COUNCIL ON GOVERNMENTAL RELATIONS

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March 4, 2005

MEETING REPORT

THE COUNCIL ON GOVERNMENTAL RELATIONS
WASHINGTON MARRIOTT HOTEL
February 10 and 11, 2005

GENERAL DEVELOPMENTS

CONTRACTS AND INTELLECTUAL PROPERTY COMMITTEE

COSTING POLICIES COMMITTEE

RESEARCH COMPLIANCE AND ADMINISTRATION COMMITTEE

GENERAL DEVELOPMENTS

1. Fox Chase Cancer Center Becomes COGR's Latest Affiliate Member

The Board voted to accept a new affiliate member. It is the Fox Chase Cancer Center, located in Philadelphia. Founded in 1940, the Center has attracted world class researchers, including Nobel Laureate Baruch Blumberg, who was recognized for his discovery of the hepatitis B virus. The Center currently receives over $50 million in federal research funding and has faculty affiliation with Temple University and the University of Pennsylvania. Research emphasis is on gene expression, molecular structure and functional analysis, viral molecular biology and pathogenesis, regulation and control of the immune system and cell cycle control. COGR's primary contact will be Patricia Harsche Weeks, Vice President, Planning and Business Development.

2. COGR President Announces Retirement in the Fall

Kate Phillips informed the Board that for entirely personal reasons she will not be able to stay for a second five year term as President. The announcement was made to the membership during the February meeting. Kate's husband, Sheldon L. Trubatch, a regulatory lawyer, has taken a position as in-house legal counsel for Bechtel, located in Las Vegas, where he works on the government's proposed high level radioactive waste repository at Yucca Mountain. Kate will join him after completion of her contract with COGR in September 2005. She told the Board that, even after twenty years with COGR, she continues to enjoy working with and for the membership and will remain an active President until a successor is found. The Board is now in the process of preparing a position description and forming a Selection Advisory Committee.

3. COGR Changes E-mail Provider System

The COGR office decided to change its electronic communication service during the week of February 21, 2005. The memberships should not feel any repercussions from this change. In case of any irregularities or unusual messages, please call the COGR office right away.

4. Congressman Porter Addresses the Membership

In his opening remarks, Congressman Porter recalled the last time when appropriations were frozen, during the Draconian budget resolution proposed by House Speaker Newt Gingrich as part of the Contract with America. Personal intervention by Mr. Porter reversed that drive and led to the protection of NIH and CDC funding, which later developed into the doubling of NIH appropriations. The task today is more difficult because the House moderates are gone, and the Senate is weaker. However, Mr. Porter believes that the task is not impossible. Of course, the

funding priorities today are no longer in the health area, but with elementary and secondary education. Basic research will suffer as increases are given to development activities. Science will suffer, unless it becomes part of funding for national security initiatives.

Mr. Porter warned that stem cell research is not on the President's agenda. New legislation could well lead to the imposing of criminal penalties on research into therapeutic cloning. Equally ominous is the growing interest among some House members to defund peer reviewed projects that seek to investigate social problems. Mr. Porter warned that the NIH intramural conflict of interest investigation could expand into an investigation of similar conflicts in extramurally funded research at universities. In that regard, the NIH Reauthorization Bill could become the vehicle for a number of unwelcome legislative changes.

In closing, the Congressman reminded the audience that the President's budget is a political document. The entitlement programs now take up so much of the budget that only a very small amount is left for discretionary funding, - after the Defense and Homeland Security Appropriations. Nevertheless, science can be sold to this administration, especially in the context of its strong links to economic competitiveness and national security. He urged the university community to reach out and ease the strain left on the relationship between the President and the academic community in the wake of the election. A lively Q&A exchange closed out the session, covering issues such as earmarks, patient advocacy groups, champions on the Hill and the increases in tuition.

5. Congressional Panel Forecasts the New Agenda

In lieu of significant changes resulting from the recent election, this panel presenting Congressional staffers replaced COGR's usual Federal panel. The panelists were asked to describe the agenda of their respective offices, with specific regard to university research issues. Tobin Smith, Senior Federal Relations Officer at the Association of American Universities, was instrumental in securing the invitations and moderated the sessions effectively.

Dr. Elizabeth Robinson, Deputy Director, Congressional Budget Office, gave a brief overview of the current budget and identified the major factors that have led to the current deficit. Overall, it appears that the post 9/11 decrease in revenue had more significant impact than did increased spending. Other events that add to the deficit baseline are the tax cuts which amount to 2% of the gross domestic product and the impact of the war(s) which is estimated at $1 trillion over 10 years.

During the next ten years, the discretionary budget will be weighed down primarily by the burden of the entitlement programs for Social Security, Medicare and Medicaid, and by the increases in the Defense and the Homeland Security budget. It is a depressing realization that even the currently healthy economy will not enable the country to cut the deficit or to balance the budget.

Dr. Beth Grossman, like Elizabeth Robinson a PhD in physics, represented the House Committee on Science. She tactfully commented on the Presidential budget, released that week, as "disappointing". Among the nine agencies, over which the Science Committee exerts oversight, few got any increases, and even at its 1.5% projected increase, the NSF cannot make

up for the loss of past years. Especially worrisome is the loss of funding for DOE science programs. She described the shift of education funding from NSF as a fundamental policy shift, but noted that nothing was final yet.

Turning to the agenda of the House Science Committee she described it as fluid. At present, the NASA Reauthorization Bill is a priority, followed by the NOAA Act and the Energy bill. She predicted that there would be either hearings or legislation on graduate education. The Committee is aware of the deemed export activities in the Department of Commerce but has not chosen to get involved at this time. The message Beth Grossman wanted to leave with the audience is that the Science Committee, particularly the Research Subcommittee, is open to contacts from the universities and will shape its agenda accordingly.

Mr. John Ford, Minority Counsel on the House Committee on Energy and Commerce stated that the priority of Chairman Joe Barton (R-TX) is the NIH Reauthorization bill. It has, however, not yet moved far along. He commented on the budget only to say that Congressional surliness was evident, but no mutiny at hand. Input from the community is clearly important, especially as the discretionary budget and NIH funding are so closely intertwined.

Among the university issues that will occupy the Committee are likely to be consulting practices, the nexus between bioterrorism and health research, drug safety and health information technology. An unresolved question is the growth of costs for building and maintaining large facilities.

6. New Friday Morning Panel Session

Kathy Irwin, COGR Board member, moderated a panel on which three senior university representatives described their experience in wrestling with compliance on export control and cybersecurity regulations.

All three panelists agreed that the Sponsored Research office is the key player in protecting the university from a lapse in compliance regarding export control regulations. Jamie Keith, COGR Board member, focused on the nexus between the fundamental research exclusion and prepublication reviews. She reminded the audience that the DOD leadership has not yet followed up on its IG report. James Bloedel, Vice Provost for Research and Advanced Studies, Iowa State University, emphasized that compliance with the export control regulations is essential and that universities may need to be ready to walk away from some awards that contain export control restrictions. The status of internally funded projects, many of which may not get reviewed for export compliance, was also discussed. The panelists agreed that some disciplines are especially vulnerable, e.g., faculty in sociology and archaeology, because they do not typically receive federal dollars and their overseas travel and research may trigger both export control issues and restrictions imposed by the Office of Foreign Asset Control (OFAC). When articles are being shipped, the scientist may claim the fundamental research exclusion, if he/she remains in the US to conduct research but the article itself may be covered by a license requirement. The question arises who is liable: the university or the shipper?

