Emory Research A to Z
ERAZ

July 17, 2014

Whitehead Auditorium
G01 Whitehead Building
Agenda

- Controlled Substances
- Sub Award Processing
- RAS Updates
- SAM Kiosk
- Federal Updates
- OSP/OGCA Training Updates
RESEARCH USE OF CONTROLLED SUBSTANCES, POLICY 7.25
AN OVERVIEW OF REGULATORY REQUIREMENTS
What does this presentation cover?

• Basics:
  – The regulators
  – The regulated
  – Scope

• Requirements for an individual using controlled substances in research:
  – Registration
  – Security
  – Records
Basics: The Regulators

• Georgia Board of Pharmacy (GBP)

• Georgia Drugs and Narcotics Agency (GDNA)

• Federal: Drug Enforcement Agency (DEA)
Basics: The Regulated

• **Practitioner** = a licensed healthcare provider or veterinarian authorized to prescribe Controlled Substances.

• **Registrant** = an investigator who holds both a
  - GBP researcher registration and
  - DEA researcher registration to use Controlled Substances in research.
Basics: Scope of Emory Policy for Controlled Substances in Research

• Covers investigators who are performing bench research or animal research using Controlled Substances.

• Does **not** cover health care practitioners or veterinarians who provide care for their patients/clients.

• Does **not** cover investigators conducting clinical trials with human participants.
  - Practitioners working in patient care and human subjects research are subject to different laws, regulations and University policies.
Registration

What do investigators need to do?

1. Register, with both GBP & DEA
2. Implement Physical Security Measures
3. Implement Personnel Security Measures
4. Follow the Proper Ordering & Procurement Process
5. Follow a Proper Disposal Process
6. Adhere to Record-Keeping Requirements
Registration – State Requirements

- Investigators must obtain a **Researcher Pharmacy** permit from the Georgia Board of Pharmacy (GBP) in order to use Controlled Substances for research.

- Registration must be renewed by June 30 of even numbered years.
  - If your initial registration was in December of an odd numbered year, the registration must be renewed in the upcoming even numbered year.
Registration – State Requirements

Inspection by GDNA:

– When the GBP notifies an investigator that his/her application has been processed, the investigator must contact the GDNA to schedule an inspection.

– The GDNA must inspect the site where Controlled Substances will be used. The inspector considers facilities, security measures and record-keeping processes.
Registration – Federal Requirements

• Investigators using Controlled Substances outside of human subject research must obtain a Researcher registration from the DEA (DEA form 225 or 225a).
  – The Researcher registration is **not** the same as a Practitioner registration.
  – The DEA has advised that if an Investigator-Practitioner plans to perform basic or animal research with Controlled Substances, then he/she must apply for a Researcher registration from the DEA.

• Researcher registration must be renewed annually.

• Research using Schedule I Controlled Substances requires a separate Researcher registration.
Registration Summary

• The Georgia Researcher Pharmacy permit is a prerequisite for DEA researcher registration.
• The DEA may rely on the GDNA’s’s inspection of a site, or it may perform its own inspection before issuing a registration.
• Separate registration is required for each separate geographical location at which research is conducted (both GBP and DEA).
Security & Records Forms

1. Security Checklist
2. Access Log
3. Emory University Employee & Agent Screening Statement
4. Controlled Substance Authorized User Signature Log
5. Controlled Substances Discrepancy Report Form
6. Controlled Substances Inventory
7. Controlled Substances Current Use & Disposition Log
8. Order/Receipt Log for Schedules I & II Controlled Substances
9. Order/Receipt Log for Schedules III - V Controlled Substances
10. DEA Power of Attorney
Security: Physical

The Registrant must ensure that Controlled Substances are secure from theft, loss, unauthorized access or removal.

Form 1 (self-assessment checklist)

- Storage area
- Storage container(s)
- Storage conditions
- Access conditions
- Inventory control
- Access permissions
- Access records
- Inventory & Records
- Reporting
Security: Personnel

- Personnel screening  Form 3
- Training
- Termination of Access  Forms 2, 4
Security: Disposal

• The Registrant must properly dispose of all Controlled Substances when:
  – the substances expire
  – the Registrant’s DEA registration is not renewed;
  – the Registrant no longer conducts research using Controlled Substances; or
  – the Registrant leaves Emory.

• The Registrant must arrange for a DEA-registered reverse distributor to accept and dispose of the substances.

• The Registrant must maintain disposal records.
Records

Registrants must keep the following records:

– Initial Inventory
  Form 6

– Biennial Inventory
  Form 6

– Use Log
  Form 7

– Purchase and Receipt Documentation
  Form 8, 9

– Discrepancy Reporting Documentation
  Form 5
Records: Inventories – Form 6

Each registered site must maintain inventory & records. Physical inventory is taken at the beginning, or at the end, of business day.

