SPIN Newsletter June 2003 Volume 3, Number 6

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SPIN Meeting Highlights

Highlights from the previous SPIN meeting are published in each issue of the SPIN Newsletter. Meeting presentations and handouts are always available on the SPA website:

http://www.ohsu.edu/ra/spa

Hot Topics

Statement of Intent

A new Statement of Intent (SOI) that includes the dollar amounts to be awarded to OHSU will replace the “willing letter” as the required document for proposing to receive a subcontract. When OHSU submits an application and others offer to be subcontractors, OHSU now requires the signature of an institutional representative on a document including both budget amounts and the proposed dates of the subcontract. This document can take the form of a face page, a budget page, or a formal SOI.

Self Addressed Envelope

A self-addressed envelope will now be provided when a signed grant is sent to the department. While the grant is finalized in the department, and while copies are being made to be sent to the sponsor, two (2) copies should be made and sent directly to RSO in the provided self-addressed envelope. Failure to send copies to RSO causes grant reviewers to waste valuable time looking for copies rather than reviewing proposals. Departments can dramatically improve the efficiency of moving their grants to account set-up by simply incorporating these copies for RSO into their grant finalization process.

June SPIN Highlights

This month’s SPIN meeting featured presentations by many staff members from the Research Support Office (RSO) discussing various aspects of the pre-award process and providing a general overview and introduction of research support topics.

Grants Specialists, Program Officers, Approaching NIH, and Late Applications
Sue Tower, Grants Analyst, RSO

When looking for help from the National Institutes of Health (NIH) the best points of contact are the Grants Management Specialist (GMS) and the Program Officer (PO). The GMS can answer questions about the application, provide administrative and financial guidance, and assist with web information. The PO can assist in identifying the best program or mechanism, provide scientific and technical assistance, and assist the Principal Investigator (PI) in targeting the best review group.

Program Officers can assist PIs in the following ways:
• By identifying one or more appropriate institutes
• By identifying a group of potential Program Officers
• By engaging in email dialogues regarding proposals
• By identifying a relevant Request for Applications (RFA) or PA
• By following up on initiated contact

Remember that late applications are much less likely to receive serious attention and funding.

Calculating Salaries for Grant Applications
Jill Cline, Grants Analyst, RSO

When calculating salaries, keep in mind that the current NIH Salary Limit is $171,900. The terms “direct salary,” “salary,” and “institutional base salary” are interchangeable—they all mean the same thing. Allow 3% inflation if calculating salaries on the initial year budget page. The inflation factor used by NIH for future years is also 3%. If the person listed on the budget page is not yet an OHSU employee, include a letter stating the intent to hire this person. There is no stated maximum rate for consultant rates, but the rate must be “reasonable”—see Chapter VI, Section 616 of the online NSF grant guide for more details:


Continued on page 2
Recent Changes - NIH Data Sharing Policy, and the Z Component
Anne Chisholm, Senior Financial Analyst, RSO

The NIH Policy on Data Sharing applies to unsolicited applications requesting $500,000 or more in direct costs in any one year (officially starting October 1, 2003). In addition, many Requests for Proposals (RFPs) for broad program project grants also require that the Policy on Data Sharing be addressed, regardless of the amount of direct costs requested. For those proposals to which the Policy applies, the application narrative must explain the plan for data sharing, and this means all intellectual property officers at all involved institutions must come to an agreement about the plan. Guidance is available on the NIH website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html. Help is also available from the NIH Program Office and from OHSU personnel: Anne Chisholm in RSO (x-4-7784, chishola@ohsu.edu), and Shelly Ziegler in Technology & Research Collaborations (x-4-3712, zieglers@ohsu.edu).

Some faculty wish to include the Z Component of their salaries (often referred to as Practice Plan salary) in the Institutional Base Salary that is included in federal budget pages. Including the Z Component is allowed; however it requires that a “Letter of Commitment” signed by the department chair and including the amount of Y salary, the amount of Z1, and the total amount to be paid if the grant application is awarded be submitted to RSO along with the application for review. Complete instructions on-line: http://www.ohsu.edu/ra/spa/mdgropsalnihgrants.pdf.

