Fed Sponsor Award Type	Subrecipient's Payment Model	Subrecipient Type	Subrecipient's Statement of Work (SOW)	NIH NoA Clinical Trial Indicator (if applicable)	Template/Sample to Use	Notes
Fed Grant or Cooperative Agreement	Cost reimbursable invoices	Domestic	SOW may include one or more of the following: • Vertebrate animal use • Human Subjects that is **not** a Clinical Trial	No	FDP Subaward Cost Reimbursable template	
Fed Grant or Cooperative Agreement	Cost reimbursable invoices	Domestic	SOW may include one or more of the following: • Vertebrate animal use • Human Subjects that is **not** a Clinical Trial	Yes	FDP Subaward Cost Reimbursable template	• Subrecipient is ***supporting*** a trial by, for example, running samples or analyzing data • Subrecipient is not enrolling patients at their own site • Select "The work being conducted by this subrecipient per this agreement is not a clinical trial." in the subaward template, Attachment 2.
Fed Grant or Cooperative Agreement	Cost reimbursable invoices	Domestic	SOW includes an NIH-defined Clinical Trial that is a Non-Traditional clinical trial (see Glossary)	Yes	FDP Subaward Cost Reimbursable template	• Select "The work being conducted by this subrecipient per this agreement is a clinical trial." in the subaward template, Attachment 2. • For these types of NIH-defined clinical trials, it is not necessary to include Attachment 2B, which is meant for Traditional Clinical Trials.
Fed Grant or Cooperative Agreement	Cost reimbursable invoices	Domestic	SOW includes an NIH-defined Clinical Trial that is a Traditional Clinical Trial (see Glossary)	Yes	FDP Subaward Cost Reimbursable template + Attachment 2B from the Clinical Research Fixed Rate sample	• Select "The work being conducted by this subrecipient per this agreement is a clinical trial." in the subaward template, Attachment 2. • The cost reimbursable template for a traditional clinical trial may be used in rare circumstances, such as

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						when the PTE has proposed a cost reimbursable structure to the federal awarding agency and/or the subrecipient is performing a clinical trial and/or supporting a clinical trial (i.e. Contract Research Organization (CRO) role).
Fed Grant or Cooperative Agreement	Fixed amount	Domestic	SOW may include one or more of the following: • Vertebrate animal use • Human Subjects that is **not** a Clinical Trial	No	FDP Fixed Amount template	• Note the difference between fixed amount and fixed rate in the Glossary below and NOT-OD-18-222
Fed Grant or Cooperative Agreement	Cost reimbursable invoices	Foreign	SOW may include one or more of the following: • Vertebrate animal use • Human Subjects that is **not** a Clinical Trial	No	FDP Foreign Subaward Cost Reimbursable sample	• Subaward sample is editable; adjust as necessary in accordance with your institutional policy
Fed Grant or Cooperative Agreement	Fixed amount	Foreign	SOW may include one or more of the following: • Vertebrate animal use • Human Subjects that is **not** a Clinical Trial	No	FDP Foreign Subaward Fixed Amount sample	• Subaward sample is editable; adjust as necessary in accordance with your institutional policy
Fed Grant or Cooperative Agreement	Fixed rate	Domestic or Foreign	NIH Multi-Site **Clinical Trial**	Yes	FDP Fixed Rate Clinical Research Subaward sample	• PDF portion of this sample is fixed and cannot be edited • Attachment 2B may be edited as necessary to align with PTE's institutional policies re: clinical trial agreements and FDP guidance documents

Fed Sponsor Award Type	Subrecipient's Payment Model	Subrecipient Type	Subrecipient's Statement of Work (SOW)	NIH NoA Clinical Trial Indicator (if applicable)	Template/Sample to Use	Notes
Fed Grant or Cooperative Agreement	Fixed rate	Domestic or Foreign	SOW includes Human Subjects and is **not** a Clinical Trial	No	FDP Fixed Rate Clinical Research Subaward sample	• PDF portion of this sample is fixed and cannot be edited • Attachment 2B may be edited as necessary to align with PTE's institutional policies re: clinical research that is not a clinical trial
Fed Grant or Cooperative Agreement	Contains both cost reimbursement and fixed rate invoices (hybrid)	Domestic	May include a per subject enrollment schedule for clinical research, or a clinical trial, AND a cost reimbursable component (e.g. PI travel expenses for meetings, PI serving on a DSMB)	May be either Yes or No	Hybrid FDP templates do not exist. If PTE wants to issue this type of agreement, the PTE must remove the FDP moniker on the agreement.	• This type of structure includes different SOWs • Consider that subrecipient's systems may not be able to support a hybrid model • PTE and subrecipient should discuss best agreement options
Fed Contract	any	Domestic or Foreign	SOW may include one or more of the following: • Vertebrate animal use • Human Subjects that is not a Clinical Trial • Human Subjects that is a Clinical Trial	N/A – read federal contract to determine if it has a clinical trial component	FDP Subcontract sample	• Sample is editable • Adjust as necessary to align with your institutional policy and Subrecipient's SOW

Glossary:

- **Payment Models:**
    - **Cost Reimbursable**: PTE pays subrecipient for actual expenses (direct and allowable Facilities and Administrative or "F&A" costs) incurred in the performance of the SOW. The subaward includes a detailed line-item budget with a not-to-exceed amount, which the subrecipient must follow closely depending on the terms of the subaward. Any funds remaining at the end of the project cannot be collected by the subrecipient and any advanced funds must be returned to the PTE if there are no corresponding actual expenses. Generally, a final invoice is required detailing all cumulative costs incurred.

- **Fixed Amount**: For a definition in Uniform Guidance (UG), see 2 CFR §200.45. A price is determined up front for a specific deliverable and is only paid if the deliverable is met. Subaward includes a payment schedule instead of a detailed budget and should include specifics on the deliverable and corresponding payment amount. Fixed price payments are generally inclusive of all costs, including F&A. Payments are not tied to actual expenses or costs incurred, do not require financial reports, and any residual balance should remain with the subrecipient. However, the subrecipient must certify in writing via a Certificate of Completion to the PTE that the activity or service was completed prior to receiving the final payment. If the required deliverables were not carried out, the amount of the subaward must be adjusted, as per UG, 2 CFR §200.201(b)(3).

- **Fixed Rate**: While there is a negotiated cost per unit, e.g. per patient/capitation 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/price," prior approval from NIH 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. See NOT-OD-18-222 for clarification of the distinction between Fixed Amount and Fixed Rate.

- **Statements of Work:**

  - **Human Subjects Research**: per 45 CFR 46, a human subject is "a living individual about whom an investigator (whether professional or student) conducting research: (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."

  - **Clinical Trial**: per NOT-OD-15-015, "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes"
    - A **Traditional Clinical Trial** is a study that involves a more than minimal risk interaction and intervention with a patient or human subject. Examples:
      - Phase II, III, IV clinical studies
      - Investigational New Drug (IND)/Investigational Device Exemption (IDE) studies
      - Some first-in-human or Phase I investigational interventions
      - Some imaging studies
      - Interventions to prevent or treat serious conditions
      - Interventions or invasive procedures with substantial risk or high potential for serious adverse events
    - A **Non-Traditional Clinical Trial** is a study that involves some interaction and intervention with a patient or human subject but is considered minimal risk. Examples:
      - Non-invasive specimen collection (e.g. blood draw, cheek swab)
      - Non-invasive routine clinical procedures (may include some forms of imaging)
      - Low risk behavioral interventions (e.g. diet, exercise)
      - Physical exam
      - Routine psychological testing

- Basic Experimental Studies with Humans (BESH): prospective basic science studies involving human participants; e.g., measuring brain activity when participants are shown image prompts

- **FDP Agreement Forms:**

  - **Template**: Any FDP form labeled "template" should not be changed, beyond filling in the text boxes of the form (i.e. Attachment 2) and making necessary adjustments to Attachment 2B for clinical trials. Use of the templates, as published, by FDP members represents a condition of their membership. FDP provides sufficient flexibility to incorporate certain language in fillable text boxes of essential state-specific laws, special terms and conditions of the federal award that need to be flowed down, human subjects data exchange terms, or special instructions for high-risk subrecipients. Institutions may not include any terms in the fillable text boxes that contradict the other fixed terms of the template.

    Institutions may choose at their own risk to make edits to the fixed portions of the FDP templates for their own purposes. However, if any edits are made the PTE MUST remove the FDP moniker, any references to FDP within the templates, and the agreement should look distinct. The subrecipient must clearly understand that commonly accepted FDP subaward standards/language have been changed, and that the version the PTE sent does not conform with the FDP templates.

  - **Sample**: Samples provide a starting point for any user to craft terms and conditions in accordance with their institution's policies, the terms of the federal contract (or non-federal agreement with some additional modification), the subrecipient type, and any project specific requirements. As with the templates, if any changes to the terms and conditions are made, all references to FDP, including the moniker on the face page of the sample, must be removed.