Initial Inventory:

- Registrant is responsible for performing and documenting an initial physical inventory of all Controlled Substances on hand when the Registrant begins work with Controlled Substances.

Biennial Inventory:

- The Registrant must perform a physical inventory of all Controlled Substances on hand within 24 months following the date of the previous inventory.
Records – Forms 7, 8 & 9

Use Log:
• The Registrant must keep a running log of his/her use and disposition of Controlled Substances, Form 7.
• The log must show the type & amount dispensed/administered; name & initials of the person responsible for the use; date of use; and purpose of use.
• A separate log is kept for each container of a Controlled Substance.

Purchase and Receipt Documentation:
• Keep all documents relating to the order, purchase and receipt of Controlled Substances in inventory, Forms 8 & 9.
• Report any discrepancies that are found in the amount of Controlled Substances at any time or during an inventory or audit, Form 5.
Record Retention Schedule:

• Keep all records relating to the ordering, procurement, inventory and use of Controlled Substances in Research for 3 years after inventory.
More Information

Policy, forms and training slides:
http://www.orc.emory.edu/controlled-substances/index.html

Contact the Office of Research Compliance to:

– Set up a training meeting
– Answer questions regarding Research Use of Controlled Substances, Policy 7.25

(404) 727-2398
orc@emory.edu
crame2@emory.edu
Finesha Colton Lee–Assistant Director of Procurement Operations
Financial Operations

SUB AWARD PROCESSING
FY14 Sub Award Volume

• 449 POs Issued (489 FY13)

• 1,740 Sub Award related invoices processed (2,814 FY13)
  ➢ 1,649 “Complete” – Payment Generated
  ➢ 91 “Pending” – Awaiting action from Department/School
Concerns

• “Lack of Communication/Notification by Purchasing”

• “Encumbrances that are WAY off in Emory Express”

• “Lack of documentation available in Emory Express”
“Lack of Communication By Purchasing”

- Automated Notification sent when an invoice is posted
- Automated Notification sent to inform “receiving is needed”
- Follow up notifications sent from Payment Services
- “Comments” tab on each PO

**Note – If departmental personnel changes, a request must be submitted to have the contact information updated.**
“Encumbrances that are WAY off in Emory Express”

• Balances were correct in Emory Express but were incorrect in Compass

• The cause of the problem was identified and solution was implemented August 2013 for newly issued POs

• Resolution for the existing POs – close the “problem” PO and re-issue for the remaining balance

• encumbrances@emory.edu
“Lack of Documentation Available in Emory Express”

- Documentation can be found in several places within Emory Express

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Shipping, Handling, and Tax charges are calculated and charged by each supplier. The values shown here are for estimation purposes, budget checking, and workflow approvals.

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**Comments (17)**

**Add Comment**

- **Show comments for Purchase Order**

**Records found: 17**

**Carla Reid** [Reply To] [New Comment]
Applies To: Purchase Order - S794989
Comment Added: 2/20/2014 3:53 PM

Please find attached the fully executed subcontract for Amendment 2 to subcontract S794989 between Massachusetts General Hospital and Emory University related to the project entitled “ISCHEMIA Trial - Ischemia Coordinating Center”.

Attachment Added: [Show File: 10.22433.10.22433.pdf] (1776)

**Denise Hadley** [Reply To] [New Comment]
Applies To: Purchase Order - S794989
Comment Added: 11/19/2013 9:28 AM

Attachment Added: [Show File: 10.22433.10.22433.pdf] (796)

**Denise Hadley** [Reply To] [New Comment]
Applies To: Purchase Order - S794080
Comment Added: 11/19/2013 9:16 AM

Attachment Added: [Show File: 10.22433.10.22433.pdf] (796)

**Denise Hadley** [Reply To] [New Comment]
Applies To: Purchase Order - S794999
Comment Added: 11/19/2013 9:06 AM

Attachment Added: [Show File: 10.22433.10.22433.pdf] (796)

**Carla Reid** [Reply To] [New Comment]
Applies To: Purchase Order - S794080
Comment Added: 11/20/2013 10:53 AM

Please find attached the fully executed subcontract for Amendment 4 to subcontract S794989 between Massachusetts General Hospital and Emory University related to the project entitled “ISCHEMIA Trial - Ischemia Coordinating Center”.