Ara Tahmassian, COGR Board member, presented a case study that illustrated how the inadvertent shipment of a small, low cost sample required the testing of 300 individuals for

potential cholera infection – fortunately with no harmful outcomes. Universities that are decentralized need to think about how to assure systematic control of laboratory safety. Universities also need to be careful about the terms they agree to with the end user of a shipment. Are universities aware of their own responsibilities regarding the recipient's capabilities? How should they establish required controls? Universities may need to consider a post shipment monitoring program.

Before turning to the cybersecurity area, the nexus between export controls and biosecurity was touched upon. The Patriot Act (Sec. 817) and the 2002 Bioterrorism Act covering select agents and toxins, are the key statutes here. They intersect when biological materials, synthetics and chemicals are being used in research or transferred for research purposes.

All panelists agreed that the federal agencies have invested significant funds in cybersecurity and expect the same of the university community. The expectations are high: reportedly the external inspectors' checklists when they arrive on campuses contain over 80 items; all websites are to be controlled and approved, a security clearance is required for key staff and background checks are mandatory.

However, cybersecurity regulations apply only when an award contains the cybersecurity clause. Inspectors insist that on web based systems, everything is expected to be covered. To cover all the university computers would be an incredible challenge. Iowa State keeps the secured laboratory s on a LAN and off the university website. The audience was advised to keep data on a hard disk and to store it in a secured safe. One should distinguish between what is classified and what is controlled under select agent rules.

Again, a case study illustrated the potential fall out from the new regulations. James Bloedel described the Ames Anthrax incident, - its impact on laboratory personnel, expenses for equipment and human costs.

7. New Federal Appointments

Axel Wolff was appointed to the position of Director of the Division of Compliance Oversight in the Office of Extramural Research, National Institutes of Health, Office of laboratory oratory Animal Welfare. He had been acting Director in the office since May of 2004, following the retirement of Stephen Potkay.

Elizabeth Nabel, M.D. was appointed Director of the National Heart, Lung and Blood Institute at NIH, moving up from Scientific Director of Clinical Studies at NHLBI. She was Chief of the Division of Cardiology at the University of Michigan before joining NIH in 1999. She succeeds Claude Lenfant, the long-term much respected leader of the Institute.

Along with the resignation of Department of Homeland Security Secretary Ridge, several other key staffers have left the department. Among them are Asa Hutchison, former Undersecretary for Border and Transportation Security, Clark Kent Ervin, the DHS Inspector General and Jack Johnson, the Chief Security Officer. We regret the departure of Carolyn Hanna, Special Assistant for External Affairs in the Science and Technology Division. Replacements have not yet been announced, pending a top-down organizational review by the incoming DHS Secretary.

CONTRACTS AND INTELLECTUAL PROPERTY

Committee: Andrew Neighbour, Chairman, University of California, Los Angeles; Susan Burkett, Carnegie Mellon University; Jilda Diehl Garton, Georgia Institute of Technology; Kathleen Irwin, University of Wisconsin-Madison; Marvin Parnes, University of Michigan; Ann Hammersla, Massachusetts Institute of Technology; John Ritter, Princeton University; James Severson, University of Washington; Thomas Sharpe, University of Missouri; Janna Tom, University of California System

1. COGR Submits Comments on CREATE Act Interim Rule

The Meeting Agenda summarized the regulations issued by the Patent and Trademark Office (PTO) on January 11, 2005 to implement the CREATE Act (P.L. 108-453). The CREATE Act provides an exemption to "prior art" patent invalidation for research collaborators from different organizations by creating a "safe harbor" provided they have entered into a joint research agreement prior to making the invention. The PTO implementing regulations set forth requirements for documentation of qualifying joint research agreements in patent applications and for filing disclaimers to address "double patenting" concerns. They revise the PTO rules of practice in such situations.

COGR submitted comments on the implementing regulations to PTO on February 10, 2005 jointly with the Association of American Universities (AAU). In the comment letter COGR/AAU lauded PTO for promptly implementing the CREATE Act through these regulations. However, COGR/AAU made a number of comments and suggestions having to do with the enforcement of the respective rights when the parties to the joint research agreement have separately patented earlier inventions that may contain similar claims. Our principal concern is that the proposed PTO changes are too restrictive in limiting the ability to enforce or separately license the patents, given that the intent of the CREATE Act is to treat them in the same manner as patents with a common owner. COGR/AAU also pointed out that the date of execution of the joint research agreement may be different than its effective date, and suggested that where this is the case both dates should be included in the submission to PTO.

The comment letter is on the COGR website at "What's New/Current Letters".

2. SBA Proposes Changes to Small Business Size Regulations for SBIR

On December 3, 2004 the Small Business Administration (SBA) announced (Federal Register, 69 FR 70180-70185) a revision to its small business size regulations regarding ownership and control of Small Business Innovation Research (SBIR) program awardees. SBA had proposed (68 FR 33412 June 4, 2003) to allow a small business owned or controlled by another business to be eligible for SBIR. The final rule, which became effective January 3, 2005, does not change the size standard requiring that an SBIR awardee, together with its affiliates, have no more than 500 employees. It allows SBIR eligibility so long as the small business is at least 51% owned and controlled by one or more individuals who are U.S. citizens or permanent residents or

another for-profit business concern that itself meets the 51% U.S. citizenship or resident requirement.

One of the issues that emerged in response to SBA's proposal was whether small businesses that are majority owned and controlled by venture capital companies (VCCs) should be eligible for SBIR. The rule does not make a distinction between VCCs and other for-profit entities, so long as the parent company and other affiliates together with the small business meet the 500 employee size standard (and the parent VCC meets the 51% U.S. citizenship requirement). However, because of the large number of comments received on the VCC affiliation issue, SBA has requested further comments (69 FR 70197) on the policy issues raised by VCC ownership of SBIR awardees. The comment deadline has been extended to April 3, 2005.

This issue has drawn the attention of the university technology transfer community. Some commenters to SBA argued that small businesses that are majority owned and controlled by VCCs do not need further funding from the government through SBIR. In their view allowing SBIR eligibility for such firms would negatively impact other small businesses that do not have access to VCC resources. However, other commenters pointed to the critical need of innovative small business concerns for capital investment, especially in fields such as biotechnology. Comments from the university community that COGR has received support this view. Many university startups have benefited from SBIR funding, which reduces the private investment risk and helps prepare early-stage technologies for market. Majority ownership by a VCC does not imply that the small business has a surplus of resources. Many small emerging high tech companies look both to venture capital and SBIR as cornerstones of their growth strategies.

The Committee discussed at length whether to submit comments to SBA on the VCC/SBIR affiliate issue. While we are generally supportive of allowing VCC affiliation, universities are not a direct stakeholder in this matter. Rather than submitting COGR comments, we concluded that it is more appropriate to alert the membership to this issue. Individual universities should consider submitting comments to SBA if they feel VCC affiliation should be strongly encouraged.

3. COGR To Develop Talking Points on AIPLA Patent Reform Proposals

The October 2005 COGR Meeting Report summarized recent recommendations of the Board of the American Intellectual Property Law Association (AIPLA) for changes in U.S. patent law. There are three principal aspects to the recommendations: 1) a set of proposals aimed at "harmonizing" U.S. patent law with that of other countries (e.g. moving from a "first to invent" to "first to file" standard for patent applications); 2) a proposal to codify the common law "experimental use" exemption from patent infringement; and 3) a proposal to broadly expand "prior user rights" beyond the current restriction to business methods.

