

IACUC Policy: Collaborative Work

The intent of this policy is to provide guidance for review of projects involving collaborative work with live animals at outside organizations.

A. Policy

1. If work with live vertebrate animals is being done at an outside organization (Collaborating Organization) through an award, sub-award, contract or sub-contract from the University of Massachusetts Amherst (UMass), UMass is accountable for ensuring that work conducted meets all applicable regulations.
2. Such projects are subject to review and approval by the UMass Institutional Animal Care and Use Committee (UMass IACUC). The UMass IACUC will typically perform a sub-committee review and acceptance of the project (usually consisting of the IACUC Chair, Consulting Veterinarian and the Research Compliance Specialist). The extent of the review will depend upon:
 - Nature of the proposed work to be conducted at the Collaborating Organization; and
 - A demonstrated ability by the Collaborating Organization to maintain the highest standards of humane care and use of animals, as evidenced by a current PHS Assurance, an active certification with the United States Department of Agriculture (USDA) or equivalent certifications. Foreign organizations should comply with International Guiding Principles for Biomedical Research Involving Animals developed by the Council for International Organizations of Medical Sciences (CIOMS) or equivalent.
 - i. When such evidence is available, the UMass IACUC may decide to not perform a duplicate review of the proposed animal use to be conducted at the Collaborating Organization.
3. For projects funded by the Public Health service (PHS)¹, the Collaborating Organization must hold a current PHS Assurance. For projects using USDA covered species² in the USA, the Collaborating Organization must be certified by the United States Department of Agriculture (USDA). Equivalent certification may be required for foreign Collaborating Organizations.

B. Procedure

1. If the live animal work proposed at the Collaborating Organization is approved by its IACUC, and the organization has a current AAALAC Accreditation, PHS Assurance, other acceptable accreditations or certifications, the UMass IACUC may elect to not

perform a duplicate review and instead enter into an administrative Inter-Institutional Agreement (IIA) with the Collaborating Organization.

2. Examples of IIAs are provided in the Appendix. The UMass IACUC will decide on an appropriate agreement on a case by case basis. The following procedure applies:
 - a. The UMass PI on the project submits an IACUC protocol to the UMass IACUC via e-Protocol with the following information:
 - Details of the collaboration and the role of the UMass PI in the project
 - Name of IACUC contact person at the Collaborating Organization.
 - b. The UMass IACUC office will initiate a IIA, asking the contact person at the Collaborating Organization for:
 - A copy of the Collaborating Organization's protocol sections describing the animal work proposed in the grant proposal
 - An approval letter from the Collaborating Organization's IACUC for the proposed animal use
 - The Collaborating Organization's applicable certifications including:
 - Current PHS Assurance number
 - AAALAC certification status
 - Current USDA registration
 - c. The UMass IACUC sub-committee reviews the protocol and IIA, the IIA is signed by both institutions once all criteria have been met.
 - d. If the Collaborating Organization does not have the certifications/accreditations UMass IACUC will decide on a case-by-case basis whether sponsored work with animals is permitted and the terms and conditions under which work can be conducted.
 - e. PI responsibilities:
 - If informed of serious incidents of animal welfare concerns or non-compliance reported to the Collaborating Organization's IACUC or external regulatory agencies, report them promptly to the UMass IACUC.
 - f. If the UMass IACUC has concerns about the welfare or humane treatment of animals at the Collaborating Organization or if there is evidence of loss of accreditation, citations by regulatory agencies or other such significant events, the UMass IACUC may require additional details from the PI or the Collaborating Organization or may revoke the agreement.
3. Appendix:

Authorization Agreements

- a. IIA with Domestic Collaborating Organizations **with** PHS Assurance
 - b. IIA with Foreign Collaborating Organizations **with** PHS Assurance
 - c. IIA with Domestic Collaborating Organizations **without** PHS Assurance
 - d. IIA with Foreign Collaborating Organizations **without** PHS Assurance
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¹Agencies under the Public Health Service (PHS) include the National Institutes of Health (NIH), Food and Drug Administration (FDA), National Science Foundation (NSF) and the Centers for Disease Control and Prevention (CDC).