Attachment Added: [Show File: 10.22433.10.22433.pdf] (596)
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[EMORY UNIVERSITY Research Administration](#)
Kathleen Bienkowski—Asc.VP for Research Administration Services

RAS UPDATE
Current Operations

• RAS Public Health
  – Piloting pre-award in GH & BSHE

• RAS Cancer & Imaging
  – 3Q14 Pre Award Survey

• RAS Medicine
  – Completed 100 faculty visits in first six months
  – OGCA Resource

• RAS Pediatrics
  – Launch May 6th
  – Director, Diane Samuel
  – OGCA Resource
Key Projects

• 1st Annual Review of SOPs
  – Updated Roles & Responsibilities Document
  – Changes Summary

• Blackboard
  – Audience: RAS organization
  – Launch: May 2014

• Website
  – Audience: PIs & Departments Served by RAS
  – Target Launch: August 2014
  – Implementation site: www.tra.emory.edu

• Key Performance Indicators (KPIs)
  – 10 identified (see next slide)
  – Tracking mechanism: Notification of Intent to Submit, Surveys, Compass milestones
## RAS KPIs

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<th>KPI Description</th>
<th>Target Performance Level</th>
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<td>Proposal Development</td>
<td>Pre-Award Engagement – Initial Response Time</td>
<td>Average cycle time in business days</td>
<td>2 days</td>
<td>Manual</td>
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<td>2</td>
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<td>FSR (Reconcile financials)</td>
<td>Timeliness of Completion of Final Report</td>
<td>% of FSRs accurately submitted by 60 days following end date</td>
<td>100%</td>
<td>Milestone</td>
</tr>
<tr>
<td>8</td>
<td>Post-Award Support</td>
<td>Faculty Satisfaction with Post-Award Support</td>
<td>PI Satisfaction</td>
<td>TBD</td>
<td>Survey – Qualtrics</td>
</tr>
<tr>
<td>9</td>
<td>Closeout (Completion)</td>
<td>Submission of Closeout Paperwork</td>
<td>% of award closeout forms submitted to OGCA on time</td>
<td>100%</td>
<td>Milestone</td>
</tr>
<tr>
<td>10</td>
<td>Post-Award Support</td>
<td>Faculty Satisfaction with Post-Award Support</td>
<td>PI Satisfaction</td>
<td>TBD</td>
<td>Survey – Qualtrics</td>
</tr>
</tbody>
</table>
Implementations

- **RAS Basic Science**
  - Target Launch: early September
  - Key dependencies
    - Fully staffed
    - Director hired
    - Space identified and available for occupancy

- **RAS Yerkes**
  - Initial conversations with leadership and research administration staff

- **Federal Contracts**
  - Current state assessment (underway)
  - Develop options for future operating model
Holly Sommers—Director, Office of Sponsored Programs

SPONSORED AWARD MANAGEMENT (SAM) KIOSK
What is the SAM Kiosk?

The SAM Kiosk was designed as a single portal through which institutional prior approval and other award management related requests can be submitted to the Office of Sponsored Programs (OSP), the Data Management Group (DMG), and the Office of Grants and Contracts Accounting (OGCA).

It is an online system through which campus users provide OSP/DMG/OGCA will information, and related attachments, for award-specific requests.
SAM KIOSK Implementation

SAM will be found at: http://sam.emory.edu.

SAM will be live for university-wide use on August 1, 2014.

Existing forms/systems will remain active as an option for use for around 2 months.

(Appropriate notice will be sent to campus before existing forms/systems are discontinued.)
SAM KIOSK Implementation

• During the transition period, any requests sent via existing forms or systems will be completed through those standard processes.

• SAM KIOSK Campus User Manual will be available via the OSP and OGCA websites a few days in advance of the August 1, 2014 “go live” date.
SAM KIOSK Implementation

SAM KIOSK Campus User Manual contains detailed information on:
- How to access SAM
- The types of requests to be submitted through SAM
- The process for submission
- Samples of submitted requests
SAM KIOSK Implementation

An announcement will also be made to campus via the ERAZ and other listservs regarding the implementation of SAM.
SAM KIOSK
FEDERAL UPDATE

-- HHS TRANSITION

-- UNIFORM GUIDANCE
HHS Transition to New Payment System

- As previously announced, HHS (including NIH) is currently transitioning all newly issued awards to a new Payment Management System.

- They also plan to transition all active awards to this new system which will create a significantly increased research administration workload (in the year of transition) for Emory.

- COGR has announced that HHS has communicated that they will extend the full transition to the new Payment Management System.
Uniform Guidance: What we do know....

• Multiple circulars being “streamlined” into one Uniform Guidance document by the OMB (Office of Management and Budget) and COFAR (council on Financial Assistance Reform)

• OMB issued the Uniform Guidance on 12/26/13
  – The effective date for Uniform Guidance is 12/26/14.
  – It is written to federal agencies and requires them to submit their implementation plans to OMB by 6/26/14.
  – They are expected to be released to us after OMB review (anticipating early fall).
  – NSF submitted their implementation early and it is now available for review and comments.
Implementation of Uniform Guidance

• Broad Concerns:

  – Will we be provided an opportunity to provide feedback?

  – Will these be effective for all active awards, awards or supplements issued after this time or ???

  – This timeline does not allow sufficient time for institutions to update their own policies and procedures.
Uniform Guidance, Procurement

• Uniform Guidance appears to require some type of competitive reviews for orders of $3,000 or above
  – Most Universities require competitive bids (or sole source justification) at a higher threshold.
  • Current requirement for Emory is $5,000 and above.
Uniform Guidance, Compensation

- When a non-Federal entity uses the cash basis of accounting, the cost of leave is recognized in the period that the leave is taken and paid for. Payments for unused leave when an employee retires or terminates employment are allowable as indirect costs in the year of the payment.
  - Do they mean “fringe benefits” instead of “indirect costs”?
  - If “fringe benefits”, process change takes time. If “indirect costs”, most will not be able to recover the costs.
  - This change could actually cost the federal government more.

- The term “Effort Reporting” is not in UG
  - But there are still standards for documentation of Personnel Expenses.
  - The concept of “institutional base salary” is introduced.
Uniform Guidance, Direct Costs

• Computing devices (including laptops, tablets, etc.) can be charged (if necessary, allocable, etc.). *Requirement for sole use is removed.*

• UG states that salaries of administrative and clerical staff may be appropriate under certain circumstances.
  – Is this really a change?
  – What does “integral” mean?
  – Would it be appropriate to allocate between awards?
  – Is it allowable if included in the budget?
  – How will this be handled for NIH Modular awards?
Uniform Guidance, Closeouts

• Uniform Guidance requires closeouts and liquidation of all obligations by 90 days
  – Staffing challenges
  – Subrecipient monitoring challenges
  – Complex awards
  – Diverse reporting and drawdown tools amongst agencies
  – Service center charges (including animal charges)
Uniform Guidance, In Summary...

• Many things that we don’t know.
• We are in regular communication with federal agency representatives.
• Hoping for further clarification with agency implementations.
• FAQs expected to be released by OMB by end of August.
• Expect changes with federal and institutional policies.
• The implementation plan for NSF has been issued and can be accessed at:
  – References to Uniform Guidance are highlighted in yellow.
Next Steps

- Emory web page covering Uniform Guidance and upcoming changes is currently available (accessible from OSP or OGCA home page).

- Uniform Guidance Emory Planning Structure is currently being formed.
  - Will include Steering Committee and approximately 8 subject teams.

- We will continue to communicate concerns to federal agencies and work with other institutions to identify strategies to manage the changes.

- The Emory Research Community will be kept up to date via the webpage, newsletter and meetings (including ERAZ).

*It is IMPORTANT that anyone involved in research administration is reading the newsletter.*
How should you prepare?

• At this point, your responsibility for preparations are limited to reading the newsletters (and visiting the webpage if you would like further information).

• Further guidance will come in the fall regarding changes and any other actions required by you.
Demetrice Bryant—Director of Training & Communications
Offices of Sponsored Programs and Grant/Contract Accounting

OSP & OGCA TRAINING UPDATES
## RAE Certification Changes

<table>
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<th>Prior to April 2014</th>
<th>April 2014 and After</th>
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<td>Introduction to Research Admin.</td>
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<td>RAE Exam</td>
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*EMORY UNIVERSITY | Research Administration*
Registering for RAE Certification in eLMS

Streamlined registration process

• Go to http://elmprod.emory.edu
• Enter ID and Password
• Click Browse Catalogue
• Click Next
• Click Office of Sponsored Programs and Office of Grants & Contracts Accounting
• Click eRAE-Emory Research Administration Certification – Pre-Award or Post-Award
  – Program Code 236001 (post-award)
  – Program Code 236002 (pre-award)
Accessing your Certification Courses

- Web address - [http://elmprod.emory.edu](http://elmprod.emory.edu)
- Click All Learning
- Click title link eRAE-Emory Research Administration Certification – Pre-Award or Post-Award link
Accessing your Certification Courses

The Research Administration Certification Program is designed for persons in research administration and will provide a basic level understanding of finding funding, proposal development, award management, and award close out.

**Prerequisites**
This section has been completed.

To complete this section complete all activities.

You may request a waiver for this activity from your manager if you have fulfilled the requirements through an equivalent learning activity.

**Secondary**
2 out of 3 needed activities have been completed for this section.

To complete this section complete all activities.
Coming Soon!

More online training!
ANY QUESTIONS