

Animal Care and Use Policy

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Responsible Office:	Office of Sponsored Programs
Responsible Executive:	Vice Provost for Research and Innovation
Applies to:	Faculty, Staff and Administrators

POLICY STATEMENT

Norfolk State University (NSU) employees may conduct research involving animals only with the prior approval of an Institutional Animal Care and Use Committee (IACUC), under the auspices of an Inter-institutional Assurance with an assured institution. NSU does not have its own IACUC. Therefore, an Inter-institutional Assurance and prior IACUC approval are required, regardless of the funding source of the research project.

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals requires that all recipient organizations receiving PHS support for research or related activities using live vertebrate animals have an approved Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW) at the National Institutes of Health (NIH) at the time of award. Institutions receiving funding for animal use must establish appropriate policies and procedures to ensure the humane care and use of animals and bear ultimate responsibility for compliance with the PHS Policy in all PHS supported activities.¹

PHS guidance concerning the use of animals in research states that any application proposing the use of animals is incomplete if it does not thoroughly address the use of vertebrate animals required in the Research Plan of the application. The applicant should provide an explanation if the involvement of animals is indefinite at the time of the application indicating when it is anticipated that animals will be used. Prior approval must be requested from the National Institute of Health awarding Institute/Center if an award is made prior to conducting any animal research or activities.

TABLE OF CONTENTS:	PAGE NUMBER
Definitions.....	2
Contacts.....	2
Stakeholder(s) (For Administrative Policy).....	2
Policy Contents.....	2
Education and Compliance.....	4
Publication.....	4
Review Schedule.....	4
Related Documents.....	4
Form.....	5

Animal Care and Use Policy

DEFINITIONS:

Animal: Any live, vertebrate animal used or intended for use in research, research training, experimentation, biological testing or related purposes, as per PHS Policy, and any regulated animal under 9 C.F.R. 1.1.

Animal Welfare Assurance: The document submitted by an institution assuring institutional compliance with the PHS Policy.

Authorized Organizational Representative (AOR): The AOR serves as the designated representative with delegated signature authority in matters related to research.

Institutional Animal Care and Use Committee (IACUC): Committee required by federal regulations for institutions that use animals in research, teaching, and testing. The IACUC has oversight role including the review and approval of animal use activities, and inspection of animal facilities.

Inter-institutional Assurance: provides assurance that the collaborative animal use has received Institutional Animal Care and Use Committee (IACUC) review

Office of Laboratory Animal Welfare (OLAW): The office at the National Institutes of Health which oversees the care and use of research animals in any public or private organization, business or agency.

CONTACT(S):

The Vice Provost for Research and Innovation and the Office of Sponsored Programs officially interprets this policy. The Vice Provost for Research and Innovation and the Office of Sponsored Programs is responsible for obtaining approval for any revisions as required by BOV Policy # 01 (2014) Creating and Maintaining Policies through the appropriate governance structures. Questions regarding this policy should be directed to The Vice Provost for Research and Innovation and the Office of Sponsored Programs.

STAKEHOLDER(S):

Faculty and Administrators

POLICY CONTENTS PUBLICATION:

This statement sets forth policy and procedures for animal care and use for all external funding sought by faculty, staff and students on behalf of NSU. NSU is subject to numerous sponsor requirements as an organization conducting research and seeking external funding. These requirements include, but are not limited to, those established by specific solicitations, general sponsor guidelines, and the OMB Uniform Guidance, as well as NSU's own institutional policy.

Procedures:

Norfolk State University does not have any active research using animals on campus and therefore does not have an IACUC nor an Animal Welfare Assurance. NSU researchers who are engaged in research involving animals do so through sub-contractual agreements with other partners who have an IACUC and an Animal Welfare Assurance. Because NSU does not have an Assurance, animal activities will be

Animal Care and Use Policy

conducted at an Assured institution named as a performance site. NSU must obtain an Inter-institutional Assurance (IIA) from OLAW at NIH, as required by PHS.

Memorandum of Understanding (MOU): Inter-institutional collaborations have the potential to create ambiguities about responsibility for animal care and use. If activities involving animals are to be conducted wholly or in part at another institution, the participating institutions should have a formal written understanding (e.g., memorandum of understanding) that addresses the responsibility for offsite animal care and use, animal ownership, and IACUC review and oversight. NSU may initiate an MOU for any collaboration (regardless of funding) where animal work is conducted at the collaborating institution and/or research project funding is sponsored by NSU. The MOU is to be used in circumstances that involve partnerships between collaborating institutions involving animal activity.

