Emory Research A to Z
ERAZ

September 18, 2014

Woodruff Health Sciences (WHSCAB) Auditorium
Agenda

• Investigational Drug Services (IDS)
• Research Administration Certification Changes
• Research Participant Payment Fund (RPPF)
• Provisional Award Number (PAN) Requests
INVESTIGATIONAL DRUG SERVICE: ROLE IN RESEARCH PROCESS AT EMORY
Regulatory Requirements for Drug Management in Research

- FDA and GCP
- JCAHO standards
- State of Georgia
- AAHRPP standards
Purpose of IDS

To insure that drugs used in research protocols are handled safely, effectively and efficiently in the hospital and clinic environments.
Locations and Areas Served

• Emory University Hospital, Room F506
  – EUH and EUHM hospitals, CRN, EUC Building B, North Decatur Building

• Emory University Clinic - Building A, Suite 1200
  – EUC Building A, WCI, Hope Clinic, ECC, Wesley Woods, Executive Park

• Hope Clinic of Emory University
Responsibilities of personnel handling investigational drugs are based on Good Clinical Practice Guidelines as described in the Code of Federal Regulations, Title 21.

They include:
- Maintain drug supplies
- Store drug supplies
- Prepare doses
Responsibilities cont’d

- Distribute drugs
- Return drug supplies
- Maintain records
- Permit inspections
Scope of IDS

- **Sponsored protocols**
  - Pharmaceutical company
  - NIH
  - NCI

- **Investigator-initiated**
How to Initiate Study with Investigational Drug Service

- Copy of protocol
- Budget
- Sponsor visit
- Notify IDS of IRB approval
Protocol Maintenance

- Patient enrollment with IDS
- Drug orders for Inpatients
- Drug orders for Outpatients
- Inventory maintenance
- Monitor visits
Protocol Closure

• Drug return

• Records retention
Contact Information

• **Telephone:**
  ▪ EUC location – 404-712-7485, 404-727-0028, or 404-727-0036
  ▪ EUH location – 404-712-4718
  ▪ Hope Clinic location – 404 712-4642

• **IDS Webpage:** [www.ocr.emory.edu/ids/index.html](http://www.ocr.emory.edu/ids/index.html)

• **Link for monitors to schedule IDS visit:**
  [www.ocr.emory.edu/ids/appointments.html](http://www.ocr.emory.edu/ids/appointments.html)
RESEARCH ADMINISTRATION CERTIFICATION CHANGES

Demetrice Bryant—Director of Training & Communications
Offices of Sponsored Programs and Grant/Contract Accounting
Training Page Updated
### RAE Certification Changes

<table>
<thead>
<tr>
<th>Prior to April 2014</th>
<th>April 2014 and After</th>
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<tbody>
<tr>
<td>Introduction to Research Admin.</td>
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<tr>
<td>A-110</td>
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<td>RAE Exam</td>
</tr>
<tr>
<td>RAE Exam</td>
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</table>
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

<table>
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<th>eRAF - Emory Research Administration Certification - Postboard</th>
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**Overview**

**Description**
The Research at Emory 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.

### Section 1 Activities

<table>
<thead>
<tr>
<th>Activity</th>
<th>Required</th>
<th>Completed</th>
<th>View Activity Progress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction to Research Administration</td>
<td>Required</td>
<td>Completed</td>
<td>View Activity Progress</td>
</tr>
<tr>
<td>CMR Circular A-510</td>
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<tr>
<td>CMR Circular A-21</td>
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<td>View Activity Progress</td>
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</table>

* 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.

### Section 2 Activities

<table>
<thead>
<tr>
<th>Activity</th>
<th>Required</th>
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<th>View Activity Progress</th>
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</thead>
<tbody>
<tr>
<td>RAE Foundation Class</td>
<td>Required</td>
<td>Completed</td>
<td>View Activity Progress</td>
</tr>
<tr>
<td>Effort Reporting ERS</td>
<td>Required</td>
<td>Not Enrolled</td>
<td>View Enrollment Options</td>
</tr>
<tr>
<td>Emory Proposal Express (EPEX)</td>
<td>Required</td>
<td>Completed</td>
<td>View Activity Progress</td>
</tr>
</tbody>
</table>

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

** You may complete this activity by completing one of its equivalent items.
Coming Soon!

More online training!
Goals & Benefits of Process Change

Why make the change?
• Support research efforts
• Improved efficiencies
• Transparency
• Decrease in turnaround time for check issuance
• Clearer defined roles and responsibilities

Benefits to making the change...
• All payment vouchers will be initiated by custodians or research team members
• Ability to look-up voucher (payment) status
• No more submission of hard copies to Controller’s Office
• Funds will be visible on the grant project
• Replenishments no longer require Controller’s Office approval
• Close process is more streamlined
Changes to Research Participant Payment Process

• Formerly Participant Stipend Fund (PSF)....now Research Participant Payment Fund (RPPF)

• New and Increase Requests
  – Requests submitted to Controller’s Office (CO) via RPPF@emory.edu
  – CO approval provided via email
  – Custodian requests initial check by submitting payment voucher

• RPPF replenishments
  – retain original receipts/logs in your files
  – CO will no longer approve replenishment requests
  – New RPPF replenishment Checklist

• Requestor can receive email when voucher has been approved
Changes to Research Participant Payment Process

• Closing the RPPF
  – Custodian will process closing of RPPF
  – CO no longer involved in closing of RPPF

• Changes in Custodian
  – No longer routed through CO
  – Dept./School will manage & track custodians
    • Custodian must be a permanent Emory employee; no temporary employees, no students, no contractors/consultants, no affiliate employees

• Changes in SK or grant project
  – Not required to notify CO
  – Depts./School will manage this
RPPF Process Rollout Plan

**August**
- School Meetings – SON, ECAS, SPH
- Communicate update to RABAB

**September**
- RPPF Policy Effective 9/1/2014 – staggered rollout
- School Meetings – SOM Dept. Administrators
- Communicate to ERAZ & OCR
- Information Sessions: Demos, information, clarification, Q&A

**October & November**
- Present to BOF
- Information Sessions: Demos, information, clarification, Q&A
- Transfer current RPPF from central to grant projects
- 10/1/14 Go Live – SPH, ECAS, SON
- 11/1/14 Go Live – SOM, Yerkes
PROVISIONAL AWARD NUMBER (PAN) REQUESTS – GENERAL REMINDERS
PANs - Overview

• A provisional award number (PAN) is a Smart Key number provided to a principal investigator for the purposes of initiating a sponsored project and incurring expenses prior to the institution’s receipt, acceptance, and processing of an award.

• This type of account is permitted and often encouraged for particular projects and circumstances in order to facilitate project activities that must begin prior to the award, for appropriate tracking of expenditures and to reduce the need to charge other unrelated accounts.
In requesting and accepting a PAN, the department or school assumes any financial risk incurred in the event the award is not made, not accepted, or if the terms of the award deem certain expenditures to be unallowable.

PANs will be issued with no budget loaded. All costs will show in deficit.
PANs - Overview

As part of the request process, described below, the requestor must provide a departmental guarantee account.

The funding guarantee account designated on the PAN form should be a non-sponsored account with adequate funding to support the guarantee.

If, for some reason, the anticipated award is not received or expenses are found to be unallowable under the terms of the award, expenditures incurred against the PAN account will be required to be funded by the designated departmental guarantee account.
Requesting a PAN

WHEN MIGHT A PAN BE JUSTIFIED OR ENCOURAGED?

• to begin a new federal project prior to its start date that is subject to Research Terms and Conditions (RTC) (i.e. option of pre-award spending permitted up to 90 days in advance of the start date) and before receipt of official notice of grant award or sub-award

• to begin a project on the designated start date but prior to receiving the official grant award notice or sub-award document from the sponsor
Requesting a PAN

- to begin a new award for which we have received an NGA, but which lacks applicable compliance approvals (IRB or IACUC), provided that the investigator signs an explicit certification that selected aspects of the project must begin but that no activities or expenses related to the pending approval will be incurred until such approval(s) is/are in place. (This will not apply to clinical trials, for which all approvals much be in place before a PAN or award can be issued.)

- to continue a project, previously awarded as a grant and originally proposed for multiple years, for which the next year’s funding increment has not yet been awarded. (See below for additional information.)
Requesting a PAN

WHEN IS A PAN NOT ALLOWED?

- PANs cannot be issued for corporate clinical trials. All required approvals, including IRB approval, and all contract signatures must be in place before award activities can begin.
Requesting a PAN

In order to establish a PAN, the following are needed:

- An EPEX proposal on file with OSP that covers the project, budget and period for which the PAN is being requested;

- A PAN request, submitted via the SAM Kiosk. (This request form will include a field for the departmental guarantee account to be used if funding is ultimately not forthcoming, along with any required certifications.)
Types of PANs

• New or Renewal Awards
  – New or Renewal prime awards to Emory
    • A new Compass Award ID is required, thus new SmartKey(s) will be provided
  – New or Renewal sub-awards to Emory
    • A new Compass Award ID is required, thus new SmartKey(s) will be provided
Types of PANs

• Continuation Award to Emory
  – Continuation of prime award to Emory (generally those with no automatic carryover)
    • New Compass Project/SmartKey(s) will be provided
  – Continuation Subaward to Emory (for awards with no automatic carryover)
    • New Compass Project/SmartKey(s) will be provided
  – Continuation Subaward to Emory (for awards with confirmed automatic carryover)
    • Existing Compass Project/SmartKey(s) will be extended to allow for continued expenditures. This type of PAN is referred to informally as a Provisional Extension
PAN Issuance

• Upon receipt of a PAN request, the appropriate OSP analyst will review the request for completeness. This includes ensuring that the PAN includes:
  – All required signatures on the request form;
  – A department guarantee account;
  – Current compliance approvals (IACUC, IRB), or a signed certification from the PI regarding animal or human use;
  – Current eCOI disclosure summary (if not provided otherwise in EPEX routing);
  – Complete information on related EPEX proposal or Compass award;
  – Clear indication of the source of funding (federal or non-federal).
• Once reviewed and approved in OSP, the PAN will be set-up in the Compass system.
Notification of PAN

• Once a PAN has been set up in Compass, and requested Smart Key(s) generated, the Data Management Group (DMG) will provide notification on the establishment of the PAN via e-mail.

• This e-mail is sent to the group of recipients who would normally receive NOAs for the department and school.

• This e-mail is the only notification that will be sent regarding establishment of a PAN.

(It is important to note that OSP/DMG does not distribute PAN information via an NOA because we cannot do so. The underlying NOA report in Compass does not capture PAN information.)
Types of PANs

All types of PAN requests (new PANs, continuation PANs, including those for Provisional Extensions) should be submitted as PAN requests through the SAM Kiosk.
ANY QUESTIONS