Minutes*

Senate Research Committee
Monday, December 5, 2011
2:15 - 4:00
238A Morrill Hall

Present: Linda Bearinger (chair), Alvaro Alonso, Melissa Anderson, Breanne Byiers, Margaret Catambay, Jerry Cohen, Maria Gini, Greg Haugstad, Frances Lawrenz, Jennifer Linde, Timothy Mulcahy, Kola Okuyemi, Federico Ponce de Leon, LaDora Thompson, Thomas Vaughan, Lynn Zentner

Absent: Arlene Carney, Anna Clark, Paul Cleary, Robin Dittman, Marc Dunham, Demoz Gebre, Seung-Ho Joo, Tucker LeBien, Christopher Nappa, Kyla Wahlstrom, Karen Williams

Guests: Professors Arthur Erdman, Michael Oakes (Individual Conflict of Review committees), Professor Daniel Feeney (Institutional Conflict of Review Committee), Jay Schrankler (Office for Technology Commercialization); Regents Professor Stephen Ruggles, Catherine Fitch (Minnesota Population Center)

Other: Jon Steadland (Office of the President)

[In these minutes: (1) impact of the conflict-of-interest policy on consulting and technology commercialization; (2) changes to the federal conflict-of-interest regulations; (3) Research Scientist proposal (and nature of appointments)]

1. Impact of the Conflict-of-Interest Policy on Consulting and Technology Commercialization

Professor Bearinger convened the meeting at 2:15 and turned to Professor Vaughan to lead a discussion about the effect of the conflict-of-interest policy on consulting and technology commercialization.

Professor Vaughan said he would begin with an overview of what he sees as the direction, mood, and spirit of the country and the University with respect to technology commercialization and the promotion of faculty entrepreneurship. He started with an April 15, 2011 letter from the federal Department of Commerce's National Advisory Council on Innovation and Entrepreneurship (NACIE, co-chaired by University of Michigan President Mary Sue Coleman) that has been signed by presidents of most of the major universities in the country, including President Bruininks for the University of Minnesota. The letter was also endorsed by the Association of American Universities and the Association of Public and Land Grant Universities. He drew attention to one portion of the letter, an item in a list of activities and efforts promoted by the members of NACIE:

Encouraging faculty innovation and entrepreneurship

* These minutes reflect discussion and debate at a meeting of a committee of the University of Minnesota Senate; none of the comments, conclusions, or actions reported in these minutes represents the views of, nor are they binding on, the Senate, the Administration, or the Board of Regents.

> Financial incentives, faculty industry sabbatical leaves, campus prizes and other forms of recognition encourage faculty innovation and entrepreneurship. To promote these ideals further, we will:
> -- Expand efforts to encourage, recognize and reward faculty interest in research commercialization by providing incentives and encouraging engagements with industry, entrepreneurs and venture partners.
> -- Create or expand programs that connect faculty and students to the resources they need: industry partners, entrepreneurial mentors, translational research and "proof-of-concept" funds, accelerator facilities and venture creation services.
> -- Encourage streamlining and reduction in reporting and compliance requirements, which would allow faculty to increase time spent on proposal writing and research.
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> We also call upon the federal government to refrain from enacting policies, such as overly stringent regulations on conflict of interest, that discourage our faculty from working with industry or developing innovative technologies.

Professor Vaughan next noted language from a press release from the Association of Public and Land Grant Universities on September 15, 2011, titled "AAU and APLU Universities Announce Economic Development Plans," and in particular,

> Research universities from across the nation today revealed details about how they are working to promote innovation, entrepreneurship and commercialization of research results leading to economic growth.
>
> The announcements are part of an effort initiated in April when more than 135 university presidents and chancellors pledged to undertake "greater efforts to advance regional and national economic growth" and to "ensure that the knowledge and technological breakthroughs developed through campus-based research was rapidly and broadly disseminated to advance the nation's social and economic interests."
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> The university announcements coincide with a ceremony at Thomas Jefferson High School in Alexandria, VA, during which President Barack Obama signed the Leahy-Smith America Invents Act (H.R. 1249) into law. The new law makes important reforms to the nation's patent system designed to encourage and innovation and economic growth.

Professor Vaughan also noted a press release from the University related to the signature of the Leahy-Smith America Invents Act that included a quotation from President Kaler:

> "I am deeply committed to being an energetic partner with Minnesota's and the nation's business communities," said U of M President Eric Kaler. "The university engages daily in groundbreaking research that helps, among other important things, to save lives, create new knowledge, protect the world's food supply and enhance technology. Transferring our great work to the global marketplace to fuel innovation, create jobs and improve the common good is a key element of our land-grant mission."

Professor Vaughan turned next to an article in The Chronicle of Higher Education and cited a paragraph from it.

'**Bridging the Valley of Death**'

> Traditionally, university start-up companies face a tough path because they are built on early-stage technologies and young companies can have a difficult time attracting the capital they need to develop an idea to a point where it becomes more commercially attractive to investors. That's what folks in the field call "bridging the valley of death." But more universities "are figuring out how to fill that gap a little bit," said Mr. Tucker, by tapping into federal commercialization funds or creating their own internal programs that can provide money to build a prototype or to finance proof-of-concept experiments that wouldn't be appropriate for an academic lab.

The article recognizes that start-up companies from universities are very fragile, Professor Vaughan said. They start with farsighted ideas but need nurturing—and they need faculty involvement.

