



EMORY  
UNIVERSITY

Research  
Administration

# Research Administration at Emory Foundation Program

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**DAY ONE:**

**Office of Sponsored Programs:  
PreAward Research Administration**

# Goals of RAE Program

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- Provide foundation of Research Administration knowledge to Emory's Research Community
- Provide support and guidance to the faculty and administrators of Emory
- Build strong, informed Research Administrators at Emory
- Minimize risk of non-compliance by ensuring those responsible for administration of Sponsored Projects at Emory are knowledgeable of the applicable rules and regulations

# Overview: Days 1-3

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Offered collaboratively by OSP, OTT and the Division of Finance, RAE is a comprehensive training and certification program designed to provide Emory Research Administrators with the base of knowledge required to meet their professional responsibilities related to research administration.

- Day 1: Presented by OSP, covers topics related to the Pre Award process
- Day 2: Presented by FGC, covers topics related to the Post Award process
- Day 3: Synthesizes what was learned through the online modules and in days 1 and 2, through the use of case studies and activities. Additionally, more information is provided on the effort reporting process, as well as, the process for determining Facilities & Administrative costs

# Today's Objectives

By the end of today, you should be able to....

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- Identify funding opportunities, mechanisms and resources for seeking funding
- Explain the elements of a proposal and general routing and proposal submission processes
- Explain components and preparation requirements of budgets
- Discuss “Just-in-time” procedures, award types and processing
- Discuss contract negotiation, common terms and conditions
- Explain basics of Award Set-Up
- Discuss compliance concerns

# Roles and Responsibilities - OSP

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## Mission and Goals

- The Office of Sponsored Programs provides central oversight of pre-award activities for all sponsored projects for the Emory research community by promoting partnerships with researchers, faculty, staff, administrators, and students
- Our goal is to provide prompt, helpful and efficient customer service, as well as to promote collective responsibility, accountability, compliance, and scholarly integrity in support of the research mission of the University which is to...
- Translate discoveries and apply knowledge gained through research to the service of humanity

# Acronyms & Definitions

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- OSP
- FGC (formerly OGCA)
- DMG (now part of FGC)
- EPEX
- NIH
- NSF
- NCURA
- IRB
- IACUC

See the reference section for a complete listing.



# Emory Research Administration Structure

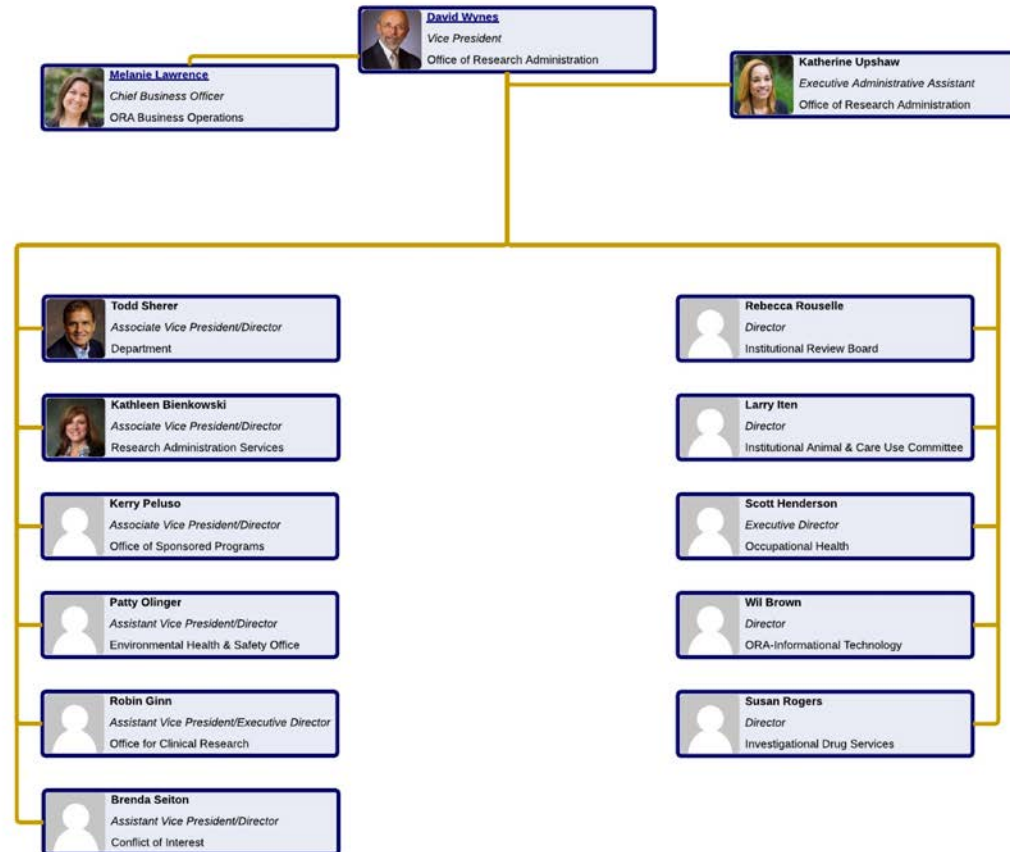


# ORA Organization Chart



Research  
Administration

## Office of Research Administration



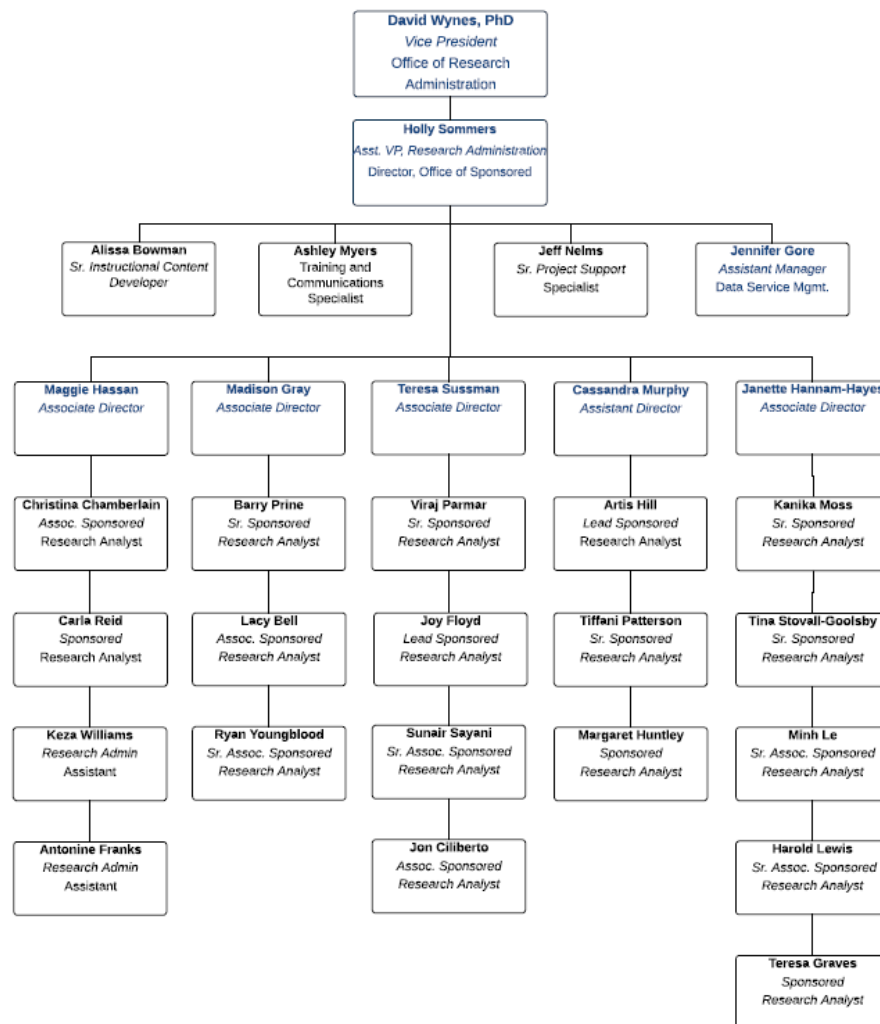
EMORY  
UNIVERSITY

Research  
Administration



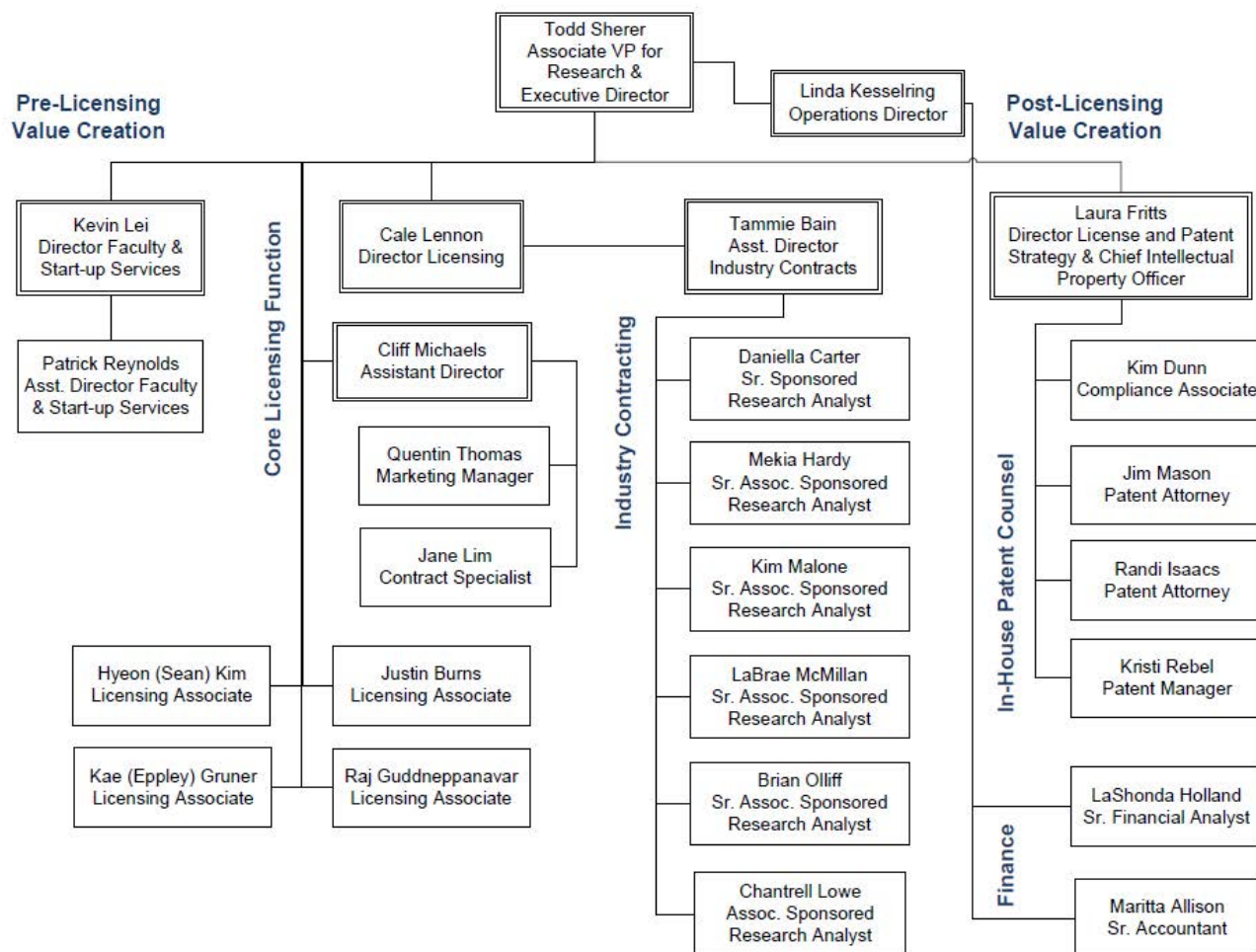
# OSP Organization Chart

## Office of Sponsored Programs



# OTT Organization Chart

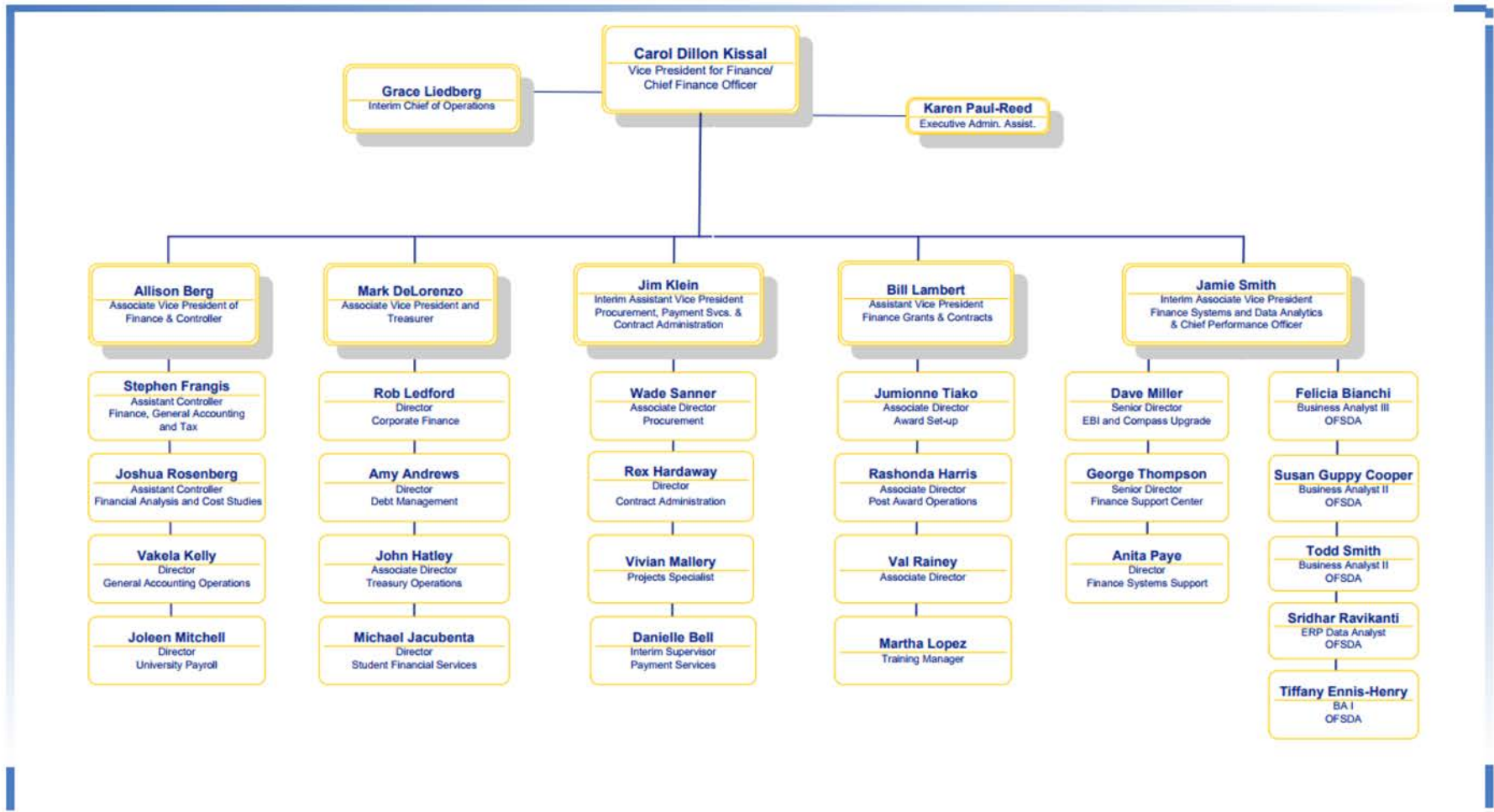
## Office of Technology Transfer Emory University



