MANAGEMENT OF ANIMAL CARE AND USE OVERSIGHT FOR ADMINISTRATIVE COORDINATING CENTERS

PERFORMANCE STANDARD: All funded activities involving animals will be assured with effective oversight and appropriate regulatory confirmation.

BACKGROUND: The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals has a defined set of stipulations for PHS-funded activities. The National Institutes of Health (NIH) provides funds for institutions to serve the role of an Administrative Coordinating Center (ACC) and assigns certain obligations to the institution, obligations which have been historically reserved for the Grants Office at the NIH. The ACC, as the primary grantee, is responsible for ensuring that all sites engaged in research involving the use of live vertebrate animals have an approved Animal Welfare Assurance and that the activity has valid Institutional Animal Care and Use Committee (IACUC) approval (NIH Grants Policy Statement 4.1.1.3 Consortiums). 4.1.1.3 Consortiums Under consortium (subaward) agreements in which the grantee <DUKE> collaborates with one or more other organizations, the grantee <DUKE>, as the direct and primary recipient of NIH grant funds, is accountable for the performance of the project, the appropriate expenditure of grant funds by all parties, and all other obligations of the grantee as specified in the NIHGPS (see Consortium Agreements chapter in IIB). The animal welfare requirements that apply to grantees also apply to consortium participants and subprojects. The primary grantee <DUKE> is responsible for including these requirements in its agreements with collaborating organizations, and for ensuring that all sites engaged in research involving the use of live vertebrate animals have an approved Animal Welfare Assurance and that the activity has valid IACUC approval. It is an institutional responsibility to ensure that the research described in the application is congruent with any corresponding protocols approved by the IACUC.

From the NIH perspective, there are three core requirements for an institution to participate as a project performance site, these are:

1. Must submit a Vertebrate Animal Section (VAS) describing the activities;
2. Must be PHS-Assured to perform the activity proposed; and
3. Must have local IACUC approval.

From the Duke perspective, there are three additional requirements for an institution to participate as a project performance site for Duke-managed funds, these are:

1. Must be AAALAC-accredited;
2. Must have no outstanding issues with the USDA (if USDA registration is required at the institution performing the work); and
3. Must complete and execute a Memo of Understanding (MOU) between the Duke animal program and the performance site animal program to clarify animal oversight expectations, ownership of the animals, and reporting lines.
APPLICABILITY: This policy applies to activities where Duke University is the primary grantee, performs the role of the ACC for NIH-funded consortiums, and issues subcontracts to consortium institutions to fund research involving the use of live vertebrate animals.

ROLES:
1. The Principal Investigator of the Consortium Grant will designate an individual as the Duke ACC (DACC).
2. The DACC will:
   a. Coordinate issuance of subcontracts.
   b. Coordinate with subcontracted institutions and provide required documents to the Duke Animal Care & Use Program.
   c. Collect and forward ongoing progress report to OAWA at the email address IACUC@Duke.edu.
   d. Assure no animal work is performed until after Duke animal program clearance is issued by the OAWA/IACUC leadership.
3. The Duke IACUC assigns protocol congruency to the OAWA and/or IACUC leadership; but shall hold ultimate authority regarding what is or is not an acceptable IACUC review by the local institution’s IACUC.
4. The OAWA/IACUC leadership review shall use a checklist (Appendix A) to assure minimal requirements for IACUC review have been met.
5. The Duke OAWA will:
   a. Serve as the Duke IACUC’s agent regarding Administrative Center reviews.
   b. Provide notice to DACC that the protocol is acceptable or is insufficient.
   c. Request and collect a Memorandum of Understanding (MOU) from the local animal care & use program overseeing the animal activity.

DEFINITION:
- **Duke Administrative Coordinating Center (DACC):** The entity created when Duke is the primary grantee to function as the Administrative Coordinating Center; funding is provided via an NIH cooperative agreement mechanism (U series). It consists of the Duke Principal Investigator and additional faculty and staff designated in the grant. The ACC activities include substantial involvement from NIH staff.
- **DACC Point of Contact:** The DACC Individual who works with OAWA and has authority to sign on behalf of DACC.
- **Project Site:** An institution that is part of a consortium funded by NIH cooperative agreement awards (U series) and supported by a specialized
POLICY:

1. **Project Selection:** Performance sites (institutions) submit research proposals (including VAS) to the DACC. The DACC coordinates the submission and peer review of the proposed projects. The NIH program staff will make the final determination of projects to receive funding through the DACC via a subcontract.

2. **Review of Animal Activities:** After selection of the project site for animal research activities:

   a. The DACC shall obtain a copy of the VAS, the local IACUC’s approved protocol and local IACUC approval letter; and provide these documents to iacuc@duke.edu for review by the OAWA/IACUC leadership.

   b. The OAWA/IACUC leadership shall:

      i. Review the approved protocol to confirm it meets or exceeds the ethical and appropriate animal use standards of Duke University (using the checklist <Appendix A> to guide the review). The OAWA shall provide notice to the DACC that:

         1. The proposal is adequate as approved by <the name of local IACUC>; OR
         2. The proposal is not sufficient and requires the following:

            <list stipulations prior to Duke endorsement of local IACUC approvals>

      NOTE: In the case where the OAWA review concerns are numerous and/or significant, the decision may be to require submission on a Duke IACUC protocol template.

      ii. Initiate an MOU with the performance site animal program leadership. The MOU will include a statement of affirmation with the NIH’s ‘Revised International Guiding Principles for Biomedical Research Involving Animals,’ if the institution is a foreign institution.

      iii. Inquire of the most recent AAALAC Site Visit regarding programmatic mandatories or suggestions.

      iv. Perform a web inquiry of the USDA status of the proposed performance site.

   c. Upon completion of steps i. – iv., and assuming no adverse outcomes of
the steps above, the OAWA will issue a ‘clearance’ notice to the DACC. The clearance notice is an indication that there are no substantive concerns with the protocol or the institution and that funding of animal procedures can begin.