Training Grants, and Budget Development Resources
Rhonda Rae, Grants Analyst, RSO

For information about budgeting issues on pre- and post-doctoral trainees refer to the following webpages:

Stipends
- National Research Service Award (NRSA) Policy: http://grants.nih.gov/training/nrsa.htm

Tuition and Fees
- For OHSU, http://www.ohsu.edu/registrar/
- For other universities and colleges, contact the institution’s registrar.

Insurance
- Unnecessary for predocs since their insurance (Student Health) is included in their tuition and fees.
- For postdocs, use either the actual cost or the maximum cost ($726/month)

To calculate tuition fees and insurance, apply all costs up to $3000 per trainee and apply 60% of all costs greater than $3000. For example, to figure health insurance for two postdoc trainees at $8,712 each, you would first multiply the fully allowable $3000 x 2 = $6000. Subtract this $6000 from the subtotal of $17,424 ($8,712 x 2) = $11,424. Multiply $11,424 by 60% = $6856. Add $6856 to $6000 = $12,856.

Trainee travel includes attendance at scientific meetings that OHSU determines to be necessary. Trainee travel is currently allowable at the rate of $2200 per year for predocs and $3805 per year for postdocs. For more information on this topic, see the NIH website: http://grants2.nih.gov/grants/guide/pa-files/PA-02-109.html.

New Developments in NIH Commons
Diane Sharon, Grants Analyst, RSO

NIH Commons was updated to Version 2 in March 2003. It is now possible to check the status of an application, view an award summary and the Notice of Grant Award (NOGA), and access the Progress Report face pages. OHSU is participating in the test of NIH’s pilot program of Electronic Streamlined Application Process (E-SNAP), and five applications have been submitted electronically so far. It is important that PI’s update the information in their Personal Profile on Commons.

To obtain a PIN for NIH Commons or NSF Fastlane: http://www.ohsu.edu/ra/nc/gcfastlaneform.shtml

ERA Commons Demo: https://commons.era.gov/commons/help/225.htm

Entering or Updating a Personal Profile on Commons: https://commons.era.nih.gov/commons/help/215.htm

Questions about NIH Commons should be directed to Diane Sharon, x-4-8545, sharond@ohsu.edu.

Subawards
Lisa Simmons, Contract Analyst, RSO

A subaward is a legally binding written document between organizations to authorize the performance of a portion of the Statement of Work. Subawards are funded under grants and other agreements, and they incorporate special terms and conditions flowed down from the sponsor.

It is important to distinguish between Subawards, Professional Services Contracts, and Consulting Agreements. A Subaward is appropriate whenever the Statement of Work utilizes facilities, employees or resources of another organization, and when a sub-PI is contributing to the scholarly or scientific conduct of the project and expects to be named as a co-author on published results of the project. A Professional Services Contract (PSC) is a specialized contract used to acquire skills, knowledge, and professional expertise not available at OHSU. Consulting Agreements hire individuals for work as “hired experts.” PSCs and Consulting Agreements are handled through the logistics office.

For incoming Subawards, where OHSU is the recipient of a subaward from another organization, the institution issuing the subaward may require OHSU’s documents to be included in their application to the sponsor. These documents must be submitted to RSO for review and institutional signature before they are returned to the department for mailing to the subawarding organization. For “first year” applications, documentation should include the following:

- Proposed Project Questionnaire (PPQ)
- Statement of Work (SoW)
- Detailed Budget (both direct costs and F&A costs)
- Any other required documents
- Include an address for the Statement of Intent

When the outside organization receives its funding, it will issue a subaward and send documentation directly to RSO. This subaward is matched to the documents previously submitted to RSO. The PI is contacted to review and approve the budget and Statement of Work. The subaward is reviewed and negotiated to ensure that OHSU’s legal, policy and fiscal objectives are met. Work can begin once the following have been satisfied:

- Subaward is fully executed (i.e., signed by both institutions)
- All necessary compliance issues are completed
- Copies of the subaward are sent to the department and to SPA for account set-up

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Incoming subawards are typically written for a year or less. For multiple year awards, OHSU will receive a new award every year. To apply for subsequent years, a Statement of Work and a detailed budget must be submitted to RSO.

When OHSU arranges an outgoing subaward with another organization, the following items are required from the potential subawardee at the time of proposal submission:
- Signed document indicating funds to be awarded
- Detailed budget (including both direct costs and F&A costs)
- Statement of Work
- Bios and other documents as dictated by the sponsor

Once OHSU receives the Notice of Grant Award (NOGA) from the sponsor, an outgoing subaward can be established with another organization. Use the Request for Subaward form available online: [http://www.ohsu.edu/ra/forms.shtml](http://www.ohsu.edu/ra/forms.shtml). Once this completed form is received by RSO, it is matched to the information previously submitted and a subaward is prepared incorporating the Terms & Conditions of the sponsor. The prepared subaward is sent to the PI for review and signature. Once the signed subaward is returned to RSO, it is given an institutional signature and forwarded to the subawardee for review and signature. The subawardee PI’s work can begin once the fully executed subaward is sent to SPA and account set-up is completed.

Outgoing subawards are written for one-year increments. Each year a new Request for Subaward and detailed budget must be submitted to RSO to continue collaboration. Amendments will be issued to cover situations such as increased funds, change in time frame, no-cost extensions, and carryover of funds.

**Industry-Sponsored Clinical Trials**

Rose Fong, Clinical Studies Coordinator, RSO

Often, an Industry-Sponsored Clinical trial begins by a pharmaceutical company contacting the principal investigator (PI) to determine his/her interest in participating in the trial. The PI may then receive the Protocol and Investigator’s Brochure, a contract and budget, and be asked to sign a Confidentiality or Non-Disclosure Agreement (CA/NDA).

The PI is reminded to submit paperwork for Institutional Review Board (IRB) review of the Protocol as soon as possible because patient enrollment cannot begin until IRB approval is obtained. The PI is also reminded that copies of the contract, budget, and CA/NDA must be provided to Rose Fong, Clinical Studies Coordinator in RSO. She reviews the contract for required terminology and for an appropriate payment and terms schedule. She reviews the budget to assure adequate reimbursement for patient services, personal time, and start-up costs, as well as the correct F&A rate (25%). Rose reviews the CA/NDA to make certain that the interests of the PI and the University are protected adequately. She also negotiates terms with the sponsor, finalizes the contract, invoices the sponsor for start-up costs, and coordinates with Sponsored Projects Administration.

For budget training of Study Coordinators and PIs, or with other questions about setting up Industry-Sponsored Clinical Trials, contact Rose Fong, x4-4856, [fongr@ohsu.edu](mailto:fongr@ohsu.edu).

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**Award Set Ups**

Barbara Carroll, Grants/Contracts Specialist, RSO

Barbara (Fisher) Carroll explained how awards are received in the Research Support Office. The following Award Notices are now sent electronically:
- Notices of Grant Award (NOGAs) from NIH and other federal sponsors
- Revisions to current federal awards (e.g., change in PI, no-cost extensions, etc)
- National Research Service Awards (NRSAs), including Activation Notices and Payback Agreements

Awards from foundations and private corporations are still sent as hard copy documents, together with the terms and conditions of the awards.

RSO is required to assemble the following information about every grant award prior to sending the award to Sponsored Projects Administration for account set-up.
- Two copies of the application
- IRB/IACUC Approval (as required)
- A budget that totals to the award made by the sponsor
- A current copy of the Conflict of Interest (COI) on file
- Proof of Responsible Conduct of Research (RCR) training

The speed of award set up is dependent upon the speed with which required information is provided to RSO. Delays commonly result from missing applications, revisions needed to the budget, failure to obtain IRB/IACUC approval or to provide COI or proof of RCR training. Delays can also be caused by pending negotiations on a given agreement.

**Pre-Award Accounts, Accelerated Spending, and OHSU Signature Authority**

David Erem, Manager, RSO

To avoid confusing the Pre-Award Spending Request and the Accelerated Spending Request remember that pre-award spending refers to account activity allowed before the very first year of an award, while accelerated spending is activity permitted in advance of a renewal or before the subsequent year in a continuing award. In either case, opening spending before formal authorization represents an institutional risk that must be evaluated before it is accepted.

OHSU Signature Authority refers to the closely guarded authority to enter into binding agreements on behalf of the institution. PIs are not legal entities and are not permitted to sign agreements on their own behalf. Official signatures may be obtained by directing documents to the pre-award office. David Erem, Deb Golden-Eppelein, and Tom Marcussen are designated as having OHSU Signature Authority.

**Grant Application Copies - Self-Addressed Envelope Now Provided**

Larry Dumas, Grants Analyst, RSO

A self-addressed envelope will now be provided when a signed grant is sent to the department. For more details, see the “Hot Topics” section on page 1 of this newsletter.

For more RSO information please call 503.494.7887, or visit them online at: [http://www.ohsu.edu/ra/gc](http://www.ohsu.edu/ra/gc).
Next month Sponsored Projects Administration will offer two classes on the effort certification process, which, as you know, has changed significantly during the past year. We will cover those changes, and go into considerable depth on cost sharing and how it should be dealt with in relation to effort certification.

We’ll answer all questions during the class about this very visible Federal regulation.

The information in the class will benefit Principal Investigators, “departmental administrators” (including departmental administrators, division managers, department fiscal managers, and especially department effort coordinators), and all others who work with the effort certification process.

Pre-registration is recommended as seating is limited and workshop materials must be prepared in advance. Please contact SPA Education (spaedu@ohsu.edu or 503-494-9063) to register.

Please see below for locations and times.

**Main Campus:**
Tuesday, July 22, 2003
9:30 am - 11:30 am
UHS 8B-60

**West Campus:**
Wednesday, July 23, 2003
9:30 am - 11:30 am
Montagna Auditorium - Primate Center
OGA Report Guide

In order to help you better manage your grant funding, we have compiled a helpful list of OGA and datawarehouse reports useful for this purpose. The list shows reports available, information that is included, and parameters that can be used on the reports. If you have any additional questions about the reports please contact the Oracle Help Desk at 503-494-4524. You will find the guide at the back of this newsletter.

OGA Training

Everyone involved in sponsored projects grants management is invited to attend an OGA training class. Classes are limited in size due to computer availability. Please join us in learning all areas of OGA.

Contact Juris Solovjovs at 494-9806 or email solovjovs@ohsu.edu to register.

OGA Training Classes

July 16, 2003  1:00-4:00 BICC 122  
August 6, 2003  1:00-4:00 BICC 122  
September 3, 2003  1:00-4:00 BICC 122  
For dates beyond September, please visit: www.ohsu.edu/ra/spa/ogaschedule.shtml

Oracle Drop-In Sessions

Here’s an opportunity for end users who have already been trained in Oracle to get one-on-one help in the system. Both a Discoverer and an OGA Trainer will be present at each of these sessions to answer any specific Oracle Grants Accounting questions.

Oracle Drop-In Sessions

July 10, 2003  1:00-4:00  BICC 122  
July 24, 2003  9:30-12:30  BICC 122  
August 13, 2003  1:00-4:00  BICC 122  
August 26, 2003  9:30-12:30  BICC 122

Purchase Order Conflicts and OHSU/Vendor Relations

When placing an order with an external vendor, please make sure a new purchase order number has been assigned by the person in your department who handles requisitions. Serious account problems can result from using an old purchase order number—even if it was originally used for the same vendor. Once a requisition has been filled by receipt of the original merchandise, the purchase order is closed and the purchase order number is no longer active. Any subsequent requisitions erroneously placed against this closed purchase number order cannot be paid. Not only does recycling a used purchase order number create internal accounting problems, it damages OHSU’s relationship with outside vendors who are understandably upset at not being reimbursed for merchandise they provided to OHSU researchers in good faith. Avoid this issue by contacting your department requisitioner whenever placing a new order.

MARK YOUR CALENDAR

Next SPIN Meeting is Thursday, July 17, 2003 in UHS 8B-60
Historically, scientists have had the freedom to share the results of their research, which can be in the form of discoveries, reagents, and protocols, with other investigators. The transfer of these “materials” was done in good faith under the premise that it would facilitate new advancements and collaborations and, ultimately, led to the greater human benefit. For many, if not most, researchers, such good faith transfer of scientific materials is still the norm and formal contracts, such Material Transfer Agreements (MTA), serve as inconveniences and, in more extreme cases, as impediments to research. This trend, however, has been changing in recent years as there has been an increase in the interaction between corporations and academic institutions. The OHSU Office of Technology and Research Collaborations (TRC) is now embarked in a revolution of sorts in which we hope to alter the flavor somewhat of how we negotiate with our corporate partners.

Pharmaceutical and biotech corporations are looking to the universities to provide the basic research that underpins many of their new products. Meanwhile, academic scientists are relying increasingly on commercial entities for a wide variety of research materials ranging from bacterial strains and fruit fly DNA to antibodies and novel cancer-fighting drugs. Since virtually all companies are keen to gain a commercial advantage from their proprietary materials, the language in their MTAs tend to be restrictive with respect to the ownership of new inventions arising out of a given project as well as the terms of licensing rights to those inventions and the ability of the researcher to freely disseminate the results of those studies. It important to note here that under an MTA, companies only provide the actual material and not financial sponsorship for the studies, so that most studies using commercially obtained materials are typically funded by Federal agencies such as the NIH, NSF, foundations, etc.

The results, reagents, discoveries, protocols, and inventions generated from the research activities at OHSU result from a considerable investment of thought, physical effort, and funding and, moreover, they form the basis for on-going, immediate and long-term future studies. A paramount goal of TRC is to protect both investment and any potential future work from far-reaching and unfair terms that are often encountered in commercial MTAs. More simply put, we try, when dealing with non-academic MTAs, to preserve for our scientists and clinicians the ability to perform unrestricted investigation in whatever lines of research that might lead, the free dissemination of their results, and the pursuit of inventions.

In contrast to our goal to provide an environment of unhindered academic freedom for our scientists, pharmaceutical and biotech corporations need to maintain both a strict control over their compounds as well as their freedom to explore and exploit new uses for those compounds. As a consequence, we often receive commercial MTAs containing language giving a company non-exclusive and royalty free rights to any OHSU invention pertaining to the study of their compound. While this may seem prima facia fair and reasonable, granting non-exclusive rights to our inventions would, in all likelihood, temper the incentive of other companies to pursue commercialization under the new invention, a position that would hinder our ability to obtain new compounds to further our research. Moreover, the terms for the exclusive license are often worded in a way as to preclude our researchers from obtaining compounds from other sources for use in our inventions. This has become a heated issue in industry-academic contracts and compounding the central issue is the need for having clearly understood and defined rights in the language of the MTA.

TRC is now working with our corporate pharmaceutical partners to change the licensing terms in their MTAs such that we can preserve the ability and incentive for drug development companies to test new products under our inventions and, ultimately, get those products out to the patient population- in fact, under the Bayh-Dole Act, universities receiving Federal sponsorship are mandated to do just this. In addition, the terms we propose help us to avoid assigning conflicting intellectual property rights to our different non-academic partners. This position should serve to preserve the partner’s willingness to work with us over the long term. The effectiveness of our enterprise will be all the greater for the OHSU scientist if we can succeed in preserving his or her ability to use funding and materials from different sources.

For More TRC information, please call 503.494.8200, or visit them online at: www.ohsu.edu/tech-transfer
The OHSU Clinical Research Program is presenting an all-day seminar on “Conducting Successful Clinical Trials”. This program, scheduled on July 16, 2003, in MacHall room 1162 is designed to provide investigators, both from the sponsor and institutional perspective, the information and tools required to successfully conduct industry sponsored clinical trials at OHSU. Experienced and new investigators conducting, or interested in conducting, industry sponsored clinical trials will benefit from attending this program. For more details, please see the agenda below.

Please contact Sandra Kollenburn at 503-494-5649 or kollenbu@ohsu.edu if you plan on attending. There is no fee for this session.

**AGENDA**

8:30 Registration and Continental Breakfast

9:00 Welcome and Introduction
Eric Orwoll, MD, OHSU Professor of Medicine; Associate Dean, Clinical Research; Assistant Vice president, Research; Program Director, General Clinical Research Center

9:15 The Drug Development Process
Michael McClung, MD, Director, Oregon Osteoporosis Center; Assistant Director, Department of Medical Education, Providence Medical Center; Associate Professor of Medicine, OHSU

10:15 AM: Relationship of Investigators, Staff and Study Sponsors
Sidney A. Spector, MD, PhD, Director, Regional Medical Research Specialist, Pfizer Inc.

10:30 AM: The Business Perspective
Charles Stark, PharmD, Director, Regional Medical Research Specialist, Pfizer Inc.

11:00 AM: Adverse Events Reporting for Industry Sponsored Clinical Trials:
Darlene Kitterman, MBA, Associate Director, OHSU Clinical Research Program; Assistant Professor, School of Nursing
Rose Fong, Clinical Studies Coordinator, OHSU Research Services Office

11:45 AM: Independent Medical Grants and Unrestricted Educational Grants
Denis Ishisaka, PharmD, Director, Regional Medical Research Specialist, Pfizer Inc.

12:15 PM: BREAK

1:00 PM: How to Get Your Clinical Trial Started
Darlene Kitterman, MBA, Associate Director, OHSU Clinical Research Program; Assistant Professor, School of Nursing
Rose Fong, Clinical Studies Coordinator, OHSU Research Services Office

2:00 PM: The IRB and Industry Sponsored Clinical Trials: What the Investigator Needs to Know
Charlotte Shupert, PhD, OHSU IRB Compliance Manager

3:00 PM: Adverse Events Reporting for Industry Sponsored Clinical Trials:
What the Investigator Needs to Know
Darlene Kitterman, MBA, Associate Director, OHSU Clinical Research Program; Assistant Professor, School of Nursing

4:00 PM: HIPAA: How Your Clinical Trials Have Been Affected
Gary Chiodo, DMD, OHSU Corporate Compliance Office, IRB Chair

5:00 PM: Program Close and Departure
Eric Orwoll, MD, OHSU Professor of Medicine; Associate Dean, Clinical Research; Assistant Vice president, Research; Program Director, General Clinical Research Center.
Coming Events

NCURA Fundamentals

**Mark Your Calendar**
Monday, September 8, 2003, 9am-5pm  
Tuesday, September 9, 2003, 9am-5pm  
Wednesday, September 10, 2003, 9am-12pm

Mark your calendar and start making room in your budget. Sponsored Projects Administration is bringing the national workshop to OHSU. Don’t miss out on this amazing opportunity to attend this excellent three-day training course without the expense of travel!!

Watch for coming announcements about registration.

Individuals involved in sponsored project administration are faced with a multitude of challenges—requirements and regulations, faculty assistance, resource information gathering, negotiation, reporting and many other tasks. This program will provide an overview on all aspects of award administration, including preparation and internal review of the proposal, negotiation and acceptance of an award, financial and administrative management, closeout and audit. Both the financial and non-financial administrator will present a comprehensive overview of this complex and constantly changing administrative environment.

July Brown Bag

**Confidentiality Agreements**

Monday, July 14, 2003,  
11:30 a.m. to 12:30 p.m.

OHSU Hospital Auditorium, Room UHS 8B60,  
(8th floor, Wing B, Room 60)  
or watch via video conference at OHSU West Campus  
Columbia Conference Room #277  
1100 CSE Compton Building, OGI

The presenters will be Mary Foley, Ph.D. and Michele E. Gunness, Ph.D., OHSU Technology and Research Collaborations.

“Can you keep a secret?” This brown bag presentation will discuss both the benefits and perils of sharing your ideas, data or inventions with others, and the constraints placed upon you when others share their ideas, data or inventions with you. The presentation will also discuss the precautions you can take to prevent theft of your ideas without a confidentiality agreement in place.

Post-award Education Program

**Effort Reporting Class (Main Campus)**
Tuesday, July 22, 2003  
9:30 am - 11:30 am  
UHS 8B-60

**Effort Reporting Class (West Campus)**
Wednesday, July 23, 2003  
9:30 am - 11:30 am  
Montagna Auditorium - Primate Center

Please see page 4 of this newsletter for a full description.