FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

Subawards Subcommittee

Amanda Hamaker, Purdue University

Amanda Humphrey, Northeastern University

Stephanie Scott, Columbia University

Agenda

- Template check in
- DTUA attachment update
- Guidance document update
- sIRB or clinical research
- Subaward delay survey results update
- Committee Structure

Template Update Check in

- How's it going?
- Use of tools and resources?
- What is useful? What could we change?

DTUA Attachment Update

- Done! It's live on the website, look for Attachment 7
- Thank you!
  - Melissa Korf for her leadership
  - Working group members and those who commented
  - Laura Register for making the PDF form
  - Jessica McDonough, Stephanie Stone and June Della Russo for testing
- Guidance and a webinar on use will be forthcoming
- Pilot

Subcontract Guidance

- It’s starting!
- Rick Alves, Northeastern University is leading the effort
- Calls start next week
- Email the subaward co-chairs if you would like to join and we will connect you

Guidance Document/FAQs

- Five new FAQs
  - Two FAQs related to flexibility to incorporate non-substantive formatting changes.
  - Removed the word “Research” from generic subaward template titles.
  - Clarification of Admin Contact and Financial Contact for 3A and 3B.
  - Changed terminology “fixed price” to “fixed amount”
- Revised FAQs and Carryover Guidance Doc to ensure consistency with Sept 2019 templates
- Draft to be released to Subawards Listserv for comment
- Let’s discuss its future…

sIRB Requirement – recap from Sept 2019 meeting

- sIRB requirement for *cooperative research* applies to all new federally funded research approved ≥ January 21, 2019
- Interpretation: Multisite studies approved *between*
  - January 21, 2019 (compliance date for most Common Rule revisions) and January 20, 2020 (compliance date for sIRB review for cooperative research)
  - …must be *transitioned* to sIRB review no later than January 20, 2020
- Were waiting for further information from OHRP.
- Subawards may need to be amended…..

Prior language in templates

Work Involving Human or Vertebrate Animals (Select Applicable Options)

☒ Human Subjects ☐ Vertebrate Animals ☐ No Human or Vertebrate Animals

Subrecipient agrees that any non-exempt human and/or vertebrate animal research protocol conducted under this Subaward shall be reviewed and approved by its Institutional Review Board (IRB) and/or its Institutional Animal Care and Use Committee (IACUC), as applicable and that it will maintain current and duly approved research protocols for all periods of the Subaward involving human and/or vertebrate animal research. Subrecipient certifies that its IRB and/or IACUC are in full compliance with applicable state and federal laws and regulations. The Subrecipient certifies that any submitted IRB / IACUC approval represents a valid, approved protocol that is entirely consistent with the Project associated with this Subaward. In no event shall Subrecipient invoice or be reimbursed for any human or vertebrate animals related expenses incurred in a period where any applicable IRB / IACUC approval is not properly in place.

The PTE requires verification of IRB and/or IACUC approval be sent to the Administrative Contact *as follows:*

IRB

Upon Request

- Upon Request
- Prior to execution of this agreement
- Prior to execution of this agreement and annually thereafter
- Not required for the following reason:

If the original subaward stated IRB approval & verification was required, you may now need to amend it to 'not required for the following reason:'

- PTE is acting as the sIRB
- There is an sIRB designated
- Exempt
- Approval will be sought after year 1.

sIRB Update – 11/21/2019

"OHRP determined that for HHS cooperative research subject to the revised Common Rule (also referred to as the 2018 Requirements), and for purposes of 45 CFR 46.114(b)(2)(ii), **an institution may continue to use multiple IRBs**, in lieu of a single IRB, for the following research:

(1) Cooperative research conducted or supported by HHS agencies other than the National Institutes of Health (NIH), if an IRB initially approved the research before January 20, 2020.

(2) Cooperative research conducted or supported by NIH if either:

a. the NIH single IRB policy does not apply, and the research was initially approved by an IRB before January 20, 2020, or

b. NIH excepted the research from its single IRB policy before January 20, 2020."

Source: Stith-Coleman, I. (2019, November 21). *Determination of Exception to the Required Use of a Single IRB for Certain HHS Cooperative Research that is Subject to the 2018 Requirements* [Email communication from OHRP to OHRP-L@LIST.NIH.GOV].

Certificates of Confidentiality (CoC) Updates

- **10/1/2017** - all **NIH-funded** research commenced or on-going as of December 13, 2016, were issued a CoC as a term and condition of the NIH award. See NOT-OD-17-109.
- No more separate Certificates.
- FDP piloted language for subaward templates to communicate to subrecipients about the CoC Policy.
- Incorporated into the Sept 2019 templates.
- However, with other sponsors, need to formally request a Certificate. But then….

