



**OUS RESEARCH COUNCIL
CHEMEKETA EOLA NORTHWEST VITICULTURE CENTER
THURSDAY, MAY 3, 2007, 9:30 A.M. – 11:30 A.M.**

1) CALL TO ORDER/ROLL CALL

Chair Rich Linton called to order the meeting of the OUS Research Council at 9:30 A.M. On roll call, the following council members answered present:

Director Kirby Dyess (telephone), John Cassady, David Woodall, Gary Tallman, and Ray Werner (telephone)

Absent: Bill Feyerherm, Wayne Embree, Nick Konidaris, and Dan Dorsa

Research Council staff present: Charles Triplett

Chancellor Office staff present: Chancellor George Pernsteiner, Patti Snopkowski, and Bruce Schafer

Other participants present: Charlotte Shupert, OHSU; Arundee Pradhan, OHSU; Don Gerhart, UO; William Hostetler, PSU; Cathleen Gal, PSU; Kim Calvery, OSU; Ed Battistella, SOU; Lynette Schenkel, UO; Brian Wall, OSU; Earl Potter, SOU; Gary Chaffins, UO; Kent Hardin, UO

2) DISCUSSION

**a. Initiatives and Approaches to Enhancing Technology Transfer
i. OHSU Campus Update**

Director Arundee Pradhan presented an overview of the OHSU Technology and Research Collaborations Office. He prefaced his remarks by stressing that there are numerous institutional models of technology transfer. At OHSU, the Technology and Research Collaborations office manages intellectual property (IP), but also manages industry-sponsored research agreements as well. The TRC also manages material transfer agreements for the university and hospital. OHSU, like many other universities, defines technology transfer as the transfer of innovation to the public. Although technology transfer has the potential to generate net-positive licensing income for OHSU, other, non-revenue-producing activities are also very important to the health of the OHSU research enterprise, and so are strongly supported by the TRC. IP management means the evaluation of technologies and their opportunity for commercialization. Like most organizations, OHSU contracts with outside counsel as necessary.

In addition to TRC's support of industry-sponsored research agreements for OHSU, the office coordinates the distribution of royalties, and serves as a point-of-contact for commercialization opportunities.

Pradhan said that material transfer is a non-revenue generating function of his office. Material transfers are used to support research and payback is achieved through better grant funding. Until 15 years ago, material transfer agreements didn't exist. The inherent value of biological materials led to a need for policies and a vehicle to facilitate transfers. The complexity is exponentially higher for materials that are transferred from private companies. Multiple licenses, confidentiality agreements, and rights to inventions created by their materials make the process very time consuming. Much of the time is spent narrowing down those agreements to insure that they do not impede academic research and future opportunities. Currently, material transfer agreements take an inordinate amount of time to manage. OHSU is attempting to automate material transfer agreements that do not require negotiation. Non-negotiated agreements are typically with other institutions and streamlining them will free up additional time to devote to more complicated agreements.

Of the industry-sponsored research agreements that are managed in the OHSU Technology and Research Collaborations Office, one key type is the NIH grant for clinical research. The grant fosters companies and universities working together. OHSU is partnering with Intel's Digital Health Initiative to research ageing. TRC also works collaboratively with the Oregon Economic and Community Development Department (OECD) and with the Portland Development Commission (PDC).

Pradhan noted that patenting represents a huge cost for OHSU. They spent \$1.2M in patent filing. The positive note is that the \$1M spent has returned \$500K in patent reimbursements. When patents are filed, OHSU typically asks the licensee to pay for the patent. The challenge is making the processes and communication seamless. OHSU has an advisory group that helps determine how best to allocate resources. Most initiatives are based on areas where limited resources will make the most impact.

ii. OSU Campus Update

John Cassady, Vice President for Research at OSU gave a high-level overview of OSU research. OSU is engaged in a strategic planning exercise and is rethinking how to organize the research office to be more inclusive. Cassady noted that nothing is carved in stone but he would like to organize research under a larger umbrella of innovation and economic development. This type of reorganization would tease out scientific integrity into a separate group and frame technology transfer under an associate vice president for innovation and economic development.

Brian Wall, Interim Director of the Office of Technology Transfer presented a summary of OSU technology transfer. IP management takes the greatest amount of time in the OSU office. The office also manages material transfer agreements but sponsored research is managed in a different office. OSU technology transfer staff work directly with research faculty in their respective colleges. They work half time in college departments "knocking on doors."

