specific observations and comments would be prepared and distributed to the institutions involved in the site visits. We further indicated that we would likely make the compendium available to the broader biomedical research community, also in a non-institution-specific format.

At the end of the day, the site visit team would meet in another executive session. Each member of the team would take time to summarize and prepare their comments for discussion with the site visit team before presenting to institutional officials in the closing plenary session. We were interested to learn of any issues of particular concern that, upon being presented to the institution, might require some kind of immediate action. We were also interested to see how consistent were our experiences of the day and if we had made any common observations.

In the closing plenary session, as site visit chairman, I would start off with some general comments and observations. It was important to inform the institutional officials of our recognition that the institution had put its best foot forward, that it had given us its best and brightest,

* We are still in the process of developing the compendium and expect that it will be available on the NIH Home Page in early 2001; however, the compendium will first be shared with the site visited institutions.
and that’s exactly what we would have expected. I also made it clear that, based upon our limited time at the institution, we were not prepared to make any definitive judgment that they were, or that they were not, a compliant organization. Rather, I indicated that each member of the site visit team would share with them their observations from the day's discussions, including the good, the bad, and the ugly. I also reiterated that any finding that would necessitate some immediate action by the institution would be deflected back to the institution and it would be incumbent upon them to initiate the action and resolve the issue.

Each of the NIH subject matter experts then presented their observations and findings to the institutional staff, striking a nice balance between the positive and negative. Questions, discussion, and in some instances, clarification, followed each of the presentations. We believed that this process represented significant value for the institutions... we also confirmed that the process had real value for us as well.

EDUCATION-OUTREACH SEMINAR

The Phase II Proactive Compliance Site Visits included a 2nd day Education-Outlet Seminar that featured presentations primarily by the NIH team but also by institutional representatives in varying degrees across all the site visits. This seminar was scheduled for three and one-half hours. It was promoted by the institution and was intended for a much broader audience of faculty and staff than those involved in the conduct of the actual site visit.

The Agenda for the Education-Outreach Seminar included:
- Compliance and Oversight
- Financial Management of Sponsored Projects
- Intellectual Property and Invention Reporting
- Data and Safety Monitoring/Clinical Trials
- Administrative/Science Partnership
- Conflict of Interest
- Administration for Faculty/Principal Investigators
- Risks Associated with Noncompliance

The attendance ranged from 150 – 300 and included faculty and staff alike. For many attendees it marked their first opportunity to see and hear from NIH officials in person. Interestingly, for some, it also marked their first opportunity to see and hear from their own institutional officials in person. In this regard, we were more than pleased to serve as a conduit.

GENERAL OBSERVATIONS AND COMMENTS

The site visit team made many observations and witnessed any number of examples of compliance in action. We also asked for feedback about the site visits from the ten institutions. Because of our commitment to the ten institutions that we will first share with them the compendium results, which are still being developed, the following represents just a few general observations:

- The proactive compliance model was universally praised.
  - It builds a foundation of acquaintance and mutual trust.
  - It allowed the site visit team to act as both a steward and partner.
  - There was value added through discussion of issues in a non-crisis, non-adversarial manner.

- Institutions want to be in compliance and they take the NIH site visits very seriously.
  - There was significant value for the institutions in preparing for and hosting the site visit.
  - The NIH presence helped increase compliance awareness within the institution.
  - The demonstration of NIH oversight is helpful to the institutions in enhancing their own oversight responsibility.

- Establishing Compliance Officer positions and/or an Institutional Compliance Committee emphasizes the institutional commitment to compliance.

- There continues to be significant issues around Financial Conflict of Interest.
  - There is a negative connotation (stigma) around the term “conflict” as in Conflict of Interest.

- There is an undercurrent of distrust around Financial Conflict of Interest issues.
  - Some faculty expressed a reluctance to properly “disclose” for fear that their Institution will somehow “use it against them”.

- The whole is greater than the sum of its parts.
  - Observations from a single site visit offer a limited view; however, there is significant value added with each subsequent site visit.

- The site visits allowed the subject matter experts to focus on important issues (as identified above).

- A recurring theme indicated that faculty resists “training” (as in Training and Education). Rather, they much prefer to be “educated”. While most would agree that this is a subtle distinction, we believe it is an important one, as faculty buy-in is key to a compliant culture. Faculty need to understand and appreciate the value added.

- The institutions acknowledged that there was real value in “hearing it from NIH”.

- Institutions expressed concern about the “cost of compliance”.

- Interestingly, while institutions appreciate the significant growth in the NIH budget, with the congressional commitment to double the NIH budget by 2003, they also expressed hope that some of the additional appropriation be used to strengthen the NIH “infrastructure” necessary to accommodate the increase in support of programs, and that the failure to do so would adversely affect the quality of the NIH work product.

