



GUIDANCE DOCUMENT - IACUC & SUBAWARDS COLLABORATION

INTRODUCTION

This Guidance document was created by a working group under the direction of the FDP IACUC and Subawards Subcommittees as a companion document to the sample FDP Memorandum of Understanding (MOU). Questions regarding this document or the MOU should be directed to the FDP IACUC Subcommittee at FDP-IACUC-L@lsw.nas.edu or the FDP Subawards Subcommittee at subawards@thefdp.org.

The [Guide for the Care and Use of Laboratory Animals, 8th Edition](#) (the Guide) states that an MOU, contract or other agreement should “address the responsibility for offsite animal care and use, animal ownership and IACUC review and oversight. In addition, IACUCs from the participating institutions may choose to review protocols for the work being conducted.” The MOU is designed to adhere to those recommendations from the Guide. The current version of the sample MOU is designed as a project-specific MOU for domestic institutions and is not intended to serve as a blanket MOU between institutions or to be used for international collaborations. We recognize the community’s desire for sample MOUs that address those needs, and hope to provide such templates in the future, employing any lessons learned from piloting the current sample MOU.

The MOU should consider the expectations and/or regulations of federal agencies that have oversight of vertebrate animal research use, testing and teaching. It is designed to be flexible so that it may be used in situations where vertebrate animal activities are funded by external federal or non-federal sponsors, or using only internal funds. It may also be used to supplement an Interinstitutional Assurance (IIA) put in place between two parties to provide more specificity regarding the roles and responsibilities of each of the parties.

Both the Office of Laboratory Animal Welfare (OLAW) and AAALAC International (AAALAC; formerly known as Association for Assessment and Accreditation of Laboratory Animal Care International) use the Guide. OLAW-assured and AAALAC-accredited institutions are expected to abide by the Guide. In addition, we have considered USDA guidelines, where appropriate. This Guidance document attempts to clarify implementation of the expectations of the Guide with respect to agreements between collaborating institutions using vertebrate animals, describes when and how the MOU is to be used, and explains in more detail certain terms used in the MOU. As with all written agreements, if circumstances evolve over the course of the collaboration, the parties should revisit the terms of the MOU and modify it accordingly, or otherwise terminate the MOU if the collaborative animal activities come to an end.

DISCLAIMER

Nothing in this document constitutes legal advice. Any interpretation is that of this working group. Please conduct your own due diligence and/or contact your institution’s legal team(s) as appropriate.

DEFINITIONS

Memorandum of Understanding (MOU): A memorandum of understanding (MOU) is an agreement between two or more parties outlined in a formal document (NCURA, Sponsored Research Administration: A Guide to Effective Strategies and Recommended Practices). Each party needs to decide, per its internal policy, who is an authorized signatory on an MOU. For the purposes of this Guidance, an MOU is to be used by collaborating institutions in circumstances that involve research with vertebrate animals. The MOU is a collegial agreement that establishes the roles and responsibilities of each party with respect to animal care and oversight of the research and may be used as supporting documentation to a research Subaward, if applicable. While FDP suggests a particular MOU format (see sample MOU), the specific language and expectations included in an



MOU are for the parties involved to decide. The ultimate goal of the sample MOU is to ensure that the parties have consistent expectations with respect to their animal research collaboration, including but not limited to the following areas: Principles of Communication, Program-wide Acknowledgements, Transportation, Ownership and Oversight, Investigation and Reporting.

OLAW-assured Institution: “OLAW assures PHS-funded animal activities. PHS funding components include the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA). Through memoranda of understanding, OLAW additionally assures animal activities funded by the Veteran’s Administration (VA), Biomedical Advanced Research and Development Authority (BARDA), National Aeronautics and Space Administration (NASA) and the National Science Foundation (NSF)” (*Obtaining an Assurance | OLAW*, n.d.) An Animal Welfare Assurance (Assurance) must be obtained from OLAW in order to receive funding from the PHS and other federal agencies listed above. **Note:** [these covered federal agencies](#) may change over time.

Interinstitutional Assurance (IIA): “The Interinstitutional Assurance is required when the awardee institution does not have its own: animal care and use program; facilities to house animals; IACUC; and does not conduct animal research on-site.” (*Obtaining an Assurance | OLAW*, n.d.) “In this situation, the awardee institution will conduct the animal activity at an Assured institution (named as a performance site).” (*Interinstitutional Assurance | OLAW*, n.d.)

