FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

Subawards Subcommittee

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Agenda

- Research Integrity
- Certificate of Confidentiality
- Subaward Templates Update
- Fixed Price / Clinical Trial Update
- Guidance Document Update, New Proposal Form
- Foreign Guidance Update

Research Integrity

- OSTP General Policy from 2000 (65 FR 76260) lays out the general requirements for conducting research without falsifying or fabricating data
- Memo applies to research funded by all federal agencies
- HHS and NSF have their own implementations, as do most agencies
  - Level of specificity varies from agency to agency
  - Most often detailed in the relevant agency grants policy statement

Research Integrity

- Upon further discussion with a Research Integrity Officer (RIO):
  - Request stemmed from discussion with HHS/NIH OIG
  - Wanted to know what institutions are doing to ensure that subrecipients have applicable policies / assurances in place
- Discussed use of:
  - Adding language specific to foreign / high risk template
  - Adding something to the FDP Clearinghouse

Research Integrity

- With respect to survey, we had presented following:
  - Add language to the templates and/or;
  - Create guidance.
- Responses to addition of Integrity language:
  - 71 responses total
  - 6 institutions had no preference
  - 42 institutions said no
  - 8 institutions were not sure
  - 15 institutions said yes

Research Integrity

- Suggested Outcome:
  - Add language to the foreign template;
  - Welcome packet for foreign institutions;
  - Explore FDP expanded clearinghouse options (including putting RIO contact on the clearinghouse);
  - No additional language for the FDP subaward templates; and
  - Add guidance explaining choices.
- Engage RIO community for feedback.

Certificate of Confidentiality

- NIH has changed their business process around Certificates of Confidentiality (COC)
  - Instead of requesting a COC from NIH, the NIH will automatically incorporate them in the issuance of the NOA
  - PTE is required to flow down to the subrecipient
- See this NOTICE for further details
- Also, this NIH WEBSITE includes valuable resources

Certificate of Confidentiality

- Survey results:
  - 71 institutions responded
  - 13 were not sure as of the close of the survey
  - 6 institutions said no language
  - 10 institutions will use both options in the coming year
  - 15 institutions will use option 1 (more detailed)
  - 27 institutions will use option 2 (less detailed)
  - Institution type did not seem to impact response (i.e. - covered entities did not overwhelmingly prefer option 1)
- Got a number of great suggestions which we will have to review

Certificate of Confidentiality

- Suggested outcomes:
  - Two choices presented to membership, longer and shorter language;
  - Will allow institutions to test and will seek feedback early next year;
    - After this meeting, both options will be posted in a word document for institutions to select from as they draft subawards;
  - Asking members to incorporate language in the additional terms section of Attachment 2 and incorporating fully in 2019; and/or
  - Creating FAQs / guidance.

Templates – Managing Content Change Requests

- Draft Guidance Document and Change Request Form
  - For content, not formatting
- Guidance Doc provides:
  - FDP Background/Purpose of templates
  - Process for making requests
  - Checklist of considerations prior to making the request
    - Should be applicable to all members.
    - Can the request be handled another way?
    - Is it already flowed down?
- Change Request Form
  - Rationale required
  - Consistency in information we collect

Template Updates

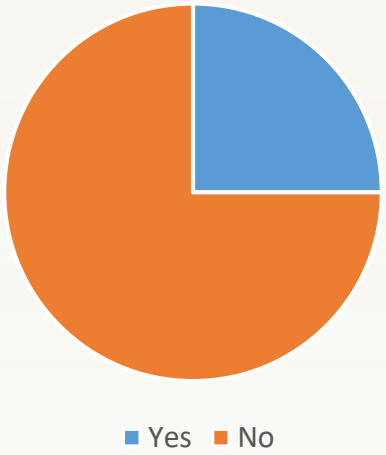
- Working on some potential modifications to code to stabilize some code (i.e. issues with inserting pages into the templates)
- Option to release this in 2018 as a minor release with no substantive changes permitted or hold until 2019 and release along with implementations of the COC language and other updates
- Will seek other suggestions at the January 2019 meeting with next substantive update in September 2019

Fixed Priced Subawards, Prior Approval, and Clinical Trials

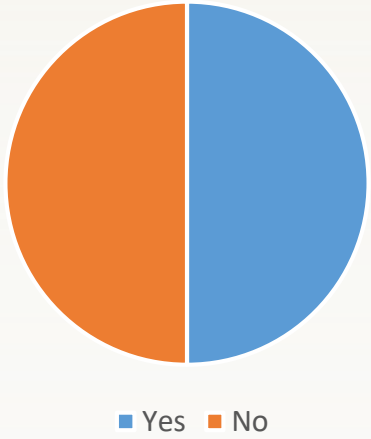
- Recap: Two prior FDP sessions on this topic
  - Fixed Priced Subawards/Prior Approval Working Group
  - Draft language when requesting prior approval, in prior slide decks
  - Clinical Trials sub-sites. What are they??
    - Subrecipients vs Vendors/Contractors
    - Mechanisms used - “Site agreements”, FP vs CR, “per subject”
  - Reminder – FDP Fixed Priced CT Sample
  - Burdens related to prior approval and exceeding the SAT

Fixed Priced Subawards, Prior Approval, and Clinical Trials

Are you issuing cost reimbursable agreements that only contain per patient payments?

