OLAW Knowledge Videos

Understanding MOUs and Agreements





This video is an extract taken from a presentation given at a webinar hosted by PRIM&R on May 14, 2025, titled "PRIM&R & OLAW Webinar: Understanding Agreement Types That Impact Your Committee."



While this information was accurate at the time presented, policies and procedures change over time. Knowledge videos are intended to provide basic background information and are not intended to provide definitive compliance guidance for every specific situation.

Please contact OLAW directly for compliance questions.

Scope

For the sake of simplicity, today OLAW will ONLY be talking about animal agreements involving Domestic institutions. If you have questions involving a foreign institution, please reach out to the OLAW Division of Assurances:

olawdoa@mail.nih.gov



Objectives

We will discuss:

Why formal written agreements are important

What needs to be in a formal written agreement (nothing new!)

Where to put the necessary information

When a formal written agreement is needed

Who is responsible for the formal written agreement

THE "WHY"



Words!

Theorem 1: 50% of the problems in the world result from people using the same words with different meanings.

Theorem 2: The other 50% comes from people using different words with the same meaning.

— Stan Kaplan, "The Words of Risk Analysis" *Risk Analysis*, 17: 407-417



Let's Start at the Beginning

Two Domestic institutions decide to collaborate

Money, supplies, animals, etc. will be shared

Somebody should probably keep track of who gets what, where everything is, and who is responsible

"If it's not written, it didn't happen."





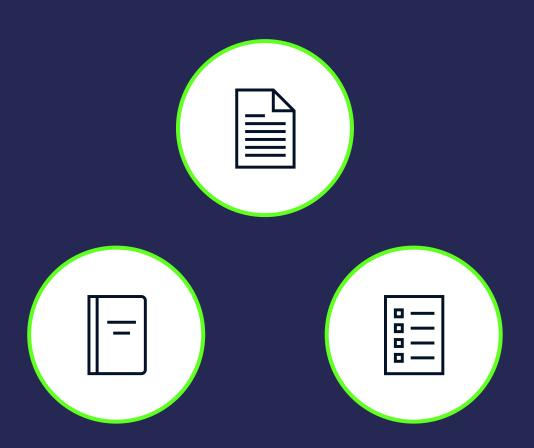
Written agreements protect you, your people, and your animals

THE "WHAT"



OLAW Guidance on Written Agreements Comes From...

NIH Grants Policy Statemen
"Should" statement abou
collaborations in the *Guid*OLAW FA





NIH GPS Chapter 15.2.1: For NIH-funded Research

The recipient must enter into a formal written agreement, signed and agreed to by both parties, with each consortium participant/subrecipient that addresses the negotiated arrangements for meeting the scientific, administrative, financial, and reporting requirements of the grant, including those necessary to ensure compliance with all applicable Federal regulations and policies and facilitate an efficient collaborative venture. If a subrecipient is unwilling to sign the written agreement outlining the requirements below, then a subaward cannot be issued...

https://grants.nih.gov/grants/policy/nihgps/HTML5/section 15/15.2 administrative and other requirements.htm

Guide p.15: For All Assured Institutions

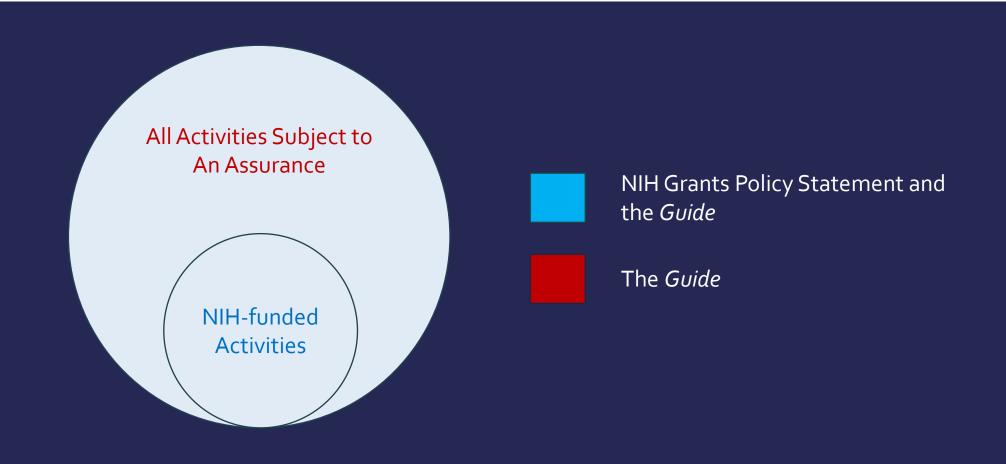
Collaborations

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.

OLAW FAQ D8:



What are the institution's responsibilities during collaborations involving animal activities?



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What are the institution's responsibilities during collaborations involving animal activities?

"...Collaborating institutions must have a formal written agreement ...addressing the scientific, administrative, financial, and reporting requirements of the award (NIH GPS chapter 15.2.1). Compliance with the PHS Policy and other applicable animal welfare regulations is a minimum requirement for receipt of NIH funds (NIH GPS 15.2.2, NIH GPS 4.1.1)... The Guide (p.15) also describes responsibilities that should be included in a formal written understanding..."

OLAW FAQ D.8 also reminds institutions that IACUC oversight "includ[es] semiannual facility inspection by an IACUC, reporting of concerns, and other IACUC functions..." as well as gives a practical description of how institutions proceed if dual review is elected.



Check Your Understanding

NIH-funded activities are subject to the requirements found in:

- a) The NIH Grants Policy Statement
- b) The Guide
- c) Both A and B
- d) Neither

Answer: C



Check Your Understanding

Activities not funded by NIH but that are subject to the PHS Policy are to follow:

- a) The NIH Grants Policy Statement
- b) The Guide
- c) Both A and B
- d) Neither

Answer: C

THE "WHERE"



Types of Agreements

Memoranda of Understanding (MOUs)

Material Transfer Agreements

Contracts

Inter-institutional Agreement (Different from an OLAW Inter-institutional Assurance!!)

Etc.

These documents may look different at different institutions.



What do these documents look like?

Depends on your institution's Office of General Counsel/Legal Affairs!

- FDP created an MOU template as a helpful starting point, but remember that OLAW is focused on the concepts as described in the NIH GPS, the Guide, and compliance with the PHS Policy.
 - We don't require you to use that template as long as you cover all the concepts somehow (listed in <u>FAQ D.8</u>).



THE "WHEN"





When do I use a formal written agreement like an MOU or contract for animal activities?

- If your activity is NIH-funded
- If your activity is subject to the PHS Policy and the Guide
- Remember, written agreements protect you, your people, and your animals!

THE "WHO"





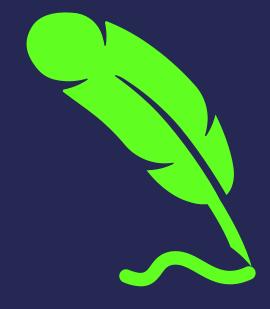
Who is responsible for the formal written agreement(s)?

- These agreements are established between the collaborating parties.
- The primary awardee *institution* is responsible:

"The primary <u>recipient</u> is responsible for fulfilling the obligations of an award and including these obligations in agreements with collaborating institutions (<u>NIH GPS</u> chapter 4.1.1.3)."



A NOTE ABOUT OTHER DOCUMENTS





Document Disambiguation (1)



Formal written agreement addressing the administrative aspects of animal care and use

This is pretty simple



The activities in the Domestic collaboration must be covered under someone's Assurance

This can be more complex



Document Disambiguation (2)

	Established Between	Designed by	When	Scope	Focus
Formal Written Agreement (i.e., MOU, contract, etc.)	The collaborating parties (directly)	The institution	Depends on the institutions' administrative needs.	Necessities and logistics of the collaboration	"addresses the responsibility for offsite animal care and use, animal ownership, and IACUC review and oversight" during the collaborative activity Guide, p. 15
Assurance	Institutions and OLAW	OLAW	At award	The institution's entire animal care and use program There are many kinds of Assurance-OLAW will reach out	 "documentation from an institution [to OLAW] assuring institutional compliance with this Policy" PHS Policy III.D Commitment to OLAW that the institution will follow the regulations A description of the entire animal care and use program Designation/signature of the Institutional Official



Activities Must Be Covered By An Assurance

Ok, so what kind of Assurance?

- OLAW Domestic Assurance: When an institution has their own animal care and use program
- OLAW Foreign Assurance: Same as above but is a foreign institution



- OLAW Interinstitutional Assurance: When the awardee does not have their own animal facility and will be conducting work at another performance site
 - NOT the same as an interinstitutional agreement between institutions
 (e.g., contract, MOU, etc.)



The Takeaway

- You need a formal written agreement for the animal-related details of the collaboration independent of anything else
- Collaborations involving animals may need additional documentation-OLAW will let you know



RESOURCES

Additional resources for drafting a written agreement or MOU are available in the Sample Documents section of the OLAW webpage.



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

Sample Memorandum of Understanding (MOUs) for Collaborating Institutions

Home - Resources - Sample Documents - Sample Memorandum of Understanding (MOUs) For Collaborating Institutions

Sample Memorandum of Understanding (MOUs) for Collaborating Institutions

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1. Introduction

*The use of this template for a memorandum of understanding (MOU) between collaborating institutions is not required and is provided for the convenience of Institutional Animal Care and Use Committees (IACUC) at Assured institutions. Sections may be added, deleted, or modified to meet the needs of individual programs.

The Guide for the Care and Use of Laboratory Animals (Guide) recommends that collaborating institutions involving animal use 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 (p.15).

To help institutions meet the requirements of the Guide and to reduce the administrative burden associated with developing MOUs, the Federal Demonstration Partnership^{ot}, in collaboration with OLAW, developed an MOU template. The template is intended to prevent problems and misunderstandings which could negatively impact research animals.

2. MOU Documents

The FDP provides two documents relevant to the MOU template. The documents can be accessed on the FDP "Animal Subjects Subcommittee" webpages and scrolling down to "Committee Resources and Tools."

- FDP IACUC MOU Sample:
 - Designed for single projects but could be modified for frequent collaborators
 - · Covers specific areas of concern for regulators
 - Program-wide acknowledgments
 - Transportation
 - · Ownership & oversight
 - · Investigation & reporting
 - Other (blank)
- FDP IACUC MOU User Guide
 - Intentionally non-prescriptive
 - · Provides definitions to "translate" from each office
 - Provides considerations for offices in choosing what documentation mechanism to utilize (i.e., MOU, subaward, Interinstitutional Assurance)
 - Provides high-level considerations for institutions on how collaborative research is documented
 - FAOs highlight specific considerations



3. Quick Answers

+ Is using this MOU template required by OLAW?

No. This example format is not required. This is being offered as a resource to assist institutions if desired.

+ What should be included a formal written agreement for animal collaborations (such as an MOU or contract)?

The exact contents of the formal written agreement may depend on the nature of the collaboration, animal activity involved, and the institution's needs.

+ What is the difference between an MOU and an Interinstitutional Assurance?

Although collaborating institutions are involved in both cases, the MOU and the Interinstitutional Assurance are different documents and do not substitute for one another.

A memorandum of understanding (MOU) is one type of document that may be used as a formal written agreement to meet the *Guide* statement (p.15^d) regarding collaborations. The purpose of a formal written agreement is to address the responsibilities for animal care and use and avoid ambiguities that can lead to noncompliance and animal welfare concerns.

The Interinstitutional Assurance is a type of Animal Welfare Assurance issued by OLAW to an awardee institution that does not have its own:

- · animal care and use program
- · facilities to house animals
- Institutional Animal Care and Use Committee (IACUC); and
- · does not conduct animal research on-site.

An official website of the United States government Here's how you know

Semiannual Report to the Institutional Official

Animal Study Proposal

U.S. Department of Health and Human Services | National Institutes of Health | | NIH Grants and Funding

VA

NASA

NSF





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Office of Laboratory Animal Welfare

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

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

Animal Study Proposal

Sample Memorandum of Understanding (MOUs) for Collaborating Institutions

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

When in doubt...

Reach out!



Division of Policy and Education: olawdpe@mail.nih.gov

Division of Assurances: olawdoa@mail.nih.gov



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