FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

Costing and Procurement Updates

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Agenda

- Update (Costing & Admin Burden)
  - Single IRB costing update
  - Costing for public data access requirements
- Procurement Requirements and Update on Micro-purchase Threshold
- NIH Update
  - Recent Notices
    - Enforcement of Closeout Policies
    - NIH notice on Standards of Documentation of Personnel Expenses
  - NIH Clinical Trial Definition

sIRB Implementation Date

REMINDER

- Extended to January 25, 2018 (NOT-OD-17-076)
  - Grant applications received by NIH on or after 1/25/2018 require the use of an sIRB for domestic sites of a multi-site study using the same protocol for non-exempt research
    - Extended from previous effective date of 5/25/17
  - Date now coincides with the effective date for the NIH policy requiring all applications involving one or more clinical trials to be submitted through an FOA specifically designed for clinical trials
  - sIRB costs can be included in an applicant's budget (even prior to January 25th if sIRB to be used)

Managing sIRB Costs

REMINDER

- NIH provides guidance on charging primary and secondary costs (FAQs) https://osp.od.nih.gov/clinical-research/irb-review/
- Multiple options for recovering the cost of sIRB activities are available but it is up to the institution to decide what approach they take.
  - Incremental or increased costs beyond what is captured in an institutions indirect cost pool can be directly charged
  - All IRB costs can be removed from the indirect cost pool and shifted to direct charging (including sIRB)
  - After establishing standard fees for sIRB activities, a recharge center can be used to recover costs (45 CFR 75.468 requirements apply relative to the operation of a recharge center)

“Polling Questions”

- sIRB
  - Is your institution going to be a sIRB or going commercial?
  - If lead for sIRB, are you developing rates to direct charge? Or do you plan to just absorb the incremental costs internally?
  - What has your faculty reaction been?
  - Are you ready?
    - Technology? Infrastructure? Faculty and Research admin staff?
  - Any concerns?

Public Access to Data Resulting from Federally Funded Research

REMINDER

- A report by the AAU-APLU Public Access Working Group offers a set of goals, recommendations, and guidance to agencies, universities, and research communities
- Summary statements extracted from the report:
  - Although there is general agreement about the value of increased public access to data, ensuring such expanded access will require a significant culture shift at universities and among their faculty, thoughtful and carefully crafted new government policies and practices, and investment in the infrastructure required to make data publicly accessible.
  - Universities will need to create the infrastructure required by the public access mandates of the federal agencies funding their research so that data collected to support federally funded research can be shared, to the extent possible, with the public.
  - Faculty will have to come to understand that the data they create with federally funded research is not "their" data alone, and therefore they will need to adapt their views concerning data sharing.
  - At the same time, federal agencies will need to fund the costs associated with making these data widely available and provide consistent and clear policies, compliance guidelines, and definitions across agencies to minimize the burden on researchers and institutions.
  - By committing to a set of shared principles and minimal levels of standardization across institutions and agencies, we can help minimize costs, enhance interoperability between institutions and disciplines, and maximize the control institutions can exert over how they ensure access to publicly funded scholarship.

“Polling Questions”

- Public Access
  - How aware/prepared is your institution for the 2013 OSTP requirement?
  - Are you seeing the requirement in proposals?
  - Using Data Management Plans to document requirements?
  - Plan to direct or indirect charge?
    - Developing rates to direct charge? Or do you plan to just absorb the incremental costs internally?
  - Are you ready?
    - Technology? Infrastructure? Faculty and Research admin staff?
  - What has your faculty reaction been?
  - Any other concerns?

Procurement

- Topics for Discussion
  - Micro-Purchase Threshold
  - Readiness for new requirements (bid, etc.)

Procurement: Micro-Purchase Threshold (MPT)

- An additional one year extension has been granted; for IHEs with a fiscal year end of June 30th implementation is required by July 1, 2018
- Micro-purchase threshold (MPT)
  - Originally set at $3,000, was revised to $3,500 in the FAR (48 CFR, subpart 2.1)
  - Instead of a benefit, would this become a new audit target for small value items (p-card transactions)?
    - When a purchase > MPT, more than one bid or quote is required

National Defense Authorization Act - Implications on MPT

- NDAA 12/23/16
  - Raised MPT to $10,000 or higher – applies to Grants, Cooperative Agreements and Contracts for all federal agencies
  - Per the NDAA: $10,000 or higher threshold as determined by the head of the relevant executive agency and consistent with clean audit findings, institutional risk assessment, or State law.

