Agenda

- RA Announcements
- RA Training Overview
- Grants Suspense
- Grants Cost Sharing
- Implementation of New PHS Regulations: What You Need to Know
- Human Subjects Research at St. Joseph’s
- Q&A
RA Announcements

- New Web Layout

- Nikki Simmons ~ Interim Director for OSP Contracts
- Demetrie Bryant ~ Director of Training & Communications

http://www.or.emory.edu/
## OSP & OGCA

### Education & Communication

<table>
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<tr>
<th>Communication</th>
<th>Training</th>
<th>Knowledge Management</th>
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<tbody>
<tr>
<td>Website</td>
<td>Instructor – Led</td>
<td>Job Aids</td>
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<td>Newsletter</td>
<td>E-Learning</td>
<td>Manuals</td>
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<tr>
<td>Forums</td>
<td>Continued Professional Development</td>
<td>Reference Materials</td>
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What’s New in OSP & OGCA Education & Communication?

- Training & Communications Director
- Professional Development
- Training Opportunities
- Feedback
What’s Coming Soon to OSP & OGCA Education & Communication?

- Recommended Training Paths
- Training Schedules
- Quick Video’s
- E-Learning
What’s on the Horizon for OSP & OGCA Education & Communication?

• Knowledge Management Structure
• Enhanced Training Website
• Guided Practice
• CME Credit
Emory Office of Research Administration
Education & Communication Overview
OSP & OGCA

Demetrice Bryant
dbryant@emory.edu
404-727-5581
Suspense: GOOB = UTBG as of 5/29/12

- Used to be Grants (UTBG)
- Grants Dates Out-of-Bounds (GOOB)

Linda Erhard
Suspense Clearing

Suspense items result from transactions that attempt to post to the Compass GL but contain invalid SmartKeys, Projects, or Accounts.

Four types of suspense items:
- GOOB (Grant Out of Bounds) – 3rd party feeder systems
- UTBG (Used to be Grant) – primarily salary transactions
- PFBG (Partially Funded by Grants) – primarily salary transactions
- 16000 Suspense – Accounts Payable and 3rd party feeder systems

The same goal for all four types – determining an active SmartKey for the charge.

For all four types, the department receives a spreadsheet listing with the suspense items and instructions for clearing.

Clearing GOOB or Account 16000 suspense items:
- Department enters a valid SmartKey and Account on the spreadsheet and returns to OGCA (GOOB) or Controller’s Office (Account 16000)

Tip: Return spreadsheet in the same format and with the same file name.

Clearing UTBG and PFBG suspense items:
- Department does RST to move the salary expense to the correct active grant account or departmental fund, and department does journal to move the non-salary expense to the correct active account or fund.
Suspense Clearing

GOOB transactions as of 5/29/2012 have been distributed to school business officers.

Please return the spreadsheet in the same format and with the same file name to Linda Erhard: lerhard@emory.edu

GOOB transactions will be treated as UTBG transactions, and will be posted to the UTBG or “Used to be Grants” Smartkey.

While we finalize reporting to tie back cleared transactions to original suspense items, please send correcting Smartkeys to Linda.

We will perform the journal entry with some additional notes in the reference field.
Emory University
Research Administration
Cost Sharing

Presented by: Christine Bullard
Quick Review, What is Cost Share?

- The portion of total project costs related to sponsored programs that is not provided by the sponsor.

- Cost sharing can be mandatory or voluntary, committed or uncommitted.

- Failure to provide the minimum cost sharing can result in returning funds to the sponsor.
How to provide Cost Sharing

• For all cost sharing - A cost sharing smartkey is setup during the Award setup process. The Awarded project will have a project smartkey and a second smartkey with fund code 2272 for cost sharing.

• For salary and salary related cost sharing, mandatory and committed – There are two options available. The first option, include cost sharing on the effort forms to document that the appropriate amount of time has been dedicated to the award. The second option, expense the salary to the cost share smartkey. If using the cost share smartkey the effort form will automatically reflect the cost sharing smartkey and you will not have to adjust the effort form.

• For non salary cost sharing – Use the cost sharing smartkey that was setup for the Awarded project.

• If you do not have a cost share smartkey that is linked to the Awarded project please contact your OGCA accountant to have one setup.
Allowable Cost Sharing

- Specific costs as cost sharing is usually determined by the sponsor’s specific award terms and conditions.

- Cost shared expenses must meet the same standards that apply to costs that are directly charged to a project and must be allowable and allocable under the principles included in OMB Circular A-21, Cost Principles for Educational Institutions.

- Certifiable in the effort distribution and certification process for cost shared effort and certifiable in the University accounting system for non salary sharing.

- Necessary and directly related to the project objectives and are capable of being quantified and documented.

- Cost used on a federal program may not be paid or used as cost sharing on another federal program unless permitted by statute.
To review Compass cost sharing use EUOGC014 – GM Project Summary report
To Review Pre-Compass cost sharing
use FORS (Financial Online Reporting Services) report

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<td>(171,986.70)</td>
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<td>171,986.70</td>
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The cost share smartkey can be funded throughout the year and must be completely funded by fiscal year end for costs incurred.

Submit a journal entry to fund the cost share smartkey using account code 91120 series.

Include in the journal entry description identifying remarks such as “funding for cost share Award XXXX”.
Useful Links

- Cost Sharing Policy – Effort Reporting:  http://policies.emory.edu/7.17

- Cost Sharing Policy – Grants and Contracts:  
  https://www.finance.emory.edu/external/polprod/gc3.cfm

- Grants guide to Reporting:  

- Sponsored Programs Handbook: 
  http://www.ogca.emory.edu/communication/handbook/index.cfm

- OGCA Staff Listing by Department:  http://www.ogca.emory.edu/about/staff/index.cfm

- Christine Bullard, MBA, Sr. Sponsored Research Financial Analyst 
  Email: mbullar@emory.edu  
  Contact Number: 404-727-5591
Implementation of New PHS Regulations:
What You Need to Know

Karly Taylor, MS
Emory University Conflict of Interest Review Office
Who Must Complete an Investigator Financial Interest in Research Report?

At a minimum, the term Investigator includes the following:

- Project Directors, Principal Investigators, and/or members of the research team identified as senior/key personnel on the grant or contract application, progress report, or any other report;

- Individuals identified by the Project Director or Principal Investigator who are responsible for and have substantial independent decision making in respect to the design, conduct or reporting of the research, such as Collaborators or Consultants named on the grant; and

- The Investigators must report Significant Financial Interests for themselves, their spouses, same-sex domestic partners, and dependent children.

Effective Now
<table>
<thead>
<tr>
<th>What must be reported?</th>
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<tbody>
<tr>
<td><strong>PHS Investigators</strong></td>
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<tr>
<td>• Report all external activities</td>
</tr>
<tr>
<td>• Report all financial interests with entities that are related to their Institutional Responsibilities</td>
</tr>
<tr>
<td>○ Teaching</td>
</tr>
<tr>
<td>○ Research</td>
</tr>
<tr>
<td>○ Administrative</td>
</tr>
<tr>
<td>○ Clinical (if applicable)</td>
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<tr>
<td><strong>Non-PHS Investigators</strong></td>
</tr>
<tr>
<td>• Report all external activities</td>
</tr>
<tr>
<td>• Provide information about their financial interests in response to specific question asked on the forms</td>
</tr>
</tbody>
</table>
What is sent to the COI Review Committee?

- Consulting fees, licensing fees/royalties, honoraria, publicly traded stock that are greater than $5000 from
  - For profit entities
  - Non-profit entities
  - Non-US institutions of higher learning, research institutes, hospitals, and medical centers

- Any ownership/equity interests in non-publicly traded stock

- Management/fiduciary positions in a non-Emory entity

- For PHS funded investigators, any travel sponsored by
  - For profit entities
  - Non-profit entities
  - Non-US institutions of higher learning, research institutes, hospitals, and medical centers
How do Investigators make disclosures?

All disclosures for Emory personnel are made through eCOI: [www.ecoi.emory.edu](http://www.ecoi.emory.edu)

Sub-awardee Investigators, whose institution does not have a conflicts of interest policy, can complete a hard copy form available on the COI Review Office website: [www.coi.emory.edu](http://www.coi.emory.edu)
**Two Disclosure Forms: PHS & Non-PHS Forms**

### Identify Funding Source
- RA’s/Coordinators/PI’s must first identify correct funding source on Proposal Financial Interest in Research Report Form (Choice: PHS or Non-PHS)
- Any portion of project funded by PHS (direct award or subaward by another organization), indicate PHS!
  - For Example: CFAR, RTOG, ACSOG, NIH flow down to subcontract institution
- Picking the correct funding source on the Proposal Financial Interest in Research Report Form will dictate which disclosure form Investigator completes (PHS or Non-PHS form)

### Choosing Incorrect Funding Source
- If the funding source was later determined to be incorrect for the project, you will be required to amend the existing Proposal Financial Interest in Research Report Form & select the correct funding source
- Investigators will then have to complete a new disclosure form
- Proposals/projects need to be entered into eCOI no later than **Aug 3rd** for the current disclosure system.
- Investigators must complete disclosures by **Aug 8th** for the current system.
- The system will then be temporarily closed and re-opened with the updated system on **Aug 13th**.
Determination of PHS Funded/Sponsored vs. Non-PHS Funded/Sponsored Research (Page 2 of 3)

Beginning summer 2012, U.S. Public Health Service (PHS) requires institutions to collect additional information regarding Investigator's Significant Financial Interests. In order to best collect this information, we ask you to identify whether this project is funded/sponsored by a PHS agency (please see list of agencies below) or a Non-PHS agency. Your response will direct you to the appropriate form to complete.

If any portion of your project will be funded by a PHS agency (either through a direct award to Emory or as a subaward from another organization), then you must indicate that the funding source is PHS (i.e., CFAR; any cancer oncology groups such as RTOG, ACOG; NIH flow down to subcontract institution). A list of PHS agencies can be found below.

It is imperative that you identify the correct funding source so that Emory University can collect the necessary information required by PHS. If the funding source was later determined to be incorrect for the project, you will be required to complete a new Proposal Financial Interest in Research Report form and the investigators, associated with the project, will need to complete a new Investigator Financial Interest in Research Report form for the project.

**PHS Agencies:**

- Administration for Children and Families (ACF);
- Administration on Aging (AoA);
- Agency for Healthcare Research and Quality (AHRQ);
- Agency for Toxic Substances and Disease Registry (ATSDR);
- Centers for Disease Control and Prevention (CDC);
- Centers for Medicare & Medicaid Services (CMS);
- Federal Occupational Health (FOH);
- Food and Drug Administration (FDA);
- Health Resources and Services Administration (HRSA);
- Indian Health Service (IHS);
- National Institutes of Health (NIH);
- Substance Abuse and Mental Health Services Administration (SAMHSA)

**Non-PHS Agencies:** The funding agency/sponsor would be an entity NOT listed above. Some examples include:

- private corporation;
- foundations/non-profits;
- internally/departmentally funded

Please click the radio button to indicate whether this project is PHS funded/sponsored (primary or flow down under a subaward/subcontract) or Non-PHS funded/sponsored:

- [ ] PHS
- [ ] Non-PHS
WHICH GRANTS ARE NOW INCLUDED?

- Wider Scope:
  - training
  - fellowship
  - construction
  - conference grant proposals

- SBIR/STTR Phase I & GRA proposals are excluded from disclosure requirements unless human subject research is involved in the proposal

Effective August 24, 2012
When Should This Be Reported?

Emory University will not submit a proposal until Emory has on file all Investigators’ Financial Interests in Research Report forms associated with a proposal. An Award cannot be issued until any management plans related to the proposal are accepted.

- Each year of a grant or contract, an Investigator must submit a new Investigator Financial Interest in Research Report. This means:
  - The form must be done at the time of the annual progress report; or
  - Twelve (12) months after the notice of award; or
  - The initiation of the research, whichever date is earliest.

- Each Investigator must report any Significant Financial Interest prior to:
  - Submitting a formal proposal to any proposed sponsor of the research; or
  - Prior to conducting the research, even if the research is internally/departmentally funded.

- Investigators are required to update their reports in real time (i.e. within 30 days) to reflect changes in or additions of Significant Financial Interests Requiring Disclosure.
  - Amend/update External Activity Reports in eCOI
  - Amend/update Investigator Financial Interest in Research Reports in eCOI
Training Requirements

Effective August 2012

- Training on PHS regulations, Institutional Policy & Disclosure Requirements
  - Prior to submitting an award under new policy
  - Prior to receiving award under new policy
  - Every 4 years thereafter
  - Immediately
    - Upon change of policy
    - Investigators new to Institution
    - Upon finding of non-compliance

- Training will occur for both Investigators and Staff within the first NOA after the August 2012 implementation
  - Training will occur in the eCOI system
  - *All users will not be able to complete an action in eCOI until you complete training (i.e., Submit Proposal, Complete Financial Interest Disclosure, Submit External Activity Report, Complete Annual Certification)
Contact Us With Any Questions!

Emory’s Conflict of Interest Review Office
Office of Research Administration
1599 Clifton Road, 6th Floor
Phone: 404-712-0046
Fax: 404-712-0069
Website: www.coi.emory.edu
List serve: COI-Office@listserv.cc.emory.edu
Human Subjects Research with Emory St. Joseph’s Hospital

ERAZ
Sarah Putney, IRB Director
July 19, 2012
Review of Recent Events

- Corporate transaction resulting in Emory owning 51% of the joint operating company that owns St. Joseph’s Hospital
- Research implications now under review
- Vision for role of research at ESJH is evolving
- MOU for Emory and SJH is pending review and signature
What We Know

- Research with human subjects is active at ESJH
  - Community Clinical Oncology Program (NCI) – SJH IRB
  - SJ Translational Research Institute – one last Phase I
  - SJ Research Institute – uses WIRB
- ESJH has an IRB and uses Western IRB
  - IRB Administrator Kristi McGinnis
- ESJH operates research under Roman Catholic Ethical Research Directives
  - Contraceptive use is addressed in Risks section of ICF template
What We Know

- ESJH may be added as a site to existing or new Emory clinical research studies going through Emory IRB
- New ESJH informed consent template posted on www.irb.emory.edu
- For now, ESJH-initiated studies should go to the ESJH IRB office (paper, not in eIRB)
- ESJH can rely on Emory IRB but not vice versa
Questions?

- Contact irb@emory.edu or Sarah Putney sputney@emory.edu
- Krisi McGinnis at ESJH IRB Kristi.McGinnis@emoryhealthcare.org or (678) 843-5770
- For specific study questions, please include the IRB file number if there is one
- Stay tuned for more information as we learn it
- Thanks!
Q&A: All

It's QUESTION TIME!!
Reminders:

- **NEXT MEETING:**
  September 20\textsuperscript{th} – 9:30 am to 11:00 am
  Woodruff Health Sciences Administration Building Auditorium, 1440 Clifton Road N.E. – 1\textsuperscript{st} Floor

- Find information about ERAZ at
  [http://www.or.emory.edu/eraz/eraz.php](http://www.or.emory.edu/eraz/eraz.php)

- Email topics and suggestions for future meetings to
  [eraz@emory.edu](mailto:eraz@emory.edu).

- Your opinion and thoughts matter. Please complete the survey that will be sent out after this meeting.