²The USDA defines 'covered species' as any warm blooded animals used for research, teaching, testing, experimentation or exhibition. It excludes: all birds, rats of the genus *Rattus* and mice of the genus *Mus* bred for use in research, and horses and other farm animals not used for research purposes, such as, but not limited to livestock or poultry used or intended for use as food or fiber, and livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber.

Inter-Institutional Agreement: **Domestic** Collaborating Organizations with PHS Assurance

I. University of Massachusetts (Amherst Campus) PHS Assurance #: A3551-01

Principal Investigator:

Project Title: *(from grant application/contract proposal, if applicable)*

UMass IACUC Protocol Number:

Sponsor or Funding Agency:

Grant/Contract Number:

II. Collaborating Organization

Name of Organization:

Principal Investigator:

PHS Animal Welfare Assurance number:

AAALAC certification status:

USDA Registration Certificate Number:

IACUC Protocol Title:

IACUC Protocol Number:

IACUC Approval Date:

A. Applicability

This Inter-Institutional Agreement between University of Massachusetts, Amherst and the Collaborating Organization is applicable to research, teaching, and biological testing with live vertebrate animals for the specific project funded by the University of Massachusetts and conducted at the Collaborating organization.

B. Collaborating Organization Responsibilities

- i. The organization agrees to comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- ii. The organization agrees to be guided by the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training and comply with the PHS Policy on Humane Care and Use of Laboratory Animals (Policy).
- iii. The organization acknowledges and accepts responsibility for the care and use of animals involved in activities under this project. As partial fulfillment of this responsibility, the organization will provide routine oversight of the project as required by local, state, and federal laws and the *Guide* including: ensuring appropriate training for animal use personnel; performing facility inspections and program reviews; providing husbandry and veterinary care; reviewing and approving

changes to the protocol as the project goes forward; investigating complaints and deficiencies related to animal use.

- iv. The organization will forward copies of the protocol, protocol amendments and protocol renewals related to the project to UMass Amherst's IACUC office along with documentation of IACUC approval.
- v. The organization will provide a copy of a report of a confirmed deficiency that could impact the project, with a plan for resolution, to UMass Amherst's IACUC office for review. In the event the deficiency could adversely affect the welfare of the animals used in the project, UMass Amherst's IACUC office will be informed immediately.
- vi. If applicable, the organization will forward copies of USDA Inspection Reports to UMass Amherst's IACUC office when the Report contains citation(s) relevant to the project, and /or reflects a programmatic problem that could impact the research along with documentation showing how each citation was addressed.
- vii. The organization must notify UMass Amherst's IACUC office immediately in the event of suspension of animal use privileges.
- viii. If the UMass IACUC has concerns about the welfare or humane treatment of animals under the study, if there is evidence of loss of accreditation, citations by regulatory agencies or other such significant events, the UMass IACUC may require additional details from the PI or the Collaborating Organization or revoke the agreement at any time.

III. Endorsement

By signing this document, the authorized officials at the University of Massachusetts, Amherst and the Collaborating Organization provide their assurances that the project identified in Part I will be conducted in compliance with the PHS Policy and the Assurance of the Collaborating Organization.

Endorsement of University of Massachusetts, Amherst

Signature of Authorized Official:

Name:

Date:

Title:

Address:

Phone:

E-mail:

Endorsement of Collaborating Organization

Name of Collaborating Organization:

Signature of Authorized Official:

Name:

Date:

Title:

Address:

Phone:

E-mail:

**Inter-Institutional Agreement: Foreign Collaborating
Organizations with PHS Assurance**

I. University of Massachusetts (Amherst Campus) OLAW Assurance #: A3551-01

Principal Investigator:

Project Title: *(from grant application/contract proposal, if applicable)*

UMass IACUC Protocol Number:

Sponsor or Funding Agency:

Grant/Contract Number:

II. Collaborating Organization

Name of Organization:

Principal Investigator:

Animal Welfare Assurance number:

AAALAC certification status (or status of another Accreditation):

IACUC/Review Board Protocol Title:

IACUC/Review Board Protocol Number:

IACUC/Review Board Approval Date:

A. Applicability

This Authorization Agreement between University of Massachusetts and the Collaborating Organization (performance site) is applicable to research, teaching, and biological testing with live vertebrate animals for the specific project funded by the University of Massachusetts, Amherst and conducted at the Collaborating Organization.