The harmonization proposals implement a recent report of the National Academy of Sciences Board on Science, Technology and Economic Policy (STEP) entitled *A Patent System for the 21st Century* (available online at http://books.nap.edu/catalog/10976.html; see June 2005 COGR Meeting Agenda). Many of these recommendations reflect longstanding AIPLA (and industry) objectives in the area of intellectual property rights. Universities (and small business) traditionally have opposed the recommendations.

AIPLA has joined with STEP and the Federal Trade Commission (FTC) in scheduling a series of regional "Town Meetings on Patent System Reform" during the spring and summer of 2005 (see http://www7.nationalacademies.org/step/; the complete program and registration information is available on the AIPLA website at http://www.aipla.org. The FTC also recently issued a report with recommendations on changes in U.S. patent law: *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy - A Report by the FTC, October 2003* (available on the FTC website at http://www.ftc.gov/os/2003/10/innovationrpt.pdf). According to AIPLA, the purpose of these town meetings is "to publicize these studies and the largely consistent recommendations of the National Academies STEP Board, the FTC, and AIPLA in anticipation of congressional hearings. Many stakeholders in the patent system will be affected by the changes recommended. We are therefore initiating this important dialogue to solicit the stakeholders' participation about what the problems are and what changes need to be made. We are proud to present these Town Meetings on Patent Reform for the purpose of hearing from the stakeholders on the issues. These Town Meetings will culminate this summer in a conference in Washington, DC, taking into account all of the feedback we receive during these programs."

It is important for the university community to be aware of these activities and to map out a strategy. COGR has been discussing with AAU and the Association of University Technology Managers (AUTM) how best to contribute to this process. COGR and AAU have jointly developed Talking Points on the pros and cons of the recommendations from a university perspective to assist universities, particularly their federal relations representatives, in understanding the implications. Representatives of the COGR CIP Committee and/or AUTM also plan to attend each of the upcoming town meetings and to make their views known. Other university representatives should consider attending the meetings in their regions.

We understand that recently opposition to some of the recommendations has surfaced within AIPLA. The proposal to codify an experimental use exemption from patent infringement appears particularly contentious, since some segments of the AIPLA membership (i.e., biotechnology companies that market research tools) see it as constituting a threat to their core business. (The exemption might be both beneficial and harmful to universities, depending on whether they view it primarily from the perspective of users or as inventors of patented technologies used in research; also see comment in 4.below about the scope of the AIPLA proposal). Because of such differing views, we understand AIPLA may be considering downgrading some of the recommendations to a "working proposal" status. We will keep the COGR membership informed of developments, and will notify the membership when the Talking Points become available.

4. COGR Continues to Collect Data on University Experience with Patent Infringement Claims

Previous COGR meeting agendas and reports have discussed the Federal Circuit decision in the case of *Madey v. Duke University* (307 F. 3d 1351, Fed. Cir.2002). The decision took a very narrow view of the common law experimental use exemption from patent infringement, and held that universities could not claim the exemption for activities that furthered their legitimate business of research and education. The COGR October 2003 Meeting Report discussed an AAU workshop held on September 30, 2003 to discuss the implications of the decision for university research. The workshop included 55 participants from universities and university associations,

among them representatives of university technology transfer, general counsel, research administration, and federal relations offices.

There was consensus at the workshop that additional data on allegations of infringement by universities should be collected over the next 12-18 months period, particularly to the extent that such data ("threat" letters, infringement claims) could be identified as a direct *Madey* effect. These data would help universities better assess their risk exposure, appropriate responses, and the extent to which further legal or legislative relief is necessary. The participants endorsed a proposal to create a central repository and mechanism that would collect the relevant information. The repository would reside in an independent organization. The American Association for the Advancement of Science (AAAS) volunteered for this purpose.

Since then COGR, a number of other higher education associations and AAAS have been surveying a representative sample of universities about their experience with patent infringement claims. Two data collection phases have been completed to date; the first covering the three six-month periods from January 2003 to June 2004 and the second from July - December 2004. The data are completely "blinded" so that particular institutions cannot be identified. The data collected so far indicate that universities generally have not experienced a great increase in infringement claims. There appears to have been a small spike in claims during the second half of 2003, with a leveling off or even slight decrease since then. However the data suggest some impacts in terms of delays or alterations in research projects and significant financial, administrative or legal costs incurred by institutions that received infringement claims.

Unfortunately because of the blinded nature of the survey, a particular institution's experience with infringement notifications cannot be tracked over time. It also is not clear whether the relatively small increase in claims received is a direct consequence of the *Madey* decision. On the other hand, there seems to be some increase in activity of this kind in the past two years, and some negative impacts on universities. We plan to complete the data collection through the third phase from January through June of this year, and then to convene another small workshop in the late summer or fall to assess the data and discuss possible future directions. We will report to the membership on these additional data collection and analysis activities. (Note: the statutory experimental use exemption discussed above that has been proposed by AIPLA covers research *on* patented technologies for a variety of purposes, but not research conducted *with* patented technologies. It would not have covered Duke's alleged infringement in the *Madey* case).

5. Federal Representatives Discuss Invention Disclosure Requirements

The COGR Meeting Agenda discussed developments with regard to invention reporting requirements for federally-funded research, including the recent Federal Circuit decision in the case of *Campbell Plastics Engineering and Mfg., Inc. v. Brownlee* (#03-1512, Fed. Cir. 11/10/04). In that case the court held that the government has virtually unlimited discretion to compel forfeiture of title to federally-funded inventions for failure to properly disclose the invention to the sponsoring agency in accordance with the requirements of the Bayh-Dole Act regulations (37 CFR 401) and the Federal Acquisition Regulations (FAR) patent clauses (FAR 52.227 - 11 and 12). In part because of concerns about the implications of this case, COGR scheduled a Thursday morning discussion session at the February 2005 meeting. It featured a panel of federal representatives, including John Raubitschek, Patent Counsel for the Department of Commerce, Thomas McDonnell, Patent

Counsel of the Navy, and John Salzman of the NIH Division of Extramural Inventions and Technology Resources in the Office of Extramural Research.

While the *Campbell* decision mandates strict compliance with disclosure requirements, the federal representatives indicated universities are not likely to start seeing a large volume of forfeiture demands in non-disclosure cases. Mr. McDonnell described the Office of Naval Research (ONR) "active invention surveillance" program and presented some data on their findings. ONR has reviewed 350 contracts over the past two years and found 298 undisclosed inventions. The majority of these apparently involve universities. He indicated that they found a mix of inventions that were not disclosed to the university technology licensing offices, and inventions that had been disclosed internally but never reported to ONR.

Despite this indication of widespread non-compliance with invention disclosure requirements, ONR has not taken strong action, but has sought to obtain confirmatory licenses (163) and/or certificates of correction (87). Mr. Raubitschek expressed the view that part of the disclosure problem may relate to the two-month "window" for disclosures mandated by the Bayh-Dole Act regulations. He indicated that he plans to propose changes within Commerce both to the regulations and the FAR patent clauses to provide for a longer time period. In response to questions from session participants, both he and Mr. McDonnell advised that invention disclosures should be submitted within the required two-month period even if incomplete. They can be amended later. The federal representatives also pointed to the fact that for federal compliance purposes, "invention" is defined as "any invention or discovery which is or <u>may be</u> patentable" (emphasis added). In their view, disclosure should be triggered by notification to the university technology licensing office of such an invention or discovery, <u>not</u> only upon a subsequent determination of potential patentability by the university.

