West Virginia School of Osteopathic Medicine

IACUC Manual
January 2016
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Institutional Animal Care and Use Committee Procedures Manual

The proper care and use of laboratory animals in research, testing, teaching and production (animal use) require scientific and professional judgement based on the animal’s needs and their intended use. An animal care and use program comprises all activities conducted by and at an institution that have direct impact on the well-being of animals. The West Virginia School of Osteopathic Medicine’s (WVSOM) Institutional Animal Care and Use Committee (IACUC) includes specific
information on the procedures surrounding animal and veterinary functions and training. WVSOM’s Use of Research Animal Policy (R-01) is located on the WVSOM website.

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Institutional Animal Care and Use Committee Procedures

B. The Institutional Animal Care and Use Committee (IACUC)

The IACUC at West Virginia School of Osteopathic Medicine (WVSOM) is properly appointed according to PHS Policy IV.A.3.a. The IACUC is qualified through the experience, expertise, and training of its members to oversee the Institution's animal care and use program and facilities. The IACUC at the WVSOM consists of 5 members plus an alternate community member and is charged with the responsibility of ensuring adherence to the Public Health Service Policy on the Humane Care and Use of Laboratory Animals and the Animal Welfare Act.

1. **Members** include the permanent IACUC Chair (a full time PhD or DO), a consulting Veterinarian, a trained doctoral scientist and Osteopathic Physician members; all of which are elected for 3 year terms by the faculty. A non-affiliated, non-scientist member and an alternate non-affiliated, non-scientist member are both chosen by the Institutional Official (IO). The Associate Dean for Affiliated and Sponsored Programs is designated as the IO. All members receive appointment letters
annually from the President of WVSOM upon the recommendation of the IO.

2. **WVSOM’s Program for Humane Care and Use of Animals will be reviewed at least once every 6 months** using the *Guide* as a basis for evaluation. All IACUC members are invited to participate. At a minimum, the IACUC Chair, consulting Veterinarian, and at least one other member of the IACUC will participate to establish a quorum. The Supervisor of Laboratory Animal services will review the Program. The IO attends when available. The modified National Institute of Health’s Office of Laboratory Animal Welfare (OLAW) semi-annual program review Checklist will be used for the review. The Guide is consulted as needed.

   a. The IACUC chair reviews issues from the previous program review and along with the Supervisor of Laboratory Animal Services discusses each line of the current checklist. All members mark each item on their checklist as acceptable (A), minor (M) or major deficiency (S) and write any comments.
   b. Written comments are made for minor or major deficiencies, paying especially close attention to all “must” identified items on the checklist. Changes from the previous review are noted and explained. Checklists are then signed, dated and filed with the Chair. Copies are kept by the Supervisor of Laboratory Animal Services.

3. **Semi-annual Facility Inspection.**

   **The IACUC will inspect (at least once every 6 months) all of the Institution's animal facilities and animal research sites,** using the *Guide* as a basis for evaluation.

   a. Facility and animal welfare inspections are carried out by the IACUC Chair, consulting Veterinarian, at least one other member of the IACUC, making a quorum (all members are invited), and the Supervisor of Laboratory Animal Resources. The IO attends if available. The date of inspection depends on
calendar availability of the IACUC members, only occurring when all required participants are available.

b. On the day of inspection each member of the team has a modified version of the “Checklist” suited to our specific rooms and facility. The entire team visits each room in the animal facility and discusses any findings and changes required by previous inspections. Each member records acceptable (A), minor (M), or major deficiency (S) with notes as needed based on their personal judgment. Our Veterinarian and each member observes every animal cage in active animal rooms. The consulting Veterinarian reviews all drugs and drug logs and informs the team of any issues regarding meeting standards of accountability, proper labeling, and use by date. Team members then are taken to each research lab where animals are utilized, discussing procedures with Lab technicians and/or PIs as present, again marking checklists for room number, acceptable status and comments as needed. Members present then have a final discussion, reach consensus on all minor and major deficiencies and determine what should be accomplished for proper correction. All members present sign and date their checklists for the Chair.

