

FDP Major Changes Summary for the 2019 Subaward Templates

Purpose: outline the major changes to the FDP Subaward template from the 2018 version to the 2019 version. While only the changes to the cost reimbursement template will be highlighted, most of the changes are applicable to the fixed price template as well with the exception of the Facepage and Attachment 5. Contact the Subaward Subcommittee co-chairs with any questions.

Changes to the amendment templates are outlined at the end of the document. This document does not cover the subcontract sample or the clinical trial sample.

Scope: describing major changes to the template language. Minor adjustments for consistency in grammar and/or style are not documented in this change sheet. Some major changes related to data fields will be summarized in this document. For details on the data fields, we have also generated a crosswalk that sets out all the fields in every version of the template, including a brief description of what information should go there.

Note: when making selections in drop down menus, make the appropriate selection. Then click (or tab) outside of the drop-down. This will populate any additional data points that may appear based on the drop-down selection. We also recommend printing your files to PDF prior to sending to your subrecipient to prevent any field changes or loss of data if inserting pages (such as NOA).

Facepage

2018 Version	2019 Version	Explanation
Header: FDP Cost Reimbursement Research Subaward Agreement	Header: FDP Cost Reimbursement Research Subaward Agreement	Not all subawards are for research activities, some like a T award, may be more oriented to training or other activities. Subaward and Agreement seemed to be duplicative, so we removed the additional word. Finally, the checkbox on Attachment 2 confirms if a subaward is for a research activity, so it was redundant and not always accurate to call out research in the header.
PTE hereby awards a cost reimbursable Subaward, as described above, to Subrecipient. The Statement of Work and budget for this Subaward are as shown in	PTE hereby awards a cost reimbursable Subaward (as determined by 2 CFR 200.330) , as described above, to Subrecipient. The Statement of Work and	As described above seemed to refer to the header of the Subaward. It is more accurate to refer to the regulation in guiding the definition of the relationship

<p>Attachment 5. In its performance of Subaward work, Subrecipient shall be an independent entity and not an employee or agent of PTE.</p>	<p>budget for this Subaward are as shown in Attachment 5. In its performance of Subaward work, Subrecipient shall be an independent entity and not an employee or agent of PTE.</p>	<p>between the two parties rather than document header.</p>
<p>Term 2: ... All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), Subaward number, and certification, as required in 2 CFR 200.415 (a).</p>	<p>All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), Subaward number, breakdown by major cost category, and certification, as required in 2 CFR 200.415 (a).</p>	<p>Cost reimbursement invoices should include major cost categories because the PTE should be reviewing the invoice to verify allowability of expenses, consistent with funding agency terms and approved budget. Major cost categories facilitate this review and monitoring.</p>
	<p>Add two drop down boxes to terms 6 and 9 to allow contacts to be identified (in addition to the Authorized Official) for each the Subrecipient and the PTE.</p>	<p>Institutions vary in their assignment of roles and responsibilities, so separating out the contacts between the PTE and Subrecipient will allow for more clarity. While the Authorized Official should still sign off on the transaction, another party, such as an admin contract, could be the best initial point of contact to initiate the transaction.</p>
<p>Specific to Fixed Amount Subaward: Header: FDP Fixed Price Research Subaward Agreement</p>	<p>Specific to Fixed Amount Subaward: Header: FDP Fixed Amount Price Research-Subaward Agreement</p>	<p>Fixed price is a FAR term (see FAR Part 16.2), applicable to contracts and subcontracts. Uniform Guidance (2 CFR 200.332), which governs grants, cooperative agreements, and subawards refers to a fixed amount subaward, thus we updated the nomenclature for consistency and accuracy.</p>

Attachment 1

<p>Program for Enhancement of Contractor Employee Protections (41 U.S.C 4712) Subrecipient is hereby notified that they are required to: inform their employees working on any federal award that they are subject to the whistleblower rights and remedies of the pilot program; inform their employees in writing of employee whistleblower protections under 41 U.S.C §4712 in the predominant native language of the workforce; and include such requirements in any agreement made with a subcontractor or subgrantee.</p>	<p>Program for Enhancement of Contractor Employee Protections (41 U.S.C 4712) Subrecipient is hereby notified that they are required to: inform their employees working on any federal award that they are subject to the whistleblower rights and remedies of the pilot program; inform their employees in writing of employee whistleblower protections under 41 U.S.C §4712 in the predominant native language of the workforce; and include such requirements in any agreement made with a subcontractor or subgrantee.</p>	<p>The program is no longer a pilot program, removed the word pilot.</p>
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Attachment 2

	<p>Added NIH Institute field to Required Data Elements section.</p>	<p>Some users may want to indicate the specific NIH institute because of variable terms. Added it to this section so that users appending the NOA could elect to forego the additional data entry. Also updated the crosswalk.</p>
	<p>NIH awards only: moved MPI term to NIH section (see more detail below).</p>	<p>NIH has increased in the number of terms applicable only to them. Moved this term to be located with other NIH specific terms that will show up only when NIH is the Federal Awarding Agency.</p>
<p>Data Sharing and Access (Check if applicable): Subrecipient agrees to comply with the Federal Awarding Agency's data sharing and access requirements as reflected in the NOA (or in the special terms below) and the Data</p>	<p>Data Sharing and Access (Check if applicable): Subrecipient agrees to comply with the Federal Awarding Agency's data sharing and access requirements as reflected in the NOA (or in the special terms below) or the Federal</p>	<p>Wanted to clarify section to ensure that users were clear on when the project could rely on the NOA/ grants guidance document from the Federal Awarding Agency and when to append a specific plan. Added a drop down for the last</p>

<p>Management/Sharing Plan submitted to the Federal Awarding Agency and [attached/provided upon request].</p>	<p>Awarding Agency’s standard terms and conditions as reference in General Terms and Conditions 1-4 above. [No additional requirements/Attached/Provided upon request] is a Data Management and/or Sharing Plan that incorporates additional requirements as submitted to the Federal Awarding Agency.</p>	<p>sentence. Last sentence only appears if you select Attached/Provided upon request.</p>
	<p>Applicable only when funding agency is USDA: updated link to NIFA policy guide and COI regulation (from as stated to solicitation to 7 CFR 550.110)</p>	<p>Links and citations were incorrect. This is also corrected in the crosswalk.</p>
<p>2 options of Certificate of Confidentiality (COC) language were available for members to pilot.</p>	<p>The Parties agree that this research funded in whole or in part by the National Institutes of Health (“NIH”), is subject to NIH Policy NOT-OD-17-109 (the “Policy”) and therefore is deemed under the Policy to be issued a Certificate of Confidentiality (“Certificate”) should the conditions outlined within the Policy apply. Accordingly, subrecipients that collect or receive identifiable, sensitive information are is-required to adhere to the Policy and protect the privacy of individuals who are subjects of such research in accordance with the Policy and subsection 301(d) of the Public Health Service Act (the “PHS Act”).</p>	<p>Solicited and received community feedback, most users felt this language was the most appropriate and easiest to follow. This section will only appear when NIH is selected as the Federal Awarding Agency.</p>
<p>Exempt determination is under Human Subjects [checkbox = yes].</p>	<p>Added checkbox for Exempt Human Subjects. When checked yes, a drop down appears asking if the exempt</p>	<p>Institutions may not register that this section is applicable to exempt human subjects research because it does not</p>

	determination letter is [attached/available upon request].	receive IRB approval. Pulling this out as a separate checkbox will highlight that while it is exempt, it is still human subjects research.
<p>Subrecipient agrees that any non-exempt human and/or vertebrate animal research protocol conducted under this Subaward shall be reviewed and approved by its Institutional Review Board (IRB) and/or its Institutional Animal Care and Use Committee (IACUC), as applicable and that it will maintain follow current and duly approved research protocols for all periods of the Subaward involving human and/or vertebrate animal research. If Subrecipient is using its own IRB and/or IACUC, Subrecipient certifies that its that the appropriate IRB and/or IACUC are in full compliance with applicable state and federal laws and regulations. The Subrecipient certifies that any submitted IRB / IACUC approval represents a valid, approved protocol that is entirely consistent with the Project associated with this Subaward. In no event shall Subrecipient invoice or be reimbursed for any human or vertebrate animals related expenses incurred in a period where any applicable IRB / IACUC approval is not properly in place.</p>	<p>Subrecipient agrees that any non-exempt human and/or vertebrate animal research protocol conducted under this Subaward shall be reviewed and approved by the appropriate Institutional Review Board (IRB) and/or its Institutional Animal Care and Use Committee (IACUC), as applicable and that it will maintain follow current and duly approved research protocols for all periods of the Subaward involving human and/or vertebrate animal research. If Subrecipient is using its own IRB and/or IACUC, Subrecipient certifies that its that the appropriate IRB and/or IACUC are in full compliance with applicable state and federal laws and regulations. The Subrecipient certifies that any submitted IRB / IACUC approval represents a valid, approved protocol that is entirely consistent with the Project associated with this Subaward. In no event shall Subrecipient invoice or be reimbursed for any human or vertebrate animals related expenses incurred in a period where any applicable IRB / IACUC approval is not properly in place.</p>	<p>This clarification incorporates changes that will more accurately reflect responsibility whether an sIRB or subrecipient's IRB is being utilized.</p>

<p>The PTE will set forth the terms of the exchange of Human Subjects Data (Select One): [below or separate Data Use Agreement]</p>	<p>The PTE will set forth the terms of the exchange of Human Subjects Data (Select One): [see Attachment 7 or separate Data Use Agreement]</p>	<p>Added Attachment 7 (to be released in October 2019 with the DTUA terms and conditions. The DTUA terms in Attachment 7 will be aligned with the DTUA templates and the subaward template to ensure all relevant terms are added and no conflict or duplication is present between the terms.</p>
	<p>The Clinical Trial Indicator in Section IV of the PTE’s NOA is stated as: YES/NO</p> <p>If YES is selected, the PTE will be prompted to indicate to the subrecipient if their SOW under the relevant subaward will be a clinical trial.</p>	<p>NIH now has a clinical trial designator on their NOAs. This should be flagged for subrecipients. This section will only appear when NIH is selected as the Federal Awarding Agency.</p> <p>Please see the new template guidance table and the Guidance Document for additional information.</p>
<p>Attachments 3A and 3B</p>		
<p>No changes.</p>		
<p>Attachment 4</p>		
<p>In accordance with 37 CFR 401.14, Subrecipient agrees to notify PTE’s [Contact person] [# of days] days after Subrecipient’s inventor discloses invention(s) in writing to Subrecipient’s personnel responsible for patent matters. The Subrecipient will submit a final invention report using Federal Awarding Agency specific forms to the PTE’s within 60 days of the end of the Project Period to be included as part of the PTE's final invention report to the Federal Awarding Agency.</p>	<p>In accordance with 37 CFR 401.14, Subrecipient agrees to notify both PTE’s [Contact person] and in iEdison within [# of days] 60 days after Subrecipient’s inventor discloses invention(s) in writing to Subrecipient’s personnel responsible for patent matters. The Subrecipient will submit a final invention report using Federal Awarding Agency specific forms to the PTE’s [contact] within 60 days of the end of the Project Period to be included as part of the PTE's final</p>	<p>Subrecipients must report in iEdison and to the PTE. This clarifies the obligations to report both to the Federal Awarding Agency through the appropriate portal and to notify the PTE.</p>

	invention report to the Federal Awarding Agency.	
Attachment 5		
No changes.		
Attachment 6		
No changes.		
Attachment 7 NEW & OPTIONAL		
The final version will be posted October 2019 with additional materials, including guidance to accompany it. This will be an <u>optional</u> attachment in which institutions may elect to incorporate Data Transfer and Use (DTUA) terms. Attachment 7 will be aligned with both the templates and the DTUA to reduce conflict and align expectations without replicating terms.		
Unilateral Modification		
Header: FDP Research Subaward Agreement Amendment [number field]	Header: FDP Research Subaward Agreement Amendment [number field]	By broadening the header and some of the field names, institutions have the latitude to use the amendment template for other types of FDP templates, including clinical trial sample.
	Effective date field removed.	Various institutions use this field differently. It was causing confusion without adding value. If an action requires an effective date, the PTE should state that in the body of the Modification text.
	Added cost share radio buttons	Added radio buttons to reflect if cost share is applicable to the subaward. The NO option is automatically selected since cost share is not applicable to most FDP subawards.
In the event that funding was not fully expended by the Subrecipient during the prior period, the amount for the prior period is hereby reduced to equal the Subrecipient's final invoice.	In the event that funding was not fully expended by the Subrecipient during the prior period, the Subrecipient is not authorized to use funds from any prior periods, unless prior approval is	Language was amended to simplify the instructions to the subrecipient about how to manage carryover funds. See updated guidance for recommendations on how to layout budget periods and carryover

	granted by the PTE. amount for the prior period is hereby reduced to equal the Subrecipient's final invoice.	authorizations for carryover restricted awards.
Bilateral Modification		
Header: FDP Research Subaward Agreement Amendment [number field]	Header: FDP Research Subaward Agreement Amendment [number field]	By broadening the header and some of the field names, institutions have the latitude to use the amendment template for other types of FDP templates, including clinical trial sample.
	Effective date field removed.	Various institutions use this field differently. It was causing confusion without adding value. If an action requires an effective date, the PTE should state that in the body of the Modification text.
	Added cost share radio buttons	Added radio buttons to reflect if cost share is applicable to the subaward. The NO option is automatically selected since cost share is not applicable to most FDP subawards.
Bilateral Modification with checkboxes		
	New option to help institutions have options to prepopulate modification templates.	<p>The use of checkboxes will hopefully help to simplify modification issuance by having standard language. Some institutions may be able to use the more data-field oriented format to pre-populate NCEs and other actions.</p> <p>Data fields are aligned with those of the Bilateral Modification (above) as much as possible).</p>