Procurement: Micro-purchase Threshold

- Data:
  - Number of transactions and dollar value:
    - less than $3,500, … $10,000, …. $25,000, …
  - Review and analyze the data
  - Where is the risk?
    - High dollar value purchases
- Clean audits/reviews
  - A-133/Single Audits
  - ONR Contracting Purchasing System Reviews
  - Other?
- Justify the increase in the MPT

"Polling"

- Procurement
  - What threshold do you plan to use? If >$10k, have you had discussions about how to coordinate this?
  - When is your FY start date? Are you ready for UG procurement requirements?
    - What changes have you made? Have you reviewed your procurement policies & procedures? What is your process to document bids? Other changes?
    - Do you have a different document process for services as opposed to commodities?
  - Did your Single Audit auditor focus on procurement this year? Did they discuss their plans for next year?
  - What is your interpretation on the importance of 41 USC par 1902?
    - Does that really set the MPT at $10k
    - How are institutions preparing?

Recent NIH Notice on the Enforcement of the Award Closeout Policy (Nov 30, 2017)

NIH Enforcement of Closeout Policies

Purpose

The purpose of this Notice is to alert the NIH extramural community that NIH is strengthening enforcement of longstanding closeout requirements, outlined in the NIH Grants Policy Statement Section 8.6, Closeout.

Notice Number: NOT-OD-18-107

Key Dates

Release Date: November 30, 2017

Related Announcements

NOT-OD-17-085
NOT-OD-17-022
NOT-OD-15-136
NOT-OD-15-135
NOT-OD-15-111
NOT-OD-14-084

Issued by

National Institutes of Health (NIH)

Purpose

The purpose of this Notice is to alert the NIH extramural community that NIH is strengthening enforcement of longstanding closeout requirements, outlined in the NIH Grants Policy Statement Section 8.6, Closeout. NIH has consistently reminded recipients of their responsibility to submit timely, accurate final grant expenditure reports, and has communicated the critical need for recipients to reconcile cash transaction reports submitted to the HHS Payment Management System (PMS) with expenditure reports submitted to NIH. In order to fulfill agency requirements under the Grants Oversight and New Efficiency (GONE) Act and HHS grants policy, NIH will no longer delay the closeout of awards unless the recipient submits a prior approval request to the IC providing an acceptable written justification.. Without prior approval from the awarding IC, NIH will initiate unilateral closeout for all awards that fail to meet closeout requirements within 120 days as required by the NIH Grants Policy Statement (NIH GPS) Section 8.6. **See below for details**.

Background

Recipient Responsibilities

The requirement for timely closeout is generally a recipient responsibility. However, NIH may initiate unilateral closeout if a recipient does not provide timely, accurate closeout reports or does not respond timely to NIH requests to reconcile discrepancies in grant records.

Recent NIH Notice on the Enforcement of the Award Closeout Policy - Highlights

- Strict enforcement of the 120 day deadline for closeouts
- Failure to submit timely reports will trigger **unilateral closeout by NIH**
  - "Failure to correct recurring reporting problems may cause…**withholding of further awards, suspension or termination**."
- **Prior approval for a delay** in closeout must be justified and approved by the awarding institute or center
- NIH compliance with the GONE Act is one of the drivers for the strengthened enforcement
- Basic recipient requirements (see: NIH Grants Policy Statement sec 8.6)
  - Submission of a final Federal Financial Report (FFR), Final Research Performance Progress Report (F-RPPR), Final Invention Statement and Certification (FIS)
  - Reconciliation of cash transactions reports submitted to PMS with expenditure reports submitted to NIH

“Polling Questions”

- Closeout (in response to November 2017 NIH Notice NOT-OD-18-107)
  - Has your institution been largely successful in closing-out timely? For financial and programmatic?
  - How many of your projects has NIH initiated unilateral closeout? Were they financial or programmatic?
  - What has your faculty reaction been?
  - Any concerns?

NIH Issues a Reminder to Recipients of the "Standards for Documentation of Personnel Expenses"

Standards for Documen

Notice Number: NOT-OD-18-108

Key Dates

Release Date: November 30, 2017

Related Announcements

None

Issued by

National Institutes of Health (NIH)

Purpose

The purpose of this Notice is to acknowledge and remind r
section of the NIH Grants Policy Statement (Sec. 7.9.1 – S
documenting personnel expenses that incorporate the flexi

Background

In accordance with Section 2034(e) of the 21st Century Cur
December 13, 2016, Reducing Administrative Burden for Researchers, NIH is clarifying the applicability and flexibility of the requirements for documentation of personnel expenses for its grants and cooperative agreement recipients. To that end, NIH supports recipients' systems that document personnel expenses charged to NIH grants and cooperative agreements that are consistent with the regulatory flexibilities discussed below.

Standards for Documentation of Personnel Expenses.

