FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

Subawards Session

4 September 2015

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Committee Updates

- Template Updates
- Compliance Attachment
- Attachment 2 Updates
- Clinical Trial Template
- eRA 21st Century Tools
- Guidance Documents
- Risk Assessment
- Expanded Clearinghouse

Template Changes in Progress

- Assign Unique Field Names to Each Field Across Forms
- Consistent Formatting Across Attachment Headings, Legal Citations,
- Consistent Formatting of Number and Dollar Amount Fields
- Consistent Capitalization of Terms
- Fix Grammatical Issues and Spelling Errors

Template Changes in Progress

- Add Citations for Certifications
- Fix Document Names when Downloaded
- Moving Data Elements from Face Page to Attachment 2

Compliance Attachment

- Led by Amanda Humphrey
  - All are welcome, contact Amanda to join
- Group is piloting Trello Board to manage the project
  - More info during Melissa Korf's update
- Hope to have a draft for the January 2016 meeting
- There will be two versions: domestic and foreign

Compliance Attachment

Scope	Drafted
IRB Assurance	✓
Scientific Misconduct	✓
General Compliance Statement	✓
COI Language	✓
Export Controls	
Human Subjects Data	
IACUC Assurance	
FAQs / Guidance	
Subrecipient Monitoring Plan (foreign version only)	

Attachment 2s and Foreign Template

- Attachment 2 for NSF and NIH have been posted to the FDP website; to be used for interim period until RTC are updated and released
- Upon release of the updated RTC, the working group will update NSF and NIH Attachment 2 templates, then begin work on other Federal Agency Attachment 2s
- Foreign subaward agreement (NIH template) for cost reimbursable and one for fixed price were posted to the FDP website
- The working group will plan to work on an NSF-specific Foreign subaward agreement template

Clinical Trials Template

- Collaborative working group between CTSI institutions and FDP
- Group of about 20, mostly clinical trial specialists
- Have met weekly since June via conference call facilitated by Vanderbilt University
- Current focus is a subagreement template for NIH sponsored multi-site clinical trials

Clinical Trials Template

- Good progress has been made, remaining subagreement template attachments to discuss are attachment 4 and 5
- Decision made not to provide significant budget detail on attachment 5 but to prepare budget guidance docs instead
- Anticipate final draft for FDP and CTSI review before the end of the calendar year
- Hope to “roll out” at the January FDP meeting

eRA 21st Century Tools

Exploring options for better management of FDP working groups through project management software

https://trello.com/b/fiwI0tKW/fdp-subawards-subcommittee

Guidance Documents

- Contact: Stephanie Scott, Columbia University, sfs2110@columbia.edu
- Resources and guidance for FDP community
  - Subawards Agreement Templates
  - Other Tools
- Promote consistency, while recognizing entities' unique structures
- Dynamic – continuous updates

Guidance Documents

Accomplished Since May 2015 Meeting

- ✓Uniform Guidance Reference Guide - **Updated**
- ✓Uniform Guidance Reference Guide: Foreign Templates - **NEW**
- ✓FAQs – **REVISED** and **NEW** Questions
  - Invoicing Guidance
  - Circumstances to use Cost Reimbursement vs Fixed Price Templates
  - Clarify R&D
  - Start Dates on Amendments
  - Templates for non-federal use
- ✓Invoice Template
- ✓New Attachments 3A & 3B

Guidance Documents

Invoicing Guidance

- Data Elements recommended for invoicing
- Specific invoicing instructions and address – revised 3A
- *Special* invoicing instructions – Attachment 2
  - Ex) High-risk concerns
- Specific remittance address – revised 3B
- Optional invoice template – for subrecipients without their own

Guidance Documents

Cost reimbursement vs Fixed Price

- Guidance outlines circumstances where it is accepted to use a fixed price agreement
- Not appropriate to issue a cost reimbursable agreement utilizing a payment schedule/deliverable type budget in order to circumvent the Uniform Guidance prior approval requirement

Guidance Documents

Current & Future Projects

- SOW Guidance
- General Guidance on Use of Templates
- Continue FAQs
- Assist other working groups, as needed
- Webinars