Research: The use of the term “research” in this guidance is intended to refer to any live vertebrate animal use in research, research training, experimentation, or biological testing or for related purposes.

Subaward: “*Subaward* means an award provided by a pass-through entity to a subrecipient for the subrecipient to carry out part of a [non-Federal or] Federal award received by the pass-through entity...A subaward may be provided through any form of legal agreement, including an agreement that the pass-through entity considers a contract.” (2 CFR 200.1 Definitions)

WHY DO INSTITUTIONS NEED MOUs?

- OLAW-assured institutions must adhere to the current edition of the *Guide for the Care and Use of Laboratory Animals* (currently 8th Edition). It states, “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.” (Guide, p. 15)
- It is up to the collaborating institutions to come up with something by which they can abide. Aside from the VA, there is no mechanism specified as a requirement by the federal agencies. Therefore, the collaborating institutions may elect to use a variety of mechanisms, including an MOU, inclusion in a subaward, or other documentation as may be appropriate and agreed upon by the collaborating institutions.

WHAT IS THE PURPOSE OF AN MOU vs. A SUBAWARD?

A subaward is the contractual mechanism for funding the subrecipient to carry out animal research, in compliance with applicable sponsor regulations and policies, as part of a collaborative project. An MOU details



how each collaborating party will ensure appropriate care and oversight of the animals involved in the project. An MOU may be supplemental to a subaward or it may be a standalone document.

MOUs:

- Provide institution-specific compliance information such as USDA registration, PHS Assurance and AAALAC accredited organization numbers.
- Specify ownership of the animals.
- Clarify roles and responsibilities for the care and use of animals.
- Specify appropriate expectations, responsibilities and notification requirements between the parties and oversight authorities in key areas such as inspections, record retention, and reporting.
- If applicable, provide details regarding transportation of the animals, such as which party is responsible during each phase of transport.
- If applicable, describe each party's expectations with regard to accessing the other party's facility for purposes of the animal collaboration, the reciprocal care and notification responsibilities of the two parties in caring for the animals, and any policies or procedures that apply to the foregoing activities.

Subawards:

- Include a Statement of Work that may describe the activities, including any animal related activities, that the subrecipient intends to perform during the project.
- Provide funding to perform such activities.
- Include any applicable flow downs from the sponsor regarding animal care and use activities.
- Ensure that the subrecipient contractually certifies that it is in full compliance with applicable state and federal laws and regulations regarding animal care and use activities.
- Include a stipulation that the subrecipient shall not invoice or be reimbursed for any animal-related expenses incurred for activities that have not been reviewed and approved by the IACUC.
- If applicable per sponsor's policies, ensures that the subrecipient certifies that any submitted IACUC approval represents a valid, approved protocol that is congruent with the project associated with the subaward.

WHO IS REQUIRED TO HAVE AN MOU/AGREEMENT?

- Two or more collaborating institutions where the institutions are subject to the Guide, including but not limited to, OLAW-assured institutions and/or AAALAC-accredited institutions.

Regardless of funding source or Assurance or accreditation status, a written agreement or MOU is valuable for eliminating ambiguities regarding animal activity roles and responsibilities.

WHO SHOULD SEE THE MOU?

- Anyone responsible for the handling or oversight of animals. This may include, but is not limited to, the IACUC, IACUC administrators, veterinarians/animal care staff, and the research team, defined as,



“principal investigators, study directors, research technicians, postdoctoral fellows, students, and visiting scientists” (Guide, p. 16).

- Sponsored projects staff
- Unit/departmental administrators who support researchers
- Institutional Official
- During the course of an inspection, the MOU may need to be available for review by the inspecting agency.

WHO IS RESPONSIBLE FOR IMPLEMENTING THE MOU?

- Anyone responsible in whole or in part for the handling or oversight of animals at both institutions. This may include, but is not limited to, the IACUC, veterinarians/animal care staff, administrators, and the research team (as defined above).
- Ongoing adherence to the terms of the MOU is expected by both parties. Both parties should be aware that regulatory agencies could review the MOU to determine to which party a citation should be issued when noncompliance with PHS Policy is identified.

