FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

Subawards Subcommittee

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Agenda

- Common Rule Changes Discussion
- Financial Questionnaire Update
- Templates & Samples
- Guidance
- Collaborations (IACUC & DTUA)
- Subaward Delays Working Group

Common Rule
Single IRB Discussion

- NIH Single IRB Policy Recap
- **Effective date**: All competing grant applications for due dates on or after January 25, 2018.
- Requires sIRB review for:
  - 2 or more domestic sites
  - Working with human subjects
  - Conducting the same protocol
  - Non-exempt research
- Took effect before Common Rule requirements took effect

Timeline of the Common Rule 2018 Requirements

- Published January 2017, amended January 2018, effective July 2018 for optional implementation of 3 provisions
- Compliance date for most elements = January 21, 2019
- Compliance date for single IRB review = January 20, 2020
- 20 agencies (including HHS) intend to follow the revised Common Rule (Subpart A of 45 CFR 46)
  - FDA is not considered a Common Rule agency because its regulations differ from the Common Rule.

sIRB Requirement – recent interpretation

- sIRB requirement for *cooperative research* applies to all new federally funded research approved ≥ January 21, 2019
- In other words, multisite studies approved *between*
  - January 21, 2019 (compliance date for most Common Rule revisions) and January 20, 2020 (compliance date for sIRB review for cooperative research)
  - …must be *transitioned* to sIRB review no later than January 20, 2020
- However, we're waiting for further information from OHRP. See letter dated May 1st, 2019 from COGR:
  - https://www.cogr.edu/sites/default/files/Final%20Joint%20Association%20Letter%20to%20OHRP%20on%20Cooperative%20Research.pdf

Where do subawards come in?

- What discussions have taken place at your institutions about active projects transitioning to Single IRB?
- Are you currently indicating which IRB is the Single IRB in your subawards?
  - Is it necessary, or nice to have?
  - Think about potential burdens.
  - The reliance agreements spell out the specifics between the institutions.
- Do we need to amend existing subawards if there is a transition to Single IRB?

Prior language in templates

Work Involving Human or Vertebrate Animals (Select Applicable Options)

☒ Human Subjects ☐ Vertebrate Animals ☐ No Human or Vertebrate Animals

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 current and duly approved research protocols for all periods of the Subaward involving human and/or vertebrate animal research. Subrecipient certifies that its 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.

The PTE requires verification of IRB and/or IACUC approval be sent to the Administrative Contact *as follows:*

IRB

Upon Request

- Upon Request
- Prior to execution of this agreement
- Prior to execution of this agreement and annually thereafter
- Not required for the following reason:

If the original subaward stated IRB approval & verification was required, you may now need to amend it to 'not required for the following reason:'

- PTE is acting as the sIRB
- There is an sIRB designated
- Exempt
- Approval will be sought after year 1.

Financial Questionnaire (FQ) for entities not subject to Single Audit

- Preparing for a pilot – FQ form with guidance for PTEs and subrecipients
- 35 of the 41 respondents indicated they would be interested in testing the FQ at their institution.
- Finalizing FQ in Adobe to make completion simple.
- Creating a data collection form to include minimal data points from PTEs
  - Excel or Qualtrics?
  - Considering our options – we want to keep it simple!
- In the long run….
  - A standardized, universally accepted FQ format
  - Future possibilities…

FQ Pilot – Possible Questions

Questions for subrecipients:

- How easy was it to understand questions?
- How long did it take to fill out?
- How helpful was the guidance?
- How willing would you be to make this information available in a public clearinghouse?

Questions for PTEs:

- What was the quality of responses?
- Time it took to receive completed FQ?
- Time it took to review the completed FQ?

Questions? Contact FQ@thefdp.org

Templates

- The 2019 templates have been posted:
  - http://thefdp.org/default/subaward-forms/
- 2019 PDF versions of:
  - FDP Cost Reimbursement Subaward Template
  - FDP Fixed Amount Subaward Template
  - FDP Foreign Cost Reimbursement Subaward Sample
  - FDP Foreign Fixed Amount Subaward Sample
  - FDP Cost Reimbursement Subaward Sample
  - FDP Fixed-Rate Clinical Research Sample

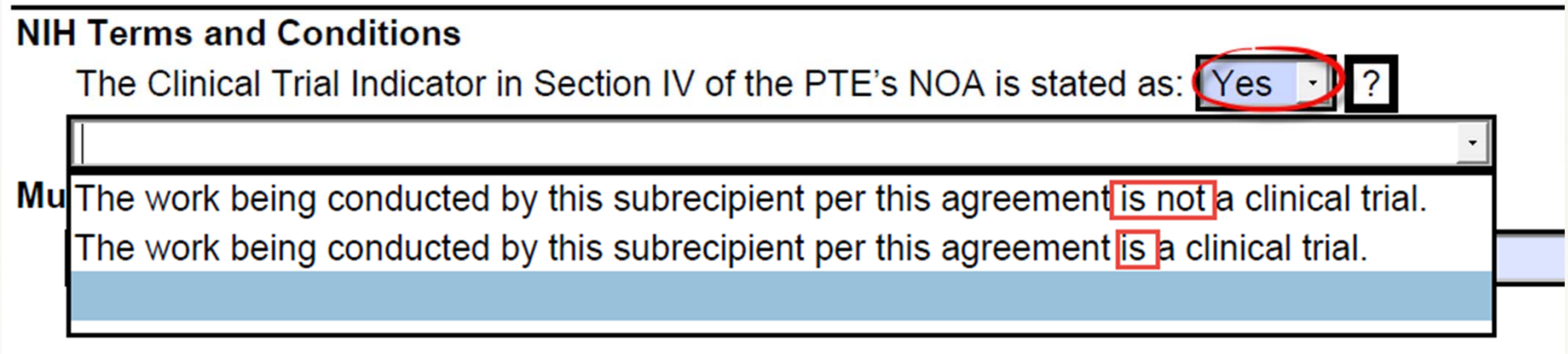
Templates

- Webinars are planned for:
  - October 22nd https://nasem.zoom.us/webinar/register/WN_t-X03WXkTHSOw49uUVrHjg
  - October 30th https://nasem.zoom.us/webinar/register/WN_hNFKb5_zSMWKKeicc-1V4A
- No need to sign up for both webinars: they have same content
- Will post one instance of the webinar
- Thinking of moving to do updates every other year, unless needed sooner because of change to a federal regulation
  - i.e. next template release would be 2021

Templates

- Accompanying documentation also available:
  - Major Changes document outlines the changes and rationale for each change
    - Use to communicate changes throughout organization or leadership as needed
  - Field Crosswalk
    - Outlines changes to the fields used in the FDP templates
    - If you program your templates into a system, we recommend providing this to your IS group to facilitate updates

Clinical Trial Indicator - NEW



In general, the billing model and SOW drive the appropriate template and additional terms

- SOW:
  - Traditional (Phase II – IV drug studies, devices)
  - Non-traditional (BESH, biobehavioral, etc)
- Billing model
  - Fixed-rate (per subject/enrollment/capitation budget model)
  - Cost reimbursable (incur expenses, then invoice for them)

Template Guidance Chart

Which template do I use for what?

SOW and Payment model drive the decision.

Special guidance for clinical trials.

Fed Sponsor Award Type	Subrecipient's Payment Model	Subrecipient Type	Subrecipient's Statement of Work (SOW)	NIH NoA Clinical Trial Indicator (if applicable)	Template/Sample to Use	Notes
Fed Grant or Cooperative Agreement	Cost reimbursable invoices	Domestic	SOW may include one or more of the following: • Vertebrate animal use • Human Subjects that is **not** a Clinical Trial	No	FDP Subaward Cost Reimbursable template	
Fed Grant or Cooperative Agreement	Cost reimbursable invoices	Domestic	SOW may include one or more of the following: • Vertebrate animal use • Human Subjects that is **not** a Clinical Trial	Yes	FDP Subaward Cost Reimbursable template	• Subrecipient is *supporting* a trial by, for example, running samples or analyzing data • Subrecipient is not enrolling patients at their own site • Select "The work being conducted by this subrecipient per this agreement is not a clinical trial." in the subaward template, Attachment 2.
Fed Grant or Cooperative Agreement	Cost reimbursable invoices	Domestic	SOW includes an NIH-defined Clinical Trial that is a Non-Traditional clinical trial (see Glossary)	Yes	FDP Subaward Cost Reimbursable template	• Select "The work being conducted by this subrecipient per this agreement is a clinic trial." in the subaward

Fixed-Rate Clinical Research sample

- Formally “fixed price”
- Formally only for clinical trials. Expanded to accommodate all multi-site clinical research studies with a fixed-rate billing model.
- NEW Guidance Document containing 12 FAQs:
  - Roles of CCC and DCC
  - Sample language for invoicing and payments
  - Guidance on drafting the payment schedule
  - Amount Funded this Action – N/A. New options:
    - The subaward amount is not to exceed_____.
    - The subaward amount is as outlined in the budget/payment schedule in Attachment 5.

Guidance

- Of course we couldn’t get by without great guidance to support the templates

- Guidance Doc working group working on minor tweaks and updates to be consistent with the changes to the FDP templates and samples

Subcontract Sample

- Final Subcontract Sample posted
- Still have work to do, plan to generate a short guidance document to accompany sample
- Guidance Working group led by:
  - Jim Fong, jim.fong@research.ucla.edu
  - Rick Alves, r.alves@northeastern.edu

Collaboration Updates

- IACUC Collaboration
  - Will be hosting webinar with goal of engaging IACUC Admins and/or IOs
  - Encourage you to send to your counterparts in the IACUC
  - Webinar will be October 9th
  - https://nasem.zoom.us/webinar/register/WN_frAMsw1pQ2iK9Tsh7KZB8Q

Collaboration Updates

- DTUA Collaboration
  - Going to pilot as a separate attachment
  - Will be a fillable PDF that may be inserted as an Attachment 7
  - Will be checking in on experience, please proactively let us know what you think
  - Will do webinars when the text is finalized, TBD

- Reminder: institutions will not be required to incorporate data use provisions in the subaward templates, it is about providing streamlined options

Collaboration Updates

- DTUA Collaboration
- Question:
  - How does your institution determine when human subjects data that may be subject to a DTUA will be included in the project /transferred between your institution and a collaborator?

Working Group: Late Subs

- Survey is ready for people to respond
- Link will be sent 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
- Open through October 31st

What's Next?

- Working groups continue their amazing work
  - Subcontract Sample Guidance
  - Subaward Delays: data analysis and report out
  - IACUC Webinar
  - DTUA discussions
  - FQ Pilot
  - Maintaining FAQs
- Are we ready to start talking about a subaward for use with federal agencies that are collaborating with research institutions?
- Invoicing?
- Close out?
- 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