Risk Assessment Subgroup Agenda

- Risk Assessment Questionnaire (RAQ)
  - Content and connection to compliance supplement
  - (re-)Design and features
- Data collection opportunities of RAQ
  - Subrecipient risk data collected by one institution
  - Opportunity to compare with more institutions
- Risk Assessment survey results (so far)
- Next steps
- Resources and links

RAQ Background

- Assumption: subrecipient risk comprised of many different factors
- Factors divided into:

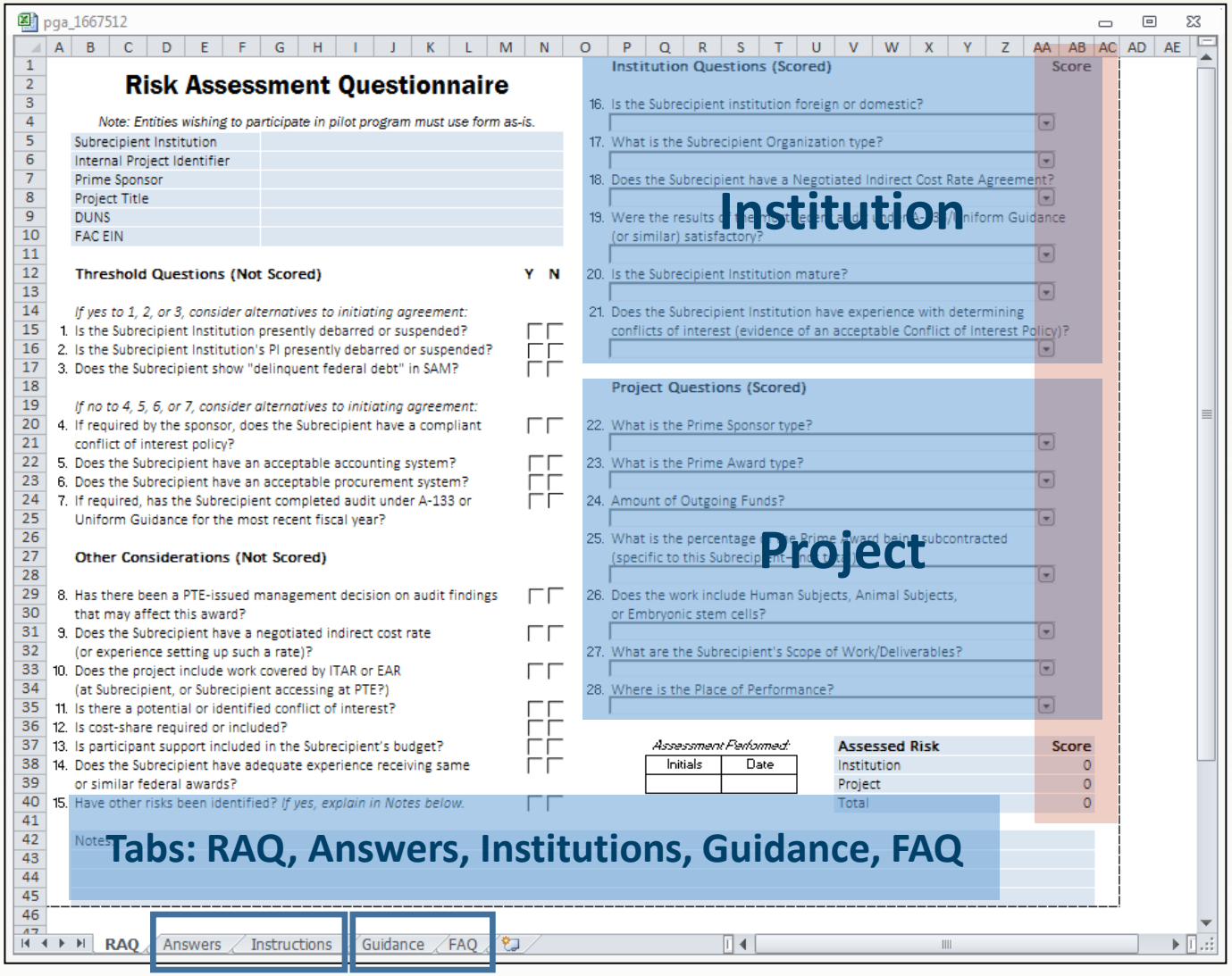
  Project-specific and Entity-specific
- Detailed review of Uniform Guidance and Compliance Supplement performed
- Balance to be struck between:

  Audit preparedness and Administrative burden
- Consideration of Entity differences in structure

RAQ Design & Features

- Full questionnaire fitted to single PDF or print page
- Updated Excel file:
  - Embedded checkboxes (threshold questions)
  - Select answers from drop-down fields; score auto-populated using formulas (scored questions)
  - Auto-calculated score total and subtotals
- Guidance on use of RAQ and RAQ FAQ's also included in file, on separate tabs
- Instructions for use of Excel file enclosed

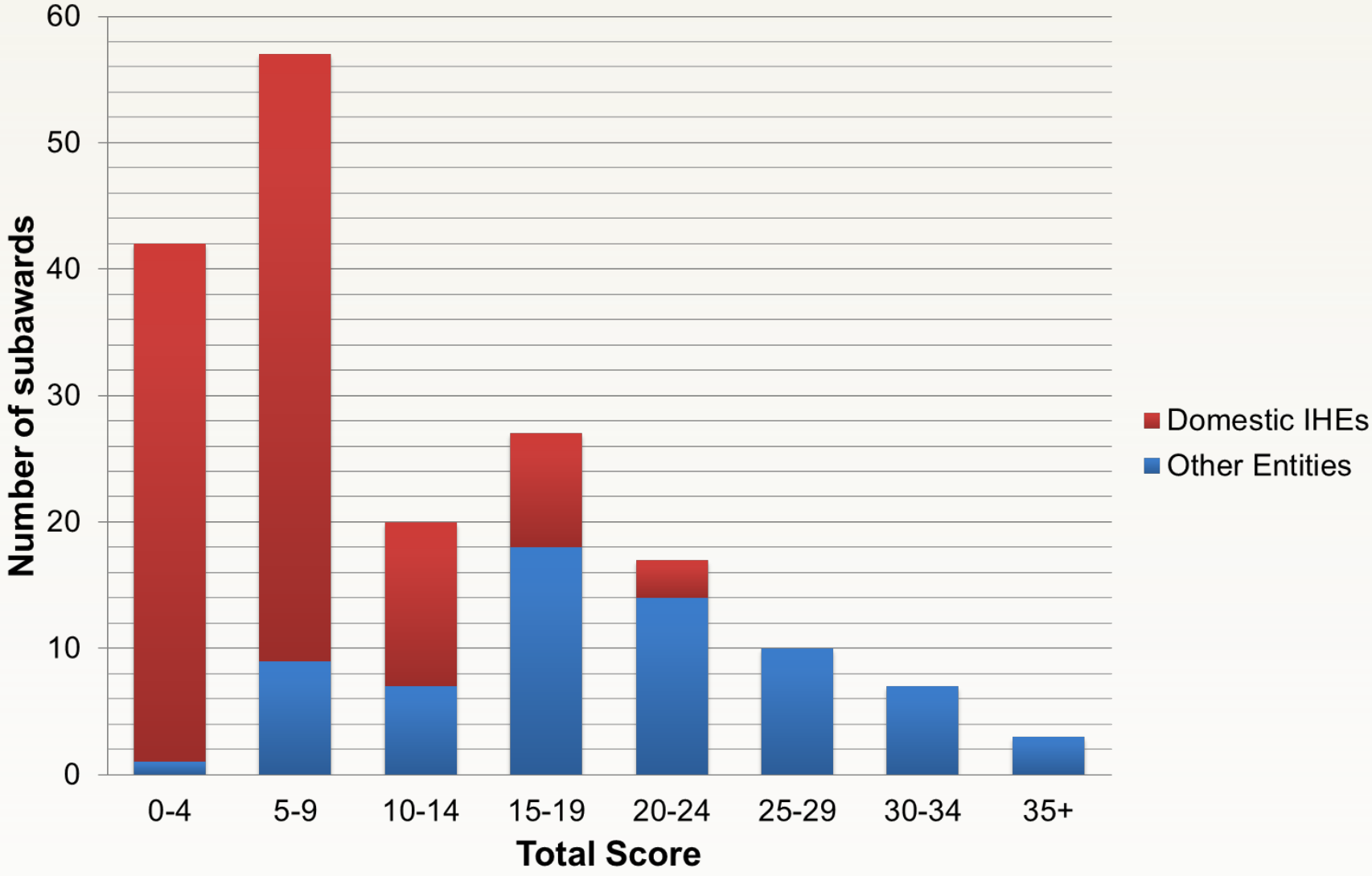
RAQ Design & Features – Labeled



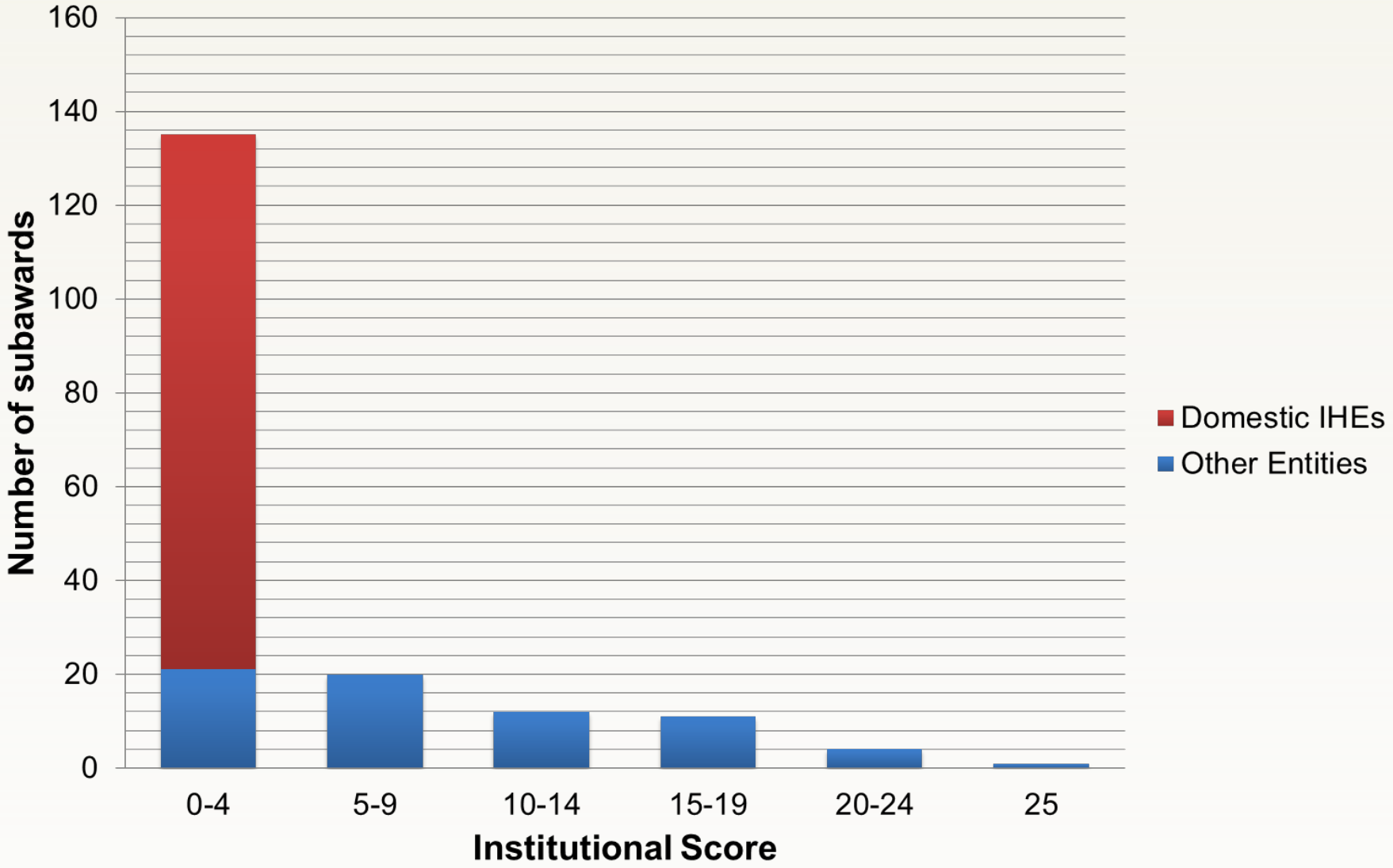
Data Collection Opportunities

- The RAQ was developed using the collective judgment and experience of the risk assessment subgroup. But we have little hard data on the subject—yet.
- One institution has scored over 180 subawards. We can begin to see how the scores are distributed, and how different types of institutions score in aggregate.

Data Collection Opportunities



Data Collection Opportunities

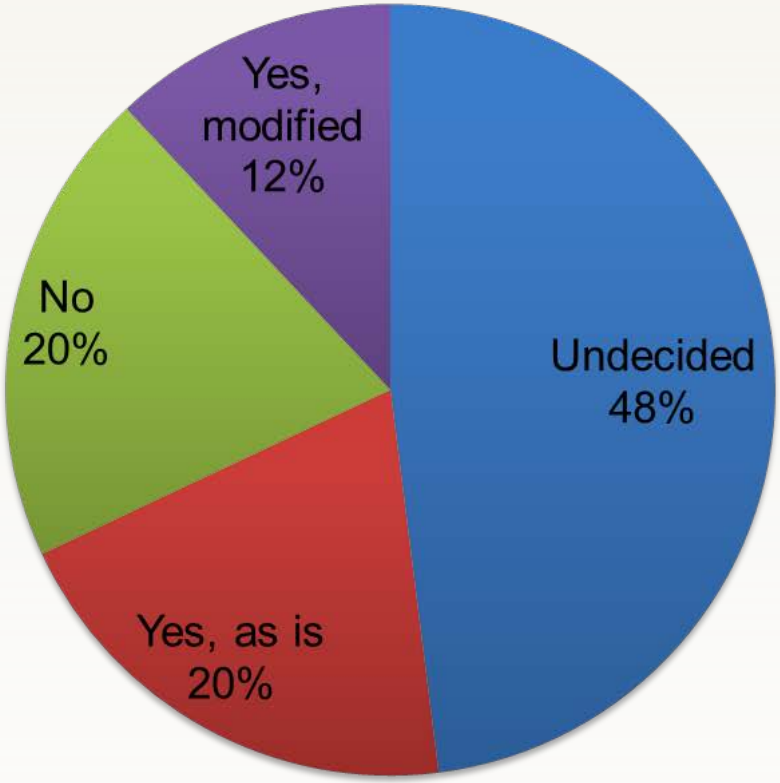


Data Collection Opportunities

- With additional institutions participating in a data pilot, we could investigate **perceived** vs. **actual** risk.
- Are there best practices for evaluating risk and setting risk thresholds? With a large data set (multiple institutions), data could drive these decisions.
- Are there statistical correlations among the different answers? If so, we might find ways to streamline the form while retaining effectiveness in identifying risk.
- To discuss sharing data collected with your institution's RAQ, please email risk.assess.quest.fdp@gmail.com.

