

## **Animal Welfare Assurance for Domestic Institutions**

I, Mary Klotman as named Institutional Official for animal care and use at Duke University, provide assurance that this Institution will comply with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy).

### **I. Applicability of Assurance**

This Assurance applies whenever this Institution conducts the following activities: all research, research training, experimentation, biological testing, and related activities involving live vertebrate animals supported by the PHS, HHS, NASA and/or NSF. This Assurance covers only those facilities and components listed below.

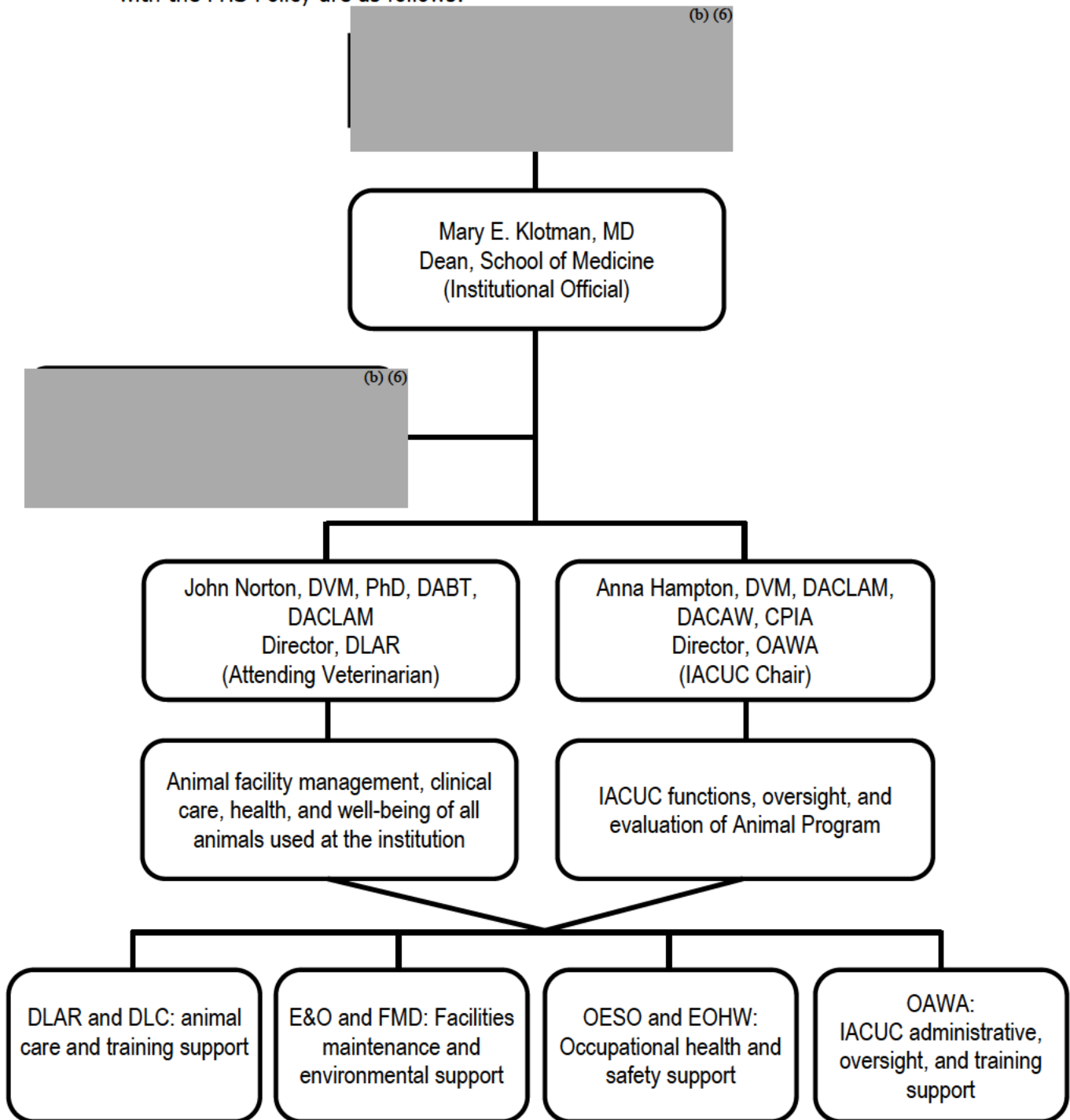
- A. The following are branches and components over which this Institution has legal authority, included are those that operate under a different name:
  - 1. Duke University
  - 2. Duke University Medical Center
  - 3. Duke Lemur Center
  - 4. Duke Marine Laboratory
- B. The following are other institution(s), or branches and components of another institution:  
None

### **II. Institutional Commitment**

- A. This Institution will comply with all applicable provisions of the [Animal Welfare Act](#) and other Federal statutes and regulations relating to animals.
- B. This Institution is guided by the "[U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training](#)."
- C. This Institution acknowledges and accepts responsibility for the care and use of animals involved in activities covered by this Assurance. As partial fulfillment of this responsibility, this Institution will ensure that all individuals involved in the care and use of laboratory animals understand their individual and collective responsibilities for compliance with this Assurance, and other applicable laws and regulations pertaining to animal care and use.
- D. This Institution has established and will maintain a Program for activities involving animals according to the *Guide for the Care and Use of Laboratory Animals* ([Guide](#)).
- E. This Institution agrees to ensure that all performance sites engaged in activities involving live vertebrate animals under consortium (subaward) or subcontract agreements have an Animal Welfare Assurance and that the activities have Institutional Animal Care and Use Committee (IACUC) approval as described in section D.6.i..

### III. Institutional Program for Animal Care and Use

- A. The lines of authority and responsibility for administering the Program and ensuring compliance with the PHS Policy are as follows:



DLAR – Division of Laboratory Animal Medicine  
DLC – Duke Lemur Center  
EOHW- Employee Occupational Health and Wellness  
E&O – Engineering and Operations

FMD – Facilities Management  
OESO - Occupational and Environmental Safety Office  
OAWA – Office of Animal Welfare Assurance

- B. The qualifications, authority, and percent of time contributed by the veterinarian(s) who will participate in the Program are as follows:

1)

Name	Degree	Training or experience in laboratory animal medicine or in the use of the species at the institution	Authority: These veterinarians have (direct/delegated) Program authority and responsibility for the Institution's animal care & use Program as indicated below	Percent time contributed to Program
John Norton	DVM, PhD, DABT, DACLAM	Dr. Norton serves as the Director, Division of Laboratory Animal Resources (DLAR) and is board-certified through the American College of Laboratory Animal Medicine (ACLAM) and the American Board of Toxicology (ABT). Dr. Norton is a Professor in the Duke Department of Pathology and an Adjunct Professor of Clinical Sciences at North Carolina State University College of Veterinary Medicine. He holds a BS degree in biochemistry and animal science. Additionally, his PhD in pharmacology was awarded from Vanderbilt University. He is a graduate of North Carolina State University, College of Veterinary Medicine. Dr. Norton has > 30 years of laboratory animal medicine and research experience including serving as Study Director and/or Manager in over 150 safety studies. Dr. Norton is a Past President of the Council of Accreditation for AAALAC International. He regularly attends national and regional continuing education provisions for maintenance of credentials and for professional development.	Direct Attending Veterinarian Authority. Has access to all animals.	FTE - 100%

(b) (6)





Anna Hampton	DVM, DACLAM, DACAW, CPIA	Dr. Hampton serves as the Director, Office of Animal Welfare Assurance (OAWA) and is the IACUC Chair. She is board-certified with the American College of Laboratory Animal Medicine (ACLAM) and American College of Animal Welfare (ACAW). She is a graduate of North Carolina State University, College of Veterinary Medicine. She has 14 years of laboratory animal medicine experience. Dr. Hampton is a Certified Professional IACUC Administrator (CPIA). She completed an internship in small animal medicine and surgery at Carolina Veterinary Specialist and a Post-Doctoral Fellowship in Laboratory Animal Medicine at the University of Michigan. She regularly attends national and regional continuing education provisions for maintenance of credentials and for professional development.	Program support (IACUC and Oversight)	FTE - 100%
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(b) (6)

FTE – Full time employee

- C. The IACUC at this Institution is properly appointed according to PHS Policy IV.A.3.a. and is qualified through the experience and expertise of its members to oversee the Institution's animal care and use Program and facilities. The IACUC consists of at least 5 members, and its membership meets the composition requirements of PHS Policy IV.A.3.b.

All IACUC members have been appointed in writing by the Institutional Official. A list of the chairperson and members of the IACUC and their names/codes, degrees/credentials, position title, and PHS policy membership requirement is included in section VIII (Membership of the IACUC) of this document.

D. The IACUC will:

- 1) Review at least once every 6 months the Institution's Program for humane care and use of animals, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual Program reviews are as follows:

Semiannual reviews of Duke's Program for humane care and use of animals are performed every 6 months. The 'Semiannual Program Review' checklist provided by the Office of Laboratory Animal Welfare is used in the review and *The PHS Policy, The Guide* and *Animal Welfare Act/Regulations* are used as references. In addition, the Duke AAALAC International Program Description (all or specific sections) may be used by IACUC members and/or Program representatives for a supportive review, as determined by the IACUC. The checklist is completed and Animal Program updates and changes are discussed during a convened meeting of a quorum of IACUC members (i.e., Programmatic Meeting). All IACUC members (primary and alternate) have the opportunity to participate in the semiannual review of Duke's Program for humane care and use of animals and are invited to the Programmatic Meeting. The IACUC membership (primary or alternate) can file a minority view at any time.

In addition to the IACUC membership, ad hoc consultants that provide support to the Duke Animal Care and Use Program may be invited to participate in the Program review and/or Programmatic Meeting. This includes, but is not limited to, representatives from the occupational health and safety, facility management, the Office of Animal Welfare Assurance (OAWA; IACUC support office), and the research community.

- 2) Inspect at least once every 6 months all of the Institution's animal facilities, including satellite facilities and animal surgical sites, using the *Guide* as a basis for evaluation. The IACUC procedures for conducting semiannual facility inspections are as follows:

Semiannual inspections of Duke's animal facilities are performed every 6 months within the same two calendar months each year. If inspections cannot occur within the same two calendar months the Animal Program ensures that the timing of the facility inspection is performed within 30 days of the 6 month interval from the last inspection to ensure there is no forward drift in the date from year to year.

The following table outlines, at a minimum, who performs the inspections and what areas are inspected.

	USDA-Regulated Species	Non-USDA Regulated Species
<b>Centrally managed location</b> (Division of Laboratory Animal Resources, the Duke Lemur Center, and the Duke University Marine Laboratory)	Semiannual by at least 2 IACUC members <sup>1</sup> by one of the following: 1. On-site. 2. Virtual with a virtual guide on site. 3. Combination of 1 and 2	Semiannual by at least one ad hoc inspector <sup>2</sup> by one of the following: 1. On-site 2. Virtual with a virtual guide on site <sup>3</sup>
<b>Non-central, PI-managed housing</b> - Satellite facility (non-USDA ≥ 24hrs) - Study area (USDA ≥ 12hrs)	Semiannual by at least 2 IACUC members <sup>1</sup> by one of the following: 1. On-site. 2. Virtual with a virtual guide on site. 3. Combination of 1 and 2	Semiannual by at least one ad hoc inspector <sup>2</sup> by one of the following: 1. On-site 2. Virtual with a virtual guide on site <sup>3</sup>
<b>Non-central surgical (minor, major, survival, non-survival) location</b>	Monitored on a schedule to effectively oversee activities at the institution. Generally semiannually.	Semiannual by at least one ad hoc inspector <sup>2</sup> by one of the following: 1. On-site 2. Virtual with a virtual guide on site <sup>3</sup>
<b>Transportation</b>	Monitored on a schedule to effectively oversee activities at the institution. Generally semiannually.	Semiannual by at least one ad hoc inspector <sup>2</sup> by one of the following: 1. On-site 2. Virtual with a virtual guide on site <sup>3</sup>
<b>All other Animal Use locations (support areas, non-central, non-surgical procedure locations)</b>	Monitored on a schedule to effectively oversee activities at the institution. Generally semiannually.	Monitored on a schedule to effectively oversee activities at the institution. Generally semiannually.

<sup>1</sup> If primary member and their alternate(s) are performing inspections at the same time the alternate member is not counted toward the two required IACUC members, as required by the Animal Welfare Act/Regulations. In general this situation usually occurs for training the alternate member(s).

<sup>2</sup> Ad hoc inspectors been approved by the IACUC and considered trained and qualified. Ad hoc inspectors will not perform independent inspections of locations for which they directly oversee. The IACUC remains responsible for the evaluation and report.

<sup>3</sup> Virtual inspections require a secure audio and video live feed to all inspectors and virtual guides.

Any IACUC members can participate in any facility inspection. Inspectors are trained and the 'Semiannual Facility Inspection' checklist provided by the Office of Laboratory Animal Welfare, *The PHS Policy*, and *The Guide* and *Animal Welfare Act/Regulations* are used as a reference during inspections, in addition to guidance documents created by the Animal Program. Inspectors report any findings to the Office of Animal Welfare Assurance (OAWA).

For free-living wild animals in their natural habitat, animals used at a non-Duke location which have documented, delegated oversight (e.g., the research facility's IACUC oversees the animal use), and sites which are not in the United States or U.S. territories (foreign sites), the Duke Animal Care and Use Program will oversee animal work through other established mechanisms which may include IACUC protocol review, IACUC protocol amendment review, annual review, establishment of a Memorandum of Understanding, postapproval monitoring, review of supportive materials (e.g., collaborator protocol, permits, funding requirements), communications with the collaborative site, etc. Furthermore, the IACUC, through the OAWA, verifies that the animal activity is covered by an OLAW Assurance as described in D.6.i..

- 3) Prepare reports of the IACUC evaluations according to PHS Policy IV.B.3. and submit the reports to the Institutional Official. The IACUC procedures for developing reports and submitting them to the Institutional Official are as follows:

- a. *How the IACUC develops, approves, and submits the semiannual reports of the Program review and facility inspection to the Institutional Official*

After the semiannual Program review, the Semiannual IACUC report, which includes recommendations and minority views, is compiled and signed by a majority of the IACUC membership. Once a majority of the IACUC membership has endorsed the report it is provided to the Institutional Official for review and signature.

The semiannual Program report contains:

- i. An executive summary outlining any major issues discussed at the Programmatic Meeting or relevant Program updates. Which would include any recommendations regarding any aspect of Duke's animal care and use program, facilities, or personnel training.
- ii. The Semiannual Program Report Summary using the NIH Semiannual Report Template. This includes:
  1. Program changes
  2. IACUC approved departures from the PHS Policy, the *Guide*, and the Animal Welfare Act/Regulations and the reason for each departure.
  3. Deficiencies identified during the Semiannual Program review or facility inspections. If a deficiency occurred the report contains a description of each deficiency, identification of each deficiency as either minor or significant, and the plan and schedule for the correction of each deficiency, if not already corrected
  4. Minority views, if applicable
  5. Status of AAALAC Accreditation
  6. Signatures of a majority of the IACUC membership
- iii. IACUC minutes of the IACUC Full Committee Program review meeting
- iv. The completed OLAW semiannual Program review checklist to document the institutions adherence to the *PHS Policy* and *the Guide*
- v. Other documents, if appropriate

In addition to receiving the written Semiannual Programmatic report, the Attending Veterinarian, IACUC Chair, and/or other relevant members of the Animal Program will meet with the Institutional Official at least semiannually to discuss the status of the Program. If an in-person meeting cannot be arranged this communication occurs via virtual meeting or email.

- b. *How the IACUC identifies and approves departures from the PHS Policy and the Guide*

All IACUC-approved departures from the PHS Policy, *the Guide*, or *the Animal Welfare Act/Regulations* are captured in the IACUC animal use protocol. The OAWA maintains a list of these approved departures. All approved departures and the reason for each departure for the semiannual period are included in the Semiannual Programmatic report to the Institutional Official.



c. *How the IACUC identifies and corrects deficiencies*

During the Program review, the 'Semiannual Program Review' checklist is reviewed at the Programmatic Meeting and the voting IACUC members in attendance affirm that the checklist components are either: acceptable, a minor deficiency, a significant deficiency, or not applicable. If an item is determined to be a deficiency, the corrective plan will be discussed and a schedule for correction will be established.