B. Collaborating Organization Responsibilities

- i. The Collaborating Organization agrees to comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals ([Policy](#)).
- ii. The Collaborating Organization acknowledges and accepts responsibility for the care and use of animals involved in activities under this project. As partial fulfillment of this responsibility, the Collaborating Organization will provide routine oversight of the project as required by local, state, and federal laws and the *Guide* including: ensuring appropriate training for animal use personnel; performing facility inspections and program reviews; providing husbandry and veterinary care; reviewing and approving changes to the protocol as the project goes forward; investigating complaints and deficiencies related to animal use.

- iii. The organization will forward copies of the protocol, protocol amendments and protocol renewals related to the project to UMass Amherst's IACUC office along with documentation of IACUC approval.
- iv. The organization will provide a copy of a report of a confirmed deficiency that could impact the project, with a plan for resolution of the deficiency, to UMass Amherst's IACUC office for review. In the event the deficiency could adversely affect the welfare of the animals used in the project, UMass Amherst's IACUC office will be informed immediately that the deficiency is confirmed with a plan for resolutions.
- v. If applicable, the organization will forward copies of USDA Inspection Reports to UMass Amherst's IACUC office when the Report contains citation(s) relevant to the project, and /or reflects a programmatic problem that could impact the research along with documentation showing how each citation in a USDA Inspection Report relevant to the project was addressed.
- vi. The organization must notify UMass Amherst's IACUC office immediately in the event of suspension of animal use privileges.
- vii. If the UMass IACUC has concerns about the welfare or humane treatment of animals under the study, if there is evidence of loss of accreditation, citations by regulatory agencies or other such significant events, the UMass IACUC may require additional details from the PI or the Collaborating Organization or revoke the Authorization agreement at any time.

III. Endorsement

By signing this document, the authorized officials at UMass Amherst and the Collaborating Organization provide their assurances that the project identified in Part I will be conducted in compliance with the Assurance of the Collaborating Organization.

Endorsement of the University of Massachusetts, Amherst

Signature of Authorized Official:

Name:

Date:

Title:

Address:

Phone:

E-mail:

Endorsement of Collaborating Organization

Name of Collaborating Organization:

Signature of Authorized Official:

Name:

Date:

Title:

Address:

Phone:

E-mail:

Inter-Institutional Agreement: Domestic Collaborating Organizations
without PHS Assurance

I. University of Massachusetts (Amherst Campus) PHS Assurance #: A3551-01

Principal Investigator:

Project Title: *(from grant application/contract proposal, if applicable)*

UMass IACUC Protocol Number:

Sponsor or Funding Agency:

Grant/Contract Number:

II. Collaborating Organization

Name of Organization:

Principal Investigator:

AAALAC certification status:

USDA Registration Certificate Number:

IACUC Protocol Title:

IACUC Protocol Number:

IACUC Approval Date:

A. Applicability

This Authorization Agreement between University of Massachusetts, Amherst and the Collaborating Organization is applicable to research, teaching, and biological testing with live vertebrate animals for the specific project funded by the University of Massachusetts and conducted at the Collaborating Organization.

B. Collaborating Organization Responsibilities

- i. The organization agrees to comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- ii. The organization agrees to be guided by the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training .
- iii. The organization acknowledges and accepts responsibility for the care and use of animals involved in activities under this project. As partial fulfillment of this responsibility, the organization will provide routine oversight of the project as required by local, state, and federal laws and the *Guide* including: ensuring appropriate training for animal use personnel; performing facility inspections and program reviews; providing husbandry and veterinary care; reviewing and approving changes to the protocol as the project goes forward; investigating complaints and deficiencies related to animal use.