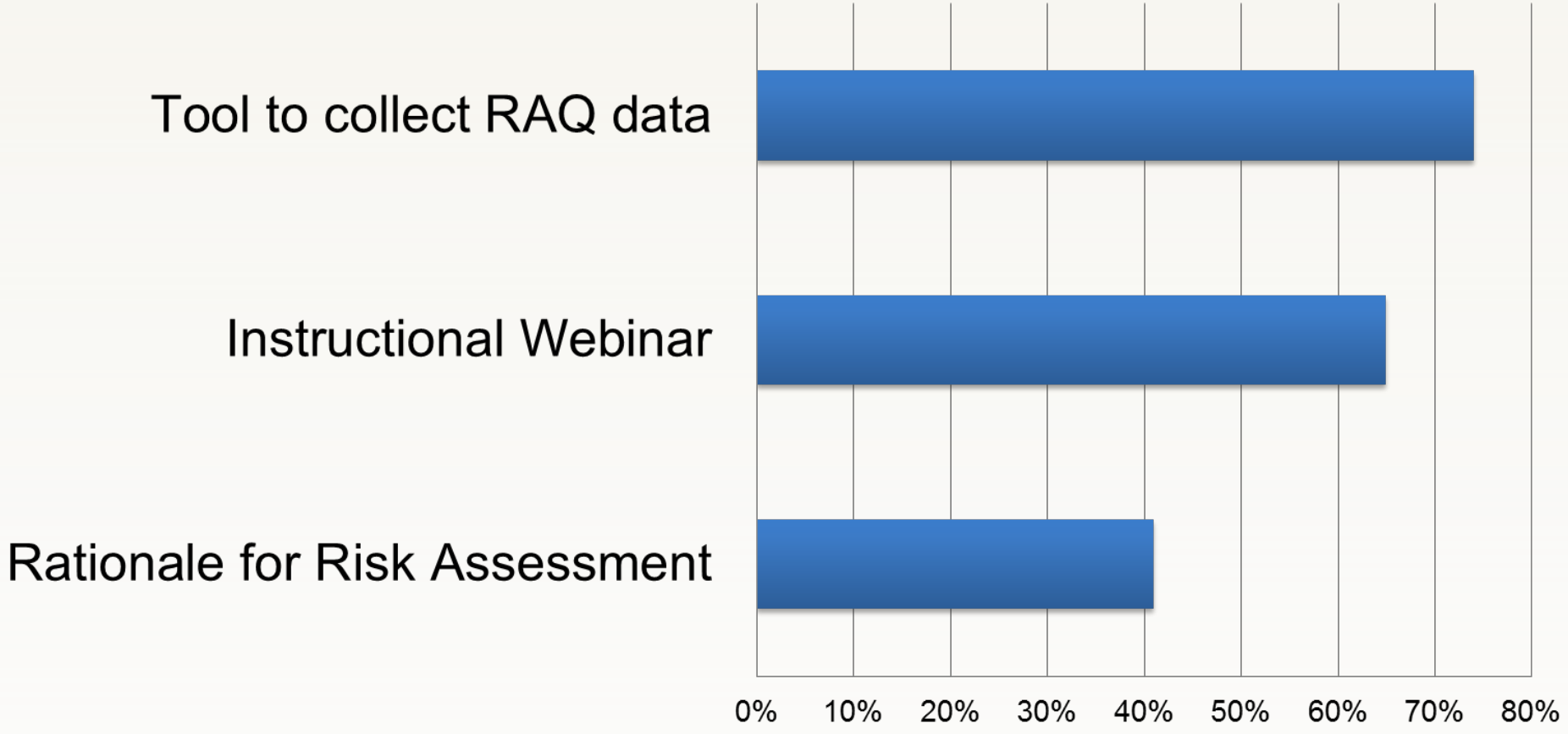
Risk Assessment Survey Results

Will your institution use the FDP Risk Assessment Questionnaire?