# Division of Finance Organization Chart

As of September 5, 2017

## Division of Finance

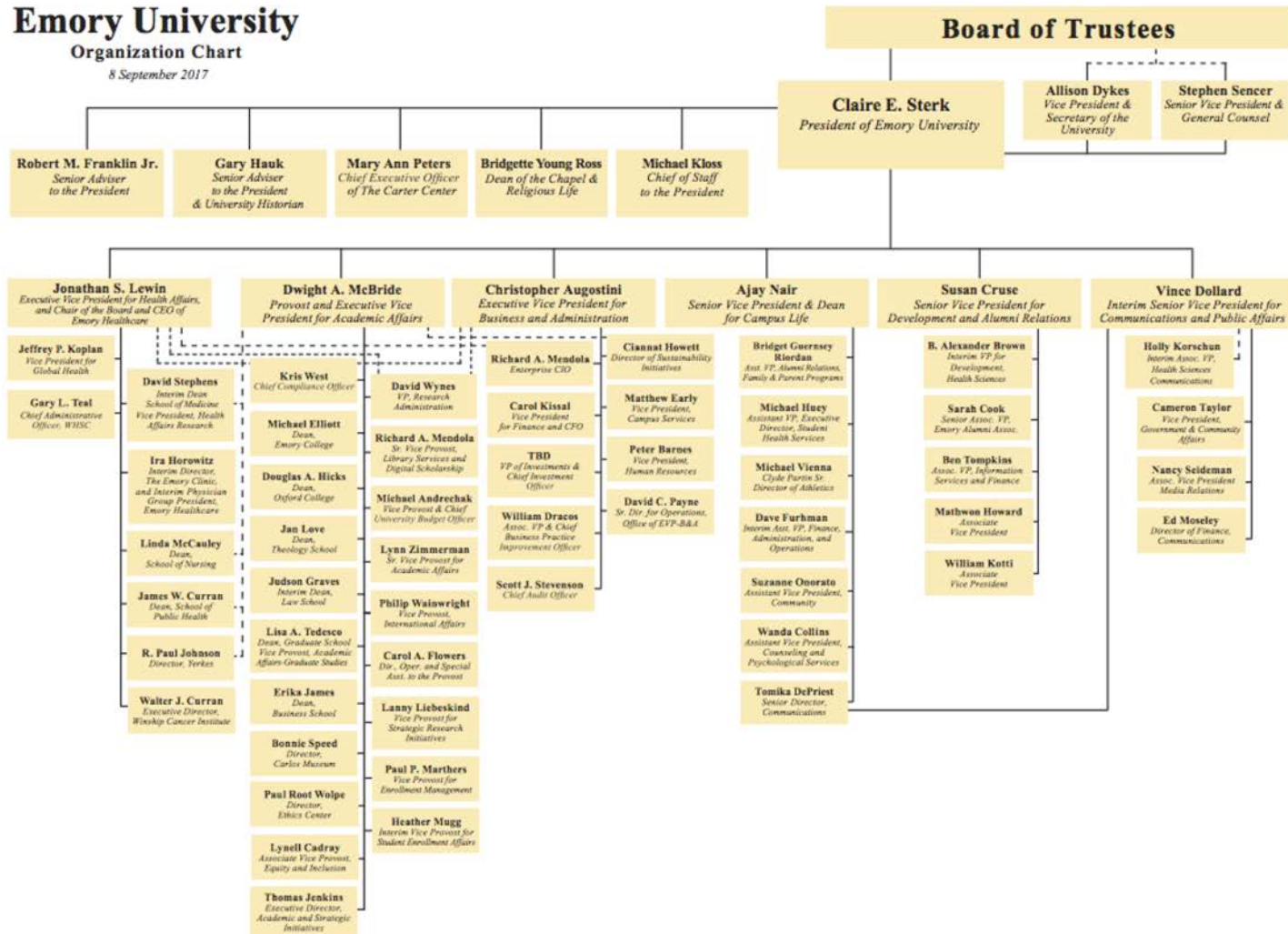


# Emory University Organization Chart

## Emory University

### Organization Chart

8 September 2017







# Office of Sponsored Programs

# Roles and Responsibilities - OSP

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- Help identify sources of support
- Clarify instructions and help with the interpretation of sponsor submission policies
- Review grant applications/proposals, prepare proposals for signature or electronic submission to agency
- Review grant award documents to verify amount of award and to review award terms and restrictions, if any, and negotiate appropriate alternative terms
- Review Just-in-Time materials for pending grant applications

# Roles and Responsibilities - OSP

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- Review incoming and prepare outgoing sub-awards
- Assist with transferring grants in or out of the university
- Act as a resource for faculty, staff and administrators: provide information about funding opportunities, terms and conditions, and to resolve non-financial issues and questions that arise during the award
- Ensure that the University can meet the obligations of the awards it accepts
- Advise PIs, administrators and others on policies as well as process for 'non-financial' post-award activities

# Roles and Responsibilities - PI

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**The PI is responsible for reviewing the terms and conditions for each grant and contract they are awarded.**

**The PI is responsible for notifying his/her program/technical official when awards provide support for the same research. If overlap exists between awards a plan must be made to address the overlap and the sponsor must be notified and asked to approve this plan.**

**It is the PIs responsibility to keep their current and pending support records up-to-date at all times and to be able to clearly articulate and differentiate the scientific aim(s) of each funding source.**

**It is the PIs responsibility to modify research aims appropriately when the grant budget is reduced; again reduction in the proposed scope of work must be approved by the Authorized Business Official.**



# Funding Opportunities Databases

## Grant Forward

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- Database includes funding opportunities from many sponsors
- Search based on deadlines, keywords, categories, funding type and more
- Includes funding opportunities for students and post docs

# Funding Opportunities Databases

## Grant Forward

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- Can search from any computer (after registration on a computer in the Emory network)
- Individual, one-time searches as well as saved searches
- Funding Opportunity Alerts sent via email listing the new or revised funding opportunities that match the criteria of all saved searches. You determine frequency of alerts

# Funding Opportunities Resources

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- Grantforward

<http://www.grantforward.com/index>

- Grants.gov

[http://www07.grants.gov/applicants/find\\_grant\\_opportunities.jsp](http://www07.grants.gov/applicants/find_grant_opportunities.jsp)

- Foundation Center

<http://fconline.foundationcenter.org/welcome.php?fpc=>

- NIH

<http://grants.nih.gov/grants/guide/index.html>

- NSF

<http://www.nsf.gov/funding/>

# Funding Opportunities via Email

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- Grant Forward Alert Service  
<http://www.grantforward.com> (log-in required)
- Grants.gov Notices  
[http://www.grants.gov/applicants/email\\_subscription.jsp](http://www.grants.gov/applicants/email_subscription.jsp)
- NIH Guide LISTSERV  
<http://grants.nih.gov/grants/guide/listserv.htm>
- My NSF  
<http://www.nsf.gov/mynsf/>

# Funding Basics

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- Funding Mechanisms
  - Grants and Cooperative Agreements
  - Contracts
  - Gifts
- Funding Announcements
  - FOA, PA, RFA
  - BAA
  - RFP, RFQ
  - Unsolicited
  - Restricted Programs

# Restricted Programs

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- An increasing number of funding opportunities have an institutional limit on how many proposals will be accepted
- OSP sends memos to school representatives to disseminate; when in doubt, please contact your OSP representative
- Internal vetting occurs so that Emory does not exceed the number of proposals allowed

# BREAK

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# RFA Exercise



# Elements of a Proposal:

## General Elements Common to Most Funding Sources

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- Face Page
  - Summarizes essential information for the sponsor
  - Indicates Emory endorsement of the proposal

# Elements of a Proposal cont.

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- Abstract (NIH)/Project Summary (NSF)
  - A concise summary that describes the aims and procedures of the proposed project
  - Usually no more than 1-page in length
  - Sometimes both a lay abstract and technical abstract are required
  
- Research Plan (NIH) Project Description (NSF)
  - The “what and why” of the project
  - Answers the question, “why is this work important?”
  - Usually contains specified sections

# Elements of a Proposal cont.

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- Research Plan/Project Description: Introduction
  - Brief description of what the proposal will address, its significance and the beneficiary
  - Outlines the proposal's purpose, goals, and objectives
  - Summarizes the proposed activities
  - Briefly describes the organization and the PI's qualifications to lead the proposed project

# Elements of a Proposal cont.

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- Research Plan/Project Description: Goals and Objectives
  - What are the proposed activities, i.e. the best way, most cost efficient, effective, most equitable solution, to this problem or issue?
  - What other potential solutions have been considered? Why were those ideas rejected?
  - What will result from those activities?
  - What is the proposed time line of the project?

# Elements of a Proposal cont.

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- Research Plan/Project Description: Procedures and Methods:
  - Describes the practical approach to be used in the proposal. This should be a systematic, step-by-step process that describes the techniques or methods to be used.

# Elements of a Proposal cont.

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- Budget
  - Estimated costs for the entire performance period
  - Should be detailed, per budget category (if required by sponsor)
  - (Sub)awards/contracts should have separate, detailed budgets
- Budget Justification
  - Summary explanation of all costs associated with the budget and how those costs are necessary for the project

# Elements of a Proposal cont.

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- Key personnel (Investigators, Other Significant Contributor, Consultants, Senior Personnel) and Biosketches
  - Participants on a project who contribute in a substantive, measurable way to the scientific development or execution of a project, whether or not a salary is involved
  - Key personnel include the PI, Co-I/Co-PI, sub recipients, etc..
  - Applicant (and any and all key people) state employment history, relevant publications, and ongoing and completed research support

# Elements of a Proposal cont.

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- Current and Pending Support (NIH will usually only request at JIT)
  - List all other projects for key personnel (PI, co-I, others identified as key) requiring a portion of the investigator's time
  - Total time on all projects cannot exceed 100%
    - Project title
    - Sponsor
    - Period of performance
    - Percentage of effort
    - Amount of award (or amount requested)
  - Should be consistent with effort reporting



# Elements of a Proposal cont.

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- References/Bibliographies: Provides citations for any literature referenced in the proposal
  - Pay attention to sponsor rules
    - Citation style
    - Use of PubMed
    - Citation order

# Elements of a Proposal cont.

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Assurances and Certifications (usually central office concern)

- Written, binding commitments an institution submits to a federal agency promising to comply with the regulations and stated procedures for achieving compliance.
- Some standard assurances include:
  - Certification regarding a drug-free workplace
  - Certification regarding lobbying
  - Delinquency on federal debt
  - Civil rights
  - Debarment and suspension
- OSP is the official signer

# Proposal Tips

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- **Read the guidelines carefully**
- Forward RFPs to your OSP Contracts Team representative (don't need to wait for routing)
- Encourage faculty to start and submit early to allow for thorough review and remind him/her of internal deadlines
- Alert your OSP Grants or Contracts Team representative, as appropriate, of any complex or late proposals as soon as possible



# QUIZ 1



# Preparing the Budget: Where do you Start?

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## Gather the Facts

### Talk to the Principal Investigator (PI)

- What is the scope of work?
- Who is the Sponsor?
- Where will the work be performed?
- Collaborators?
- Consultants?

# Preparing the Budget:

## Things to Consider- Sponsor Guidelines

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- Instructions and Contractual Terms
- Request for Proposal/Quote (RFP/RFQ)
- Request for Application (RFA)
- Funding Opportunity Announcements (FOAs)
- “Unsolicited” Applications

# Preparing the Budget: Other Considerations

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- Sponsor Guidelines and limitations
  - Salary caps
  - F&A limitations
  - Direct Cost or Total Cost limits
- Sponsor Guidelines and limitations
  - Recover F&A as direct costs from non-governmental sponsors
- May be School-specific rules

# Preparing the Budget

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Costs requested in the proposal budget must:

- Be Allowable. Factors used in determining allowability:
  - Allocable
  - Reasonable
  - Consistently Treated (through application of GAAP)
  - Not disallowed (by limitations or exclusions in the sponsored agreement)
- Directly benefit the proposed project



# Preparing the Budget: Regulatory Guidance

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48 CFR 9905.501 (formerly CAS 501) referenced in Uniform Guidance, 2 CFR 200.419

“The purpose of this Cost Accounting Standard is to ensure that each educational institution’s practices used in estimating costs for a proposal are consistent with cost accounting practices used by the institution in accumulating and reporting costs.”

- Costs recovered through the F&A rate should not be also direct charged.
- Proposed costs must have basis in accounting history.

# Preparing the Budget: Salary

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- Salary requests are expressed as % effort or person months
- Plan realistically
  - Determine the percent of effort for all key personnel needed to conduct the project
  - Downward adjustments of effort may need sponsor approval
- Percent of effort = Percent of Salary requested
  - Cost sharing is discouraged
  - Avoid hourly rates
- Cannot usually direct charge clerical salaries or administrative salaries costs

# Preparing the Budget:

## Allowability of clerical and/or administrative staff

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- Generally part of F&A costs
- *Possible exceptions* (see Uniform Guidance, 2 CFR 200.413)
  - (c) The salaries of administrative and clerical staff should normally be treated as indirect (F&A) costs. Direct charging of these costs may be appropriate only if all of the following conditions are met:
    - (1) Administrative or clerical services are integral to a project or activity;
    - (2) Individuals involved can be specifically identified with the project or activity;
    - (3) Such costs are explicitly included in the budget or have the prior written approval of the Federal awarding agency; and
    - (4) The costs are not also recovered as indirect costs.
- Individual projects requiring project- specific tasks such as database management, etc..

# Preparing the Budget: Fringe Benefits

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- Fringe Benefits are charged as a % of Salary
- Emory's published Fringe benefit rates for federal and non-federal sponsors:

<http://www.osp.emory.edu/facts/fac-rates.html>

# Preparing the Budget: Equipment

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- Definition
  - Equipment costs \$5,000 or more per item, and has a useful life of more than 1 year
- Justification
  - Why is this item necessary to support the science?
  - When is it necessary?
- Availability
  - Is the equipment available elsewhere in the University?
- Competitive Bid Requirement?

# Preparing the Budget: Office Supplies

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- Generally not treated as direct costs
- Can be allowable if specifically related to the project, for example:
  - Specific aim of the project is to create a manual or other instructional media
  - Extensive human subjects data accumulation, questionnaires, etc., is required
- Must be necessary for the conduct of project, as an exception to the Cost Accounting Standards

# Preparing the Budget: Travel

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- Usually restricted to employees
- Domestic
- Foreign
  - See Fly America Act, if Federal \$\$
  - May require prior approval even if in budget

# Preparing the Budget:

## Patient Care

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- Typically Defined as:

“...routine and ancillary services provided by hospitals to individuals, including patients and volunteers...[including] regular room services, minor medical and service supplies...X-ray, operating room, laboratory, pharmacy, [etc..]...”
- Excluded from MTDC base and F&A calculations



# Preparing the Budget:

## What is not included in Patient Care

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- Subject reimbursement and travel
- Costs of ancillary tests performed outside the hospital on a fee-for-service basis
- Costs accumulated in Service Centers at Emory
- Consulting physician fees
- All of the above are “other” or “consultant” expense

# Preparing the Budget: Subcontracts

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- Budget, including F&A costs
- Copy of subcontractor's checklist
- Statement of Work (SOW)
- Cover page/Letter of Intent *with authorized Signature*
- Reps & Certs, if required by Sponsor (federal contract proposals)

# Preparing the Budget: Consultants

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- Emory staff cannot be included in this category
- Consultant Letter of intent and costs (not on a university letterhead)
  - All costs related to the consultant are usually accumulated in this category
- Statement of Work (SOW)
  - Description of consultant's activities

# Preparing the Budget: Other Direct Costs

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- Service Center charges
- Publication Costs
- Rent, when appropriate, but excluded from MTDC
- Animal per diem
- Subject compensation and travel
- Protocol review fees, when appropriate (not on federal grants)

# Preparing the Budget: F&A Costs

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- Facilities & Administrative (F&A) (fka, Indirect Costs or Overhead)  
Pays for many costs that cannot be allocated to a specific project, i.e. utilities, payroll, and other support services, etc..
- Emory's posted indirect cost rate agreements contain the federally negotiated F&A rate
  - Emory University
  - Yerkes National Primate Research Center

# Preparing the Budget: F&A Costs

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- Modified Total Direct Costs (MTDC)

MTDC base excludes

- equipment
- patient care costs
- student stipends/tuition
- alterations and renovations
- rental of off-site facilities
- the portion of each sub-award in excess of \$25K (once for the life of the competitive segment)

- Check sponsor guidelines for appropriate base

# Preparing the Budget: F&A Costs

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## Which rate to Use?

- **Research Rate**

- On Campus – 56%
- Off Campus A -28.2%
- Off Campus B – 26%
- Yerkes -78.5%

- **Instruction Rate**

- On Campus – 55%
- Off Campus A – 37.5%
- Off Campus B – 26%

- **Other Sponsored Activities**

- On Campus - 39%
- Off Campus A – 27.8%
- Off Campus B – 26%

Examples: clinical trials; health or community service projects, seminars, conferences, exhibitions, lecture programs

# Preparing the Budget: F&A Costs

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- Corporate-funded projects
  - CTs (30% - TDC)
  - non-CTs (federal rate)
- Emory's and Yerkes' F&A agreements can be found on the OSP website
- Determination of rate is based on type of agency/sponsor, project type (type of activity) and location

***Note: Off-campus Adjacent (A) is a location within 50 miles commuting distance of the University***

***- SOM can identify the appropriate buildings***

***Off-campus non-Adjacent (B) is a location beyond 50 miles commuting distance of the University***



# Preparing the Budget: Don't Overlook...

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## **Are there Humans involved?**

- Subject compensation and travel?
- Related patient care costs?
- Equate cost proposed to research plan, such as a consideration of the number of subjects involved

## **Are there Animals involved?**

- Prepare detail cost estimate including shipping and box charges
- Animal purchase or use fees
- Animal per diem
- Equate cost proposed to research plan (e.g., number of animals involved)

# Preparing the Budget: And more...

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## **Are there large pieces of equipment?**

- Installation and set-up included?
- Maintenance contracts?
- Space available or renovations costs included (provide a quote)
- Freight costs

# Preparing the Budget:

## Reasons for carefully preparing the budget

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- Ensures all costs are covered
- Aids post award management
- Aids the department in budget planning
- Can reduce the possibility of significant budget cuts by the sponsor
- Significant budget changes are interpreted by sponsors as a change in scope!

# Preparing the Budget: Budget Justification

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- Each line item usually requires specific justification
- Unusual or extraordinary expenses such as equipment, clerical salaries and administrative expenses, may require additional information
- Check sponsor guidelines for requirements

# Preparing the Budget: Cost Sharing Considerations

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- Cost Sharing: portions of the project costs not funded by sponsor
- Types
  - **Mandatory:** Required by the Sponsor
  - **Voluntary Committed:** Not required by sponsor but Emory PI promises to provide cost-sharing
  - **Matching or In-Kind:** Some sponsors require Emory to match funds (i.e. **50/50** ) or provide “in-kind” cost-sharing

# Preparing the Budget: Cost Sharing Considerations

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- Record keeping obligations
- What is allowable
  - Can't use federal \$ without prior approval
  - Can't use the same \$ for two different projects
  - Time period requirements
  - Cost sharing \$ subject to the same allowability rules as award
  - Department needs to provide funding

# Preparing the Budget:

## Cost Sharing Considerations

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- Cost sharing that is proposed or required must be indicated in EPEX when submitting the proposal
- List source of funding and appropriate Department ID for the non-salary cost share funds
  - Proposals must be accompanied by documentation from the individual or unit responsible for the funds committing indicating their approval of the use of their funds for the cost-sharing commitment identified in the proposal

# BUDGET EXERCISE then BREAK

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# Steps to Proposal Submissions

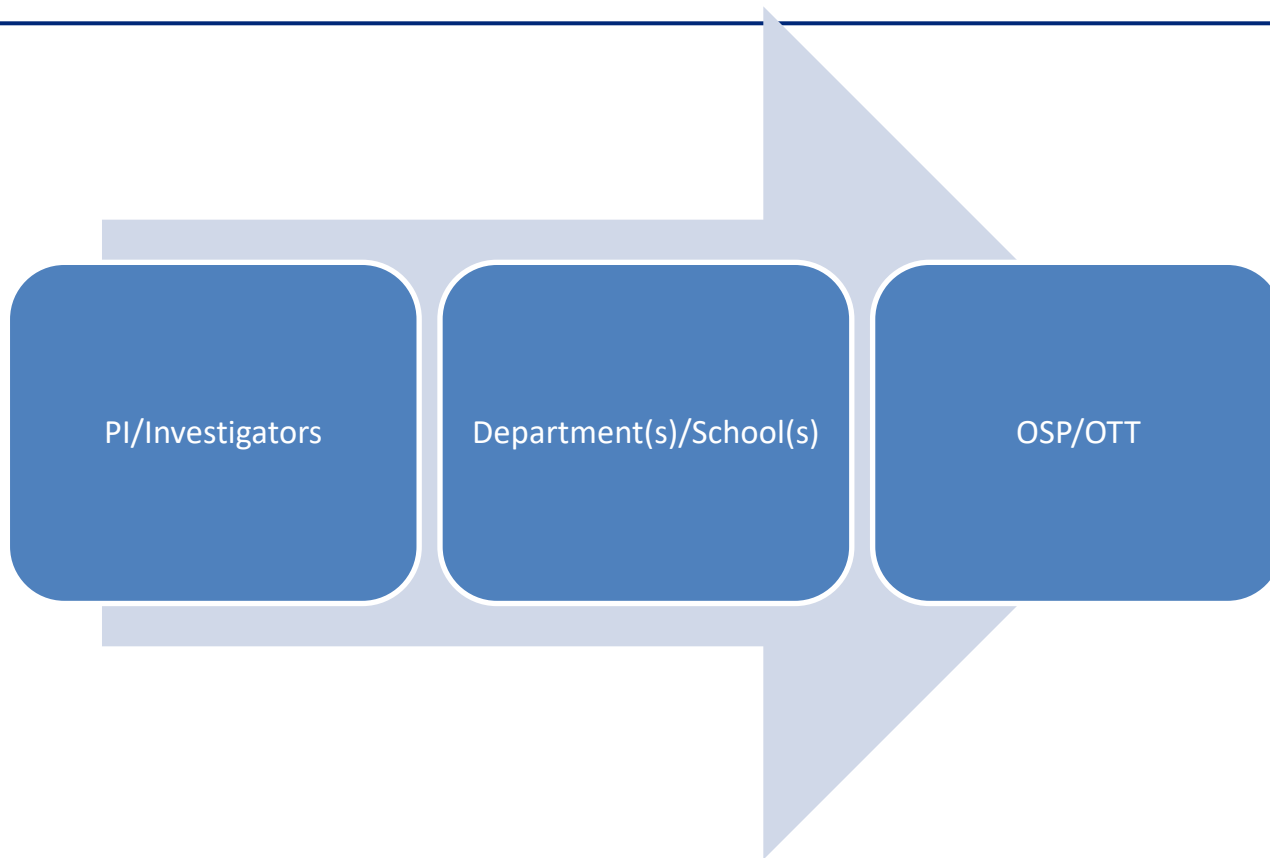
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In this section you will review the following:

- Proposal routing requirements
- Emory Proposal Express (EPEX) Requirements
- How to submit a proposal
  - (paper/ electronic)

# Proposal Routing Process

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# Proposal Routing Process

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The proposal routing process through EPEX obtains the necessary internal approvals to allow OSP/OTT to review, sign and/or submit a proposal to a sponsor.

The proposal routing process also creates a record of the proposal in the Compass financial system.

# Proposal Routing: EPEX

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- EPEX: Emory Proposal Express
  - Emory's Electronic Routing System
  - Does not go to sponsor/agency
  - Departments/RAS/Schools – provides opportunity to review/approve the following:
    - approve effort commitment
    - resources
    - space
    - financial commitments that are made to projects
    - approve science and agree that projects are consistent with objectives of department and/or school

# School/RAS Proposal Review

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Departments/RAS/Schools – provides opportunity to review/approve the following (continue):

- Is cost-sharing involved, and if so, in what form?
- If there is direct charging of administrative salaries to federal grants?
- Budget is accurate, including salary verification, fringe benefits and overhead calculations.
- Proposal conforms with School and Emory policies, and all applicable sponsor guidelines.

[School review of proposal may not be required depending on commitments made in the proposal. (Streamlined process under RAS structure.)]

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# Proposal Routing:

## OSP Internal Deadlines

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- OSP requests receipt of the complete and final routed application, either in Cayuse or as or other electronic file (if applicable for the specific agency) five (5) business days prior to the agency deadline to allow time for a thorough review and to ensure the application is successfully submitted to the sponsr.
- Receipt of applications after this time will be reviewed as completely and promptly as possible in the order received, given volume and time allotted prior to the agency deadline.
- Submitters should account for routing time, including any guidance or deadlines from individuals schools or units, when planning for the submission process.

# Proposal Routing: EPEX (cont.)

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- Provides PI and investigator assurances/ certifications re: project responsibilities, and institutional policies, including the of Financial Interests in Research Investigator Report
- Data from EPEX are managed in Compass for reporting and tracking purposes
- Provides key project data re: compliance and regulatory issues

# Proposal Routing: EPEX

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- |                       |                        |
|-----------------------|------------------------|
| •Title                | •Type of Proposal      |
| •Sponsor Deadline     | •Subcontracts          |
| •Agency/Institution   | •Period of Performance |
| •Sponsor Contact      | •Cost Sharing          |
| •Emory Contact        | •Compliance Data       |
| •PI name/effort       | •Collaborative Splits  |
| •University Approvals | •Conflict of Interest  |
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# Proposal Routing

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- Applications requiring additional information (e.g., detailed information from OSP, OTT or FGC) require more time
- Responses to Request For Proposals (RFPs): entire RFP sent to OSP ASAP since OSP must provide more information than a standard grant application

# Proposal Routing cont.

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- EPEX proposal routing is also utilized to route incoming grants transferred to Emory from another institution
  - PIs transferring from another institution should begin the transfer process as soon as they have accepted a position at Emory
  - Mechanisms are in place to allow for such routing prior to arrival

# What does it mean when you certify a proposal in EPEX?

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EPEX is a proposal routing system that allows the PI to certify, and allows department/division, school and OSP to approve that each unit understands and is compliant with applicable fiduciary and regulatory matters pertaining to the proposed research and that we are in a position to meet those obligations.

EPEX certification is personal in nature.

# EPEX Certification

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## PRINCIPAL INVESTIGATOR/PROJECT DIRECTOR ASSURANCE

My Signature below certifies that: 1) the statement herein are true, complete and accurate to the best of my knowledge; 2) I am aware that any false, fictitious, or fraudulent statement or claims may subject me to criminal, civil, or administrative penalties; and 3) I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.

## INVESTIGATOR DATA

**INVESTIGATOR(S) CERTIFICATION:** My signature below certifies that (1) I am not delinquent on any federal debt; (2) I am not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from current transactions by a federal department or agency; (3) I have not and will not lobby any federal agency on behalf of this award; (4) ) I am aware and agree to abide by Emory's Drug Free Workplace; (5) I agree to abide with the University's research policies including Sponsored Research and Intellectual Property policies; (6) I agree to be bound by the terms and conditions of the outside grant or contract which supports this proposed activity; and (7) I confirm my assignment of any copyright, patent, or other intellectual property rights generated under this project to Emory in accordance with the terms and conditions of Emory's Intellectual Property Policy and agree to execute any documents that are requested to document such transfer or facilitate protection of such intellectual property.

Certify

Deny

Hold

Edit

# Proposal Submission

## Electronic Proposal Submission

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- Numerous agencies require the electronic submission of applications (e.g., DOD, CDMRP, FastLane, Proposal Central [Foundations], AHA and HRSA)
- Cayuse 424
- Grants.gov
- Read the proposal guidelines
- Does the PI or Institution need to be registered users?
- **All** electronic applications must be approved by OSP before submitting to sponsor even if the sponsor does not require an institutional signature

# Just-In-Time (JIT)

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- National Institutes of Health (NIH) uses the JIT feature to request specific information prior to issuing an award
- The purpose of JIT is to reduce the number of documents due at the time of application
- If the application receives a favorable score, then JIT information is requested. Just because JIT information is requested, however, does not necessarily mean the application will be funded

# JIT cont.

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- Several other agencies follow this same concept; however, only NIH calls it JIT
- Different agencies request varying types of information at the JIT phase
- NIH requests the following information at the JIT phase:
  - Current Other Support
  - Certifications (IRB approval and/or IACUC approval)
  - Human Subjects Education (for grants involving Human Subjects)

# JIT cont.

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- NIH also uses this opportunity to request any additional information that they need in order to issue the award.
- JIT information requested by NIH is submitted using the Just-In-Time feature of the eRA Commons.
- Occasionally, JIT information requested by NIH may be submitted directly to the Grants Management Office. This information must be countersigned by an authorized business official in OSP. This is rare and should only be done when specifically requested by the GMS.



# JIT cont.– Important IACUC/IRB reminders

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- There are no “generic” IRB or IACUC approvals.
- If a PI wishes to use an existing protocol for a new grant, an amendment must be filed to the protocol. This would be rare for IRB approvals. The amendment should provide the new funding information, including title and grant number.
- For IACUC, each funding source must be listed in its own animal section.
- For IRB, the IRB must do a “grant-to-protocol” review, so they must be provided with a copy of the final grant application.
- In these cases, the grant does not have IRB/IACUC approval until such a modification is approved.
- Therefore, OSP cannot certify to such approval until the modification is formally approved by the appropriate office.

# Federal Award Types

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## ■ Grant

- Purpose: To transfer money, property, services, or anything of value to a recipient in order to accomplish a public purpose.
- Involvement: No substantial involvement is anticipated between government and recipient during the performance of activity.

## ■ Contract

- Purpose: To acquire property or services for direct benefit or use of the federal government
- Involvement: Varying amounts anticipated between government and recipient during performance activity.

# Federal Award Types cont.

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## ■ Cooperative Agreement

- Purpose: To transfer funds to recipient to accomplish a public purpose
- Involvement: Substantial amounts anticipated between government and recipient during performance activity.

# Types of Awards

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## ■ Intergovernmental Personnel Act

- Agreement used by federal agencies; at Emory primarily from the CDC and the VA
- Used for personnel who contribute part of their effort at a federal agency

## ■ Subcontract

- A document that formalizes an acquisition or procurement relationship with a third party to perform substantive sponsored project effort based upon a *Sponsored Contract or Sponsored Award* made to the University

# Types of Awards cont.

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## ■ Subaward

- A document that formalizes an award of financial assistance to a third party to perform collaborative sponsored project effort based upon a *Sponsored Award* made to the University
- The term does not include technical assistance, which provides services instead of money; other assistance in the form of loans, loan guarantees, interest subsidies, or insurance; and direct payments of any kind to individuals

# Types of NIH Awards

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- **Research Grants (R series)**
  - R01, R03, R13, R15, R21, R34, R41/R42, R56
  - R01 is most common NIH research grant
- **Career Development Awards (K series)**
  - Career Development Awards
  - May be both mentored or non-mentored awards
  - Generally have a minimum effort requirement around 75% effort
- **Research Training and Fellowships (T & F series)**
  - Individual Fellowships (F series), pre- and post-doc
  - Institutional Research Training Grants (T series), pre- and post-doc
- **Program Project/Center Grants (P series)**
  - Program project/center grants are large, multi-project efforts that generally include a diverse array of research activities.
  - Examples are P01, P20, P30, and P50

# Types of NIH Award cont.

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- **Cooperative Agreements (U01, U19, U54)**
  - A support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities

# NIH Award Identification Numbering System

Application Type	Activity Code	Organizational Code	Serial Number	Suffixes	Grant Year
3	R01	CA	012921	-04	S1A1

- **Application Type Code**
  - A single-digit code identifying the type of application received and processed.
- **Activity Code**
  - A three-digit code identifying a specific category of extramural activity.
- **Organizational Code**
  - A two-letter code identifying the primary NIH institute/center funding the grant. In the example above, “CA” refers to the National Cancer Institute.
- **Serial Number**
  - A six digit number generally assigned sequentially to a series within an Institute, Center, or Division.
- **Suffixes**
  - A field composed of the following components
    - Grant Year
    - Supplement (represented by the letter “S”)
    - Amendment (represented by the letter “A”)
    - Allowance (represented by the letter “X”)



# NIH Award Identification Numbering System cont.

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- Code Types
  - 1 - **New**
    - Request for DHHS support of a project that has not yet been funded.
  - 2 - **Renewal** (Competing Continuation)
    - Request for an additional term of support based on a funded previous project; must compete for available funds.
  - 3 - **Revision** (Supplement)
    - Request for additional funds for a current award, to cover increased costs (noncompeting) or to expand the scope of work (competing).
  - 4 – **Extension** (considered a “competing” award)
    - Request for additional funds beyond the years previously awarded; limited to certain activities, including MERIT (R37) and certain Fellowship (F) and Career (K) awards. These F and K applications do not compete for funds. R37’s do require National Advisory Council review.

# NIH Award Identification Numbering System cont.

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- Code Types (cont.)
    - **5 - Noncompeting Continuation**
      - Request to pay next budget increment of a current award; does not compete for available funds.
    - **6 - Change of Organization Status (Successor-In-Interest)**
      - Request for support of a funded project at an institution where the legal status of the organization has been changed through an approved Successor-In-Interest action.
    - **7 - Change of Grantee or Training Institution**
      - Request for support of a funded project that has been transferred from one grantee or training institution to another.
    - **8 - Change of Institute or Division**
      - Noncompeting continuation that has been transferred from one I/C to another.
    - **9 - Change of Institute or Division**
      - Competing continuation (cf. Type 2) that has been transferred from one I/C to another.
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# CONTRACTS

# Contracts (Research)

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## Purpose

- To acquire goods or services for direct benefit or use for the sponsor, with a public benefit objective for institution
- To establish a clear understanding of how Emory and the sponsor will do business together (administrative expectations, legal protections, dispute resolution, invoicing and payments, intellectual property ownership, etc.)
- To provide an objective, documented roadmap for understanding the research activity and specifying requirements related to the research activity (scope of work, reports, publication, etc.)

# Contracts

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- In addition to establishing clear expectations, contracts serve important risk management purposes:
  - Confidentiality (new drug/device testing)
  - Compliance (HIPPA, FDA regs, etc.)
  - Patient Safety/Consent
  - Costs associated with subject injury (industry only)
  - Liability and Indemnification (industry only)
  - No warranties for research results (commercial applications may vary)

**Research is “big business”, with substantial amounts of money and significant business risks**

# Contract Types

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- Contracts vary in their purpose and may or may not include a funding component
- Contract types differ by sponsor (federal, non-profits, for-profits)
- Contract types differ by project type (agency/sponsor-initiated vs. investigator-initiated)

# Contract Types

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- Most Commonly Used Contracts
  - Confidentiality/Nondisclosure Agreements (CDA/NDA)
  - Federal Contracts
  - Federal Cooperative Agreements
  - Clinical Trial Agreements (CTA)
  - Sponsored Research Agreements
  - Research Service Agreements
  - Material Transfer Agreements (MTA)
  - Data Transfer/Data Use Agreements (DTA/DUA)

# Contracting Life Cycle

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	<b>Grant</b>	<b>Cooperative Agreement</b>	<b>Contract</b>
<b>Basic Purpose</b>	Provides Assistance with few restrictions	Provides assistance with substantial involvement between parties	Procure tangible goods and services
<b>Solicitation Method</b>	Application kit or guidelines	Request for Applications (RFA)	Request for Proposal (RFP) for federal contracts Direct contact from sponsors for industry contracts
<b>Award Instrument</b>	Short, may refer to general conditions	Describes involvement, part relationships	Long, detailed specs, clauses, regulations, and expected results
<b>Involvement by Sponsor</b>	Generally none	Substantial	May be extensive
<b>Re-budgeting</b>	Flexible	Usually flexible	More restrictive; typically requires contract amendment
<b>Equipment Title</b>	Grantee	Varies; specified in terms of contract	Varies; specified in terms of contract
<b>Performance Period</b>	Specified in grant	Specified in coop agreement	Specified in contract
<b>Patent Rights</b>	Generally liberal	May be involved	Provision in contract
<b>Publications</b>	May ask to be informed	May ask to be informed	Prior review (timeframe more restrictive for clinical trial agreements)
<b>Technical</b>	Annual summary report	Frequent reports	Detailed, maybe frequent

# Important Contract Elements/Provisions

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- “Standard” contract – 15-20 sections and about 17-20 pages in length
- Federal contracts differ in length, scope and format from non-federal contracts
- FAR clauses in federal contracts (add considerable time to contract review)
- Most important sections: indemnification (industry), confidentiality, patient protection (HIPAA, communication of adverse events, etc.), publication, intellectual property, budget/payment schedule, and subject injury (industry)
- Others: termination, data ownership, use of results, use of name

# Important Contracting Issues

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- **Publications** – significant issue for many industry sponsors and export controlled federal projects
- **Intellectual Property (IP)** –ownership/grant of rights to (IP) can be an important issue for industry contracts
  - University's position is to retain ownership of IP and grant rights to sponsor through a commercial license to be negotiated after IP is created
  - Sponsor may own IP under certain circumstances (sponsor-designed clinical trial, performance of research services)
- **Budget/Payment schedule** – IRB and other study start-up fees (non-refundable) if non-federal, total amount and frequency of payments (including hold back provisions)

# Important Contracting Issues

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Indemnification: Defend/hold harmless in event of lawsuit

- Who provides? (industry partners; rarely provided if project is PI initiated; not provided by governmental entities or foundations)
  - Who is covered? (Emory and its employees, subcontractors, agents, directors, officers, and affiliates)
  - What is covered? (negligence and willful misconduct of sponsor or their representatives/agents, Emory's use of sponsor's drug/device, experimental portion of patient care when sponsor designs the protocol, use of results by sponsor)
  - Exceptions (Emory's own negligence, failure to follow protocol or regulations, etc.)
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# Important Contracting Issues

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Subject Injury: Who pays for diagnosis and treatment if a patient is injured by participating in a clinical study

- Who provides? (primarily from industry partners; rarely provided if project is PI initiated; not provided by governmental entities or foundations)
- Who is covered? (only the patients)
- What is covered? (harm caused by the drug/device or the experimental portion of the study)
- Exceptions (the underlying disease, Emory's own negligence, failure to follow protocol or regulations, the patient's failure to follow instructions, etc.)

# Other Important Contracting Issues

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- **Term and Termination** – non-industry contracts almost always have an expiration date, some industry contracts may not have an expiration date, reciprocal rights, coverage for incurred expenses
- **Data ownership** – critical for sponsored research agreements and investigator-initiated projects
- **Use of results** – critical to meet Emory's academic mission
- **Use of name** – Generally prohibited except for federal registries (clinicaltrials.gov), required reporting and some publications. Commercial purposes almost always prohibited.

# Important Contracting Issues

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- **Confidentiality (scientific)** – “everything we give you and everything you do for the study,” length of time, exceptions, reciprocity
- **Confidentiality (patient)** – HIPAA, restrict use to what is expressly agreed to in the informed consent form
- **Publication** – right to publish independently and without restrictions, “approval” vs. “review”, non-profit status (IRS)
- **Communication with the Press** – no appearance of censorship!

# Important Contracting Issues

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- **Amendments** – any change in terms to the contract (contractual obligation, PI change, sponsor/agency name, term, budget, scope of work, etc.)
- **No cost extensions**
  - Agreement may include a finite term that must be extended contractually in order to continue research
  - Most clinical trial agreements are ‘open ended’ contracts (expire when all obligations are satisfied)- initially set up for 10 yrs with up to 10 yr extension with each NCE
- **Signature authority** – Emory signature policy



# BREAK

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# Setting up the Award

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- After a grant or program is selected for award, OSP will receive an award notice from the agency.
  - Receipt via e-mail (most federal awards; many subawards)
  - Receipt in hard copy (if sent directly to PI, please forward a copy as soon as possible to OSP)
- OSP reviews the award terms and conditions along with any special restrictions placed on the award or expenditure of funds
- OSP negotiates alternative terms, when appropriate, to ensure the award is within Emory policy and that Emory can meet its obligations under the award

# Setting up the Award

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- OSP reviews the amount of the award relative to the original proposal. Contacts agency as necessary to discuss if there are errors or a change in scope is necessary
- OSP works with department contacts to obtain all necessary documentation to set the award up in the Compass system:
  - All necessary compliance approvals (IRB and IACUC approvals)
  - Specific documentation required by sponsor (e.g., Statement of Appointment, etc.)

# Setting up the Award

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- Necessary Compliance Information includes:
  - **Institutional Review Board (IRB)**
    - Any project involving human subjects requires the review and approval of the Emory IRB
  - **Institutional Animal Care and Use Committee (IACUC)**
    - Any project involving vertebrate animals requires the review and approval of the Emory IACUC
  - **Emory Conflict of Interest Office**
    - COI disclosures required with every proposal routed in EPEX
    - eCOI system found at [www.coi.emory.edu](http://www.coi.emory.edu)

# Setting up the Award

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Once OSP/OTT have performed the functions noted above, OSP/OTT initiates an Award Set-up Request in the Compass financial system

The electronic Emory Award Set-up page is a custom module in Compass which allows electronic management and tracking of the award set-up process. General steps include:

- OSP/OTT initiates/approves a set-up request and provides all relevant documentation (e.g., Notice of Grant Award, executed contract, etc.)
- FGC conducts the set-up process
- FGC generates the award and associated SpeedTypes
- FGC issues the internal Notice of Award Acceptance (NOA document)
- FGC distributes the NOA through the OnBase imaging system
- FGC sets up award for billing/invoicing

*More information the award set-up process will be described in RAE Day 2*



# COMPLIANCE AND REGULATORY CONTROLS

# Compliance and Regulatory Controls

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- Definition:

**com·pli·ance**

Pronunciation: k&m-'pli-&n(t)s

Function: *noun*

**1 a** : the act or process of [complying](#) to a desire, demand, or proposal or to coercion **b** : conformity in fulfilling official requirements

**2** : a disposition to yield to others

**3** : the ability of an object to yield elastically when a force is applied

**[FLEXIBILITY](#)**

*Merriam Webster Online*

# Compliance, how we do it...

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- Compliance permeates every aspect of University administration
- It requires a sustained coordinated effort between central administration, schools, faculty, research personnel and students...and many others
- The key components of effective compliance are: communication and a clear delineation of roles and responsibilities
- A vast number of individuals are involved within the University to ensure that the infrastructure supports and protects the research enterprise.



# Who and what are we trying to protect? (compliance refined)

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- People
  - those who conduct research
  - those who contribute as research subjects
- Animals
  - those who work with animals
  - the animals
- Academic freedom
  - the right to freely investigate
  - protection of intellectual property
  - the rights of other researchers



# What else are we protecting?

## The University's Reputation

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- the most valuable asset an institution has is the public's perception that the research conducted meets the highest ethical and scientific standards
- the public's memory is long and unforgiving
- any allegation of malfeasance or misconduct is damaging

# Conflict of Interest Disclosure

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- The University's reputation depends on the objectivity of our research
  - All investigators (see definition) must complete and submit a disclosure form with any proposal routed in EPEX
  - These forms are required at the time of routing and for every type of proposal—new, continuation, etc..
  - “Investigator” may include more people than you think it does!
  - Emory personnel use the eCOI system to fill out a **University Investigator Report of Financial Interests in Research (PFIRR)** ([www.coi.emory.edu](http://www.coi.emory.edu).)
  - Non-Emory individuals use a paper disclosure form <http://www.osp.emory.edu/forms/other/index.cfm>
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# Conflict of Interest: Who is an Investigator?

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**At a minimum, the term *Investigator* includes :**

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

# Who Submits a Disclosure Form?

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- The need for a conflict of interest form is **not** predicated on whether a person is employed by Emory or whether a person is paid from the grant!
- Anyone who meets the definition on the previous slide must submit a disclosure. This could include:
  - Consultants, paid or unpaid
  - Other Significant Contributors
  - Collaborators, paid or unpaid
- OSP will compare the disclosures provided to the list of senior/key personnel. It is up to the PI to determine if anyone not listed as senior/key personnel meets the definition of investigator

# Sub-awards and Disclosure

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- If the recipient institution certifies that it has an enforceable FCOI policy that is compliant with the current regulations and that the sub-award personnel will be covered under that policy, we do not need disclosure forms for the sub-award personnel.
- If the recipient institution does not have an enforceable FCOI policy that is compliant with the current regulations, the sub-award personnel will have to be covered under Emory's policy. In this case, we do need a paper certification from any personnel who meet the definition of "investigator."
- The Federal Demonstration Partnership (FDP) has established a database of institutions who have compliant policies, so you can look up your sub-awardees to see if they are in the list. [http://sites.nationalacademies.org/PGA/fdp/PGA\\_070596](http://sites.nationalacademies.org/PGA/fdp/PGA_070596)

# PI Compliance Responsibility

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- **Scientific Compliance:** The PI is responsible for the programmatic management of the grant or contract. This entails executing the technical aspects of the project, including all progress and technical report requirements.
  
- **Regulatory Compliance:** Adhering to all University and sponsor requirements for:
  - Human subjects
  - Lab animals
  - Biohazards, safety and security
  - Conflict of Interest disclosure of outside responsibility
  - Effort Reporting
  - Subrecipient monitoring

# And Good Financial Stewardship!

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- Initiating forms -- salary reallocations, personnel action forms, employment agreements, purchase orders -- for expenses that are necessary for the conduct of the sponsored project.
- Reviewing expenditures on a monthly basis to determine that all charges and credits are appropriate.
- Exercising fiscal responsibility for maintaining and controlling the transactions processed on a grant/contract account.





# Quiz 2

# Useful Links

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- OSP Website:  
<http://www.osp.emory.edu/>
- Grants.gov  
<http://www.grants.gov>
- NIH Funding Opportunities and Newsletter:  
<http://grants.nih.gov/grants/guide/index.html>
- NSF Funding Opportunities and Newsletter:  
<http://www.nsf.gov/mynsf>
- NIH Proposal Tutorial:  
<http://grants.nih.gov/grants/oer.htm>
- NSF Proposal Tutorial:  
<http://www.nsf.gov/funding/preparing/>
- UG Proposal Quick Guide:  
[http://osp.emory.edu/documents/ugep/ug\\_proposal\\_guide\\_11\\_25\\_14.pdf](http://osp.emory.edu/documents/ugep/ug_proposal_guide_11_25_14.pdf)



# QUESTIONS?