NOTE: Transfer of funds for animal activities must not begin until the ‘clearance’ notification from OAWA to the DACC has occurred.

3. Ongoing Reporting:
   a. The local institution shall provide an annual progress report for proposed research activities.
   b. Either the performance site annual progress report or the Duke annual progress report may be used, assuming the performance site report is robust and includes animal numbers, narrative of activity regarding funded animals, and any adverse events or unanticipated outcomes that occurred during the period and involving funded activities or animals.
   c. The DACC will collect the annual progress report and forward them to the OAWA via iacuc@duke.edu
      i. The OAWA/IACUC leadership shall review the annual progress report provided by the DACC.
      ii. OAWA/IACUC will notify the DACC that the work is ‘cleared’ for the subsequent year.

4. Duke Protocol:
   a. Institutions may submit a protocol to the Duke IACUC at any time.
   b. While protocols may be approved at the local institution, and while it is the assumption that most institutions have a robust and detailed review, if the local (performance site) protocol is determined as sub-par for the standards of the Duke protocol standards, then a Duke protocol will be required.
1. ADMINISTRATIVE INFORMATION

Administrative Coordinating Center (ACC):
Duke PI/Contact: Duke Unique ID: 
Duke Email: Office Phone: Cell Phone: Funding Source:

Study Site/Institution: Principal Investigator: Emergency Contacts: Protocol Title:
Registry Number: Approval Date: USDA Customer Number: PHS Assurance: AAALAC Unit Number:

2. MERIT REVIEW

☐ The proposal was reviewed for scientific merit by funding agency.

REVIEWER COMMENT:

3. ANIMAL USE

Species: Number required: __________
☐ Choice of animal species and number required is scientifically justified with consideration of possible replacement of animals with non-animal techniques (in vitro techniques, computer models, etc.), use of less sentient species, or alternate models requiring fewer animals or less invasive procedures that minimize pain and distress.

REVIEWER COMMENT:

4. CATEGORY OF USE/PAIN AND DISTRESS

☐ No painful procedures (i.e. no greater pain than would be expected from simple injections).
☐ Protocol provides appropriate anesthetic/analgesic treatment for pain relief (Category D).
☐ Protocol includes painful procedures for which anesthetics and/or analgesics must be withheld (Category E) with acceptable scientific justification.

REVIEWER COMMENT:

5. LITERATURE SEARCH FOR ALTERNATIVES TO PAINFUL PROCEDURES

☐ Literature search performed for alternatives to potentially painful and distressful procedures.
☐ No appropriate alternatives were found.
☐ Scientific justification is provided for why the alternatives discovered in the search are not acceptable.
☐ The proposed work is not unnecessarily duplicative.

REVIEWER COMMENT:

6. EXEMPTIONS FROM ANIMAL WELFARE STANDARDS

☐ No
☐ Yes. An exemption from Housing Density Standards is requested and justified.
☐ Yes. An exemption from Social Housing Standards is requested and justified.
☐ Yes. An exemption from Cage Change Frequency Standards is requested and justified.
☐ Yes. An exemption from Environmental Enrichment Standards is requested and justified.
☐ Yes. An exemption from Radio / Sounds / Noise Standards is requested and justified.
☐ Yes. An exemption from Environmental Conditions (temp, humidity, light, HVAC) standards is requested and justified.
☐ Yes. An exemption from Aquatics Water Quality Standards is requested and justified.
☐ Yes. An 'OTHER' exemption is requested.

REVIEWER COMMENT:
7. PHYSICAL RESTRAINT
☐ Physical restraint of awake animals is required and scientifically justified for achieving the research objectives. The period of restraint is the minimum required to accomplish the research objectives.

REVIEWER COMMENT:

8. NEUROMUSCULAR BLOCKING AGENTS (PARALYTTICS)
☐ Paralytics agents are required during the procedure. The protocol describes adequate anesthetic monitoring parameters to ensure appropriate anesthesia while animal is undergoing neuromuscular blockade.

REVIEWER COMMENT:

9. EXPERIMENTAL AND HUMANE ENDPOINTS
☐ Humane endpoints are appropriate to prevent or alleviate undue pain and distress.
☐ Experimental endpoints will be reached prior to humane endpoints.
☐ Animals will be allowed to experience natural death as a result of experimental procedures. Appropriate scientific justification is provided for why alternate endpoints (weight loss, evidence of morbidity, etc.) cannot be used as a surrogate for death as an endpoint.

REVIEWER COMMENT:

10. EUTHANASIA
☐ The protocol utilizes AVMA approved methods of euthanasia.
☐ The protocol proposes methods of euthanasia that are acceptable with conditions to reliably meet the requirements of euthanasia. The specific conditions are appropriately met.

REVIEWER COMMENT:

11. PERSONNEL
☐ Personnel are appropriately qualified and experienced for conducting proposed procedures or a provision for proper training is described.

REVIEWER COMMENT:

12. SURVIVAL SURGERY
☐ Animals undergo a single survival surgical procedure.
☐ Multiple survival surgery is proposed and is appropriately justified for scientific purposes.
☐ Appropriate pre-surgical and post-surgical medical care and observation is provided.

REVIEWER COMMENT: ADDITIONAL COMMENTS: