A. Purpose

The purpose of this policy is to describe the Institutional Animal Care and Use Committee’s (IACUC) policy and procedures for conducting semi-annual facility inspections and program review.

B. Background

The IACUC is mandated by federal law (Public Health Service (PHS) Policy and USDA Animal Welfare Act (AWA)) to review the Institution’s animal research program components, facilities, and animal use areas. In performing this review on a regular basis, the IACUC ensures animal well-being of the animals and compliance with Federal Regulations and Guidelines. The AWA and PHS policy require that these reviews occur at least once every six months.

C. Policy

Semiannual Animal Facility Inspections:

The IACUC will conduct inspections of animal housing facilities and study areas every six months using the WSU IACUC Facility Inspection checklist. The inspections include:

• All animal housing locations where WSU vertebrate animals are held for greater than 12 hours. Support areas such as feed & bedding storage, cage wash, & loading facilities are also included.
• All surgical locations.
• WSU owned animal transport vehicles and trailers.
• Other animal support areas may be added based upon need and circumstances.

Semiannual Program Review
The IACUC will conduct a complete review of the WSU Animal Care and Use Program every six months using the WSU program review checklist which is based on the checklist created by OLAW.

D. Procedures

Semiannual Facility/ Laboratory Inspection
The IACUC must have access to all animal housing and use areas for the purpose of verifying that the housing conditions are consistent with the AWA Regulations and ILAR Guide and that activities involving animals are conducted in accordance with the proposal approved by that committee.

The AWP Office will contact the area supervisor/manager (facility manager, investigator, research personnel) or the PI a few weeks before the inspection to schedule the site visit. The area supervisor/manager coordinating the inspection must have access to the facility, and be familiar with procedures.

The IACUC will look for specific regulatory requirements, including but not limited to:
• Training records for personnel
• Animal use consistent with approved protocol
• Animal containment, safety & space requirements
• Animal husbandry including daily monitoring, feeding, watering & frequency of sanitation
• Appropriate drug storage, control, and expiration date monitoring
• Expired drugs & supplies are separated, marked, and/or disposed of properly
• Drug/controlled substances log
• Current (up to date) calibration of anesthetic vaporizers & appropriate scavenging of anesthetic waste gases
• Separate surgery areas for preparation, procedure, and recovery for USDA regulated species
• Aseptic technique used in all survival surgeries
• Anesthesia and surgical records
• Animal use, monitoring, treatment & medical records
• Staff knowledgeable of protocol
• General cleanliness of lab areas
• Physical plant conditions associated with safety, sanitation, security and HVAC
• SOPs are appropriately displayed or accessible
• Occupational safety measures
  o Hazard identification & standard operating procedures posted
  o Current biosafety cabinet or fume hood testing
  o Required personal protective equipment present & in use
  o No human food and/or drink in any animal housing room
  o Door signage and other notices

If any IACUC checklists of the previous site visit cycle are available, they will be presented to the IACUC inspection team and facility manager or investigators.

**Inspection Team**

The IACUC Inspection teams are coordinated by the Animal Welfare Program (AWP) Office and are comprised such that they are in compliance with all applicable regulations. The inspection team typically will include at least one IACUC member, but more members are often utilized. At least, two IACUC members are required to complete the inspection in areas where AWA regulated animals are housed. No IACUC member may be excluded from an inspection in which they wish to participate. In some facilities, special entry requirements for non-essential personnel due to their controlled environments (e.g. specific pathogen free facilities), or special occupational health issues (e.g. Current TB Test) may need to be considered before allowing access to members.
Per the PHS policy ad hoc consultants may be utilized to assist in the inspection but the IACUC is ultimately responsible for the evaluation and report. AWP staff may be utilized for remote locations (not involving AWA regulated species) or for follow-up visits to ensure items noted by the IACUC have been addressed. Videos or use of live video streaming can be utilized to allow members to review facilities in unique circumstances. Summaries of the visits will be prepared by the AWP staff however the IACUC is responsible for review and approval for the final report.

**Conduct of Inspections**

Inspection team members are provided with inspection checklists. During the inspection, the team assesses the different aspects of the animal care and use program, as recommended for evaluation by the Office of Laboratory Animal Welfare (OLAW) and the AWA and listed in the final inspection report. The inspection is conducted in accordance with what is allowed by regulations and approved by the IACUC. The magnitude of any deficiencies and any other comments related to the inspected areas are documented. The timeline for the correction of each deficiency is indicated on the inspection report. AWP staff circulate a draft inspection report to the inspection team prior to finalizing. Any minority opinions are documented on the form and discussed at a convened meeting. An exit meeting with the facility manager should occur at the conclusion of each inspection so they are aware of any of the site visitors concerns and have an opportunity to clarify any potential misunderstandings.

**Deficiencies & Suggestions for Improvement**

The IACUC may cite any deficiency they observe. Deficiencies fall into two categories, “minor” and “significant.”

- **Significant Deficiency:** A deficiency that is, or may be, a threat to the health or safety of animals.
- **Minor Deficiency:** Deviation(s) in policy, procedure, or facility condition from the standards enunciated in The Guides, PHS Policy, the AWA Regulations, WSU IACUC policies and procedures, which are/were not justified exceptions to those standards. In comparison to the significant deficiencies noted above, minor deficiencies are variances which require correction but which are not serious breaches of policy or conditions endangering the health and safety of the animals and/or people.
• **Suggestions for Improvement (SFI):** When other animal care and use issues are noted that do not fall into the minor or significant deficiency categories – these could be listed as suggestions for improvement. These are less serious in nature and are to be used to improve the facility and care of the animals.

The AV and/or designee(s) along with the AWP staff review the final reports and ensure that deficiency categories are consistent. The final deficiency list is included as part of the semi-annual program review for IACUC member review.

**Follow-up**

The semi-annual inspection findings are provided to the IACUC for their review and approval during the semi-annual program review meeting. The IACUC may require further actions or explanation of any finding or the corrective action timeline. The IACUC staff documents all meeting decisions, communicates any additional requirements or requests to the responsible parties and coordinates the resolution.

**Corrective Actions**

**Deficiencies:** Unless specified otherwise, the timeline for corrective actions begins when the facility manager, or the PI responsible for the space, receives formal notification from the AWP office. It is the responsibility of the facility manager/investigator to correct the deficiencies identified in the report by the date required by the IACUC and to inform the IACUC staff of the corrective actions taken. The IACUC staff documents these corrections. Any significant deficiency that is not corrected by the specified date is reported to the Institutional Officer (IO) immediately and to the appropriate regulatory agencies within 15 business days following the specified date. Any minor deficiency that is not corrected by the specified date is reviewed by the IACUC, and necessary action is determined on a case-by-case basis.

**Suggestions for Improvement (SFI):** Items noted as suggestions for improvement do not require a response back to the WSU IACUC. If a response is returned to the WSU IACUC pertaining to an SFI, it will be documented with the formal inspection report/checklist for that facility, laboratory and/or area.
Reporting of Results to the Institutional Official (IO)

The semiannual report to the IO includes the findings from both the facility inspections and the program review along with a list of all of the exceptions to the Guide or Animal Welfare Act that have been approved by the IACUC during the previous six months. Any delays, minority views or other issues related to the inspections are documented in the report. The report to the IO is reviewed at a convened meeting of the IACUC and signed by all IACUC members present at the meeting.

E. References

1. USDA Animal Welfare Act and USDA Animal Welfare Act Inspection Guide
   https://www.aaalac.org/about/Ag_Guide_3rd_ed.pdf
4. Public Health Service Policy on Humane Care and Use of Laboratory Animals