Recommendations for planning and institutional communication related to the MOU

Institutions should consider communication flow, process-related issues and other institution-specific information sharing and processes that may be documented in institutional SOPs, such as:

- Who should sign the MOU?
- Who defines roles and responsibilities in carrying out the MOU?
- What are the key points to address with others when discussing the expectations of an MOU across the institution?
- Under what circumstances should MOUs be entity-specific, project specific, or both?

FAQs

Q: When during the lifecycle of a project should an MOU be issued?

- A. The MOU should be issued at any point before the start of the animal work at the collaborating institution(s).

Q: Under what circumstances should an institution develop and implement an MOU? (MOU scenarios). For the purposes of this FAQ, instead of referring to Institution A and B, we utilize Party 1 and Party 2, because the roles may vary based on the specific nature of the collaboration.

A: The role of the parties with respect to the live vertebrate animal research is collaborative, i.e. not a vendor/service relationship. Examples of scenarios which could necessitate an MOU include:

- Transportation of research animals*; OR
- Party 1 is funding either directly or via a subaward Party 2's purchase and use of live vertebrate animals in Party 2's facility; OR
- Staff/employees of Party 1 will visit the facility of Party 2 to care for/use animals in research; OR
- Party 1 purchases and retains ownership of the animals while Party 2 cares for/uses the animals in research; OR
- Party 1 owns and cares for the animals and will use a substance or device on the animals that is produced by Party 2; OR
- The parties are establishing a long-term collaboration that will span several projects; OR



- The sponsor of the project imposes terms and conditions that requires Party 1 to have specific oversight over the animal research activities of Party 2; AND
- The parties have not otherwise executed another contract between them that addresses the responsibility for offsite animal care and use, animal ownership, and IACUC review and oversight. In some cases, a subaward may describe these responsibilities.

Note that the Guide recommends that the parties establish an MOU regardless of whether funds are exchanged to ensure clear communication regarding the care of live vertebrate animals.

*If the collaboration involves only the transportation of research animals, you may establish some other mechanism or agreement to document the transportation (see p. 107 of the Guide for details) and an MOU is likely not required.

Q: Does the USDA require an MOU?

A: The USDA recommends having a written agreement between the collaborating parties. During the inspection process in the event of a noncompliance with the Animal Welfare Act, the USDA will look for a written agreement to determine responsibilities.

Q: How does an institution apply for a PHS Assurance?

A: For instructions on obtaining an Assurance from OLAW, go to <https://olaw.nih.gov/guidance/obtaining-an-assurance.htm>.

Q: How does an institution obtain an Interinstitutional Assurance (IIA)?

A: For information on obtaining an IIA, go to <https://olaw.nih.gov/resources/documents/interinstitutional-assurance.htm>

Q: What if my institution is engaging in multiple animal research collaborations with another Party - is an overarching institutional MOU between the two institutions acceptable, or must we execute an MOU for each individual project?

A: The sample MOU is designed for project-specific collaborations. However, institutions may modify the MOU sample as necessary to facilitate larger, broader, institutional collaboration. If the terms and conditions are significantly modified for any reason, including amending the template to create an institution-level MOU, please remove the FDP moniker from the first page header.

Q: How do we determine who is an appropriate institutional point of contact for the MOU, including defining their role in the process?

A: In the context of the MOU, each Party should define who would be the responsible individual for signing the MOU, as well as for making and receiving applicable reports and identify them as the contact in the MOU. Establishing an MOU, signature authority and reporting responsibilities may lie with different parties. Identifying the appropriate personnel depends heavily on institutional roles and responsibilities.

Q: What is the “Other Requirement Not Addressed Above” section of the sample MOU intended to address?

A: Parties should consider using this section of the MOU template if the existing categories of the template do not address unique terms and conditions of a particular award or collaboration, or in instances where the collaboration/project is particularly high-risk (procedurally or reputationally) which may dictate certain additional safeguards.



Q: What should we consider when determining who will sign the MOU?

A: This will vary by institution. The MOU recommends that the IACUC chair, IACUC administrator, attending veterinarian (AV) and/or the Institutional Official (IO) be the signatories for this document, as it relates directly to animal care and use. However, some institutions have chosen to have the MOU flow through another office. As long as the required offices are communicating, institutions should assign responsibilities as suits their work flow.

