FDP Meeting Summary

5/19/2019 - 5/21/2019

Expanded Clearinghouse/Subawards Subcommittee

Point of Contact	Lynette Arias, Pamela Webb (Expanded Clearinghouse); Amanda Hamaker, Amanda Humph
Activities/Progress to Date	Expanded Clearinghouse: •Small pilot non-FDP member cohort (34 institutions) received invitations to participate in the Expanded Clearinghouse with a go-live anticipated for July •The Business Use Agreement has been updated and renamed to "Profile Participation Agreement" for all future participants. Other doc updates include the API Use Agreement, Instructions, and Data Dictionary. •Request API Token Form and Help Desk Online Form were created. •Non-frequently used fields were removed based on survey results from participants. •Reminder to keep profiles updated (many still need to update with their FY18 audit information) Template 2019: Almost done looking at the template update for the September 2019 release. Changes will be added to the documents in the coming months. Will include a major changes document for communication to institutions and developers. •One item left for discussion is the Certificates of Confidentiality (CoC) language. See Key Decisions Pending section. •Template Formatting - NIH has a specific subset of terms and conditions that are hidden for all other sponsors. Want to include a specific attachment 2A for NIH only to cover these. •Additional discussion regarding the effective date field for modifications. Question to audience – how do you use this field and is it necessary? Do we need it? Seems to be an added data point. It is being used in various ways by institutions. There is an FAQ with various scenarios/examples for reference. One institution uses it for USAID. One says it is useless. One uses as the date they send out the subaward and use it as a metric to track timeliness – but could deal with it if it went away. Overwhelming number would be happy to see it go. How do you look at the differences between the effective date and the execution date? Audience indicated this is a further cause of confusion. Discussion over what the FAQ says. Point made that the effective date should be in the body of what is being amended. Determination made that there is so much confusion over this field we will remove it and revise FAQs to address how to include effective dates when necessary. Late Subawards: Survey development is almost complete, we are working through the review and approval stage now. We will send to the FDP Admin Reps, as well as posting to the Subawards list serv. Institutions are encouraged to submit one response per submitting office, please try to coordinate. Financial Questionnaire Update: Draft Financial Questionnaire (FQ) was sent to the Expanded Clearinghouse and Subaward listservs for comment with brief survey on Feb 28,

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	2019. Received 41 responses to survey and some additional feedback via email. 35 of the 41 respondents indicated they would be interested in testing the FQ at their institution. Responses were generally positive, but a small handful of expressed concerns about length. Already received request from an institution to use the draft FQ – we think this demonstrates the need and want for the FQ. DTUA Collaboration: Collaborating with the DTUA group to provide a resource. This will be an optional resource for institutions recognizing that every institution has unique policies. Goal is to formulate consistent, useful language – OPTIONAL for institutions to use. •Opportunity to reduce burden. •One document with all obligations. •Will come with guidance as to when it's best to incorporate the DTUA or issue a separate document. IACUC Collaboration - Institutions have asked about incorporating IACUC information to obviate the need for a separate MOU. Subawards and IACUC compliance subcommittee and co-hosted a second session at this meeting. They are exploring clarifications around MOUs, guidance and how/when subaward language could cover obligations of the Guide. Attendees are encouraged to connect with their IACUC and engage on this topic. See additional information under participation below.
Agenda/Discussion Points	
Pending Decisions	Certificates of Confidentiality: Reminder that pilot language is on the website. Two choices available. Discussed recommendation as to which language to include in each of the templates/samples. Want to be as consistent as possible across the various documents. Long language is more comprehensive. Shorter language is better for foreign template since the subrecipients are less likely to be familiar with all of the details related to the CoC. Concern discussed over why these are proposed in this manner – seems counter-intuitive. Longer language drives home the point better for purposes of clinical trials and protecting human subjects data. Responsibility is to communicate the CoC policy. Shorter language is simpler and easier to understand which is why it is recommended for the foreign subs. Questions were asked of the audience and a follow-up survey was sent after the meeting: •Which does your organization use? •Does your organization have a strong preference? •Agree that one piece of language is the best choice? •Agree that the long language is the best choice? •Agree that short language will be best choice for foreign?
Participation	Approximately 100 people attended the session Cont'd: Fixed-Rate Clinical Trial Sample Update: •An interim sample with revisions was issued in November 2018. This is based on a per patient billing model. Meeting since the end of last year to revamp the sample.

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	oName change from Clinical Trial to Clinical RESEARCH. Clinical research term covers broader use – people were hesitant to use it since it said 'clinical trial'. oPayment term schedule added to make more sense with how payments are issued under these awards. Amount Funded box changed to reference payment schedule. oAligning with other FDP templates for consistency. oUG required data elements will be clarified with NIH as they relate to fixed rate agreements – for example, §200.331(a)(1)(vi) Amount of Federal Funds Obligated by this action by the pass-through entity to the subrecipient, and UG 200.201(b)(3), a fixed amount award must certify in writing that the project was completed or the level of effort was expended. These UG requirements need clarification. oGeneral cleaning up and rearranging to put all clinical terms in Attachment 2B. •Created guidance document to use as reference guide for clinical research sample: oCovers when to use the clinical sample vs. generic template. oIn depth information regarding payment types and writing payment schedules for fixed rate agreements. oGuidance on issues specific to clinical trials. oExplanation of what can be changed in the sample. •Discussion over formatting options for the Clinical Research Sample (Word versus PDF). •Working group drafted a matrix to use when determining which template or sample to use for all FDP provided templates and samples. This will be further refined based on conversation at the meeting and provided to the community once completed.
Key Risks/Issues	Upcoming Activities: Expanded Clearinghouse: Non-FDP pilot cohort to go-live July 2019. Templates: 2019 version to be released in September. Financial Questionnaire: Assess a potential pilot. IACUC: Discussions are continuing. See the Session Summary from this session.
Meeting Summary	The session covered the following: •Updates from Expanded Clearinghouse subcommittee •Updates from working groups – Included updates for 2019 Templates, Clinical Trials, Late Subawards, DTUA Collaboration, and 2019 Templates. •Financial Questionnaire updates from survey and next steps. •IACUC Collaboration – Session held at January and May meetings to discuss incorporating IACUC information in the subaward templates to obviate the need for a separate MOU. •Certificates of Confidentiality (CoC) Follow up and discussed next steps.
Volunteer Opportunities	Email subawards@thefdp.org is you would like to join this group.