We anticipate that the compendium of non-institution-specific observations and examples of compliance in action will be available on the NIH Home Page in early 2001. The compendium will include each of the following subject matter areas:

- Roles and Responsibilities
- Training and Education
- Financial Management of Sponsored Projects
- Financial Conflict of Interest
- Bayh-Dole Act/Invention and Patent Reporting
- Clinical Trial Data and Safety Monitoring

WHERE DO WE GO FROM HERE

The NIH is committed to fulfilling the congressional mandate of providing effective oversight of the administrative management of sponsored projects research. We anticipate that a certain number of site visits will be conducted during FY2001 and in subsequent years, although the character and nature of the site visits have not yet been determined. Frankly, we would expect that each year would bring about certain changes and modifications in order for the NIH to be appropriately responsive to the issues at hand.

While the NIH will continue to pursue compliance and oversight through the proactive model, we are also prepared to respond to specific allegations of noncompliance as they are brought to our attention. Accordingly, “for-cause” site visits or “administrative-management” site visits will also be performed as required to satisfy our compliance and oversight responsibility.

Finally, we look forward to the continuing good relations that our initial proactive compliance effort has manifested. Working as “Partners and Stewards Together” we can minimize and hopefully eliminate the incidents of noncompliance that place the biomedical research enterprise and subsequently the public welfare at risk.

Gary Thompson is the Director of the Division of Grants Compliance and Oversight, Office of Policy for Extramural Research Administration, Office of Extramural Research at the National Institutes of Health.
Postscript
by JoAnn Moretti, Co-Chair

We listened to political pundits, danced to the beat of election returns under palm tree shaped balloons, watched as NCURA members morphed into TV personalities, and attended a score of professional development sessions. These are just some of the highlights from NCURA's Annual Meeting "New Skills, New Strengths, New Connections" held November 5 – 8 at the Hilton Washington, DC.

Before I share anything more about the (to borrow a favorite descriptor from the NCURA National Office staff) fabulous meeting, I must pay homage to the Annual Program Committee one last time. As a Committee we began, to be perfectly frank, as a motley crew. This was a challenge to those of us who are order prone. However, the Committee in its greater wisdom proved once again that out of disorder comes order and created a program with the diversity that we had all envisioned. And the “piece de resistance” is the fact that this meeting set a new record for Annual Meeting attendance -- just a bit short of our goal for 1,500.

The workshop sessions attracted over 800 attendees. No surprise that the compliance related workshops were quite popular, as well as the NIH and NSF full day workshops on Thursday which together had more than 100 participants.

Another first was the timeslot dedicated to personal and professional development sessions sponsored by NCURA’s Nominating and Leadership Development Committee, chaired by Cheryl-Lee Howard, Assistant Dean for Research Administration, Homewood Division, The Johns Hopkins University. Linda Patton, Director, Office of Sponsored Programs, University of San Diego, did a fantastic job as the Track Chair for these offerings which attracted several hundred attendees. One of the sessions had a packed house with members spilling out the door.

There was considerable thought given to the networking and welcoming activities. There were some new ideas launched, such as the Saturday and Sunday Orientation for the Newer Member sessions – and some twists on the traditional activities such as the Dessert Reception for First Time Attendees. A special thanks goes to Janie Morales-Castro and everyone else involved in the Annual Meeting hospitality activities.

I have to admit that I couldn’t wait for this year’s meeting to arrive. The month of October (and up until the time I left for DC) seemed like sheer agony. And it was an agony that I shared enthusiastically, particularly with the National Office staff who had to endure my endless calls to ask “what's the count?”. But it was over in a flash and now I am left with only post-meeting depression. I guess I'll just have to pine away until next year.

JoAnn Moretti is the Director of Sponsored Programs Administration at Harvard Medical School.
Attendees stopped by exhibits throughout the meeting.

Members get a chance to see the inner workings of NSF during the Thursday on-site workshop.

Region VI shows its Annual Meeting spirit!

In-depth talks on the hot topics of the day took place...

Keynoters Eleanor Clift and Tony Blankley have a lively debate about the outcome of the next day’s Presidential Election. Who knew?!

Up close and personal during the many Annual Meeting Discussion Groups.

Members check their email and update their member profile during break-time.
SARCASTIC INTRODUCTION
The Federal Financial Assistance Management Improvement Act of 1999, more commonly known as Public Law 106-107, is indeed a wondrous thing to behold. In eleven short sections it seeks to (from SEC. 3 PURPOSES):

(1) improve the effectiveness and performance of Federal financial assistance programs;
(2) simplify Federal financial assistance application and reporting requirements;
(3) improve the delivery of services to the public; and
(4) facilitate greater coordination among those responsible for delivering such services.

And the Congress has graciously condescended to permit an entire 18 months to carry out all the actions required. Rarely has the world seen such largess. While the President signed this bill into law and so shares the responsibility, it should be noted that he did so reluctantly, citing the short time frame for implementation and the lack of funding.