Q: Under what circumstances should MOUs be project or institution specific?

A: The project specific version is most useful when you have a single project or small subset of collaborative projects with similar requirements. In these cases, it is useful to be able to track the specific details of each collaboration. There are institutions with whom you may have a high volume of collaboration and thus an institution level MOU may reduce burden.

Q: Should I append a copy of the MOU to my subaward or vice versa?

A: The MOU is designed such that it can be and often is utilized as a standalone document. However, this will vary by institution. Some institutions, based on their business processes and workflows, may find appending the MOU reduces burden.

Q: What office or individuals should be provided a copy of the fully executed MOU and any amendments?

At a minimum, a copy of the fully executed MOU and any subsequent amendments should be made available to the following individuals at both institutions (or otherwise be informed that a copy of the MOU is available upon request):

- IACUC Chair and/or IACUC coordinator
- MOU signatories
- Attending Veterinarian
- Principal Investigators

Institutions should consider whether further distribution or access to the fully executed MOU and subsequent amendments is warranted based on institutional processes.

Q: Are there any particular considerations in regards to sharing information between public and private institutions?

Disclosure obligations should be considered before sharing any information across institutions. The parties to the MOU should be mindful about differing requirements as they relate to private vs. public institutions and state laws. It is recommended that the parties consult general counsel before sharing sensitive information.

Q: How is the sample MOU to be used when an IIA is in place between two parties?

An IIA is required when an institution receives Public Health Service (PHS) funds through a grant or contract award and will conduct the animal activity at an Assured Institution, but does not have the following:

- its own animal care and use program;
- facilities to house animals; and
- an Institutional Animal Care and Use Committee (IACUC).



The IIA provides a broader statement of institutional responsibilities for the awardee and Assured institution, but does not specify in detail the roles of each of the two parties as it relates to animal care and use. As such, the sample MOU may be used to supplement the IIA to provide more specificity regarding the roles and responsibilities of each of the parties.

Q: Can the sample MOU be used for all types of collaborations, including non-PHS collaborations and those involving international parties?

No. The current version of the sample MOU is designed as a project-specific MOU for domestic institutions and is not intended to serve as a blanket MOU between institutions or to be used for international collaborations. We recognize the community's desire for sample MOUs that address those needs, and hope to provide such templates in the future, employing any lessons learned from piloting the current sample MOU. However, institutions may modify the MOU sample as necessary to facilitate other types of collaborations if desired. Please remove the FDP moniker if MOU sample terms and conditions are modified.

Q: Who is responsible for [congruency reviews](#)?

The two parties should agree who will perform the congruency review at the time of negotiating the MOU. If it is a prime/subrecipient relationship, the prime will have the final decision as to which institution's review constitutes the official congruency review.

Q: What are some scenarios that may result in a modification or termination of the MOU?

Some scenarios that may necessitate a modification to or termination of the MOU include (but are not limited to) the following:

- Grant or project terminated by the sponsor
- A change in where animals will be housed or where research will be performed
- Substantive change in scope of work
- Change in PI
- PI and project transfer to another institution
- Non-compliance remediation

The parties should terminate the MOU at the end of the project once animal activities have been completed or termination of one or both IACUC protocols.

REFERENCES

1 Obtaining an Assurance | OLAW. (n.d.). Retrieved September 26, 2020, from <https://olaw.nih.gov/guidance/obtaining-an-assurance.htm>

2 Interinstitutional Assurance | OLAW. (n.d.). Retrieved September 26, 2020, from <https://olaw.nih.gov/resources/documents/interinstitutional-assurance.htm>

3 National Research Council. Guide for the Care and Use of Laboratory Animals. 8th ed. Washington, D.C.: The National Academies Press, 2011.

4 AAALAC International Connection newsletter, Spring 2003. Retrieved October 25, 2021, from https://ar.aaalac.org/publications/Connection/Spring_2003_lowres.pdf

5 USDA Animal Welfare Inspection Guide | Revised January 2021. Retrieved October 25, 2021 from https://www.aphis.usda.gov/animal_welfare/downloads/Animal-Care-Inspection-Guide.pdf



6 OLAW FAQs. Retrieved October 25, 2021 from <https://olaw.nih.gov/faqs/#/guidance/faqs>