Professor Vaughan noted the agenda for a "Presidents-Investors Summit" scheduled for January 18 in Washington, D.C. The top higher-education leaders in the country will meet with investors to talk about the role of higher education "in start-up generation and acceleration" and to measure progress on the pledge letter sent in April.

The America Invents Act sounds wonderful, Professor Vaughan said, and he counts himself as a would-be faculty entrepreneur. This is a strong initiative, from President Obama to President Kaler.

But the usual experience of faculty members is one that was laid out for the Faculty Consultative Committee by a faculty member unknown to Dr. Vaughan, in response to its annual request to faculty members for issues that it should consider taking up:

> Translational research is a heavily promoted topic at the UMN, NIH and NSF. The UMN publically encourages faculty to engage in translational research and to work with industry to make faculty discoveries available for the benefit of the public. The U of MN has a large translational research institutional grant. The success of the thrust for translational research is endangered by an alarming, expanding UMN administrative mentality that faculty who seek to develop, perfect and commercialize their research discoveries have a conflict of interest (COI) and must prove innocence before improper activity occurs. There seems to be an obsession to stamp out even a remote possibility that an action of faculty might be interpreted by the news media, public, government agency or others as arising from a COI. Perhaps this is a holdover from our experience as a NIH “exceptional” institution or highly publicized instances of accused excessive compensation. I ask if all of this activity about what might happen a positive stimulus for encouraging faculty to perform translational research? Should we not step back and review this process?
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> Recent COI committee decisions imply that when the UMN Office for Technology Commercialization (OTC) decides not to patent and commercialize a faculty member’s invention those faculty who proceed to develop, test and eventually see their product to market, while holding an active appointment, have a COI. Does this suggest that faculty should not perform research that will benefit them, directly or indirectly or that might benefit any business entity, especially one in which they themselves or a relative are associated? This attitude can have a chilling effect on translational research.

> All researchers are biased toward the products of their research. It is a natural and necessary effect of the zeal necessary to perform meaningful research. It follows that most faculty have an inborn COI, even when communicating their results. But must researchers be suspected of improper bias or improper reporting of their research results to either benefit their discoveries, their self-esteem or their reputation? With such self interests should they be permitted to be the Principle Investigator on grant proposals? A yes answer implies that their work and publications should be monitored. But are not such attitudes contrary to the principles of professionalism, of academic freedom and to fulfillment of the aims of translational research?

So there is a mismatch between the reality on the ground and the rhetoric at the top, Professor Vaughan concluded. His main point is that he would like someone at the top to read opinions from someone at the bottom. They are still running into difficulties at the bottom.

With respect to the first item he introduced, the letter from NACIE, Professor Vaughan said that the faculty do not see encouragement or recognition or reward for interest in commercialization of knowledge, with incentives provided. However, he has been at the University for 12 years and has seen a significant improvement in the Office for Technology Commercialization under the leadership of Mr. Schrankler.

Professor Vaughan said that what he sees as the impediment is the conflict-of-interest committees; his complaint is not directed at particular individuals or policy writers, who are doing their jobs. He said he is not sure where the fault lies and it may be a systemic problem at the federal level. When he meets with conflict-of-interest committees, he sees them doing three things to minimize conflicts: disallow faculty leadership of a start-up company, disallow pay from a start-up company, and minimize the equity a faculty member can have in a start-up company. But the definition of entrepreneur is "a person who organizes and manages any enterprise, especially a business, usually with considerable initiative and risk." If the University takes away management and initiative, one cannot define a person as an entrepreneur, so he sees the committees and current policy as a roadblock to faculty entrepreneurship. (And one must almost wear a scarlet letter "C" because one has to notify everyone if a conflict is identified). He said he appreciated the need for much of the conflict management and avoidance efforts, but when it is done to excess and without alternative solutions, it makes people not want to try to be entrepreneurs.

Again the University Presidents' pledge, Professor Vaughan noted: "We also call upon the federal government to refrain from enacting policies, such as overly stringent regulations on conflict of interest, that discourage our faculty from working with industry or developing innovative technologies." This would seemingly apply as well to the Universities issuing this call.

Professor Bearinger thanked Professor Vaughan for his presentation and asked the Committee what questions should be posed for the time when this item appears again on the agenda in February. Professor Vaughan noted that the last item he presented is already scheduled for the agenda. He reiterated that he was not singling out individuals and that he recognizes the need for the conflict-of-interest committees and management of conflict. But the way it is executed in many cases discourages faculty innovation and entrepreneurship. That is what the documents he brought are about. It is difficult to start companies in this environment; faculty members need help, not hurdles.

Professor Feeney asked Professor Vaughan what his field is and what his issue is. Professor Vaughan reiterated that the contribution he shared from the FCC was not his. He then answered that he is in the Departments of Radiology in the Medical School as well as on the graduate faculty in Electrical and Biomedical Engineering, and has tried to start three companies through the University, with no success (for different reasons in each case). In the latest effort, he received a Small Business Technology Transfer (STTR) Grant; in order to accept it, he was required to reduce his equity in the valueless start-up company to 4.9%, and had to give up any leadership and compensation so that he could remain out of conflict.

