

FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

Subawards Subcommittee

Jennifer Barron, Johns Hopkins University
Amanda Hamaker, Purdue University
Amanda Humphrey, Harvard University

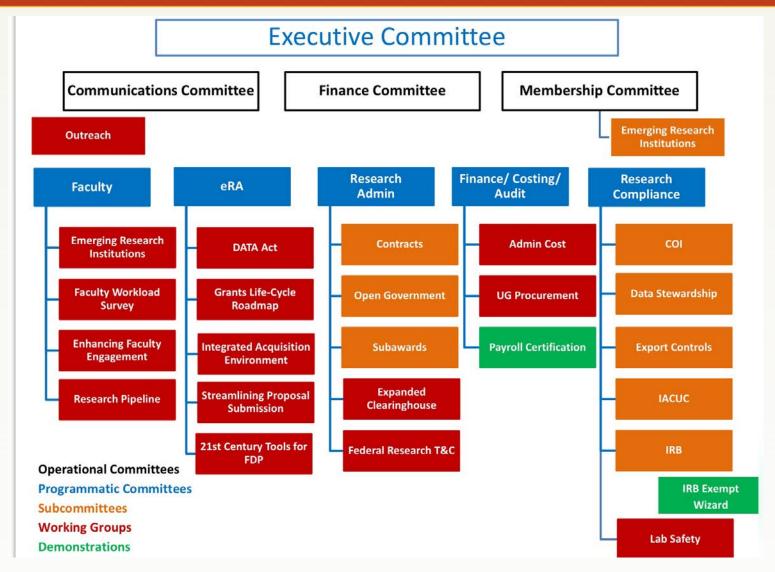
- Review of FDP Committee Structure
- Subawards Subcommittee Background
- Updates/Suggested Template Changes
- Attachment 2 Updates
- Compliance Attachment Update
- Guidance Documents Update
- Clinical Trial Update
- RAQ Update

Executive Committee

- Operational Standing Committees
- Functional Standing Committees: Research Administration
 - Subawards Subcommittee
 - Subcommittee Working Groups



Committee Org Chart



Subawards Subcommittee Background

- Subcommittee created during Phase III (1996-2002)
- Template first created for use only with FDP institutions
 - Updated for use by all in 2005
 - Foreign Subaward Template
 - Subcontract Sample
 - Fixed Price Template
- Continually updated lots of changes for UG
- Phase VI: emphasis on guidance documents, more tools/samples

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

Approval Process

- Subcommittee Co-chairs: Fix typos, formatting, clarity
- Working Groups: Interpretations, reorganizing
- Membership: New clauses, material changes
- Research Admin Chair: New templates, tools
- Executive Committee: New projects



Structure of Templates

- Face Page: FP and CR versions. Can't change!
- Attachment 1: Lobbying, Debarment, Audits. Can't change!
- Attachment 2: Agency Specific Terms, copyright and data rights. Can't change!
 - Prime award special terms can add, sparingly.
- Attachment 3: Contact Info, FFATA
- Attachment 4: Reporting. Don't change unless adding prime award requirement.
- Attachment 5: SOW and budget. Flexible.
- Attachment 6: Compliance (NEW)

Template Updates

- Fixing:
 - Typos
 - Grammatical inconsistencies
 - Citation inconsistencies
 - Format cleanup
- RTCs coming will update face page when finalized
- More attachment 2 changes coming
- No more updates to non-UG templates
- Have requests/updates? Email us!



Organize Attachment 2 sub-working group activities:

Implement interim Attachment 2 agency-specific template revisions

Conference call to be scheduled soon

 Assign one person per agency to serve as agency expert for the group

Stay informed as to agency-specific updates and revise Attachment 2 accordingly

Engage agency for review/comment on Attachment 2 template revisions

 Subaward template, Attachment 2, and Attachment 6 sub-working group leads work collaboratively to ensure appropriate considerations are taken when contemplating template revisions by each group

Contemplated revisions to Attachment 2:

- Revise all agency-specific T&C language and web links
- Add certain data elements from Subaward face page
- Add Multiple PI checkbox
- Move COI section to Attachment 6 (Compliance)

- September 2015 revisions available on FDP web site
 - Cost reimbursement and Fixed price (NIH specific)
 - Review for next revisions for Foreign Subaward face page and Attachment 2
- Finalize NSF specific Foreign Subaward template

VOLUNTEERS please contact
Tyra Darville-Layne
(td-layne@northwestern.edu)

Compliance Template

Just about finished!



- 9/10/15 OMB Technical Corrections:
- Technical corrections issued Sept 10th, 2015:

 (vi) Amount of Federal Funds Obligated by this action by the pass-through entity to the subrecipient;
 (vii) Total Amount of Federal Funds Obligated to the subrecipient by the pass-through entity including the current obligation;
 (viii) Total Amount of the Federal Award committed to the subrecipient by the pass-through entity;

Original:

(vii) Amount of Federal Funds Obligated by this action; (vii) Total Amount of Federal Funds Obligated to the subrecipient;

(viii) Total Amount of the Federal Award;

Accomplishments

- ✓ Carryover Guidance
- **✓ NIH MPIs**
- ✓ Assisted Compliance Attachment Workgroup

Final Invoices: T&C #3

- Proposed dropdown to T&C #3 Cost Reimbursement template:
- "A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to PTE's Contact, as shown in Attachments 3A, NOT LATER THAN 60 days after: [ADD DROPDOWN LIST WITH "each annual budget period," or "the end of the project period"]. The final statement of costs shall constitute Subrecipient's final financial report."

Carryover Guidance

- Defines carryover (automatic and not automatic)
- Provides two Options for PTEs to issue subawards that require PTE prior approval
 - Issue new agreement every budget period invoice end of project
 - Issue mods with suggested language invoice every budget period
- Expenses incurred outside the budget period are not allowable
- FAQs

 Should the NIH MPI Leadership Plan be a part of the subaward agreement if the MPIs are at different institutions?

Discuss!

FAQs

FAQ on NIH Attachment 2

 Use the Generic Attachment 2 in the interim for the other HHS agencies (non-NIH) until others are issued. PTEs should attached prime NOA and redact information as necessary.



Guidance Document Workgroup

- Weekly calls
- Many thanks to the members!
- Can join on a project basis
- For more information:

Stephanie F. Scott, MS, CRA
Columbia University
sfs2110@columbia.edu



Clinical Trial Template: Background

- February 2015 NCATS/CTSA leadership identified need
- Goals:
- Minimize the administrative burden associated with executing a subaward under a federally sponsored clinical trial
- Build on the success of the Accelerated Clinical Trial Agreement (ACTA)



Background

- June 2015 Representatives from both groups joined efforts with a common goal
- Create a subaward template for federally funded clinical trials that most domestic institutions could accept thereby negating the need for tedious negotiations



Background

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Working Group

- Representatives from CTSA Institutions and FDP member Institutions
- Weekly conference call meetings
- 6 month goal
- Start with standard FDP Fixed Price Subaward template
- Incorporate ACTA accepted clauses as necessary

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Working Group

- Parameters identified
 - Start with NIH
 - Start with fixed price
 - Domestic enrolling sites only
 - Ensure all federal regulations covered
 - Adhere to ACTA terms when possible
 - Allow study specific terms to be added
 - Create budget guidance



Deliverable

- FDP Fixed Price Clinical Trials Subaward Agreement - NIH
- Budget guidance document and FAQs



Next Steps

- Obtain NCATS/CTSA Leadership approval (2 levels)
- Open for comment on FDP listserv
- Obtain FDP approval
- Obtain CTSA large working group approval
- Post on FDP website and announce availability
- Post on ACTA website and announce availability
- Complete budget guidance and FAQ document
- Update template, attachments and guidance as changes warrant



Future Deliverables

- Review FDP Subaward modification template, modify as necessary
- NIH Cost Reimbursable Clinical Trial subaward
- NIH Subaward templates for foreign enrolling centers (Fixed price and cost reimbursable)
- Clinical Trial subaward templates for other federal agencies (FDA, CDC, etc.)
- Template for device studies



Thank you!

