



FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

Agreements between Collaborating Institutions Using Vertebrate Animals

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Agenda

- Summary of 2019 actions
- Summary of FDP Member Feedback
- Webinar and response
- Next Steps
- Questions from the community (Q&A)



IACUC/Sub Working Group: Progress in 2019

- At 2 FDP meetings, held sessions to:
 - Frame the administrative burden,
 - Discuss member questions, and
 - Gather additional information from members on current practices, as well as where the FDP could help to reduce burden
- Generated, disseminated and analyzed an informal survey on current practices and areas for potential burden reduction
- Held a webinar to further engage IACUC administrators on this topic and support institutional conversations



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 we held one just a few months ago...



Webinar Report out

- We hosted a webinar October 2019
- 450 attendees from a variety of FDP and non-FDP member institutions
- Got a lot of great follow up and engagement



Responses from Webinar

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



Responses from Webinar

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

262 Responses

89 or 34% = Always, even if there is a subaward

25 or 10% = Only if there is not a subaward

62 or 24% = We do not issue MOUs, we consider the OLAW assurance of the subrecipient/collaborator to be sufficient

86 or 33% = I don't know

**rounded percentages for simplicity, thus it equals 101%*



Responses from Webinar

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.



Responses from Webinar

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

282 Responses

26 or 9% = Directly to OLAW, no notification to the PTE

123 or 44% = Directly to OLAW, with notification to the PTE
(either as a cc: or separately)

35 or 12% = To the PTE with a request for them to pass to OLAW

98 or 35% = Not sure what our process is.

**Somehow, the rounding worked out here.*



Responses from Webinar

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.



Responses from Webinar

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

271 Responses

50 or 18% = The MOU process and subaward process are closely aligned (subaward not issued unless MOU issued first)

113 or 42% = The MOU process and subaward process are mutually exclusive (not tied together at all)

26 or 10% = MOU language is included in the subawards, one office responsible for both parts.

82 or 30% = I don't know.

**Again, the rounding worked out here, hooray!*



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.
- 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?



What have we learned?

- At this point we have more questions than clear answers
- There are many important variables, we don't want important things to fall through the cracks!
- This is an area where there is a lot of variable perspective, practice and understanding



What have we learned?

- We are not ready to leverage the subaward as the final solution just yet
 - May have multiple solutions
- Subaward first may inhibit adoption
- Ultimately, we want:
 - Consensus among institutions
 - Less confusion
 - To reduce burden either issuing and/or reviewing MOUs
- The final product should not be defined yet.



Two key areas for action

- Interpretation of the requirements: variable interpretation of the *Guide*
 - Guidance
 - Getting different offices on the same page, maybe via glossary, documentation, outreach
 - Understanding standard institutional practices around when MOUs are issued and how
- MOU Sample:
 - Work to create an MOU sample
 - Identify what makes a good MOU
 - How does the MOU inform the guidance?
 - How could an MOU inform subaward language?



Proposed Working Group

- Scope
 - Do we have it right?
 - What should we be thinking about?
- Single stream or dual stream approach
 - Guidance or MOU first or tackle both in parallel?
- Outreach and communication
 - Keep engaging across institutional silos
 - Ensure various stakeholders in each working group
- Pilot?



Next Steps

- We have a lot of volunteer interest, we will reach out and set up calls
- Working group(s) will start working
- Will update websites
- Communicate through both IACUC and subaward list serves
- Will likely not have a session in May: focus on having a deliverable for the September meeting



Contact Us

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Automatically goes to:

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



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.**