During semiannual facility inspections, the inspector(s) will provide a report of the findings to the Duke Office of Animal Welfare Assurance for documentation, follow-up, and tracking. If a deficiency is identified the inspector(s) will categorize it as minor or significant. For minor deficiencies the plan will be written either by the inspector(s) or determined by OAWA. For Significant deficiencies, the inspector(s) or OAWA will notify the clinical veterinarian and/or Program leadership for action and resolution of the animal health or safety concern. In addition, the significant deficiency will be brought to an IACUC Full Committee meeting for further review and/or categorization, as appropriate. At which time, if it has not already corrected, the IACUC will ensure a specific plan and schedule for correction is in place. Specific details will be handled on a case-by-case basis.

Deficiencies identified outside of the semiannual review process will be brought to an IACUC Full Committee meeting for further review and/or categorization, as appropriate. At which time, if it has not already corrected, the IACUC will ensure a specific plan and schedule for correction is in place. Specific details will be handled on a case-by-case basis.

All deficiencies, the correction plan, and schedule for correction are reported to the Institutional Official. The IACUC monitors all deficiencies until resolved.

4) Review concerns involving the care and use of animals at the Institution. The IACUC procedures for reviewing concerns are as follows:

a. *Mechanisms that facilitate/enable individuals to report concerns.*

The Duke Animal Care and Use Program offers multiple mechanisms for individuals to report concerns related to any component of the Duke Animal Care and Use Program.

These include:

- i. The emergency veterinary pager
- ii. The husbandry supervisor pager
- iii. The Division of Laboratory Animal Resources main phone number
- iv. The IACUC Office of Animal Welfare Assurance main phone number
- v. The Animal Welfare Hotline phone number
- vi. Any IACUC/OAWA or Division of Laboratory Animal Resources contact
- vii. The Office of Audit, Risk and Compliance (OARC) main phone number or contacts on website
- viii. Three external hotlines that provide a toll-free, anonymous reporting service for potential concerns. They are:
  1. Duke Health Integrity Line
  2. Duke University Compliance and Fraud hotline
  3. HIPAA Privacy Line

Details of these mechanisms are provided on the Duke Animal Care and Use Program's public website. In addition, information on reporting concerns to the Duke Office of Audit, Risk, and Compliance can be found on their website. Furthermore, the research community is educated on these reporting mechanisms through required training modules and an outline of the mechanisms for reporting animal welfare concerns is posted at animal use locations.

The Duke Animal Care and Use Program's public website contains information on maintaining anonymity and protection against reprisal of the individual. Individuals do not need to identify themselves to report a concern. In addition, Duke maintains three external hotlines for toll-free, anonymous reporting.

The non-retaliation and non-retribution policy are contained in the *Duke University's Statement of Ethical Principles and Code of Conduct* for the University and the Duke Integrity in Action for Duke Health. Confidentiality of individuals reporting violations of laws, rules or policies will be maintained to the extent practicable, and individuals reporting violations in good faith will be protected from retaliation.

b. *How the IACUC reviews reported concerns*

Most concerns are routed through the Office of Animal Welfare Assurance (OAWA) which provides administrative and oversight support for the IACUC. All concerns received by OAWA are sent to the Attending Veterinarian, IACUC Chair, and OAWA compliance staff for review and action. OAWA staff will review the concern, corrective measures, and seek clarification if necessary. Furthermore, if the incident involves a non-compliance concern, they will provide assistance to regain compliance. OAWA staff will also follow-up on any clarifications or questions as requested by the Attending Veterinarian and/or IACUC Chair, or designees. The Attending Veterinarian or designee will evaluate and resolve all animal welfare concerns.

All concerns are provided to the IACUC membership at a Full Committee meeting. Concerns that may be a serious or continuing noncompliance with the PHS Policy or a serious deviation from the provisions of the *Guide* are discussed at the IACUC Full Committee meeting. The IACUC will determine by vote if additional investigation or corrective actions are required and if the incident is a serious or continuing noncompliance with the PHS Policy or a serious deviation from the provisions of the *Guide* (i.e., reportable to OLAW through the IO if the activity was conducted or supported by PHS funding or funding which falls over the oversight of OLAW). The IACUC will establish deadlines, if needed, and will monitor the corrective measures until the item is closed.

The IACUC may suspend any approved activity only after review of the matter at a convened meeting of a quorum of the IACUC and with the suspension vote of a majority of the quorum present. If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, will review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW if the activity was conducted or supported by PHS funding or funding which falls over the oversight of OLAW.

IACUC members and the Institutional Official can request additional information or investigation for any concern reported to the OAWA/IACUC at any time.

c. *How the IACUC reports concerns and relates findings and recommendations to the Institutional Official*

The Institutional Official receives every IACUC Full Committee meeting agenda packet. This packet contains a list of all concerns with a brief summary. In addition, it contains the minutes from the previous IACUC Full Committee meeting that includes the outcome of concerns. Any suspended activity or concern determined to be reportable to the OLAW by the IACUC is reported to OLAW through the Institutional Official.

- 5) Make written recommendations to the Institutional Official regarding any aspect of the Institution's Animal Program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are as follows:

The established, standard process of making written recommendations to the Institutional Official regarding any aspect of the Institution's Animal Program, facilities, or personnel training is through the Semiannual Report process described in III.D.3.a. This report would include any recommendations regarding any aspect of Duke's animal care and use program, facilities, or personnel training. Other avenues the Institutional Official is provided updates on the Duke Animal Care and Use Program is through (1) Review of the IACUC Full Committee meeting packet which contains drafts of any new or revised Program policies and the minutes from the previous IACUC Full Committee meeting that includes Program changes, deliberations, and IACUC decisions, (2) Review of reports that will be provided to OLAW, and/or (3) Communication between the IO, IACUC Chair, and/or Attending Veterinarian.

- 6) Review and approve, require modifications in (to secure approval), or withhold approval of PHS-supported activities related to the care and use of animals according to PHS Policy IV.C.1-3. The IACUC procedures for protocol review are as follows:

a. *How protocols are received.*

Protocols are submitted by email as PDF attachments.

b. *The pre-review or initial screening process, if one is used.*

All protocols receive:

- i. A pre-review by IACUC support staff.
- ii. A pre-review by a professional veterinary reviewer.
- iii. Verification by the Office of Animal Welfare Assurance that all protocol members have completed training and employee health activities, as required.
- iv. Additional protocol clearances, if required. Required clearances may include: safety review, Memorandum of Understanding, animal transport request, use of the Duke Lemur Center, employee health items, etc.

c. *How members are notified.*

- i. All IACUC members (primary and alternate) are provided a list electronically (e.g., through secured email or other electronic file sharing application) of proposed protocols that are under review.
- ii. All IACUC Committee members (primary and alternate) are invited to the IACUC Full Committee meetings. The dates of the IACUC Full Committee Meetings are posted on the Duke Animal Care and Use Program website. In addition, IACUC members receive email notification of IACUC meetings dates and/or a calendar invitation to all Full IACUC Committee meetings.

d. *How materials are distributed to members.*

- i. All IACUC members (primary and alternate) are provided a list electronically (e.g., through secured email or other electronic file sharing application) of proposed protocols that are under review. At a minimum this list will contain (1) the name of the PI, (2) the protocol number, and (3) the protocol title.
- ii. All IACUC members can access the full written description of all proposed protocols through a secure online system.

e. *How meetings are conducted.*

IACUC Full Committee meetings are typically held monthly. All Committee members (primary and alternate) are invited to attend the Full Committee meeting. If a primary member is in attendance their alternate member is considered non-voting and they are not counted toward quorum. The alternate member will become a primary voting member if the primary member leaves the meeting and is no longer available. Alternate member assignments are in accordance with the OLAW Notice: NOT-OD-11-053.

IACUC meetings may be held in-person, by telecommunication (e.g., virtual) and/or select IACUC members may attend the meeting by telecommunication (e.g., virtual). If telecommunications is used to conduct official IACUC business which requires a quorum of IACUC members to be present, the guidance on use of telecommunications provided by OLAW (NOT-OD-06-052) and the USDA (Animal Welfare Inspection Guide 7.1.8.) are followed. This includes:

- i. All members are given notice of the meeting.
- ii. Documents normally provided to members during a physically-convened meeting are provided to all members in advance of the meeting.
- iii. All members have access to the documents and the technology necessary to fully participate.
- iv. A quorum of voting members is convened and verified when required by PHS Policy and/or Animal Welfare Act/Regulations.
- v. The forum allows for real time verbal interaction equivalent to that occurring in a physically-convened meeting (i.e., members can actively and equally participate and there can be simultaneous communication).
- vi. If a vote is called for, the vote occurs during the meeting and is taken in a manner that ensures an accurate count of the vote. A mail ballot or individual telephone polling cannot substitute for a convened meeting.
- vii. Opinions of absent members that are transmitted by mail, telephone, fax or e-mail may be considered by the convened IACUC members but may not be counted as votes or considered as part of the quorum.
- viii. Written minutes of the meeting are maintained in accord with the PHS Policy section IV.E.1.b. and Animal Welfare Regulations.

