



FEDERAL DEMONSTRATION PARTNERSHIP
Redefining the Government & University Research Partnership

*Agreements between
Collaborating Institutions
Using Vertebrate Animals*

Presented by

FDP IACUC and Subawards Subcommittees



Speakers

(in alphabetical order)

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Agenda

- Background
- Definitions
- Clarification of Expectations
- Summary of FDP Member Feedback
- Next Steps
- Questions from the community (Q&A)



Framing OLAW's Engagement

- None of the potential work product arising from this project should be construed as a government mandate.
- While OLAW serves on the FDP IACUC Subcommittee, their role, as with all our federal members, is to provide guidance.



The Ultimate Questions

- How do you ensure that roles and responsibilities are defined when more than one institution is conducting work with vertebrate animals funded by the same grant?
 - Same question applies if there is no grant.
- What type of agreement should be used between collaborating institutions that will ensure the appropriate individuals are aware of each of their roles?
- What's the least burdensome way to do this?



Background

Both the Office of Laboratory Animal Welfare (OLAW) and the AAALAC International (formerly known as Association for Assessment and Accreditation of Laboratory Animal Care International) use the National Academy of Sciences' *Guide for the Care and Use of Laboratory Animals*, 8th Edition (*Guide*).

NIH OLAW has incorporated the *Guide* by reference.



Guide for the Care and Use of Laboratory Animals, 8th Edition

It contains guidance on inter-institutional collaborations, specifically,

- *“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.” (Page 15, 2011)*



Background

Guide provides collaborating institutions conducting research with animals with flexibility in approaching how to designate and acknowledge responsibilities between institutions.

FDP IACUC and Subawards Subcommittee received requests to recommend a formalized approach to these responsibilities.



Most Recently....

“NIH, USDA, and FDA convened a Working Group of federal subject matter experts to identify inconsistent, overlapping, and unnecessarily duplicative regulations and policies and prepare a report of their recommendations as directed in the 21st Century Cures Act.” - [NOT-OD-19-136](#)

The report on [Reducing Administrative Burden for Researchers: Animal Care and Use in Research](#) (PDF) describes the efforts of the Working Group, their recommendations, and the decisions of NIH, USDA, and FDA on the recommendations.



Definitions

- Memorandum of Understanding (MOU):
 - The MOU is to be used in circumstances that involve partnerships between collaborating institutions involving animal activity.
- Inter-Institutional Assurance (IIA)
 - The IIA is required when the awardee institution does not have its own animal program and will conduct the animal activity at a secondary Assured institution(s) named as the performance site.
- 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



OLAW Expectations

- Based on the *Guide*, OLAW's expectation is that there will be an MOU or other written document in place to ensure the end result:
 - Appropriate oversight, care and use of vertebrate animals when the activity is PHS, HHS or NSF-supported
- Support does not always = money
- Support can consist of work related to NIH funding, perhaps through unfunded collaboration.



Why subawards?

- In 2015, the FDP subawards subcommittee added vertebrate animal use language to the subaward, as part of effective subrecipient monitoring
- It was intended to cover subrecipient monitoring / financial compliance by clarifying when vertebrate animals would be used
- Some institutions asked if this met the expectations of an MOU per the *Guide*
 - OLAW suggested additional clarification would be necessary. Current language is not to replace reliance agreements or other MOUs as may be required by your IACUC.



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 the appropriate 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 the appropriate 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 any human or vertebrate animals related expenses incurred in a period where any applicable IRB / IACUC approval is not properly in place.**



So what?

- The additional clarification may require information held by the IACUC office
- Questions arose about roles and responsibilities, at some institutions, operations may be apportioned in such a way that it is difficult for institutions to align and ensure appropriate oversight
- So the subawards group limited the intent to exclude MOUs, but institutions have since asked to explore this further



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* requirements
 - However some have expressed a preference to tweak to the FDP Subaward templates to more clearly state this



Question #1 of 3

Does your institution issue MOUs when multiple institutions are working with vertebrate animals on the same research project?

A: Always, even if there is a subaward

B: Only if there is not a subaward (unfunded project)

C: We do not issue MOUs, we consider the OLAW assurance of the subrecipient/collaborator to be sufficient

D: I don't know

*Individual responses will not be associated with your institution, so please answer freely



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



What triggers an MOU?

- Based on FDP member feedback, during the congruency review, which is usually done during Just in Time (JIT), though not always.
- This leads us to talking about the congruency review.....



What is a congruency review?

- What is it?
- Who does it?
- When is it done?



Reporting to OLAW

- Reporting: Guide states the Pass Through Entity (PTE) or primary grantee reports, but often the subrecipient reports directly to OLAW
- MOU should state clearly who reports to OLAW if there is a problem.



Question #2 of 3

When you are a subrecipient on a NIH funded project where do you report any animal welfare issues?

A: Directly to OLAW, no notification to the PTE

B: Directly to OLAW, with notification to the PTE
(either as a cc: or separately)

C: To the PTE with a request for them to pass to OLAW

D: Not sure what our process is.

*Individual responses will not be associated with your institution, so please answer freely



Initial FDP member feedback

- Sent informal survey to FDP Admin reps in February of 2019
 - Received 18 responses
- Focused on understanding
 - Which office issues MOUs?
 - How often do you issue MOUs?
 - How often do you receive MOUs?
- We realized we needed more IACUC engagement and a webinar would be the most helpful (so here we are)



Engaging IACUCs and Other Central Offices

- Do we need streamlining in this area?
- When do you issue the MOU during the lifecycle of the project?
- We need FDP members to engage across the IACUC, compliance and/or central offices to discuss where they are now and what they might like to see.



Proposed Working Group

- Initiate a working group
- What items should be included in an MOU? What should the language be?
 - Is it a checklist?
 - What items should always be included to make the MOU language strong?
 - However, it should be streamlined to only include the must-have's.
- After a draft template or language is developed:
 - Discuss when it is issued, where, and by whom?
- Pilot it.
- Written guidance



Question #3 of 3

How is operational alignment between your institutions' IACUC office (when issuing MOUs) and the office that issues subawards?

A: The MOU process and subaward process are closely aligned (subaward not issued unless MOU issued first)

B: The MOU process and subaward process are mutually exclusive (not tied together at all)

C: MOU language is included in the subawards, one office responsible for both parts.

D: I don't know.



Questions from the Community

- Is an MOU required for all funding mechanisms?
- Who should initiate the MOU, the PTE or subrecipient?
- Do MOUs need to be renewed, revised, and/or terminated? Should the grant funding drive this?
- Should the subrecipient be conducting congruency reviews?



Questions from the Community

- Institution A has a field station that is used by different institutions performing seasonal research. Institution A's IACUC reviews the other institution's approved animal use protocol, collecting permits and provides comments to the PI directly when the Committee has concerns about the work proposed. However, Institution A does not have the authority to require the modification nor are they sure about their authority. Would an MOU be useful?



We come full circle....The Ultimate Questions

- How do you ensure that roles and responsibilities are defined when more than one institution is conducting work with vertebrate animals funded by the same grant?
 - Same question applies if there is no grant.
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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 MOU templates or MOU language?
- Contact us if interested in participating in this group.



Contact Us

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