FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

Fixed Price Prior Approval Working Group

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Agenda

- Overview
- NIH implementation
- Draft guidance
- Data from sponsor requests
- FDP Clinical Trial Subaward sample
- Clinical Trial FOAs
- Discussion

Housekeeping

Get out your cell phones and make sure you are connected to wi-fi!

This session will be interactive!

Resources

- Uniform Guidance 200.332 and 200.201
- NIH GPS – post Oct. 2016 section 8.1.2.11
- OMB FAQ 332-1
- COGR email to OPERA – March 2017
- DOD R&D General Terms and Conditions Sept 2017 Part7 Sub Article XII
- Just found in award from AMRMC: *You are not authorized to treat this award or any subawards that you enter into under this award, at any tier, as fixed-amount awards. The inherently unpredictable nature of basic and applied research makes it rarely, if ever, possible to define specific research outcomes in advance, which makes fixed-amount awards inappropriate for research. This is not applicable to procurement contracts entered into under this award for acquisition of supplies, equipment, or general support services you need to carry out the project or program.*

Language for proposals

Draft Guidance to include with proposals:

The subaward to [name of subrecipient] documented in this proposal meets the criteria described in 2 CFR 200.201(b) and [name of your institution] is therefore requesting prior agency approval of issuing this as a Fixed Price Subaward. [Institution] will consider this subaward approved if an award is made and no contrary guidance from the agency is included in the award notice."

Language for proposals

Draft Guidance to include with proposals for clinical trials:

Pursuant to 2 CFR 200.332 and 45 CFR 75.201, we intend to enter into clinical trial subawards in a fixed price manner. Subaward payments will be made when the subrecipient meets the enrollment milestone as outlined in the subaward as required by the regulations. As we have not selected all subrecipients who will be enrolling in the trial, we are seeking universal approval for any clinical trial subaward we enter into during the duration of the project in order to expedite clinical site activation, provided that such subawards based on fixed amounts (as defined in 45 CFR Part 75.2) **satisfy the conditions for such subawards cited in the NIH GPS Section 8.1.2.11 (1) through (5) [omit if not NIH]**. [Institution] will consider this universal request approved if an award is made and no contrary guidance from the agency is included in the award notice.

May also include pricing information as applicable- Example: The pricing structure is as follows: $X [enter cost] for Y # of “patients” [enter quantity].

Language for post-award

Draft Guidance for post-award prior approval request for a general fixed price agreement:

- Pursuant to 2 CFR 200.332 and 45 CFR 75.201*, we are writing to request prior approval to enter into a fixed-price subaward with _____. Subaward payments will be made when the subrecipient meets the milestones/deliverables as outlined in the subaward and such payments are based on a reasonable estimate of actual costs. [Provide justification for fixed price methodology if applicable]. We request that the approval be provided by issuance of a revised Notice of Award.

*Insert correct citation if non-DHHS sponsor

Language for post-award

Draft Guidance for post-award prior approval request for a clinical trial agreement:

- Pursuant to 2 CFR 200.332 and 45 CFR 75.201, we are writing to request prior approval to enter into clinical trial subawards in a fixed price manner. Subaward payments will be made when the subrecipient meets the enrollment milestone as outlined in the subaward as required by the regulations. We request that prior approval be granted as a universal approval to cover any clinical trial subawards we enter into during the duration of the project in order to expedite clinical site activation, provided that such subawards based on fixed amounts (as defined in 45 CFR Part 75.2) satisfy the conditions for such subawards cited in Section 8.1.2.11 (1) through (5). We also request that the universal approval be provided by issuance of a revised Notice of Award.

Language for post-award

Draft Guidance for post-award prior approval request for a clinical trial exceeding the SAT:

Additionally, we are seeking prior approval to exceed the Simplified Acquisition Threshold for this project. Under the Uniform Guidance (200.332 Fixed amount subawards), a PTE may enter into fixed price subaward "up to the Simplified Acquisition Threshold". The NIH GPS 8.1.2.11 references 45 CFR Part 75.2, but neither speak directly to the SAT limit. However, the FAQs published by the COFAR and OMB makes it clear that agencies may modify the threshold when necessary to minimize administrative burden (please see full text below):

*insert full text from *https://cfo.gov//wp-content/uploads/2017/08/July2017-UniformGuidanceFrequentlyAskedQuestions.pdf*

In the case of clinical trials, our position is that it would be highly burdensome to limit these clinical sites to the SAT for the following reasons:

