Worker Training Program
Business Official Session

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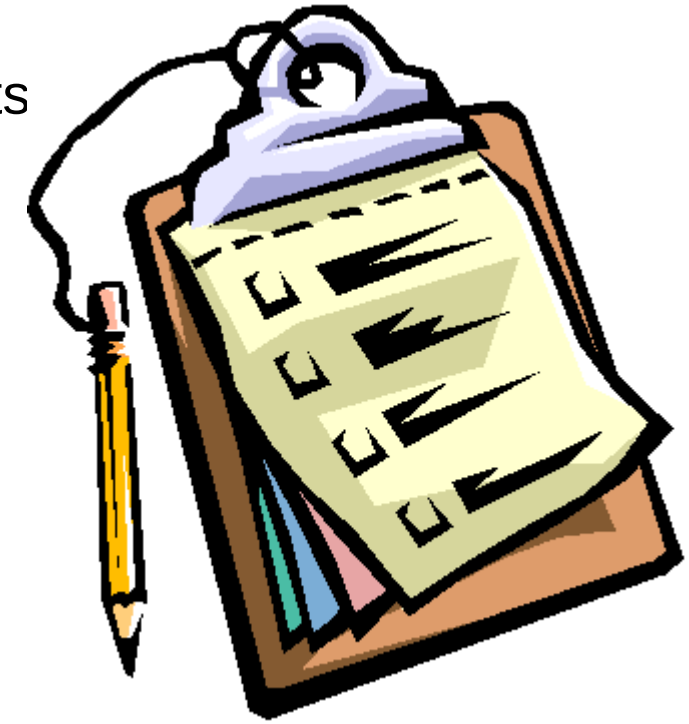
Grants Management Officer
National Institute of Environmental Health Sciences

Agenda

- Reminders and Program Notes
- Policy Special Topics
  - Prior Approval Requirements
  - Program Income
  - Human Subjects
  - Closeout



Reminders and Program Notes

Deadlines

- Research Performance Progress Report (RPPR)
  - 60 days prior to budget period end date
- Federal Financial Report (FFR)
  - 90 days after the calendar quarter the budget ends in
- Closeout Documents (Final/Interim RPPR, Final Invention Statement, Final FFR)
  - 120 days after the project period end date
- Single Audit
  - The earlier of: a) 30 days after auditor's report or b) 9 months after organization's fiscal year.

Tips for better communication

- Include your grant number in the email subject line.
- Official Requests should clearly come from the **Signing Official**, with PI concurrence, and be addressed to the Grants Management Officer and copy the Program Officer.
- If you call and leave a voice-mail, follow-up with an email.
- Send separate requests for separate grants.

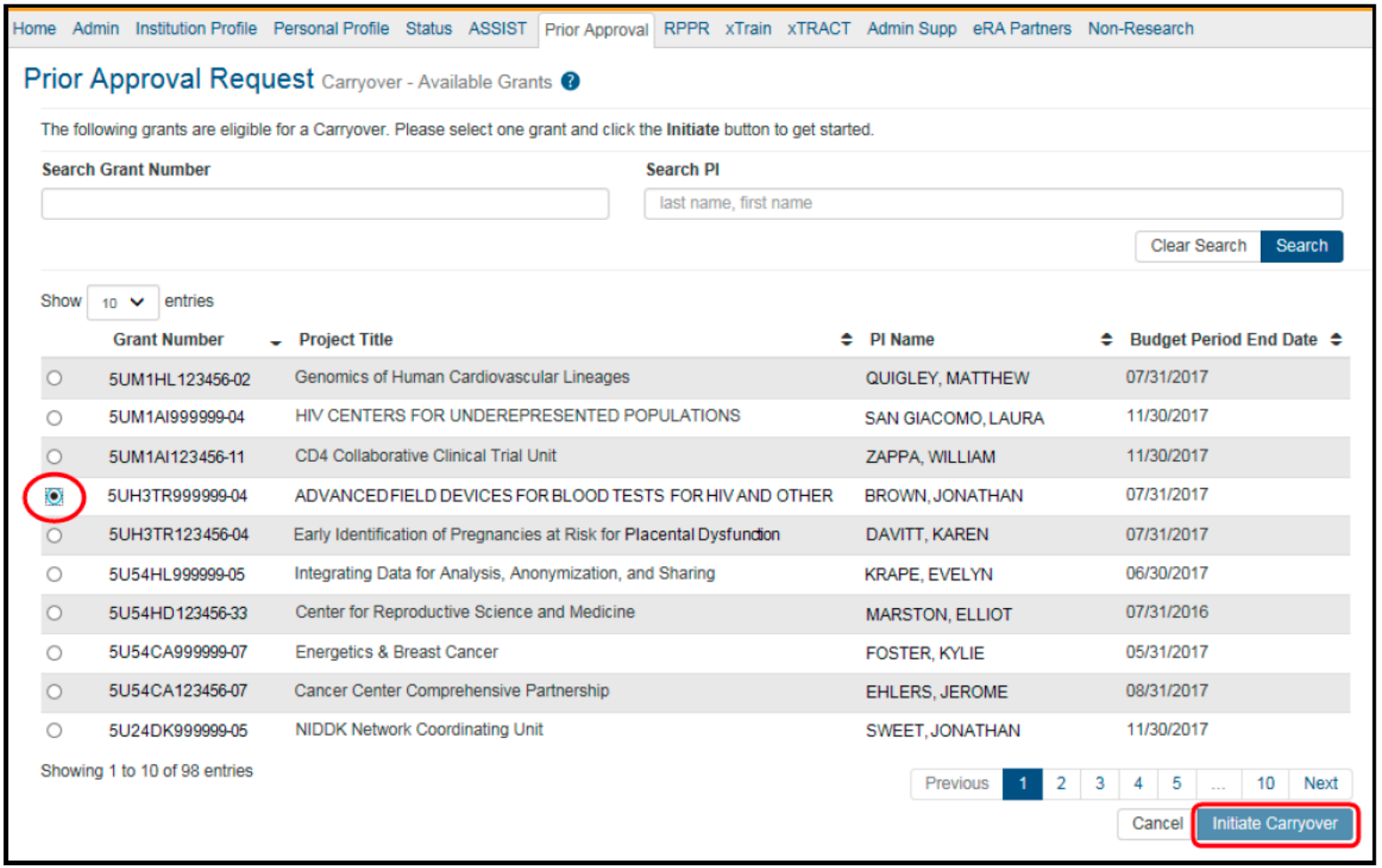
Policy Special Topic: Prior Approval Requirements