In accordance with 45 CFR 75.430(i), charges to Federal awards for salaries and wages must be based on records that accurately reflect the work performed, as follows (in part):

Records of personnel expenses must:

Purpose

The purpose of this Notice is to acknowledge and remind recipients that NIH implemented the provisions of 45 CFR 75.430(i), Standards for Documentation of Personnel Expenses. This section of the NIH Grants Policy… addresses compensation for personal services and the **various certification systems and other forms** of documenting personnel expenses that incorporate the **flexibilities provided** by OMB's Uniform Guidance.

NIH Issues a Reminder to Recipients of the "Standards for Documentation of Personnel Expenses"

- NOT-OD-18-108, issued late in November, reminds recipients of NIH awards of the requirements for documenting personnel expenses charged to grants and cooperative agreements

- Includes language from 45 CFR 75.430(i) that provides the detailed guidance on approaches to documenting personnel expenses on federal awards

- Key issues:
  - Compliance with current effort policies and processes & need for appropriate internal controls
  - Cost shared salary is subject to the same level of documentation
  - Charges for… nonexempt employees…must also be supported by records indicating the total number of hours worked each day.

“Polling Questions”

- “Standards for Documentation of Personnel Expenses” (NIH Notice NOT-OD-18-108)
  - Have you changed your effort system?
  - Still requiring certification? If yes, are you considering changing this in the near future?
  - Conv with Cognizant? DS-2 changes?
  - Added flexibility? Ideas to reduce burden?
  - What has your faculty reaction been?
  - Any concerns?

New Clinical Trial Definition

The NIH Announces New Review Criteria for Research Project Applications Involving Clinical Trials

Notice Number: NOT-OD-17-118

Key Dates

Release Date: September 21, 2017

Related Announcements

None

Issued by

National Institutes of Health (NIH)

Purpose

This notice informs the community of *additional* review criteria that NIH will apply to clinical trial applications for research projects submitted to due dates on or after January 25, 2018.

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This notice informs the community of *additional* review criteria that NIH will apply to clinical trial applications for research projects submitted to due dates on or after January 25, 2018.

Update on NIH's Modifications to Their Definition of "Clinical Trial"

- NIH modified their definition of clinical trial in late 2014.
- Many researchers believe that it inappropriately classifies basic research as clinical trials
- Primary concerns of the research community:
  - The case study tool used to help institutions determine whether proposed research meets the NIH definition of clinical trial in and of itself modifies the definition to include fundamental and basic health-related research
  - Inconsistencies and clarity issues within the tool will lead to different conclusions from institution to institution regarding the application of the NIH definition of clinical trial
  - The impact on an investigator and research study of the expanded application of the definition is more significant than has been acknowledged
- Impact of the new definition coupled with the recent NIH clinical trials FOA policy
  - Basic research studies will become subject to the clinical trials FOA policy
  - Registration and results reporting in Clinical Trials.gov will be required for basic research studies
  - Good Clinical Practice training will be required for basic research studies
  - Ineligibility for Training Awards due to the use of the Clinical Trials FOA policy will negatively impact the technical development of research scientists
  - Basic research would be subject to additional restrictions and oversight (sIRB review, etc.)

NIH Announces Additional Review Criteria for Clinical Trial Applications

- These additional criteria will be added to the existing review questions for clinical trial applications (grants and cooperative agreements) submitted on or after 1/25/18
- Application of this additional rigor in reviewing CT applications is part of NIH's "multi-faceted approach to strengthening policies across the life cycle of a clinical trial"
- The additional questions will probe the following areas; significance, capabilities of investigator(s), innovation, study design, data management and statistical analysis, environment, and study timeline
- The announcement NOT-OD-17-118 contains the detailed questions and additional information

“Polling Questions”

- Clinical Trial Definition
  - Are you aware of this?
  - Is it adversely impacting your institution? Particularly in the non-Medicine areas?
  - What has your faculty reaction been?
  - Any concerns?

Discussion and Questions

FYI - session description

- **Monday, January 8, 2018 1:00 – 2:15pm**
- **Costing and Procurement Update**
- **Topic:** This session will review several topics including Single IRB costing and readiness, direct charging of public data access requirements including a recent communication from PAWG, new NIH notices focused on Enforcement of Closeout Policies and NIH Standards for Documentation of Personnel Expenses. UG Procurement requirements will also be discussed, including obtaining approval for a micro-purchase threshold over $10,000 consistent with the National Defense Authorization Act (NDAA) for FY17 and readiness for your institutions implementation. Please send questions from your institution to Sara Bible at sbible@stanford.edu.

- **Speakers:** Jim Luther, Duke University, Edwin Bemmel, University of Miami, Doug Backman, University of Central Florida and Sara Bible, Stanford University