OSU tends to have a lot of non-exclusive licenses. Due to activity within OSU's College of Agriculture, one OSU focus is on funneling crops out to farmers in the Pacific Northwest. The increase in the technology transfer office size has led to an increase in inventions. Invention disclosures are expected to continue growing. Three start-up companies have been formed in the past 18 months and 2008 is already looking strong. Wall stressed that all university research offices employ a unique approach to managing their responsibilities. The location and culture of the university has a direct effect on the research model. The Research Office strategic planning exercise is expected to help OSU define the strength of its location and colleges.

iii. PSU Campus Update

William Hostetler, Commercialization Officer, gave a summary presentation of technology transfer at PSU. The PSU Office of Research and Sponsored Projects is in the process of hiring a director of technology transfer. OHSU provided help with technology transfer until 2005. PSU is an urban university focused on community engagement. They've entered into multiple partnerships to strengthen research opportunities. MBA students engage in technology and innovation management programs, and a PSU joint program with the School of Law at Lewis and Clark College is focused on entrepreneurship.

Hostetler said that PSU research is growing rapidly. A PSU business accelerator – created in 2005 – has formally accepted 20 companies. Many of the pieces of a successful commercialization office are beginning to fit together. PSU continues to invest in technology transfer and is developing strong connections in the economic development arena.

Hostetler added that most conversations about academic research and economic development fail to recognize the contribution of graduate students who continue to develop innovations outside of the university. These contributions must be recognized as a part of the whole university innovation cycle. Hostetler pointed to a handout on start-up companies formed at PSU. He noted the significant lag time between invention and protection and the significant cost associated with protecting IP.

iv. UO Campus Update

Don Gerhart, Director of Technology Transfer gave an overview of tech transfer at UO. Gerhart was recruited to Oregon from North Carolina's Research Triangle region. Prior to his arrival in Oregon in December 2000, Gerhart's career included five years of for-profit, private-sector experience with an Research Triangle-based pharmaceutical development company, seven years as a faculty member and inventor at Duke University, and one year as Associate Director of Technology Transfer and Industry Research at North Carolina State University. Gerhart's experiences in NC gave him a good understanding of the interface between research and commercialization. For the last 6.5 years, the University of Oregon has been building out a "2nd Generation" —or "2G" — technology transfer program. To document the multi-year span of this UO commitment, Gerhart directed everyone's attention to a handout for a workshop on 2G Technology Transfer that was held in Corvallis during the fall of 2002, and that had been co-sponsored by the University of Oregon, Oregon State University, and Hewlett Packard. North Carolina's Mark Crowell – one of the top leaders in moving technology into the community –

was a guest speaker at the 2nd generation event, as was the University of Washington's Professor Ken Walters, and Gerald Barnett – the former UW innovation leader that coined the term “2G” technology transfer.

The University of Oregon focuses on moving innovations into society to benefit people. The UO technology transfer office acts as a catalyst and entrepreneurial facilitator of innovation, rather than as a gatekeeper. Using a second handout, Gerhart presented data showing that UO research had grown 50% since 2000. In that same span of time, invention disclosures had grown 500%, and licensing income had grown 1280%. Although UO does not focus on making money as a primary objective, Gerhart said that the University of Oregon had increased innovation-derived income to \$4.3 million in FY2006 through the successful application of a 2nd generation model of technology transfer. The last handout Gerhart provided describes income sharing at UO. Many faculty members re-direct their technology transfer income into their research laboratory; in many such cases, the Vice President of Research also re-invests the institutional share of tech transfer income into the lab or department as well. Performance measures – committed to by all parties – provide incentive to perform. Oregon's 2G-technology transfer program de-emphasizes patenting, and views patents as an input rather than an end goal. Oregon's approach closely mirrors the core recommendations suggested by the Kauffman Foundation, including the recommendations recently released a working paper titled *Commercializing University Innovations: A Better Way*. Gerhart held up four magazine covers — including the covers of *National Geographic* magazine and *Newsweek* magazine — that highlighted several commercialized innovations derived from UO research. In summation, Gerhart noted that UO research programs have excellent national reputations in several strategic areas, and stated that the University of Oregon is finding great success with its unique approach to research commercialization.

v. Discussion and Action Items

Chair Linton thanked everyone for their presentations and asked participants if there were any questions. John Cassady suggested that it's important to develop a coordinated, multi-institutional vision for the Oregon Commercialization Institute before further presentations and proposals to the Kauffman Foundation. Linton clarified Cassady's comments by saying that there are ongoing conversations with Kauffman on how Oregon conducts tech transfer. A presentation on the Kaufmann approach was scheduled during this meeting but additional campus conversations are necessary. When appropriate, a presentation of this unique approach will be given to the Research Council. The question is how the council can help foster better tech transfer. 2nd generation is one model to talk about but there are questions about inter-institutional collaboration. Eric Stenehjem, in the Governor's Office, is helping research inter-institutional collaborations. Linton suggested that this may be a good opportunity to inventory university resources and talk about new approaches. Cassady agreed that the discussions could add value but cautioned that campuses need to be appropriately engaged. This could be very synergistic if we approach it properly.

b. Responsible Conduct of Research – Status of Policies and Implementation

i. OUS Perspectives on Compliance

Chair Linton introduced the second topic of discussion, research compliance. He explained that research compliance is becoming more complicated everyday. Two presenters this morning will provide a foundation for this discussion, Patti Snopkowski from OUS and Lynette Schenkel from UO. Linton encouraged Research Council members to think about the Council's work and begin prioritizing the issues. This discussion stems from the joint Provosts' and Research Council meeting in March. The Research Council will be leading the charge in this area.

Patti Snopkowski provided a brief system overview of research compliance. She noted the recent increases in internal controls created under the Sarbanes-Oxley Act. Government standards have agreed to adopt new internal controls which may increase scrutiny and expanded coverage. Snopkowski said that internal controls are processes to achieve control. She highlighted a list of internal control best practices provided in the slides and noted that three areas are critical in compliance: control environment, risk assessment, and control activities. Oregon has a decentralized model that makes control environment challenging. Risk assessment helps to identify vulnerabilities and insure that an institution's energy is properly directed. Control activities refer to the proper documentation of policies for consistency. OUS disclosures to the federal government necessitate good documentation of campus policies. Adequately segregating pre and post award functions is also important.

Snopkowski said that one of the most difficult challenges in a decentralized model is communication and information management. If things go wrong, good documenting processes insure that OUS maintains its credibility. She added that although challenging, the rewards of good policies and procedures will out weigh the costs.

ii. Campus Concerns – Research Compliance

Lynette Schenkel opened her presentation noting a focus on the list of topics generated by Chair Linton during the last Research Council meeting. Vulnerable infrastructure issues were a key focus of the presentation. Six infrastructural vulnerabilities common to OUS campuses were 1) the growth of support resources (staff and systems) has not kept pace with the growth of research; 2) policies and procedures may not exist or may not be up to date; 3) decentralization has caused roles and responsibilities lack clearly definition; 4) communication strategies may not be in place for both regular and urgent matters; 5) in general there is insufficient random and for cause monitoring; and 6) in general there is insufficient, organized, consistent and comprehensive training and education programs. These infrastructural vulnerabilities underlie the functional high risk areas that Schenkel next highlighted. The top four high risk functional areas are: post award grants management (PAGM), conflicts of interest/commitment, human subject research, and research integrity or scientific misconduct. She said that these are the areas of common interest to the Office of Inspector General (OIG), the National Science Foundation (NSF), and the Department of Health & Human Services (HHS), and can be found on their respective work and audit plans. In addition, the federal government appears to be unsatisfied

with A-133 audits and the information they're receiving from these audits. As a result, Schenkel expects there will be an increase in "not for cause" audits from select agencies.

Oregon universities face unique challenges with conflict of commitment policies. Faculty salaries are low compared to regional and national markets. At the same time, Oregon institutions are expected to be regional economic drivers and faculty members are encouraged to be entrepreneurial. These factors require flexibility when considering conflict of interest or commitment policies. They also demand very careful disclosure policies and review processes.

Schenkel said the human subject research regulations are always on the increase. The Association for the Accreditation of Human Research Protection Programs (AAHRPP) is the human subject accrediting body. At this time, approximately 80% of AAU institutions are accredited or in the process. Human subject accreditation is definitely a key area to monitor.

Schenkel introduced research integrity as the last topic of her presentation. The federal Office of Research Integrity is now hosting a two to three day "boot camp" in an intensely focused environment for University Research Integrity Officers (RIO's). RIO's are responsible for a variety of research integrity issues and work with faculty members, senior administrators and legal counsel to insure that institutions comply with regulatory policies. Schenkel noted a draft responsible conduct of research, responsibility matrix handout that she developed for UO. The tool is still in process and is not fully vetted at the institution but it helps to organize compliance officers' responsibilities and promotes accountability. A second handout – the research compliance risk assessment tool – is also a draft work in progress. It is intended to be a high level tool to help compliance officers determine overall risk in a variety of risk areas. The completed module presented at the meeting focused on PAGM. Modules under development are in the area of Conflict of Interest/Commitment. Schenkel welcomed feedback on the two tools.

iii. Discussion and Action Items

Chair Linton asked participants if they had any comments or questions. Charlotte Shupert said that OHSU may be ahead of OUS institutions in these areas because OHSU has a higher level of risk in light of its medical research orientation and extensive NIH grant funding. She added that faculty are prized for being creative, but creativity is often associated with flexibility of rules. Regulation costs are increasing substantially. Linton asked Shupert how much OHSU spends annually on compliance. She replied that between human and animal research they budget approximately \$2M annually.

Arundee Pradhan said that the economic development focus of his office returns equity and necessitates legal counseling to insure that OHSU is not engaged in insider trading. The process often takes months. Linton asked if the process was imbedded in OHSU policy. Pradhan answered "no" and said that it is just an attempt to limit exposure.

Cathleen Gal asked if UO is in the process of accreditation by the Association for the Accreditation of Human Research Protection Programs (AAHRPP). Schenkel replied that the process takes a while. The UO has developed good practices, but these have not always been documented sufficiently. She added that accreditation is based largely on documented policies

and less on the interview and site visit process. Charlotte Shupert said that OHSU is in a similar position. They have good procedures but sometimes lag in good documentation. She added that compliance programs are not funded at the appropriate level.

Linton asked Schenkel to talk about the evolution of her office at UO. She said that she was hired to create the research compliance office. They are building an infrastructure that in the past has not kept pace with the research growth and expanding regulatory requirements. Shupert agreed and said that compliance is a slow process and compliance budgets are often tempting to underfund. Linton added that compliance and the cost of compliance is a major concern with senior research officers in the AAU. He said that everyone engaged in this area is painfully aware of F&A where the “A” or administrative portion is capped by the federal government and thus hinders effective funding of compliance efforts.

Snopkowski agreed that some of the challenges are budget related but said that how universities allocate funds is also important. She added that there are political issues at play as well.

Earl Potter reminded participants that the regional campuses do not engage in the same level of activity, but they are bound to the same regulations. He suggested that mission and regulatory creep is difficult to manage and encouraged Research Council members to help tie regional institutions into the expertise to cope with these issues. It is possible that regional institutions will make mistakes due to a lack of resources and expertise in this area.

Shupert added that there are several successful models to review. In Seattle several institutions mutually review compliance policies. She said that consortium or “help” models are available. In the area of human research protection programs, Schenkel and Shupert said that they were familiar with at least one consortium, the Dana Faber Harvard Cancer Center, (DFHCC) that has been accredited. This consortium consists of seven separate institutions. This precedence suggests that other universities can form a consortium for accrediting purposes. Another suggestion that was discussed was that of a “compliance circuit rider.” This would be an individual or individuals from one of the larger OUS campuses that would regularly visit the regional campuses to assist with infrastructure, policy or other compliance related issues.

Gary Chaffins said that UO, as most research institutions, struggles with departmental level turnover in grants and contracts administration. Shupert acknowledged the challenge and said that the key to successful compliance is a faculty investigator and associated grants administrative staff who understand the risk. She noted that she recently suspended someone’s approval because they didn’t have an adequate understanding of the responsibility and supply resources to compliance. She said that these challenges have to be addressed in the “trenches.”

Schenkel asked how to most effectively reach into the departments – to staff and investigators. Mandatory training is one approach but without that, a change in the institution’s culture is necessary.

Snopkowski said that the University of Washington implemented a cultural shift by having top-level faculty champion the changes. Shupert agreed that campus leaders must champion any significant changes.

Linton noted that a high profile negative event also sends a strong message for change. Schenkel agreed and cited two former settlement cases of whistle blowing. These types of catalyzing events may have the desired effect but they present their own challenges.

Chair Linton thanked everyone for the great overview and reiterated the council's interest in this area. He suggested that a sub-group of the compliance personnel from the various institutions represented at the meeting work together to review the research assessment tool, and look at how compliance can be strengthened and supported at the various campuses. One idea was to perhaps create a library of tools to help focus the council on the areas highlighted in the presentation. Chair Linton tasked Schenkel with organizing and leading the subgroup, and to have a report back to the council by the July meeting if possible.

Linton reminded participants of the close link this area has to the Provosts' Council. He asked if a system-level institutional conflict of interest policy would be helpful and asked campuses to provide feedback on the idea. The regional universities would likely benefit from shared compliance resources. He encouraged everyone to consider the benefits of the consortia examples.

3) ADJOURNMENT

The meeting adjourned at 11:30 A.M.