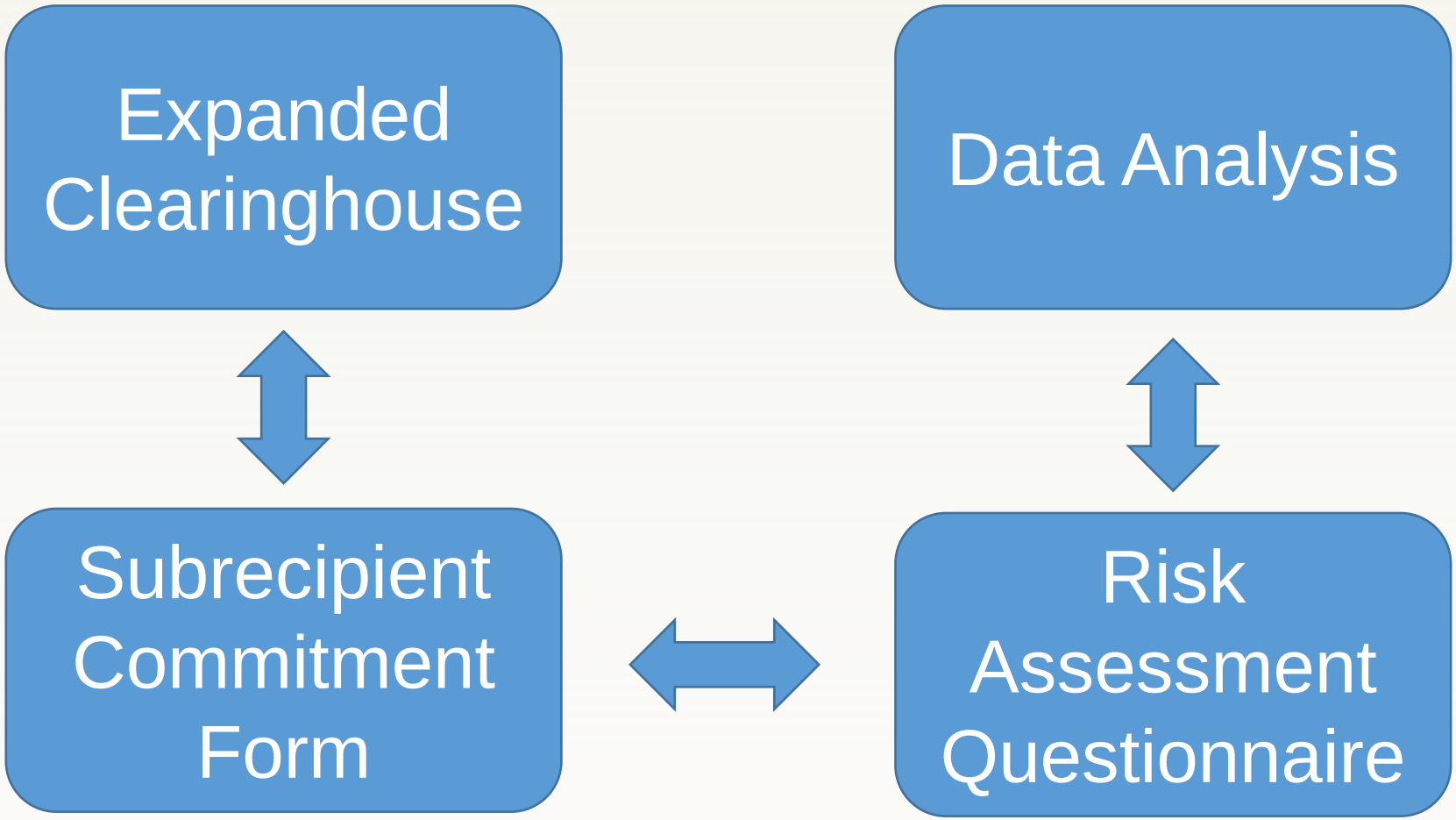


Risk Assessment Survey Results

What additional resources would be helpful in implementing the FDP RAQ?

