

Guidance on the Use of the FDP Fixed-Rate Clinical Research Sample

INTRODUCTION

This guidance document, created by a working group under the direction of the FDP Subawards Subcommittee, pertains to the FDP [Fixed-Rate](#) Clinical Research Agreement sample. The sample is intended to be used by pass-through entities (PTEs) that need to issue a subaward under an NIH grant or cooperative agreement in which the subrecipient is enrolling subjects on a **per subject/capitation billing model**. These studies may fall under the [NIH definition of a clinical trial](#), or the [NIH definition of clinical research](#). They are typically multi-site studies.

PTEs wishing to issue subawards using a **cost reimbursement or fixed-amount** billing model, including projects that fall under NIH's definition of a clinical trial or clinical research, must use other appropriate FDP subaward templates available on our website at <http://thefdp.org/default/subaward-forms/>. A chart providing guidance on the appropriate template to use for specific circumstances is also available on the website.

Questions regarding this document can be directed to the FDP Subawards Subcommittee co-chairs at subawards@thefdp.org.

Components and Structure of the FDP Fixed-Rate Clinical Research sample:

Face page - includes fillable fields for PTE to include project-specific information (such as name of PTE and Subrecipient, names of PIs, Federal Award No., Subaward No.) and contains general terms and conditions and Uniform Guidance references common to all federal awarding agencies. These terms were agreed upon among FDP members, and therefore, **cannot be edited**. Having these already agreed upon terms reduces administrative burden by eliminating the need for PTEs and subrecipients to negotiate.

Attachment 1 - Certifications and Assurances - contains assurances required by federal awarding agencies, and overarching terms PTEs agree to when they accept federal funds that must also be flowed down to subrecipients. **Cannot be edited**.

Attachment 2A - NIH Prime Award Terms and Conditions - includes general terms and conditions per Uniform Guidance, and the terms and conditions specific to NIH. **Cannot be edited**.

Attachment 2B - Special Terms and Conditions - includes terms and conditions specific to clinical research and clinical trials that are typically accepted by academic institutions. **This attachment can be edited, as necessary**, and terms can be added or deleted to meet institution and project-specific needs. If additional terms need to be included, *they should not conflict with or duplicate existing terms elsewhere in the sample. FDP members should not include additional terms to other FDP members except for the following: project-specific terms, data transfer and use terms, or terms necessary to mitigate issues found after conducting a subrecipient risk assessment per your institution's policies. Do*

not include indemnification, law and venue clauses as public institutions can never accept these conditions.

Attachment 3A - PTE Contacts - **Cannot be edited.**

Attachment 3B pages 1 & 2 - Subrecipient Contacts - Contains important information for FFATA reporting. **Cannot be edited.**

Attachment 4 - Reporting and Prior Approval Terms - addresses the non-financial reporting requirements, with frequency and types of reports. Unlike the FDP Cost Reimbursement Research Subaward Agreement template, the FDP Fixed-Rate Clinical Research sample addresses carryover by stating that it is not applicable. This **cannot be edited**. Terms referencing carryover in the Notice of Award (NoA) do not flow down to a subrecipient receiving a fixed-rate payment as they will not have an unobligated balance. This attachment **cannot be edited**, however, PTEs have flexibility in the type of reporting and frequency they require.

Attachment 5 - Statement of Work and Payment Schedule - includes a description of the work the subrecipient is to perform including, for example, references to the protocol. Detailed payment terms and, if applicable, a sample invoice should be included here.

Attachment 6 - Notice of Award (NoA) and any additional documents - a placeholder for the PTE to include a copy of the original NoA, or any additional documentation submitted to the federal awarding agency that is relevant to the subrecipient. If the NoA contains information that you do not wish your subrecipient to view (examples include restrictions specific to the PTE PI) then you can redact information.

Attachment 7 - Form of Transfer Record - optional form, should entities wish to utilize. To be used if subrecipient is transferring subject material, per terms in Attachment 2B.

Some important definitions specific to the FDP [Fixed-Rate](#) Clinical Research Agreement sample:

A **Clinical Coordinating Center (CCC)** in a clinical research study is typically responsible for designing and planning the study, project managing the study, ensuring that participant recruitment and other performance milestones are met, monitoring the scientific conduct of the study, and leading the analysis and dissemination of results.

A **Data Coordinating Center (DCC)** contributes to the study design, ensures appropriate adverse event monitoring and reporting, establishes and maintains a data capture system; prepares interim data reports for the data and safety monitoring board (DSMB), conducts statistical analyses; and helps with the dissemination of the results.



Other definitions, such as the NIH definition of a clinical trial, and a traditional clinical trial, can be found on our website in the [Template Guidance Chart](#).

FAQs

- 1. Under what circumstances should we use the FDP Fixed-Rate Clinical Research sample vs. the other FDP subaward templates for the different types of NIH-funded clinical trials and other human subjects studies?**

In general, the Statement of Work (SOW) and billing model are what drives the appropriate FDP template for use. For guidance see [FDP Template Guidance Chart](#).

- 2. Why should I use the FDP Fixed-Rate Clinical Research sample?**

The sample streamlines negotiations for both sides as all but Attachment 2B is fixed and is considered standard language that has been successfully piloted by FDP members and the Trial Innovation Network (a collaborative initiative within NCATS' CTSA Program) since its inception in 2016. Attachment 2B can be modified (per instructions in this document) and contains terms relevant to human subjects protections not available in the FDP Cost Reimbursable template; these terms are critical when the subrecipient's SOW includes the enrollment of human subjects into a clinical study.

Using the sample also ensures that institutions are using current federal terms that have been reviewed and discussed by an FDP working group and its members; this sample will continuously be updated in line with the other FDP templates/samples.

- 3. What types of clinical research can be used with this sample?**

This sample can be used when the PTE is issuing a subaward on an NIH grant or cooperative agreement and the subrecipient is conducting clinical research (that may or may not be classified as a clinical trial) on a fixed-rate basis. Studies with a per subject price structure are properly classified as fixed rate. Studies with a cost reimbursement price structure should not use this sample. Studies which are part of the Trial Innovation Network (TIN) should refer to the TIN website at <https://trialinnovationnetwork.org/elements/fdp-ctsa-trial-innovation-standard-agreement/>.

This sample should be used when the SOW for the subrecipient involves enrolling subjects in a clinical research project, most frequently an NIH multi-site clinical trial. The use of this sample is dictated by the activity happening at the subrecipient's institution, as opposed to the PTE's institution. For example, if the PTE is the Coordinating Center for a network and is distributing fixed-rate (capitation) funds for the project, the FDP Fixed-Rate Clinical Research sample is the correct choice because the subrecipients are enrolling subjects under the PTE's



grant/cooperative agreement. This remains true if the structure of the network provides separate administrative grants directly to the subrecipients.

The sample may be used for subrecipients that are not conducting traditional multi-site clinical trials but are conducting work that falls under the expanded NIH definition of a clinical trial or the NIH definition of clinical research. As long as the billing model is fixed rate and the work is clinical research, the sample should be used. For those projects that are not traditional clinical trials, terms may be removed from Attachment 2B as appropriate. See this link for more information on defining the different types of clinical research:

<https://www.nih.gov/sites/default/files/about-nih/public-trust/clinical-trials-infographic.pdf>

Again, the [FDP Template Guidance Chart](#) provides guidance to help you decide which template or sample to use for various circumstances.

4. Which terms should I flow down to the subrecipient?

The PTE's Notice of Award (NoA) is between the federal awarding agency and the PTE. The PTE then enters into a subaward with the subrecipient. In the subaward, the SOW is agreed-upon between the PTE and subrecipient, and the subrecipient is subject to any applicable terms from the PTE's NoA that are applicable in the SOW and that must then flow down. Most of these terms will be located in the "Special Terms and Conditions", "Additional Terms" or referenced requirements (e.g. data sharing plan, multiple PI plan, etc) that were submitted in the original application to the federal awarding agency that becomes as part of the PTE's NoA.

