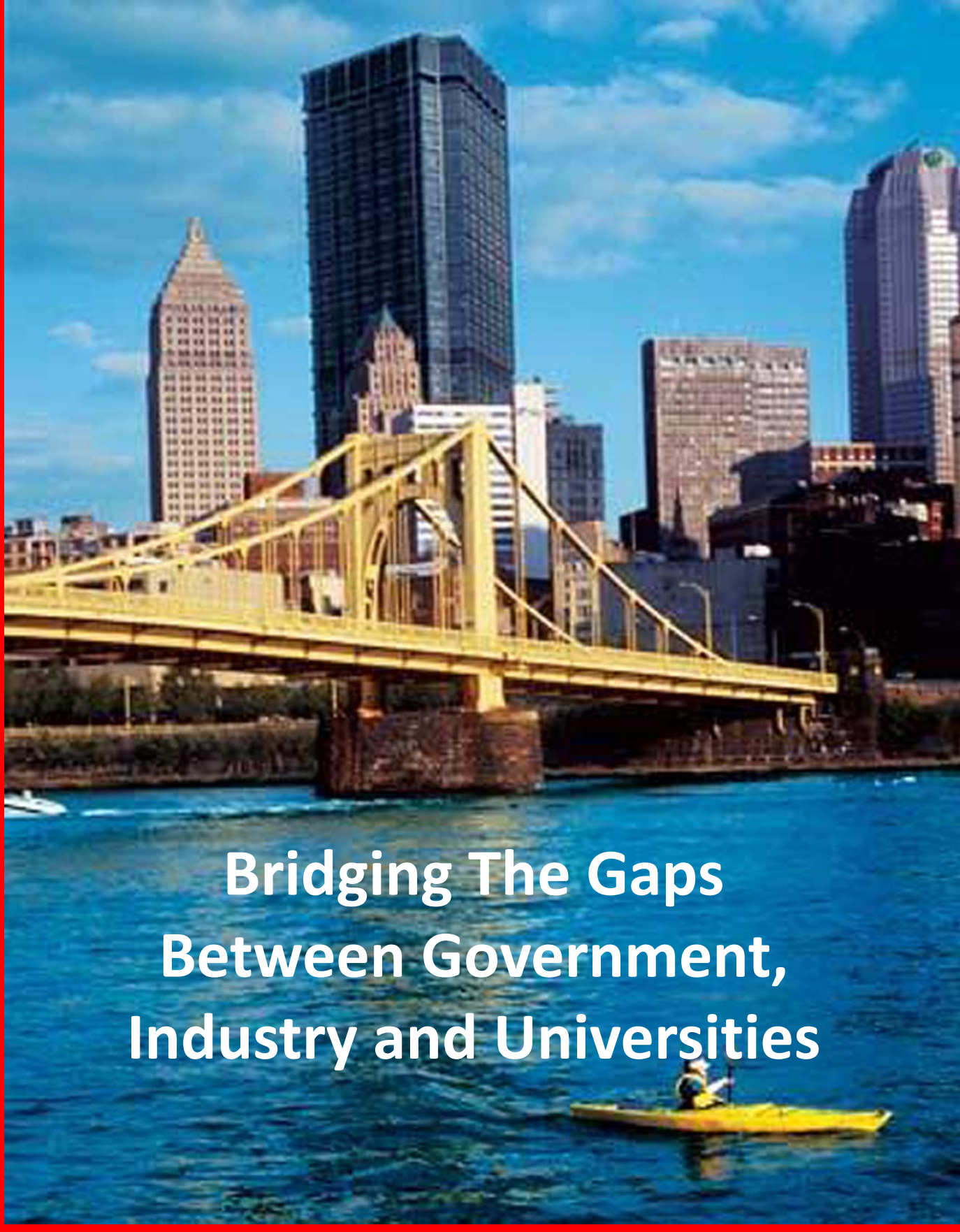
NCURA Region II



Bridging The Gaps Between Government, Industry and Universities

2008 Spring Meeting
Pittsburgh, Pennsylvania
April 27 to 29, 2008

National Council of University Research Administrators
Region II

Delaware · Maryland · New Jersey · New York · Pennsylvania · Washington, DC · West Virginia

NCURA Region II 2008

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CITY OF PITTSBURGH

"America's Most Livable City"

Office of Mayor Luke Ravenstahl

Dear Friends:

On behalf of the residents of the City of Pittsburgh, I am honored to welcome the attendees of the National Council of University Research Administrators to "America's Most Livable City." This conference couldn't be in a better city; we are privileged to boast so many universities and colleges.