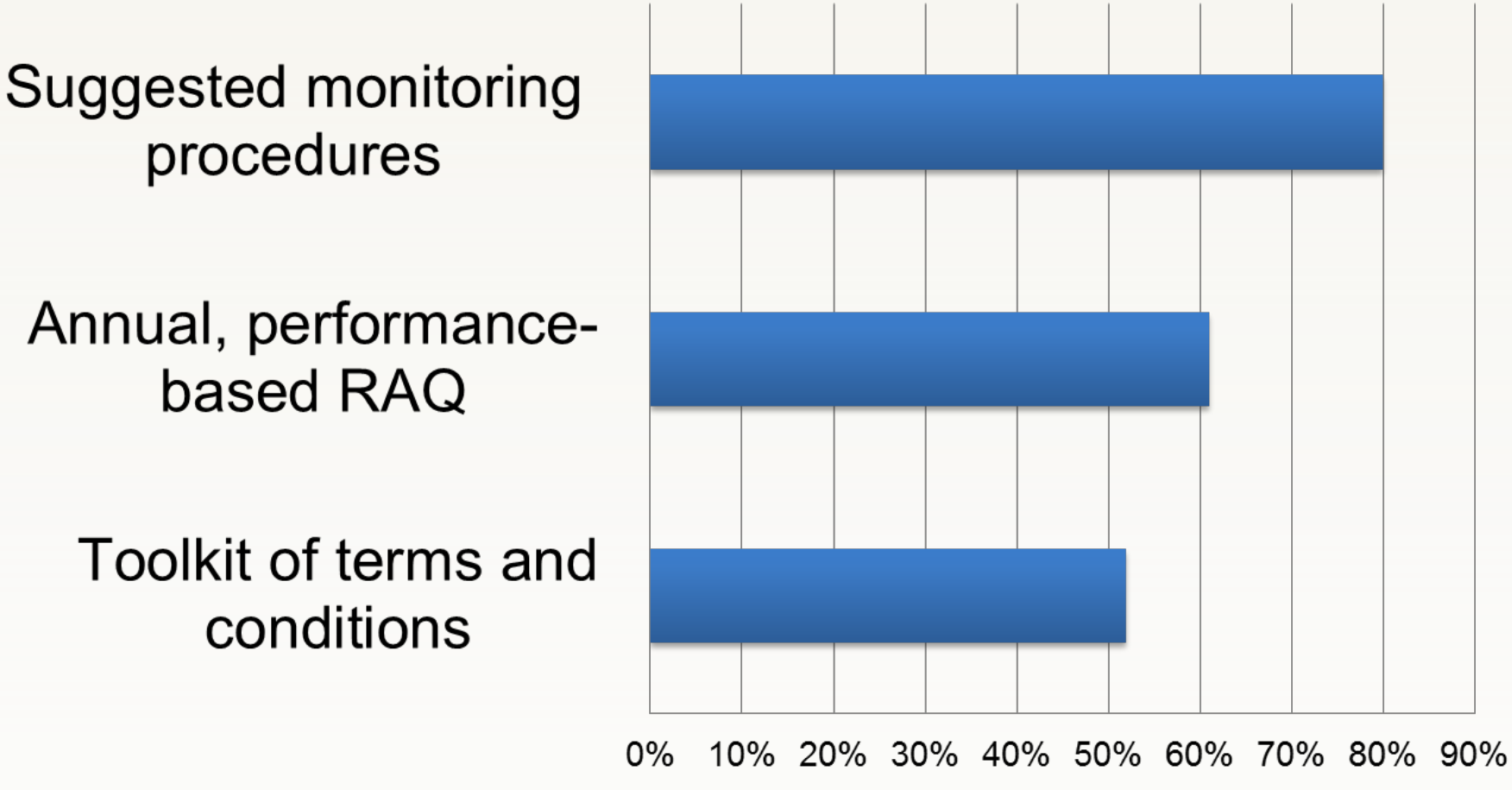


Risk Assessment Survey Results



Risk Assessment Survey Results

What additional tools could be offered to institutions that identify subrecipient risk?



Next Steps for RA Subgroup

- Prepare further resources based on survey results:
  - Annual risk assessment tool
  - Risk webinar
- Community Resources - begin immediately:
  - subrecipient monitoring toolbox (Trello)
  - new FDP listserv (FDP Risk Assessment)
  - Basic, unofficial, Subrecipient Commitment Form to support RAQ
- Longer term:
  - Begin data collection pilot
  - Practices & procedures for risk assessment

Resources & Links

- Risk Assessment Survey:

  https://utexas.qualtrics.com/jfe/form/SV_b3GqcfdIEC5UH7D

- New FDP Risk Assessment Listserv

  http://sites.nationalacademies.org/PGA/fdp/PGA_054596

- Trello Toolbox:

  https://trello.com/b/f00C5bj5/subrecipient-toolbox

- Companion subrecipient commitment tool:

https://docs.google.com/document/d/1bP0FJVjppHIYVmoke6hidBJdysetF-ZEeutZN2soMwM/edit?usp=sharing

Contact Information

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Expanded Clearinghouse

Charge

- To develop one single web based repository for all FDP entities (and potentially others) to enter, upload, maintain and update all entity related information about their organization
- To utilize this centralized online repository of entity information to enable Pass-Through Entities to obtain and review all necessary subrecipient entity information and conduct sub-recipient monitoring and risk assessment activities in a timely and streamlined fashion without requiring time and resources to send and collect various forms to obtain information

Expanded Clearinghouse

Initiatives

- Propose FDP Demonstration to develop, implement and maintain an Expanded FDP Clearinghouse
- Standard FDP Subrecipient Certification Form (as pilot phase prior to online system)
- Expanded FDP Clearinghouse (web-based online system)
- FDP Clearinghouse users group to support ongoing review and updating of clearinghouse data elements and/or structure, reports and other aspects
- Subrecipient monitoring Best Practices (Proposal to Closeout)