Mr. Salzman described the current status of the NIH *i*Edison electronic invention reporting system. He indicated that the current emphasis is on improving its "back end" utility to other federal agencies. He noted some problems with the data received in invention utilization reports from universities, particularly with regard to data on products that have received FDA approval. He indicated NIH would welcome feedback from universities on possible enhancements to the utilization reports. COGR worked closely with NIH on the implementation when the requirement first was added to include identification of the commercial name of any FDA-approved product utilizing the invention that has reached the market. (See the COGR October 2001 Meeting Agenda and Report). Mr. Salzman also reminded participants that the annual invention reporting requirement is separate from the disclosure requirement.

The ONR findings suggest that lack of compliance with federal invention disclosure requirements may be widespread among universities, and may not necessarily be restricted to ONR awards. While the lack of strong concerns expressed by the federal representatives at this session is reassuring, we cannot assume that this view is uniformly shared by federal agencies. The General Accounting Office (GAO) is charged with periodically reviewing Bayh-Dole Act implementation, and in the past has raised concerns about compliance with the disclosure requirements. With the current heightened attention being paid by Congress and the public to university technology transfer practices, there is greater potential for adverse effects on universities from such findings. The *Campbell* decision gives federal agencies a "big stick" tool

to enforce compliance. Universities may want to review their current processes for disclosing federally-funded inventions with these considerations in mind.

6. COGR Meets with Representative of BIO

The Committee met with Lila Feisse, Director of Intellectual Property, Biotechnology Industry Association (BIO) to discuss areas of common interests and ways in which COGR and BIO might work together. Several areas for potential cooperation were identified.

a) Bioprospecting - One of the emerging concerns is about "bioprospecting," where BIO has been heavily involved. The concern arises because some countries are adding disclosure requirements for patent applications with regard to the source and chain of custody of biological materials. Guidelines for the collection and sharing of materials have been developed pursuant to the International Convention on Biodiversity. Often the underlying research is performed by university faculty, and failure to adhere to the guidelines could be problematic with regard to the ability to subsequently patent inventions involving such materials. This has become an issue in current world trade negotiations. BIO is concerned that in the negotiation process U.S. representatives may agree to concessions in this area that could adversely affect the ability to patent inventions in the U.S. The university technology transfer community generally is not well-informed about trade issues. BIO offered to provide briefings to COGR member institutions and to keep us informed of developments.

b) Merck v. Integra - On other matters of common interest, BIO plans to file an *amicus curiae* brief to the Supreme Court in the case of *Merck v. Integra* (No. 03-12370). That case involves the proper scope of the infringement exemption provided under the Hatch-Waxman Act (35 USC 271(e)(1)) for uses related to the development and submission of information to the FDA required for regulatory drug approval. While the case is limited to the 271(e) exemption, the Supreme Court might address broader issues of experimental use in its opinion. The BIO membership is split on the AIPLA experimental use exemption codification proposal (see 3. above). BIO may support some of the AIPLA patent harmonization proposals such as establishing a new post-patent grant opposition procedure, but has not taken a position on others that are of concern to the university community (e.g. expansion of prior user rights). It could be useful for COGR and BIO representatives to further discuss the proposals and compare views. BIO is very concerned about the Administration proposal to eliminate the NIST Advanced Technology Program (ATP), which has been beneficial to BIO members in developing early stage technologies. Finally, BIO is concerned about the tightening of export control regulations. More information from COGR on developments in this area would be helpful to them.

It was agreed that the interests of COGR and BIO members appear to intersect on some key points. Establishing an ongoing dialogue appears useful to both associations.

7. Updates

a) Recent Developments on Export Controls - The COGR Meeting Agenda discussed the recent meeting of the AAU Presidential Task Force on Export Controls with Department of Commerce representatives. As a follow-up to that meeting, a meeting of technical experts from the AAU Task Force institutions and representatives of the Commerce Bureau of Industry and Security (BIS) is scheduled for February 22 in Washington, D.C. The meeting will address the application of dual use export controls to certain specific technologies where Commerce believes deemed export controls are most likely to apply to university research. University attendees will include both task force representatives and scientific experts.

The agenda for the meeting includes discussion of export control concepts for dual use items covered by the Commerce Export Administration Regulations (EAR), a description of the EAR licensing process and exceptions, and a review of the national security significance of the specific technologies. Commerce hopes that with this information, universities will be better able to identify the potential application of deemed export requirements at universities to these technologies and provide related data (i.e., the number of researchers working with the technologies) to inform Commerce of the potential licensing implications. We hope to clarify for Commerce the nature of university research in these areas and the impacts for that research of increased licensing requirements. One useful distinction might be to compare and contrast the normal open academic research environment with the performance of proprietary research by universities under confidentiality agreements with industry sponsors.

This exchange of information also will help provide the basis for planning future campus visits by Commerce to assess the potential impacts of the recent Inspector General (IG) recommendations. Commerce has yet to arrange these visits, but we understand a number of universities may have received *ad hoc* visit requests from Commerce/BIS staff. COGR member universities are requested to inform the COGR office of such requests, so that we may coordinate any such visits with the activities of the AAU Task Force.

We also understand that Commerce plans to publish shortly in the Federal Register a request for comments on the IG recommendations. It is unclear in what context the comments will be requested. We will alert the COGR membership when any such request is published, and continue to keep the membership informed of developments related to export controls.

b) Troublesome Clauses in Federal Research Awards Continue - COGR has continued to hear from the membership about restrictions in government research awards received by universities since issuance in April, 2004 of the AAU/COGR Task Force report to OSTP on *Restrictions on Research Awards: Troublesome Clauses* (available on the COGR website under "Comment Letters;" see COGR June 2004 Meeting Agenda for a summary). While the volume of such clauses may not have increased, universities

report that negotiations with federal sponsoring agencies (and industry prime contractors) to modify or eliminate the restrictions are becoming more contentious.

COGR has considered a follow-up report, but it is not clear what the purpose or intended audience for such a report would be. Universities seem to be coping with such restrictions on a case-by-case basis; successfully negotiating them in some cases and rejecting awards in others. It might be useful for universities to share information more systematically as to these coping strategies and negotiating successes and failures. We will consider scheduling a discussion session for this purpose at the June 2005 meeting. This might include discussion of the cost and resource implications associated with extensive negotiations. In the meantime universities are encouraged to continue to report their receipt of such restrictions to the COGR office, so that we can remain informed of the situations that universities are encountering.

COSTING POLICIES

Committee: Jerry Bridges, Chairman, Johns Hopkins University; Jan Ackerman, Yale University; Jerry Fife, Vanderbilt University; Albert Horvath, Columbia University; Natalie Krawitz, University of Missouri; Yoke San Reynolds, University of Virginia; V'Ella Warren, University of Washington; Mary Lee Brown, ACUA Liaison, University of Pennsylvania; Fred Cantrell, University of Florida; Joanne DeStefano, Cornell University; John Shipley, Purdue University

1. Clarification of Federal Agency Salary Distribution Policy

a) NIH Briefing - As indicated in the Meeting Agenda materials, NIH Office of Extramural Research officials have informed us that the COGR/Association of American Medical Colleges (AAMC) proposal to revise the three standards an institution must meet to include clinical compensation and effort as the basis to charge salary to NIH grants, has been accepted. The agreement setting forth the revised expectations will allow institutions that have one or more clinical practice plans affiliated in some way with the institution, to include the salary and effort as charges to NIH awards if they choose to do so. The NIH Guide Notice, when it is published, is likely to establish a fourth criterion that reiterates the record keeping requirement of OMB Circular A-110 for audit purposes, in instances where an affiliated entity provides part of the compensation.