Pittsburgh is filled with many historical, recreational and social attractions. It is a city that has something for everyone. Take a ride on the inclines and check out the "Nighttime View from Mount Washington"—ranked No. 2 on *USA Weekend* magazine's 10 most beautiful places in America. An eclectic array of restaurants and entertainment venues in the Strip District or Station Square offer a relaxing atmosphere to socialize with colleagues. In addition, our museums offer everything from dinosaurs to Andy Warhol and our Cultural District—the largest of any such arts district outside of New York's Broadway—offers spectacular shows and cutting-edge galleries.

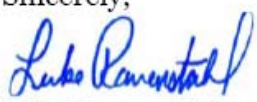
As we enter into our 250th year as a city, Pittsburgh is at a particularly exciting point in its history. We have exceptional universities and medical facilities, a diverse economy, cutting edge research and technology facilities and Downtown revitalization projects in the works. Our Neighborhoods First campaign is in full swing, aimed at making our City one of the cleanest and safest in the country.

This year, Pittsburgh will celebrate its 250th anniversary with events throughout the region. Now is a perfect time to discover the treasures that surround us each day here in Pittsburgh, as well as the individuals in our communities who make it a special place to live, work and play.

While you are enjoying all that Pittsburgh has to offer, you will also leave energized by a terrific conference agenda. Complete with educational workshops and an array of outstanding speakers, this conference will help promote an understanding of the needs and differences between research partners. Tomorrow's world will require this, so please take the time to share your thoughts and ideas.

We hope you enjoy your time in Pittsburgh and that you will come back and visit us often. The City of Pittsburgh is thrilled to have you here.

Sincerely,



Luke Ravenstahl
Mayor, City of Pittsburgh

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"Bridging the Gaps Between Government, Industry, and Universities"

Hilton Pittsburgh in Pittsburgh, PA
April 27-29, 2008

Sunday, April 27, 2008

12:00 noon – 5:00 p.m. **Registration**

1:00 p.m. – 4:00 p.m. **Workshops**

Core Competencies: OMB Circular A-110 and Beyond: Understanding the Basics of Administering Federal Research Awards

Research Administrators must meet the challenges of managing awards in a manner that ensures compliance with federal and state regulations, as well as the organization's policies and procedures. The administrative requirements of OMB A-110 are the back bone of these regulations and policies. This workshop will allow the attendees to explore the most relevant sections of the A-110 and understand how they impact research administrators at a transactional level.

Items of discussion will include: Definition of terms, pre and post-award requirements, cost sharing, program income, the rules of re-budgeting, procurement standards and record retention.

Denise Clark, Assistant Vice President, Research Administration & Advancement, University of Maryland; and *Marti Dunne*, Associate Vice Provost for Research Compliance and Administration, New York University

The Principals of S^3 (Subawards, Subcontracts, Subrecipients)

Subawards, subcontracts, subrecipients … whatever you call them, collaborative relationships continue to grow as research becomes more interdisciplinary, inter-institutional and international.

This workshop will focus on the nuts and bolts of subaward management and administration. Among topics to be presented will be:

- How to prepare and submit proposals with subawards
- How to develop and administer subawards, including
  1. Appropriate flow-down from prime awards
  2. Cost analysis and subrecipient monitoring
  3. Closeout
- Considerations when working with industry or foreign sites

The session will include presentations as well as case studies. The workshop will be most useful for beginning to intermediate central research administrators and department administrators.