- Colleen Lawrence and Terri Edwards of Vanderbilt University CTSA
- Jennifer Barron, Johns Hopkins University
- Sarah White, Georgia Regents Research Institute
- Jennifer McCallister, Duke University
- Diana Boeglin, University of Iowa



Open Discussion

• FDP Fixed Price Clinical Trials Subaward Agreement - NIH



- Risk Assessment Questionnaire (RAQ)
 - Updates & added features
 - Single-audit functionality
- Data Collection
 - More risk data from one institution
- Next steps
- Contact information

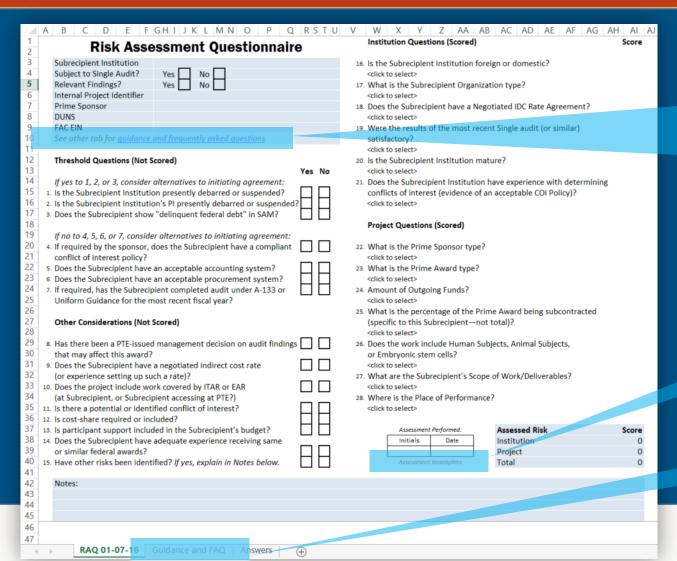


Risk Assessment Questionnaire: Updates to Excel File

- All-in-one, user-friendly file; users have all needed when completing or updating RAQ; separate, Word files discontinued.
- Guidance and FAQ's combined into single tab (now 3 total tabs: dated RAQ; Guidance & FAQ's; Answers source data).
- Updates to Guidance, including on entities not subject to single audit.
- "Assessment Incomplete" appears in red if any questions remain unanswered.
- Cells vs. checkboxes better suited to autopopulation, including synchronization with
- Auto-completion functionality populates answers based on answer to initial two Yes/No questions: "Subject to Single Audit?" & "Relevant Findings?"



RAQ: Added Features & Changes



Prominent
link to
"guidance
and
frequently
asked
questions:

"Assessment Incomplete"

"Guidance and FAQ" tab



RAQ: Added Single Audit Feature

| Risk Assessment Questionnaire Subrecipient Institution Subject to Single Audit? Relevant Findings? Internal Project Identifier Prime Sponsor DUNS FAC EIN See other tab for guidance and frequently asked questions Threshold Questions (Not Scored) Yes No If yes to 1, 2, or 3, consider alternatives to initiating agreement: 1 1 Is the Subrecipient Institution questions (scored) 16. Is the Subrecipient institution foreign or domestic? U.S. based institution 17. What is the Subrecipient Organization type? Subject to Single Audit 18. Does the Subrecipient have a Negotiated IDC Rate Agreement? Yes 19. Were the results of the most recent Single audit (or similar) Satisfactory? < click to select> 20. Is the Subrecipient Institution mature? Yes 21. Does the Subrecipient Institution have experience with determining conflicts of interest (evidence of an acceptable COI Policy)? | 0 0 |
|--|-------|
| Subject to Single Audit? Relevant Findings? Internal Project Identifier Prime Sponsor DUNS FAC EIN See other tab for guidance and frequently asked questions Threshold Questions (Not Scored) If yes to 1, 2, or 3, consider alternatives to initiating agreement: 1 1 Is the Subrecipient Institution presently debarred or suspended? U.S. based institution 17. What is the Subrecipient Organization type? Subject to Single Audit 18. Does the Subrecipient have a Negotiated IDC Rate Agreement? Yes 19. Were the results of the most recent Single audit (or similar) Satisfactory? < click to select> 20. Is the Subrecipient Institution mature? Yes 10. Does the Subrecipient Institution have experience with determining conflicts of interest (evidence of an acceptable COI Policy)? | 0 |
| The shold Questions (Not Scored) The shold Questions (Not Scored) The subject of the subje | |
| Prime Sponsor DUNS FAC EIN See other tab for guidance and frequently asked questions Threshold Questions (Not Scored) Yes Yes Yes Yes Yes 18. Does the Subrecipient have a Negotiated IDC Rate Agreement? Yes 19. Were the results of the most recent Single audit (or similar) satisfactory? < click to select> 20. Is the Subrecipient Institution mature? Yes If yes to 1, 2, or 3, consider alternatives to initiating agreement: 1 1 Is the Subrecipient Institution presently debarred or suspended? 10 Does the Subrecipient Institution mature? Yes 21 Does the Subrecipient Institution have experience with determining conflicts of interest (evidence of an acceptable COI Policy)? | |
| DUNS FAC EIN See other tab for guidance and frequently asked questions Threshold Questions (Not Scored) If yes to 1, 2, or 3, consider alternatives to initiating agreement: 1 1 Is the Subrecipient Institution presently debarred or suspended? Yes Yes Yes 19. Were the results of the most recent Single audit (or similar) satisfactory? <click select="" to=""> 20. Is the Subrecipient Institution mature? Yes 21. Does the Subrecipient Institution have experience with determining conflicts of interest (evidence of an acceptable COI Policy)?</click> | 0 |
| FAC EIN See other tab for guidance and frequently asked questions Threshold Questions (Not Scored) If yes to 1, 2, or 3, consider alternatives to initiating agreement: 1 1 Is the Subrecipient Institution presently debarred or suspended? 18. Were the results of the most recent Single audit (or similar) satisfactory? click to select> 20. Is the Subrecipient Institution mature? Yes 21. Does the Subrecipient Institution have experience with determining conflicts of interest (evidence of an acceptable COI Policy)? | 0 |
| See other tab for guidance and frequently asked questions Satisfactory? Click to select> | |
| Threshold Questions (Not Scored) Yes No Yes If yes to 1, 2, or 3, consider alternatives to initiating agreement: 1 1 Is the Subrecipient Institution presently debarred or suspended? Conflicts of interest (evidence of an acceptable COI Policy)? | |
| Threshold Questions (Not Scored) 20. Is the Subrecipient Institution mature? Yes No If yes to 1, 2, or 3, consider alternatives to initiating agreement: 1 1 Is the Subrecipient Institution presently debarred or suspended? 20. Is the Subrecipient Institution mature? Yes 21. Does the Subrecipient Institution have experience with determining conflicts of interest (evidence of an acceptable COI Policy)? | |
| Yes No Yes If yes to 1, 2, or 3, consider alternatives to initiating agreement: 1 1 Is the Subrecipient Institution presently debarred or suspended? Yes No Yes 21 Does the Subrecipient Institution have experience with determining conflicts of interest (evidence of an acceptable COI Policy)? | |
| If yes to 1, 2, or 3, consider alternatives to initiating agreement: 1 | |
| 1 1 Is the Subrecipient Institution presently debarred or suspended? COI Policy)? | 0 |
| | |
| | |
| 2 2 Is the Subrecipient Institution's PI presently debarred or suspended? Yes | 0 |
| 3. 3. Does the Subrecipient show "delinquent federal debt" in SAM? | |
| Project Questions (Scored) | |
| If no to 4, 5, 6, or 7, consider alternatives to initiating agreement: | |
| 4. 4. If required by the sponsor, does the Subrecipient have a compliant 22. What is the Prime Sponsor type? conflict of interest policy? | |
| | |
| 5. 5. Does the Subrecipient have an acceptable accounting system? 6. 6. Does the Subrecipient have an acceptable procurement system? x | |
| 7. 7. If required, has the Subrecipient completed audit under A-133 or x 24. Amount of Outgoing Funds? | |
| Uniform Guidance for the most recent fiscal year? | |
| 25. What is the percentage of the Prime Award being subcontracted | |
| Other Considerations (Not Scored) (specific to this Subrecipient—not total)? | |
| (spects of this society) | |
| 8. 8. Has there been a PTE-issued management decision on audit findings 26. Does the work include Human Subjects, Animal Subjects, | |
| that may affect this award? or Embryonic stem cells? | |
| 9. 9. Does the Subrecipient have a negotiated indirect cost rate x < click to select> | |
| (or experience setting up such a rate)? 27. What are the Subrecipient's Scope of Work/Deliverables? | |
| 10. 10. Does the project include work covered by ITAR or EAR Click to select> | |
| (at Subrecipient, or Subrecipient accessing at PTE?) 28. Where is the Place of Performance? | |
| 11 11 Is there a potential or identified conflict of interest? | |
| 12 12 Is cost-share required or included? | |
| 13. Is participant support included in the Subrecipient's budget? Assessed Risk Assessed Risk | Score |
| 14. 14. Does the Subrecipient have adequate experience receiving same Initials Date Institution | 0 |
| or similar federal awards? | 0 |
| 15. Have other risks been identified? If yes, explain in Notes below. Total | 0 |
| Notes: | |
| | |

"Subject to Single Audit?" **Yes**

To select a checkbox for an answer, now necessary to type an "x" into the cell.



RAQ: Added Single Audit Feature

| | Risk Assessment Questionnair | е | Institution Questions (Scored) | Score |
|-----|---|-----------------|--|---------|
| | Subrecipient Institution | | 16. Is the Subrecipient institution foreign or domestic? | |
| | Subject to Single Audit? Yes x No | | U.S. based institution | 0 |
| | Relevant Findings? Yes No | | 17. What is the Subrecipient Organization type? | |
| | Internal Project Identifier | | Subject to Single Audit | 0 |
| | Prime Sponsor | | 18. Does the Subrecipient have a Negotiated IDC Rate Agreement? | |
| | DUNS | | Yes | 0 |
| | FAC EIN | | 19. Were the results of the most recent Single audit (or similar) | |
| | See other tab for guidance and frequently asked questions | | satisfactory? | |
| | | | <click select="" to=""></click> | |
| | Threshold Questions (Not Scored) | | 20. Is the Subrecipient Institution mature? | |
| | | Yes No | Yes | 0 |
| | If yes to 1, 2, or 3, consider alternatives to initiating agreement: | | 21 Does the Subrecipient Institution have experience with determining | |
| 1. | 1 Is the Subrecipient Institution presently debarred or suspended? | | conflicts of interest (evidence of an acceptable COI Policy)? | |
| 2. | 2. Is the Subrecipient Institution's PI presently debarred or suspended? | | Yes | 0 |
| 3. | 3. Does the Subrecipient show "delinquent federal debt" in SAM? | | | |
| | | | Project Questions (Scored) | |
| | If no to 4, 5, 6, or 7, consider alternatives to initiating agreement: | | | |
| 4. | If required by the sponsor, does the Subrecipient have a compliant | \Box | 22. What is the Prime Sponsor type? | |
| | conflict of interest policy? | | <click select="" to=""></click> | |
| 5. | 5 Does the Subrecipient have an acceptable accounting system? | × | 23. What is the Prime Award type? | |
| 6. | 6. Does the Subrecipient have an acceptable procurement system? | × | <click select="" to=""></click> | |
| 7. | 7. If required, has the Subrecipient completed audit under A-133 or | × | 24. Amount of Outgoing Funds? | |
| | Uniform Guidance for the most recent fiscal year? | | <click select="" to=""></click> | |
| | | | 25. What is the percentage of the Prime Award being subcontracted | |
| | Other Considerations (Not Scored) | | (specific to this Subrecipient—not total)? | |
| | | | <click select="" to=""></click> | |
| 8. | 8. Has there been a PTE-issued management decision on audit findings | $\sqcup \sqcup$ | 26. Does the work include Human Subjects, Animal Subjects, | |
| | that may affect this award? | | or Embryonic stem cells? | |
| 9. | 9 Does the Subrecipient have a negotiated indirect cost rate | × | <pre><cli><cli><cli><cli><cli><cli><cli><cli< td=""><td></td></cli<></cli></cli></cli></cli></cli></cli></cli></pre> | |
| 10. | (or experience setting up such a rate)? | | 27. What are the Subrecipient's Scope of Work/Deliverables? <click select="" to=""></click> | |
| IU. | been the project mende tront core and y man or arm | \Box | | |
| 11. | (at Subrecipient, or Subrecipient accessing at PTE?) 11. Is there a potential or identified conflict of interest? | | 28. Where is the Place of Performance? <click select="" to=""></click> | |
| 12. | • | HH | volice to selects | |
| 13. | 12. Is cost-share required or included? 13. Is participant support included in the Subrecipient's budget? | HH | Assessment Forformed: Assessed Risk | Score |
| 14. | So participant support included in the subrecipient's budget? Does the Subrecipient have adequate experience receiving same. | | Initials Date Institution | o Score |
| | or similar federal awards? | | Project | 0 |
| 15 | 15. Have other risks been identified? If yes, explain in Notes below. | | Assessment Incomplete Total | 0 |
| - | Have other risks been identified: if yes, explain in Notes below. | | Total | Ü |
| | Notes: | | | |
| | | | | |
| | | | | |

"Subject to Single Audit?" **Yes**



Auto-completed:
5 Unscored
questions;
5 Scored,
Institutional
questions



RAQ: Added Single Audit Feature

| | Ť | Diels Assessment Overtiennei | | Institution Questions (Scored) | Score |
|-----|-----|---|--------|---|-------|
| | | Risk Assessment Questionnai | re | | |
| | | Subrecipient Institution | | 16. Is the Subrecipient institution foreign or domestic? | |
| | | Subject to Single Audit? Yes x No | | U.S. based institution | 0 |
| | | Relevant Findings? Yes No x | | 17. What is the Subrecipient Organization type? | |
| | | Internal Project Identifier | | Subject to Single Audit | 0 |
| | | Prime Sponsor | | 18. Does the Subrecipient have a Negotiated IDC Rate Agreement? | |
| | | DUNS | | Yes | 0 |
| | | FAC EIN | | 19. Were the results of the most recent Single audit (or similar) | |
| | | See other tab for guidance and frequently asked questions | | satisfactory? | |
| | | | | Yes, audit is clean (no findings) or no relevant findings | 0 |
| | | Threshold Questions (Not Scored) | | 20. Is the Subrecipient Institution mature? | |
| | | | Yes No | Yes | 0 |
| | | If yes to 1, 2, or 3, consider alternatives to initiating agreement: | | 21. Does the Subrecipient Institution have experience with determining | |
| 1. | 1. | 1. Is the Subrecipient Institution presently debarred or suspended? | x | conflicts of interest (evidence of an acceptable COI Policy)? | |
| 2. | 2. | 2. Is the Subrecipient Institution's PI presently debarred or suspende | d? x | Yes | 0 |
| 3. | 3. | 3. Does the Subrecipient show "delinquent federal debt" in SAM? | × | | |
| | | | | Project Questions (Scored) | |
| | | If no to 4, 5, 6, or 7, consider alternatives to initiating agreement: | | | |
| 4. | 4. | 4. If required by the sponsor, does the Subrecipient have a compliant | : x | 22. What is the Prime Sponsor type? | |
| | | conflict of interest policy? | | Foundation or Routine Granting Agency | 0 |
| 5. | 5. | 5. Does the Subrecipient have an acceptable accounting system? | x | 23. What is the Prime Award type? | |
| 6. | 6. | 6. Does the Subrecipient have an acceptable procurement system? | x | Grant | 0 |
| 7. | 7. | 7. If required, has the Subrecipient completed audit under A-133 or | x | 24. Amount of Outgoing Funds? | |
| | | Uniform Guidance for the most recent fiscal year? | | Outgoing Funds \$1 - \$24,999 | 0 |
| | | | | What is the percentage of the Prime Award being subcontracted | |
| | | Other Considerations (Not Scored) | | (specific to this Subrecipient—not total)? | |
| | | | | 0-24% | 0 |
| 8. | 8. | 0 | gs x | Does the work include Human Subjects, Animal Subjects, | |
| | | that may affect this award? | | or Embryonic stem cells? | |
| 9. | 9. | | x | No | 0 |
| | | (or experience setting up such a rate)? | | 27. What are the Subrecipient's Scope of Work/Deliverables? | |
| 10. | 10. | 10. Does the project include work covered by ITAR or EAR | × | Subrecipient will only submit progress reports | 0 |
| | | (at Subrecipient, or Subrecipient accessing at PTE?) | | 28. Where is the Place of Performance? | |
| | | 11. Is there a potential or identified conflict of interest? | x | All work will be performed at the Subrecipient's Institution | 0 |
| | | 12. Is cost-share required or included? | x | | |
| | | 13. Is participant support included in the Subrecipient's budget? | x | Assessment Performed: Assessed Risk | Score |
| 14. | 14. | 14. Does the Subrecipient have adequate experience receiving same | | Initials Date Institution | 0 |
| | | or similar federal awards? | x | Project | 0 |
| 15. | 15. | i. 15. Have other risks been identified? <i>If yes, explain in Notes below.</i> | X | Total | 0 |
| | | N.A | | | |
| | | Notes: | | | |

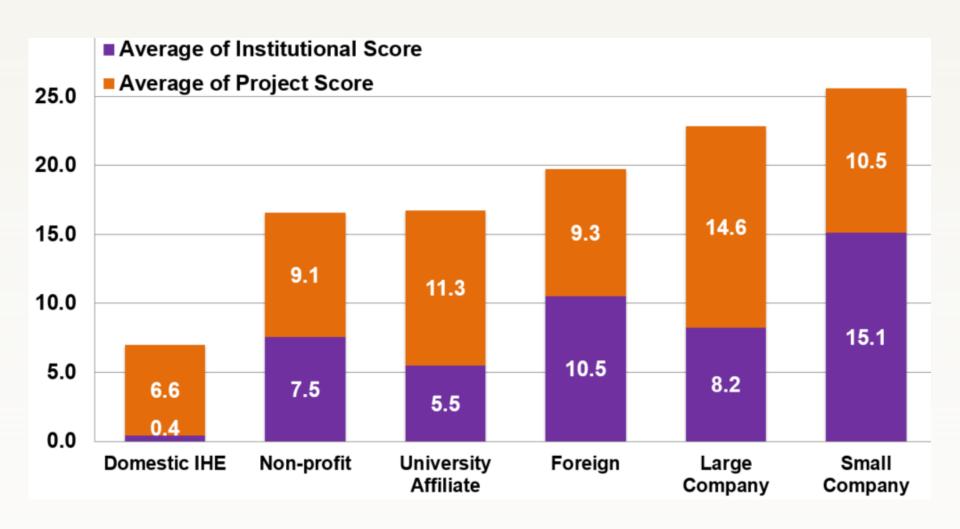
"Relevant Findings?:
No"

Auto-completed: Institutional question #19



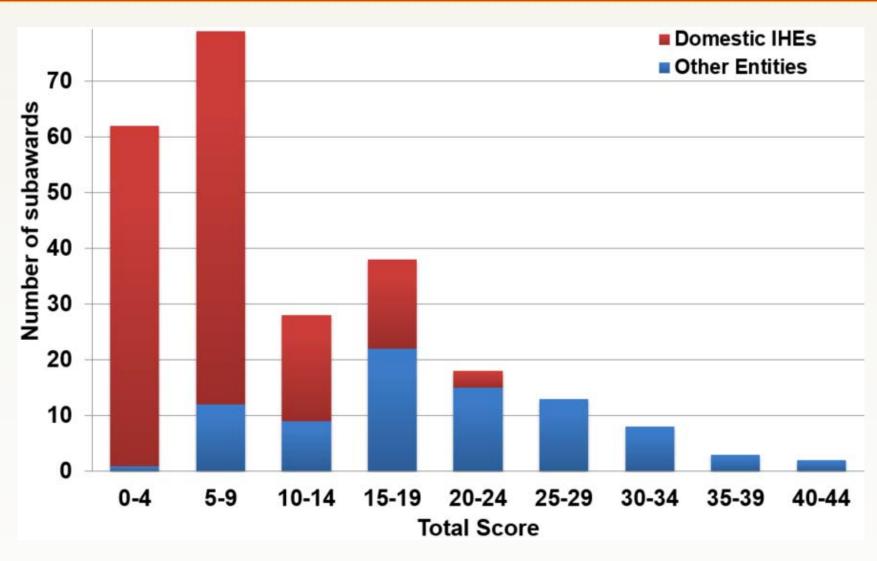
- What one institution has done, now:
 - Over 250 subawards scored.
 - RAQ scores, including individual questions, tracked in a spreadsheet, alongside sub and prime data.*
 - Desk review candidates selected from high/mid-risk pools.
 - Reviews conducted, findings summarized in twice-yearly report.**
- Some updated graphs available:
 - Average Risk Score Makeup
 - Total Risk Score Distribution

Average Risk Score Makeup, by Entity Type





Total Risk Score Distribution





Next Steps for RA Subgroup

- Develop Annual Tool:
 - Anticipated first version by May FDP meeting
 - If you would like a voice in this, we welcome you!
- Integrate/coordinate with Entity Profile, eRA groups
- Data Collection Pilot:
 - Goal: develop Excel macro to collect data, send automatically
- Upcoming:
 - FRA in New Orleans
 - Regional Presentations
 - Training Session at NCURA National

We welcome questions about risk assessment, the RAQ, and related issues.

We are very curious to know how people are using the RAQ, assessing risk, etc.

As before, please email:

risk.assess.quest.fdp@gmail.com

Contact Information

- Steve Carter, Risk Assessment Subgroup Chair UCSD - Scripps Institution of Oceanography stevecarter@ucsd.edu
- Sara Clough
 The University of Texas at Austin sarac@austin.utexas.edu
- Robert Prentiss
 The University of Texas at Austin rprentiss@austin.utexas.edu