

Federal Demonstration Partnership Frequent Q&A Excerpts for UA Users

Uniform Guidance (UG) data elements contained in the FDP Subaward Templates

1. How can I ensure that the required UG data elements per §200.331 (a) are included in the FDP Subaward templates?

An FDP working group was formed in the fall of 2014 to interpret the data elements and update the FDP subaward templates to incorporate the required UG data elements. That working group created a document table titled APPENDIX 1: TABLE OF REQUIRED SUBAWARD DATA ELEMENTS & LOCATION IN UPDATED SUBAWARD TEMPLATES, which is appended to this FAQ document.

OMB has since issued technical corrections to the Uniform Guidance on September 10, 2015. Some data elements were clarified. The FDP closely monitors revisions to the required data elements and updates as appropriate to ensure the latest information is included in the templates and UG data elements table.

2. What is the definition of Subaward Period of Performance Start and End Date, per UG §200.331(v)?

The Subaward Period of Performance (Budget Period) field on the face page of the FDP Cost Reimbursement, Fixed Price, and Amendment Subaward Templates meets the UG requirement of §200.331(v) Subaward Period of Performance Start and End Date. It is the period for which the subaward is being made, based both on the PTE's prime federal award and PTE's discretion. For instance, if the prime federal award for a multi-year project is authorized in annual increments, then the PTE could authorize incremental periods in the subaward. On the other hand, if funding for the entire project period is authorized in the prime federal award, then the PTE may also authorize the entire period in the subaward. However, the PTE may always elect to award shorter increments than those authorized by the federal award. This would be communicated to the subrecipient on the face page of the template (and amendments as applicable) via the Subaward Period of Performance End Date.

In contrast to the Subaward Period of Performance, the Estimated Project Period on the face page is the total project period for which work is planned to be performed by the subrecipient. The end dates of these periods may not be the same. For example, if the subaward on a multi-year project is to be incrementally funded by the PTE, the end date of the Subaward Period of Performance on the face page of the Subaward Template will be prior to the Estimated Project Period end date. On the other hand, the end dates would match if the PTE elects to authorize the full project period to the subrecipient (consistent with the PTE's prime federal award). However, in no event should the end date of the Subaward Period of Performance exceed the end date of the Estimated Project Period.

It is important to note that the Estimated Project Period is not final, since many factors - such as changes in the PTE's prime award or the subrecipient performance - can affect the subaward's future year award amounts and end dates. PTE's will need to monitor these factors throughout the award lifecycle, and issue modifications accordingly.

3. Are the Estimated Project Period and Incrementally Estimated Total required fields?

According to OMB, §200.331(viii) Total Amount of the Federal Award committed to the subrecipient by the pass-through entity as stated in the UG is a required field, and indicates the amount planned to be issued to a subrecipient in the future. This field is captured in the FDP Subaward face page under

Incrementally Estimated Total. The FDP's position is that these elements should always be completed on the face page in order for subrecipients to track anticipated funds. PTEs and subrecipients should be aware that the information provided in this field is an estimated commitment, since the final obligated amount will be contingent upon actual funding under the prime award (which may be reduced in out years), continued subrecipient performance, and/or budget or program changes that cannot reasonably be anticipated at the time of issuance of the subaward.

4. Can you define the Incrementally Estimated Total?

Incrementally Estimated Total was incorporated into the FDP subaward templates to address the UG data requirements §200.331(viii) Total Amount of the Federal Award committed to the subrecipient by the pass-through entity, which was clarified by OMB on 9/10/2015. This is a required data element according to UG and should be completed by the PTE. According to OMB, "committed" is the planned, dedicated, or promised amount from the PTE to the subrecipient.

For example, if a PTE plans to issue a three-year research project of \$400,000 to a subrecipient, \$100,000 for first two years and \$200,000 for the third year, the Incrementally Estimated Total should be \$400,000. FDP sees Incrementally Estimated Total as meeting the requirement for UG as many factors can affect the future year award amounts. For example, the prime awardee's issuance of a subaward is contingent upon the issuance of the federal award to the PTE. A subrecipient's performance can also impact future year amounts. PTEs will need to monitor such contingencies throughout the lifecycle of an award.

