



# FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

## IACUC & Subawards Collaboration

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# Agenda

- Define the administrative burden and its underlying regulatory nexus
- Explain the intended scope of the potential project
- Listen to the community
- Determine next steps



# Before we start...Definitions

- **Memorandum of Understanding (MOU):**
  - Used when the subrecipient will be conducting vertebrate animal federally-funded research under its own assurance
- **Inter-Institutional Assurance (IIA)**
  - Used when one party to a collaboration will be conducting vertebrate animal research under the other party's assurance
- **Subaward**
  - Used to document the Terms and Conditions (T&C) of the collaboration between the parties, currently T&Cs do offer choices to collect the IACUC approval letter



# Regulatory Context

- So where did this come from?
- It came from the Guide!
- 7<sup>th</sup> edition:
  - “OLAW recommends the IACUC of the awardee institution have a mechanism for obtaining a copy of the performance site’s IACUC approval.” 1996 page 43
- Current version (8<sup>th</sup> edition):
  - “formal written understanding e.g., a contract, memorandum of understanding, or agreement) that addresses the responsibility for offsite animal care and use, animal ownership, and IACUC review and oversight (AAALAC 2003). In addition, IACUCs from the participating institutions may choose to review protocols for the work being conducted.” Page 15, 2011



## So what?

- When the FDP subaward subcommittee added the vertebrate animal section to the subaward, we received questions about if the addition of this language was intended to cover the requirements of the Guide
- It was not, it was intended to cover subrecipient monitoring / financial compliance by clarifying the when vertebrate animals would be used



# MOU and Subawards

- Some institutions require a separate MOU for vertebrate animal studies conducted on federally funded awards
- Some institutions believe their assurance and the FDP subaward template largely cover the Guide's requirements
  - However some have expressed a preference to tweak to the FDP templates to more clearly state this



# Framing the Admin Burden

- Interpretation of the requirements: variable interpretation of the Guide
  - Variable business processes or operational gaps
  - Ensuring the best possible care for animals is paramount
- MOU/Agreement Type: Variable form and format of the MOUs (or other types of agreements) means:
  - Potential that MOU / subaward will have conflicting terms
  - Review and signature time
- Reporting: OLAW requires the Pass Through Entity (PTE) to report, but often the sub reports directly to OLAW



# Potential Scope

- Support COGR activities: OLAW is looking at admin burden for research activities
  - Make sure we communicate and provide data, but how to collect the information?
- Leveraging the FDP Subaward template
  - Two institutions have proposed language they would like FDP to consider
- Sample MOU like the UBMTA
- Look at the reporting requirements
- Guidance



# Potential Scope

- None of the potential work product arising from this project should be construed as a government mandate
- The most we can say is that to the best of our understanding, this meets the requirements
- While OLAW serves on the IACUC subcommittee, their role, as with all our federal members, is to provide guidance



# Your Thoughts

- Reporting question:
  - Do you report directly to OLAW or to the PTE?
- Sample MOU: Would your institution be interested?
- Could your institution leverage the subaward?
  - How do you communicate with your colleagues in central office / IACUC office?
- Who should we engage? Federal agencies? Members?
- What information would you need to have the right discussions and collect the right information at your institution?
- What are you doing now? Are you willing to consider changes?



# Next Steps

- We ask that those interested in working on this topic be aware of the practices of their institution.
- Confirm if your home institution would be interested in discussing this further through a working group.
- Confirm that both your IACUC and central office would like to see streamlining or changes made in this area.
- Does your institution have resources to share, such as templates?



# Potential Clauses

- **Michigan Proposal:**

- “The expenditure of federal funds on vertebrate animal activities must comply with the governing standards and the Terms and Conditions of the grant. The subrecipient’s Institutional Animal Care and Use Committee (IACUC) will oversee all supported vertebrate animal activities. The subrecipient’s animal care and use program is accredited by AAALAC International Inc., registered with the USDA as a research organization, and maintains a current OLAW approved animal welfare assurance. Unless otherwise noted, the vertebrate animals used in the supported activities are the property of the subrecipient. The subrecipient will notify the appropriate agencies of deviations in the regulatory standards governing animal activities.”



# Potential Clauses

- **Partners Proposal:**

- “In accordance with the Subrecipient’s Animal Welfare Assurance, the Subrecipient is responsible for reviewing and reporting instances of non-compliance to OLAW that occur in regards to the work described in the Statement of Work, along with overseeing other aspects of the IACUC-approved protocol, as required. The Subrecipient owns the animals used to complete the Statement of Work and is responsible for routine husbandry and veterinary care for the animals in accordance with aforementioned federal and policy in this Article. Subrecipient shall notify PTE of any changes in status to its Public Health Service (“PHS”) Assurance, USDA Registration or Associate for Assessment and Accreditation of Laboratory Animal Care International accreditation (if applicable), as well as any notifications to OLAW or USDA for non-compliance or adverse events pertaining to animals used for research under this Agreement.”



# Contact Us

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