OCCUPATIONAL HEALTH AND SAFETY REQUIREMENTS

PERFORMANCE STANDARD: Animals care and use is performed in a safe manner with proper health assessments and effective disease prevention.

BACKGROUND: The NRC reference titled: Occupational Health and Safety in the Care and Use of Research Animals states that ‘the goal of an occupational health and safety program is to prevent occupational injury and illness.’ The obligation of the institution is to provide a safe and healthy workplace for all individuals who participate in institutional programs. Duke University has an integrated and mutually supportive campus-wide program including a commitment to perform animal care and use activities in an occupationally reasonable and healthy manner.

ROLES & APPLICABILITY:
1. All personnel working with animals under a Duke IACUC approval will abide by this policy, or animal care and use privileges may be restricted or removed by the IACUC, Occupational and Environmental Safety Office (OESO), or Employee Occupational Health and Wellness (EOHW).
2. OESO is responsible for establishing processes to evaluate issues involving occupational safety decisions.
3. EOHW is responsible for establishing processes to evaluate issues involving personnel health and healthcare decisions.

POLICY: All personnel must have appropriate safety and health provisions, and protections from developing animal acquired disease or injury. The application of this policy may vary based upon the situation.

- For situations where protocol personnel are associated with Duke and the work is performed at a Duke-managed or Duke-operated facility: The Institutional Animal Care & Use Committee (IACUC) will review and may approve proposed animal care and use activities, but will withhold the IACUC approval letter until all individuals are cleared by OESO and EOHW.

- For situations where the work is being performed by Duke personnel outside of the Duke OESO umbrella (e.g. other institution): The PI should contact the safety office at the "home" or performing institution to determine their requirements regarding health & safety clearance.

- For situations where the work is being performed by a non-Duke person and is occurring at another institution: Clearance from personnel’s home health and safety office shall be required prior to release of the animal protocol approval letter. The exception to this statement is if the individual participating on the protocol is in a foreign country and not at an institution having a safety program (e.g. indigenous peoples).
- For situations where the work is being performed by a non-Duke person and is occurring at off-campus location sponsored by Duke (e.g., field station, foreign country): OAWA will provide a copy of the protocol application to OESO within 5 days of receipt. OESO will review for obvious risks and share any potential travel medicine issues with EOHW. The PI on the protocol will provide written assurance that all participants shall be afforded as safe working environment as possible, and that if any injury occurs to any participants, they shall be provided immediate first-aid and transported to a regional healthcare facility for continued healthcare provisions.

Procedures:

1. OESO Review:
   a. OAWA will provide a copy of the protocol application to OESO, generally within 5 business days of receipt of the application for IACUC processing.
   b. OESO will perform an initial review of all proposed protocols for proper safety procedures, locations, and equipment, generally within 5 business days of receipt. OESO currently reviews training during lab audits, so a cleared lab audit implies training compliance.
   c. OESO will advise the Principal Investigator of any issues or concerns that must be resolved prior to obtaining clearance.
   d. OESO will work with the PI to resolve any safety concerns, reporting back to OAWA when all concerns have been resolved that the proposed protocol has been 'CLEARED.'

2. EOHW Review:
   a. EOHW has determined that all personnel handling animals require annual completion of the Animal Handler Health Review (AHHR) form. Those individuals working with non-human primates (NHPs) must also have annual TB clearance and documented measles immunity.
   b. EOHW will review all AHHRs and provide clearance dates for AHHRs, TB clearance, and measles immunity in their database. These clearance dates are then imported into the Duke Safety (OESO) database. No personal or protected health information is shared with any member of OAWA at any time.
   c. OAWA runs a report to compare the requirements for all personnel on a new protocol with the data from EOHW. OAWA will advise the PI of any protocol personnel who have outstanding issues or concerns that must be resolved to obtain EOHW clearance.
   d. EOHW will work with protocol personnel to resolve any medical concerns, and will flag individuals as 'CLEARED' when all concerns have been resolved.
   e. OAWA will consult the database to confirm that all protocol personnel have been cleared by EOHW. Note: OAWA does not have access to specific health information, only whether or not an individual has been cleared.
3. IACUC Review:
   a. OAWA will process the proposed activity for IACUC review, noting the presence (or absence) of outstanding OESO / EOHW issues.
   b. The IACUC will review protocols without consideration of OESO or EOHW concerns.
   c. If the protocol is IACUC approved prior to receipt of a notice that the proposal has ‘CLEARED’ OESO and EOHW, the OAWA will not release the IACUC approval letter to the Principal Investigator. The original IACUC approval date will be the date used for the initiation of the protocol lifecycle.

NOTE 1: While OESO does not have the authority to conduct safety assessments of work being performed at the Durham VAMC or other non-Duke facilities, the OESO will support Duke employees in addressing potential safety concerns at these locations. The Duke OAWA or IACUC may request OESO review of proposed activities to confirm a reasoned approach to safety-related issues at the other institution.

NOTE 2: OAWA will provide a certification letter (if requested) to the funding agency after IACUC approval, without the requirement for OESO or EOHW clearance.

NOTE 3: In addition to new protocols, protocol amendments that are classified as significant changes will also be sent to OESO for review. OESO clearance will be required before providing the approval letter to the Principal Investigator.

NOTE 4: The addition of personnel to protocols will require that the individual has received clearance from EOHW. OAWA will consult OESO records to ensure that all new protocol personnel have completed the required animal-related training prior to amendment approval.