During the COGR meeting, the AAMC hosted a conference call briefing by Joe Ellis, Acting Director of the NIH Office of Policy for Extramural Research Administration, entitled "Effort Reporting: Total Professional Activity vs. Institutional Activity." Mr. Ellis' slides are available on the COGR web site under "Meetings/February 2005 Presentations". About 30 COGR representatives listened in on the call. The most important points were:

- NIH considers cost transfers to be a barometer of the effectiveness of an institution's accounting and business systems. In Mr. Ellis's slide showing the top ten issues on salary costs on NIH grants, salary cost transfers to avoid overruns is one of the ten.
- Total professional effort compensated by institutional base salary is defined by the institution. NIH does not define either, and is not going to establish a standard based on a 40 hour week or any other basis.
- If salary and effort involves more than one entity, NIH will refer to the three criteria an institution must meet if it chooses to include such salary and effort for compensation purposes on NIH awards. These criteria will be revised soon by a Policy Notice, to reflect the recommended changes proposed by COGR and AAMC.
- All types of organizational structures are allowed – the key is consistent treatment of costs regardless of funding source.

- For Career (K) awards, there is a ceiling established for salary compensation, but funds may be re-budgeted to provide additional salary charged to the grant up to the legislatively mandated salary cap.

No questions were taken during the conference call briefing. It is our understanding that the entire audio of the call will be available soon on the AAMC web site at www.aamc.org.

b) COGR White Paper and AAU Workshop – Jan Ackerman has been reviewing existing material on payroll distribution/effort reporting principles, policies, and best practices in order to develop a COGR white paper. This will serve at least two purposes – an education and guidance piece for the COGR membership, and as background material for an upcoming Association of American Universities' workshop on effort reporting. We reported earlier that the AAU has formed an Effort Reporting Subcommittee of its Cost of Research Committee. The Subcommittee plans to evaluate the current state of affairs with effort reporting and will consider whether any change is needed at the federal policy level. The workshop will be limited to the members of the Subcommittee and a few other invited representatives from selected universities. COGR staff and Board members will assist AAU in the workshop.

2. The Direct Charging of Certain Compliance Costs is Debated

a) Discussion Draft – During the COGR meeting there was much discussion about a provision in a recently negotiated university Facilities and Administrative rate agreement which states that the DHHS Division of Cost Allocation will consider approving a change to the university's current accounting method for certain compliance costs if OMB and DHHS change their policy for charging these types of costs to federal agencies. This statement raises the possibility for direct charging compliance costs that might otherwise be treated as F&A costs. During recent discussion of this provision, OMB officials expressed interest in working with COGR on a methodology for direct charging certain compliance costs. The Costing Policies Committee developed a draft paper for discussion during the committee and Board meeting, and during a Thursday morning session with the membership. None of the three discussions led to consensus, and a decision on whether to proceed was tabled until additional technical analysis and policy considerations can be taken into account. The draft paper is available on the COGR web site at "Meetings/February 2005 Presentations".

b) Further Analysis of IRB Costs – In the draft paper one of the Committee members developed a direct charge rate to cover the operating costs of its Institutional Review Board (IRB) related to the protection of human research participants. We have asked several other university representatives to prepare a similar analysis, and to identify any weaknesses or missing components that we should evaluate.

c) Policy Considerations – Some university representatives believe that universities are being forced by the federal government into developing a method for direct charging costs that should be indirect, due to the government's inability or unwillingness to address the real issue – the 26% cap – and that we should not fall into that trap. Another

consideration against direct charging is that the faculty would strongly object to having direct funds taken out of the research budget, making the university administrators even more of a target for faculty outrage. Conversely, others argued that if we have an opportunity to recover costs in certain key areas of compliance such as human subjects protection, we should pursue it. Some indicated that as more faculty, Department Chairs and Deans understand the need for adequate cost recovery, direct charging in a limited fashion for certain costs would be accepted, even though grudgingly. That is why in addition to the technical analysis described above, we asked the universities to discuss the concept of direct charging with key department heads, deans, and faculty to gauge their level of support.

Furthermore, some university representatives pointed out that they are still below the 26% cap, and others are very close to it, and would be unwilling to pull any costs from the F&A rate calculation that would result in lower overall recovery. For this reason, it was agreed that if COGR did go forward with a proposal to OMB, we would insist that direct charging costs such as IRB costs would be optional for the institution. There was general consensus that if COGR decided to go forward and if we were successful in getting OMB agreement to allow institutions the option to direct charge IRB costs, we should only use this strategy for new compliance areas. Otherwise, pulling other existing compliance costs out of the F&A rate calculation to charge directly – hazardous materials, for example – would undermine the F&A rate process, and create a real outcry among the faculty.

If you have comments, suggestions, or questions after reading the draft paper, please contact Tony DeCrappeo in the COGR office.

3. Bond Counsel Discusses Options for Approaching IRS on the Tax Status of Bonds Used for Research Facilities

Under IRS rules, federally-funded research is considered private use for determining the tax status of bonds issued to finance research facilities. According to IRS safe harbors established in IRS Revenue Procedure 97-14, such use can meet the qualification for tax exempt status if all other potential users of the resulting research technology receive the same terms as the sponsor. However, since the federal government receives a royalty free non-exclusive license to inventions from its sponsored research, and universities do not typically provide those same terms to other potential users, the literal interpretation leads to the conclusion that the safe harbor is not available to universities, and, therefore, the bonds should be taxable.

In spite of this understanding, most bond counsel and tax advisors have been relatively comfortable relying on their interpretation that the intent of the law is not to penalize universities financially for what appears to be a legal inconsistency, and that there are other facts and circumstances that allow such bonds to be tax exempt. However, it appears that bond counsel and tax advisors are now becoming less comfortable with this interpretation.

COGR has been working closely with the NACUBO Tax Council on this issue on two fronts. One of our member universities is seeking clarification by a private letter ruling from the IRS, based on an invention resulting from federally funded research in an existing facility financed

with tax exempt bonds. COGR and NACUBO representatives have been coordinating technical assistance for the university to help it weigh the downside risk of a private letter ruling, and if it decides to go forward, to help to prepare the best arguments for a positive outcome.

At the same time, COGR and NACUBO have been assessing whether the university community should re-consider taking direct action with the IRS. To assist in our deliberations, members of both the Costing Policies and Contracts and Intellectual Property Committees, and a NACUBO representative, met with two partners from Venable, LLP, to discuss options. In order to facilitate our meeting the Venable partners provided a discussion memorandum which provides very useful background information on the tax law changes in 1986, the Bayh-Dole Act, and a range of options to be considered should the associations decide that action is needed. The memorandum is available on the COGR web site at "Meetings/February 2005 Presentations". Several points in the memorandum are worth highlighting.

- **Federal Government as Private User** - On the subject of why the federal government is considered a private user, Venable states that "Underlying the denial of tax-exempt bond financing for the benefit of the Federal Government is the rationale that the Congressional grant of tax-exemption for interest paid on municipal bonds is in substance a form of subsidy provided by the Federal Government and that the subsidy is not an efficient financing tool compared to other funding sources available to the Federal Government. Accordingly, the reasoning proceeds, the Federal Government should not avail itself of the indirect benefit of such an inefficient subsidy nor erode the benefit of the subsidy to state and local governments by further expanding the volume of tax-exempt municipal bonds to include those issued to benefit the Federal Government."

- **Safe Harbors and Bayh-Dole Provisions** – The basis for such an argument is the general Explanation of the Tax Reform Act of 1986 prepared by the Staff of the Joint Committee on Taxation. A convincing argument can be made that certain corporate sponsored research agreements and certain joint industry-government cooperative research arrangements are to be eligible for tax-exempt financing. The text of that legislative history refers to "arrangements currently sponsored by the National Science Foundation" as an example of a qualifying cooperative research award, indicating a tacit acknowledgement that federal agency rights under Bayh-Dole would not result in private business use. At the time of the drafting and enactment of the Tax Reform Act of 1986, the Bayh-Dole Act (enacted in 1980) had been in effect for several years, so that any research award from the National Science Foundation or similar agencies of the federal government would contain appropriate Bayh-Dole rights. By using such an award as an example, the legislative history arguably confirms the intent that federal agency receipt of Bayh-Dole rights should not disqualify otherwise compliant awards from being exempt from private business use characterization.

  However, the Venable memorandum cautions that, "Although the legislative history to the Tax Reform Act of 1986 clearly contemplates that typical research awards with the Federal Government would be exempted, the implementation of those exceptions by the IRS in Revenue Procedure 97-14 failed to fully effect that intent as (a) the definition of 'basic research' to which the exceptions apply is carved too narrowly to encompass as a practical matter much of the research funded by the federal government and (b) the

requirements for the specific exception for cooperative research arrangements fails to take into account (i) 'march-in rights' that apply to federal government contracts or (ii) the sale of intellectual property rights in the context of the federal government as the sole sponsor."

- **Options and Next Steps** – The range of options described in the Venable memorandum includes taking no action, asking the IRS for revisions to either the Revenue Procedure safe harbors or to the commercial objective standard, requesting a private letter ruling, or seeking a legislative fix. After discussion by the Costing Policies Committee and the full COGR Board, it was decided that COGR would take not action at this time. This decision was based on two key points raised during our discussion with the law firm's representatives: 1) that there is no current IRS enforcement action on this issue, nor has the issue been an audit finding in recent IRS reviews at universities; and 2) the ability of bond counsel to be comfortable providing an unqualified opinion on the tax status of bonds becomes more difficult as more guidance or rulings are issued, and asking the IRS for more guidance could lead to greater rather than less uncertainty. COGR will continue working with NACUBO to monitor developments very closely, particularly with respect to the potential request by a university for a private letter ruling.

4. Uncertainty Remains on Interoperability of Certain Activities Under Federally Funded and Non-Federally Funded Stem Cell Research

We described in the Meeting Agenda material that NIH posted revised Frequently Asked Questions at http://stemcells.nih.gov/info/faqs.asp#nihfund. NIH provides guidance on how to ensure that federal funds are not used, through recovery of Facilities and Administrative costs on federal awards, to support inappropriately research on stem cells outside of the perimeter of federal law. The President's policy on research with human embryonic stem cells includes a provision that no federal funds may be used, either directly or indirectly, to support research on human embryonic stem cell lines that do not meet the criteria established by the President on August 9, 2001 (http://stemcells.nih.gov/policy/NIHFedPolicy.asp). Accordingly, research on lines (or their derivatives) not listed on the NIH Human Embryonic Stem Cell Registry may not be supported by federal funds.

There remains uncertainty, however, particularly at institutions that conduct a significant level of stem cell research outside the federal policy, over the allowability of sharing information, materials and resources, at institutions where research in both areas is conducted. According to recent reports by scientists, some potential collaborators are expressing reservations, concerned that the federal government will withhold federal funds from anyone perceived to be involved with stem cell research beyond the President's policy. For example, it has been reported that a researcher submitted a reimbursement request for a book about stem cells. The agency program official responded that stem cell research at this time is quite controversial and that "at the moment, we can't pay for anything related to stem cell research." In another example, an NIH administrator was asked whether an application could include supporting data generated by colleagues working with non-federally approved cell lines. Reportedly the response was no, because these data might give rise to the perception that non-federally fundable cell lines were being used as a means to obtain federal funds. In another situation, a PI stated that "we need to understand how to deal with use of reagents that may have been developed with NIH grant

funds. Experiments may need to be done in human embryonic stem cell research using new vectors to express particular proteins, and these vectors may have been made in the course of NIH-sponsored work." The FAQ do not sufficiently address these uncertainties.

Another issue has been raised with respect to new research facilities financed by tax-exempt bonds. Since bonds issued as tax exempt are considered a federal subsidy, it has been suggested that conducting State-sponsored stem cell research not covered under the President's policy in a facility financed with tax-exempt debt constitutes federal support, and is, therefore, a violation of the federal policy.

We have contacted the NIH Office of Extramural Research to begin discussions on these issues and to seek clarification.

5. COGR Seeks Information to Share on F&A Negotiation Outcomes

A Costing Policies Committee member shared with the Committee a summary of his institution's successes and challenges during their recently completed F&A rate negotiation. This report included a brief description of the overall outcome, and highlighted what issues were raised by the government on equipment, space, library costs, and certain operations and maintenance cost allocations. The other members of the Committee found this helpful, and agreed to prepare a similar document, for each institution that had recently completed a rate negotiation. The summaries will not include any identifying information, but will indicate whether the rate was negotiated with ONR or DHHS, and which DHHS regional office was involved. Once the COGR office receives a representative number of summaries they will be posted to the "members only" section of the COGR web site. If you have questions or would like to provide a summary of your institution's experience, please contact Tony DeCrappeo in the COGR office.

RESEARCH COMPLIANCE AND ADMINISTRATION

Committee: Jane Youngers, The University of Texas Health Science Center at San Antonio, Chairman; Wendy Baldwin, University of Kentucky; Mark Brenner, Indiana University; Peter Dunn, Purdue University; Todd Guttman, Ohio State University; Jamie Lewis Keith, Massachusetts Institute of Technology; Gunta Liders, University of Rochester; Ara Tahmassian, University of California San Francisco; Suzanne Polmar, Yale University; David Wynes, University of Iowa

1. Individual Financial Conflicts of Interest

a) Broad Prohibitions on Intramural Researchers - COGR will continue to monitor the impact of the National Institutes of Health's (NIH) new intramural policy for individual financial conflicts of interest. Announced by NIH Director Elias Zerhouni and published in the Federal Register on February 3, 2005, the broad prohibitions of the intramural policy on engaging in either compensated or uncompensated activities affect all NIH employees. The policy describes some exceptions and the process for requesting waivers.

The broad prohibitions and the requirement for employees to divest themselves within 150 days of most holdings in affected organizations (e.g., biotechnology and pharmaceutical companies) raised concerns within the agency and in the academic university community. These concerns were heightened recently by press reports that 50% to 80% of the alleged improper financial relationships were cleared by NIH as the result of errors in the investigations conducted by Congress and government investigators.

Nonetheless, the NIH intramural policy and continuing discussion may draw additional attention to the policies governing the extramural research community. As we reported in the February Meeting Agenda, Reps. Tom Davis (R-VA) and Henry Waxman (D-CA) requested information from NIH on its policies for extramural investigators and peer-review panelists.