Data from sponsor requests

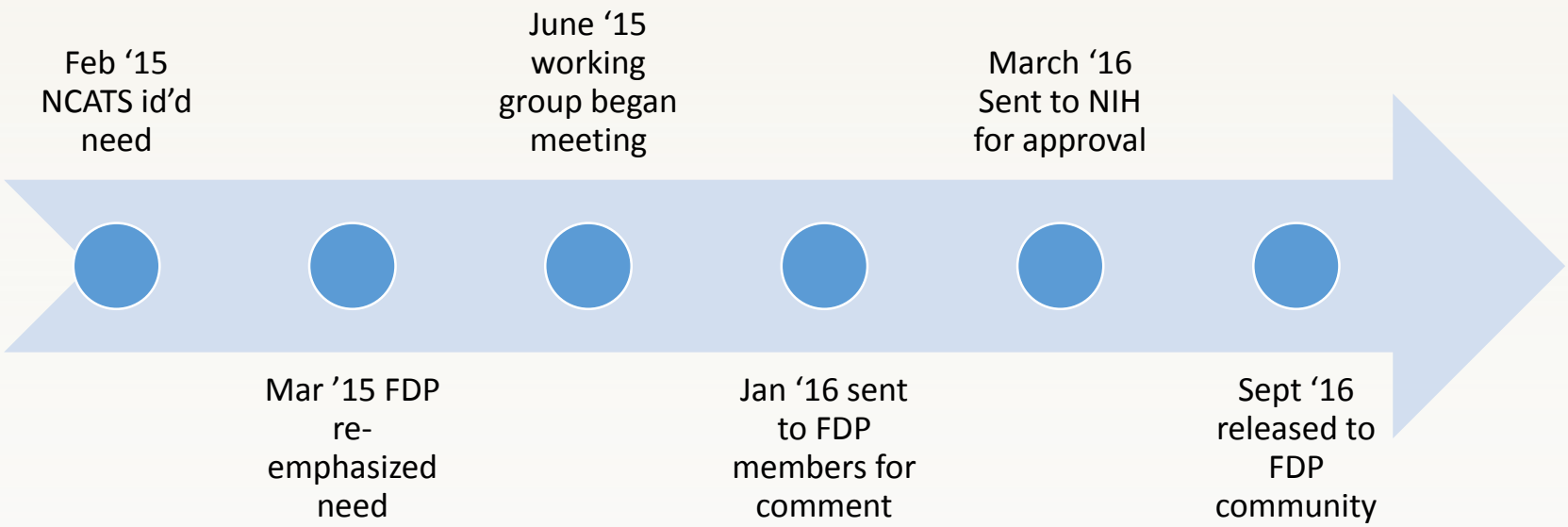
Agency/Institute	How was the request made?	Was the request approved?	Method of approval	SAT request?	Notes
NIH - NIAID	prior approval after award	Y	Email	Y - denied	Originally no procedure 4/17
NIH - NHLBI	prior approval after award	Deemed not necessary	N/A	N	GPS is not applicable
NIH - FIC	prior approval after award	Y	Email	N	FIC was looking into providing waiver for their grants
NIH - NCATS	JIT	Y	NoA with explicit approval	N	none
NIH - NIDCD	prior approval after award	Y	Email	N	none
AHRQ	RPPR	Y	Issuance of standard NoA	N	approval was implied in issuance of the current year NoA
DoD	prior approval after award	Deemed not necessary	N/A	N	No change in SOW, not fixed between gov. and institution so not necessary
DoD	prior approval after award	Deemed not necessary	N/A	N	No change from proposal
FDA	prior approval after award	Y	Email	N	We had to educate all parties assigned to this award at the FDA first on the ruling requiring our request and then the provisions of the UG which allowed for our request and provide justification as to why we were seeking the request for prior approval.
Dept of Energy	prior approval after award	Deemed not necessary	email	N	The agreement and arrangement of your business interaction with the sub-awards is your discretion therefore if you would like to change the payment method from a cost reimbursement to a fixed amount there is no need for pre-approval for this. No further escalation and approval is required for this award
NIH NINDS	prior approval after award	Y	email	N	received approval in 7 working days
DoD	prior approval after award	Deemed not necessary	email	N	GMO was provided with OMB notification about the implementation of the prior approval, but kept the 'No Approval Needed' position (in writing).
NIH/NILBI	prior approval after award	Deemed not necessary	Email	N	GMS mentioned this wasn't a deviation from normal "procurement practices"; Took six weeks to get approval after back and forth emails and phone calls
NIH/NHLBI	prior approval after award	Yes	Email	Yes-denied	
NIH/NHLBI	prior approval after award	Deemed not necessary/Y	Email	N	Originally deemed not necessary, sent COGR email and came back within hours to clarify approval was granted.

FDP Clinical Trial Subaward Sample

- Created at request of NCATS/CTSA leadership
- Goals
  - Minimize the administrative burden associated with executing a subaward under a federally sponsored clinical trial
  - Build on the success of the Accelerated Clinical Trial Agreement (ACTA)

FDP Clinical Trial Subaward Sample

- Working group had representatives from CTSA institutions and FDP member institutions
- Parameters identified
  - Start with NIH
  - Start with fixed price
  - Domestic enrolling sites only
  - Ensure all federal regulations covered
  - Adhere to ACTA terms when possible
  - Allow study specific terms to be added
  - Create budget guidance


Feb ‘15 NCATS id’d need
Mar ’15 FDP re-emphasized need
June ‘15 working group began meeting
Jan ‘16 sent to FDP members for comment
March ‘16 Sent to NIH for approval
Sept ‘16 released to FDP community

Clinical Trial FOA

- PAR-18-407 Clinical Coordinating Center for Multi-Site Investigator-Initiated Clinical Trials – NHLBI
  - Separate itemized budgets must be prepared for each subcontract.
  - Questioned NHLBI on enrolling sites being subawards
  - NHLBI suggested either do a separate budget or do a single sub for all and explain in the budget narrative that it is multiple sites.

- What are you seeing in FOAs? How are you handling submissions for clinical sites?

Fixed Price Prior Approval Working Group

Please go to **kahoot.it** on your phone or computer and enter the PIN on the screen. Create a nickname and wait for the questions!

Contact Us

- Email any experiences making requests to Jennifer McCallister- jennifer.mccallister@duke.edu the the following information:

1. What sponsor did you make the request of (Agency/Institute)?
2. How was the request made? (post-award prior approval, in proposal, JIT, RPPR, etc)
3. Was the request approved? (Y, N, or deemed not necessary)
4. Method of approval (revised NoA, email, etc)
5. Was there a request to exceed the SAT?
6. Any additional information you would like to provide?