Agenda

• Announcements
• Just In Time for NIH – Holly Sommers
• New Approach to Award Set-Up – Todd Bruce
• Conflict of Interest Reminders – Karly Taylor
• Office for Clinical Research – Bridget Strong
Announcements

Next ERAZ meeting:

May 15, 2014
9:30-11:00am
WHSCAB Auditorium - 1440 Clifton Road NE, 1st Floor

Newsletters are available at:

http://blogs.emory.edu/ranews
NIH Just In Time Requests

Holly Sommers, Director
Office of Sponsored Programs
NIH Just-in-Time (JIT) Requests

• NIH requests certain information only in the event that an application scores well enough to be considered for potential funding. The types of information generally include:
  – Current Other Support for all senior/key personnel designated in the application
    • This must include details on how any budgetary, scientific or effort overlap will be addressed if the application is funded.
    • For Career Development Award applications, information must be included for the candidate, sponsor(s), and senior/key persons
      – Certifications and/or Approvals for IACUC/IRB/Human Subjects Education/Human Embryonic Stem Cells
      – Any other information requested by the awarding NIH Institute or Center
NIH Just-in-Time (JIT) Requests

- NIH’s current process is that a standard notice will be generated for all applications receiving an impact score of 40 or less. (This level is reflective of NIH’s generally current payline, but does not reflect the payline of any individual Institute or Center within NIH.)
- Notices are sent via e-mail two weeks after release of the impact score.
- For all applications, the eRA Commons JIT link will be opened and available for submission of JIT information within 24 hours after the impact score is released.
NIH JIT – Other Support

Current Other Support – Per NIH guidelines:

Provide active support information for all individuals designated in an application as senior/key personnel—those devoting measurable effort to a project. Other support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual’s research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes or gifts are excluded.


Effort devoted to projects must be measured in person-months.
Other Support Reminders

**Do The Math**

- Effort on active awards listed in Other Support cannot exceed 12 person months!
- Combined effort on active awards, plus award under consideration also cannot exceed 12 person months. If it would, then the Investigator/Key Person in question must provide information on how effort will be adjusted should the application under consideration be funded.
- For the PI and any Key Personnel named in the NGA, effort reductions of 25% or greater from the commitment made to NIH must have NIH *prior approval*.
  - Know your Roles: In Compass, an individual who is named on an NGA will have the role of Named Investigator. A co-investigator who is not named (and, therefore, not held to the 25% prior approval standard), will have the role of Co-Investigator.
Other Support Reminders

• Effort listed in Other Support reported to NIH must be consistent with what Emory has on file, including what is in Compass. (The effort in Compass reflects what was proposed to the agency, or any reductions which have received NIH approval since award.)

• To run lists of effort commitments in Compass, use the following queries:
  – Proposals: EU_GM_PROPOSED_EFFORT_BY_EMPLID (enter EMPLID of the investigator in question). All proposals still under consideration at the agency must be included. Exclude only those for which it is known that it will not be funded or for which enough time has elapsed since submission that funding is unlikely.
  – Awards: EU_GM_AWARDED_EFFORT_BY_EMPLID (enter EMPLID and today’s date)

• Each query must be run for the PI and each individual listed as Key Personnel
NIH JIT – IRB Approval/Citi Certifications

For applications involving human subjects research, the following must be provided:

• Current IRB approval. It is rarely appropriate to add a new human study to an existing protocol. However, if it is the case where it may be appropriate to add the new study to an existing protocol, a modification must be filed with the IRB to add the new grant, including any new procedures or changes to the existing protocol. (The IRB will review the grant application during the process of reviewing any new procedures or studies.)

• Human Subjects Education. Please provide certification that any person identified as senior/key personnel, along with the PI, who is involved in human subjects research has completed an education program in the protection of human subjects.

• Human Embryonic Stem Cells: If the proposed project involves hESCs and the applicant did not identify an hESC line from the NIH Human Embryonic Stem Cell Registry in the application, the line(s) may be submitted as an “Other Upload” file.
NIH JIT – IACUC Approval

For applications involving animal subjects research, the following must be provided:
• IACUC Approval letter. While OSP will certify the date to NIH, a copy of the IACUC Approval e-mail must be provided to OSP.
• As with IRB, if the PI proposes to add the new grant to an existing protocol, a modification must be filed to add the new grant as a funding source to the IACUC.
• The above holds true if the new award is a fellowship and the fellow, and their grant, is being added to their mentor’s existing protocol.
NIH JIT – Other Materials

• It may also be the case that an NIH Institute or Center requests additional information not described above.
• In such cases, we naturally need to respond with the information requested.
• In certain cases, it is helpful that you provide OSP any supporting documentation you may have to verify the information to be certified by OSP to NIH.
JIT Reminder – VA MOUs

• Finally, remember that if an individual on the proposal has a VA MOU, the JIT stage is the time to start the process of obtaining signatures on a new VA MOU.

• Because new funding would naturally alter the allocation of an individual’s time, per NIH policy, a new, fully-signed MOU will be needed prior to award set-up.
New Approach to Award Set-Up:
Process for Early Issuance of SmartKeys and Monitoring Award Budget

Todd Bruce, Operations Manager
Research Administration Shared Services Center
New Approach to Award Setup

**Objective:** Provide Principal Investigators accelerated access to SmartKeys

- Applicable to PIs serviced by RAS units only
- Existing RAS Units: New approach will apply to awards granted to PIs on or after April 1, 2014
- Future RAS Units: New approach will be implemented 30 days after official RAS launch date
- Set-Up approach varies based on Award Type

<table>
<thead>
<tr>
<th>Award Type</th>
<th>Set-Up Approach</th>
</tr>
</thead>
<tbody>
<tr>
<td>Set Budget <em>(Contracts and awards with strict spending requirements)</em></td>
<td><strong>OSP</strong> will continue to input detailed budgets prior to issuing SmartKey</td>
</tr>
<tr>
<td>All Others</td>
<td><strong>RAS</strong> will input budgets into PeopleSoft after SmartKey is issued</td>
</tr>
<tr>
<td>Subcontracts</td>
<td>No change in process</td>
</tr>
</tbody>
</table>
New Approach to Award Setup – Process Overview

- OSP receives the top-line budget ("Master Budget") for award upon receipt of Notice of Grant Award
- DMG establishes Smartkey and provides it to RAS & PI
- For an award with a single project, there is only the Master Budget. School/Unit policy determines whether the PI is required to provide a detailed budget
- For an award with two or more projects, there is a Master Budget and Associate Budget(s).
  - RAS works with PI to negotiate Inter-Collaborative Agreement (ICA) which establishes detailed budget for each project with an Associate Budget – after their SmartKeys have been issued
  - RAS will provide a monthly report to Departments listing all awards with multiple projects and no detailed budgets.
    - Note: It is the department’s responsibility to ensure the PI submits a detailed budget if that is a departmental requirement
- If a detailed budget is not provided for awards with Associate Budget(s), the PI & Department responsible for the Master Budget are accountable for all award deficits
Process Flow – Establish SKs and award budget in Compass

Example, an award comprising 4 projects that total $350,000 a year plus F&A

Budgets set up in Compass with $100 for each Associate Budget

Project 1
- Master Budget $349,700 (+F&A)

Project 2
- Associate Budget $100 (+F&A)

Project 3
- Associate Budget $100 (+F&A)

Project 4
- Associate Budget $100 (+F&A)

Total award budget $350,000

The $100 budget will be the flag that there are no detailed budgets in Compass
Process Flow – PIs then incur expenses on projects

Example, an award comprising 4 projects that total $350,000 a year plus F&A

- Budgets setup in Compass
- RAS now has access to budget page in Compass
- RAS updates budget for Master and each Associated Project
- No need for RSTs as expenses have already been booked to correct SmartKey

- Expenses booked directly to project Smartkeys
- Associate Projects will be in deficit until detailed budgets received

<table>
<thead>
<tr>
<th>Project 1</th>
<th>Master Budget</th>
<th>$349,700 (+F&amp;A)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project 2</td>
<td>Associate Budget</td>
<td>$100 (+F&amp;A)</td>
</tr>
<tr>
<td>Project 3</td>
<td>Associate Budget</td>
<td>$100 (+F&amp;A)</td>
</tr>
<tr>
<td>Project 4</td>
<td>Associate Budget</td>
<td>$100 (+F&amp;A)</td>
</tr>
</tbody>
</table>

Total award budget $350,000
Process Flow – PIs provide detailed budget

Example, an award comprising 4 projects that total $350,000 a year plus F&A

Budgets setup in Compass

<table>
<thead>
<tr>
<th>Project</th>
<th>Budget Provided</th>
<th>Expenses</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Master Budget</strong></td>
<td>$349,700 (+F&amp;A)</td>
<td>$164,000 ($164,000)</td>
</tr>
<tr>
<td><strong>Associate Budget</strong></td>
<td>$100 (+F&amp;A)</td>
<td>$92,000 ($92,000)</td>
</tr>
<tr>
<td><strong>Associate Budget</strong></td>
<td>$100 (+F&amp;A)</td>
<td>$50,000 ($50,000)</td>
</tr>
<tr>
<td><strong>Associate Budget</strong></td>
<td>$100 (+F&amp;A)</td>
<td>$44,000 ($50,000)</td>
</tr>
</tbody>
</table>

Total Award Budget $350,000 ($356,000)

Deficit of $6,000 will be the responsibility of the co-PI’s department
Example, an award comprising 4 projects that total $350,000 a year plus F&A

### Process Flow – If NO detailed budgets are provided

**Example**

- **Master Budget:** $349,700 (+F&A)
- **Associate Budget:** $100 (+F&A)

**Budgets setup in Compass**

<table>
<thead>
<tr>
<th>Project</th>
<th>Master Budget</th>
<th>Associate Budget</th>
<th>Expenses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project 1</td>
<td>$349,700 (+F&amp;A)</td>
<td>$100 (+F&amp;A)</td>
<td>$349,700</td>
</tr>
<tr>
<td>Project 2</td>
<td>$100 (+F&amp;A)</td>
<td>$100 (+F&amp;A)</td>
<td>$100</td>
</tr>
<tr>
<td>Project 3</td>
<td>$100 (+F&amp;A)</td>
<td>$100 (+F&amp;A)</td>
<td>$100</td>
</tr>
<tr>
<td>Project 4</td>
<td>$100 (+F&amp;A)</td>
<td>$100 (+F&amp;A)</td>
<td>$100</td>
</tr>
</tbody>
</table>

**Total Award Budget** $350,000

**Deficit of $6,000** will be the responsibility of the prime PI’s department

---

**Master Budget (no detail)**

- **Expenses**

- **Total Award Budget $350,000**

- **Deficit**

---

**Deficit**

- **$6,000**

---
Proposed Process Flow –
RAS Monitoring, Communications & Escalation

RAS Actions:

- **Receives detailed budget** from PI
- **Loads detailed budgets into Compass** for each project using SOP2003’s job-aid on “Making Project Budget Adjustments” and, going forward, monitors & reconciles using existing award reconciliation processes as defined in SOP2008
- Provides **monthly reporting to departments** listing awards with no detailed budgets
- **Clears project deficits** at end of the award by transfer from Master Budget to Associate Budgets if no detailed budgets have been received & loaded into Compass
Conflict of Interest Reminders

Karly Taylor, Senior COI Specialist
Conflict of Interest Office
All Regular Full & Part Time Faculty 2013 Annual Certifications Due

• The 2013 Annual Certifications are available for completion through the eCOI system.

• A PowerPoint help guide is available for this individual section (and other eCOI components) on the COI website: www.coi.emory.edu

• Emory Faculty must complete by June 30, 2014; SOM has earlier deadline of March 31, 2014.

• Faculty hired after July 1, 2014 must complete a 2013 Annual Certification within a reasonable period of time upon their start date.
WHEN to Enter Projects into eCOI System & WHEN to Complete New Disclosures?

• For **ALL** research performed at Emory, remember to create a new Proposal Financial Interest in Research Report form in the below listed situations:
  
  • At time of initiation for the project,
  • On an annual basis for the life of the award/project
    – at time of annual progress report,
    – twelve months after the Notice of Award, and/or
    – twelve months after initiation of the project

• It is important that investigators are completing new disclosures each year of the project. This includes No-Cost Extensions.
Training Grants Friendly Reminder

All training grants must include investigator disclosures.
Mandatory Training for Emory Clinical Research Staff

Bridget Strong, Director for Education & Outreach
Office for Clinical Research
Review the **Clinical Research Education Requirements**.
What Drives Us?

• Research
  • As a research tool, the internet is invaluable. – Noam Chomsky

• Subjects
  • The one thing that I do is take really complicated systems and subjects and make them accessible to regular people. – Matt Taibbi
Registration

- Registration is facilitated via Emory Learning Management System (ELMS).
  - Investigators can register in ELMS.
  - Coordinators and Nurses must complete pre-requisites prior to registration.
Part 1 of Training

- Review the OCR’s training page at http://ocr.emory.edu/training/index.html.

- Mandatory trainings started in March 2012 named Key Concepts in Clinical Research for Investigators. Investigators are scheduled to recertify in March 20, 2014.

- Coordinators and Nurses are scheduled to recertify in September 2014 and Fellows and Residents (functioning in a coordinator role) will recertify in December 2014.
Part 2 of Training

• The following is required for recertification:

• 1 module on new Emory policies and procedures

• 3 elective modules from various clinical research topics

Those set to recertify will be notified by OCR.
Certification of Completion

• Print the ELMS Certificate of Completion because it has the expiration date for verification and upload for any Emory IRB new or amended application.

• The CME certificate of attendance issued by OCR is no longer acceptable. These certificates will be issued only upon request.
Questions?

• Contact:
  Office for Clinical Research (OCR)
  404-778-4960
  ocr@emory.edu
ERAZ Notices

- **NEXT MEETING:**
  
  May 15, 2014— 9:30 am to 11:00 am
  WHSCAB Auditorium - 1440 Clifton Road NE, 1st Floor

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

- If you have questions or comments regarding today’s meeting please register them through our survey at:
  
ANY QUESTIONS