FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

Fixed Price Prior Approval Working Group

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Agenda

- UG regulations
- NIH implementation
- Draft FDP guidance on prior approval
- Sponsor responses
- Discussion

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- Uniform Guidance

200.332

With prior written approval from the Federal awarding agency, a pass-through entity may provide subawards based on fixed amounts ***up to the Simplified Acquisition Threshold****, provided that the subawards meet the requirements for fixed amount awards in § 200.201 Use of grant agreements (including fixed amount awards), cooperative agreements, and contracts.*

200.201 highlights*:*

- Payments are based on meeting specific requirements of the Federal award.
- Negotiated using the cost principles (or other pricing information) as a guide.
- The project scope is specific and if adequate cost, historical, or unit pricing data is available to establish a fixed amount award with assurance that the non-Federal entity will realize no increment above actual cost.
- Partial payments for milestone or unit price for a defined unit are both options

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NIH Implementation

- Originally waived in Feb 2015 FAQs
- Reinstated in Oct. 2016 GPS under section 8.1.2.11
- OPERA clarified the following in March 2017:
  - Only applies to new subawards issued on awards with a budget period beginning on or after 10/1/16
  - Must meet the conditions in 45 CFR 75.201 and has to be demonstrated in request to NIH
  - If contained in proposal, NoA will serve as prior approval
  - NIH would consider incorporating OMB FAQ 332-1 into GPS recognizing it is acceptable to have more than one fixed price subaward to same recipient if necessary to complete the work.

OMB FAQ 332-1

Fixed Amount Subawards
My institution has a fixed amount subaward issued on an active Federal award and it is over the $150,000 Simplified Acquisition Threshold; it will continue to be active after 12/26/14. Instead of modifying the subaward, can I give my subrecipient a new fixed amount subaward to cover just this year's funding so I can stay below the threshold?

It is acceptable to have more than one fixed amount subaward with the same subrecipient if necessary to complete work contemplated under a Federal award. It is expected, however, that each fixed amount subaward will have its own distinct statement of work and be priced for the work and deliverables that will be due under that subaward, and that prior approval of the Federal awarding agency is required for each subaward issued under funding received on or after 12/26/14, as outlined in 200.332. Non-Federal entities having special circumstances, including an unanticipated need to increase a fixed price subaward above the threshold, should consult with their Federal awarding agency for guidance on how to complete the planned scope of work with the least amount of administrative burden.

Types of Fixed Price subawards

- 8.1.2.11 in the NIH GPS
- https://grants.nih.gov/grants/policy/nihgps/HTML5/section_8/8.1_changes_in_project_and_budget.htm?Highlight=fixed%20price#Provid

- Milestone based – partial payments, an event triggers payment
- Unit price basis – defined unit with defined price
- One payment at subaward completion

Consortium Agreement

"Procedures to be followed in reimbursing each consortium participant for its effort, including dollar ceiling, method and schedule of reimbursement, type of supporting documentation required, procedures for review and approval of expenditures of grant funds at each organization and timing of applicable reporting requirements. This includes provisions on access to core facilities and resources and whether access will be provided as a fee-for-service." – doesn't differentiate CR vs FP

15.2.1 – NIH GPS

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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."

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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].

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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

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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.

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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:

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Sponsor responses:

NIH varies from not applicable to very formal approvals with absolute restriction on SAT, but only have a few samples

DoD – only example received has been that approval isn't necessary

Please note that DOD R&D General Terms and Conditions Jul 2016 Part7 Sub Article XII Section B contains situations that do not require prior approval, including a discussion on clinical trials.

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Let’s discuss!

Contact Us

- Email any experiences making requests to Jennifer McCallister- jennifer.mccallister@duke.edu; interested in what the sponsor response was and what items were required to make the request.