5. Does the subrecipient need the FAIN number?

Yes! The subrecipient needs the FAIN number. It is a requirement per UG in §200.331 (a) (iii).

The federal sponsors are required to include the FAIN number in the NoA per UG §200.210 (a) (3). PTEs should pay close attention to when the NoA was issued, the terms and conditions included, and if that NoA obligates new or incremental funding subject to UG. If yes, the NoA has to have a FAIN number. If a Federal sponsor did not include the FAIN number or any other required data elements, and they should have (because it is subject to UG) then it is the responsibility of the PTE to contact the sponsor to obtain a corrected NoA.

6. Some of our subrecipients request that we, as the PTE, include a copy of the federal award with our subaward agreement. What should we do? -

The FDP strongly recommends including the full NoA with redacted information as necessary. If your NoA contains information that you do not wish your subrecipient to view (examples include restrictions specific to the primary PI) then you can redact information by blacking out information on the NoA. As a PTE, you have privity with your subrecipients and the prime federal agency. The subrecipient does not have privity with the federal agency. The subrecipient may request the PTE to flow down certain clauses or request that you attach the NoA, but they cannot require it.

7. How are you incorporating the Uniform Guidance (UG) data elements into your lower tier subaward agreements?

This would be the situation when your institution receives federal flow through funds from a Pass Through Entity (PTE) and will pass a portion onto a third lower tier institution. I'm not sure how to reflect the required data elements to a third tier entity. Each PTE, regardless of tier, is responsible for flowing down all required data elements under the UG, plus any other additional elements. See Attachment 1, which is appended to this FAQ document.

Some fields, such as the FAIN, CFDA, CFDA Title, Federal Award Number, Federal Awarding Agency, Federal Award Issue Date, and identification of whether the award is R&D should all come from the federal Notice of Award. Other fields, such as the Subaward No., Subaward Period of Performance, Estimated Project Period, Incrementally Estimated Total and dollar amounts obligated and committed to the subaward are specific to the PTE's award to the subrecipient.

8. Can you clarify the checkbox "This Subaward Is: Research & Development" located in Attachment 2? Is It meant to identify the primary award as R&D? Or, the subrecipient's subaward as R&D? - REVISED

PTEs should indicate whether the federal Notice of Award (NoA) made to the PTE is a Research & Development (R&D) award. The definition of R&D is in UG §200.87 is "R&D means all research activities, both basic and applied, and all development activities that are performed by non-Federal entities. The term research also includes activities involving the training of individuals in research techniques where such activities utilize the same facilities as other research and development activities and where such activities are not included in the instruction function." The Federal agencies are required to include whether the award is R&D in the prime NoA. The subaward template has this checkbox pre-selected by default in order to ensure the PTE flows this data element down to the subrecipient, as required by the Uniform Guidance.

9. I noticed that the FDP subaward templates now include IRB / IACUC language and requirements. Could you please clarify: what is the intended scope of this language? Why has this been added? Does this replace anything? – NEW

This section of the templates, called 'Work Involving Human or Vertebrate Animals', contains two parts:

- a. Language/Certification - The FDP Subawards Subcommittee seeks to reduce the amount of negotiation time between member institutions by including minimal terms and conditions. Member institutions suggested including language highlighting IRB / IACUC information, when applicable, to ensure compliance for both the subrecipient and the PTE. This language is intended to clearly articulate if human subjects or vertebrate animals will be used in the course of the research project. It includes a certification from the subrecipient to ensure it is responsible for obtaining the appropriate, valid approvals consistent with the project, and will not invoice the PTE for any human or vertebrate animal related expenses unless approvals are in place. This section is not to replace reliance agreements or other MOUs as may be required by your IRB / IACUC.
- b. Verification of IRB and/or IACUC approval - Options are provided for PTEs to instruct subrecipients on how to provide verification of IRB and/or IACUC approvals. PTEs may choose to request verification 'upon request' or prior to subaward execution (either initially or

annually thereafter). They may even forgo requesting it at all by providing a justification. Options became available to alleviate the burden of requesting additional (or providing) paperwork since the subrecipient certifies it will obtain the appropriate approvals in the preceding section.

However, institutional policies, or sponsor requirements, may dictate which option a PTE must select in this section. For example, the Department of Defense (DoD) will issue the PTE an award with a restriction that expenses cannot be incurred for human / animal expenses until their IRB / IACUC oversight body has approved the approval letters of both the PTE and subrecipient. In situations such as this we recommend that you should use the special terms box to alert the subrecipient to the restriction and copy and paste the language directly from the DoD NOA (or attach a copy of the NOA).

10. How should additional terms and conditions for high risk subrecipients be incorporated into the FDP subaward agreement templates? - REVISED

Attachment 2 has space for “Additional Special Terms” which a PTE may use to include special terms and instructions for high-risk subrecipients. Examples include references to an appended subrecipient monitoring plan, special invoicing instructions (such as format, back-up documentation, etc.) and special progress reporting instructions. For additional reporting instructions - use Attachment 4.

As stated earlier, whether including special terms for high-risk subrecipients, or project-specific terms to low-risk subrecipients, the PTE must communicate these terms to the subrecipient ahead of the issuance of the subaward, with justifications.

11. In Attachment 2, what is the intent of the “Additional Terms” box? - NEW

The intended use of the “Additional Terms” box is to include reasonable terms and conditions that the PTE may need to incorporate into the FDP Template, such as state-specific laws, project-specific terms and additional restrictions for subrecipients identified as high risk. FDP strongly discourages the use of this space for generic imposition of additional terms like choice of law, insurance requirements, and indemnification. Additionally, PTEs should not include terms that may conflict with any term in the FDP Template language.

The FDP Subaward Template should not be changed by member institutions when issuing subawards to other member institutions. Use of the Templates, as published by FDP members, represents a condition of their membership and changes should be limited. Using Attachment 2 to modify sections of the FDP Template is a misuse of the Templates and is in direct conflict with the FDP mission (See FAQ 4).

For non-member institutions, you may use the Templates appropriately by using them as-is. If you choose to modify the Templates, then we ask that you respect the Template language, and remove the FDP moniker so that it is clear the FDP Standard Template language was altered. Adding pages of additional terms and conditions in Attachment 2 that may conflict with other terms or sections of the FDP Template language is not an appropriate use of the Templates.

12. I note that neither Attachment 1 nor 2 specifically refers to compliance with regulations governing human stem cell research. How can I ensure a subrecipient is compliant with these regulations? - REVISED

In the Uniform Guidance, §200.300 Statutory and National Policy Requirements, federal agencies are directed to communicate all public policy requirements with which recipients must comply and incorporate them either directly or by reference in the terms and conditions of the federal award. Appendix C - National Policy Requirements of the Research Terms and Conditions (RTCs) contains the Human Stem Cell Research regulation in accordance with the President's Executive Order 13505 of March 9, 2009, and July 30, 2009 Memorandum for the Heads of Executive Departments and Agencies. See NIH Guidelines for Human Stem Cell Research, July 7, 2009 at

<https://stemcells.nih.gov/policy/2009-guidelines.htm>. Because the RTCs are incorporated into the Subaward Templates, it was not necessary to state this regulation in either Attachments 1 or 2.

In the rare case where a project requires use of human stem cells of a type or in a manner that requires approval as per NIH policy, the PTE may choose to insert language in the subaward Attachment 2 "Additional Special Terms" to mirror the following language: "This project involves human stem cell research. Subrecipient agrees to comply with the NIH Guidelines on Human Stem Cell Research, effective July 7, 2009. Requests for approval to utilize stem cell lines under this Subaward must be submitted to PTE to be forwarded, as appropriate, to the federal agency for approval."

13. I noticed the 2017 version of the subaward templates now has an option called 'Data Sharing and Access Check if applicable'. When should I check this box, and how has this section changed from the 2016 version of the templates? – REVISED

The intent of this section is to provide the PTE with the option of drawing attention to a separate Data Management or Data Sharing Plan that was included in the original proposal by the PTE to the federal agency. If the subrecipient is subject to complying with the PTE's Data Management or Sharing Plan, the subrecipient should be made aware of the contents of the plan. Therefore, the PTE has the option of including a copy of the plan in the subaward, providing additional language that provides the requirements for the subrecipient in the Additional Terms, or stating that the subrecipient may see the plan per their request. The PTE is not required to complete this section.

However, if the PTE knows a plan was included in the proposal but it is not referenced in the NOA, it is preferable to include a reference to it in the Additional Terms to make the subrecipient aware such a plan exists. As a best practice, if a data management plan or data sharing plan is specifically noted in the NOA, it is best to review the plan contained in the original proposal to see if the plan needs to be followed by the subrecipient and flowed down in the subaward. The subrecipient may have been involved in the development of the plan.

This checkbox was NOT intended to be used for policies concerning the public access of publications (for example, the NIH Public Access Policy). Compliance with public access to publications is already covered and referenced in sponsor policy statements and terms and conditions when checking the appropriate sponsoring agency on the first page of Attachment 2. To reduce confusion, the term 'public access' was removed from this section in the 2017 version of the templates.

14. Export Controls restrictions and regulations may be included in an awarded contract. Where should compliance with those regulations be included in an FDP Subaward? - REVISED

Different situations may arise for the need to include export control regulations in a subaward. Below we'll describe when it may be necessary, and where they should be included in the FDP Subaward Templates.

The Council on Governmental Relations (COGR) explains that, "vigilance is required to ensure that the availability of the fundamental research and other exemptions are not lost due to inadvertent acceptance of contractually imposed restrictions on access to, dissemination of, or participation in research. To the extent the activities of universities involve shipping equipment abroad or teaching or training foreign students on campus or foreign colleagues abroad how to use equipment, export control issues do arise." (COGR Brochure - Export Controls and Universities - Information and Case Studies, 1/2/2004). In addition, to the extent that the activities of universities involve the receipt (or purchase of) of materials, software, technology or technical information, export control issues may arise to the extent that such items and information do not fall within the fundamental research or other exemption. PTE's should note that the fundamental research exemption does not apply to activity in or with countries subject to OFAC trade sanctions.

If a project is classified as fundamental research, publication and dissemination of information will be allowed without restriction. Broadly speaking, grants and cooperative agreements will either confirm that the program is considered fundamental research in the program announcement or include standard R&D terms consistent with a fundamental research designation. Sponsors may also include this designation on the NOA. More recently, the Department of Defense (DoD) has begun to use Technology Readiness Levels (TRLs) associated with a DoD-funded project's Scope of Work as indicative of whether or not the research qualifies as fundamental; TRLs 1 through 4 have been designated as the range in which a PTE is performing fundamental work. If it is not clear whether the project is classified as fundamental research, the university should clarify this with their partners or the sponsor prior to the start of the award.

As between U.S. based entities under a grant or cooperative agreement: Generally, when a PTE receives a grant or cooperative agreement designed as Research & Development on the NOA, then the research is fundamental. In issuing any subaward to domestic entities, the PTE should consider the following to determine whether the research meets the definition of "fundamental research": whether the research results are intended for publication; whether there is a pre-publication approval process which may restrict publication of research results; whether participation on the project by foreign national students and employees is restricted. If the research is fundamental research, this reduces the risk of noncompliance with export control regulations. However, the PTE should also consider whether any materials under the project will be exported by the subrecipient outside of the U.S, whether any export-controlled items or information will be sent to/received by the subrecipient, and if there is the potential for PTE funds to be used in or in association with a country subject to comprehensive OFAC trade sanctions. If so, this may increase the export control risk and should be reviewed carefully. Ultimately, if the subaward is to a domestic entity, fewer export control issues are likely to arise. However, in instances when they do arise, the export control risks may be addressed in Attachment 2 of the FDP Subaward template under Special Terms and Conditions.

15. What is the intent of the 'Human Subjects Data' Section in Attachment 2? – REVISED

The purpose of this section is to give the parties the opportunity to incorporate terms and conditions that may otherwise be included in a separate Data Transfer and Use Agreement (DTUA) within the subaward to alleviate the need for the parties to execute a separate agreement, with the understanding that many institutions may still require a separate DTUA due to their institutional policies, procedures and/or structure. This section is intended to prompt institutions to consider whether a DTUA or incorporation of special language in the subaward at the time that the initial subaward is issued, as this could help alleviate delays in the transfer of human subjects data needed to perform the project. The FDP Data Stewardship Subcommittee has issued several guidance documents to assist organizations in determining whether human subjects data will be exchanged, and whether a DTUA (or additional terms in the subaward) may be necessary. See the FDP website at http://sites.nationalacademies.org/PGA/fdp/PGA_170894 for more information. If you plan to issue a separate DTUA, there is no need to include additional terms here.

Three options are provided in the drop-down menu for 'Human Subjects Data':

- Not Applicable - to be selected when it has been determined that a DTUA or additional terms are not necessary.
- Applicable - to be selected when it has been determined that either a DTUA or additional terms will be necessary to address the transfer of human subjects data.
- Human subjects data will not be addressed in this agreement - if it cannot be determined at the time of the subaward issuance whether a DTUA or additional terms will be necessary, or if the PTE and subrecipient agree to address human subjects data separately from the subaward, then this option can be selected.

16. Do I need a DTUA for non-human subjects data? - NEW

Your institution may elect to have a DTUA or additional terms in Attachment 2 for transferring non-human subjects data. The subaward templates do not specifically call out this option. For more information, refer to the DTUA Guidance Chart and other guidance materials from the FDP Data Stewardship Subcommittee at

http://sites.nationalacademies.org/PGA/fdp/PGA_170894.

17. How does the 'Human Subjects Data' section relate to the 'Data Rights' Section of Attachment 2? - REVISED

The 'Data Rights' language included in the Special Terms and Conditions section of Attachment 2 provides the Pass-through Entity (PTE) with the right to use the data created during the performance of the subaward. This is different from the 'Human Subjects Data' section of Attachment 2, which provides both parties with options to address in the agreement how the data is to be exchanged. For example, the subrecipient may be required by law or regulation (for example, HIPAA) to include additional terms in an agreement (either in the subaward or a separate DTUA with the PTE prior to transferring the data to the PTE. The 'Human Subjects Data' section provides these options.

17. What types of data are included in 'Human Subjects Data'? - REVISED

Refer to the FDP Tool for Classifying Human Subjects Data at http://sites.nationalacademies.org/PGA/fdp/PGA_170894. For the purposes of this section in Attachment 2, human subjects data can include a pre-existing data set or data created in the performance of the subaward.

18. If the NIH Notice of Award includes Multiple PIs (MPIs) and names the Subrecipient PI as one of the MPIs, should this be reflected in the subaward agreement? - REVISED

Yes. The PTE should select the appropriate dropdown in Attachment 2 to make this designation. If the subrecipient PI is one of the MPIs stated on the NOA, then the subrecipient subject to MPI Plan, therefore select “This subaward is subject to an MPI Leadership Plan. Both parties will follow the finalized MPI Leadership Plan.”

19. Should the MPI Leadership Plan, as accepted by NIH, be included as part of the Subaward Agreement between the two parties? – REVISED

PTEs have the option of attaching the finalized MPI Leadership Plan to the subaward agreement, if both parties agree. However, this is not required.

The PTE has two options in the drop down menu in the subaward, by selecting either: a) The PTE will make the MPI plan available upon request; or b)The MPI plan is attached as part of Attachment 2.

Whether MPI Leadership Plan is included in the subaward agreement or not, close collaborations and discussions should take place between the PIs and two institutions if revisions to the Plan are necessary. Amendments may be necessary if there if a change in the Leadership Plan impacts the scope of work and/or there is a change in roles and responsibilities of the MPIs.

20. Could you clarify what address needs to be included in Place of Performance Address for FFATA reporting on the top of Attachment 3B? - REVISED

The Place of Performance Address should indicate where the actual work is being performed. It is not intended for the subrecipient’s main administrative offices or institutional address. This address must be provided by the subrecipient in the subaward because every project is distinct. It cannot be determined by reviewing information included in the FDP Expanded Clearinghouse. Some subrecipient entities choose to use the PI’s lab as the Place of Performance Address, and that may be appropriate depending on the nature of the work being done. This address will be used by the PTE to complete required data fields for FFATA reporting.

Subrecipients may use the Legal Address on the bottom of Attachment 3B to distinguish the legal institutional address.

If the PTE completes any of the other information on Attachment 3B on behalf of the subrecipient, the subrecipient should make sure to review this Attachment for accuracy.