- iv. The organization will forward copies of the protocol, protocol amendments and protocol renewals related to the project to UMass Amherst's IACUC office along with documentation of IACUC approval.
- v. The organization will provide a copy of a report of a confirmed deficiency that could impact the project, with a plan for resolution of the deficiency, to UMass Amherst's IACUC office for review. In the event the deficiency could adversely affect the welfare of the animals used in the project, UMass Amherst's IACUC office will be informed immediately that the deficiency is confirmed with a plan for resolutions.
- vi. If applicable, the organization will forward copies of USDA Inspection Reports to UMass Amherst's IACUC office when the Report contains citation(s) relevant to the project, and /or reflects a programmatic problem that could impact the research along with documentation showing how each citation in a USDA Inspection Report relevant to the project was addressed.
- vii. The organization must notify UMass Amherst's IACUC office immediately in the event of suspension of animal use privileges.
- viii. If the UMass IACUC has concerns about the welfare or humane treatment of animals under the study, if there is evidence of loss of accreditation, citations by regulatory agencies or other such significant events, the UMass IACUC may require additional details from the PI or the Collaborating Organization or revoke the Authorization agreement at any time.

III. Endorsement

By signing this document, the authorized officials at the University of Massachusetts, Amherst and the Institutional Official and IACUC Chairperson at the Collaborating Organization (performance site) provide their assurances that the project identified in Part I will be conducted in compliance with all the applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals. The organization agrees to be guided by the U.S. government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research and Training.

Endorsement of University of Massachusetts, Amherst

Signature of Authorized Official:

Name:

Date:

Title:

Phone:

Address:

E-mail:

Endorsement of Collaborating Organization

Name of Collaborating Organization:

Signature of Authorized Official:

Name:

Date:

Title:

Phone:

Address:

E-mail:

Signature of IACUC Chair:

Date:

**Inter-Institutional Agreement: Foreign Collaborating
Organizations without PHS Assurance**

I. University of Massachusetts (Amherst Campus) OLAW Assurance #: A3551-01

Principal Investigator:

Project Title: *(from grant application/contract proposal, if applicable)*

UMass IACUC Protocol Number:

Sponsor or Funding Agency:

Grant/Contract Number:

II. Collaborating Organization

Name of Organization:

Principal Investigator:

Certification for animal use issued by the country (if applicable):

AAALAC certification status (or status of another Accreditation):

IACUC/Review Board Protocol Title:

IACUC/Review Board Protocol Number:

IACUC/Review Board Approval Date:

A. Applicability

This Authorization Agreement between University of Massachusetts and the Collaborating Organization (performance site) is applicable to research, teaching, and biological testing with live vertebrate animals for the specific project funded by the University of Massachusetts, Amherst and conducted at the Collaborating Organization.

B. Collaborating Organization Responsibilities

- i. The Collaborating Organization agrees to comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals ([Policy](#)).
- ii. The Collaborating Organization acknowledges and accepts responsibility for the care and use of animals involved in activities under this project. As partial fulfillment of this responsibility, the Collaborating Organization will provide routine oversight of the project as required by local, state, and federal laws and the *Guide* including: ensuring appropriate training for animal use personnel; performing facility inspections and program reviews; providing husbandry and veterinary care; reviewing and approving changes to the protocol as the project goes forward; investigating complaints and deficiencies related to animal use.

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- v. If applicable, the organization will forward copies of USDA Inspection Reports to UMass Amherst's IACUC office when the Report contains citation(s) relevant to the project, and /or reflects a programmatic problem that could impact the research along with documentation showing how each citation in a USDA Inspection Report relevant to the project was addressed.
- vi. The organization must notify UMass Amherst's IACUC office immediately in the event of suspension of animal use privileges.
- vii. If the UMass IACUC has concerns about the welfare or humane treatment of animals under the study, if there is evidence of loss of accreditation, citations by regulatory agencies or other such significant events, the UMass IACUC may require additional details from the PI or the Collaborating Organization or revoke the Authorization agreement at any time.

III. Endorsement

By signing this document, the authorized officials at UMass Amherst and the Collaborating Organization provide their assurances that the project identified in Part I will be conducted in compliance with the International Guiding Principles for Biomedical Research Involving Animals or other acceptable standards for the humane care and use of animals.

Endorsement of the University of Massachusetts, Amherst

Signature of Authorized Official:

Name:

Date:

Title:

Address:

Phone:

E-mail:

Endorsement of Collaborating Organization

Name of Collaborating Organization:

Signature of Authorized Official:

Name:

Date:

Title:

Phone:

Address:

E-mail: