

MOUs for Collaborating Institutions: New Template from the Federal Demonstration Partnership (FDP)



January 19, 2023

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Agenda

- What is the Federal Demonstration Partnership (FDP)?
- OLAW's regulatory context
- Why FDP created these tools
- MOU tool overview
- User Manual overview
- Q&A

What is the Federal Demonstration Partnership?

FDP mission:

Association of federal agencies, academic and nonprofit research institutions, and research policy organizations that work together to streamline the administration of federally sponsored research and foster collaboration to enhance the national research enterprise, while maintaining high standards of stewardship and accountability.

Researchers doing research, not administration

What is the Federal Demonstration Partnership?

- A longstanding partnership between federal funding agencies and research institutions that works to reduce administrative burden associated with research grants and contracts.
- 10 federal agencies and more than 200 research institutions
- A program convened by the Government-University-Industry Research Roundtable of the National Academies.
- A unique forum for individuals from universities and nonprofits to work collaboratively with federal agency officials to improve the national research enterprise.



OLAW Jurisdictional Oversight



OLAW oversees Public Health Service (PHS)-funded animal activities; PHS funding components include the:

- National Institutes of Health (NIH)
- Centers for Disease Control and Prevention (CDC)
- Food and Drug Administration (FDA)
- Biomedical Advanced Research and Development Authority (BARDA)



Through memoranda of understanding, OLAW additionally oversees animal activities funded by the:

- National Aeronautics and Space Administration (NASA)
- National Science Foundation (NSF)
- Department of Veterans Affairs (VA)

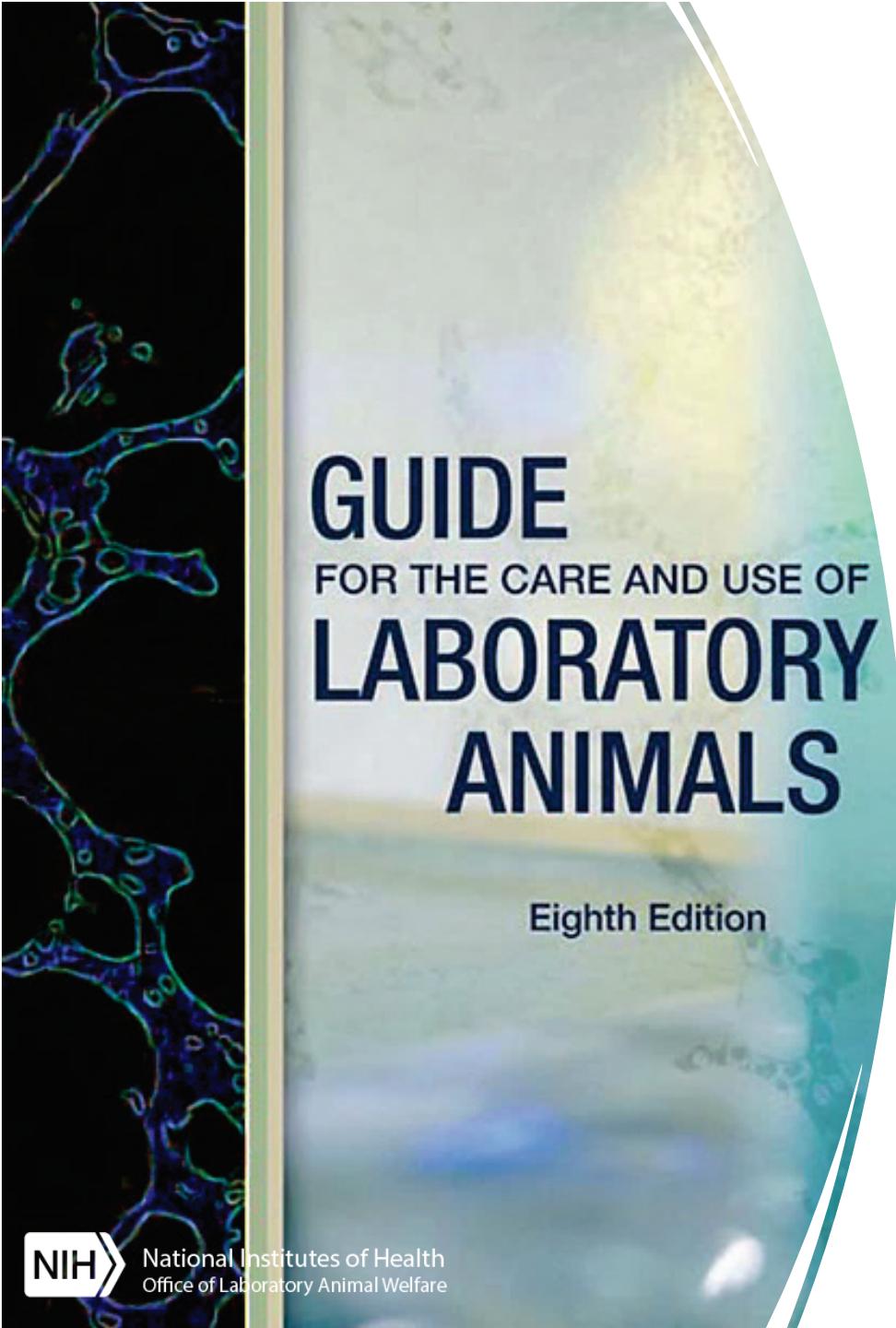
Ground rules for Institutions

For projects subject to the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy):

- The Policy states that the PHS requires institutions to use the *Guide for the Care and Use of Laboratory Animals (Guide)* as a basis for developing and implementing an institutional program for activities involving animals.
- All performance sites must be covered under an Assurance.

Collaborative agreements serve to ensure that the requirements of the PHS Policy are met at all performance sites, and therefore may prevent reportable noncompliances.





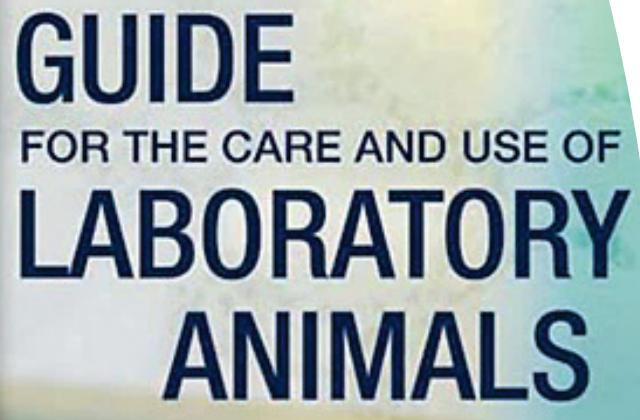
Collaborations

Guide, p. 15

- Interinstitutional collaboration has the potential to create ambiguities.
- In cases of animal use collaboration beyond animal transport, the participating institutions should have a formal written understanding that addresses:
 - Responsibility for offsite animal care and use,
 - Animal ownership,
 - IACUC review and oversight (AAALAC 2003).
- IACUCs from participating institutions may choose to review protocols.

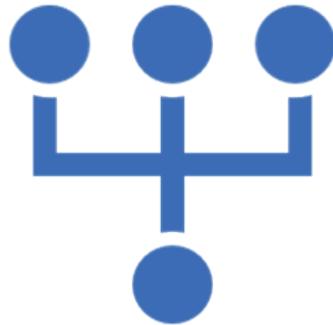
Collaborative Agreements

Guide, p. 15

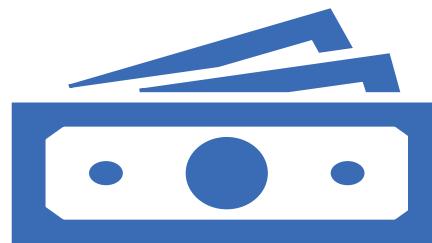


- The participating institutions should have a formal written understanding such as a contract, memorandum of understanding, or agreement.
- The *Guide* offers flexibility in development, provided the outcomes listed on the previous slide are met.

OLAW's Regulatory Context



OLAW will ask to examine the MOUs or equivalent documents in place to ensure 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, such as provision of expertise, contribution to data sets, interpreting data, etc.

FDP Created These Tools Because of...

Admin burden stemming from variations in:

- Interpretation of the requirements in the *Guide*
 - Variable business processes or operational gaps
 - Ensuring the best possible care for animals is paramount
- MOU/Agreement type/format
 - Potential that MOU/subaward will have conflicting terms
 - Review and signature time
- Reporting practices
 - OLAW has required non-compliance reporting but collaborating institutions may not be aligned as to who should do the reporting and if the collaborator should be notified.

Development of the MOU

- A working group was established to develop a generic MOU template applicable to collaborating institutions using animals.
- Burden reduction by allowing:
 - Use of the MOU as written,
 - Modify MOU to establish an institution-specific document, or
 - Option not to use.
- The MOU is intended to prevent problems and misunderstandings which could negatively impact research animals.
- *NOTE: Use of the MOU template is **not** required by OLAW.*



FDP Tools Designed to Answer...

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/on the same project (even unfunded)?

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?

FDP's 2019 Survey on MOUs

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

262 Responses

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

25 (10%) = Only if there is not a subaward

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

86 (33%) = I don't know

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

FDP's 2019 Survey on MOUs

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

282 Responses

26 (9%) = Directly to OLAW, no notification to pass through entity (PTE)

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

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

98 (35%) = Not sure what our process is

**Somehow, the rounding worked out here.*

FDP's 2019 Survey on MOUs

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

271 Responses

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

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

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

82 (30%) = I don't know

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

What Did we Learn?

- 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

Two-Pronged Approach

- **User Manual:**
 - Clarify interpretation of the requirements
 - Getting different offices on the same page
 - Understanding institutional practices around MOUs (i.e., when and how MOUs issued)
- **MOU Sample:**
 - Identify what makes a good MOU
 - How does the MOU inform the guidance?
 - Sample product for institutions to be able to use across variety of funding agencies (including OLAW, USDA, VA, etc.)

Where to Find These Resources (FDP)

[Home](#) / [Committees](#) / [Research Compliance](#) / [IACUC](#)

<https://www.thefdp.org>

IACUC

Reviews existing and new administrative requirements imposed by federal regulations and program officers related to animal use and care. The emphasis should be on harmonization of requirements across federal agencies, reduction of redundancies and identifying good practices.

Initiatives

[Compliance Unit Standard Protocol \(CUSP\)](#)

[Universal Protocol Template \(UPT\)](#)

Resources

- Webinar - [Agreements between collaborating institutions using vertebrate animals](#)(recorded 10/9/2019)
- [Slides to webinar](#)
- [FDP MOU Sample May 2022](#)
- [IACUC MOU Guidance May 2022](#)

IACUC/Subawards Working Group Meeting - June 15, 2020

- [Video](#)
- [MOU Slides](#)
- [VA Template Tool Slides](#)

Documents

Where to Find These Resources (OLAW)



National Institutes of Health
Office of Laboratory Animal Welfare



Search

About OLAW Contact Us

Office of Laboratory Animal Welfare

Policies and Laws

Guidance

Education

Resources

Sample Documents

[Annual Report to OLAW](#)

[Domestic Assurance](#)

[Foreign Assurance](#)

[Interinstitutional Assurance](#)

[Semiannual Program Review and Facility Inspection Checklist](#)

[Semiannual Report to the Institutional Official](#)

[Animal Study Proposal](#)

[Memorandum of Understanding \(MOUs\) for Collaborating Institutions](#)

Sample Documents for Implementation of the PHS Policy on Humane Care and Use of Laboratory Animals

Annual Report to OLAW

Information and form for fulfilling the annual reporting requirement of the PHS Policy.

Domestic Assurance

Sample Animal Welfare Assurance for Domestic Institutions.

Foreign Assurance

Sample Animal Welfare Assurance for Foreign Institutions.

Interinstitutional Assurance

Sample Interinstitutional Assurance.

Semiannual Program Review and Facility Inspection Checklist

A tool to assist IACUCs in conducting semiannual reviews of institutional programs and facilities for the care and use of animals.

Semiannual Report to the Institutional Official

Sample report for preparing the semiannual report to be submitted to the Institutional Official by the IACUC.

Animal Study Proposal

Sample animal study proposal to aid institutions and IACUCs in the development of institutional animal care and use protocol forms.

Sample Documents

[PHS Policy Tutorial](#)

[Featured Topics](#)

[Disaster Planning and Response](#)

[Enrichment and Social Housing](#)

[Investigator Resources](#)

[Research Using Vertebrate Animals](#)

[What Investigators Need to Know \(PDF\)](#)

[Additional Resources](#)

[Publications Available From OLAW](#)

[Useful Links](#)

[Historical](#)

[AWSR Symposium 1985 to 2010](#)

[Policy and Guidance Archive](#)

[Memoranda of Understanding](#)

[USDA/FDA](#)

[VA](#)

[NASA](#)

[NSF](#)

MOU Highlights

- Designed for single projects, but could be modified for institution-wide assurance for frequent collaborators
- Covers specific areas of concern for regulators:
 - Program-wide acknowledgements
 - Transportation
 - Ownership & oversight
 - Investigation & reporting
 - Other (blank)

Indicate affirmative agreement or N/A to each of the terms below then sign and return this form to []					
INSTITUTION A		Program-wide Acknowledgements		INSTITUTION B	
Yes	N/A	The parties acknowledge that each institution maintains an independent program of animal care and use qualified to perform animal care and use activities in compliance with all applicable federal and state animal welfare laws, regulations and policy. Both institutions agree to notify the other party promptly of any changes in such status.		Yes	N/A
Yes	N/A	The parties agree to share any information necessary to comply with regulatory requirements related to program procedures or activities associated with this MOU, upon request.		Yes	N/A
INSTITUTION A		Transportation		INSTITUTION B	
Yes	N/A	The parties agree that transportation of animals between or within respective institutions will comply with the requirements of the Animal Welfare Act Regulations, the <i>Guide for the Care and Use of Laboratory Animals</i> , the Guide for the Care and Use of Agricultural Animals in Research and Teaching (Ag Guide), as applicable.		Yes	N/A
INSTITUTION A		Ownership & Oversight		INSTITUTION B	
Yes	N/A	The parties acknowledge that ownership of animals related to this MOU resides with INSTITUTION [Choose one: A/B]. No transfer of ownership is implied unless otherwise described in another agreement between the parties.		Yes	N/A
Yes	N/A	The parties acknowledge that each institution is responsible for appropriate care and oversight of animals while in their possession, and the provision of appropriate husbandry, peri-procedural care, pain management, and methods of disposition.		Yes	N/A

User Manual Highlights



Intentionally non-prescriptive



Provides definitions to “translate” from each office



Provides considerations for offices in choosing what instruments to utilize (i.e., MOU, subaward, IIA)



Provides high level considerations for institutions to think through how collaborative research is documented



FAQs highlight specific considerations

Questions?



Use the chat to enter additional questions!

Question 1:

Is using this MOU sample document mandatory? The *Guide* only states that a “formal written understanding” (e.g., MOU document) “should” be used.

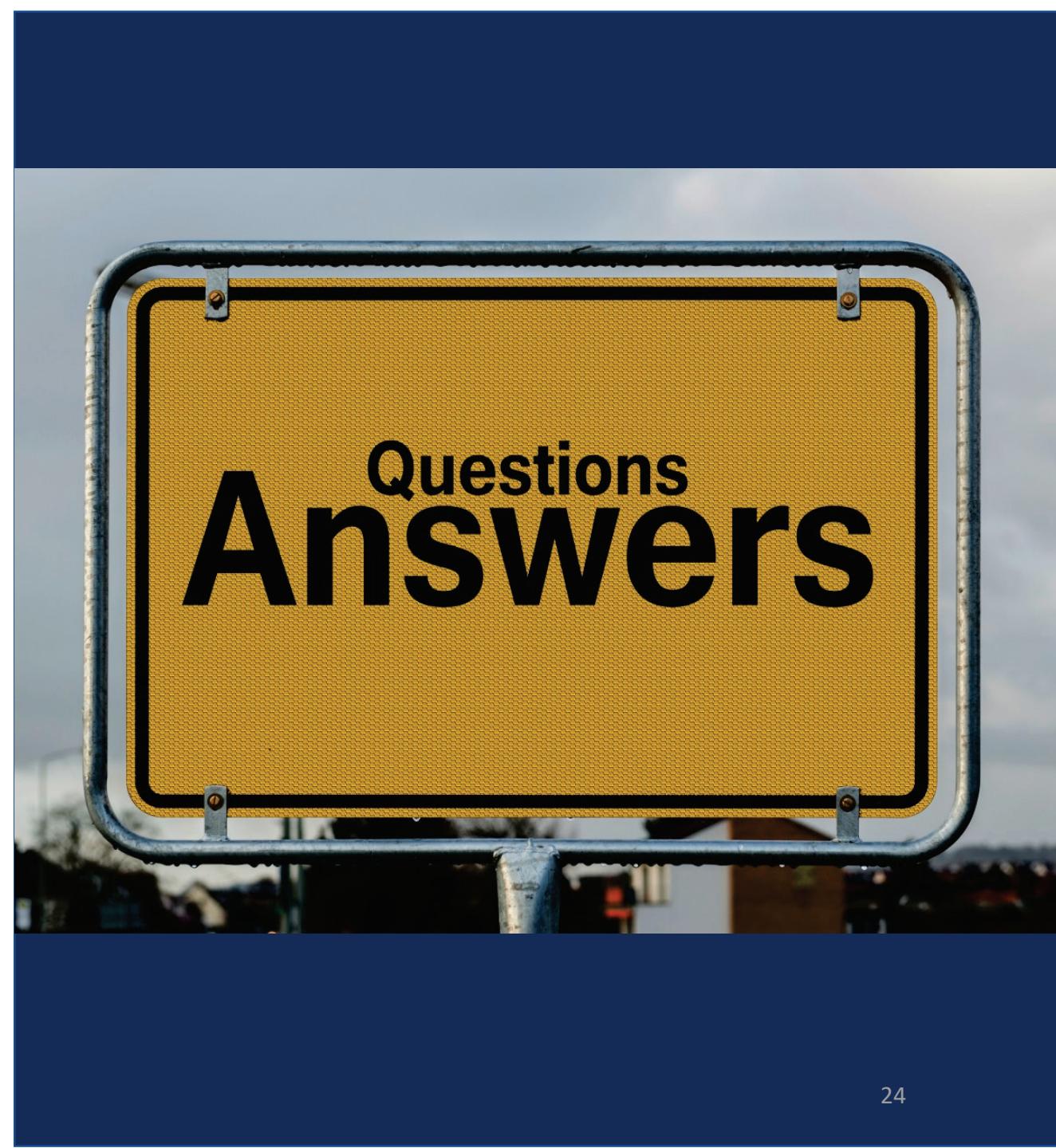


Question 1:

Is using this MOU sample document mandatory?

Answer:

- No, **BUT**, use of a written document such as an MOU is a “should” statement in the *Guide*, indicating a strong recommendation for achieving a goal. Individual circumstances might justify an alternative strategy.
- Using an MOU can help ensure humane animal care and use and to help avoid confusion between collaborating institutions. The sample document is intended to simplify drafting of an MOU.



Question 2a:

What is the difference between an MOU and an Interinstitutional Assurance (IIA)?



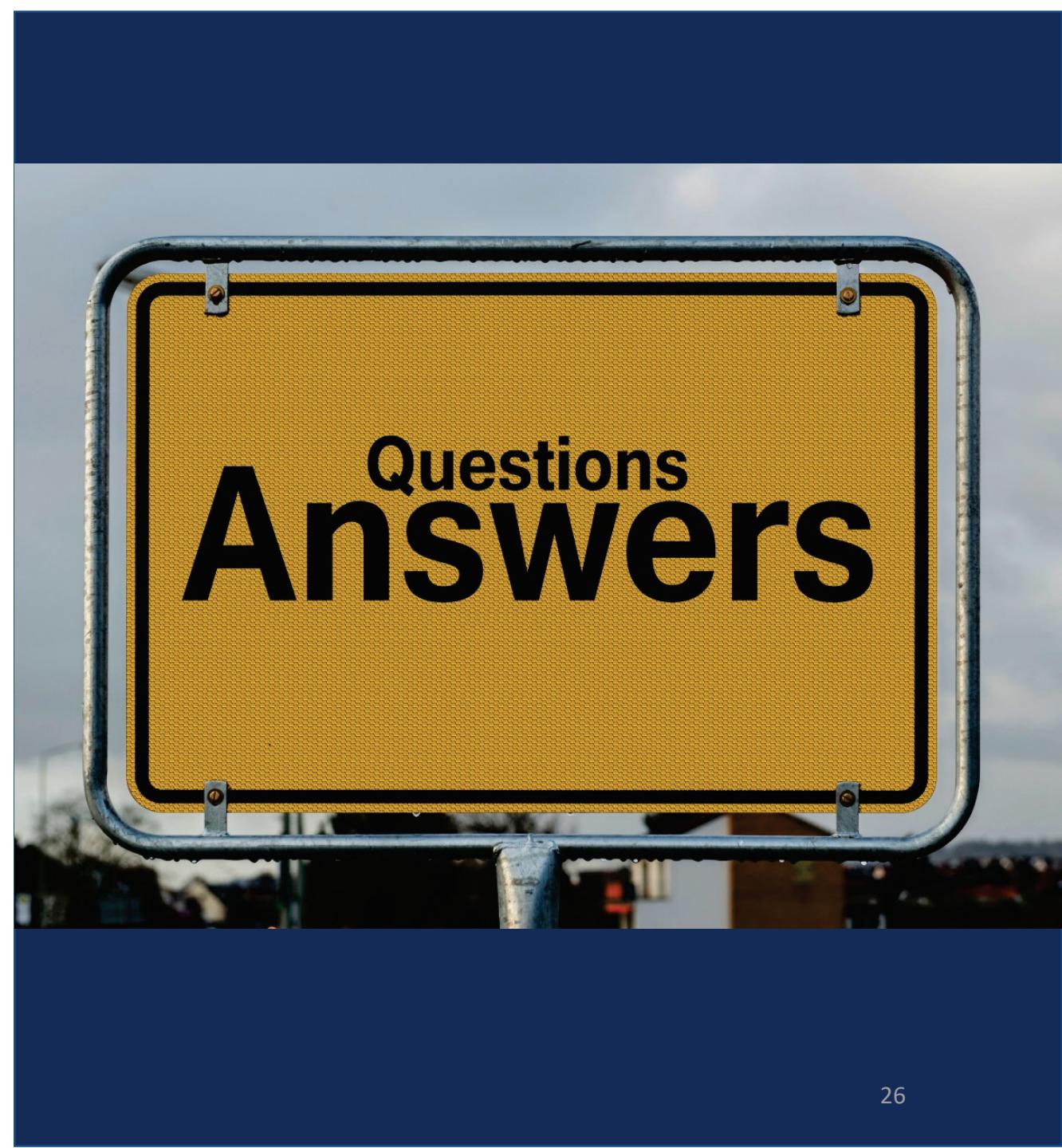
Question 2a:

What is the difference between an MOU and an Interinstitutional Assurance (IIA)?

Answer:

- **MOU:** Recommended in *Guide* for collaborating institutions to address responsibilities for animal care and use and to avoid ambiguities.
- **IIA:** Assurance issued by OLAW to an awardee institution that does not have its own animal program and uses an Assured institution to conduct the animal activities.

These documents do NOT substitute for one another.



Question 2b:

How does an MOU and an Interinstitutional Assurance (IIA) relate to an institution's Assurance?



Question 2b:

How does an MOU and an Interinstitutional Assurance (IIA) relate to an institution's Assurance?

Answer:

- The MOU is independent of any Assurance.
- The IIA is a type of Assurance for an institution that does not have its own animal program but depends on a performance site with its own Animal Welfare Assurance issued by OLAW.



Next Webinar: Spring 2023

Topic TBD

