

Clarification: Fixed Amount Award Definition and Implementation for Clinical Trials

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Key Dates

Release Date: September 06, 2018

Related Announcements

None

Issued by

National Institutes of Health ([NIH](#))

Purpose

The purpose of this notice is to provide the extramural community with clarification of the definition of fixed amount subawards, specifically regarding their use in clinical trials and other types of human subject studies.

The concept of fixed amount awards was introduced in the Uniform Administrative Requirements, [45 CFR 75.2](#). A fixed amount award is a type of grant agreement under which the Federal awarding agency or pass-through entity provides a specific level of support without regard to actual costs incurred under the award. This type of Federal award reduces some of the administrative burden and record-keeping requirements for both the agency and recipients or pass-through entities. The NIH Grants Policy Statement, section [8.1.2.11](#), states that with NIH prior approval, a pass-through entity may provide subawards based on fixed amounts, when certain conditions apply.

Historically, NIH has funded clinical trials and other types of human subject's study capitation costs through awards to coordinating centers, which fund individual sites via consortium agreements or purchase service agreements. NIH is not making any changes to this model. However, many recipients have questioned whether they are required to use fixed amount subawards to distribute capitation funds. For this reason, NIH is clarifying the distinction between a fixed-amount subaward and a fixed-rate agreement.

In a fixed amount subaward, the total value of the award is negotiated upfront. This requires the pass-through entity to know both the unit price and the total number of units that will be provided. In a fixed-rate agreement, while there is a negotiated cost per unit, e.g. per patient cost in a clinical trial (or participant in a non-Clinical Trial Human Subjects Study), the total amount of the award may be unknown when the agreement is created. Since this type of agreement is based on a "fixed rate" as opposed to a "fixed amount" as defined by [45 CFR 75.201](#), prior approval is not required to enter into this type of agreement provided there are no other factors that would require NIH prior approval consistent with NIHGPS, section [8.1.1.4](#). By issuing this clarification, NIH is acknowledging that no changes have been made to our current capitation funding model and recipients can continue to distribute capitation funding consistent with their current institutional policies.

Recipients with questions regarding the appropriate mechanism for distributing capitation funding should consult with the Grants Management Specialist listed on their Notice of Award.

Inquiries

Please direct all inquiries to:

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