Gunta Liders, Associate Vice President for Research Administration, University of Rochester; *Cheryl Williams*, Assistant Director, Office of Research and Project Administration, University of Rochester; and *John Hanold*, Senior Associate Director of Sponsored Programs, The Pennsylvania State University

The In's and Out's of Creating and Negotiating an MTA, NDA, MOU, CRADA, and OTA

This interactive workshop/discussion group will allow the participant to learn the ins and outs of effectively creating and negotiating the terms and conditions of a variety of special agreements including material transfer agreements, non-disclosure agreements, memoranda of understanding, inter-personnel agreements, cooperative research and development agreements, and other transactional agreements. Case studies and personal examples from both participants and session leaders will be used to explore the intellectual basis for decisions on the use of a particular instrument, as well as, the terms and conditions used in the instrument.

David Richardson, Assistant Vice President for Research, The Pennsylvania State University; *Allen DiPalma*, Director, Office of Research, University of Pittsburgh; *Gregory C. Slack*, Director, Office of Research and Technology Transfer, Clarkson University; and *Anita M. Jesionowski*, Manager, Business Development & Licensing, Carnegie Mellon University

5:30 p.m. – 7:30 p.m. Welcome Reception

Entertainment provided by students from Carnegie Mellon University

8:00 p.m. – 11:00 p.m. Hospitality Suite open

Visit Our Vendors

7:30 a.m. – 5:00 p.m. **Registration**

7:30 a.m. – 8:30 a.m. **Continental Breakfast**

8:45 a.m. – 10:30 a.m. **Plenary Panel**

Bridging the gap between Universities, Industry, and Government Agencies

Moderator: Richard McCullough, Vice President for Research, Carnegie Mellon University

Panel Members: Larry Seitzman, Engineering Manager, Virtual Product Development, Technology and Solutions Division, Caterpillar, Inc
Chuck Brandt, Vice President and Chief Technology Officer, The Technology Collaborative
Joanne Kyriacopoulos, Contracts Officer, Carnegie Mellon University
Allen DiPalma, Director, Office of Research, University of Pittsburgh

Bridging the gap between universities, industry, and government agencies can be a challenge. In today's world of shrinking research and development budgets, and increased pressure on universities to act as the economic stimulators for their respective regions, researchers are increasingly seeking funding through non-traditional collaborations. These non-traditional agreements include or require clear methods for partnering with industry, technology transfer and commercialization of the results of the partnership. The panelists bring years of experience in dealing with issues research administrators face daily and how they resolved those issues so that researchers could bring their ideas to reality. The panel will discuss successes, such as master research agreements, common difficulties between universities and industry, and new government regulations. The plenary will contribute to and inform discussions in many of the conference sessions.

10:30 a.m. – 10:45 a.m. **Break**

10:45 a.m. – 12:00 noon **Concurrent Sessions**

Current Issues at the National Institutes of Health

What's new at NIH? This session will provide an update on the NIH budget, funding priorities, new laws and policies, hot topics, and eRA. Some interesting topics include the focus on new investigators, efforts to enhance peer review, and Financial Conflict of Interest. Implementation of new laws concerning ClinicalTrials.gov and Public Access Policy will be addressed, as well as the latest information about the Grants.gov transition to Adobe forms.

David Curren, Division of Grants Policy, Office of Policy for Extramural Research Administration, National Institutes of Health

Assessing the Grants Office

The Chronicle of Higher Education has featured numerous articles about assessment and accountability in higher education. More colleges and universities are requiring departments to submit not only annual reports, but assessment plans. How does this call for accountability and assessment impact our grants offices? Often we are asked the bottom-line dollar amount of what we procured in a given year, but this can vary depending on whether the grants faculty chose to submit to and funding availability. What about the other functions of our grants offices, such as assisting new faculty in submitting grants, assisting with press announcements, conducting workshops, and drafting policies? What are other measures and benchmarks that grants offices can use to demonstrate our contribution to our colleges and universities and evaluate our success? This session will explore the topic of assessment, examples of assessment models, and practices for assessing the office. This session will focus primarily on pre-award offices at Predominantly Undergraduate Institutions, but all are welcome to attend. Discussion will be encouraged.

Danielle Woodman, Director, Office of Academic Grants, Daemen College

Technology Transfer – Partnerships in Progress

A brief presentation of a product developed by a university and purchased by almedtrac LLC under a contract guaranteeing exclusive marketing rights, intellectual property protection and royalty fees. A discussion of the advantages and issues of such an arrangement as conditions and the product change and recommendations needed to create a win-win relationship through negotiated agreements will follow.

Michael J. Malley, Senior Partner, almedtrac LLC; *Kenneth C. Malley*, Executive Vice President for Business Development, almedtrac LLC; *Max Fedor*, Informatics Executive, LSGH

Research Reveals That We Are From the Same Planet: Debunking the Myth That They Are From Mars and We Are From Venus

Do your industry partners seem like they are from another planet? Join us for an interactive discussion on ways to reach common ground when negotiating with industry. Find out what you can do at the proposal stage to lay the foundation for smoother negotiations down the road, how to identify and reconcile differences in objectives between universities and industry, and what to do when it seems obstacles are too big to overcome.

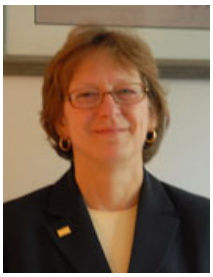
Alexandra A. McKeown, Associate Dean for Research Administration, Johns Hopkins University, Bloomberg School of Public Health; *Jennifer Barron*, Director, Contracts, Charles River Analytics

12:00 noon – 1:30 p.m. Luncheon

NCURA Welcome ***Denise Clark, President-Elect, NCURA National***

Presentation of 2007 Region II Distinguished Service Awards

Ken Forstmeier
The Pennsylvania State University



Erica Kropp
University of Maryland Center for Environmental Science

Region II Business Meeting

Mary Louise Healy, Region II Chair

1:45 p.m. – 3:00 p.m. Concurrent Sessions

National Science Foundation Update

A comprehensive review of what is new and developing with the National Science Foundation's programs, policies, people and budgets. Come learn about changes affecting your institution and researchers, new programs of interest, and NSF electronic initiatives.

Beth Strausser, Senior Policy Specialist, Policy Office, Division of Institution and Award Support (DIAS), Office of Budget, Finance and Award Management (BFA), National Science Foundation

IP and Industry Agreements – Is It OK to Say 'Yes' Sometimes?

The Rochester Institute of Technology's President has proposed a new way of providing research and development services for industry in a relatively IP-friendly environment. Session presenters will elaborate on the rationale for this initiative, its rollout, and practical details.

David Bond, Director, Sponsored Research Office, *Katherine Clark*, Associate Director of Grants and Contracts and Intellectual Property, Sponsored Research Office, Rochester Institute of Technology; *George R. McGuire*, Chair, Intellectual Property Practice Group Bond, Schoeneck & King, PLLC

Workshop: Train the Trainer Bootcamp (this session will run until 4:30 pm)

In this short two-and-one-half hour session, you will learn about common presentation pitfalls and actions you can take to improve your instructional skills. We will discuss items that can cause audiences to disengage and techniques for keeping participants engaged. Other discussion items will include how to best organize your presentation, why practicing is so important, and the use of visual aids. The final part of this presentation will provide attendees with common resources that can aid in further improving their skills.

Ronald J. Placone, Director of Learning and Development, Carnegie Mellon University

Practical Tips and Advice in Assessing Complex Biomedical Agreements

For those of us who work in a medical school or institution involved in biomedical research, complex agreements are becoming more commonplace. Scenarios involving multiple parties, proprietary materials, and international participants present unique challenges. Knowing how to evaluate and apply the necessary regulations can be confusing. This session will touch on the areas that present challenges in complex agreements and offer practical tips to help one arrive at the right answers. Real examples will be used to illustrate points.

Allen A. DiPalma, Director, Office of Research, Kelly Downing, Assistant Director for Clinical and Corporate Research, Office of Research, *Nancy Spice*, Assistant Director for Grants Management, Office of Research, and *Linda Feuster*, Associate General Counsel, Office of General Counsel, University of Pittsburgh

3:00 p.m. – 3:15 p.m. Break

3:15 p.m. – 4:30 p.m. Concurrent Sessions

Growing an Academic Grants Office at a Small PUI

At small PUIs, research administrators are often in the role of marketing the services of the grants office and encouraging faculty members, most of whom have a heavy teaching load, to apply for grants. The office may also serve many additional functions, such as developing policies and procedures to ensure compliance. This session is targeted at the research administrators who are working to increase the number of faculty who are submitting proposals and who are also juggling others duties, such as compliance. This session will offer strategies for engaging faculty members and administrators in applying for grants. It will address some of the challenges and prospects of increased grant activity, as well as strategies for adapting to change and sustaining growth. Discussion will be encouraged.

Danielle Woodman, Director, Office of Academic Grants, Daemen College

Small Business Technology Transfer Program (STTR)

The US Small Business Administration Small Business Technology Transfer (STTR) program, including level of activities of the five participating federal agencies, will be discussed. The three phase program will be explained, as well as criteria for nonprofit research institutions for eligibility that can potentially lead to other technology transfer opportunities.

Darwin Molnar, Vice President of Wheeling Operations, Wheeling Jesuit University/National Technology Transfer Center

Washington Update

As politicians jockey for jobs and power this year, the Federal agencies continue to promulgate regulations, policies and guidance to manage the research relationship. This session will focus on recent Federal regulations and implementation challenges for research universities. The discussion

will examine what a research administrator is or will see come in award documents and agreements, and some strategies for responding to these changes in terms and conditions. Topics will cover questions such as: what do you need to do about the FAR Code of Business Ethics and Conduct (if anything) and who is responsible for meeting the NIH Public Access requirement? There will be warnings and predictions of things to come about research administration.

Carol Blum, Director, Research Compliance and Administration, Council on Governmental Relations

Workshop: Train the Trainer (continued)

Ronald J. Placone, Director of Learning and Development, Carnegie Mellon University

4:00 p.m. — 6:00 p.m. **Reception for New Members and First Time Conference Attendees**
Hospitality Suite

5:30 p.m. – 8:30 p.m. **Gateway Clipper Dinner Cruise of the Three Rivers**

The dinner cruise on the Liberty Belle will be available for boarding from 5:30 to 6:00 pm at the 6th Street dock, walking distance from the hotel. As the Liberty Belle begins the cruise of the three rivers, a dinner buffet will be served. There will be music, dancing, and sightseeing from the top deck. The Liberty Belle will return to the dock by 9:15 pm.

9:00 p.m. – 12:00 p.m. **Hospitality Suite open**

Tuesday, April 29, 2008

7:30 a.m. – 10:00 a.m. **Registration**

8:00 a.m. – 9:00 a.m. **Continental Breakfast**

9:00 a.m. – 10:30 am **Concurrent Sessions**

Educational Research Agreements

Does your university engage students in educational research within a course setting? The session will examine the issues pertaining to educational sponsored projects where students are developing intellectual property in classroom settings. This session will examine the management of intellectual property ownership, educational sponsor rights, student rights, and other issues as they pertain to educational sponsored research.

Matt Bartman, Contracts Officer, Carnegie Mellon University; *Gregory C. Slack*, Director, Office of Research and Technology Transfer, Clarkson University; *George R. McGuire*, Chair, Intellectual Property Practice Group Bond, Schoeneck & King, PLLC

Clinical Trials: From (Phone) Call to Completion: Everything an Academic Researcher Should Know About Working with Government and Industry

This session will include a discussion of the various issues to consider when negotiating and then entering into an agreement with industry (or the NIH) to conduct a clinical trial for the PI or administrator. Specific topics to be addressed include the following:

a) Confidentiality Agreements: sponsor-investigator, coordinating center-site, investigator-vendors and others
b) Conflict of Interest
c) Contracts: "sticky" clauses or how to protect the PI (and your institution's) interests. (Subject injury, indemnification, publication, intellectual property)
d) Getting to "Go": hurdles to clear prior to recruitment, how much time it may take, and tips to speed up the process!
e) Key issues concerning Clinical Trials and biological specimen banking

Expected outcomes include: a greater understanding of the legal issues surrounding the conduct of clinical trials, confidentiality concerns, subcontracting of responsibilities, and key language in clinical trial agreements. After this session, attendees should have a better knowledge base regarding the contractual and documentation requirements prior to starting a clinical trial.

M. Aileen Shinaman, Instructor, Clinical Trials Coordination Center, University of Rochester

Proposing and Administering Federal Contracts: A Primer for the Department Administrator

Just when you think you have finally learned it all, your Chair tells you the department is going to submit a proposal to a federal contract RFP. Now you have a whole new language to learn. This workshop will look at federal contracts from the point of view of those administrators who have to make it all happen. We'll take you through the life of the project: (1) reading (and understanding) the 100+ page RFP, (2) preparing the VERY DETAILED budget and cost documentation, (3) the final proposal revision and small business subcontracting plan, (4) work of coordinating the reports, (5) getting Contracting Officer's approval for what seems like everything, and (6) understanding how FARs differ from typical grant terms and conditions. Central research office administrators will also find it valuable to learn how they can advise and assist their campus partners.

Jeanne Galvin-Clarke, Contract & Grant Administrator Office of Research & Development; *Janet Simons*, Director, Research Administration and Development, and *Gloria J. Smedley*, MARCE Research Administrator, Center for Vaccine Development, University of Maryland, Baltimore

Research Financial Compliance Issues

Compliance issues are getting attention in Federal reviews and audits. What should we know and remember when development of institutional practices?

Mark Davis, Managing Director, Bearing Point, Inc

10:30 a.m. – 10:45 a.m. Break

10:45 a.m. – Noon Concurrent Sessions

Basics of Grants.gov

Back to the basics. With an increased use of the Grants.gov submission process, this session will update users on the current Grants.gov initiatives while providing common tips to help with a smooth submission.

Joseph Sullivan, Manager, Preaward Systems and Administration, Carnegie Mellon University; *Ruth Tallman*, Associate Director and Compliance Officer, Lehigh University

Mixing Bowl: Universities, Industry, and Federal Funds

Research Administrators face unique challenges when federal agencies fund industry, who, in turn, fund academic institutions. This session will explore the SBIR/STTR funding mechanism and other types of flowdown contracts. It will focus on applicability of terms and conditions oftentimes flowed down to the academic institution in error, provisions that need to be modified for universities to incorporate A-21, A-110 and A-133, as well as problematic clauses typically encountered in these types of agreements. Panelists will also discuss office procedures for developing, negotiating and processing these types of awards.

Deborah Fisher, Director, Preaward Administration, University of Pennsylvania; *Jill Fabbri*, Contract Negotiator, The Pennsylvania State University; *Janet Simons*, Director, Research Administration & Development, University of Maryland, Baltimore; *Heather Lewis*, Preaward Associate Director, University of Pennsylvania

Trial by Fire: How to Navigate Clinical Trial Billing Compliance

2007 saw a flurry of activity around CMS' Clinical Trial Policy. This policy has a significant impact on hospital processes for clinical research billing and budgeting for patient care procedures between a hospital and an academic institution. This panel will discuss:

1) A high level overview of the Policy and its requirements

2) Challenges complying with the Policy

3) Frameworks that hospitals and academic medical centers use for implementing compliant billing processes for patient care cost in the context of research

4) A Case Study: West Penn Allegheny Health System

Christina Panos, Director of Patient Financial Services Department, and *Robert Michalski*, Vice President and Chief Compliance Officer, West Penn Allegheny Health System; and *Allecia Harley*, Manager, Clinical Research Solutions and Healthcare Compliance, Huron Consulting Group

12:00 noon Adjourn

Pittsburgh Hilton