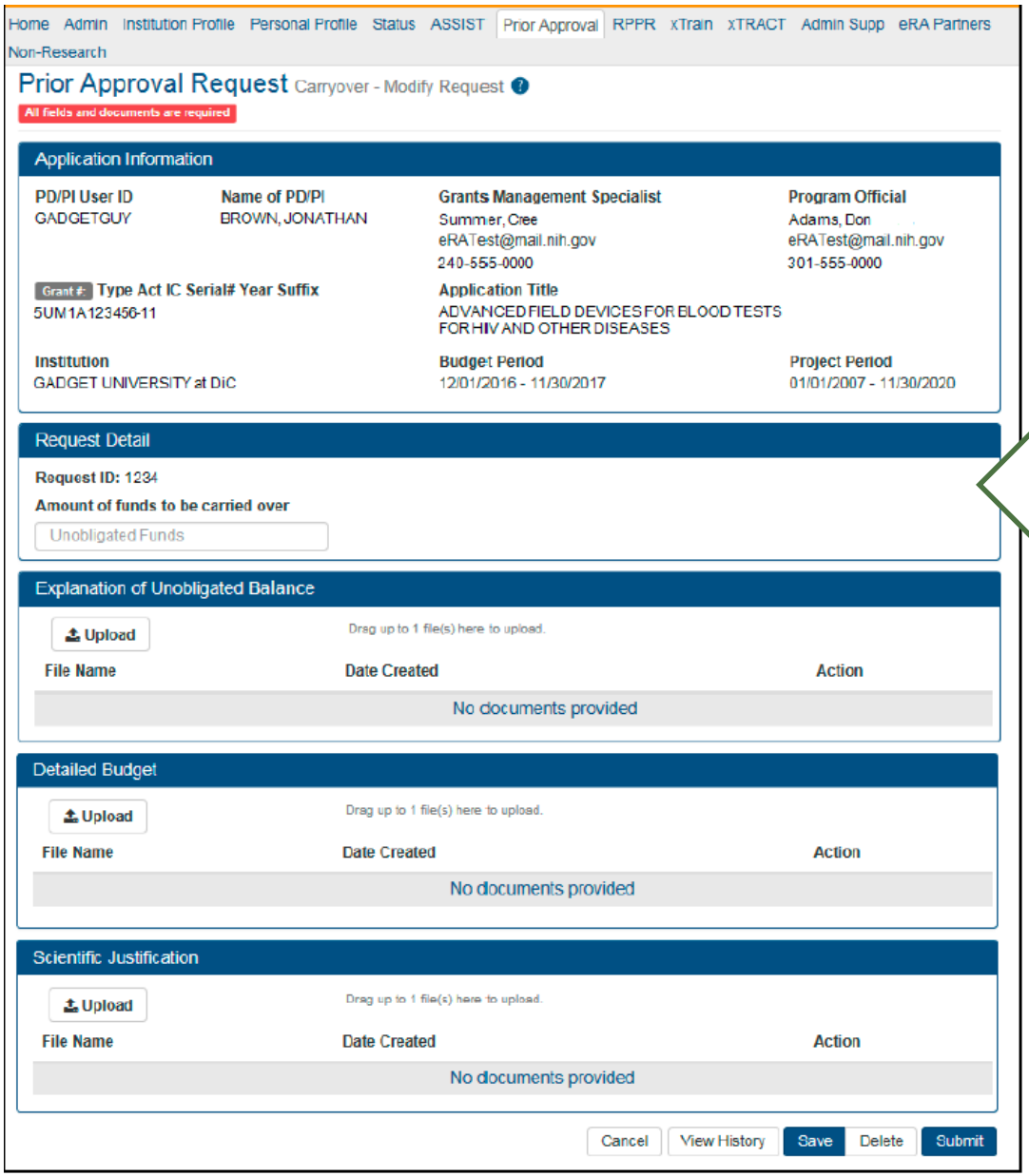
Prior Approval Requirements

- Must be submitted by a **Signing Official.**
- Some examples of when you need prior approval:
  - Change of key personnel named on award.
  - Rebudgeting of funds, if restricted on award.
  - Carryover of unobligated balance, if restricted on award.
  - No-cost extensions:
    - If this is the first extension, you can do this in eRA Commons without NIH prior approval, as long as you submit before the final budget period end date.
- Email vs. eRA Commons
  - Not all prior approval types can go through eRA Commons.
  - Emails can get lost in inboxes.

