Welcome to...RAIN
(the meeting formerly known as SPIN)

Presented by: the folks in RDA, today's emcee is Dana Director
Date: January 20, 2011
Agenda
Dana Director

- Intros
- Updates & timely information from the units:
  - Office of the VPR
  - RGC
  - SPA
  - Research HR
  - ORIO
  - OCTRI
  - CTO
  - CRBO
  - RFDS
  - TTBD

- Q & A
• VPR
  – Office of the Vice President for Research
• Changes at NIH
• PwC analysis timeline
• Bancroft Building & better RDA integration

• New RDA Education Coordinator:
  – Margaret Gardner
• RGC
  – Research Grants & Contracts
• Staff Update
  – Danny Stockdale started 1/10/11
  – One open GCA position
• NIH operating under continuing resolution

• Deadline for submitting proposals to RGC
  – Completed application, including final science due to RGC 3 business days before deadline
### Sponsor Deadline*  |  RGC Deadline*  
---|---  
Monday  |  Prior Wednesday  
Tuesday  |  Prior Thursday  
Wednesday  |  Prior Friday  
Thursday  |  Prior Monday  
Friday  |  Prior Tuesday  

*Deadline time is dependent on the time the proposal is due to the Sponsor. If the Sponsor requires it by 5pm on the deadline day, then the RGC deadline is also at 5pm. If the Sponsor requires submission by 1pm on the deadline day, then the RGC deadline is also at 1pm.

*For most sponsors, if a deadline date falls on a Saturday or Sunday, the deadline is moved to the following Monday.*
InfoEd – B1 vs B forms
- K, F, T, D mechanisms – B1 forms required as of 1/25/11
- All Other mechanisms – B1 forms required as of 5/7/11
• SPA
  – Sponsored Projects Administration
• SPA Electronic Suggestion Box
  – http://www.ohsu.edu/research/rda/spa/

• Signing on behalf of others
  – Sign your name
  – Write “on behalf of [person’s name]” of “for [person’s name]” underneath or next to your signature
• Labor Cost Transfer Approval (LCTA) form
  – Now accepting copies of signatures as originals
  – Reserve the right to reject illegible forms
    • Usually results from poor quality fax machines or multiple faxing of the form
• Jul10-Dec10 Effort Period
  – Effort Period Ended December 31, 2010
  – Effort Period Closes February 14, 2011
  – LCTA forms due to SPA February 11, 2011
  – Statements scheduled to be distributed the week of February 28, 2011.

• R12 Effort Statement Preview
**Employee Effort Certification Form**
For The Period of 1-Jul-2010 - 31-Dec-2010

**Employee Name:** Schultz, Charles  
**Employee Number:** 12345  
**Primary Organization:** SM Peanuts Laboratory

<table>
<thead>
<tr>
<th>Project Number / GL Account</th>
<th>Award Number</th>
<th>Project Description</th>
<th>Award Name</th>
<th>Committed</th>
<th></th>
<th></th>
<th></th>
<th>Actual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assignment Number 12345</td>
<td></td>
<td></td>
<td></td>
<td>0.00</td>
<td>0.00</td>
<td>20.00%</td>
<td>0.00</td>
<td>0.00</td>
</tr>
</tbody>
</table>

**Effort Category:** GL Related Activities

<table>
<thead>
<tr>
<th>Award Name</th>
<th>Cost Share %</th>
<th>LD Effort %</th>
<th>Corrected LD %</th>
<th>Cost Share %</th>
<th>Total Effort %</th>
</tr>
</thead>
<tbody>
<tr>
<td>APEAN0001 DHHS Snoopy Study of classical music and the brain</td>
<td>30.00%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>APEAN0001 DHHS Snoopy Study of classical music and the brain</td>
<td>15.00%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GPEAN0003 NSF Snoopy Beagle behavior study</td>
<td>35.00%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total Effort For Assignment</strong></td>
<td>100.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
<td>0.00%</td>
</tr>
</tbody>
</table>

**Note on Suspense Activity**
Suspense activity must be cleared before certifying the statement. When returning the statement please write neatly, in ink, what the funding sources should have been and attach a copy of all appropriate back-up documentation.

**Note on Cost Sharing**
Please enter the amount of cost sharing the Cost Share % Column. When the cost share column is completed correctly it should sum to zero.

**Note on Federal Salary Cap**
It is the department's responsibility to ensure salary charges on NIH, SAMSHA, and AHRQ awards are not distributed at a rate in excess of the salary cap for those sponsors. If the covered individual's total salary is in excess of the cap then the LD % cannot be certified equal to Total Effort % on each applicable project. The difference between allowable salary distribution and actual effort should be reflected in the Cost Share% column or captured in a Cost Share companion account.

**Certification Statement**
I certify that I have reasonable means of verifying the activities performed by the above mentioned employee and that the distribution of effort represents a reasonable estimate of the actual work performed by the employee during the period covered by this report.

**Covered Individual**  
**Date**

Or

**Responsible Person**  
**Title**  
**Date**

The Responsible Person's relationship to the Covered Individual must be Principal Investigator or Supervisor.

RAIN: 01.20.2011
• What’s new
  – Consolidated Cost Share column
  – Dedicated column for corrected LD changes
  – Removal of the old “Relationship” check box
  – Committed Effort and Cost Share columns
    • These columns will remain inactive until data is available
• Training Grant Reminder
  – Rebudgeting from the stipend and tuition/fees categories to cover items classified as training related expenses is not allowed
  – Training related expenses are intended to cover health insurance as well as PI and/or admin salary (where applicable)
• Research Outreach Project (ROP)
• What is ROP?
  – The Research HR team wanted to identify needs and satisfaction regarding the workplace from the research ranked employees’ perspective.
  – We wanted to find a way to fully connect with the research-ranked staff members in a meaningful way.
  – We wanted to hear directly from them and be able to have a proactive and comprehensive plan for next fiscal year to 1) deliver what is most needed to our research-ranked staff member community and 2) stop the reactive approach to HR needs and issues for this population in Research and across OHSU.
What have we “ROP”ed in so far?

- So far, since November, we have conducted 16 focus groups (four being at West Campus) with 91 randomly selected research-ranked employees.
- Based on the information gathered in those focus groups, we have developed a comprehensive survey, including “hot topics” we heard in the focus groups.
- The survey will be sent out today (hopefully) to our 1800 researchers across OHSU.
• What is next?
  – After we receive the results from the survey, we will analyze the trends from the focus groups and the overall survey.
  – We will determine what programs, offerings, changes, and additions we will recommend to research and academic leadership based on this project.
  – We will share the findings with you!
• ORIO
  - OHSU Research Integrity Office
• Welcome Bill Dale
  – Research Integrity Officer
• OCTRI
  – An overview & latest updates
Translational Research at OHSU as supported by OCTRI

Julie Earnest, PhD
Exec. Director, OCTRI
January 20, 2010
What is translational research?

Moving from health application to evidence-based guidelines

Disseminating to providers and comparing effectiveness

Moving laboratory findings into animal and human models
The NIH CTSA Initiative

**THEN**
- General Clinical Research Centers (GCRC)
- Individual investigators doing clinical research

**NOW**
- CTSA Clinical & Translational Science Awards
- Multidisciplinary teams collaborating on translational projects

Budget cuts resulting in $3M decrease in FY12, transition to fee-for-service model for most services, with subsidies for certain categories of services and investigators.
Cindy McEvoy, MD, MCR

Impact of Vitamin C on toxicity of maternal smoking

- Eliot Spindel pilot data
- CREF Award from GCRC
- HIP degree lead to K award
- Statistical, lab, data warehousing services from OCTRI
- Pilot project funding for joint OHSU-KPCHR study
How can OCTRI help me?

Going from an idea to a research project

Designing a Study  
Fulfilling Compliance  
Funding  
Nursing & Laboratory  
Data Analysis  

Education & Training

OCTRI Navigator Service – Gateway to OCTRI resources  
octri@ohsu.edu

www.octri.org/services
How can OCTRI help me?

**OCTRI-sponsored CORES shown in bold**

- Advanced Computing Center
- Advanced Light Microscopy Core
- Bioanalytical / Pharmacokinetics
- **Biolibrary**
- **Biomedical Informatics**
- **Bionutrition Unit**
- **Biostatistics**
- **Community Practice Research**
- **Clinical & Translational Research Center**
- DNA Microarrays

- **DNA Services**
- **Electronics & Instrumentation Design**
- **Flow Cytometry**
- **Histopathology**
- **Massively Parallel Sequencing**
- **Pediatric Clinical & Translational Research Center**
- **Primate Research Center**
- Proteomics
- **Transgenic Mouse Models**
How can OCTRI help me?

- Clinical & Translational Research Center
- Regulatory Support
- Research Data Warehouse
- Clinical Informatics
- Biostatistics Consulting
- Bioinformatics / Statistical Genomics
- Community Engagement
How can OCTRI help me?

- Organizational umbrella for OHSU’s various biospecimen collections
- Web portal provides information on collections and ability to search specific collections

OHSU BioLibrary

A Joint Project between OCTRI and the Knight Cancer Institute

The OHSU BioLibrary provides information on campus collections of biospecimens originating from OHSU patients. The BioLibrary is a joint initiative of the Oregon Clinical & Translational Research Institute and the Knight Cancer Institute.

The BioLibrary Search Engine is a user-friendly, online search tool that allows OHSU researchers to search for suitable biospecimen samples without having to know any protected patient information. As of October 2010, the BioLibrary Search Engine contains data on over 600,000 biospecimens. The Search Engine accesses data from the OHSU Cancer Registry, the Department of Pathology, and the OCTRI Research Data Warehouse.

- Go to the BioLibrary Search Engine.

www.ohsu.edu/biolibrary
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OCTRI Navigator Service – Gateway to OCTRI resources
octri@ohsu.edu

www.octri.org/services

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• ISIS & CTO
  – Investigator Support & Integration Services
  – Clinical Trials Office
• Investigator Support & Integration Services (ISIS) Voluntary Services
  – Grant and study budget development
  – IRB applications
  – Regulatory consultation
    • IND/IDEs
    • GCP monitoring for IND/IDEs
    • DSMB planning
    • Clinicaltrials.gov registration
• Other ISIS functions:
  – CTO Contracting: Clinical trial Contracts
  – OCTRI Navigator Service
  – Study Coordinator training
• CRMS Update
  – Vendor selected
  – Next steps:
    • Contract with vendor
    • Brown bag
    • Sandbox will be made available
• CRBO
  – Clinical Research Billing Office
Medicare Advantage changes 01/01/11
- Eliminates additional out-of-pocket expense & removes disincentive to enroll on study
  • OHSU to file with Med Adv Plan on patient’s behalf after payment from Medicare
  • Out-of-pocket should be equal to Med Adv co-pay -- OHSU will bill
  • No difference for in-network and out-of-network
• Notifying Med Adv patients
  – Currently enrolled and new study patients should be notified
  • Form located at http://www.ohsu.edu/xd/research/about/integrity/irb/clinical-research-billing.cfm
  • No patient signature required
  • No IRB approval required
• Device trial enrollment notification
  – Email CRBO@ohsu.edu with patient name, MRN & study at time of enrollment

• Research Rates forms
  – Updated old form and created new – either one can be used
  – Located at http://ozone.ohsu.edu/research/rates/index.shtml
• Next month:
  – Final Invention Statement Process
Wrap Up

Everyone

Q & A

Next Meeting: February 17, 2011, 9:30 AM

Send agenda item requests to: rain@ohsu.edu