

Federal Demonstration Partnership Frequent Q&A Excerpts for h 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?

Incrementally Estimated Total. The FDP's position is that

This would be the situation when your institution receives federal flow through funds from a Pass Through

annually thereafter). They may even forgo requesting it at all by providing a justification.

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

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, 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 to use Technology Readiness Levels (TRLs) associated with ~~awarded~~ 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 fun

The purpose of this section is to give the parties the opportunity to incorporate terms and conditions

Refer to the FDP Tool for Classifying Human Subjects Data at [http://sites.nationalacademies.org/PGA/fdp/PGA\\_170894](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