The IACUC Chair or designee conducts the IACUC Full Committee meeting. Items which may be discussed in the meeting include: IACUC business items, animal concerns, protocols, amendments, and other items as requested by the membership.

f. *The methods of protocol review.*

One of the following review methods must occur at least once every 3-years.

- i. **Designated Member Review (DMR)** – All IACUC members (primary and alternate) are provided a list of proposed protocols that are under review. At a minimum this list will contain (1) the name of the PI, (2) the protocol number, and (3) the protocol title. All IACUC members can access the full written description of all proposed protocols on the list through a secure online system. This list is distributed electronically to the IACUC Full Committee (primary and alternate) prior to processing the protocol for DMR. IACUC members are provided at least 3-business days to review the proposed protocol. If no member requests Full Committee review of the protocol it is processed through DMR.

At least one member of the IACUC, designated by the IACUC Chairperson and qualified to conduct the review, is then assigned the protocol. IACUC members indicate their availability to perform protocol DMR for a specific period of time through a sign-up. If a member does not sign-up for a specific period they are considered unavailable to perform this duty and their alternate member can perform the DMR if they indicate availability. The IACUC Chairperson designates the DMR reviewer through approval of the IACUC member sign-up sheet. The IACUC Chairperson considers all IACUC members as qualified to conduct the review; furthermore, at least one dedicated, qualified IACUC member veterinarian is assigned as a Designated Member reviewer for every protocol that undergoes DMR review. If the IACUC Chairperson is unavailable, they may delegate responsibilities to the IACUC Vice-Chair. The IACUC Vice-Chair is appointed by the IO and the delegation is in writing. Any IACUC member (primary or alternate) may participate in the protocol review.

Possible outcomes of the DMR process include approval, requires modification in to secure approval, or refer the Full Committee Review. If more than one IACUC member performs the designated member review, they must be unanimous in the protocol disposition decision otherwise the protocol is deferred to the Full Committee for further review. If more than one DMR is appointed and there are additional modifications required to secure approval, each DMR reviewer reviews identical versions of the protocol and if modifications are requested by any one reviewer(s), the other reviewer(s) are aware of and must agree to the modification prior to final approval. The approval date is on or after the date that the designated member(s) approve the study. The entire DMR review process is conducted electronically (e.g., through secured email or other electronic file sharing application).

Animal work cannot begin until a protocol covering the proposed activity is approved. The protocol decision is communicated to the PI in writing.

- ii. **Full Committee Review (FCR)** - A quorum of the IACUC members reviews the protocol at a convened meeting. Full Committee Review is required for IACUC protocols for which an IACUC member has requested FCR. In addition, protocols may undergo FCR due to specific criteria (e.g., unrelieved pain or distress or use of certain species).

Possible outcomes of the Full Committee process include approval, requires modification in to secure approval (deferred for designated member review or deferred for Full Committee), or withhold approval. Approval is granted by a majority of the present quorum voting for approval. Withhold approval is granted by a majority of the present quorum voting for withhold approval. If there remain modifications required to secure approval, the Committee may vote by a unanimous decision of voting members in attendance to refer the application to the Designated Member Review (DMR) process. If the vote is not unanimous, the protocol will return for review by the Full Committee.

**Use of DMR subsequent to FCR:** All IACUC members have agreed in advance in writing that the quorum of members present at a convened meeting may decide by unanimous vote to use DMR subsequent to FCR when modification is needed to secure approval. If the DMR subsequent to FCR process is used the IACUC Chairperson appoints at least one, qualified, IACUC member to perform the review. The IACUC Chairperson can appoint one or more appropriately qualified IACUC member(s) to serve as the designated member review via the following methods (1) the IACUC Chairperson appoints the IACUC member(s), (2) a designated IACUC Chairperson appoints the IACUC member(s) if the IACUC Chairperson is not available, this designation is in writing, or (3) as agreed upon by the IACUC Chairperson and IACUC members in the signed DMR subsequent to FCR document which indicates that the individual(s) performing DMR will be the IACUC Chairperson and/or designee, and any IACUC member who chooses to serve as DMR as designed by the IACUC Chairperson.

Possible outcomes of the DMR subsequent to FCR process include approval, requires modification in to secure approval, or refer the protocol back to the Full Committee for further review. If more than one IACUC member performs the designated member review, they must be unanimous in the protocol disposition decision otherwise the protocol is deferred back to the Full Committee for further review. If more than one DMR is appointed and there are additional modifications required to secure approval, each DMR reviewer reviews identical versions of the protocol and if modifications are requested by any one reviewer(s), the other reviewer(s) are aware of and must agree to the modification prior to final approval. The approval date is on or after the date that the designated member(s) approve the study. The entire DMR review process is conducted

electronically (e.g., through secured email or other electronic file sharing application).

All IACUC members can access the full written description of all proposed protocols through a secure online system in advance of FCR or DMR subsequent to FCR. Any member of the IACUC may, at any time, review the proposed protocol and/or request FCR of the protocol.

The Institutional Official is provided with a written summary of IACUC FCR decisions. Animal work cannot begin until a protocol covering the proposed activity is approved. The protocol decision is communicated to the PI in writing after the IACUC Full Committee meeting or after DMR subsequent to FCR. If the Full Committee Review decision was to withhold approval, the PI is provided the reason and an opportunity to respond.

Animal work cannot begin until a protocol covering the proposed activity is approved. The protocol decision is communicated to the PI in writing.

g. *How conflicts of interest are handled*

Any IACUC member who is listed as the PI, co-investigator, sponsor, protocol participant, collaborator on the protocol application and/or protocol-related amendments OR an individual with obvious personal/financial interest in the outcome of the application (e.g., spouses, funding recipient/provider) is defined as having a conflict of interest. In addition, an IACUC member can self-identify a conflict of interest and/or indicate they should not participate in the IACUC function. During Full Committee IACUC meetings, individuals with defined or self-identified conflict of interest leave the room (physical or virtual) during deliberation and vote for the item. They may provide information requested by the IACUC. They are not counted toward quorum. During Designated Member Review (DMR), IACUC members will not be assigned as a DMR if they have a known, defined conflict of interest with the application. If a DMR self-identifies a conflict of interest during review, they notify OAWA and another DMR is assigned that review as described in section III.D.6.f.i.

h. *The voting process.*

- i. **Full Committee Review** protocols are reviewed at a convened meeting of a quorum of the IACUC. A majority of the quorum voting in favor of the recommendation is required to approve or withhold approval of a protocol. The entire quorum voting in favor of the recommendation is required to refer the application to the Designated Member Review (DMR) process. If the DMR subsequent to FCR vote is not unanimous the protocol will be brought back for review at an IACUC Full Committee meeting.
- ii. **Designed Member Review(s)** protocols are reviewed electronically (e.g., through secured email or other electronic file sharing application). All assigned DMR(s) must unanimously accept a final version of the protocol through electronic documentation (e.g., The Duke animal program considers a message of protocol acceptance from a '@duke.edu' email account as a valid signature of that individual).

i. *Alternative processes.*

Collaborative animal activities which occur at a non-Duke performance site that are conducted or supported by Duke require completion of a Memorandum of Understanding (MOU) which addresses responsibilities for animal care and use, ownership, and IACUC review and oversight. If the performance site does not have an IACUC the Duke IACUC will review the MOU which describes the animal activity as described in section III.D.6. and III.D.7. For PHS, BARDA, VA, or NASA conducted or supported activities the performance site must have an OLAW animal welfare assurance (domestic, international,



or captured in Duke's OLAW animal welfare assurance). For NSF conducted or supported activities the performance site must have an OLAW animal welfare assurance, as described above, or the animal activity performed at the facility must be consistent with a field study or fall within the normal operations of the facility (i.e., not alter or influence the activity of the animals).

All activities performed by an alternative process are described in an IACUC approved policy and/or SOP. Any member can request re-review by the Full Committee of any activity at any time.

- 7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities according to PHS Policy IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are as follows:

a. *How amendments are received.*

Amendments are submitted by email as PDF attachments.

b. *The pre-review or initial screening process, if one is used.*

All amendments receive:

- i. A pre-review by IACUC support staff.
- ii. A pre-review by a professional veterinary reviewer.
- iii. Verification by the Office of Animal Welfare Assurance that all amendment members have completed training and employee health activities, as required.
- iv. Additional amendment clearances, if required. Required clearances may include: safety review, Memorandum of Understanding, animal transport request, use of the Duke Lemur Center, employee health items, etc.

c. *How members are notified.*

- i. All IACUC members (primary and alternate) are provided a list electronically (e.g., through secured email or other electronic file sharing application) of proposed amendments that are under review.

d. *How materials are distributed to members.*

- i. All IACUC member (primary and alternate) are provided a list electronically (e.g., through secured email or other electronic file sharing application) of proposed protocol modifications under review with written descriptions available upon request. At a minimum this list will contain (1) the name of the PI, (2) the protocol number, (3) the protocol title, and (4) a brief description of the change. Full written description of all proposed amendments are available upon request.

e. *The methods of amendment review.*

Significant changes (SC) to approved protocols that must be approved by one of the valid IACUC approval methods as described in PHS Policy IV.C.2. may be reviewed by:

- i. **Designated Member Review (DMR)** – All IACUC members (primary and alternate) are provided a list of proposed amendments that are under review. At a minimum this list will contain (1) the name of the PI, (2) the protocol number, (3) the protocol title, and (4) a brief description of the change. Full written description of all proposed amendments are available upon request. This list is distributed electronically to the IACUC Full Committee (primary and alternate) prior to processing the amendment for DMR. IACUC members are provided at

least 2-business days to review the proposed amendment. If no member requests Full Committee review of the amendment it is processed through DMR.

At least one member of the IACUC, designated by the IACUC Chairperson and qualified to conduct the review, is then assigned the amendment. IACUC members indicate their availability to perform amendment DMR for a specific period of time through a sign-up. If a member does not sign-up for a specific period they are considered unavailable to perform this duty and their alternate member can perform the DMR if they indicate availability. The IACUC Chairperson designates the DMR reviewer through approval of the IACUC member sign-up sheet. The IACUC Chairperson considers all IACUC members as qualified to conduct the review; furthermore, at least one dedicated, qualified IACUC member veterinarian is assigned as a Designated Member reviewer for every amendment that undergoes DMR review. If the IACUC Chairperson is unavailable, they may delegate responsibilities to the IACUC Vice-Chair. The IACUC Vice-Chair is appointed by the IO and the delegation is in writing. Any IACUC member (primary or alternate) may participate in the amendment review.

Possible outcomes of the DMR process include approval, requires modification in to secure approval, or refer the amendment Full Committee Review. If more than one IACUC member performs the designated member review, they must be unanimous in the amendment disposition decision otherwise the amendment is deferred to the Full Committee for further review. If more than one DMR is appointed and there are additional modifications required to secure approval, each DMR reviewer reviews identical versions of the amendment and if modifications are requested by any one reviewer(s), the other reviewer(s) are aware of and must agree to the modification prior to final approval. The approval date is on or after the date that the designated member(s) approve the study. The entire DMR review process is conducted electronically (e.g., through secured email or other electronic file sharing application).

Animal work described in an amendment cannot begin until an amendment covering the proposed activity is approved. The amendment decision is communicated to the PI in writing.

- ii. **Full Committee review (FCR)** - A quorum of the IACUC members reviews the amendment at a convened meeting. Full Committee Review is required for IACUC amendments for which an IACUC member has requested FCR. The FCR process for amendments is exactly the same as described for protocols in section III.D.6.

Animal work described in an amendment cannot begin until an amendment covering the proposed activity is approved. The amendment decision is communicated to the PI in writing.

f. *How conflicts of interest are handled*

Conflicts of interest for amendments are handled exactly the same as described for protocols in section III.D.6.

g. *The voting process.*

The voting process for amendments is exactly the same as described for protocols in section III.D.6.

h. *Alternative processes.*



- i. **Veterinary Verification and Consultation (VVC)** – Specific significant changes may be handled administratively according to IACUC-reviewed and -approved policies in consultation with a veterinarian authorized by the IACUC. The Duke IACUC considers any veterinarian who is designated by the Attending Veterinarian as authorized to perform VCC amendment approval. Upon verbal or written verification by the authorized veterinarian the amendment is approved.

The veterinarian is not conducting DMR but is acting as a subject matter expert to verify that there is compliance with IACUC-reviewed and -approved policies or other IACUC-reviewed and -approved specific source documents (SOPs, guidelines, references, and/or forms) that are appropriate for the animals in the specific circumstance. Consultation with the veterinarian and the approved change is documented in writing and included as part of the protocol file. This method of review and approval is consistent with the OLAW Guidance on Significant Changes to Animal Activities NOT-OD-14-126. Only changes that are not expected to negatively impact animal health or welfare can be approved via the VVC method. Only proposed changes in the following categories that fall within IACUC-reviewed and approved policies or IACUC-reviewed and approved specific source documents (SOPs, guidelines, references, and/or forms) can be approved via VVC.

1. Anesthesia, analgesia, sedation, or experimental substances;
2. Experimental substance administration of already approved compounds that does not exceed published and IACUC approved guidelines;
3. Euthanasia to any method approved in the AVMA Guidelines for the Euthanasia of Animals;
4. Duration, frequency, type, or number of procedures performed on an animal.

The veterinarian can refer any amendment to the IACUC for review (DMR or FCR) for any reason and must refer any request that does not meet the parameters of the IACUC-reviewed and approved policies or IACUC-reviewed and approved specific source documents (SOPs, guidelines, references, and/or forms).

- ii. **Administrative review** – Other changes that may be handled administratively by the Office of Animal Welfare Assurance (OAWA) staff based on IACUC-reviewed and -approved policies and IACUC-reviewed and -approved SOPs without additional IACUC consultations or notifications include:

1. Increase in animal numbers  $\leq 20\%$  for non-USDA regulated species
2. Change in personnel, other than the PI (There is an administrative review to ensure that all such personnel are appropriately identified, adequately trained and qualified, enrolled in occupational health and safety programs, and meet other criteria as required by the IACUC.)
3. Change in animal use location or animal housing to a [centrally managed area](#)
4. Correction of typographical errors
5. Correction of grammar
6. Contact information updates
7. Change in funding information
8. Changes in controlled substance source or registration
9. Change in protocol title
10. Deletion of information (e.g., species, procedures, locations)

The administrative staff can refer any amendment to the IACUC for review (VVC, DMR, or FCR, as appropriate) for any reason and must refer any request that does not meet the parameters of the IACUC-reviewed and approved policies or IACUC-approved specific source documents.

These alternative methods of review and approval is consistent with the OLAW Guidance on Significant Changes to Animal Activities NOT-OD-14-126.

Any proposed change to an animal activity that does not meet the parameters for VVC or administrative review in the IACUC-reviewed and approved policies or IACUC-approved specific source documents is reviewed by the Full Committee Review or Designated Member Review process.

All activities performed by an alternative process are described in an IACUC approved policy and/or SOP. Any member of the IACUC can request re-review by the Full Committee of any activity at any time.

- 8) Notify investigators and the Institution in writing of its decision to approve or withhold approval of those activities related to the care and use of animals, or of modifications required to secure IACUC approval according to PHS Policy IV.C.4. The IACUC procedures to notify investigators and the Institution of its decisions regarding protocol review are as follows:

The IACUC notifies the investigator of the decision regarding protocol or amendment review electronically (e.g., through secured email or other electronic file sharing application). If approved they are provided online access to their full approved IACUC protocol/amendment. If modifications are required to secure approval they are provided a summary of the requested modifications, and if approval was withheld, the written notification includes the reason why and the investigator is afforded an opportunity to respond in person or in writing.