NIH responded to the Congressmen by providing a brief description of its "Objectivity in Research" regulations (42 CFR Part 50, Subpart F) and a much more elaborate discussion of its policy to screen peer-review panelists and members of its advisory council. NIH highlighted its outreach activities, i.e., the semiannual Regional Seminars, Proactive Compliance Site Visits, and notices in the NIH Guide, as the principal mechanism for assuring compliance with its regulations.

b) Reflections on a Government-Wide Policy for Individual Financial Conflicts of Interest - On Thursday morning, Beth Israel, Executive Director, Projects and Grants, Columbia University and Wendy Baldwin, COGR Board member, led attendees in a lively discussion of possible features of a government-wide policy on individual financial conflicts of interest. There was a predictable diversity of approaches used by research institutions to meet the current NIH and National Science Foundation (NSF) regulations and policies. It appears that the differences, e.g., annual vs. transactional disclosures; coverage for all research or only NIH and NSF applications; use of dollar or ownership thresholds; etc., result from the relationship of the conflicts policy to other university policies, the effect of state statutes, and the complexity of the institution's research portfolio.

This diversity of institutional approaches highlights the need for a simple, non-prescriptive government-wide policy that sets a standard of objectivity without limiting the procedures and processes that institutions use to meet that standard. The simplest approach would be a certification at the time of an award that federally funded research will not be compromised or have the appearance of being compromised by the financial relationships and interests of the investigators.

Although there is not much hope that the Committee on Science (COS) or the Committee's Research Business Models Subcommittee will endorse a simple certification, COGR will develop a brief paper outlining key features of a government-wide policy which might be proposed in discussions with members of the Subcommittee.

c) VA Conflict of Interest Policy - The December 28, 2004 publication of a Department of Veteran's Affairs (VA) Handbook outlining its Financial Conflicts of Interest policies and procedures was reported in the Meeting Agenda. The Handbook was "temporarily withdrawn" in early February 2005. COGR will follow-up to determine the reasons for its withdrawal and the VA's plans for re-issuing the policy.

2. NIH Office of Biotechnology Activities Site Visits

Members of the Committee met with Allan Shipp, Director of Outreach for the NIH Office of Biotechnology Activities (OBA), before the February meeting to discuss OBA's announced site visits and its response to allegations of non-compliance with the NIH Guidelines for Research Involving Recombinant DNA (rDNA) Molecules (see discussion in the February Meeting Agenda).

Shipp described the not-for-cause site visits as an opportunity to educate the community about the requirements of the NIH Guidelines and to allow OBA to gain a sense of institutional practices with a possible goal of developing good practices or model approaches to compliance for research institutions. These proposed site visits complement OBA's new emphasis on assisting the research community in achieving compliance and enhancing the quality of institutional practices. The recently published memoranda and Frequently Asked Questions (FAQs) on Institutional Biosafety Committee minutes, meetings, etc., are a part of this effort.

OBA plans to visit up to twenty institutions identified by size, level of recombinant DNA research, location, etc. There is no direct relationship between the site visits and the complaints filed and report issued by The Sunshine Project in 2004. OBA continues to review and, if appropriate, request information from institutions that are the subject of complaints filed by the Sunshine Project. The communication with the institutions is an effort both to gather information and assist the institutions to be in compliance.

During the discussion of OBA's memoranda and FAQs, Shipp noted that the NIH Guidelines were first issued in the 1976 in a very different context. At that time, recombinant DNA research was new and local communities feared the uncontrolled release of genetically altered organisms. The general approach of the Guidelines was to provide a relatively transparent process of review and management of rDNA research. Shipp invited comments on the NIH Guidelines, including proposals to modify the requirements. The need for review and modification may become increasingly important in light of the changed context – the tension between national security and transparency – and the proposed management of dual use biological research. COGR will review opportunities for revisions of the NIH Guidelines through the RCA and Research Security Working Group.

3. Animal Research

a) NIH Guidance on Animal Reports - On February 24, 2005, NIH's Office of laboratory oratory Animal Welfare (OLAW) issued guidance on the prompt reporting requirements of the Public Health Service (PHS) Policy on the Humane Care and Use of laboratory oratory Animals. The guidance appeared in the NIH Guide (NOT-OD-05-034).

COGR members noticed intermittent changes in the requirements for reporting over the past few months, in particular, requests for the name(s) of the investigator involved in a situation of non-compliance. The changes in interpretation of the policy and the issuing of this recent guidance follow directly on the announcement of the permanent appointment of Axel Wolff as director of the OLAW Division of Compliance Oversight. Dr. Wolff served in an acting capacity since May 2004 when these changes began to appear.

The new guidance reviews the current reporting requirements and offers examples of situations that should prompt reporting, sets a timeframe for reporting, and outlines what should be included in the report. Unfortunately, some of the examples do not appear to rise to the policy standards of "serious" and "continuing non-compliance." The examples represent instances of non-compliance but, one could reasonably argue that the failure of the IACUC to achieve a quorum at a single meeting does not constitute serious and continuing non-compliance that threatens the health and safety of animals.

It is more unsettling that the guidance calls for submission of reports, notably preliminary reports, on PHS-supported and non-PHS-supported research. The latter are based on functional, programmatic, or physical situations that could affect PHS-supported research. The guidance does not request the name of the investigator – just the PHS grant number, if applicable.

COGR is interested in the membership's response to this new guidance. Please forward any reactions or comments to Carol Blum (cblum@cogr.edu) as soon as possible. This guidance is certain to be a topic for discussion at the PRIM&R meeting in San Diego beginning March 13, 2005 and we will report to the membership following that meeting.

b) Update on USDA Animal Inspection Report Posting – The February meeting agenda reported on the US Department of Justice's determination that the Department of Agriculture (USDA) must post annual animal inspection reports to its E-FOIA web site. In a recent meeting with USDA staff we learned that the posting will begin soon and will redact names and specific locations (buildings and room numbers) to protect the security of the institution's facilities. USDA is migrating the inspection reports to a web-based system that will allow the inspector to automatically redact this security-sensitive information from the E-FOIA posting as the inspection report is entered into the USDA system.

USDA is reviewing the comments it received on the implementation of regulations governing the use of birds, rats, and mice not bred for research under the Animal Welfare Act. Final regulations are being "fast tracked" by USDA.

4. EPA Strategy for Using Human Tests

On February 8, 2005, the Environmental Protection Agency (EPA) published a notice in the Federal Register describing the agency's plan for creating a framework for using human studies in its development of regulatory norms and its current case-by-case process for evaluating human subjects studies. Comments on the plan and current process are due May 9, 2005 (See 70 FR 6661)

The EPA uses human studies for much of its work but questions have been raised about the use of third-party studies with regard to the regulation of pesticides. The EPA can assure compliance with federal human subject protection regulations when the EPA conducts (first-party) or sponsors (second-party) human studies, but third-party studies, conducted by companies without federal support and without federal oversight, may or may not have received review by an Institutional Review Board (IRB). Company-sponsored studies that intentionally exposed subjects to pesticides triggered the debate. The subsequent use of various company-sponsored, third-party pesticide studies in the development of regulations embroiled the EPA in a contentious debate, and a legal appeal of its December 2001 decision to not consider or rely on any third-party pesticide studies until the National Academy of Sciences completed a study for the EPA.

The February notice describes EPA's proposed plan including: 1) issuing a clarification of its case-by-case review process; 2) developing a policy to encourage submission of proposed studies for EPA IRB review; 3) publishing non-binding guidance on the extension of the human subjects Common Rule to all third-party studies; 4) conducting outreach to journals to improve reporting ethics information with published articles; 5) expanding its role in the pre and post human subjects IRB review; and 6) issuing a new rule concerning compliance with the human subjects review including implementing protections for vulnerable populations.

COGR is reviewing the notice to determine the need for a formal comment on the plan and EPA's case-by-case review. The relationship between the EPA IRB review and a local institution's review needs to be clarified.

