Subawards Subcommittee

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Agenda

- Subcontract template discussion
- Certificate of confidentiality discussion
- Subrecipient Risk Assessments
- Research Integrity
- General working group updates
- Subaward templates feedback

Subcontract Template Discussion

- Templates are also posted for discussion and comment

- Specifically wanted to ask about subcontract versus subrecipient / subaward nomenclature

- Comment period through end of February

Certificates of Confidentiality

- NIH has changed their policy regarding the issuance of Certificates of Confidentiality (CoC)
  - Why? Resulted from the need to implement Section 2012 of the 21st Century Cures Act, **enacted 12/13/16** – key date!

  - Requires HHS Secretary to issue CoC to investigators/institutions engaged in biomedical, behavioral, clinical, or other research in which identifiable, sensitive information is collected, to protect the privacy of individuals who are subjects of research

  - Funded wholly or in part by Federal Government

Certificates of Confidentiality

- <u>Previous CoC process</u>: institution had to request a CoC from the NIH upon determining that it was within the scope of this Policy

- <u>New process:</u> (effective 10/1/17) all research that was commenced or ongoing on or after **12/13/16** and is within the scope of this Policy is deemed to be issued a CoC and required to protect the privacy of individuals who are subjects of such research
  - NIH will automatically incorporate the CoC by virtue of issuing the NOA
  - Included by reference to the NIHGPS (sec 4.1.4.1) as a standard T&C for new and non-competing grants

CoC – Award Recipient Responsibilities

- "Institutions and their investigators are responsible for determining whether research they conduct is subject to this Policy and therefore issued a Certificate." – see NIHGPS 4.1.4.1 on making the determination

- Responsible for ensuring that any subrecipient that receives funds to carry out part of the NIH award involving a copy of identifiable, sensitive information protected by a CoC issued by this Policy are also subject to the Policy

- See NOT-OD-17-109

- See NIH's CoC Website

Certificate of Confidentiality

- Discussion: options for incorporating into FDP subawards:
  - Update the template (concerns re: planning IT resources if we have another release in 2018)
  - Providing optional language for the additional terms section of Attachment 2 and incorporating fully in 2019
  - Relying on the NIHGPS and creating FAQs / guidance

- Potential Location: Attachment 2, perhaps correlated to the data use section of the template

Certificate of Confidentiality

- Language proposed by Partners:

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.

Fixed Price Subawards

- This is an emerging area
- Workgroup session tomorrow to continue the discussion from September
  - Fixed Price vs Cost Reimbursement
  - Fixed Price: prior approval and Standard Acquisition Threshold
  - Where do clinical trials fit in?
- What role should we play, and what are our next steps?

Research Integrity

- OSTP General Policy from 2000 (65 FR 76260) lays out the general requirements for conducting research without falsifying or fabricating data

- HHS has their own implementation, but the memo applies to research funded by all federal agencies
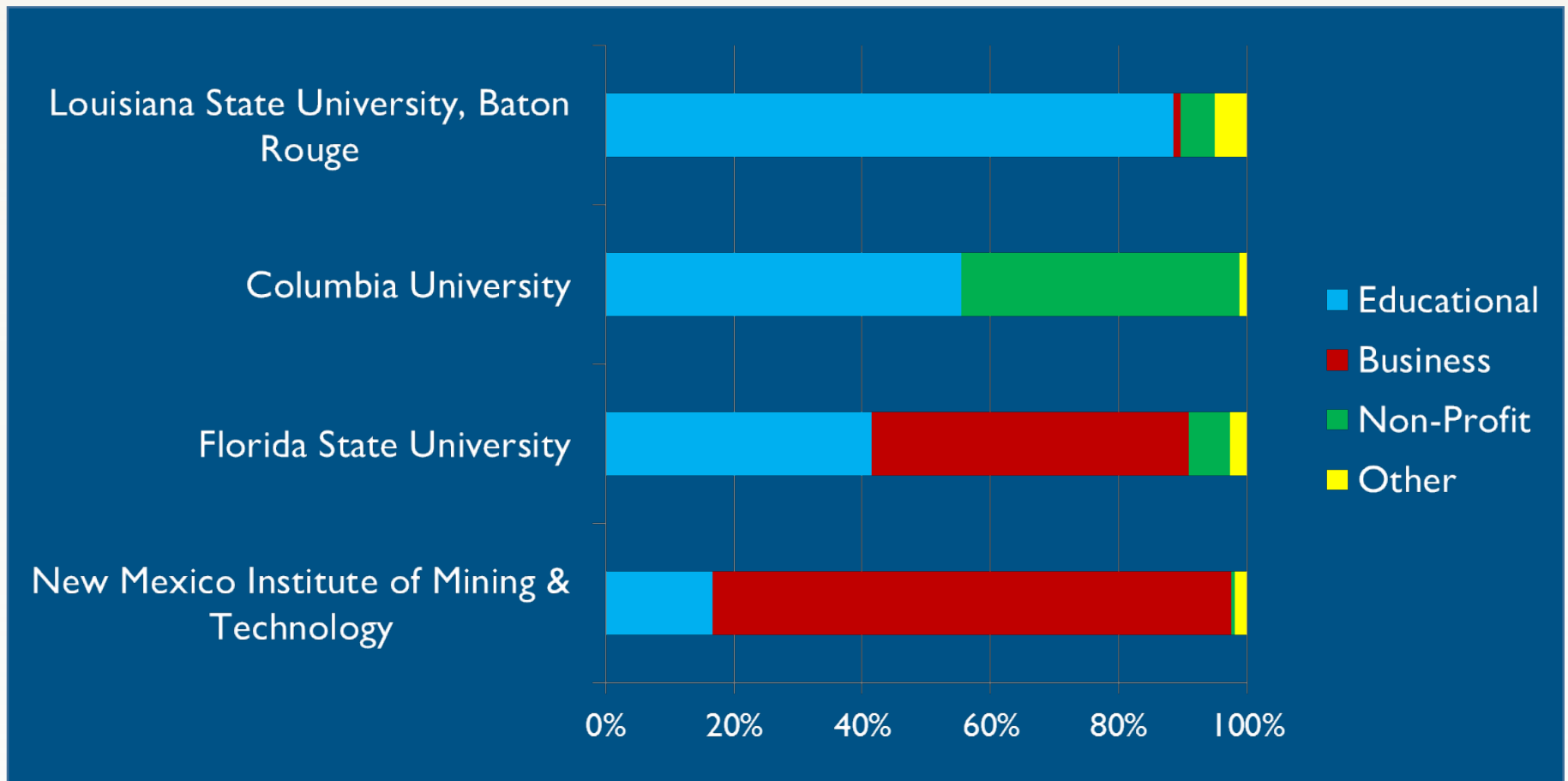
Research Integrity

- Could add to Attachment 2, similar to fCOI:
  - The Subrecipient attests that it will adhere to any research misconduct and integrity policies as may be required by the Federal Awarding Agency as stated in 65 FR 76260-76264 and Attachment 2, General Terms and Conditions 1-4. The subrecipient should make any reports in accordance with these provision to the PTE's [drop down]. The parties will work together in good faith to make any reports to the federal awarding agency, as well as any other reports or communications that may be required.

RAQ Scoring

2012-2014 Federal subrecipient expenditures by subrecipient type

What's Next?

- Working groups continue their amazing work
  - Subcontract - finalizing
  - Foreign – now it is onto FAQs
  - Guidance

- Please send suggestions for the May meeting to us

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

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