The PTE may include flow down provisions from any agreement entered into by the PTE that relates to the study (the PTE's NoA, Clinical Coordinating Center (CCC) or Data Coordinating Center (DCC) agreement, drug/device agreement, etc.) that are applicable to the work the subrecipient performs **in Attachment 2B**. Flow down terms may include intellectual property (IP), liability, and data security provisions from a drug manufacturer or the DCC.

5. What does "fixed rate" mean and how is it different from "fixed amount"?

Per NIH Notice [NOT-OD-18-222](#), *Clarification: Fixed Amount Award Definition and Implementation for Clinical Trials*, "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 subject 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."

6. How does a cost reimbursable budget differ from a fixed-rate budget?



A cost reimbursable subaward is used to pay for actual expenses incurred in the performance of the SOW. Cost reimbursable subawards include a detailed, line-item budget with a “not to exceed amount” (the maximum dollars available to the subrecipient), which the subrecipient must, depending on the terms of the subaward, adhere to when applying costs to their work. Upon receipt of a line-item invoice provided by the subrecipient for actual incurred expenses, the PTE reimburses the subrecipient for allowable expenditures up to the “not to exceed amount.” If the subaward does not allow for automatic carryover, any funds remaining up to the “not to exceed” amount cannot be collected by the subrecipient after a certain period of time as stipulated by the subaward unless and until the subrecipient is granted carryover approval by the PTE.

A fixed-rate subaward is used under NIH grants and cooperative agreements to provide subrecipients with a per subject (capitation) payment based on subject enrollment. Under fixed-rate subawards the total amount of the subaward is unknown when the subaward is created. Subrecipients are paid the per subject fee as subjects are enrolled based on data provided to the PTE using a study-defined mechanism (e.g. data forms, electronic data capture systems, etc.). Invoicing by the subrecipient may or may not be required. Required invoices will look very different from a line-item cost reimbursement invoice. Any funds paid to the subrecipient in excess of actual costs expended by the subrecipient at the end of the project will be retained by the subrecipient.

7. What if my subrecipient has two budgets: one cost reimbursable and one fixed rate?

There are scenarios when issuance of both a cost reimbursable and a fixed-rate subaward to the same institution is necessary under one NIH-funded clinical trial. Typically in these scenarios, the SOW for the two different types of subawards will be very different. The SOW for the cost reimbursable subaward will typically require a commitment of effort beyond the activities involved in enrolling subjects. This type of subaward reimburses for actual expenses for activities that go above and beyond enrolling subjects per the protocol. The SOW for the fixed-rate subaward is generally for the performance of the study protocol. The fact that the statements of work and billing models for these two activities are different should necessitate separate subawards.

Examples:

Cost reimbursable SOW - PI analyzing data from all sites, co-authoring publications, traveling and presenting data, participating in advisory committees.

Fixed-rate SOW - enrolling subjects.

Some PTEs choose to issue one subaward containing both the cost reimbursable activities and the fixed-rate activities. However, the financial system of the subrecipient might be unable to accommodate these “blended” or “hybrid” subawards. Additionally, the issuance of a “blended” or “hybrid” subaward that includes two separate and distinct Statements of Work creates a



scenario where it is difficult for the PTE to take corrective action should one Statement of Work not be completed satisfactorily. As stated above, the disposition of remaining funds at the end of the project becomes more complicated when a ‘blended/hybrid’ subaward is issued. If the PTE issues the “blended/hybrid” subaward using the FDP Cost Reimbursable Subaward template but allows the subrecipient to retain the remaining funds from the fixed-rate activities, an audit concern could ensue.

Considering these issues, while the issuance of one subaward instead of two might represent less administrative burden for the PTE, it can result in additional administrative burden for the subrecipient, as well as more difficulty for the PTE to conduct subrecipient monitoring more efficiently. Therefore, it is suggested that PTEs who want to issue “blended/hybrid” subawards communicate with the subrecipient prior to issuing this type of subaward. The FDP does not have a template or sample containing terms for a hybrid/blended model. If the subrecipient agrees to accept a “blended/hybrid” subaward, the PTE must remove the FDP moniker from the FDP Subaward template and include terms appropriate to both payment models prior to sending it to the subrecipient.

Ideally, PTEs and subrecipients should discuss how subawards will be issued during the proposal and budget preparation stage, prior to submission of the proposal to the sponsor. This will be helpful for the PTE to consider the potential impact on F&A calculated during the budget development stage if the PTE needs to account for multiple subawards to the same entity. This is also an opportunity for the subrecipient to voice any concerns with regards to the types of agreements they can accept with different billing models.

8. How do I address payments other than capitation/per subject payments?

Start-up costs are generally fixed payments and include activities relevant to getting the study running at the subrecipient institution. Start-up costs may be inclusive of payment for different activities (based on the project needs) and can be the same fixed amount paid to each subrecipient or vary based on the subrecipient’s needs. It is suggested when creating the payment schedule that timing of start-up cost payments should be clearly addressed in the subaward so that if subjects never fully enroll it is clear whether the subrecipient is reimbursed for start-up costs.

Travel costs: In general, travel costs for study personnel (as opposed to *subject* travel) are cost reimbursable expenses that should not be addressed in a fixed-rate subaward. Options for paying travel costs to study personnel include 1) PTE reimburses the subrecipient directly (not via the subaward) from the PTE’s budget by submission of travel receipts; or 2) if the subrecipient PI has an additional role on the study other than enrolling subjects (such as providing committed effort in the project design or conduct of the study), the travel can be included in a separate cost reimbursable subaward for the additional role and separate scope of work. In general, study subject travel should be included in the per subject fee.



9. How do I structure invoicing and payment language in a fixed-rate subaward?

The FDP Fixed-Rate Clinical Research Subaward sample addresses invoicing and payments in Term & Condition #2 on the subaward face page, and again in Attachment 5. In order to complete these sections, you need to understand how the study team will pay the subrecipient. Ask the study team:

- (1) How often will you pay the subrecipient?
- (2) What action(s) will trigger payment? AND
- (3) Will you pay after a certain number of milestones are completed (e.g. subject visits as outlined in the payment schedule) or on a fixed time schedule (e.g. monthly or quarterly based on the number of subjects seen during that time period)?

The study team may have access to the study's data capture system and will see the subrecipient's reporting of enrollment/milestone targets, or the subrecipient may send case report forms ("CRF") to a study team member or the Data Coordinating Center ("DCC"). Ask the study team if payment will be triggered by (a) the entry or submission of the data in the study's data capture system, (b) the submission of CRFs *alone* or (c) if they need the subrecipient to *submit invoices* that certify how many enrollment/milestone targets have been met. The study team may also be generating invoices first to then send to the subrecipient for confirmation.

These types of invoices are documents that certify the enrollment/milestone targets met within a given time period at the fixed rates outlined in the budget. These types of milestone invoices are not line item cost reimbursable invoices that are addressed in a cost reimbursable subaward.

If the data capture system/CRF alone acts as a trigger, you need to know at what interval your study team gathers the data/CRFs to then calculate when to pay the subrecipient (i.e. monthly, quarterly, after ### enrollment). However, if the subrecipient has to submit invoices, you need to know at what interval and what the invoices should include (i.e. monthly, quarterly, after ### enrollment?). Consider attaching a sample invoice to the subaward to guide the subrecipient appropriately.