5. FDA Considering Changes in Reporting of Adverse Events

The Food and Drug Administration (FDA) announced a public hearing to gather information on how IRBs manage the review of adverse events that occur during clinical trials. The hearing will be held on March 21, 2005 at the FDA offices in Rockville Maryland. Written comments must be submitted by April 21, 2005. The notice of the hearing and the request for comments appeared in the February 8, 2005 issue of the Federal Register (70 FR 6693).

The FDA is most interested in determining what information about adverse events is "necessary or useful" for IRBs in their role of protecting human subjects. Recognizing that there are a number of parties involved in the review of adverse events – investigators, Data Safety Monitoring Boards, the FDA, Sponsors, and IRBS – the goal of the hearing is to focus on defining the appropriate role for the IRB; determining what information it needs to meet its responsibilities; and charting the best course to obtain that information.

COGR will prepare a comment and welcomes the membership's ideas, suggestions, and participation in preparing the comment. Contact Carol Blum (cblum@cogr.edu). If individuals want to attend the public hearing, the FDA requires registration and that information is included in the notice on the FDA web site at www.fda.gov.

6. OSTP & OMB Propose Streamlining the Research Enterprise

The implementation of government-wide standard grant and cooperative agreement terms and conditions, the endorsement of the model subagreement and the directive for recognition of co-principal investigators are initiatives of the Research Business Models (RBM) Subcommittee of the Committee on Science. Since its establishment in August 2003, creating consistent approaches to federal grants and cooperative agreements has been one of the priority areas of the RBM. In January, OSTP and the Office of Management and Budget (OMB) took major steps forward on streamlining the research enterprise.

a) Government-wide Grant Terms and Conditions - On January 28, 2005, OSTP and OMB published a proposed policy to establish government-wide standard terms and conditions for research and research-related awards with a request for comments. The policy proposes government-wide implementation of the terms and conditions developed under the Federal Demonstration Partnership (FDP) over the past twenty years. The terms and conditions, including a matrix of agency exceptions titled "Prior Approval and Other Requirements", are available at the RBM website at http://rbm.nih.gov/rrtc.doc and NSF-supported FDP Website at: http://www.nsf.gov/awards/managing/fed_dem_part.jsp. COGR commented on the proposed policy by enthusiastically endorsing the establishment of standard, government-wide terms and conditions for research and research-related grants and cooperative agreements. We offer only two recommendations: one, a warning against the proliferation of agency exceptions to the

standard; the second, requesting a definition of the terms "research" and "research-related". A copy of the letter is posted on the COGR web site: www.cogr.edu.

COGR members participating in the FDP know that the list of agency exceptions (Prior Approval and Other Requirements) has weakened the promise of a truly streamlined and uniform approach. Some of the agency exceptions are required by statute and cannot be avoided; others represent agency policies that can be and should be re-evaluated in light of this new policy. We asked OSTP/OMB to establish specific criteria for the approval of new agency exceptions and to review and, if possible, eliminate current exceptions to the FDP terms and conditions.

COGR's second recommendation asked for the terms "research" and "research-related" to be defined. While the meaning of these terms appears obvious, some agencies have applied very narrow definitions with the result that streamlining was not achieved.

COGR members who have not participated in FDP will want to acquaint themselves with the FDP terms and conditions in preparation for the implementation of this policy. It will take some time to expand the list of agencies using these terms from the current ten to all grant awarding agencies but institutions may want to consider modifying internal mechanisms and processes to accommodate the changes.

b) OSTP & OMB Endorse Model Subagreement - In a related action, OSTP and OMB notified the National Science and Technology Council (NSTC, a Federal interagency council operating parallel to the OSTP) of their endorsement for the broad use of the FDP model subagreement by institutions. This subagreement includes Federal and non-Federal requirements that must flow down from a awardee to its subawardees. The endorsement of OSTP and OMB allows an institution to use the subagreement with confidence that it meets Federal requirements and offers predictable language for both the subawardee and the Federal sponsor. A copy of the model subagreement is available on the FDP web site at: www.thefdp.org.

c) Recognition of Co-PIs - In special recognition of research investigators' concerns, OSTP Director John Marburger directed the federal research agencies on January 4, 2005, to accommodate two or more Principal Investigators (PIs) on research grants and contracts. The formal recognition of co-principal investigators is an initiative designed to support interdisciplinary, multi-disciplinary, and multi-institutional research. The RBM Subcommittee is developing an implementation strategy for this directive. Some institutions are concerned that the identification of multiple PIs will result in additional work for the agencies and the awardee institutions. Under the current approaches of NSF and NIH, the co-investigators have distinguishable roles for scientific and technical direction of the project, but a single, Principal Investigator assumes the responsibilities for the project. The formal agency recognition of co-Principal Investigators with, one assumes, shared responsibilities for the project, submission of reports, and other non-scientific tasks may require more formal agreements between institutions including detailed management plans.

7. OHRP Accepting ONLY FWAs

The Department of Health and Human Services (DHHS) Office of Human Research Protections (OHRP) finally received approval from OMB for its Federal-wide Assurance (FWA) forms and related documents and Institutional Review Board (IRB) registration forms. As a consequence, effective February 10, 2005, the only assurances that OHRP will accept are the FWA. Any institution operating under an OHRP-approved Multiple Project Assurance (MPA) or Cooperative Project Assurance (CPA) must submit an FWA for approval by December 31, 2005.

OHRP has sought to implement the new forms and requirement for the FWA and IRB registration processes since December 2000. When the submission of the FWA application was a voluntary effort, COGR endorsed a simplification of the process in March 2001, but questioned the broadening of training requirement and additional compliance steps go beyond the regulations at 45 CFR 46.

OHRP revised the forms and posted the now-approved registration and assurance forms on its web site in March 2002. They finally received OMB approval and can now require a FWA – phasing out the MPA – by December 31, 2005. OHRP "welcomes" comments. COGR is interested in its members' thoughts and comments on the new registration and assurance processes as well.

8. September 17th Constitution Day Observations

The Consolidated Appropriations Act of 2005 requires educational institutions that receive federal funds to hold an educational program for students about the U.S. Constitution on September 17th of each year. Federal agencies are required to provide educational materials to new employees and to all employees every year on the September 17th anniversary of the signing of the U.S. Constitution by the delegates to the Constitutional Convention that met in Philadelphia, Pennsylvania from May to September 1787.

Some might argue that June 21st is a better anniversary date for this celebration of the U. S. Constitution. The Constitution had to be ratified by nine states before it could take effect and ratification was not assured. Many citizens of the then-loosely confederated states feared the potential tyranny of a federal government. Ratification was only possible when the Convention delegates pledged to amend the proposed Constitution to ensure the protection of fundamental freedoms of citizens of the newly-established United States of America. Delaware became the first state to ratify, on December 7, 1787. It was followed by Pennsylvania, New Jersey, Georgia, Connecticut, Massachusetts, Maryland, and South Carolina. On June 21, 1788, New Hampshire became the ninth state to ratify, thus making the Constitution legally effective.

Fulfilling his campaign promise, James Madison, elected to the first Congress, pushed through a series of proposals that became the first ten amendments, the Bill of Rights, to the U.S. Constitution. The states ratified the Bill of Rights in 1791.

Located in the District of Columbia, the Council on Governmental Relations (COGR) is an association of research universities, affiliated medical centers, and independent research institutes. COGR was founded 1948, and we remain true to our mission by supporting our members in the areas of research administration and compliance, financial oversight, and intellectual property. COGR's primary function is to advocate for policies and practices that fairly reflect the mutual interests and separate obligations of federal agencies and research institutions as it relates to research and graduate