SCOPE OF THE LAW AND WHERE THE RESEARCH COMMUNITY FITS IN
When we first saw the law many of us thought, “Aha, another effort to move research grant processes to the electronic world.” This categorization of the law’s objectives was accurate but not at all complete.

First of all, the law pertains to all federal grants. We’ve heard a lot of rhetoric over the past few years about how important research is to our economy and how it is responsible for some incredible portion of our economic growth. Nevertheless, in terms of the federal government’s overall grant-making expenditures, research grants are a very, very small percentage of the pie (the exact figures vary depending on whose numbers you use and what’s categorized as research, but research certainly comprises less than ten percent). And, by the way, those other federal grants build roads, provide educational funding, and welfare; while these sorts of grants may not have the economic leverage research grants do, they certainly have been known to effectively leverage votes. Make no mistake, the “tail” of federal research grants will never wag the “dog” of overall federal grant making. Research grants fare somewhat better when you consider the numbers of grants made; here the split between research and non-research is much closer to 50-50. This certainly bolsters the case for accommodating the special needs of federal research grant making; it just does not give us the raw leverage that money does.

Second (and how could we have overlooked this?), the law addresses not only electronic “stuff” but also basic procedural issues like application and reporting requirements. Simply, the law is attempting to address all aspects of the federal grant making process. It provides a wonderful opportunity to reengineer the system while also making it electronic.

As we begin working with our federal agency partners to take advantage of the opportunities Public Law 106-107 presents, we must keep in mind both the breadth of opportunity and our relative influence on the government’s overall grant-making enterprise.

FEDERAL IMPLEMENTATION
According to the law, there are four, non-federal agency, stakeholder groups: state governments, local governments, tribal governments, and nonprofit organizations (including most of us in the research community). The law goes on to mandate the use of a “common application and reporting system” mandated by the law (SEC. 6. (a) (1)). The question needs to be asked: “Does the law really intend for these four diverse stakeholder groups to use a single, one size fits all, system?”

Let’s hope that the obvious and correct answer is “no way.” The needs of these four stakeholder groups are not similar enough to justify the imposition of a single common system. This issue was addressed at several public meetings including the Interagency Electronic Grants Committee (IAEGC)’ meeting of May 16, 2000. Unofficial but broad consensus seems to have been reached: while the law mandates a “common … system,” the term can be interpreted with some latitude. By way of example, the common system might be called the Federal Commons - but within that common umbrella system there would be subsystems for the research, state and local, and perhaps tribal communities.

Those of you who have heard about the Federal Commons probably recognize that one of the objectives of the Commons is to provide the common face to federal research-related grant making. As currently envisioned, the Commons will provide grant receiving research institutions with several alternative electronic grant submission technologies. In essence, the Federal Commons will be an umbrella system for submission technology alternatives available to the research community. So, it is not at all a far stretch to consider broadening the reach of the Federal Commons umbrella to cover the needs of the other Public Law 106-107 stakeholder groups. It appears that the Office of Management and Budget (OMB) as well as many federal agencies agree with this basic assessment and are generally holding the Federal Commons as the presumptive framework for the common system mandated by Public Law 106-107.

The law mandates that the Director of OMB “coordinate, and assist Federal agencies” (SEC. 6. (a)) while also permitting the Director to “designate a lead agency to assist” (SEC. 6. (b)). Not an office known to be overflowing with resources, the OMB chose to designate an organization to lead the Public Law 106-107 process. That organization is the General and Policy Oversight arm of the Grants Management Committee (George Strader (HHS) is the chair) of the Chief Financial Officer’s Council. The General and Policy Oversight group is co-chaired by Joe Kull (OMB) and Charlie Gale (Health and Human Services).

The General and Policy Oversight group is divided into four subgroups. The groups and their attendant areas of focus are:

1. Pre-award - Chaired by Mark Herbst (DoD)
   a. Streamlining application forms
   b. Terms and conditions
   c. Debarment and suspension

2. Post-award - Chaired by Rick Noll (National Science Foundation)
   a. Streamline reporting requirements and procedures
   b. Joint Financial Management Improvement Program (JFMIP) document
   c. Cost principles
   d. Pooled payments
   e. Use of Payment Management System (PMS) and Automated Standard Application for Payments (ASAP)
The IAEGC is established to coordinate, promote and facilitate the effective use of electronic commerce (EC) throughout the federal grants community, under sponsorship of the Federal Electronic Commerce Program Office. In the Access America Report on automation and re-engineering opportunities for the National Performance Review (NPR), Access America, the Government Information Technology Services Board (GITSB) identifies Federal grants distribution as an area ripe for automation and the application of electronic commerce solutions. The IAEGC was established in response to that report.

When I was asked to write this article about how NSF managed the transition to our goal of a paperless proposal and award system by October 1, 2000, I thought it was timely to take a retrospective look in order to attempt to answer the question of “How Did It Go?”. The FastLane Project from the beginning has been more than an information technology project. It has been a collaborative effort of all NSF organizations involved in the grants process. Through this collaborative effort, NSF published in 1998 our vision for the future. It's appropriate to look back at what we said in 1998 and what we said this past September, as the October 1, 2000 deadline approached. In September 1998, the Director of NSF issued Important Notice 123 to university and college presidents and the heads of other grantee organizations. This issuance by the NSF Director continued to emphasize that NSF management fully supported this effort. The title of this notice, “Working Toward a Paperless Proposal and Award System”, was well chosen. It contained NSF’s vision for paperless proposal and award processing and how we intended to work toward implementing that vision. In addition to outlining the steps NSF would be taking to bring the vision to reality, the Important Notice included a schedule for grantees’ required use of FastLane components. This notice was NSF’s public commitment to using electronic processing for its standard business processes with a target date of October 1, 2000 for implementing a totally electronic business process with grantees. When this target was proposed in 1998, we recognized that full implementation of FastLane by October 1, 2000 would be a challenging goal and we asked our customers to join with us in achieving it.

We should look back at where we were on October 1, 1998 -- just one month after establishing our vision. Although FastLane encompasses the entire grants lifecycle at NSF including approximately 40 separate modules, the measure of success has always focused on our primary transaction, the proposal. At the end of FY1998, 17.5% of proposals had been submitted via FastLane. This meant that FY1999 (starting October 1, 1998) would be a critical year for demonstrating that we could meet our vision of requiring full electronic proposal submission. By the end of FY1999, 44% of all proposals were submitted via FastLane. Some of the major accomplishments during FY1999 were: a new FastLane Homepage, significant enhancements to the Project Reporting System, the implementation of the FastLane External Help Desk, and expanded outreach to our customers through training and presentations. Although much was accomplished during the year, we had one year to go and there was still much work to be done to get ready for October 1, 2000.

As we started FY2000, we were dealing with many challenges. We had to ensure a reliable infrastructure including servers and Internet availability. Although we had implemented the FastLane Help Desk, we began efforts to expand coverage and to ensure quick and accurate responses to customer inquiries and problems. Coordination with our external customers has always been a hallmark of the FastLane project and continued to be a major focus in FY2000.

Although we had implemented the FastLane Help Desk, we began efforts to expand coverage and to ensure quick and accurate responses to customer inquiries and problems. Coordination with our external customers has always been a hallmark of the FastLane project and continued to be a major focus in FY2000.

As summer approached, we knew that one of the key events would be the CAREER solicitation in late July. One of NSF’s challenges, even in the paper world, has always been how to deal with big deadlines. Besides the load on our servers and infrastructure, the deadlines of large solicitations often generate so many phone and e-mail requests that can overwhelm Help Desk staff and frustrate PI’s and SRO’s. The CAREER solicitation in FY1999 had exhibited a number of problems with server reliability and this deadline would test our capability to process a large workload. It would also test all the improvements that had been made throughout the year and would give us a confidence factor as October 1 approached. A special CAREER response team was formed to handle the anticipated surge of user inquiries. During the three-day CAREER solicitation, 1,783 proposals were submitted; these proposals included e-signatures in lieu of paper cover sheets.

By early September 2000, we realized that approximately 80% of proposals would be submitted electronically for all of FY2000 and that nearly 90% were being submitted electronically each month. On September 11th, the Director issued Important Notice 126 with the appropriate subject of “NSF’s Paperless Proposal and Award System – Next Steps”. This was NSF's official notice that the October 1, 2000 target date would be met and that all specified transactions (including proposal submission) would be required electronically via FastLane. The Director thanked our customers for their patience, cooperation and feedback in helping NSF reach this goal. The Director also emphasized NSF's commitment to continue working with our customers, especially those customer groups who are having or might have difficulty with electronic submission.

To come back to the original question of “How Did It Go?”, the milestone was met through a lot of effort by NSF and our customers. We owe our thanks to the NSF Director, Deputy Director and senior management in supporting our efforts. We owe as much or more to our customers for working with us, in good times and bad. October 1 was not the end, but a target, and we now focus on continuing to work closely with our customers to discuss remaining challenges and to develop solutions. NSF continues to work with other federal research agencies to develop common face solutions across all grant-making agencies. In addition to NSF FastLane efforts, NSF remains an active and coordinating partner on the interagency development of a “common face” for Federal grants known as the “Federal Commons.” NSF is looking to the next generation of e-business solutions by collaborating with academia, industry and government to begin a dialogue on the future directions of e-commerce activities related to grants. We look forward to partnering with you and taking those “next steps” together.

Jerry Stuck is Deputy Director, Division of Information Systems, National Science Foundation.
Overview
Portable Document Format (PDF) is increasingly required in many electronic research administration (eRA) applications, because it provides a means of overcoming many hardware and software compatibility issues. PDF generation products convert such things as formatted text, equations and scientific notation, and graphics created in virtually any common hardware platform and software product into files that preserve the original appearance, and that can be viewed and printed by others who use different platforms and products. Applications of PDF in eRA range from providing application forms that can be downloaded over the internet, to capturing complex scientific documents and transmitting them electronically for viewing and printing. But is it really this simple? This article describes some of the limitations and problems with PDF.

Requirements for PDF in eRA
For many investigators and administrators, the first exposure to PDF generation was the proposal technical narrative required to be uploaded into the National Science Foundation’s (NSF's) FastLane electronic research administration system. Researchers scrambled to obtain PDF-generating software, computing support staff scurried to install and support the software, and sponsored projects offices struggled to provide information and advice in an area outside their expertise.

The use of PDF in FastLane was consistent with the earliest eRA planning. Since inception, the 194 'Transaction Set' data standard has envisioned PDF attachments for at least the technical narrative, and possibly for other information as well. The NSF technical reporting module also requires PDF. Presently, NSF makes the most extensive use of PDF in eRA, but as the Federal Commons comes on-line, all other federal funding agencies will likely have the same requirements as NSF.

Other eRA systems that do or will require PDF documents include:
- The NIH Commons, for SNAP progress reports
- The Federal Commons [includes the research offices of the three military services, the Departments of Agriculture, Health and Human Services (various sub-entities), Energy, Education, Commerce, Interior, Justice, Labor, Transportation (FRA), Housing and Urban Development, National Aeronautics and Space Agency, National Science Foundation, National Endowment of the Humanities, and the Environmental Protection Agency]
- Space Telescope Science Institute (the contractor that manages the Hubble Space Telescope)

The Sponsored Projects Office at the University of California, Berkeley maintains a website that compiles eRA initiatives. This is a good site to watch for new eRA initiatives. It is: http://www.spo.berkeley.edu/Procedures/era.html. The Federal Demonstration Partnership committee on P.L. 106-107 also monitors these developments, and that website is: http://ftp3.org/PL106-107.htm.

A Cautionary Tale
Here at the University of Illinois at Urbana-Champaign, a situation arose in connection with submission of an NSF final technical report. The PI produced his report on his PC using LaTeX, converted it to PDF, and uploaded it to FastLane. After uploading it, he tried to open it, and could not. Neither could the FastLane systems staff. After extensive diagnosis by the FastLane technical staff, it was determined that although the file didn’t appear sophisticated from a graphics or font-use standpoint, there were fonts that were not properly imbedded, and therefore the PDF file could not be processed at NSF’s end. Note that both the source file and PDF file first produced by the PI could be opened and read when transmitted as e-mail attachments…the PDF file just couldn’t be opened after it was uploaded to FastLane. After following the extensive instruction for PDF generation provided on the FastLane site, the PI was able to successfully submit his final technical report. A colleague at MIT similarly describes the situation where the PDF could not be generated because of an Å (angstrom) in the text.

The Devil is in the Details
The vast majority of PDF conversions are accomplished successfully by routine point-and-click’s. But when there are problems, identifying the source of the problems can be very tedious. The reason for this is that there are numerous variables to be considered, such as:

- Platform and operating system version that generated the source file
  - UNIX
  - machines of a dozen or more vendors using X Windows version 11, releases 4, 5, or 6
  - Sun workstations running SunView
  - VAX and Alpha systems running Open VMS
  - IBM PC compatibles running Windows 95/98/NT
  - Macintosh with System 7 or later
- Software package and version that generated the source file
  - Tex or LaTex on Unix, Mac, or PC platforms
  - Microsoft applications, Office 97 or 2000
  - Corel applications
  - Various graphics programs on the three major platforms
- Font sets
  - TrueType
  - PostScript Type 1
- PDF conversion and viewer software and version
  - Adobe
    - Acrobat 3.x
    - Acrobat 4.x
  - Ghostscript
    - Ghostscript 6.X for the various platforms and operating system.

Note that this list is not comprehensive, and there are an almost infinite number of combinations of platform/operating systems, software packages, fonts, and PDF conversion/viewer software.

Options for PDF Conversion
There are two options for PDF conversion. One is Adobe Acrobat, which lists for $99 per copy, with some nominal volume discounting possible. The other is Ghostscript that was developed at the University of Wisconsin and available at no cost. Since it is important that the source file and the PDF file be produced on the same computer, every computer producing PDF files needs to have one or the other of these products. The Ghostscript version that NSF stipulates for FastLane is 6.0 or higher, but documentation doesn’t yet exist for versions after 5.5. Also, somewhat more technical sophistication is needed to use Ghostscript. Use of Adobe Acrobat 3.X is still acceptable at FastLane. The 4.0 version costs more and requires the user to do more in the way of manipulating settings. Adobe PDF Writer cannot be used at all for creating PDF documents to be uploaded to FastLane.

Observed Problems
For the vast majority of conversions to PDF, the process is routine and trouble-free. Some problems that have arisen in connection with FastLane (the only eRA application in widespread use at this time) include:

- The PDF file does not look like the source file, e.g., figures do not have the same level of resolution as in the original document. This problem can be addressed by adjusting the settings to something other than the standard PDF conversion program defaults.

(Continued on page 10)
Donations of Patents to Universities

by Jilda Garton

Over the past two years, a number of universities and not-for-profit educational or research organizations have been offered patented intellectual property as gifts from the companies who own the technologies. Sometimes these are single patents, but often, they are portfolios of several patents and possibly other disclosures or copyrighted material. Changes in federal tax rules now make it possible for companies to treat such donations as charitable gifts. The opportunity to take a tax deduction for donating patents that are not contributing to the bottom line, or that do not fit the business strategy of the company, is an enticing incentive for a company to consider donating the technology to a university or not-for-profit research organization.

Companies have technologies they do not need because they frequently invest in patenting inventions in anticipation of commercialization. Companies may also acquire ownership of patents when they merge with or buy another company. For a variety of reasons these technologies may not be viable business opportunities for the companies. They may, however, be great opportunities for universities if the technology fits an ongoing research program or if the university has a ready licensee.

A donated patent might be used by a university in several ways. First, it may be used in an ongoing research program designed to lead to new commercializable intellectual property. A donated patent might also be bundled with patents in the same field that are already owned by the university and then licensed for commercial development. A new company might be formed to commercialize the technology alone or in conjunction with other university-owned patents. Both models have been successfully used by universities in accepting donations of intellectual property.

A company that is donating a patent might also donate related equipment to the university. The company will also agree to assist the university, usually at the university's expense, in patent filings, office actions, and defending the intellectual property.

Most universities that accept patents as gifts have developed policies and procedures for handling them. The policies take into account a number of the strings that are attached to the donation. First, the Internal Revenue Service (I.R.S.) requires that the university accepting the gift agree, in a written document, with the valuation of the gift. In general, a third party expert establishes the value of the gift. The I.R.S. also requires the university to agree to maintain the patents, including the foreign filings, for a period of at least two years. Finally, the university must offer to the company a commercialization plan for the technology. If further research is necessary, the commercialization plan will usually include a research plan.

Accepting a gift of patented intellectual property requires close coordination among a number of administrative offices in a university. Each has traditional roles and responsibilities that it brings to this relatively new process. The final decision is often made at the highest levels of the university but should be supported by each of the professional offices that must come together to make the donation a success.

- The development office or other entity that solicits and accepts gifts is often the office responsible for the actual donation. Although a third party valuation is used to establish the value of the gift, this office has expertise in reviewing and accepting gifts that will be tax deductible to the donor.
- The office of technology transfer must be involved early in the process. The patented intellectual property must be evaluated by a third party, usually patent counsel, skilled in determining the strength of the patents and in doing a patent search that will identify other patents in the field. The technology transfer office is in a unique position to evaluate the market for the technology.
- Factors such as the age of the patents in relation to the amount of time it will take to bring them to the market or the number of superior technologies already patented are important considerations. The office of technology transfer will also be responsible for maintaining the patents and will be involved in determining the costs of doing so.
- The general counsel of the university will generally evaluate the terms of the donation agreement. These agreements often include a provision for the university to indemnify the donor that may be a problem for state institutions and others that cannot accept such provisions. Insurance may be an option. The process of evaluating the offer itself usually requires that a non-disclosure agreement be executed between the university, the donating party, and perhaps third parties.
- The sponsored programs office may be called upon to help find sources of funds for additional research needed to bring the technology to market. In the event that the technology fits into a proposed or ongoing sponsored research project, the sponsor may need to receive information about the donated patents and will likely have to approve, either in the award or as a matter of prior approval, the use of funds to further the technology.
- Faculty and other researchers expert in the field, of course, play key roles. For technologies that need further development prior to commercialization, the researchers are in the best position to recognize and understand the possibilities and opportunities. If the technology is to be licensed together with other university-owned technology, the inventors will be the ones who recognize the value of the donated patent from a technological perspective. The researchers will have to participate in the development of the research and commercialization plans. They will not, however, have the same role that researchers usually have as inventors of university-owned technology. For example, in the intellectual property policies of most universities, there would be no provision for these researchers to receive a share of the royalties earned from a license of the donated technology. They would however, receive royalties for improvements or derivative work. Faculty and other researchers who participate in a start-up company based on the technology would be subject to the university's conflict-of-interest policy as it applies to such matters.

In summary, the offer of intellectual property as a gift to the university requires a high degree of coordination among administrative offices. Those university officials who are called upon to consider or to negotiate the donation will usually use or develop a policy and procedure that spells out the various roles and responsibilities. The things they need to consider include (but are not limited to):

1. The valuation of the gift
2. The quality of the patent being offered
3. The fit with the mission and research programs of the university
4. The terms of the donation agreement
5. The sources of funds that will be used to pay for patent maintenance for at least two years
6. The sources of funds to be used for research and development of the technology
7. The market for the technology, the research and/or commercialization plan
8. How any revenue from licensing the technology will be distributed and used by the institution
9. Any potential conflict of interest

Jilda Garton is the Associate Vice Provost for Research and General Manager of GTRC, Georgia Institute of Technology.
NCURA Needs to Recognize its Own
by Anthony Merritt

One of the luxuries of retirement is time, time to think about things in different ways, time to view events from different perspectives than one can when not swept up in rush of everyday business. As I was reading a recent issue of the Newsletter in somewhat greater detail than I may have in the past, two unrelated articles started me thinking about issues that NCURA needs to address if it is to reach its full potential.

The first article was the announcement of the selection of Dick Seligman as the recipient of the award for Outstanding Achievement in Research Administration, a well-deserved honor for one of our long-time leaders. It was certainly not concern about who received the award that piqued my interest. What did trouble me was that many other deserving individuals would not receive any recognition because NCURA makes only one award each year. One would expect that a number of well-qualified individuals were nominated for the award and that the selection committee was faced with a difficult decision in choosing the recipient. But what of those who were not selected? These people whose names will never be known, will receive no recognition despite the fact they were deemed by at least some of their peers to have made significant contributions to our field. Should there not be some other way to recognize their contributions?

The second article that caught my eye was Mary Husemoller’s discussion of the forces leading to the recent governance changes for NCURA. One of these forces as stated in the article was “...to develop leaders by involving more people...”– a worthy cause and absolutely vital to an organization like NCURA. However, to be successful in this, we need to not only recruit the best and brightest of our members for leadership roles but also to provide a means to give full and lasting recognition for their contributions. Those of us who have served in such capacities know the time and effort required. While we also know the sense of self-satisfaction to be gained, it would be very gratifying to also receive some more lasting form of recognition.

My first response to Tony Merritt’s article on recognition is “Thank you!” Your thoughts embody one of the greatest strengths of NCURA, the fact that its members care about the organization, its membership, and its practices.

My second response is that Tony is correct. We do have some work to do with respect to recognizing the members who contribute to our programs, publications, conferences and activities. It should come as welcome news that both the Professional Development and the Nominating and Leadership Development Committees have this year been considering additional ways of recognizing the contributions of time and talent that are made by so many of our members. For example, the PDC has implemented a formal process for acknowledgement of authors of NCURA micrographs. Tony’s suggestions for specialized awards are good and will be under consideration by NCURA in the coming year. I echo his call for suggestions from our membership for other forms of reward and acknowledgment.

I would also ask that we all consider what role awards play in attracting the “best and brightest” to contribute their time and effort to NCURA. One of the ongoing discussions during the governance changes, when we focused on the goal to “...develop leaders by involving more people...” was on the fact that people want to be involved in the work of NCURA for many reasons. Among these are the excellence of its programs, the professional experience and exposure gained in writing an article for RMR, the contacts made and collegial relationships developed in serving on a committee, or the technical knowledge acquired by working on a particular task force.

I am also cognizant, as you can see in my article in another part of this Newsletter, that in our calls for members to participate we must realize that we are all volunteers, with increasingly busy professional lives. Our first responsibility to those who wish to contribute to the work of NCURA is to hold reasonable expectations for what can be accomplished within a particular timeframe, and to provide adequate resources to get the job done.

I wholeheartedly agree that, in addition to providing resources, guidance and the encouragement needed to complete a project or attain a goal, and realizing the personal growth and satisfaction that results from its accomplishment, NCURA should continue to consider additional ways of formally recognizing the achievements of our members.

Finally, I cannot say it any better than Tony did: “NCURA’s most valuable asset is its members”. Please share with us your comments on reward, recognition, and why you volunteer for NCURA. Suggestions may be sent to NCURA at info@ncura.edu.

Regina White is the 2001 NCURA President and serves as the Director, Office of Sponsored Programs at the University of Vermont.
PRE-CONFERENCE WORKSHOPS: Registration Limited

Additional Fee Required

Sunday, 2/25, 8:00 am - 12:00 pm

☐ $75 Workshop 1: The Other Side of the House: Understanding What the Pre-Award Folks Do

☐ $75 Workshop 2: What Pre-Award and Departmental Folks Need to Know About Post-Award and the Cost Analysis Functions: The Financial Compliance Stuff

If you would like to join NCURA and receive the discounted registration fee of $350, please include an additional $145 for 2001 Membership Dues.

☐ $350 NCURA Member Fee

☐ $400 Non-member Fee

☐ $75 Workshop Fee (If Applicable)

☐ $145 Membership Dues for 2001 (Optional)

TOTAL AMOUNT DUE $ __________________________

Check Enclosed ☐ Purchase Order ________________

Credit card (please select one) Visa MasterCard American Express

Card Number __________________________ Expiration date __________

Printed Name of Card Holder __________________________________________

Card Holder Signature ________________________________________________

Registration Policy: Refunds of the registration fee, less a $50 administrative charge, will be honored if a written request (no faxes or e-mails) is received no later than February 12, 2001. AFTER THAT DATE NO REFUNDS WILL BE MADE. You must receive written confirmation of your cancellation request from NCURA to receive a refund. A registration may be transferred to another person by the original registrant with ADVANCED written notice to NCURA.