The IACUC notifies the Institution of decisions regarding protocol or amendment review in the following methods:

- i. If approved, the approved status of protocol is placed into the IACUC/OAWA database to track IACUC status, protocol characteristics (e.g., PI, facility use, etc.), and expiration.
- ii. If approved, the approved status of protocol is placed into the centralized database to track IACUC status, protocol characteristics (e.g., PI, animal number approved, etc.), expiration, and animal use.
- iii. The Institutional Official receives the IACUC Full Committee meeting packet which contains a list of all IACUC protocols undergoing consideration that month, a summary of all amendments considered, and the minutes from the previous IACUC Full Committee meeting that includes Full Committee protocol and amendment deliberations and IACUC decisions. The IO has online access to all approved protocols. The Institutional Official is also advised of any critical items related to the IACUC's decisions regarding protocol/significant change review during the semiannual review and report process as described in III.D.3.

Investigators may withdraw their protocol or amendment from IACUC consideration at any time during the review. If this occurs the IACUC will stop the review and the application will be marked as withdrawn.

- 9) Conduct continuing review of each previously approved, ongoing activity covered by PHS Policy at appropriate intervals as determined by the IACUC, including a complete review at least once every 3 years according to PHS Policy IV.C.1.-5. The IACUC procedures for conducting continuing reviews are as follows:

All protocols are approved for 3-years unless a shorter approval period is defined by the IACUC. The OAWA notifies the PI when a protocol is approaching the 3-year approval period. This provides the opportunity to submit and secure approval of the appropriate De Novo renewals prior to a lapse in approval of the animal activity. For protocols at the end of their 3-year approval period, the PIs can submit a De Novo protocol for continuation of the animal activity. This protocol is considered a new protocol and is

reviewed as described for new protocols in section III.D.6. Upon approval, animals may be transferred from the expiring protocol to the De Novo (renewal) protocol.

For protocols approaching expiration for any reason (PI elected to close or nearing the end of the 3-year approval period) the animal census is tracked prior to expiration and arrangements are made to ensure that animals do not remain on the protocol after it has expired. This may include transferring the animals to an IACUC-approved Holding Protocol.

Other methods of animal activity review, which are inherent to the Animal Program, are performed on a routine basis, this may include but is not limited to:

- i. Laboratory visits by the veterinary, safety, and/or IACUC groups,
- ii. IACUC semiannual facility inspections and Program reviews,
- iii. OAWA postapproval monitoring, and/or
- iv. Communication between the veterinary group, IACUC group and animal use community.

Investigators may close their protocol at any time after approval. A request for closure is processed as an amendment. If this occurs the Investigator must verify there are no ongoing animal activities and protocol closure will not affect any associated grants, awards, contracts, etc. In addition, OAWA verifies no animals remain on the protocol prior to closure.

More frequent (e.g., annual) IACUC reviews can be performed upon request and are performed for USDA-regulated and VA funded activities.

10) Be authorized to suspend an activity involving animals according to PHS Policy IV.C.6.

The IACUC may suspend an ongoing activity if it determines that the activity is not being conducted in accordance with applicable provisions of the *Animal Welfare Act/Regulations, the Guide*, the institution's OLAW Animal Welfare Assurance, or the *PHS Policy*. The IACUC may suspend ongoing activity only after review of the matter at a convened meeting of a quorum of the IACUC membership and with a vote for suspension by a majority of the quorum present. The Institutional Official (IO) may be consulted when the IACUC determines that suspension of a protocol is a potential. This consultation with the IO may include a review of the reasons for the potential suspension and potential corrective actions. If the IACUC proceeds with a suspension, the IO is promptly provided with the reasons for the suspension and consulted regarding the corrective action plan. If the IACUC suspends an activity involving animals, the IACUC, through the IO, would promptly report the action to OLAW and the USDA with a full explanation, if appropriate.

E. The risk-based Occupational Health and Safety Program for personnel working in laboratory animal facilities and personnel who have frequent contact with animals is as follows:

The Duke Animal Program works closely with the Duke Occupational and Environmental Safety Office (OESO) and Duke Employee Occupational Health and Wellness (EOHW).

The Duke Occupational Health and Safety Program uses a hierarchical strategy for control and prevention. This includes:

- a. Hazard identification and risk assessment.
  - i. For protocol related hazards, the Duke OESO performs a review of all new protocols and changes to approved activities that are adding a hazardous agent or physical hazard, or modifying use of a previously-identified hazard. During this review, hazardous agent and physical hazard use are identified, appropriate safety procedures are reviewed, an agent-specific SOP is developed, and clearances are secured for hazardous agent use.

- ii. For non-protocol related hazards, the directors and supervisors of the animal facility will identify hazards and work with OESO and EOHW to ensure appropriate safety procedures are in place. In addition, the Laboratory Safety, Occupational Hygiene and Safety, and the Ergonomics Divisions of OESO work with the Division of Laboratory Animal Resources Safety Committee and participate in comprehensive safety audits for the major animal care facilities.
  - iii. All laboratories receive routine Duke OESO audits, which includes assessment of hazardous agent use and guidance on proper control and prevention strategies.
  - iv. Prior to hazardous agent use in animals, animal care personnel are notified in writing so that any necessary safety arrangements can be made prior to initiation of the activity. In addition, signage is used to identify hazardous agent use at both the room entrance and animal cage level.
  - v. All personnel involved in the care and use are required to have a medical clearance assessment by EOHW prior to initiation of work with animals.
- b. *Facilities, equipment, and monitoring*
  - i. Facilities are designed to minimize exposure to anticipated hazards. This is accomplished through engineering controls (e.g., quarantine space, individually ventilated cages, barrier rooms/facilities, use of appropriate hoods/biological safety cabinets, HVAC design, etc.).
  - ii. The appropriate facilities, equipment, and monitoring required to safely handle animals to reduce the possibility of physical injury or health risk to personnel are identified during the hazard identification and risk assessment process, EOHW medical clearance assessment, and/or by the Attending Veterinarian or designee with regards to routine animal husbandry procedures for that species. In addition, employees are encouraged to report near misses and safety concerns to OESO (<https://www.safety.duke.edu/contact-us>). Appropriate provisions will be made based on these evaluations and reports and can include engineering controls, development of standard operating procedures, and provision for personal protective equipment. This includes provisions for appropriate waste and carcass disposal.
  - iii. Furthermore OESO and EOHW work with the Animal Program to continuously evaluate facilities, equipment, and monitoring procedures.
- c. *Personnel training*
  - i. Individuals entering animal facilities (i.e., animal care personnel, animal users, facility/housekeeping personnel) and individuals that are listed as a protocol participant that will handle animals in the facility are required to take online training on hazardous awareness for animal facilities.
  - ii. An orientation is required for individuals entering centrally managed animal facilities. Visitors to centrally managed animal facilities must be chaperoned by approved personnel and receive information on occupational risk and hazards related to animal activities.
  - iii. Training is required before an individual is provided access to the animal facility.
  - iv. For animal use outside of centrally managed areas, the PI assures that hazard training procedures are in place.
  - v. Training is required of all individuals involved in animal care in use. These modules include training on zoonoses, allergies, hazards, and personnel protective equipment and precautions in certain life or health stages (i.e., pregnancy, illness, or decreased immunocompetence). In general this training is captured through online training modules.
- d. *Personal hygiene*
  - i. Personal hygiene requirements are established through policy and/or standard operating procedures.
  - ii. Appropriate personal protective equipment (PPE) is provided at appropriate stations near the animal use or housing location. In addition, facilities are