Professor Feeney noted that he chairs the Institutional Conflict of Interest Committee. The biggest issue they see is individuals who wish to continue to do research and be entrepreneurs—with no firewalls between the two. No one cares if someone wants to be entrepreneurial, but if he or she violates individual conflict-of-interest rules as the University interprets them, or the institutional conflict-of-interest rules, there are issues that must be resolved. The usual problem scenario is individuals involved with a start-up company based on previous research while continuing to perform agency-funded research on the same or closely related topics as regular faculty. The concern here is the credibility of the University of Minnesota "brand" and the assurance of objectivity in the research performed. From an institutional standpoint, the two interests must be reconciled or the University becomes lax and individuals can have equity interests and conflicts of interest. The question is how the institution can manage what could go wrong, protect students, and retain the University's reputation. Professor Feeney also serves on the Academic Health Center Conflict of Interest Committee and has been through a conflict-of-interest resolution himself over 10 years ago. If the University Conflict of Interest Committees have taken too conservative a stance, they need to hear that from the top. Professor Feeney pointed out that all three chairs of the conflict-of-interest committees complete their service on December 31 of this year—at their choice—so the University can appoint new chairs and change its philosophy if it wishes.

Professor Erdman said it is important to say that there has been a transition in the Office for Technology Commercialization and there is a new policy in place that is much improved.

There is also a new procedure for managing conflicts of interest a la Professor Vaughan, Professor Oakes said.

They are working with the Office for Technology Commercialization to address the issue of start-ups and initial equity, Professor Erdman said. A company is worth nothing at the start but it could turn out to be worth a great deal, and there is interest in addressing these issues. They have had excellent meetings between the conflict-of-interest programs and the Office for Technology Commercialization.

Professor Oakes agreed that there has been considerable change and improvements to address the issues Professor Vaughan has raised in order to encourage entrepreneurship and manage start-up companies more tenderly in their first few years.

The broader question for this Committee, Professor Oakes said, is what the University wants to do about entrepreneurial work. It wants to encourage it, but there is a line—where the line is is not clear—where one is no longer a professor but is a business person. There is often a transition period where one fits in both camps. Students need to know, patients need to know, NIH needs to know that one's activities could advance the interests of a company. They are trying to find a balance and believe the University has been too conservative, which is the reason for the push to nurture start-up companies.

Professor Bearinger inquired about strategies that could consider the developmental stage of a start-up, i.e., differing rules regarding the management of conflict depending on the newness of a particular commercialization enterprise. That is exactly what has been happening the last six months, Professor Oakes responded.

Mr. Schrankler said the reason the U.S. government funds research is to help improve the quality of life. That is why the Bayh-Dole Act was adopted. That is why the federal government has created small-business programs to get technologies out of universities so they can be used more broadly. They have focused on these issues to change the path; one can form a company before a license is issued for a technology and a faculty member can own 51% of the company under the new policy. A faculty member can also apply for grants before a license is issued. If a grant is awarded and one applies for a grant, then faculty ownership decreases. Federal guidelines provide that if one is doing human-subjects research, there is a hard line at 5% ownership; otherwise the rules allow more.

Where more work is needed is on the institutional side of conflict of interest, Mr. Schrankler said, and he emphasized Professor Vaughan's point that this is not about the people involved, it is about the process. When someone spins a company out but still wants to do research at the University, that is a roadblock that needs to be addressed.

Professor Oakes asked about progress on conflict-of-interest in the Office for Technology Commercialization. It has been tremendous on the individual side, Mr. Schrankler said; they have not addressed institutional conflicts of interest.

Professor Vaughan said this sounds wonderful, but if one can only own 4.9% of a company, can't lead it, and can't earn money from it, why would anyone want to start one? Ms. Zentner commented that since she came to the University, The Conflict of Interest Program and the conflict-of-interest committees have worked hard to comply with the federal PHS rule, commonly referred to as the NIH conflict-of-interest rule. Only faculty and staff involved in PHS funded research are required to comply with this rule, however, the University has, for many years, applied the rule University-wide. The federal rule establishes a conflict-of-interest threshold in the equity context of $10,000 in value or a percentage share of 5%. If a faculty member reaches either threshold and the company's business is related to one's University responsibilities or expertise, there is by definition a conflict of interest. When a conflict of interest is found to exist, the federal rule requires that the conflict be eliminated, reduced, or managed. The onus is then on the institution to do just that. When she first came to the University and assumed responsibility for the conflict-of-interest program, the focus was often on eliminating the conflict. However, over time, the conflict-of-interest review process has become increasingly focused on managing identified conflicts rather than eliminating them. As a result, the process now provides greater flexibility for faculty. For example, one can serve a consultant or chief scientist for a company; however, the University has said "no" to a role on the Board of Directors (University legal counsel has advised that one should not have a fiduciary role in a company and at the same time have a fiduciary role at the University). If it is important, for the success of the company, for the individual to assume a leadership role in the company, the conflict must be managed. Where the individual is also a PI or a co-PI on research that could affect the commercial interests of the company, whether sponsored by the company or not, substantial effort is taken to ensure the integrity of the conduct of the research. In this regard, conflict-of-interest committees often identify an individual to provide oversight of the research, typically focused on the data collection and data analysis aspects of the research. This oversight process, while

beneficial to fostering commercialization efforts, at the same time creates additional burden for the University. For University start-up companies supported by OTC, the Conflict of Interest Program, with substantial input and support from the COI Committee Chairs and legal counsel, has recently created a professors-emeritus oversight committee. Efforts have also been undertaken with the Office of Human Resources about various "leave" opportunities, e.g., leaves of absence and sabbaticals that faculty may use in order to devote increased time to work with their company. The University allows the use of University space for company purposes if an external sales agreement is created and approved through the Controller's office. If a conflict of interest is found to exist, a conflict management plan will require disclosure of the conflict, primarily to research colleagues, students, research sponsors, in the context of publications and presentations, and to patients in the clinical health-care context. As a result of all of these efforts, over the past few years, the University has developed ways to allow a person to be very engaged with a start-up company and, at the same time, remain active in their University role, Ms. Zentner concluded.