You will receive an acknowledgement from NCURA confirming your registration and indicating the status of your enrollment in the workshop you (may have) requested. Please do not make airline reservations until you receive your confirmation.

© 2001 National Council of University Research Administrators
One Dupont Circle, N.W., Suite 220, Washington, D.C., 20036
Phone: 202.466.3894 • Fax: 202.223.5573 • info@ncura.edu

Visit the NCURA website for details-www.ncura.edu!
REGISTRATION — 2000/2001 Videoconference Series

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 Videoconferences will be aired from 11:30 am - 3:30 pm Eastern Time. A test signal will be transmitted one hour (10:30 - 11:30 am Eastern Time) prior to air time to give ample time to locate us.

Live: Those institutions that choose the live presentation will receive the handout information, satellite coordinates to receive the show live on their campus, and telephone number to call in their questions on the day of the broadcast, and a license to tape the show for future on-campus training.

Tape: Those who select the tape option will receive handout information when they receive their copy of the tape.

A check, purchase order or credit card information must accompany registration form. For credit card payments, please complete the information below. Registrations received without payment or purchase order will not be processed. Please make check payable in U.S. currency to NCURA and send payment and registration to NCURA, One Dupont Circle, NW, Suite 220, Washington, DC 20036.

A check, purchase order or credit card information must accompany registration form. For credit card payments, please complete the information below. Registrations received without payment or purchase order will not be processed. Please make check payable in U.S. currency to NCURA and send payment and registration to NCURA, One Dupont Circle, NW, Suite 220, Washington, DC 20036.

CANCELLATIONS: Notification of cancellation must be received in writing no later than 14 business days prior to the each telecast and are subject to a $50 cancellation fee. Cancellations received after the deadline will not be refunded. You must receive confirmation from NCURA to receive a refund.
## NCURA PUBLICATIONS ORDER FORM

<table>
<thead>
<tr>
<th>MONOGRAPHS</th>
<th>Member Price</th>
<th>Non-member Price</th>
<th>Quantity</th>
<th>Total Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Trials Handbook</td>
<td>$37.00</td>
<td>$42.00</td>
<td>________</td>
<td>$__________</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>MICROGRAPHS</th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost Accounting Standards</td>
<td>$7.00</td>
<td>$8.25</td>
<td>________</td>
<td>$__________</td>
</tr>
<tr>
<td>The Role of Research Administration</td>
<td>$8.75</td>
<td>$10.25</td>
<td>________</td>
<td>$__________</td>
</tr>
<tr>
<td>Facilities and Administrative Costs</td>
<td>$8.25</td>
<td>$9.75</td>
<td>________</td>
<td>$__________</td>
</tr>
<tr>
<td>in Higher Education</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Total Amount Due** $__________

A check, purchase order made payable to NCURA or credit card information must accompany your order.

Name ___________________________________________ ID# ________________________________

Inst./Org. ___________________________________________

Address ___________________________________________

City/State/Zip _______________________________________

Phone # ____________________________________________

Please Circle One:  
Visa  MasterCard  American Express

Credit Card # ___________________________ Expiration Date __________________

Signature ___________________________________________

Please print name ____________________________________

Mail to:  
NCURA  
One Dupont Circle, NW  
Suite 220  
Washington, DC 20036  

Please Allow 4-6 weeks for delivery.

NCURA, in cooperation with NACUBO and Atlantic Information Services, offers the valuable new resource on Federal Grants, A Guide to Managing Federal Grants for Colleges and Universities. For subscription information on this publication, please call Atlantic Information Services at 1 (800) 521-4323.

Questions? Please feel free to contact the NCURA Office at (202) 466-3894 or info@ncura.edu
Establishment of a NCURA Volunteer Coordinator

NCURA’s success depends on the talent and energy of its members. To better use this talent and energy, NCURA’s board approved the establishment of the position of Volunteer Coordinator (VC) at its November meeting and named John Storer of the State University of West Georgia as the first VC.

While the role of the Volunteer Coordinator is still a work in progress, possible responsibilities of this position include maintaining the existing NCURA volunteer bank and improving communication on volunteer issues. The broader charge is to ensure that:
1) members can become involved with a minimum of barriers;
2) a volunteer’s experience is positive and rewarding and;
3) members’ skills and interests are matched with available roles within NCURA.

Specific initiatives for improving the volunteer process are in development, so watch for future announcements. John is asking for your input on anything at all connected with volunteerism in NCURA. He is interested in hearing both about your past experiences and receiving your suggestions. You can e-mail him at jstorer@westga.edu.