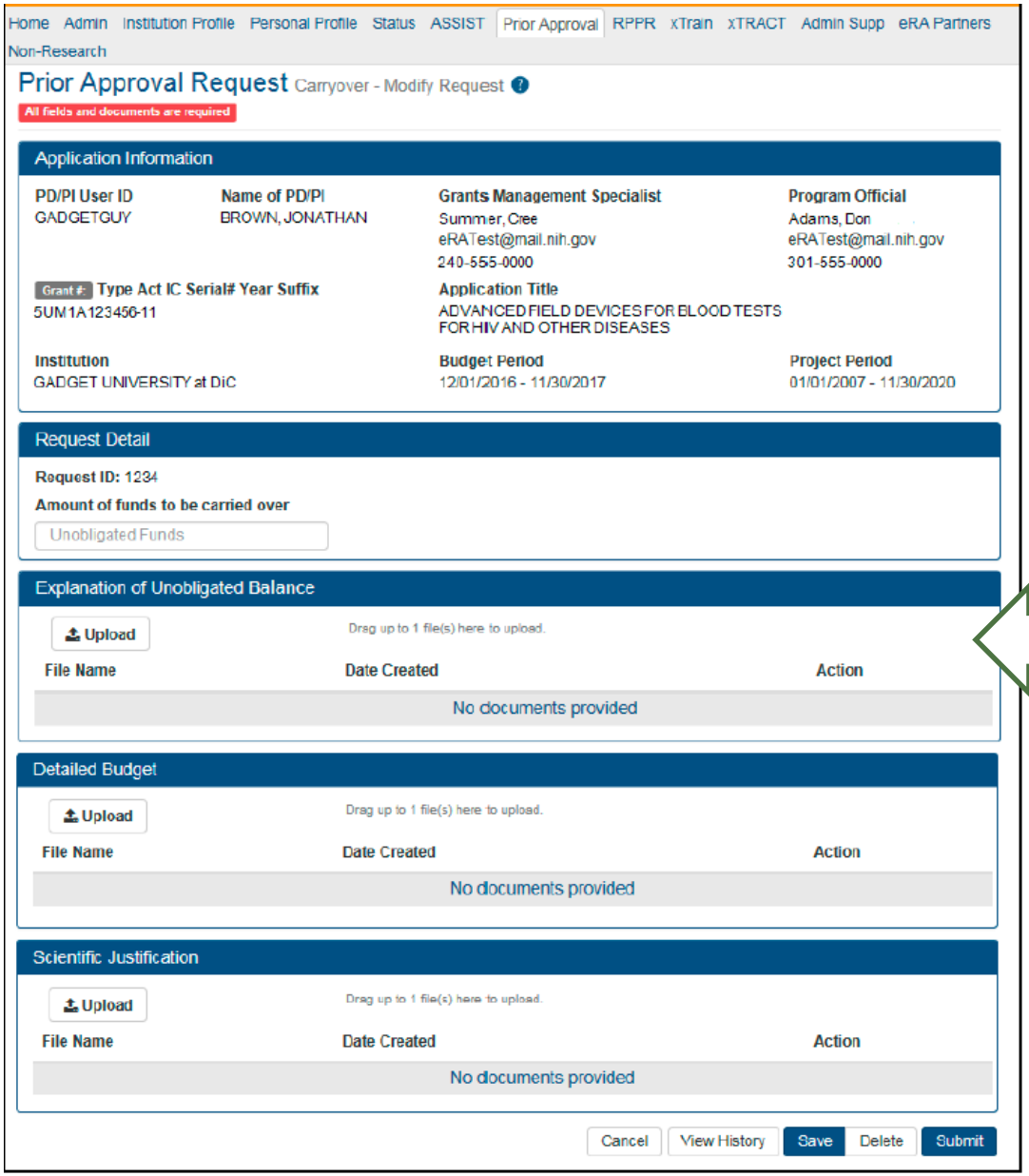
Electronic Request of Prior Approvals

- New since last year – Carryover Requests!