So there have been strategies put in place so faculty members can stay engaged, Professor Bearinger said. The University must find the balance between incentives and disincentives, given the excerpt from the NACIE letter Professor Vaughan cited at the beginning the meeting.

Ms. Zentner said these are big issues with no easy answer. The Conflict of Interest Program works with Mr. Schrankler's office and the faculty member to develop a conflict-management plan that addresses the individual's role both at the University and with the start-up. The Conflict of Interest Committee Chairs and conflict-of-interest committees play a significant role here as well. The process is a challenging one. No two circumstances are the same.

Professor Cohen said he looks at this differently because he has been on both sides. What is missing from Professor Vaughan's presentation is that he identifies a problem but there are legitimate reasons to have conflict-of-interest rules. What is missing is that Professor Vaughan has not identified what rule is not needed or what change is required to make entrepreneurship easier. The faculty members on the conflict-of-interest committees are trying to make the process work. He said he would like to see ideas that recognize the legitimate need for conflict-of-interest rules while also making life easier for faculty entrepreneurs. At Virginia Tech they have the Virginia Bioinformatics Institute, where the experts in making the move from academic research to a start-up company work closely with the scientists. Since often the problem is in communication, this reduces the barriers and thus decreases conflict-of-interest situations. Another issue is that these activities bring no indirect-cost funds to a college, so deans are not happy when faculty members are involved in business options and perhaps seen as not fully focused on writing R01 grant proposals. While there could be many other issues in the University structure that could make entrepreneurship work better, there are also legitimate conflict-of-interest concerns, Professor Cohen emphasized; there are faculty members who are just greedy and who make stupid decisions. That fact must be recognized. But there may be institutional avenues that could make the process friendlier.

Professor Cohen commented that Small Business Innovation Research grants might be better for the University to handle in such cases as Professor Vaughan described because they do not contain the 5% cap on equity ownership. That is something the Committee needs advice on. Everyone at the University has a vested interest in making entrepreneurship happen, both for the long term and in fulfilling the responsibilities of a public university to the state.

What troubles him about the points that Professor Vaughan has raised is that he seems to want the conflict-of-interest process to just go away, Professor Cohen concluded. That is not going to help in the longer term; if colleagues get in a mess, one's own research life will be made more difficult. But there does need to be an environment that encourages entrepreneurship and one that lets faculty members see the rewards from it.

Mr. Schrankler said that what must change at the University is managing growth, not what it can lose, and not just saying "no." Is there a way to own more than 5%? Dean Ponce de Leon said that 5% is vague and there is a difference between a company worth $1 million and one worth $100 million. Professor Vaughan said it is artificial to focus only on commercial money as a conflict of interest; conflict comes in many forms and it is not accurate to say that it is just money. There is also grant money, ambition, career, scientific agenda, politics etc. all of which can be sources of a conflict of interest.

Part of the problem is the perception of a conflict of interest, Professor Cohen said. The publisher does not see the conflict of interest between one's name on a paper versus dollars in the pocket.

Professor Bearinger thanked Professor Cohen and the Committee's guests for participating in the discussion and affirmed that the Committee would return to the topic in February.

2. Changes to the Federal Conflict-of-Interest Regulations

Professor Bearinger now asked Ms. Zentner to review changes in federal conflict-of-interest regulations.

Ms. Zentner began by commenting that, at the same time that we are trying to be innovative and more flexible in managing conflicts of interest, the University now faces new federal regulations from the Public Health Service, effective August 24, 2012, which are substantially more restrictive than the current PHS regulation and which create additional burden for the University. The Public Health Service (PHS) encompasses a number of federal agencies, including NIH, CDC, FDA, and a number of others. She provided a handout comparing the current University policies and the revised PHS rules (appended at the end of these minutes) and reviewed what she sees as the significant differences.

Ms. Zentner reported that there are8900 “covered individuals” at the University which means they are required to file a REPA, 1243 discrete individuals with PHS funding, and 337 discrete individuals on PHS funded sub awards, for a total of 1580 discrete individuals potentially impacted by the new regulations. She also observed that there is some likelihood that NSF (the National Science Foundation) will follow PHS in this regard.

The University has options for application of the new PHS regulations, Ms. Zentner said. The University could decide to limit the application of the new regulations to investigators with PHS funded research or to make them applicable to all 8900 “covered individuals” as defined under University policy. There will also be an impact on the REPA:

-- SFI (Significant Financial Interest) threshold for remuneration received and equity interests in a publicly-traded company has been lowered to $5,000 (the current threshold in the University's conflict-of-interest policies is $10,000 except for clinical health practitioners, for whom the threshold is already $5,000)

-- Income from non-profit and professional organizations must now be included. Current University conflict-of-interest policies exempt this income from conflict of interest review.

- Any equity interest in non-publicly-traded entity is an SFI (current threshold in University conflict of interest policies is $10,000 or 5%, except for clinical health practitioners, for whom the threshold is the same as the new federal rule.

-- Information related to reimbursement for or payment of sponsored travel must now be reported (but not the dollar value of the reimbursement or payment made). The University's conflict-of-interest policies do not require the reporting of this information.

There will also be an impact on training:

-- Training is required at least every 4 years vs. current 3 year requirement under University COI policy, so in this regard the revised federal rule is less demanding than current University policy.

