



FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

Subawards Subcommittee

Amanda Hamaker, Purdue University

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Agenda

- Updates:
 - Clinical Trials
 - FAQs/Guidance
 - Financial Questionnaire for non-single audit entities
 - Templates: minor release for 2018
- IACUC
- DTUA
- Certificates of Confidentiality (CoC) Follow up
- Late Issuance of Subawards Discussion



Update: Fixed Price Prior Approval

- COGR & FDP collaboration – hooray!
- NOT-OD-18-222: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-222.html>
- Prior approval waived to issue ***fixed-rate*** domestic subawards of any dollar amount for ***clinical trials only***.
- Fixed-rate subaward agreement for clinical trials:
 - Negotiated per patient cost
 - Total amount of the award may be unknown
 - “prior approval will not be required to enter into this type of agreement provided there are no other factors that would require NIH prior approval consistent with [NIHGPS Chapter 8.1.1.4](#).”
 - SAT threshold will not apply to these types of agreements since they are not based on “fixed amounts”



SAT – Fixed Price/Amount Subawards

- Still need prior approval for fixed price/amount subawards up to the SAT
- June 20, 2018 memo:
- <https://www.whitehouse.gov/wp-content/uploads/2018/06/M-18-18.pdf>
- *New SAT of \$250k applies now in advance of revisions to the FAR at 48 C.F.R. Subpart 2.1 and the Uniform Guidance.*
- Also see [NIH-OD-18-219](#), issued 8/28/18.



What's Next for Clinical Trials?

- Revise FDP Fixed Price sample/template – Interim guidance:
 - Use Attachment 2B to indicate that the term “fixed price” is replaced universally by the term “fixed rate”.
 - Other updates/formatting.
- The NIH Clinical Trial definition and its impact on subawards.
- Different flavors of clinical trials, see the NIH case studies:
<https://grants.nih.gov/policy/clinical-trials/case-studies.htm>



Flavors...to discuss!

Traditional Clinical Trial

- Per patient/capitation budget
- FDP FP/CT sample
 - Needs revisions, now fixed-rate

Traditional Clinical Trial, but...

- With cost reimbursable expenses
- No FDP template for that
- Workarounds-----
FDP CR template with Att 2B and no moniker
- BUT not ideal.

NIH Clinical Trial Definition

- Project-specific
- Budget may or may not be fixed rate/capitation
- Template – it depends!!!!



Next steps....

- Where should we take this?
- What are the expenses that are not included in the per patient amount? What types of costs are these? Easier to have two subawards?
- How many “hybrids” out there? Huge part of the portfolio?
- Revise the FDP CT sample, but what else?
- CT Definition? Thoughts?



FAQs/Guidance Workgroup

- **NEW Hot Topics section 2018/2019**
 - CoC – the FDP pilot language options
 - Single IRB
 - Research Integrity
- **NEW FAQs:**
 - When is it appropriate to request backup of an invoice?
 - How long is it appropriate to leave the condition for backup to invoices in place? - UG 200.207
 - What is considered backup documentation of an invoice?
 - What *Effective Date* should I use when issuing a modification for the following circumstances?
- **FEEDBACK if you don't agree!**



Foreign Template Guidance

- Led by Julie Renkas, College of Charleston, RenkasJO@cofc.edu
- Added content to existing FAQs, with some new FAQs:
- Examples:
 - Structure of foreign templates/flexibility in their use
 - Invoicing frequency
 - Best practices/recommendations for communicating with and educating foreign subrecipients.
 - Governing language
 - Special subrecipient considerations – email/snail mail
 - Using an appropriate invoice template
 - SAM registration/DUNS #s



Financial Questionnaire (FQ)

- Financial Questionnaire for subrecipients not subject to single audit (i.e. under the 750K threshold or for-profit entity) in process.
- Survey to be sent out under the Admin Rep listserv
- See slides from Clearinghouse session.
fq@thefdp.org



Templates: 2018

- Minor release will be posted to the site in September
- Only changes are coding updates, per agreement with members
 - Helpful for those manually completing templates
- It is NOT required to use the 2018 version: there are no substantive term and condition changes
- Webinar / online training will be forthcoming, info to be posted to list serv



IACUC

- Institutions have been reaching out to ask about incorporating IACUC information to obviate the need for a separate MOU
- Reached out to IACUC compliance subcommittee and are working with them on a future session
- In the meantime, we ask that you:
 - Talk to your IACUC, when do they require separate MOUs?
 - Would they like to incorporate this into the subawards?
 - What operational barriers and opportunities are there at your institution in terms of implementing sharing this kind of information?



DTUA: Another Fun Collaboration

- DTUA pilot going live, please [check out the templates](#) and very useful supporting resources
- The subaward templates are set up to incorporate data use language, which some leverage
- Want to have a working group 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



DTUA: Another Fun Collaboration

- Why are we looking at this?
 - Opportunity to reduce administrative burden
 - One document with all obligations, when appropriate
- What is the scope of this?
 - Looking at streamlined clauses to add to subaward templates
 - Guidance on when it is ideal to use the subaward template or a separate DTUA
 - Guidance on discussing if there are opportunities to incorporate data use language into subawards issued by your institution



DTUA: Another Fun Collaboration

- We recognize there is a lot of complexity involved when an institution incorporates DTUA terms into a subaward and it may not work for all institutions
 - The goal is to build out resources to facilitate discussion and understanding
- If you want to be involved, contact:
 - Melissa Korf melissa_korf@hms.harvard.edu
 - Martha Davis mdavis@brandeis.edu
 - Amanda Humphrey a.humphrey@northeastern.edu



Certificates of Confidentiality

- We posted two options of languages after the May meeting
- Anyone using it?
- Which version?
- What has been the experience?
- We will be sending out a brief survey after the September meeting to the Admin Reps
 - Please communicate with your admin rep



Subaward Delays

Kathleen Kreidler
Associate Vice President



The University of Texas
Health Science Center at Houston

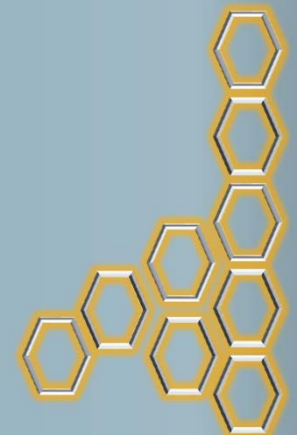
**Sponsored Projects
Administration**

FDP TEMPLATES:

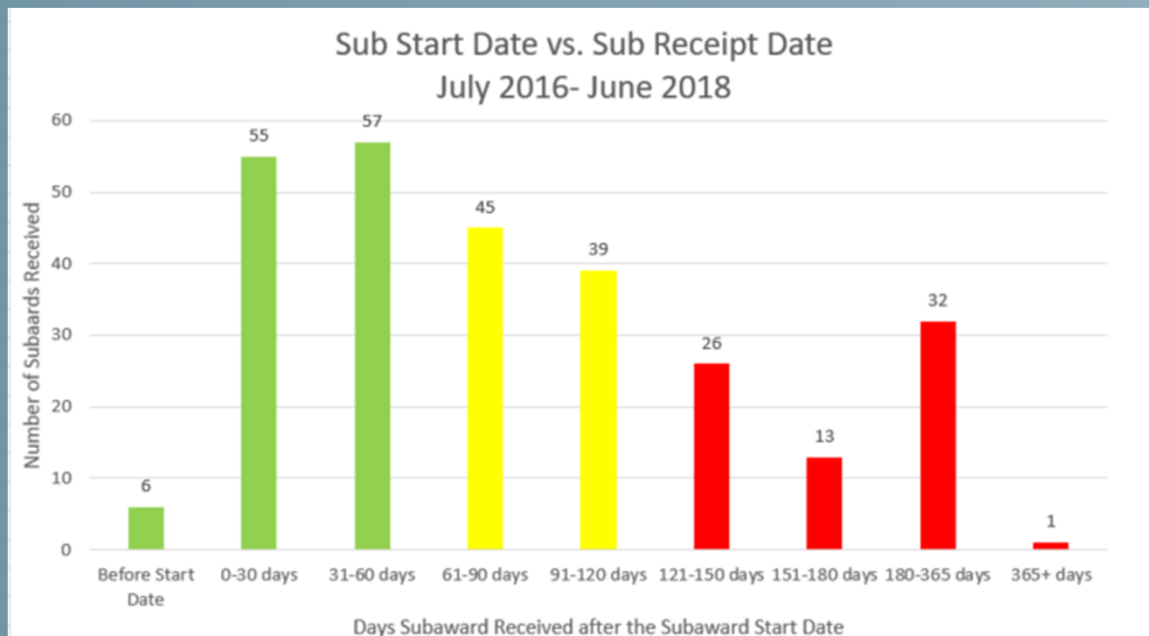
- Expedite Review
 - Eliminate or minimize negotiations
 - Standardization
 - Reduce admin burden
 - Conform to Uniform Guidance and sponsor terms and conditions

FDP Cost Reimbursement Research Subaward Agreement			
Federal Awarding Agency: <input type="text" value="Select from drop down options"/>			
Pass-Through Entity (PTE):		Subrecipient:	
<input type="text"/>		<input type="text"/>	
PTE PI:	<input type="text"/>	Sub PI:	<input type="text"/>
PTE Federal Award No.:	<input type="text"/>	Subaward No.:	<input type="text"/>
Project Title: <input type="text"/>			
Subaward Period of Performance (Budget Period):			
Start:	<input type="text" value="2"/>	End:	<input type="text" value="2"/>
Amount Funded This Action (USD):		\$ <input type="text"/>	
Estimated Project Period (if incrementally funded):			
Start:	<input type="text"/>	End:	<input type="text"/>
Incrementally Estimated Total (USD):		\$ <input type="text"/>	

So why do they still take so long?

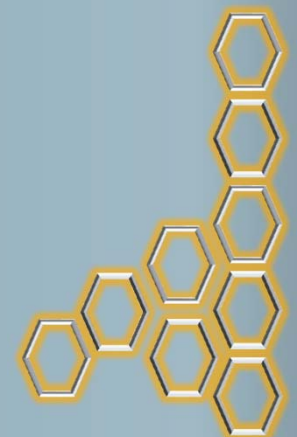


Incoming Subawards:

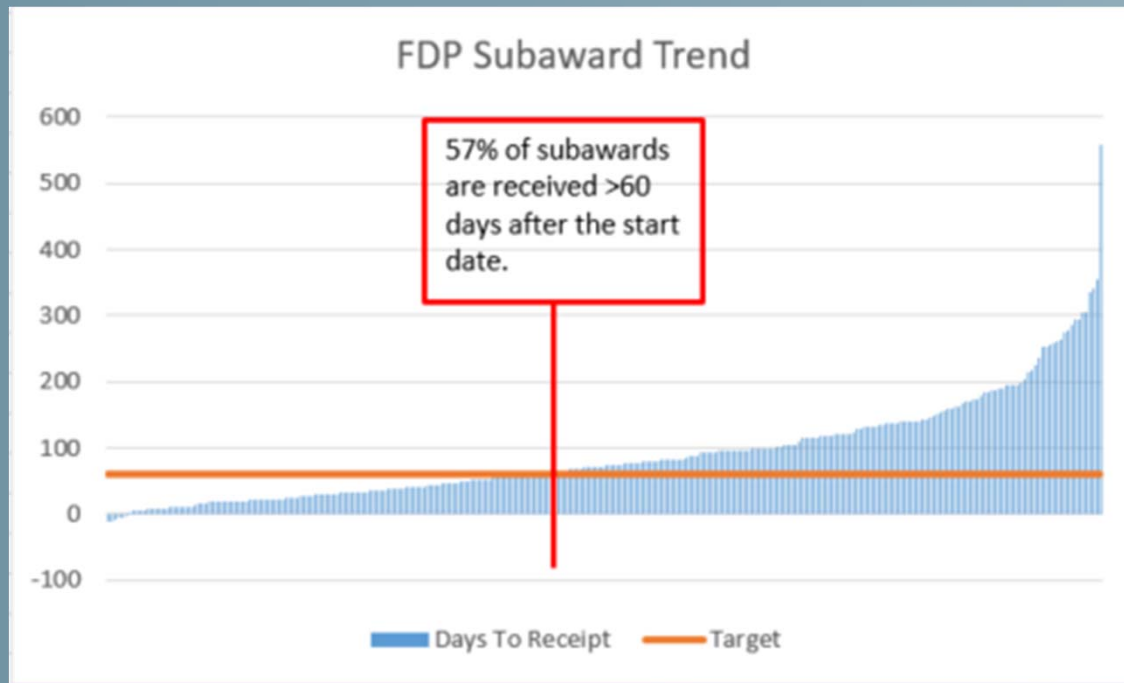


274 Subawards Received:

- New, FDP only
- From 107 institutions
- Average 91 days
- Range from start date to date received:
 - 12 days to 557 days



Incoming Subawards:



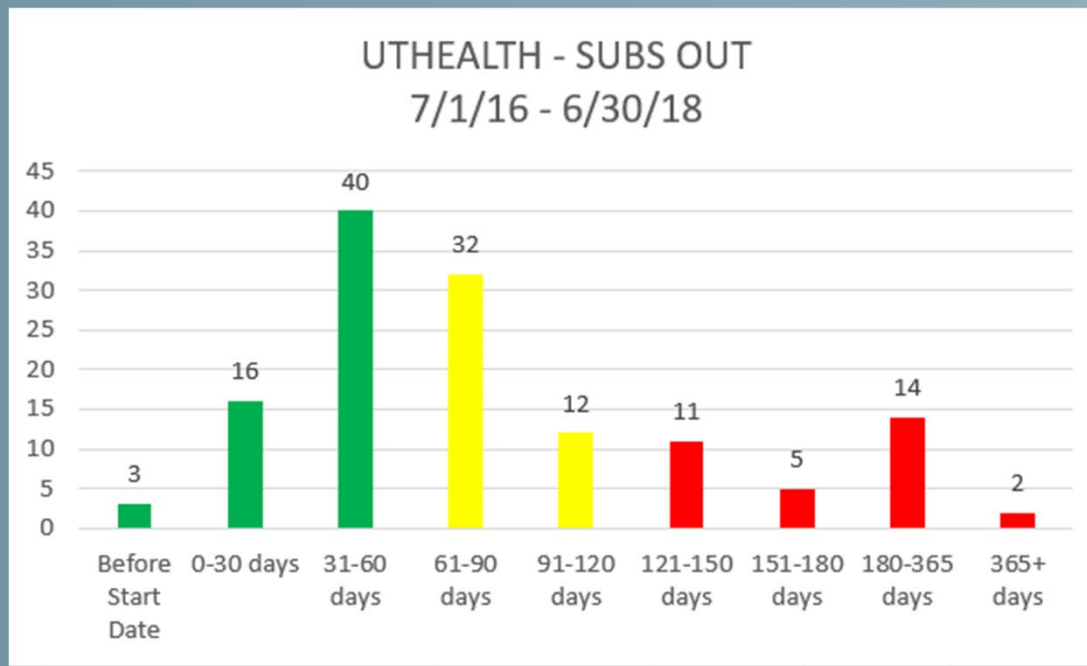
156 of the 274 subawards were received more than 60 days after the award start date.

17 institutions with 4 or more subawards issued to UTHealth in the 2 year period:

- Only one institution was within 30 days every time
- Two others were within 60 days every time.

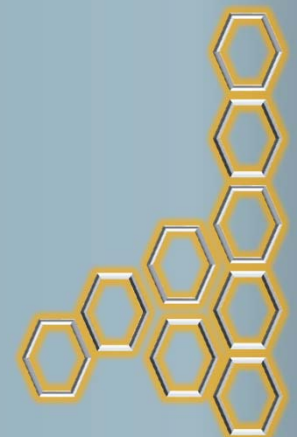


Outgoing Subawards:

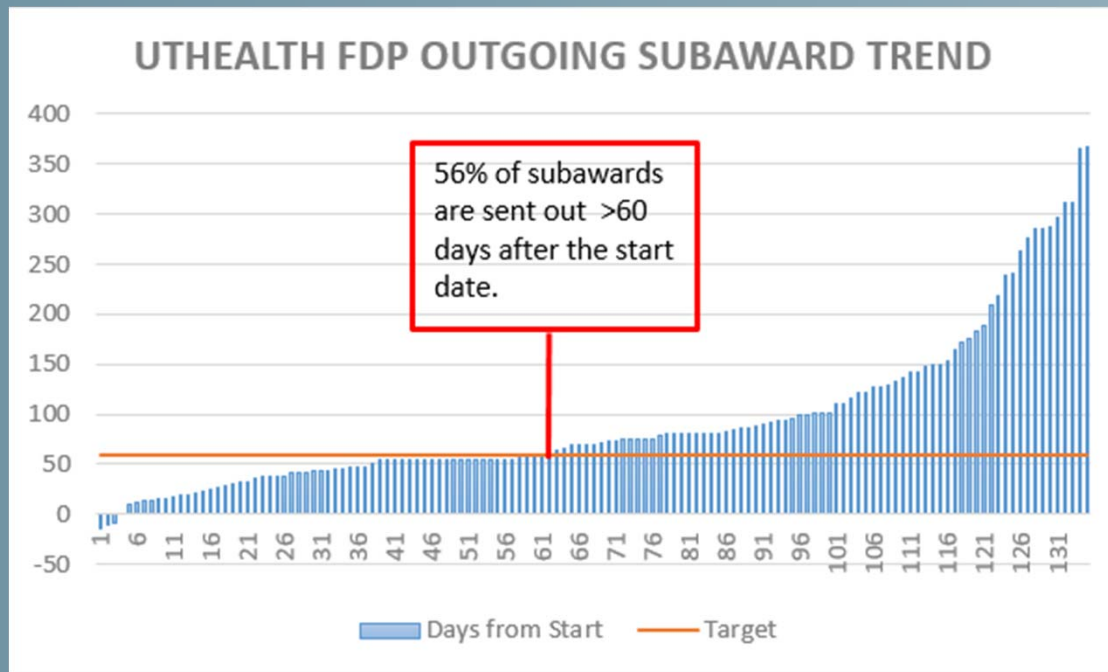


135 Subawards Received:

- New, FDP only
- To 86 institutions
- Average 92 days
- Range from start date to date received:
 - 15 days to 368 days



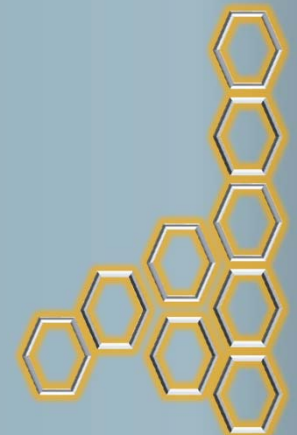
Outgoing Subawards:



76 of the 135 subawards were sent out more than 60 days after the award start date.

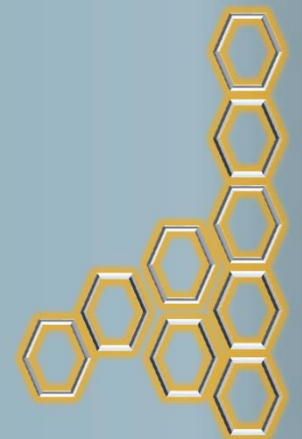
Only 4 institutions received 4 or more subawards from UTHEALTH.

- No consistency in the range of days



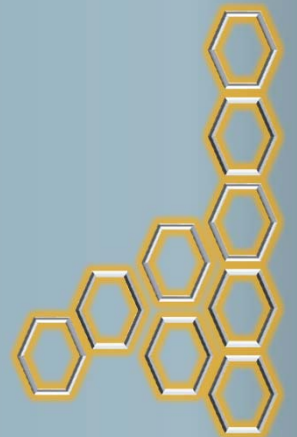
Impact on the receiving institution:

- Need to set up preliminary / guarantee account or,
- Cost transfers / effort reporting Issues
- Unbilled accounts receivable balances
- “Churning”
- Science delays



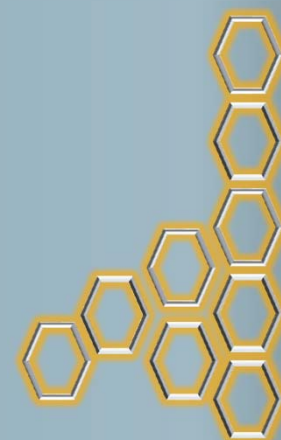
Potential Causes for Delays:

- Institutional processes
 - Responsible office, review and approval steps
- Prioritization
- Staffing / workload
- Medium or high risk level
- Finalizing SOW and budget
- Compliance approvals



Moving Forward:

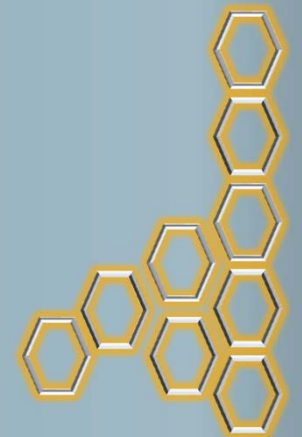
- Identify Best Practices
 - Pilot Data Collection / Survey
 - Learn from those who do this well
 - Think outside the box for new options
- Give guidance to help institutions implement best practices
- Re-measure for impact/success



Thank You!

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What's Next?

- Working groups continue their amazing work
 - Subcontract Sample
 - Foreign
 - Guidance
 - Clinical Trials
 - Template updates for 2019
 - IACUC discussions
 - DTUA discussions
- Other suggestions?



Contact Us

subawards@thefdp.org

Automatically goes to all three co-chairs:

Amanda Hamaker, Purdue University

Amanda Humphrey, Northeastern University

Stephanie Scott, Columbia University