Certificates of Confidentiality (CoC) Updates

- **5/2018 for CDC**: https://www.cdc.gov/od/science/integrity/confidentiality/guidance.htm
- **10/1/2018 for FDA**: NOT-FD-19-002
- **HRSA: although a term and condition of the award, must apply for the CoC.**
- https://www.hrsa.gov/public-health/clinical/human-subjects/index.html
- **SAMHSA: although a term and condition of the award must apply for the CoC.**
- https://www.samhsa.gov/grants/gpra-measurement-tools/certificate-confidentiality

CoCs and Subawards

- Current boilerplate language only applicable for NIH
- Other sponsors, responsibility of PTE to include necessary language.
- To discuss options.

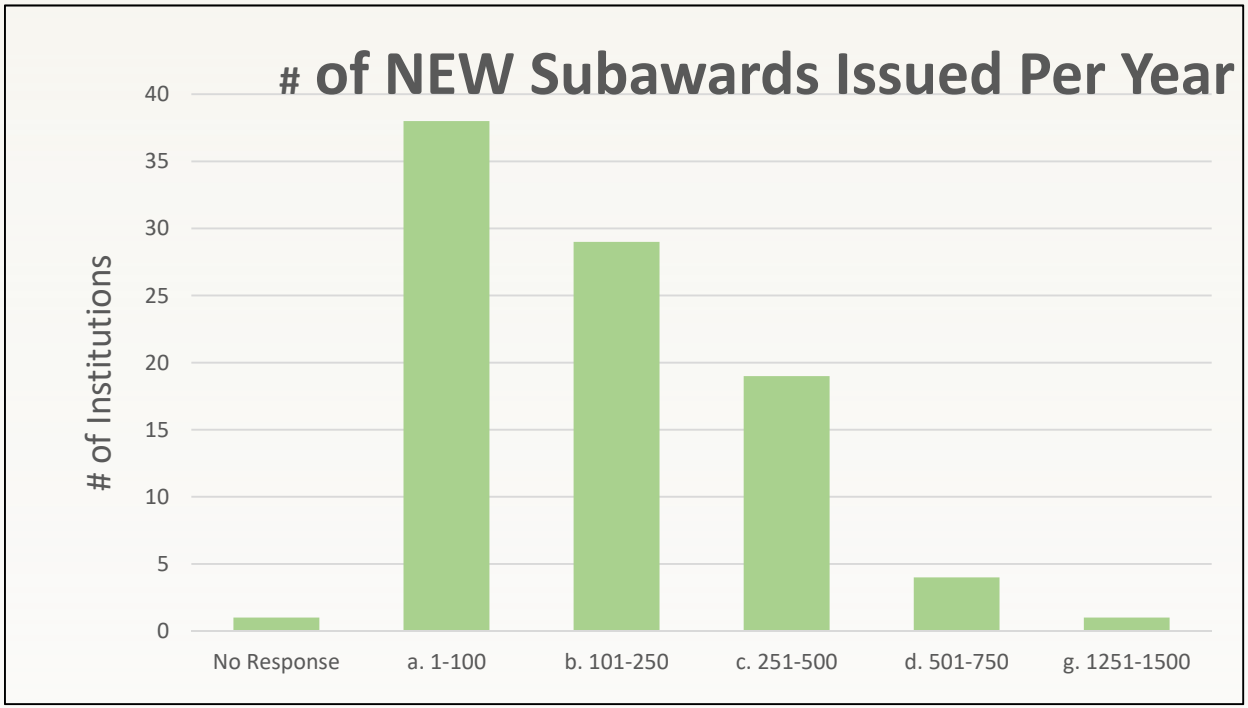
Subaward Delay Survey

Project History

- Original Presentation, September 2018
- Formed working group to develop survey
  - 31 volunteers
  - Development: October 2018-May 2019
  - Survey Responses: November & December 2019
- 92 institutions responded

