

Managing the Higher Education Research Enterprise in a Time of Change: Compliance, Conflicts of Interest, Contracting and Other Legal Issues

Presented in cooperation with the Association of American Universities, the Association of American Medical Colleges, and the Council on Governmental Relations.

Wednesday, November 12, 2008

1:00pm – 1:15pm
Blue Room

Welcome and Introduction to the Program

Theresa Colecchia, University of Pittsburgh
Kathleen Curry Santora, Chief Executive Officer, National Association of College and University Attorneys
Mary Kennard, American University, President, National Association of College and University Attorneys

1:15pm – 2:30pm
Blue Room

01. Sponsored Research with Foundations: Evolving Roles and Changing Contract Terms

- Foundations' goals for commercialization of developments they fund
- Treatment of revenue derived from the commercialization of foundation-funded research
- Balancing the rights of parties when multiple funders support a common project
- Ensuring the appropriate documentation of collaborative structures so foundation goals are met (does your technology transfer office know what your research office agreed to?)
- Publication rights and dissemination of data-is acknowledgement of funding all that a foundation wants?

Theresa Colecchia (*Moderator*), Associate General Counsel, University of Pittsburgh
Karen Andrees, Counsel, Multiple Myeloma Research Foundation
Erik Iverson, Associate General Counsel, The Gates Foundation

2:30pm – 2:45pm **Break**

2:45pm – 4:00pm

Blue Room

02A. Taming the MTA Monster - Policies and Practices to Manage the Effective Transfer of Materials

- Dealing with difficult IP terms
- Take-it-or-leave-it terms (e.g., foreign law)
- Indemnification provisions
- Tactics to improve tracking MTAs
- Other problematic provisions

Fletcher Fahey (*Moderator*), Associate University Counsel, University of North Carolina - Chapel Hill
Dianne Archer, Coordinator - Private Contracts & Grants, University of California
Cathy Innes, Director, Office of Technology Development, University of North Carolina - Chapel Hill
BethLynn Maxwell, Senior Attorney, The University of Texas System
Kathy Schutt, Licensing Associate, Office for Technology Development, The University of Texas Southwestern Medical Center

Congressional A & B

02B. Conducting Research Overseas: Setting Up Operations and Regulatory Compliance

- Establishing a legal presence overseas: foreign registration, memoranda of understanding, tax exemptions, special purpose entities, and liability protection
- Meeting expectations of federal sponsors and monitoring compliance remotely
- Understanding roles of institutional review board and ethics committees in oversight of human subjects research overseas
- Complying with local laws, regulations, policies and customs in the conduct of human subjects research overseas

Edward Silver (*Moderator*), Associate General Counsel, Columbia University
William Ferreira, Hogan & Hartson LLP, Washington DC
Gerianne Sands, Associate General Counsel, Fred Hutchinson Cancer Research Center

4:00pm – 4:15pm **Break**

4:15pm –
5:30pm

Blue Room

03A. Reporting Non-Compliance in Human and Animal Subjects Research: Best Practices

- Regulatory overview of reporting requirements for OHRP, FDA, OLAW, USDA and OBA
- What is a reportable event? Who makes the determination? Who makes the report? When do you report? What do you include in the report?
- Risks of under-reporting and over-reporting
- Reporting requirements for accrediting bodies

Barbara Shiels (*Moderator*), Associate General Counsel, University of Minnesota

Theresa Colecchia, Associate General Counsel, University of Pittsburgh

Eric Swank, Research Compliance Advisor, Indiana University

Congressional A & B

03B. Monetizing Assets: The Sale of Patents and Royalty Streams

- Establishing value of R & D patents
- Negotiating transactions
- Current status of the intellectual property marketplace
- Intellectual property patent auctions

Arjun Sangha (*Moderator*), Associate Vice Chancellor for Research and Technology Transfer, The University of Texas System

Rangar Olson, Associate, Ocean Tomo, LLC

Paul Reidy, Intellectual Ventures, Inc.

5:30pm – 6:30pm

Reception for Registrants and Presenters

Sponsored by Hogan & Hartson LLP
Empire Ballroom

Thursday, November 13, 2008

8:00am –
9:15 am

Blue Room

04A. Investigator Initiated Studies-INDs and IDEs: Who Holds the Responsibility and How to Manage the Risk

- When to obtain an IND or IDE
- Sponsor responsibilities under an IND or IDE
- Clinical investigator responsibilities under an IND or IDE
- IRB responsibilities under an IND or IDE
- Sponsor, clinical investigator and IRB non-compliance in FDA warning letters-common regulatory failures
- Effective habits of sponsors and clinical investigators to avoid regulatory correspondence

Judith Leonard (*Moderator*), Vice President for Legal Affairs and General Counsel, University of Arizona

Karena Cooper, Regulatory Counsel, Office of Compliance, Center for Drugs Evaluation and Research, FDA

Sonali Gunawardhana, Regulatory Counsel, Office of Compliance, Bioresearch Monitoring Center, FDA

Congressional A & B

04B. Current Patent Legislation and Case Law Update

- Origins of the effort at patent reform and the complex perspectives of higher education
- The roles played by the National Academy of Sciences, FTC, AAU, COGR and others
- Will the energy behind efforts at patent reform have implications for other technology transfer legislation (e.g. Bayh Dole)?
- Patent Law Review: A discussion of notable Supreme Court and Federal Circuit decisions in the last year
- Patent Law Perspectives: The impact of USPTO rulemaking and the eBay, Medimmune, and KSR progeny by a patent litigator and a patent prosecutor

Robert Hardy (*Moderator*), Director, Council on Governmental Relations

Jonathan Fritz, Whyte Hirschboeck Dudek, S.C.

Jason Sheasby, Irell & Manella LLP, Los Angeles, CA

9:15am – 9:30am

Break

9:30am – 10:45am

Blue Room

05A. Effort Reporting: Best Practices and Recent Enforcement Actions

- Basic principles of effort reporting under OMB Circular A-21
- HHS OIG's proposed guidance on effort reporting
- Lessons learned from NSF's recent stories of comprehensive effort reporting audits
- Enforcement of effort reporting compliance under the False Claims Act
- Avoiding trouble-the role of university counsel

Judith Curry (*Moderator*), Associate General Counsel, North Carolina State University
David Kennedy, Director, Costing Policies and Studies, Council on Governmental Relations
Robert Kenney, Hogan & Hartson LLP, Washington DC

Congressional A & B

05B. Suing for Patent Infringement: Evaluating the Costs and Weighing the Risks and Benefits

- Anatomy of a patent case
- Handling the decision to commence suit
- Preparing for litigation* Managing the litigation
- Process of settlement* Handling unexpected results

Jason Sheasby (*Moderator*), Irell & Manella LLP, Los Angeles, CA
Augustine Cheng, Chief Legal Officer, Arizona Technology Enterprises
Michael Falk, Wisconsin Alumni Research Foundation
Terri Lynn Turner, Associate General Counsel, Johns Hopkins University

10:45am – 11:00am **Break**

DISCUSSION GROUP SESSIONS

11:00am – 12:00pm

Capitol
06A. Simplification of Informed Consent Documents

Susan Ehringhaus, Association of American Medical Colleges

Embassy
06B. Establishing Effective Research Compliance Programs

Peter Harrington, Bowditch & Dewey, Worcester, MA
Eric Swank, Research Compliance Advisor, Indiana University

Calvert
06C. Select Agent Research and Biosecurity Concerns

Patrick Schlesinger, University of California

Governor's
06D. Clinical Research Subject Injury: Negotiating Compensation Clauses

Karen Mullin, Boston University

Forum
06E. Reviewing FAR Clauses: Preferred Clauses for Universities

Robert Hardy, Council on Governmental Relations
Alex McKeown, Johns Hopkins University

Congressional A & B
06F. Taking Your MTA Tracking and Management System Online

Cathy Innes, University of North Carolina at Chapel Hill
Kathy Schutt, The University of Texas Southwestern Medical Center

12:00pm – 1:30pm
Hampton Ballroom

Luncheon *Sponsored by Whyte Hirschboeck Dudek*

Research Institutions, Difficult Economic Times and a New Administration
John C. Vaughn, Executive Vice President, Association of American Universities

1:30pm –
2:45pm

Blue Room

07A. Drugs and Devices for Unique Situations: Humanitarian, Compassionate and Emergency Use

- Overview of regulatory requirements
- Clarifying confusion between compassionate and emergency use
- Informed consent requirements
- Obligations of physician, IRB, institution, FDA and drug/device company
- Applicability of sponsored research agreements to these unique situations

Stephanie Gold (*Moderator*), Hogan & Hartson LLP, Washington DC

Wayne Matelski, Arent Fox LLP, Washington DC
Kathleen Meyerle, Legal Counsel, Mayo Clinic

Congressional A & B

07B. Export Control in the Technology Transfer Setting: You Can't License That Over There

- Current export controls, sanctions and embargoes
- When over here is "over there": controls on deemed exports
- Special export control issues for technology with military or space applications
- Enforcement trends under U.S. trade controls
- The future of export controls in the technology transfer setting

BethLynn Maxwell (*Moderator*), Senior Attorney, The University of Texas System

J. Scott Maberry, Fulbright & Jaworski L.L.P., Washington DC

2:45pm – 3:00pm

Break

3:00pm –
4:15pm

Blue Room

08A. Protecting Your Animal Research Program: New Risks and New Tactics

- Legal and legislative strategies of animal rights groups
- Legal and legislative strategies of institutions
- Strategies for handling public records requests
- On-campus and off-campus security strategies
- Coordination with law enforcement
- Public relations strategies

Barbara Shiels (*Moderator*), Associate General Counsel, University of Minnesota

L. Amy Blum, Campus Counsel, University of California - Los Angeles

Patrick Schlesinger, Office of Ethics, Compliance and Audit Services, University of California

Frankie Trull, President, National Association for Biomedical Research

Congressional A & B

08B. Enforcing the University's Rights in Intellectual Property with Faculty: Case Studies from the Trenches

- Non-disclosure of inventions by faculty members
- Securing faculty compliance with university policies
- Enforcing institutional policies and rights against third parties dealing with faculty
- Federal funding and Bayh-Dole considerations
- Resolving institutional and faculty disagreements re enforcement against alleged infringers

Kenneth Hairston (*Moderator*), General Counsel, Alabama Agricultural and Mechanical University

Robert Firestone, Associate General Counsel, University of Pennsylvania

Steven Rosen, Attorney, The University of Texas System

4:15pm – 4:30pm

Break

DISCUSSION GROUP SESSIONS						
4:30pm-5:30pm	Capitol 09A. Update on Export Control Regulations Affecting Research J. Scott Maberry, Fullbright & Jaworski	Embassy 09B. Alternative Structures for the Oversight of Human Subjects Research Stephanie Gold, Hogan & Hartson LLP, Washington DC Judith Leonard Vice President for Legal Affairs and General Counsel, University of Arizona	Calvert 09C. Managing the Risk to the Research Enterprise in Troubling Economic Times Edward C. Dolan, Hogan & Hartson, LLP, Washington, DC	Governor's 09D. Tax Implications of Industry Sponsored Research Robert Bienstock, Yale University Peter Harrington, Bowditch & Dewey, Worcester, MA	Forum 09E. Managing Institutional Conflict of Interest-Getting Past the Pretty Words and Enacting a Meaningful Policy Susan Ehringhaus, Association of American Medical Colleges	Council 09F. Complying with the NIH Open Access Requirement Madelyn Wessel, University of Virginia

Friday, November 14, 2008

8:00am – 9:15pm
Blue Room

10. Industry Relations Policies for Academic Medical Centers-Beyond Standard Conflict of Interest Policies and Considerations

- Research (risk stratification from human to non-human research)
- Education
- Clinical practice linked to medical schools
- Start-up companies based on university discoveries

Stephanie Gold (*Moderator*), Hogan & Hartson LLP, Washington DC
Guy Chisolm, Chairman of the Lerner Research Institute Department of Cell Biology, The Cleveland Clinic Foundation
Susan Ehringhaus, Associate General Counsel for Regulatory Affairs, Association of American Medical Colleges
Ann James, Senior University Counsel, Stanford University

9:15am – 9:30am **Break**

9:30am – 10:45am
Blue Room

11. Negotiating Effective Clinical Trial Agreements-Industry Perspectives and Institutional Concerns

- Expectations of the bio/pharmaceutical company and academic medical institution when negotiating clinical trial agreements
- Key issues: Confidentiality: What can a bio/pharmaceutical company reasonably expect? Publication: Why so important to academic medical institutions? Intellectual Property: How can bio/pharmaceutical companies ensure that their intellectual property rights are appropriately protected? Indemnification: Who should be responsible and for what?
- Practical and effective methods to streamline the negotiation of clinical trial agreements

BethLynn Maxwell (*Moderator*), Senior Attorney, The University of Texas System
Dennis LaCroix, Managing Counsel, Genzyme Corporation
Karen Mullin, Contract Officer, Boston University Medical Campus

10:45am – 11:00am **Break**

11:00am–
12:15pm
Blue Room

12. Ethical Considerations for Counsel in Representing Faculty and Staff in Governmental Investigations

- Preserving privilege—who is the client?
- Joint representation and the Rules of Professional Conduct
- Joint defense agreements
- Indemnification and fee reimbursement-institutional policies and revised DOJ guidelines
- Dealing with refusals to cooperate with internal and external investigations or misrepresentations to government investigators
- Duty to defend and institutional insurance policies
- State deviations from model rules of professional conduct

Karl Brevitz (*Moderator*), Director of Legal Resources, National Association of College and University Attorneys

Lisa Estrada, Arent Fox LLP, Washington DC

Patricia Bergeson, Rosalind Franklin University of Medicine and Science

12:15pm

Adjourn