The MOU shall remain in effect for as long as the collaboration is ongoing, and includes all third year resubmissions including those involving change in protocol number. OLAW's expectation is that there will be an MOU or other written document in place to ensure the end result. Appropriate oversight, care and use of vertebrate animals when the activity is PHS, HHS, or NSF-supported.

An IIA is established if the recipient of an award using animals for research does not have its own:

- Animal care and use program
- Facilities to house animals
- IACUC, and
- Does not conduct animal research on-site.

The IIA allows the institution to perform the animal activity at a secondary Assured institution named as the performance site.

The requirements of the Inter-institutional Assurance are:

- Statement of applicability and institutional responsibilities
- Endorsement of awardee institution
- Endorsement of Assured institution
- Interinstitutional Assurances are approved for the life of the grant/contract up to 5 years.

Inter-institutional Agreements are intended to assure that collaborative activities using vertebrate animals receive appropriate Institutional Animal Care and Use Committee (IACUC) review, that all parties involved are aware of their respective roles in providing for humane care and use of study subjects, and that a communication system is in place to meet federally required compliance and reporting requirements. Under the Inter-institutional Assurance, the recipient and performance site agree that the research will be conducted under the auspices and program of animal care and use of the performance site's Assurance.

Inter-institutional Assurance Application Process

The application process begins when the funding component makes a determination to award a grant or contract. The funding component will notify OLAW that an Assurance is required for the pending award. OLAW will contact the awardee institution to negotiate the applicable Assurance(s).

Animal Care and Use Policy

Institutions should not submit an Assurance unless requested to do so by OLAW. OLAW will not process unsolicited applications.

If you have been notified that the grant or contract will be awarded and have not been contacted by OLAW, contact the Office of Sponsored Programs by email. OSP will contact OLAW on behalf of the Investigator.

An Interinstitutional Assurance for a Domestic Performance Site form, if the animal activity will be performed at an animal facility located in the United States or territory of the United States, is required and an Interinstitutional Assurance for a Foreign Performance Site form if the animal activity will be performed at an animal facility located in a foreign country is needed. The corresponding form will be completed by the OSP, as it requires the signature of the Authorized Organizational Representative.

EDUCATION AND COMPLIANCE:

The Office of Sponsored Programs will make every effort to educate and train all stakeholders and appropriate audiences on the policy's content as necessary.

All stakeholders have a shared responsibility for complying with this policy and the federal government framework for grants management, commonly called Uniform Guidance.

PUBLICATION:

This Policy shall be widely published and distributed to the University community. To ensure timely publication and distribution thereof, the Responsible Office will make every effort to:

- Communicate the policy in writing, electronic or otherwise, to the University community within 14 days of approval.
- Submit the policy for inclusion in the online Policy Library within 14 days of approval.
- Post the policy on the appropriate SharePoint Site and/or website.
- Educate and train all stakeholders and appropriate audiences on the policy's content as necessary. Failure to meet the publication requirements does not invalidate this policy.

REVIEW SCHEDULE

- Next Scheduled Review: October 1, 2027
- Approval by, date: 1-27-2025
- Revision History: New Policy, Supersedes former Animal Care and Use Policy

RELATED DOCUMENTS

- [Guide for the Care and Use of Laboratory Animals, 8th edition. National Academies Press \(nih.gov\)](#)
- [Reducing Administrative Burden for Researchers: Animal Care and Use in Research. 2019 \(nih.gov\)](#)
- [Interinstitutional Assurance | OLAW \(nih.gov\)](#)

FORMS

1. **FDP Memorandum of Understanding for Animal Care and Use Oversight (Sample) 2.**
- Interinstitutional Assurance for a Domestic Performance Site**

Animal Care and Use Policy

OMB Number 0925-0765
Expiration Date: 11/30/2022

Interinstitutional Assurance for a Domestic Performance Site

The Interinstitutional Assurance is used by awardee institutions that receive Public Health Service (PHS) funds through a grant or contract award when the institution has neither its own animal care and use program, facilities to house animals, nor an Institutional Animal Care and Use Committee (IACUC) and will conduct the animal activity at an Assured domestic institution (named as a performance site).

I. Awardee Institution

Name of Awardee Institution:
Address: [<i>street, city, state, zip code</i>]
Project Title: [<i>title of grant application or contract proposal</i>]
Grant or Contract Number:
Principal Investigator:

A. Applicability

This Interinstitutional Assurance between the awardee institution and the Assured domestic institution is applicable to research, research training, and biological testing involving live vertebrate animals supported by the PHS and conducted at the Assured institution.

B. Awardee and Assured Institutional Responsibilities

- i. The institutions agree to comply with all applicable provisions of the Animal Welfare Act and other Federal statutes and regulations relating to animals.
- ii. The institutions agree 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 institutions acknowledge and accept responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, the institutions will make a reasonable effort to ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, as well as all other applicable laws and regulations pertaining to animal care and use.

Animal Care and Use Policy

- iv. The awardee institution acknowledges and accepts the authority of the IACUC of the Assured institution where the animal activity will be performed and agrees to abide by all conditions and determinations as set forth by that IACUC.

Name of Assured Domestic Institution:
Domestic Assurance Number:
Address: [<i>street, city, state, zip code</i>]

II. Institutional Endorsement

By signing this document, the authorized official at the awardee institution and the Institutional Official (IO) and IACUC Chairperson at the Assured domestic institution (performance site) provide their assurances that the project identified in Part I will be conducted in compliance with the PHS Policy and the Assurance of the domestic institution.

A. Endorsement of Awardee Institution	
Name of Awardee Institution:	
Authorized Official:	
Signature:	Date:
Title:	
Address: [<i>street, city, state, zip code</i>]	
Phone:	Fax:
E-mail:	
B. Endorsement of Assured Domestic Institution	
Name of Assured Institution:	
Institutional Official*:	
Signature:	Date:
Title:	
Address: [<i>street, city, state, zip code</i>]	
Phone:	Fax:
E-mail:	

Animal Care and Use Policy

IACUC Chairperson*:	
Signature:	Date:
Title:	
Address: [<i>street, city, state, zip code</i>]	
Phone:	Fax:
E-mail:	
Date of IACUC Approval: [<i>within 3 years, pending not acceptable</i>]	

[*Both the IO of record (or person with signature authority for the IO) and the IACUC Chairperson of record (or designee verifying IACUC review and approval) must sign.]

III. PHS Approval [*to be completed by OLAW*]

Signature of OLAW Official:	Date:
Name/Title: Office of Laboratory Animal Welfare (OLAW) National Institutes of Health Bethesda, Maryland Phone: +1 (301) 496-7163 Fax: +1 (301) 451-5672	
Grant/Contract #:	Animal Welfare Assurance #:
Effective Date:	Expiration Date: (<i>duration of project, up to 5 years</i>)

Statement of Burden

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0765). Do not return the completed form to this address.



Animal Care and Use Policy

FDP MEMORANDUM OF UNDERSTANDING FOR ANIMAL CARE AND USE OVERSIGHT BETWEEN COLLABORATING PUBLIC HEALTH SERVICE (PHS)-ASSURED INSTITUTIONS

The purpose of this Memorandum of Understanding (MOU) is to establish expectations and responsibilities of collaborating institutions for the humane care and use of vertebrate animals for research, teaching, and/or testing. In accordance with the *Guide for the Care and Use of Laboratory Animals* (p. 15)^{1,2}, and/or USDA Inspection Guide³ and/or as stipulated by the applicable federal funding agency, institutions should have a formal written understanding (*e.g.*, a Memorandum of Understanding) that addresses responsibilities for animal care and use, ownership, and IACUC review and oversight. This MOU may be used for both funded and unfunded collaborations.

APPLICABILITY: This MOU applies only to the protocol(s) specifically listed below.

NAME OF INSTITUTION A (Initiating institution and/or recipient of prime award if grant funded):

USDA Registration Number:

OLAW Assurance Number:

AAALAC Accreditation Date:

AAALAC Accreditation Status:

Principal Investigator Name: (please provide a table, if multiple)

Protocol Number: (please provide a table, if multiple)

Protocol Approval Date: (please provide a table, if multiple)

Protocol Title: (please provide a table, if multiple)

Sponsor(s): (please provide a table, if multiple)

Award Number(s): (please provide a table, if multiple)

Projected Award End Date(s): (please provide a table, if multiple)

¹ See OLAW FAQ D8, <https://olaw.nih.gov/guidance/faqs#D>.

² See *Guide* p. 15. <https://www.nap.edu/read/12910/chapter/3#15>

³ See USDA Inspection Guide: https://www.aphis.usda.gov/animal_welfare/downloads/Animal-Care-Inspection-Guide.pdf

Animal Care and Use Policy

NAME OF INSTITUTION B: (Receiving institution and/or recipient of subaward if grant funded)

USDA Registration Number:

OLAW Assurance Number:

AAALAC Accreditation Date:

AAALAC Accreditation Status:

IACUC Administrative Contact: (name, email address, phone)

PI Name: (please provide a table, if multiple)

Protocol Number: (please provide a table, if multiple)

Protocol Approval Date: (please provide a table, if multiple)

Protocol Title: (please provide a table, if multiple)

INSTITUTION A		Indicate affirmative agreement or N/A to each of the terms below then sign and return this form to []	INSTITUTION B	
Yes	N/A		Yes	N/A
Program-wide Acknowledgements				
		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.		
		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.		
Transportation				
		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.		
Ownership & Oversight				
		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.		
		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.		
		All animal activities related to this MOU will be reviewed and approved by INSTITUTION [Choose one: A's/B's/A's & B's] IACUC prior to the initiation of those activities.		

Animal Care and Use Policy

		The parties acknowledge that INSTITUTION Choose one: A/B will ensure animal use activities associated with this MO		
		The parties acknowledge that each has a process for monitoring on-going animal related activities on their property, including established procedures for identifying and reporting potential adverse events and any non-compliance associated with animal care and use at its facility.		
Investigation and Reporting				
		The parties agree that INSTITUTION [Choose one: A/B] is responsible for notification, investigation, and reporting of serious or continuing incidents of noncompliance and protocol suspension to OLAW, the accrediting body, or regulatory agency (e.g., AAALAC, USDA) in accordance with reporting requirements. Copies of these reports and any responses received are forwarded to the other INSTITUTION.		
		The parties acknowledge that INSTITUTION A is responsible for contacting the Grants Management Officer (GMO) in the event of significant noncompliance. Such noncompliance may necessitate the return of federal funding. In such cases, if the significant noncompliance involves animal use activities approved at INSTITUTION B, the parties will work collaboratively to ensure timely, accurate, and complete disclosure to the GMO.		
		INSTITUTION B agrees to promptly notify INSTITUTION A, within 30 days of identification, any potentially reportable events, specific to the protocol related to this MOU <u>and/or</u> any significant programmatic deficiencies occurring during the conduct of the activities associated with this MOU that directly impact animal welfare or well-being.		
		INSTITUTION A agrees to promptly notify INSTITUTION B, within 30 days of identification, any potentially reportable events, specific to the protocol related to this MOU <u>and/or</u> any significant programmatic deficiencies occurring during the conduct of the activities associated with this MOU that directly impact animal welfare or well-being.		
		INSTITUTION B is responsible for reporting USDA-regulated animal activities annually on the USDA Annual Report (APHIS FORM 7023). Such reports must include any corresponding IACUC-approved exceptions to the animal welfare standards, as applicable.		
		The parties acknowledge that each institution's IACUC is responsible for reporting to the USDA any IACUC suspensions of animal activities and any failures to correct significant deficiencies within the IACUC-established time frame for correction related to animal activities associated with this MOU and which fall under their institution's IACUC approval.		
Other Requirements Not Addressed Above				

**Signatures of Animal Program Representatives (IACUC
Chair, AV, IACUC Administrator, or IO)**

Animal Care and Use Policy

This MOU becomes effective upon the date of last signature, and will remain in effect for five (5) years (unfunded collaborations) or for the duration of portion of the funding related to this MOU (funded collaborations) unless sooner terminated by either party on notice to the other. Either party may terminate this MOU without cause upon sixty (60) days written notice. Both parties acknowledge that INSTITUTION A will notify the funding agency of the change in performance site, as applicable.

Date:

Name:

Title:

E-Mail: Phone:

Date:

Name:

Title:

E-Mail: Phone: