FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

Subawards Subcommittee

Amanda Hamaker, Purdue University

Amanda Humphrey, Northeastern University

Stephanie Scott, Columbia University

Agenda

- Expanded Clearinghouse
- Clinical Trial Agreement
- Subaward Template Updates
- Active Working Groups
  - DTUA collaboration
  - IACUC
  - Subcontract Sample
  - FQ Group

FEDERAL DEMONSTRATION PARTNERSHIP
Redefining the Government & University Research Partnership

FDP Expanded Clearinghouse

Lynette Arias, University of Washington
Pamela Webb, University of Minnesota
Courtney Swaney, University of Texas Austin
Chris Renner, Vanderbilt University Medical Center

FDP Meeting – May 2019

Cohort 5 | Non-FDP members

- COHORT 5 (Non-FDP Members) invitation sent 5/14!
  - 34 organizations invited to meet target of:
    - Domestic, single audit entities that have previously expressed interest (14 organizations)
    - Institutions included among the top 100 institutions with highest R&D expenditures (per NSF HERD survey) (14 organizations)
- COHORT 5 Readiness activities aplenty!
  - Revamped instructions, organizational worksheet, webpages, timelines, and resource documents
  - Updated functionality
  - Removed agreed-upon fields
  - Fee set by Executive Committee for non-members of $750

Cohort 6 waiting list started!

Cohort 5 – Invited Organizations

Albert Einstein College of Medicine, Inc.	Scripps Research Institute
Baylor College of Medicine	SouthCentral Foundation
Buck Institute	St. Ambrose University
Carnegie Mellon University	Sutter Health CPMC Research Institute
Cincinnati Children's	The Miriam Hospital
Cold Spring Harbor Laboratory	The New School
Drake University	Universities Space Research Association
E.P. Bradley Hospital	University of Colorado Denver and Anschutz Medical Campus
Fred Hutchinson Cancer Research Center	University of Maryland Baltimore County
Kaiser Foundation Research Institute	University of Rhode Island
Lehigh University	University of Texas at El Paso
Louisiana State University, Baton Rouge	University of Texas M. D. Anderson Cancer Center
Oregon State University	University of Texas Southwestern Medical Center
Princeton University	University of Utah
Rhode Island Hospital	Virginia Polytechnic Institute and State University
Rutgers, State U. New Jersey, New Brunswick	Wake Forest School of Medicine
Salk Institute for Biological Studies	Washington State University

Updated documents

- The Business Use Agreement has been updated and renamed to "Profile Participation Agreement" for all future participants. You will see changes in the Expanded Clearinghouse referencing the new “Profile Participation Agreement”. Please note that the terms do not impact current users under their existing “Business Use Agreement”.
- The “API Use Agreement” has been updated to include vendor name if an organization works with a vendor system, as well as a signature from the vendor to indicate they will only use the API token related to the specific client.
- Instructions
- Data Dictionary
- Updated web pages, (Home, Help, Resources)
  - Added additional helpful text
  - Adjusted to reflect non-FDP members joining

Updated “functionality”

- Updated the “Request API Token” form
  - Added field requesting vendor name (if you use a vendor system)
  - Added functionality to upload a copy of API Use Agreement signed by the vendor.
  - Must be logged in to use (user will be prompted)
- Added a “Helpdesk” on-line form
  - Obtain better, more complete information from the requestor
  - Helps us track what questions are being asked
  - Must be logged in to use (user will be prompted)
  - Requests for assistance can still go to fdpechelp@gmail.com but form is preferred

Profile fields removed

- Fields hidden/removed on Profile (based on survey)
  - Registration Tab:
    - DDTC Registration code
  - Certification Tab:
    - Lobby Explanation if the selection is “No”
  - Assurance Tab (rest assured other related fields on this tab remain in place):
    - PHS/OLAW Assurance Approval Date
    - AAALAC Assurance Issuance Date
    - AAHRPP Approval Date
    - USDA Type of Institution
    - NRC Radioactive Materials

Cohort 5 Tentative Timeline

Target Date	Event
5/14/19	• Invitation email sent
6/4/19	• Acceptance responses due
6/10/19	• Cohort 5 kick off email to be sent
7/1/19	• All new participating organizations' profiles published • Fee to be collected prior to publishing profile • Final list of new participants will be distributed to ALL members

MDM9

Please Update Your Profile

- Key items to check often and update
  - F&A and Fringe Benefit Rate Agreements
  - Contacts
  - SAM and other certification expiration dates
  - Assurances expiration dates
  - Annual Single Audit information & actual Audit Report
- It's Single Audit season, some audits need updating!

Slide 10

MDM9 Consider just higlighting "18 audits" still need updating and remove slide 12
Moody, Denise M, 5/16/2019

MDM10

2018 Single Audit Updates Needed

- 18 orgs are missing FY 2018 audits
  - Some institutions have acknowledged our reminders; others haven't.
- 13 orgs have 2018 audits that are included in pending updates.
  - Updates have been created, but are waiting for certification
  - Certification is required prior to arrival for final FDP review

Wondering if you are on this list? Come up front at the end of the session –we have a list?

Slide 11

MDM10 Consider removing this slide
Moody, Denise M, 5/16/2019

MDM11

2019 CY plans for rest of year

- Publish first cohort of non-FDP member org profiles
- If all goes well, consider adding a 2nd cohort
- Developing a business plan for the Clearinghouse
  - Potentially obtaining more resources
- Continue sponsor awareness campaign
- Merge in some other data sources at FDP
  - FDP member institution Profile

Slide 12

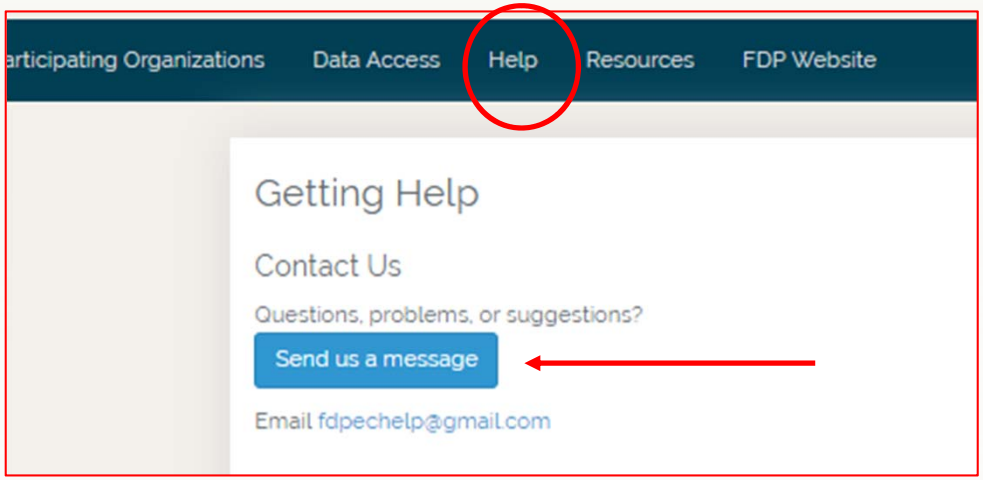
MDM11 "allowing purchase of API" could lead to a lot of questions - do we want to remain silent on that now until we have more info - perhaps by Sept?
Moody, Denise M, 5/16/2019

Steering Committee

Area/Role/Functions	Lead Partners
Overall Direction & Oversight	Lynette Arias/Pamela Webb (co-chairs)
Federal Agency Liaison(s)/Champions	TBD in 2019
Project Management	Courtney Swaney/Denise Moody
Help Desk	Courtney Swaney
Web Based System	Chris Renner/Michael Johnson
Education, Outreach & Evaluation	Julie Thatcher/Neal Hunt
Profile Review & Approval (new)	Lynette Arias/Pamela Webb
Profile Review & Approval (updates) & Data Analysis	Robert Prentiss/Webb Brightwell
Financial Questionnaire	Sara Clough/Lesley Schmidt Sindberg
Long Term Planning	Jennifer Rodis/Amanda Hamaker

Key Links & Helpdesk

- Expanded Clearinghouse Webpage
  - http://thefdp.org/default/committees/research-administration/expanded-clearinghouse-subcommittee/
- FDP Clearinghouse web-based system
  - http://fdpclearinghouse.org/
- General Helpdesk
  - fdpechelp@gmail.com
- API Helpdesk
  - fdpapihelp@gmail.com



Co-Chair Contact Info

- Lynette Arias
  - University of Washington
  - ariasl@uw.edu

- Pamela Webb
  - University of Minnesota
  - pwebb@umn.edu

Working Group: Templates

- Want to check in on one thing: COC language
- Pilot has long (Option 1) and short (Option 2) language
- Thinking is to have one piece of language that will be used across most templates for ease of maintenance and review
- Suggestion to use the long piece of language for the:
  - Clinical Trial Template
  - FDP Subaward Templates (both versions)
- Use the shorter language (for simplicity) in the:
  - Foreign Template

Working Group: Templates

- COC Language (Long):

  The Parties understand that all biomedical, behavioral, clinical, or other human subjects research funded wholly or in part by the National Institutes of Health ("NIH"), whether supported through grants, cooperative agreements, contracts, other transaction awards, or conducted by the NIH Intramural Research Program, that collects or uses identifiable, sensitive information (including identifiable biospecimens or individual-level genomic data) as defined by NIH Policy NOT-OD-17-109 (the "Policy") (hereinafter, "ISI"), and that was commenced or ongoing on or after December 13, 2016, is deemed under the Policy to be issued a Certificate of Confidentiality ("Certificate"). All institutions and investigators collecting or receiving ISI under a Project that has been issued a Certificate are required to 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").

  In compliance with the Policy, Subrecipient hereby certifies that if a Certificate has been issued for this Project and Subrecipient collects or receives ISI in the performance of the Project, Subrecipient and its investigators understand that their use and disclosure of ISI is subject to a Certificate issued pursuant to the Policy, and Subrecipient and its investigators will comply with the Policy, the NIHGPS and 301(d) of the PHS Act, including but not limited to the disclosure restrictions therein, in their use and disclosure of ISI. This term survives the expiration of this Agreement and the close of the Project.

- COC Language (Short):

  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 apply. Accordingly, the subrecipient 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").

Working Group: Templates

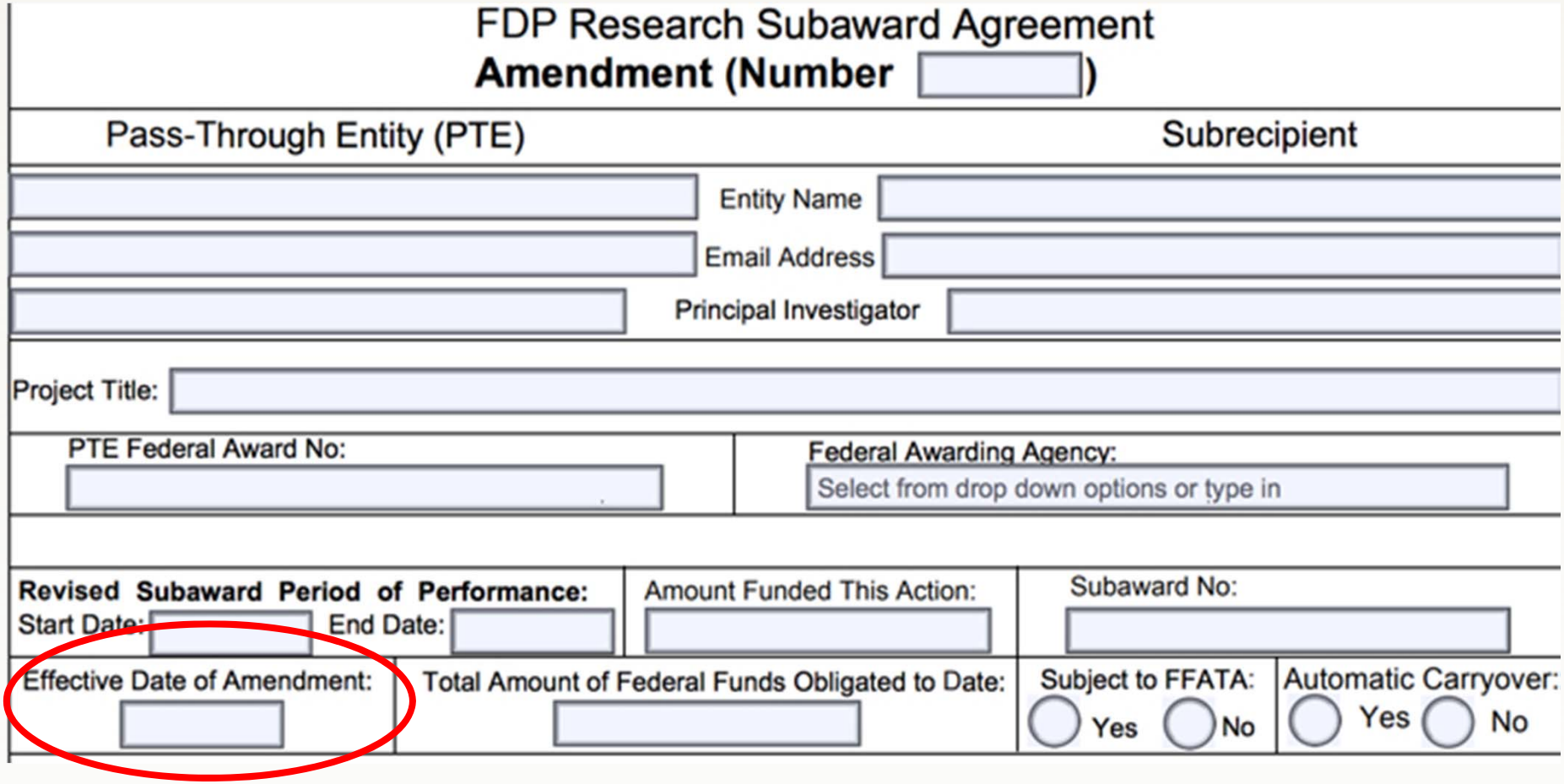
- COC Discussion Questions:
  - Which does your organization use?
  - Does your organization have a strong preference?
  - Agree that one piece of language is the best choice?
  - Agree that the long language is the best choice?
  - Agree that short language will be best choice for foreign?

Working Group: Templates

- Review of requests has been completed
- Next steps will be to update the template and test it
- Will also update field crosswalk
- Will also create a major changes document for this release

Working Group: Templates

- Effective Date: do we need this field?



FDP Research Subaward Agreement

Amendment (Number)

Pass-Through Entity (PTE)		Subrecipient
	Entity Name	
	Email Address	
	Principal Investigator	

Project Title:

PTE Federal Award No:

Federal Awarding Agency: Select from drop down options or type in

Revised Subaward Period of Performance: Start Date: End Date:

Amount Funded This Action:

Subaward No:

Effective Date of Amendment:

Total Amount of Federal Funds Obligated to Date:

Subject to FFATA: Yes No

Automatic Carryover: Yes No

Template Formatting

- Speaking of formatting…
- Thinking of re-formatting Attachment 2 to put NIH specific terms, such as MPI, COC and clinical trial designation on a single Attachment 2A
- If it is a cost reimbursement trial, should we also permit institutions to add Attachment 2B to cover any applicable clinical trial terms?

Fixed-Rate Clinical Trial Sample

- Interim sample issued with revisions Nov 2018
- Working group kicked off led by:
  - Brenda Kavanaugh, Brenda.kavanaugh@rochester.edu
  - Jennifer McCallister, jennifer.mccallister@duke.edu
- Discussion Areas for today:
  - General Status update
  - Definition of Clinical Trial and when to use standard FDP template versus the clinical trial template
  - Formatting questions and user experience

Clinical Trial Sample

- Revised clinical trial sample – major revisions include:
  - Name change from Clinical Trial to Clinical RESEARCH
  - Amount Funded box changed to reference payment schedule
  - Aligning it to the FDP generic templates as much as possible
  - Clarifying issues with NIH on UG interpretation for fixed rate
  - General cleaning up and rearranging to put all clinical terms in Attachment 2B

Clinical Trial Sample

- Clinical Guidance document
  - Created guidance document to use as reference guide for clinical sample
  - Covers when to use the clinical sample vs. generic template
  - In depth information regarding payment types and writing payment schedules for fixed rate agreements
  - Guidance on issues specific to clinical trial
  - Explanation of what can be changed in the sample

Clinical Trial Sample

- Formatting, sounds easy, but it's not
- Option A: Everything in Adobe PDF
  - Pro: Single Document, low risk of changes to terms, consistent formatting
  - Con: cannot redline
- Option B: Everything in Word
  - Pro: Single document, easy to redline
  - Con: higher risk of changes to areas outside of 2B, we will not program/format because hard to maintain
- Option C: PDF for all except Attachment 2B
  - Pro: low risk of changes to terms outside of 2B while also having consistent formatting, can still redline 2B
  - Con: two documents to manage / merge

Working Group: Late Subs

- Survey is almost completed, we are working through the review and approval stage
- We will send to the admin reps, as well as posting to the list serv
- Institutions are encouraged to submit one response per submitting office, please try to coordinate

Update: Financial Questionnaire for entities not subject to single audit

- Draft Financial Questionnaire (FQ) was sent to the Expanded Clearinghouse and Subaward listservs for comment with brief survey on Feb 28, 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.

Next Steps: Potential FQ Pilot

Determine metrics and design of pilot

Test questions, guidance, & risk mitigation strategies

Collect feedback from both PTE's and Subrecipients

Measure burden relieved

After the pilot...

- Determine whether FQ could be incorporated into Expanded Clearinghouse for entities not subject to single audit.
- If not, FQ remains useful, standard tool with guidance and best practices for subrecipients to more readily recognize - likely reducing some

IACUC Collaboration

- We are collaborating with the IACUC subcommittee to explore clarifications around MOUs, guidance and how / when subaward language could cover obligations of the Guide
- We encourage you to connect with your IACUC and let them know about this topic, if you have not already done so

Working Group: DTUA collab.

- We continue to collaborate with the DTUA group to create some optional T&Cs to cover DTUA obligations as part of the FDP subaward
- Goal is to formulate consistent, useful language
  - For clarity: institutions will not be required to incorporate data use provisions in the subaward templates, but it is a useful option

What's Next?

- Working groups continue their amazing work
  - Subcontract Sample
  - Late Subawards
  - Template updates for 2019
  - IACUC discussions
  - DTUA discussions
  - Clinical Trial/Research
- Other suggestions?

Friendly Reminder: Changes

- Templates created to make things easier – don't change them!
- Let us know if you get one with changes, we'll contact the institution.

Contact Us

subawards@thefdp.org

Automatically goes to all three co-chairs:

Amanda Hamaker, Purdue University
Amanda Humphrey, Northeastern University
Stephanie Scott, Columbia University