- Sample language for no invoicing: "Subrecipient will record enrollment data into the Data Capture System (DCS) maintained by PTE. On a quarterly basis, PTE will review the DCS and prepare payments to Subrecipient based on milestones completed as evidenced by Subrecipient's entries into the DCS."
- Sample language for invoicing: "Subrecipient will submit invoices on a monthly basis using a template substantially similar to the attached page. The invoice will state the dates and descriptions of milestones completed during the period covered by the invoice, the price per milestone, the total requested for the month and the payment address for Subrecipient."

Guidance on drafting a payment schedule, i.e. a routinized, clear mechanism for paying the various subrecipients involved in the study. PTEs may place milestone targets and



other reasonable and necessary contingencies, such as site monitoring visits or enrollment of a certain number of subjects, on payments. However, keep in mind that subrecipient must still be reimbursed, per Termination and Suspension in Attachment 2A, for all tasks completed in accordance with the protocol even if particular contingencies are not met.

10. Do I need prior approval from NIH to issue fixed-rate subawards?

PTE does not have to seek prior approval to enter into subawards based on a “fixed rate” as opposed to a “fixed amount” as defined by [45 CFR 75.201](#), provided there are no other factors that would require NIH prior approval consistent with NIHGPS, section [8.1.1.4](#).

11. How should I issue the subaward when the Clinical Coordinating Center (CCC) and Data Coordinating Center (DCC) are separate entities?

Depending on the structure of the study, the CCC and DCC may have separate grant awards directly from the federal funding agency to each fund their portion of the study, or the DCC may be a subrecipient to the CCC who receives all of the funding for the study. Typically, a CCC for a multicenter clinical study is awarded funding for clinical site enrollment and issues subawards to the enrolling sites. A DCC doesn’t usually provide funding to the subrecipients but does store and secure all of the data from the study and may perform audits of subrecipients to ensure data accuracy.

The FDP Fixed-Rate Clinical Research sample is written to govern the relationship between the PTE and subrecipient so you, if you are the CCC, may need to make edits to Attachment 2B to incorporate third party involvement like a DCC.

Subrecipients will want to ensure that the DCC is subject to all the same applicable terms and conditions that protect the subrecipient’s data, such as Data Use/Ownership, Monitoring and Clinical Trial Auditing, Confidentiality, HIPAA/PHI, Human Subjects, and Safety Reporting. Therefore, you need to indicate in the subaward that the DCC is responsible for complying with those provisions and has agreed to comply in an agreement with you as the CCC, or with the federal awarding agency as a direct grantee.

As a way to reduce administrative burden, you can avoid the need for all subrecipients to have a separate data transfer and use agreements directly with the DCC if the PTE adds certifications regarding what the DCC has already certified to with regards to the handling of data in other existing agreements for the study.

12. How do I include a ‘not to exceed amount’ in the subaward sample?

The face page of the FDP Fixed-Rate Clinical Research sample includes a drop-down field that includes two options:

- The subaward amount is not to exceed_____.



- The subaward amount is as outlined in the budget/payment schedule in Attachment 5.

The drop down provides options for the PTE to either instruct the subrecipient to follow the attached payment schedule or define a *not to exceed* spending amount.

If choosing to define the subaward amount using the payment schedule, the payment schedule will provide the payment per subject, any additional fixed payments such as start-up costs and, if applicable, a maximum allowable number of subjects. If a maximum enrollment applies to the Subrecipient, the payment schedule should provide the total amount of the subaward (based on the maximum # of subjects and payment per subject, plus any additional fixed costs). If the total amount of the subaward is not provided in the payment schedule, it can be identified by the subrecipient based on the *projected* number of subjects and payment per subject.

It may be necessary for the PTE to select the *not to exceed* option in the drop-down menu if the sponsor indicates a *not to exceed* amount for subrecipients. At times, it may be necessary for the PTE to have a not to exceed amount if the PTE's financial systems are dependent on that figure for purchase order creation/reconciliation.