-- The training module needs to be revised to include new PHS standards.

-- By 8/24/12, approximately 1600 individuals with PHS funding need to be educated on the PHS changes.

-- There is also a need to incorporate a process to ensure that new PIs timely complete the training.

Ms. Zentner said she recently reviewed the requirements associated with the new federal rule with members of the Executive Oversight Compliance Committee (Vice Presidents Brown, Friedman, Mulcahy, and O'Brien, University Auditor Gail Klatt, General Counsel Mark Rotenberg, and Associate Vice President Kris Lockhart). The EOCC decided to forward the following recommendations to President Kaler, Ms. Zentner reported:

-- Apply the revised PHS regulations only to PHS researchers (which is about 25% of the University's PIs);

-- Revise the University's two COI Policies to incorporate the new regulations;

-- Revise the REPA to incorporate questions pertaining to the new regulations (roll out of the REPA in 2012 will be delayed as a result);

-- Give written notice of the revised regulation to PHS researchers via various communication approaches about who is affected and how (email communications, departmental newsletters, Research on Line, a specific notice when faculty and staff are required to take a particular action, e.g., file a REPA or take COI training, and other methods); and

-- Adopt the "every 4 years" approach to COI training.

-- With respect to mitigation plans and the "bias" evaluation, the Office of the Vice President for Research (OVPR) will take the lead on managing this process, utilizing the scientific integrity assessment approach.

-- With respect to the requirement to make certain COI-related information publicly available, begin by implementing the "written response within 5 days" approach, rather than creating a public website, and evaluate implementation challenges associated with this approach versus a public website.

-- Require confirmation from sub recipients that their COI policies comply with the revised regulations. OVPR will take the lead on managing.

What is the rationale for not imposing the new requirements on everyone, Professor Cohen asked? He would not argue for more restrictions on faculty research, but there are reasons to do so for public perception. If the PHS has decided these are general rules, excluding 75% of researchers is not a wise policy. He said he hated to argue for something more complicated, but this is a matter of perception. To have the perception that some research is not as rigorously examined as others is not good for the University.

Professor Alonso disagreed. Some reporting is without meaning, he said, but the University does it because it is afraid of what others might think—so it gets more conservative and creates problems for everyone. Why report conflicts of interest, Professor Cohen responded? Because of perception. The University needs public relations, not lawyers, Professor Alonso replied.

The Committee continued briefly to discuss the new regulations. Ms. Zentner concluded by saying that she understood Professor Cohen's point but that there are already different regulations for some people (e.g., those involved in clinical care), and those differences are managed effectively. The University can do the same in this case.

Professor Bearinger thanked Ms. Zentner for her report.

3. Research Scientist Proposal (and Nature of Appointments)

Professor Bearinger now welcomed Regents Professor Ruggles and Dr. Fitch to the meeting. She said that it has come to the attention of the Committee multiple times, with respect to the incentives for research, that there is a potential disincentive that the Committee might address: the types of position that non-faculty research staff can hold. The Provost's Research Council recently received a report on the review of the Minnesota Population Center (which Professor Ruggles directs); Professor Ruggles had raised a question about the nature of such appointments and how, given the way they are currently structured, they could be counterproductive. Today the Committee will have a general discussion to see if it wishes to bring the issue back for a discussion with Vice President Brown (Human Resources).

Professor Ruggles explained that the Minnesota Population Center (hereafter MPC) reports to Associate Vice President Frances Lawrenz and is a University-wide center with 110 staff, 50 of whom are full time, 30 of whom are P&A Ph.D.s, and the rest are students. The budget is about $8 million in direct costs and $2.5 million in indirect cost funds that are also available. All positions in MPC are on soft money.

MPC has about 100 faculty affiliates, Professor Ruggles related, and MPC may pay part of their salaries because of grants obtained through MPC, or MPC may pay people to do tasks. In both cases, they are not counted as part of the staff of MPC.

The 30 Research Associates with Ph.D.s in the MPC perform a wide range of tasks: conduct analyses, prepare reports, serve as project managers, and so on. They can write proposals, and sometimes do, and in many cases are co-investigators on research grants.

Their biggest problem, Professor Ruggles said, is that there are newly-minted Ph.D.s and people with 20 years of experience in one job classification that has no promotional track. This makes it difficult to keep salaries up and have faced retention issues as a result—they have lost two key staff members.

Professor Ruggles recalled that two years ago they made two proposals: (1) Move the more academically-oriented positions to the continuous professional series, something they have not been able to do, and (2) create a Research Scientist promotional series that would have three steps, analogous to regular faculty appointments. (The proposal is appended to these minutes, following the comparison of conflict-of-interest policies.) Dr. Fitch said they made the descriptions parallel to the departmental 7.12 statements required by the tenure regulations for regular faculty; they want the ability to recognize a broad range of activities. They did not address the length of appointment, Professor Ruggles added, all of which are now one year, but it would be considerably more attractive to offer longer appointments. But that issue was not discussed when this proposal was initially developed.

Research Associates and Senior Research Associates are P&A appointments, Professor Bearinger observed, and follow rules established by Human Resources: annually-renewable appointments. So if a grant is ending that supports their salaries, individuals receive a letter of termination, and if the funding continues from the same or another source, they will receive another letter of reappointment at about the same time. This is a demoralizing process and it is difficult to think of oneself as part of the University when one receives an annual termination letter.