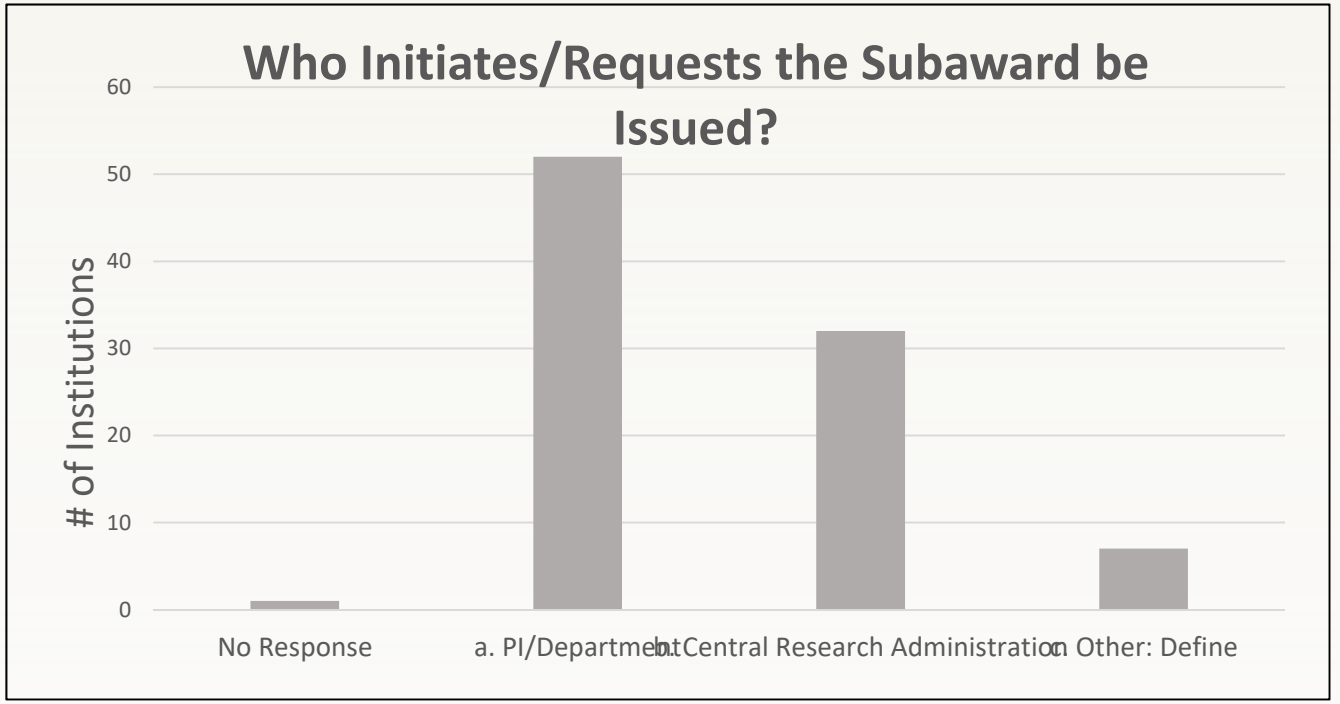
Subaward Delay Survey

Preliminary Results



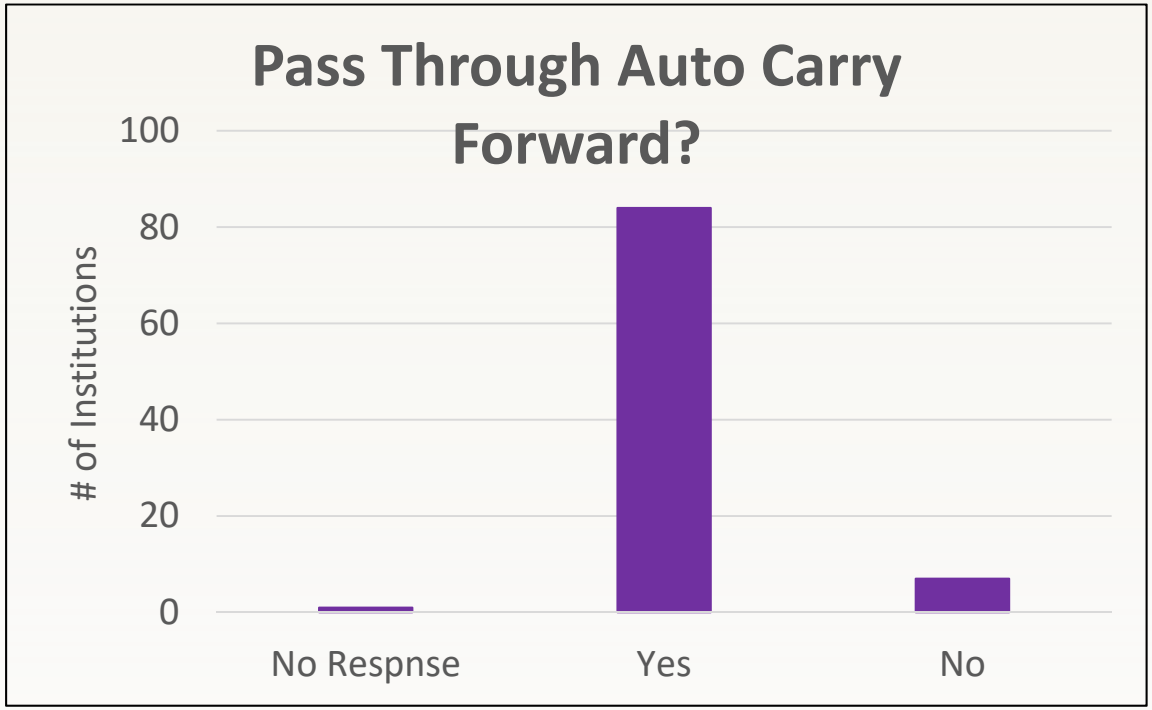
Subaward Delay Survey

Preliminary Results



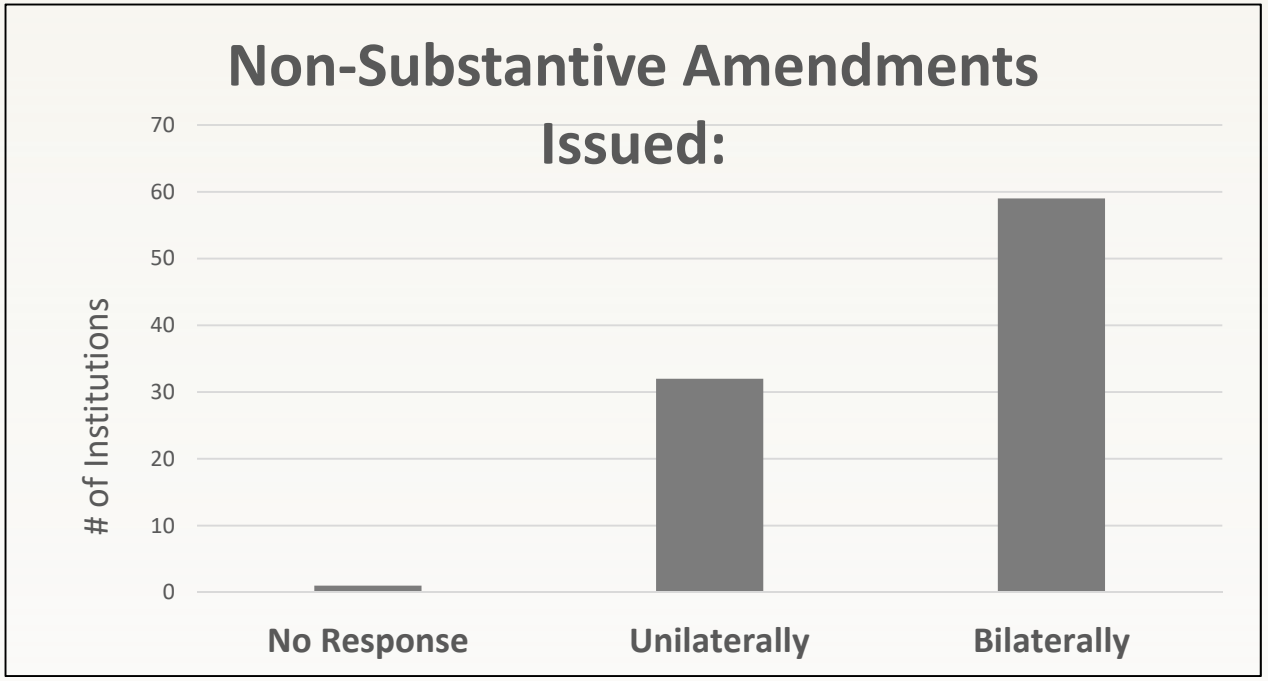
Subaward Delay Survey

Preliminary Results



Subaward Delay Survey

Preliminary Results



Subaward Delay Survey

Next Steps

- Complete data analysis
  - Follow up with respondents as needed
- Present full results & discuss at next meeting
- Draft recommendations for best practices

Committee Structure

- Succession planning
- Ensuring continuity during transitions

What would you like to see for the future?

- Create Subawards Steering Committee?
  - Workgroup leads
  - Members at large
  - Federal partners
- Number of Co-Chairs?
- Expectations for volunteerism

Leads

So far…….

- Laura Register and Stephanie Stone – Templates
- Cathy Harlan and Julie Renkas – Guidance Docs/FAQs
- Brenda Kavanaugh and Jennifer McCallister – Clinical trials, clinical research and fixed rate sample

Role of Subcommittee Co-Chairs

- Facilitate discussions with members to explore areas that furthers the FDP's mission to streamline the administration of federally sponsored research.
- Identify potential *demonstrations* – surveys, tools, pilot projects, guidance documents, etc.
- Oversee workgroup activities.
- Field questions from members and non-members.
- Mediate disputes regarding the use of the subaward templates.

Friendly Reminder: Changes

- Templates created to make things easier – don't change them!
- Let us know if you get one with changes, we'll contact the institution.

Contact Us

subawards@thefdp.org

Automatically goes to all three co-chairs:

Amanda Hamaker, Purdue University
Amanda Humphrey, Northeastern University
Stephanie Scott, Columbia University