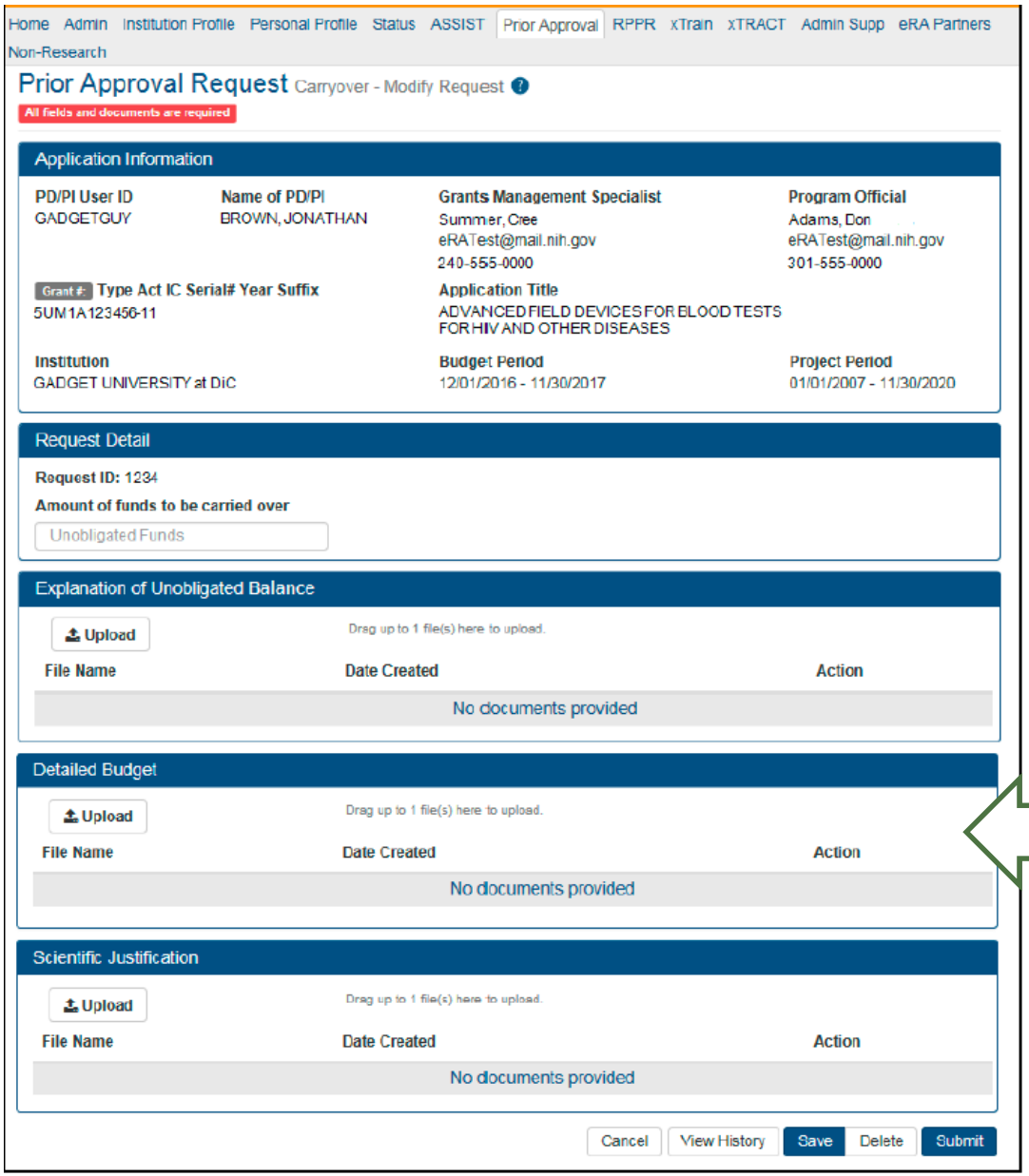




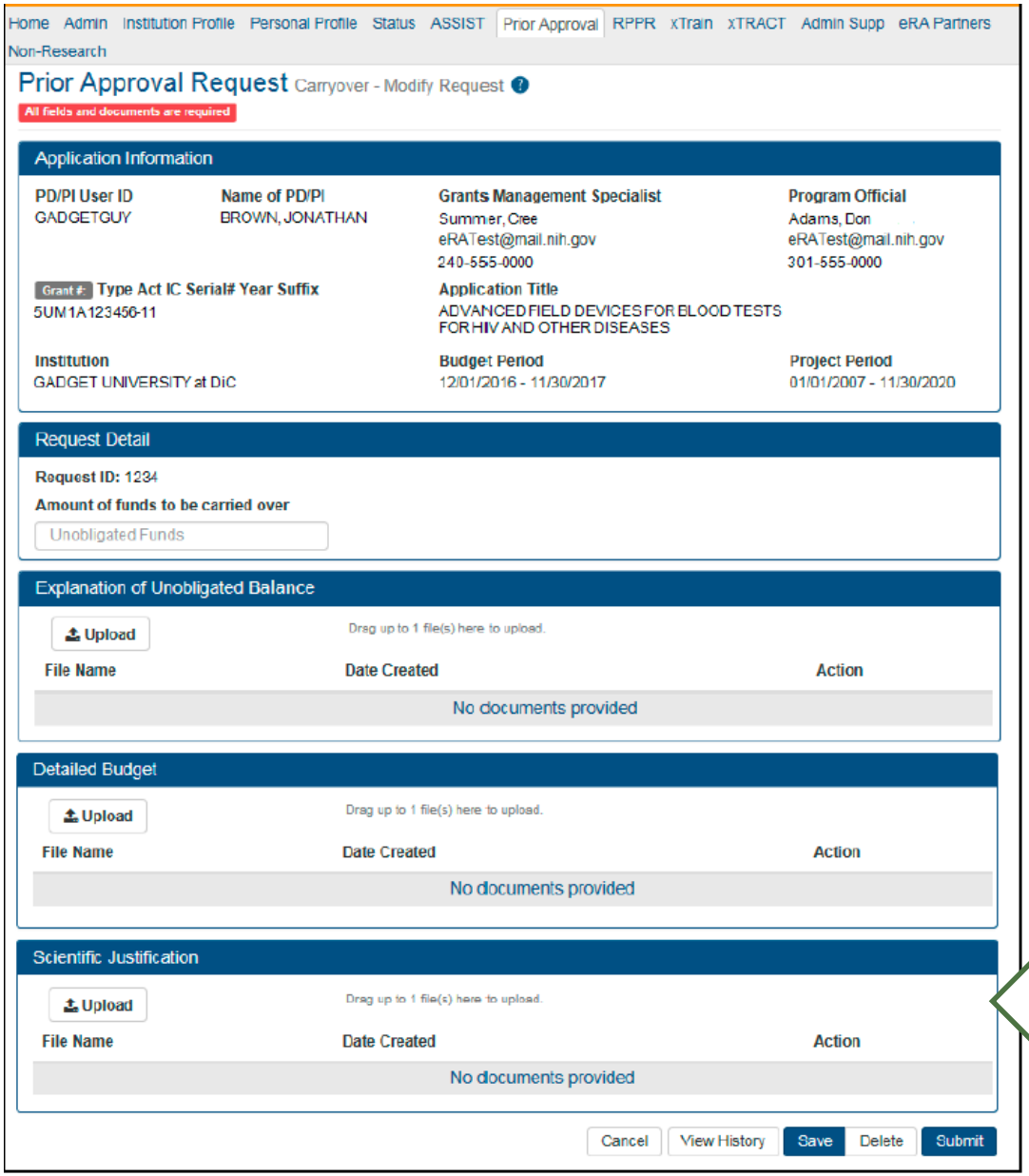
Request Detail:
Amount of funds to be carried over.