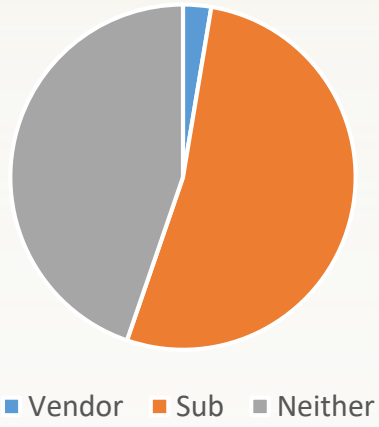


Do you issue subawards that include both cost reimburseable and fixed per patient terms?

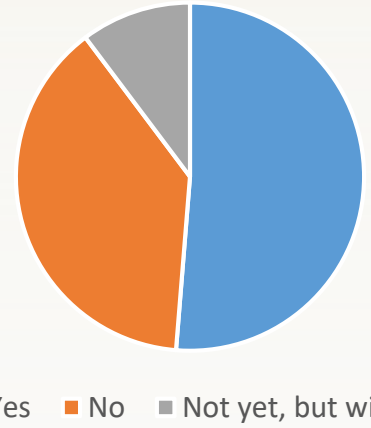


Fixed Priced Subawards, Prior Approval, and Clinical Trials

What does your institution consider a clinical "site"?



Has your institution adopted the FDP Clinical Trial subaward sample?



Speaking of SAT……

- The National Defense Authorization Act for Fiscal Year 2018 (NDAA FY18):
  - Micro-purchase threshold to $10,000
  - Simplified acquisition threshold (SAT) to $250,000.
  - See https://www.acquisition.gov/sites/default/files/page_file_uploads/CAAC%20Letter%202018-02.pdf?utm_medium=email&utm_source=govdelivery
- Letter dated 2/16/18 from GSA Office of Governmentwide Policy
- “This CAAC letter is effective immediately, and remains in effect until the increased thresholds are incorporated into the FAR or is otherwise rescinded.”

FDP/COGR Partnership

- COGR Research Compliance & Administration (RCA) Committee
- Met with NIH OPERA on 2/21/18
- Presented burdens and alternatives
  - *Can NIH GPS be amended to give blanket prior approvals on awards that fund clinical trials?*
    - *NOA/Clinical Trial designator allow for FP subawards*
    - *Do not negate prior approval for foreign sites*
  - *Can NIH grant prior approvals exceeding the SAT?*
  - *Position on Subrecipient vs Contractor? New third category?*

FDP/COGR Partnership – where we stand

Provided NIH with draft language for GPS, based on language found in DoD General Research Terms & Conditions 9/2017:

Section 8.1.2.11 Provide Subawards Based on Fixed Amounts:

- **NEW** - (6) NIH recognizes that pass-through entities holding awards that involve clinical trials may provide funding to clinical trial sites or subsites based on budgets calculated using a per-patient, per-procedure, or protocol milestone basis. Direct cost payments are expected to be priced based on actual projected costs for the individual trial site, or based on an average of actual projected costs across all sites performing similar activities under the protocol. Pass-through entities, including Clinical Trial Coordinating Centers, are expected to provide F&A costs to their sites consistent with 45 CFR 75.352.
- Since this type of site agreement is a "fixed rate" rather than a "fixed amount" subaward as defined in 45 CFR 75.353 and 45 CFR 75.201, NIH prior approval is not required to enter into this type of transaction, provided that there is no other factor (e.g., foreign site or the site agreement constitutes a change in scope) that would itself require NIH prior approval. Because these types of transactions are not based on a "fixed amount", this type of agreement is also not subject to Simplified Acquisition Threshold cap.

Guidance Document Working Group

- Next projects
  - Finalize Change Request Form & Guidance Doc
  - New FAQs
    - Clarify Term ‘Effective Date’ for Mods (how and when it is used).
    - Certificates of Confidentiality - language options
    - Research Integrity
    - sIRB - how it was incorporated into the templates
    - Revise FAQ7 - formatting change requests
    - New FAQs on template change requests
    - New FAQ on when it is appropriate for PTEs to request back-up of invoices.
    - Carryover Doc – TAFFOD! Know what that is?
- Want to join? Contact Stephanie at sfs2110@columbia.edu

Foreign Subaward Guidance/FAQs

- Foreign subawards may require different terms from domestic ones.
- Either separate appendix to FAQs, or, call-out differences in existing FAQs
- Will be led by Julie Renkas, renkasjo@cofc.edu.

What's Next?

- Working groups continue their amazing work
  - Subcontract - finalizing
- Looking ahead: September meeting
  - Closeout
  - Back up for invoices
  - Foreign / high risk subrecipient informational packet?
  - Collaboration agreement for federal entities.

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

Long range planning

- Items under consideration include:
  - Mandatory use by FDP Member Organizations
  - Inviting/allowing non-FDP Member Orgs to join
    - To charge or not to charge
    - Phases or cohorts to be invited in
    - Single Audit orgs first
  - Federal involvement ? How ?
    - SAM.gov mapping project. SAM webservices
    - Federal Audit Clearinghouse
  - Financial Questionnaire added to Clearinghouse system
  - Merging other components of FDP page in – FCOI Clearinghouse, A133 Database, FDP member institutional profile, others?
  - FDP responsibility and ownership of data in Clearinghouse / use of data for FDP

Contact Us

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