



FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

IACUC & Subawards Collaboration

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Agenda

- Quick overview of context
- Examples from OLAW of when MOU would be constructive
 - Q&A / Feedback of community on examples
- Action items / role of this working group
- Engagement of IACUCs
- Next steps



Regulatory Context

- The Guide for the Care and Use of Laboratory Animals is published by the Institute for Laboratory Animal Research (National Research Council of the National Academies)
- NIH OLAW has incorporated the Guide by reference.



The *Guide* states....

Current version of *Guide* ([8th edition](#)), page 15, 2011:

Collaborations

“Interinstitutional collaboration has the potential to create **ambiguities about responsibility** for animal care and use.

In cases of such collaboration involving animal use (beyond animal transport), the participating institutions should have a **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.”



Current Language in Subaward

“Subrecipient agrees that any non-exempt human and/or vertebrate animal research protocol conducted under this Subaward shall be reviewed and approved by its Institutional Review Board (IRB) and/or its Institutional Animal Care and Use Committee (IACUC), as applicable and that it will maintain current and duly approved research protocols for all periods of the Subaward involving human and/or vertebrate animal research. Subrecipient certifies that its IRB and/or IACUC are in full compliance with applicable state and federal laws and regulations. The subrecipient certifies that any submitted IRB/IACUC approval represents a valid, approved protocol that is entirely consistent with the Project associated with this Subaward. In no event shall Subrecipient invoice or be reimbursed for an human or vertebrate animals related expenses incurred in a period where any applicable IRB/IACUC approval is not properly in place.”



Initial feedback

- Received 18 responses
- Which office issues MOUs?
- When during the lifecycle?
- Preferences?



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: Guide states the Pass Through Entity (PTE) reports, but often the sub reports directly to OLAW



OLAW Expectations

- Based on the Guide, when OLAW shows up to do an inspection, the expectation is that there will be an MOU or other document/method in place to ensure the end result:
 - Appropriate oversight, care and use of vertebrate animals when the activity is supported by NIH
- Support does not always = money
- Support can be that the work is related to NIH funding, perhaps through unfunded collaboration



OLAW Expectations

- Case study examples presented by OLAW
- Please ask questions, share experiences and opinions



Engaging IACUCs

- Engaging the IACUC, compliance and/or central offices will be key
- Need IACUC perspective on what they are seeing and they need to hear what central offices are seeing
- Potential Webinar?



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 (see reference)
 - Pros and Cons to sub versus MOU
 - Operational challenges
- Sample MOU like the UBMTA
- Look at the reporting requirements
- Guidance



Next Steps

- Webinar aimed at engaging IACUCs
- Working group to look at:
 - Sample MOU
 - Guidance
 - Which do we start with?
- Could your institution leverage the subaward?
 - How do you communicate with your colleagues in central office / IACUC office?
- Other action items?
- Let us know if you are interested in joining us



Reminder

- 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



Contact Us

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Automatically goes to:

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We will share with Axel and Ara, our IACUC co-chairs



Potential Clauses (reference)

- **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 (reference)

- **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.”



Definitions (reference)

- Memorandum of Understanding (MOU):
 - Used when the subrecipient will be conducting vertebrate animal federally-funded research under its own assurance (not legally binding)
- 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 (legally binding)