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

Presented by: the folks in RDA, today’s emcee is James Trotter
Date: November 18, 2010
Agenda
James Trotter

• Intros
• Updates & timely information from the units:
  ✓ TTBD
  ✓ Special guests (2)
  ✓ SPA
  ✓ RGC
  ✓ Research HR
  ✓ ORIO
  ✓ CTO
  ✓ CRBO
  ✓ Office of the VPR
  ✓ RFDS

• Q & A
• MTA Process
  – Materials Transfer Agreements
  – [see TTBD slides attached to the end of this presentation, courtesy of TTBD]
• Guest presenter:
  – OHSU Campus Store
  – Karen Seresun
• **OHSU Campus Store**
  – Online: [www.ohsu.edu/store](http://www.ohsu.edu/store)
  – In person: OHSU Student Center
  – Call customer service: 503.488.4290

• **Discounts for OHSU employees**

• **Customize items for your unit:**
  – Sweatshirts, caps, shirts, drinkware, USB drives, writing instruments
Guest Presenter:
- Research Value Analysis Task Team
- Donna Johnson
Membership

• 17 research departments, 33 members represented
• Cross collaboration between PI’s, lab managers/personnel, department administrators, Oracle users, research support, and Purchasing

Initiatives

• Community driven
• Cost savings opportunities
• Effective communication
• Value added focus
Savings 12/2009 to 10/2010

- Remi equipment maintenance management program- $41,792
- Thermo service contract- $34,229
- Fisher savings- $58,179
- VWR and E&I contract- $58,376
- Buyer sourcing- $17,393
- Rainin free freight- $7,768
- Rainin OnSite PM- $1,719
- Large lab orders- $1,786
- Roche bulk buy- $2,144, plus green savings
- Savings opportunity of the month, Custom Oligos- $880

Total Savings- $224,266
RVATT Highlights:

- Research procurement portal [LIVE](http://pdxlogapps.svr.ohsum01.ohsu.edu/logistics/purchasing/ResearchProcurementPortal.html)
- Research purchasing blog [LIVE](http://ozone.ohsu.edu/blogs/researchpurchasing/)
- Greening research waste: recycling and surplus
- Novation Medical Research Advisory Council
- Savings opportunities
- RVATT roadshows
Looking Ahead:
- Maximize contracts
- Partner with area universities
- Equipment needs database
- New lab set-up
- Blog utilization
- Product categories for review
- Buyer mentoring
- Track savings

Questions?
• SPA
  – Sponsored Projects Administration
• **Labor Distribution (LD) Queue Purge**
  – Necessary for Oracle Release 12 (R12) conversion
  – All pending LD adjustments will be purged the week of December 6th
  – Labor Distribution Module will be locked down from Wednesday 12/8/10 through Monday 12/13/10

• *Note: This is not an effort reporting related purge, however the process will be the same*
• **Effort Reporting**
  - Statements were due 10/19/10
  - 1\textsuperscript{st} & 2\textsuperscript{nd} outstanding notices have been sent
  - 3\textsuperscript{rd} notice from SPA Director to Department Administrator goes out 11/23/10
• RGC
  – Research Grants & Contracts
• NIH Updates:
  – Notice of Revised NIH Term of Award on use of DUNS Number and New Term of Award on Maintaining an Active CCR Registration (NOT-OD-11-004) National Institutes of Health
  – Notice of New NIH Term of Award on Transparency Act Subaward and Executive Compensation Reporting Requirements (NOT-OD-11-005) National Institutes of Health
  – Notice of Revised Eligibility Requirements and Award Administration Information in NIH Funding Opportunity Announcements (NOT-OD-11-006) National Institutes of Health
• NIH Updates continued:
  – Non-Competing Grant Awards under the Current Continuing Resolution (NOT-OD-11-015) National Institutes of Health
  – Notice of Need to Expire and Reissue Fellowship Applications (Fs) to Comply with Language in New Application Forms (NOT-OD-11-018) National Institutes of Health Agency for Healthcare Research and Quality
  – New Format Change Announced for NIH, AHRQ, CDC, and FDA Funding Opportunity Announcements (FOAs) (NOT-OD-11-019) National Institutes of Health
**Submission Mechanism/Form Information**

Proposal Sponsor is set to **National Institute of Arthritis & Musculoskeletal & Skin Diseases/NIH/DHHS**.

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<th>Yes</th>
<th>No</th>
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Opportunity Number: PAR-10-282

**Grants.Gov Submission Information**

Opportunity Number: PAR-10-202

Opportunity Title: Pilot and Feasibility Clinical Research Grants in Arthritis and Musculoskeletal and Skin Diseases (R21)

Offering Agency: National Institutes of Health

Open Date: 17-Oct-2010

Close Date: 10-Jul-2013

CFDA Number: 93.846

CFDA Description: Arthritis, Musculoskeletal and Skin Diseases Research

Competition ID: ADOBE-FORMS-B1

Form Version: ADOBE-FORMS-B

RAIN: 11.18.2010
Research HR:
Amber Bruner & Rachel Borsch

Community Giving

- Community Giving Campaign
  - Update
• ORIO
  – OHSU Research Integrity Office
Human Data/Tissue Repository Policy Rollout continues...

- We are 3 months into our year long program

- Website: http://www.ohsu.edu/xd/research/about/integrity/irb/repository-policy.cfm

- Compliance program ends: August 19, 2011
• What is considered a human data or tissue repository?

  – The collection and storage of human data/specimens becomes a research repository when there is a specific intention for the human data/specimens to be used repeatedly for research purposes, or stored for future research and/or shared with other investigators.

  – Any collection of human data/specimens is considered to be a repository when there is no explicit plan to destroy the materials when the specific research project that generates the materials ends.
There are three main routes to achieving compliance with the Human Repository Policy using eIRB:

- Create a “Repository Only” submission
- Create a “New Study” submission that includes a repository component
- Complete additional policy requirements within an existing submission, either through Modification or Continuing Review
• Questions?
  – Contact an IRB analyst
    • 4-7887, option 1
  – We are available to meet or present
    • Contact Mindy Roberts or Susan Bankowski, IRB Chair
• CTO
  – Clinical Trials Office
Consulting Agreements

Currently:
- Investigators must enter into consulting agreements with companies independently (outside OHSU)
- Receive any income from consulting directly

Issues
- Conflict of interest
- OHSU does not receive $
- Liability to investigator

Potential solution being considered: Give investigator the option for OHSU to negotiate/execute consulting agreements
Clinical Trial Contracting: Educating clinical trial investigators

- CTO has experienced problems with investigators not understanding clinical trial contracting
  - Process
  - Investigator responsibilities
- CTO outreach to new clinical trial investigators
  - Introductory email
  - Encourage “meet and greet”
    - Meet negotiator
    - Review process
    - Review first study/potential issues
- Complex agreements (investigator initiated, coordinating center, co-developments, etc.): Meetings to review study prior to negotiation
- Other ideas?
• CRBO
  – Clinical Research Billing Office
• New staff
  – Kristin Pattee-Couture – Clinical Research Coverage Analyst

• New email address
  – CRBO@ohsu.edu

• New Clinical Research Billing Schedule
  – Located in IRQ in eIRB
  – Mandatory starting 12/1/10 for new submissions
• VPR
  – Office of the Vice President for Research
• School of Medicine proposal approval routings

• PPQs & InfoEd
  – Route to Dean Mark Richardson
  – Dean’s office staff triage for signatures/InfoEd approvals
Q & A

Next Meeting: January 20, 2011, 9:30 AM
(Happy New Year!)
“The vision of OHSU is to be a national and international leader in healthcare, education, research and technology development.”
Background: What is an MTA?

Contract that governs the transfer of research materials between organizations

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<th>Types</th>
<th>Parties</th>
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<tbody>
<tr>
<td>Simple</td>
<td>Academic &amp; non-profit institutions</td>
</tr>
<tr>
<td>Negotiated</td>
<td>Industry</td>
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“The goal of research commercialization is to bridge the gap between promising research and public benefit.”
Background: Why are MTAs important?

"Promote innovation and an entrepreneurial culture which enables the transfer of research from laboratory to market for public benefit."
MTA: In versus Out

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MTA Out

MTA In

Outside Organization
MTA Out Process

**Non-Profit / Academic MTA Request**
- Recipient contact
- Recipient PI brief research description

**Signature Process**
- Create and email MTA
- We do not sign!

**Receive Signed MTA**
- Authorize shipment

Industry MTA Out Requests are **not** MTAs

**License Agreement Negotiation**
MTA In Process

MTA Request
- MTA draft
- Recipient contact
- PI brief research description

Acceptable?

Yes
- Signature Process

No
- Negotiation
  - Publication rights
  - Invention rights
  - Indemnification
  - Material definition
  - Jurisdiction

Simple MTAs

Negotiated MTAs
Negotiated MTAs: Key Considerations

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Benefits
• Publication rights
• Federal compliance
• Ownership rights over inventions
• Enable important research

Burdens
• Indemnification
• Overly inclusive “material” definition
• Jurisdiction
• Onerous confidentiality restrictions

Company

Benefits
• Nonexclusive invention rights
• Exclusive option over invention
• Data and results of research

Burdens
• Loss of immediate control over:
  - Proprietary material
  - Inventions related to proprietary material
Resources

- Coordinators: Travis Cook, Arvin Paranjpe

- Managers: Arundeep Pradhan, Kristin Rencher, Michele Gunness, Andrew Watson, Chris Andon

- Online: ohsu.edu/techtransfer