Professor Linde reported that she was a Research Associate and is now a contract faculty member. How would the Research Scientist differ from a Research Associate, and would they potentially have indefinite appointments or would they be part of the contract faculty series? Professor Ruggles said they have not addressed the issue. Professor Linde said that Research Associates are renewed if the funding continues; who would pay if the grant funding runs out? What is the University's obligation to a Research Scientist if the dollars go away?

They are aiming more for promotional levels, Dr. Fitch said, and a big leap over the Research Associate appointments, given that a considerable number of their staff are anywhere from one to ten years post-Ph.D. in experience. This proposal was not seeking more than annual appointments, although having them would be very valuable. Professor Ruggles said they have been concerned about a way to offer job security; at the Institute for Social Research at Michigan, research scientists can receive a guaranteed five-year contract once they achieve some level of seniority. That option would be tremendous, and at the MPC, they have been setting aside funds for them, funds that have not been used.

Professor Cohen said he is convinced that most large universities would employ everyone on soft money, non-tenure tracks. When one looks at the positions in MPC, one asks why they are not tenure-track appointments. He said that the MPC's proposal excludes some from participation in faculty

governance; there are tracks for P&A staff but the options are restricted. Further, promotion is decided by one person who is not a faculty member. In his unit, the promotion is decided on by the faculty; he said he did not like promotion dependent on one person. Academic professionals should be promoted by a team. That is why a Research Professor track would be desirable and he has been surprised it is not used. Professor Ruggles said they would be required to move some to a Research Professor track, which they do not have. Professor Cohen said that if it were him, he would push for the Research Professor track because it would provide more protection. Professor Linde demurred.

Professor Okuyemi said he sympathized with the goal of creating an academic track between Research Associate and regular faculty and said that creating faculty positions, tenure-track or not, is almost impossible. This proposal might allow units that are losing bright minds to retain them, because right now unit heads have no power to do so. This is a desirable proposal to create appointments to retain people.

Professor Ruggles observed that MPC is not a department and has no faculty lines—nor do they want them. What they want is a Research Scientist line separate from a Research Faculty line—because not all who do this kind of work want to be faculty members. Within the University, the faculty title provides assurances about promotion being based on academic standards and not at the discretion of a single person, Professor Cohen said, and also establishes positive interactions with other faculty members.

Dr. Haugstad related that he manages a group of P&A Research Associates. Scholarly activity is not the only matter by which promotion (to senior research associate) is judged. There are other activities/duties that he as director is the individual most able to judge. But he agreed with Professor Cohen that scholarly activity should be judged by a committee. He noted that the College of Science and Engineering has voted not to have Research Professor appointments. CLA does not permit them either, Professor Ruggles added.

Professor Alonso asked what the University's response has been to the MPC's proposal. For P&A staff, their supervisor must write an evaluation. In the case of a Research Associate, the University cannot promise an appointment beyond the duration of grant funds; departments do not want to commit to funding to retain a person. It would be difficult with someone on soft money to offer them more security than what the grant offers.

Dr. Fitch said it is unclear where their proposal should go; it has not yet gone to Human Resources. It has been tied up with the discussion of Research Professor appointments.

Has this been a topic of discussion at the Council of Research Associate Deans, Professor Bearinger inquired? It has not, Dean Ponce de Leon said. He said that this seems to be a proposal that is very specific to MPC; is the goal to change employee classification? Professor Ruggles said it has more general application than just the MPC. Dean Ponce de Leon surmised that CRAD would support it, and he concurred with Professor Cohen's point that there should not be only one decision-maker when it comes to promotion. He added that he would allow individuals to pursue a faculty track.

Professor Bearinger said the proposal would be brought back to the Committee for a recommendation to Vice President Brown and Provost Hanson. She adjourned the meeting at 4:10.

-- Gary Engstrand

University of Minnesota

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Current University Individual Conflicts of Interest Policies and Revised Public Health Service (PHS) Rules Comparison
Final Rule Issued August 25, 2011
Effective Date: August 24, 2012

	Topic	PHS (Public Health Service) 2011 Final Rule[1]	U of M Policies on Individual Conflicts of Interest
1	Application of the rule	Applies to institutions and investigators that apply for or receive PHS-funded grants or cooperative agreements with a Notice of Award issue date after 8/24/12.	Currently in effect; applies to all UMN faculty and staff and others acting on UMN's behalf regardless of source of funding.
2	Disclosure of Significant Financial Interests (SFI) - thresholds	$5000 (remuneration/equity interests) in a publicly traded entity. Same threshold applies re remuneration from a non-publicly traded entity but all equity interests in a non-publicly traded entity must be reported. All Intellectual property rights (royalties) must be reported upon receipt of income. Applies to Investigator, spouse & dependent children.	$10,000 or more 5% or greater equity interest **Clinical Health Care:** Must report all remuneration, equity interests and royalties. Applies to covered individual, covered individual's spouse, dependent children, & any other family member who may benefit.
3	Which SFIs need to be disclosed once a threshold is met? (the "relatedness issue")	All SFI related to the investigator's institutional responsibilities. Examples of "institutional responsibilities": research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels (e.g. IRBs and DSMBs).	All significant financial interests and business interests of the covered individual and their family members that are related to the covered individual's University expertise or responsibilities.

[1] See http://www.gpo.gov/fdsys/pkg/FR-2011-08-25/pdf/2011-21633.pdf for full text of Final Rule

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4	Excluded from disclosure requirement	• Remuneration paid by the institution to include salary, IP rights assigned to the institution and agreements to share in royalties related to such rights • Income from seminars, lectures, or teaching engagements sponsored by and service on advisory or review panels for a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an institution of higher education. • Also excludes income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.	• Remuneration paid by the University • Remuneration paid to adjunct faculty by their primary employer • Income from seminars, lectures, or teaching engagements sponsored by governmental agencies, or • by non-profit entities organized solely for educational, religious, philanthropic, or research purposes (with the exception of non-profit entities created by for-profit corporations); • Income when serving as a special reviewer or review panelist for a public (governmental) or nonprofit entity; • income from services provided to professional organizations; • income from a private practice plan or private professional practice plan pursuant to Board of Regents policy; • royalties received under Board of Regents Policy: *Commercialization of Intellectual Property Rights*, where the covered individual who received the

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			royalties does not have any other relationship with the business entity paying the royalties that could result in a conflict of interest.
5	Reporting period	• Disclosure is required for all payments received and equity held during the 12 months preceding the disclosure.	• Disclosure is required re all remuneration, equity interests and royalties received for the prior and current calendar year.
6	Travel reimbursements and sponsored travel	Report any reimbursed travel or sponsored travel related to institutional responsibilities (including purpose of trip, sponsor/organizer, destination, and duration). Excluded: travel reimbursed or sponsored by a federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute that is affiliated with an	No requirement to report expense reimbursement.

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		institution of higher education. The institution will determine if any travel requires further investigation, including determination or disclosure of the monetary value.	
7	When must an Investigator submit an updated disclosure of SFIs?	• At least annually and • Within 30 days of discovering or acquiring a new SFI	Annually and within 30 days of substantial change in business or financial interest or change in U responsibilities related to existing business or financial interests.
8	When must a conflicting significant financial interest be reported to PHS?	• Prior to the expenditure of any funds under a PHS-supported research project • If a conflicting SFI is found after the initial Financial Conflict of Interest (FCOI) report is submitted, an updated report must be submitted within 60 days of identifying the conflicting SFI. • If: o a new investigator discloses an SFI, o an existing investigator identifies a new SFI, or o an investigator fails to timely disclose an SFI or a disclosed SFI was not reviewed by the institution, the institution must determine whether a FCOI exists within 60 days and implement a CMP at least on an interim basis.	University policy specifies that it will follow reporting requirements of governmental agency sponsoring the research.
9	CMP Compliance	• Whenever an institution implements a CMP, the CMP must be monitored on an ongoing basis until completion of the research.	• University policy requires compliance with a CMP. To ensure compliance, the University confirms compliance with the plan within 90 days of its effective date and annually until the plan is retired.
10	What information re a FCOI must be reported to PHS?	INITIAL REPORT • Project number and name of the PI • Name of the investigator with the FCOI	University policy specifies that it will follow reporting requirements of governmental agency sponsoring the research. In practice, the

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		• Name of the entity with which the investigator has a FCOI • Nature of FCOI, e.g., equity, consulting fees, travel reimbursement, honoraria • Value of the financial interest in specified increments • A description how the financial interest relates to PHS-funded research and the basis for the institution's determination that the financial interest conflicts with such research • Key elements of the institution's management plan ANNUAL REPORT • Status of the FCOI • Any changes to the management plan	University's conflict management plan format already reflects the information that must be reported.
11	Mitigation plans	Whenever an FCOI is not identified or managed in a timely manner either because an investigator did not disclose or a failure of the institution or an investigator fails to comply with a CMP, the institution must: • Conduct a retrospective review within 120 days to • Determine whether there was bias in the design, conduct, or reporting of the research Prepare a report and if bias is found, the institution must notify PHS and submit a mitigation report.	No comparable provision.
12	Maintain up to date written enforced COI policy that complies with the PHS rule.	Policy must be on a publicly accessible website or provided within 5 business days of a request. Institututional standards that are more stringent than those of PHS govern.	University COI P&Ps are currently available on a publicly accessible website. It is University practice to require compliance with its standards when they exceed federal requirements.
13	Informing and training Investigators	• Inform each investigator of the institution's FCOI policies, the investigator's disclosure obligations under the policy and the PHS rule on FCOI. • Require each investigator to complete training re the same: o Prior to engaging in PHS-funded research	• Information regarding the University's revised COI P&Ps has been widely disseminated. • COI educational module must be completed every 3 years by all individuals required to file a REPA.

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		○ At least every 4 years thereafter ○ Whenever the institution revises its P&Ps that affect investigators ○ Whenever an investigator is new to an institution ○ Whenever an institution finds an Investigator who fails to comply with the institution's COI P&Ps or a CMP	
14	Subrecipient Institutions/Investigators and Reporting of identified FCOIs	• Institution must take reasonable steps to ensure that any subrecipient investigator complies with the PHS rule. • Institution must enter into a written agreement that states whether the FCOI policy of the awardee institution or that of the subrecipient will apply to subrecipient investigators and include time periods to meet disclosure and/or FCOI reporting requirements. • If the subrecipient's policy will apply, it must certify that its policy complies with the PHS rule. If unable to provide the certification, it must comply with the awardees P&Ps. • Subrecipients who rely on their FCOI policy must report identified FCOIs to the awardee institution in sufficient time to allow the awardee institution to timely report the FCOI to PHS. • Institutions must provide FCOI reports to PHS re all FCOIs of sub recipient investigators prior to the expenditure of funds and within 60 days of a newly identified SFI.	As required by the research sponsor, the University will take reasonable steps to ensure that subrecipients are informed of the obligation to comply with all applicable COI requirements imposed by state & federal law and University policy.
15	Determining when an SFI is related to PHS-funded research	An SFI is "related to PHS-funded research" when: • the institution reasonably determines that the SFI could be affected by the PHS-funded research; • the SFI is in an entity whose financial interest could be affected by the research; or	No definition of "relatedness" in policy but, in practice, the University applies the same approach.

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		• The SFI could directly and significantly affect the design, conduct or reporting of the research	
16	Managing FCOIs	• Require disclosures in publications & to research participants • Appoint an independent monitor to ensure research is free from bias • Change personnel responsibilities or disqualify individual from participation in all or a portion of the research • Reduce or eliminate the financial interest • Sever relationships that create FCOIs	Same.
17	Maintaining records of financial disclosures	Maintain records of investigator disclosures of financial interests and the institution's review of, and response to such disclosures for at least 3 years from date of final expenditure report to PHS.	U of M practice: Maintain records indefinitely.
18	Public Accessibility	• Make certain information available concerning identified FCOIs held by senior/key personnel via a publicly accessible Web site or by a written response to any requestor within five business days of a request, and update such information as specified in the rule. The website must be updated annually and include the following: o Investigator's name, title and role on the research o The name of the entity in which the SFI is held o The nature of the SFI, o The approximate value of the SFI in dollar ranges or a statement that the value cannot be readily determined. • Or provide written response to any requestor within 5 business days including same information.	Voluntary reporting via a publicly accessible website for AHC faculty and staff. Not operational to date. COI policy for clinical health care says U will amend public disclosure rules to conform to PHS requirements.

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19	Remedies	• If the failure of an investigator results in bias, the institution must immediately inform PHS of the corrective action taken. • PHS may inquire at any time re any investigator disclosure of financial interests and the institution's review of that disclosure. • The institution is required to permit on site review of all records. • PHS may determine that a particular financial COI will or has biased the objectivity of the research and require further corrective action, may impose special award conditions or suspend funding or take other enforcement action until the matter is resolved. • In any case in which a PHS funded clinical trial involved the evaluation of the safety or effectiveness of a drug, medical device, or treatment, and the investigator had an FCOI that was not managed or reported by the institution as required, the institution shall require the investigator to disclose the FCOI in each public presentation of the research results and to also request an addendum to previously published presentations.	University policy: • provides for a range of discipline and • also recognizes that additional adverse action may be taken by UMP or Fairview when the investigator is involved in clinical health care.

* * *

Proposed Research Scientist Promotional Series

(Proposal developed by sub-committee of the Minnesota Population Center Advisory Board)

This is a proposal for a new P&A job class for PhD research staff, replacing the Research Associate to Senior Research Associate promotional path that now exists at the University.

Distinguishing characteristics of Research Scientist track

Compared to a research professor series, the research scientist

- Plays a key leadership role in large research projects, but is not necessarily the Principal Investigator on those projects.
- Is actively engaged in research but is not expected to have the distinct and coherent line of research expected for research professors.
- Is expected to build a record of publications that may consist largely of scientific databases, reports, training materials, and documentation, along with some publications in traditional academic venues such as scholarly journals.

Research Scientist track

The basic job description for Research Scientist would be similar to the current description for Research Associate. A Ph.D., but no subsequent experience, is required for the entry-level position. This is not envisioned as an "up or out" system; researchers may remain at the basic research scientist level for an indefinite period.

Promotion from Research Scientist to Senior Research Scientist

In order to earn promotion from Research Scientist to Senior Research Scientist candidates must show evidence of research productivity, leadership and engagement commensurate with the Senior Research title. Criteria for promotion include:

Research productivity

- Publishing scholarly work, including some mix of articles, books, book chapters, reports, data releases or activities that lead to the public availability of data products and innovative research tools.
- Presenting at national and/or international workshops and conferences: these presentations can include a mix of paper and poster presentations on substantive research questions; paper and poster presentations on MPC data resources; and conducting data training workshops.

Evidence of leadership on MPC research projects

- Taking a management role on funded research projects: supervising a staff (including students and/or professional employees), establishing and meeting project milestones, and/or co-authoring grant proposals and serving as Co-investigator.

Evidence of active engagement with the MPC and the University community

- Presenting at MPC colloquia or other seminars on campus,
- Mentoring graduate research assistants in formal or informal capacity, and/or

- Communicating research results to audiences outside the university in the Twin Cities.

Promotion from Senior Research Scientist to Principal Research Scientist

Research productivity that has contributed to a national reputation

- Publishing articles in top-tier journals, books and/or book chapters i with top-tier presses
- Publish other significant scholarly works, including some mix of articles, books and/or book chapters, reports, data releases or activities that lead to the public availability of data products and innovative research tools.
- Active participation in and reputation within relevant national and international organizations.

Significant record of leadership on MPC research projects

- Serving as a Principal Investigator or co-investigator on sponsored research.
- Taking responsibility for day-to-day management of large research projects, including budgetary responsibilities and significant supervisory responsibilities.
- Supervising or directing other MPC research scientists who manage large research projects.

Evidence of active engagement with the MPC and the University community

- Participating in the leadership of MPC by serving as a core director or leading an MPC-wide committee or initiative.
- Continuing active engagement with the MPC and on campus (presenting at MPC colloquia or other seminars on campus, mentoring graduate research assistants in formal or informal capacity, and/or communicating research results to audiences outside the university in the Twin Cities.)