- provided and kept in working order to allow for personal hygiene practices, where appropriate (e.g., restrooms, hand washing stations, shower, dressing rooms, laundry facility/services)
  - iii. Personnel are not allowed to eat, drink, use tobacco products, apply cosmetics, or handle or apply contact lenses in rooms or laboratories where animals are housed or used.
- e. *Animal experimentation involving hazards*
- i. Safe-guards for hazardous agent use in animals are established through policy and/or standard operating procedures.
  - ii. The Duke Animal Care and Use Program uses a collaborative approach to evaluate appropriate safety measures involving animal experimentation involving hazards. This includes:
    1. OESO review of the protocol for hazard identification and risk assessment and establishing appropriate protective measures.
    2. Investigators notifying animal care personnel prior to hazard use.
    3. Investigators placing room entrance and cage level signage when hazards are being used with specific information on the hazard.
    4. OESO auditing laboratory spaces and OESO, IACUC, and veterinary inspections of satellite facilities.
    5. Routine communication between OESO representatives, the Attending Veterinarian and IACUC.
- f. *Personal protection*: Protective clothing and equipment is provided by the institution as appropriate and based on the risk assessment. PPE requirements are determined on a case-by-case basis with input from OESO, EOHW, and the Attending Veterinarian or designee. Signage, standard operating procedures, and/or policy outline appropriate use of PPE, where required.
- g. *Medical evaluation and preventive medicine for personnel*
- i. Individuals entering animal facilities (i.e., animal care personnel, animal users, facility, housekeeping personnel, or individuals performing IACUC semiannual facility inspections to include IACUC members and ad hoc participants) and individuals that are listed as a protocol participant that will handle animals are required to complete a medical evaluation form. Clearance is required before access to the facility and/or protocol/amendment approval.
  - ii. The medical evaluation is reviewed by Employee Occupational Health and Wellness providers or staff. They provide clearance for the individual to participate in animal activities.
  - iii. Any necessary protective measures are communicated to the individual by EOHW providers or nurses. This includes (1) required immunizations or vaccinations related to animal care and use, which will be provided by EOHW, Student Health or other healthcare professional, (2) follow-up and training on allergies, and (3) follow-up and training, including special precautions to be taken, if the employee self-identifies a work or health status for which consultation with a healthcare professional is needed (e.g., pregnancy, illness, or decreased immunocompetence).
  - iv. The evaluation, review, and potential recommendations are kept confidential. Only the designation clear or not cleared is communicated to select members of the Animal Program.
  - v. Post-offer preplacement screening may occur for select activities.
  - vi. Animal care and use personnel report any injury or near miss related to animal care or use (bites, scratches, injuries, etc.) to their supervisor, EOHW, or through work-related accident, injury, or illness forms. If necessary, injuries are treated by EOHW, Student Health, or other healthcare professional. These reports can be completed anytime. In addition, Employee Occupational Health and Wellness personnel are available 24 hours a day, 7 days a week and can be reached through a hotline number. Furthermore,

emergency care is provided at any time through Duke Hospital Emergency Services.

- vii. Duke Employee Occupational Health and Wellness offers appropriate medical support including tetanus vaccinations to all employees at Duke. In addition, confidential reproductive health counseling is available at any time.

h. *Special precautions for personnel working with nonhuman primates*

All animal care and use personnel that will be working with nonhuman primates are required to take training on working safely with nonhuman primates. This provides information on tuberculosis and *Macacine herpesvirus 1*. In addition, they are trained on appropriate procedures to take for bites, scratches, or other NHP exposures. Nonhuman primate exposure kits are available in all primate housing and use locations. Proof of measles immunization and annual PPD/tuberculosis test or documentation of alternative clearance by Employee Occupational Health and Wellness is also required to work with nonhuman primates. In addition, every IACUC member and ad hoc that participates in semiannual facility inspections are required to receive clearance (e.g., nonhuman primate training and/or measles and tuberculosis clearance) prior to entering specific non-human primate locations.

- F. The total gross number of square feet in each animal facility (including each satellite facility), the species of animals housed there and the average daily inventory of animals, by species, in each facility is provided in the attached Facility and Species Inventory table.

The Facility and Species Inventory table is included in section X (Facility and Species Inventory) of this document.

- G. The training or instruction available to scientists, animal technicians, and other personnel involved in animal care, treatment, or use is as follows:

- a. Research Personnel have to document training/experience prior to animal use. This is accomplished by:
  - i. Capturing past education, skills, experience, and/or training in regards to the specific animal activities they will be performing in the protocol.
  - ii. Verifying that personnel have completed the Duke required training and clearance activities. All protocol participants receive training in the proper and humane care and use of laboratory animals. Including but not limited to the 3-R's (refinement, replacements, and reduction) which contains information on research or testing methods that minimize the number of animals required to obtain valid results and limit animal pain and distress. The defined training is required prior to IACUC approval (new protocols and/or amendments to add protocol personnel). This includes reoccurring or continued training.
  - iii. Ensuring personnel have received a facility orientation, where appropriate.
  - iv. Animal Program's oversight of animal activities, which includes formal postapproval monitoring and other methods to ensure adequate training/experience in procedures being performed (e.g., annual reviews, laboratory inspections, OAWA/DLAR/DLC observation, IACUC mandated re-evaluations, etc.).
  - v. Provision of additional training and instruction opportunities on a routine basis (e.g., provision for hands-on training, institutional continuing education presentations, access to AALAS Learning Library modules, monthly Animal Program newsletters, etc.) and training at any time upon request.
- b. Animal Care Personnel: The Department of Laboratory Animal Resources and the Duke Lemur Center have dedicated training staff to ensure animal care personnel are adequately educated, trained, and/or qualified to perform their duties, as described in their animal care SOP's. This includes training on the proper and humane care and use of laboratory animals, identifying and minimizing pain and distress, and refinement, replacements, and animal number reduction strategies. Noting that the Duke Lemur




Center breeds animals based on the species survival plan. All training available to research personnel is also available to animal care personnel.

- c. IACUC members: Prior to participation in IACUC activities, IACUC members complete AALAS Learning Library training modules specific to IACUC functions and duties, are provided the core reference material (i.e., the *PHS Policy*, the *Guide*, the *Animal Welfare Act/Regulations*, the *AVMA Guideline for the Euthanasia of Animals*, etc.), and receive an orientation by the Office of Animal Welfare Assurance or IACUC leadership. After appointment to the IACUC by the Institutional Official, the IACUC member receives continuing education at IACUC meetings and/or through other avenues (e.g., monthly digital CE, review of training modules, apprenticeship-style training while performing IACUC duties, support for regional or national conferences/meetings, and on-demand training by IACUC/OAWA/DLAR leadership). In addition, all IACUC members are aware of and have access to the most current OLAW Animal Welfare Assurance through a secure online system. All training available to research personnel is also available to IACUC members.
- d. Online module training is required of all individuals involved in animal care in use. These modules include training on the 3-R's which includes the concept, availability, and use of research or testing methods that limit the use of animals or limit animal distress. Furthermore, additional training opportunities, including one-on-one consultation and hands-on training, are provided to all Duke's animal program participants.

#### **IV. Institutional Program Evaluation and Accreditation**

All of this Institution's Programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC within the past 6 months and will be reevaluated by the IACUC at least once every 6 months according to PHS Policy IV.B.1.-2. Reports have been and will continue to be prepared according to PHS Policy IV.B.3. All IACUC semiannual reports will include a description of the nature and extent of this Institution's adherence to the PHS Policy and the *Guide*. Any departures from the *Guide* will be identified specifically and reasons for each departure will be stated. Reports will distinguish significant deficiencies from minor deficiencies. Where Program or facility deficiencies are noted, reports will contain a reasonable and specific plan and schedule for correcting each deficiency. Semiannual reports of the IACUC's evaluations will be submitted to the Institutional Official. Semiannual reports of IACUC evaluations will be maintained by this Institution and made available to the OLAW upon request.

- (1) This Institution is Category 1 — accredited by the [Association for Assessment and Accreditation of Laboratory Animal Care International \(AAALAC\)](#) . As noted above, reports of the IACUC's semiannual evaluations (Program reviews and facility inspections) will be made available upon request.

#### **V. Recordkeeping Requirements**

- A. This Institution will maintain for at least 3 years:
  - 1. A copy of this Assurance and any modifications made to it, as approved by the PHS
  - 2. Minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations
  - 3. Records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was granted or withheld
  - 4. Records of semiannual IACUC reports and recommendations (including minority views) as forwarded to the Institutional Official, Dr. Mary Klotman
  - 5. Records of accrediting body determinations
- B. This Institution will maintain records that relate directly to applications, proposals, and proposed changes in ongoing activities reviewed and approved by the IACUC for the duration of the activity and for an additional 3 years after completion of the activity.

- C. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

## **VI. Reporting Requirements**

- A. The Institutional reporting period is the federal fiscal year (October 1 – September 30). The IACUC, through the Institutional Official, will submit an annual report to OLAW after September 30, but on or before December 1 of each year. The annual report will include:
  - 1. Any change in the accreditation status of the Institution (e.g., if the Institution obtains accreditation by AAALAC or AAALAC accreditation is revoked)
  - 2. Any change in the description of the Institution's Program for Animal Care and Use as described in this Assurance
  - 3. Any change in the IACUC membership
  - 4. Notification of the dates that the IACUC conducted its semiannual evaluations of the Institution's Program and facilities (including satellite facilities) and submitted the evaluations to the Institutional Official, Dr. Mary Klotman.
  - 5. Any minority views filed by members of the IACUC
- B. The IACUC, through the Institutional Official, will promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
  - 1. Any serious or continuing noncompliance with the PHS Policy
  - 2. Any serious deviations from the provisions of the *Guide*
  - 3. Any suspension of an activity by the IACUC

For all live vertebrate animal activities conducted or supported by the PHS, BARDA, VA, NSF, and/or NASA.

- C. Reports filed under VI.A. and VI.B. above will include any minority views filed by members of the IACUC.



## VII. Institutional Endorsement and PHS Approval

<b>A. Authorized Institutional Official</b>	
Name: Mary E. Klotman, M.D.	
Title: Dean, School of Medicine; Vice Chancellor for Health Affairs	
Name of Institution: Duke University	
Address: (street, city, state, country, postal code) Duke South Clinic 200 Trent Drive, (b) (4) Davidson Building Durham, NC 27710	
Phone: (b) (6)	Fax: (b) (6)
E-mail: <a href="mailto:Mary.Klotman@Duke.edu">Mary.Klotman@Duke.edu</a>	
Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution's responsibilities under this Assurance, I assure the humane care and use of animals as specified above.	
(b) (6)	Date: June 29, 2021

<b>B. PHS Approving Official</b> (to be completed by OLAW)	
<div>Name/Title: Office of Laboratory Animal Welfare (OLAW) National Institutes of Health 6700B Rockledge Drive Suite 2500 Bethesda, MD USA 20892-7982 (FedEx Zip Code 20817) Phone: +1 (301) 496-7163 Fax: +1 (301) 915-9465</div> <div><b>Nicole L. Lukovsky-akhsanov</b> -S</div> <div>Digitally signed by Nicole L. Lukovsky- akhsanov -S Date: 2021.07.01 15:29:27 -04'00'</div>	
Signature:	Date:
Assurance Number: D16-00123 (A3195-01)	
Effective Date: 7/1/2021	Expiration Date: 7/31/2025

## VIII. Membership of the IACUC

Date: 02/25/2021			
Name of Institution: Duke University			
Assurance Number: D16-00123 (A3195-01)			
<b>IACUC Chairperson</b>			
Name*: Anna Hampton			
Title*: Director, Office of Animal Welfare Assurance			Degree/Credentials*: DVM, DACLAM, DACAW, CPIA
Address*: (street, city, state, zip code)2424 Erwin Road, Durham, NC 27705			(b) (4)
E-mail*: Anna.Hampton@Duke.edu			
Phone*: (b) (6)		Fax*: (b) (6)	
<b>IACUC Roster</b>			
Name of Member/ Code**	Degree/ Credentials	Position Title***	PHS Policy Membership Requirements****
John Norton	DVM, PhD, DABT, DACLAM	Attending Veterinarian, Director, Division of Laboratory Animal Resources, Duke University	Attending Veterinarian
(b) (6)			Nonscientist
			Scientist
			Scientist
			Scientist
			Scientist
			Scientist
			Scientist
			Scientist
			Scientist
			Scientist
			Nonaffiliated
			Scientist
			Nonscientist
			Scientist
			Scientist
			Veterinarian

(b) (6)			Scientist/Veterinarian
			Scientist
			Scientist/Veterinarian
			Veterinarian
			Scientist
			Scientist
			Scientist
Anna Hampton (Chair)	DVM, DACLAM, DACAW, CPIA	Director, Office of Animal Welfare Assurance, Duke University	Scientist/Veterinarian
(b) (6)			Veterinarian
			Veterinarian
			Veterinarian
			Scientist/Veterinarian
			Scientist
			Scientist
			Scientist
			Scientist
			Nonaffiliated
			Nonaffiliated
			Scientist
			Nonscientist
			Veterinarian
			Scientist/Veterinarian
			Scientist
			Veterinarian
			Veterinarian
			Scientist/Veterinarian
			Scientist
			Scientist

<sup>1</sup>The nonaffiliated members are not hired or contracted by Duke University. Their only affiliation with Duke is their participation on the Duke IACUC. Their IACUC appointment is in accordance with *NOT-OD-15-109 Guidance on Qualifications of IACUC Nonscientific and Nonaffiliated Members*.

<sup>2</sup>The nonscientific members do not have scientific training. Their backgrounds include library and information science/communications, philosophy/English, and education/training respectively. Their positions at Duke are nonscientific. Their IACUC appointment is in accordance with *NOT-OD-15-109 Guidance on Qualifications of IACUC Nonscientific and Nonaffiliated Members*.

\* This information is mandatory.

\*\* Names of members, other than the chairperson and veterinarian, may be represented by a number or symbol in this submission to OLAW. Sufficient information to determine that all appointees are appropriately qualified must be provided and the identity of each member must be readily ascertainable by the institution and available to authorized OLAW or other PHS representatives upon request.

\*\*\* List specific position titles for all members, including nonaffiliated (e.g., banker, teacher, volunteer fireman; not "community member" or "retired").

\*\*\*\* [PHS Policy](#) Membership Requirements:

<i>Veterinarian</i>	veterinarian with training or experience in laboratory animal science and medicine or in the use of the species at the institution, who has direct or delegated Program authority and responsibility for activities involving animals at the institution.
<i>Scientist</i>	practicing scientist experienced in research involving animals.
<i>Nonscientist</i>	member whose primary concerns are in a nonscientific area (e.g., ethicist, lawyer, member of the clergy).
<i>Nonaffiliated</i>	individual who is not affiliated with the institution in any way other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution. This member is expected to represent general community interests in the proper care and use of animals and should not be a laboratory animal user. A consulting veterinarian may not be considered nonaffiliated.

[Note: all members must be appointed by the CEO (or individual with specific written delegation to appoint members) and must be voting members. Non-voting members and alternate members must be so identified.]

## IX. Other Key Contacts (optional)

If there are other individuals within the Institution who may be contacted regarding this Assurance, please provide information below.

<b>Contact #1</b>	
Name: Anna Hampton, DVM, DCALAM, DACAW, CPIA	
Title: Director, Office of Animal Welfare Assurance	
Phone: (b) (6)	E-mail: <a href="mailto:Anna.Hampton@Duke.edu">Anna.Hampton@Duke.edu</a>
<b>Contact #2</b>	
Name: John Norton, DVM, PhD, DABT, DACLAM	

Title:   Attending Veterinarian and Director, Division of Laboratory Animal Resources	
Phone: <span style="background-color: #cccccc;">(b) (6)</span>	E-mail: <a href="mailto:John.Norton@Duke.edu">John.Norton@Duke.edu</a>

## X. Facility and Species Inventory

Date: 3/12/2021			
Name of Institution: Duke University			
Assurance Number: 2016-00123 (A3195-01)			
Laboratory, Unit, or Building*	Gross Square Feet [include service areas]	Species Housed [use common names, e.g., mouse, rat, rhesus, baboon, zebrafish, African clawed frog]	Approximate Average Daily Inventory
(b) (4)	1,450	Mice	317
		Rats	50
		Rabbits	12
	2,165	Fish	100
		Birds	100
		Frogs	70
	4,727	Mice	1184
		Rats	17
		Birds	96
		Fish	750
	46,600	Mice	5005
		Rats	402
	260	Mice	8
	713	Rats	0
	61,150	Mice	1809
		Rats	238
		Cats	6
		Dogs	17
		Rhesus	98
		Baboons	5
		Rabbits	107
		Swine	11
		Calf	0
		Sheep	0
		Hamsters	30
		Guinea Pigs	0
		Squirrels	3
		Frogs	1
		Amphibians	1
		Birds	0
		Ferrets	12
	881	Mice	72
		Fish	74500
	550	Mice	190
		Rats	10
	36,000 + 52.6 acres	Lemurs	229
	1,600	Fish	0
	17,761 + 7 acres	Swine	3
	5,500	Rats	600
		Fish	4500
	1055	Mice	44
		Ferrets	16
		Hamsters	4
	162	Mice	50

(b) (4)		Mice	13157
	76,605	Rats	1
		Mice	36
	1,998	Fish	41000
		Mice	1360
	6,333	Fish	11000
		Mice	292
	4,245	Rats	13
	20,625	Mice	5365
		Mice	1888
	7,437	Rats	7
		Birds	96
	4,605	Fish	120000
		Rabbits	2
	457	Rats	50
		Mice	159
	1,515	Rats	6
	144	Chickens	12

\*Institutions may identify animal areas (buildings/rooms) by a number or symbol in this submission to OLAW. However, the name and location must be provided to OLAW upon request.