Explanation of Unobligated Balance:
~ Table 1



Detailed Budget:
~ Table 2



Home Admin Institution Profile Personal Profile Status ASSIST Prior Approval RPPR xTrain xTRACT Admin Supp eRA Partners Non-Research

Prior Approval Request Carryover - Modify Request

All fields and documents are required

Application Information

PD/PI User ID	Name of PD/PI	Grants Management Specialist	Program Official
GADGETGUY	BROWN, JONATHAN	Summer, Cree eRATest@mail.nih.gov 240-555-0000	Adams, Don eRATest@mail.nih.gov 301-555-0000

Grant #: Type Act IC Serial# Year Suffix	Application Title
5UM1A123456-11	ADVANCED FIELD DEVICES FOR BLOOD TESTS FOR HIV AND OTHER DISEASES

Institution	Budget Period	Project Period
GADGET UNIVERSITY at DiC	12/01/2016 - 11/30/2017	01/01/2007 - 11/30/2020

Request Detail

Request ID: 1234

Amount of funds to be carried over

Unobligated Funds

Explanation of Unobligated Balance

Upload — Drag up to 1 file(s) here to upload.

File Name	Date Created	Action
No documents provided		

Detailed Budget

Upload — Drag up to 1 file(s) here to upload.

File Name	Date Created	Action
No documents provided		

Scientific Justification

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File Name	Date Created	Action
No documents provided		

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Scientific Justification:
~ Cover Letter

Policy Special Topic: Program Income

Reminder from earlier:

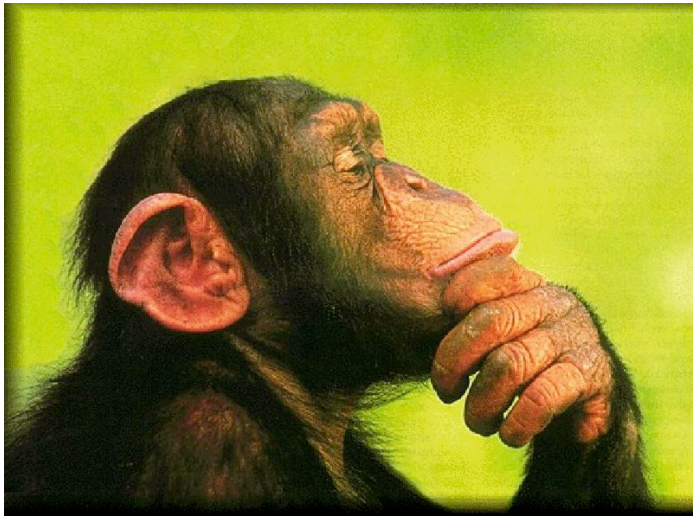
“Program income is gross income—earned by a recipient, a consortium participant, or a contractor under a grant—that was directly generated by the grant-supported activity or earned as a result of the award.”

NIH GPS Section 8.3.2.

Where can program income come from?

- The leasing or renting of equipment purchased with grant funds.
- Royalties or other profits from technology generated under the grant.
- Registration fees for conferences or training provided by the grant.

Uniform Grants Guidance (2 CFR 200 // 45 CFR 75), Section 305.b(5):
Use of resources before requesting cash advance payments. **To the extent available, the non-Federal entity must disburse funds available from program income** (including repayments to a revolving fund), rebates, refunds, contract settlements, audit recoveries, and interest earned on such funds **before requesting additional cash payments**.



So now that we've reviewed the regulations, what does this mean for your institution?

Reviewing your current institutional policies:

- Is your institutional policy consistent with the latest regulations?
- Is your institutional policy consistent with how you actually do business?
- What are the consequences of a bad policy?

Is your institutional policy consistent with the latest regulations?

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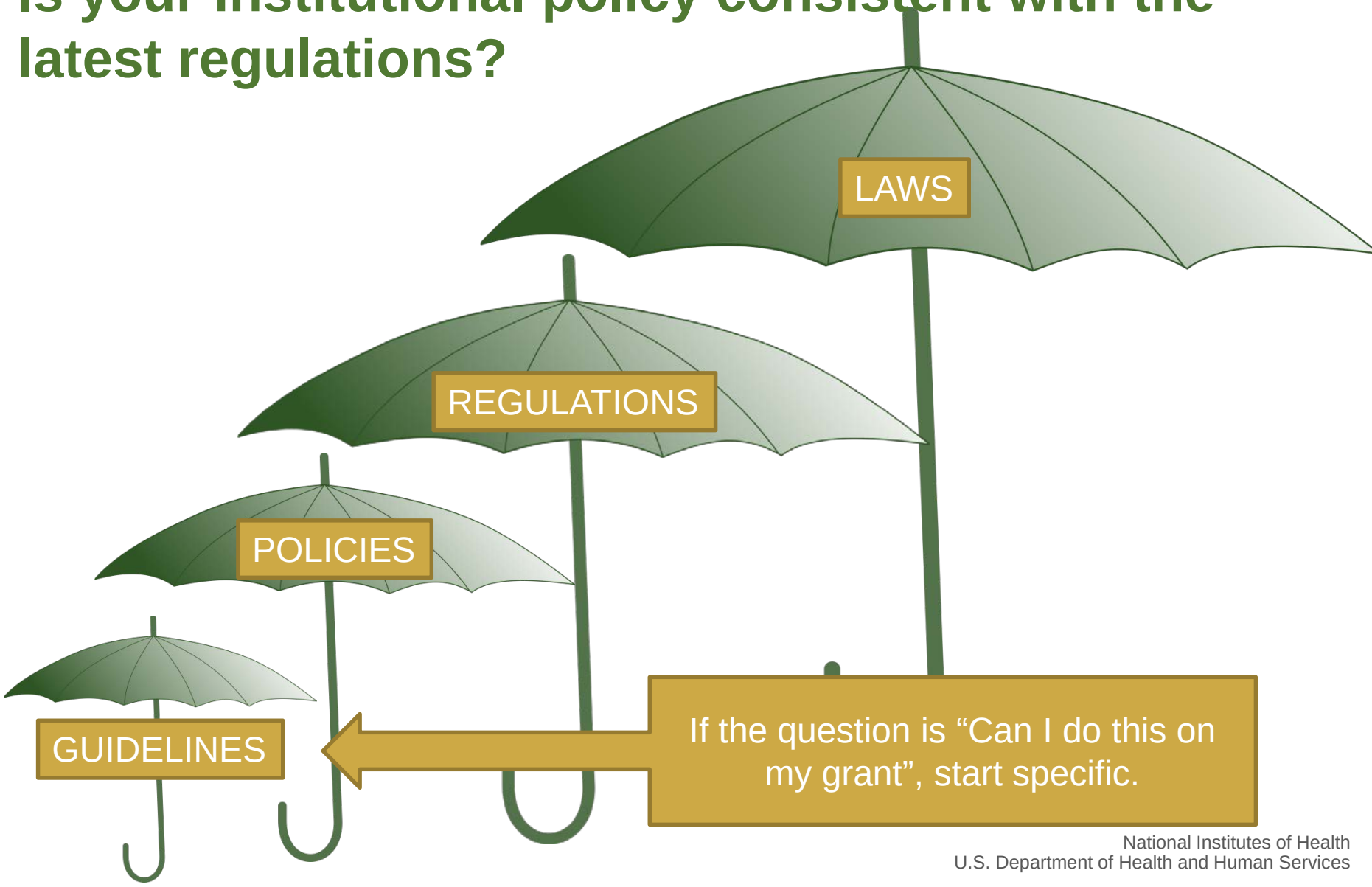
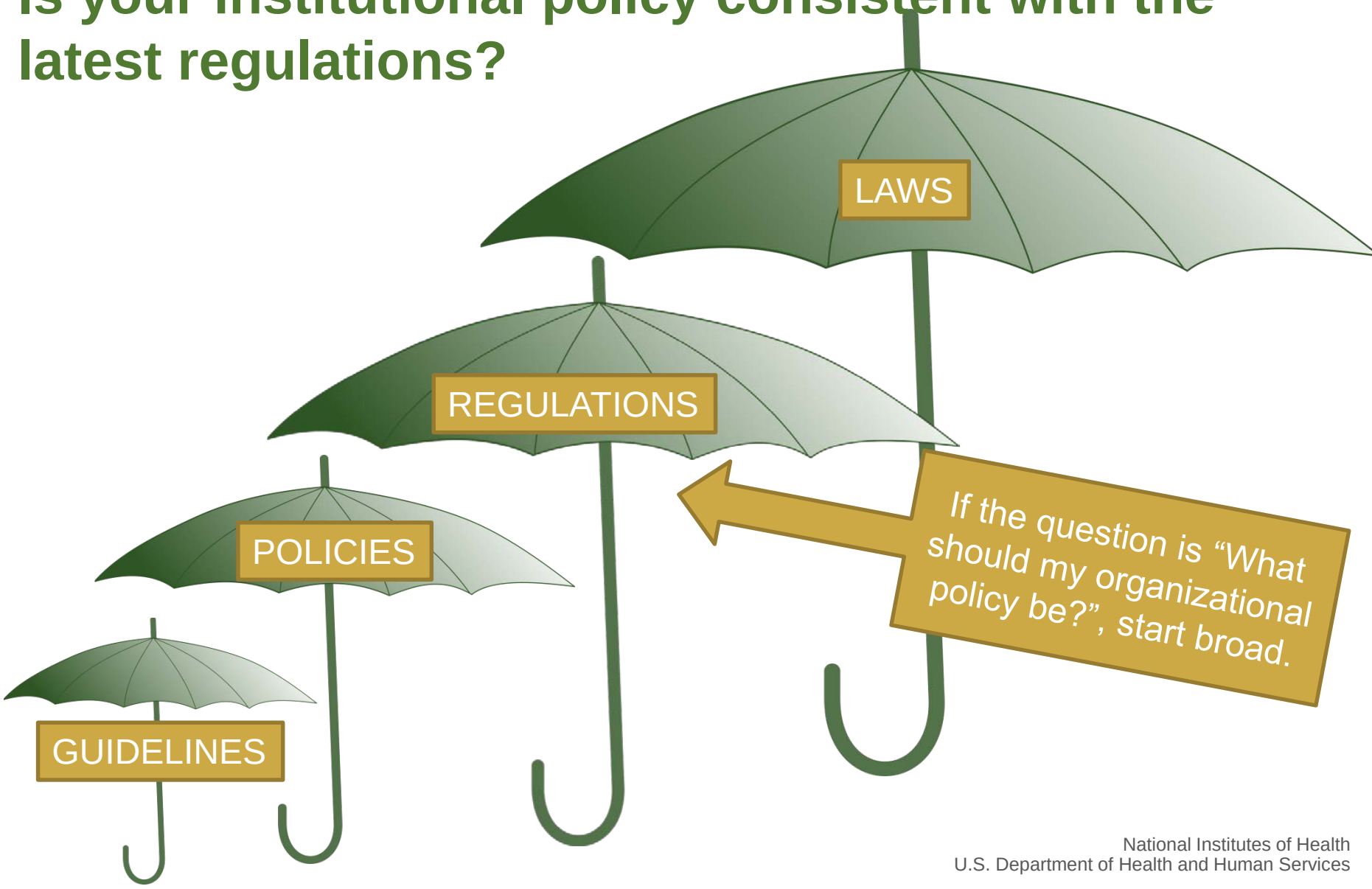


Is your institutional policy consistent with the latest regulations?



Is your institutional policy consistent with how you actually do business?

- For example, the regulations indicate program income funds are to be spent “to the extent available”. How does your organization define available?
  - How do the PI’s know what funds are available when?
  - Is there an account management system that can track program income receipts and program expenditures?
  - Are there limitations to what program income funds are available, such as state or local laws that pre-empt grant regulations?

Is your institutional policy consistent with how you actually do business?

- What about subawards / consortium agreements?
  - NIH Grants Policy Statement indicates that disposition of program income should be part of the agreement, but doesn't prescribe how. (NIH GPS 15.2.1)
- What about progress reports?
  - Who does your financial reporting and how do they communicate the financial balances to the people filling out the RPPRs?

There are lots of opportunities to clarify definitions!

"extent available"
"directly generated"
"grant-supported activity"
"gross income"
"cash-advance"

What are the consequences of a bad policy

- Audit findings
  - Disallowed costs
  - Increased agency monitoring / more restrictive terms and conditions
- Inconsistent practices at your organization
- Lost opportunities due to funding expiration

Need help?

- NIEHS Staff
- Auditor
- NIH Office of Policy for Extramural Research Activities
  - Compliance Inbox (GrantsCompliance@od.nih.gov)
  - Policy Inbox (GrantsPolicy@od.nih.gov)
- Professional Societies
  - National Council of University Research Administrators (NCURA) Peer Advisory Services
  - Society for Research Administrators (SRA) Consulting Services

Policy Special Topic: Human Subjects

Several Changes to Human Subjects Requirements

- New Forms and Funding Opportunity Announcements
- Single IRB for Multi-Site Studies
- Clinical Trial Requirements:
  - Training in Good Clinical Practices
  - Registration in ClinicalTrials.gov
  - Special Review Criteria for Clinical Trials

What counts as human subjects?

"Research involving a living individual about whom an investigator obtains *either* data through interaction *or* identifiable, private information."

- Research: is a systematic investigation designed to develop or contribute to generalizable knowledge.

What counts as a clinical trial?

A clinical trial is a study that is characterized to include:

- Prospective assignment of human subjects
- One or more interventions, and
- Identification of one or more health-related biomedical or behavioral outcomes

Policy Special Topic: Closeout

What is required to closeout a grant?

- Final Invention Statement
- Final Research Performance Progress Report (or Interim Research Performance Progress Report).
- Final Federal Financial Report
- Final Quarterly Draw from Payment Management System
- SBIR – Final Life Cycle Certification

When are closeout reports due?

- Reports are submitted 120 days after the project period end date.
- If any reports are late, NIH will unilaterally close the grants after 270 days. Unilateral closeout can result in:
  - Administrative actions taken against current/future awards
  - Loss of funds or federal debt recovery

Questions?