c. The IACUC Chair then summarizes the checklists, writes minutes of the meeting and generates the semi-annual inspection report and program review. The report includes a list of all minor and major deficiencies with ‘fix by” dates assigned after conferring with the Supervisor of Laboratory Animal Resources and other maintenance supervisors.

d. The Semiannual Program Review and Facility Inspection minutes, and report to the IO, are provided for full committee review, discussion, modification and final approval. The report specifically identifies any departures from the Guide and PHS Policy, and distinguishes between minor and major deficiencies. The IACUC understands that a significant deficiency is one which, consistent with PHS Policy and in the judgment of the IACUC and IO, is, or may be, a threat to the immediate health or safety of animals and/or humans in our facility. Any minority views are openly discussed and included in the minutes and semi-annual report.
4. The IACUC chair submits the Semi-annual Report to the IO.

The report includes all minority views, lists all minor and major deficiencies, is signed by a majority of IACUC members, and is accompanied by the IACUC minutes for the Program Review and Facility Inspector.

a. Documentation of required actions with “fix by” dates is then provided to the Supervisor of Laboratory Animal Services. In turn, the Supervisor informs the IACUC Chair, in writing, when issues are corrected.

5. IACUC Concerns, Complaints and Reporting.

Concerns involving the care and use of animals at the Institution are handled as follows:

a. All faculty, staff and students utilizing animals in research are informed that they have an obligation to report any concern regarding the welfare of animals or humans in our animal research program. They will be advised to directly report to the Supervisor of Laboratory Animal Resources, the IACUC Chair or any member of the IACUC, the Associate Dean of Affiliated and Sponsored Programs, (IO), or the President of the WVSOM, anonymously if they so choose.

b. A notice is posted in the Animal Facility and forms are available at the animal facility and online at the WVSOM website as to how to report concerns about the animal research program. If anyone feels an activity is inappropriate but does not want to file a written form, they can elect to discuss their concern with any member of the IACUC or the Associate Dean of Affiliated and Sponsored Programs. The WVSOM adheres to the regulatory authority of the Animal Welfare Act, Section 2.32, (c), (4). No employee, IACUC member, or student shall be discriminated against or be subjected to any reprisal for reporting violations of the regulations or standards of the Animal
Welfare Act or concerns they may have regarding mistreatment of animals within the School.

c. Every formal complaint will be taken immediately to the Associate Dean for Affiliated and Sponsored programs and/or the IACUC Chair who appoints the ad-hoc committee to investigate the concern.

d. If a member of the full IACUC Committee is involved in the concern, the person will not serve on the investigation or proceedings of the IACUC on the matter. If a PI is involved in the concern and is also an IACUC member, they will be recused and act only in the role of PI outlined below. If the Chair is involved in the concern, the remaining committee will choose a member to be acting Chair for this investigation. If our consulting Veterinarian is involved in the concern, the WVSOM will hire an independent Veterinarian to serve on the investigation of the submitted concern. Concerns brought forward verbally may result in follow up by means other than a full investigation by the IACUC in the absence of a written complaint.

e. The ad-hoc committee investigates the concern; including discussions with all individuals relevant to the incident or who have witnessed the incident including the PI, faculty, staff, and/or students. A summary of their findings is submitted to the full IACUC.

f. The findings will be reviewed at the next meeting of the IACUC. If concerns warrant immediate action to protect the welfare of any animals, an emergency meeting will be convened at the earliest possible time. The consulting Veterinarian, or their replacement for this concern, has authority to temporarily stop the relevant activities until the IACUC meets. The IACUC committee is informed that they have the absolute right to suspend any activity if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide or our Assurance as stated in section IV.C. PHS Policy as discussed in III.D.10 below.

g. The principal investigator or staff in charge of the reported
concern may be offered the opportunity to attend the IACUC meeting to discuss the concern and findings, to resolve any misunderstandings and to jointly find solutions to the alleged concern.

h. The IACUC will then continue in private to take appropriate action, or request any additional information prior to taking action. Minutes will record votes on actions to be taken along with any minority viewpoints. Actions may include but are not limited to the following:

i. Dismissal of the complaint.
ii. Require immediate adherence to an amended approved IACUC protocol.
iii. Require a change in previously approved procedure in a protocol or standard operation procedure.
iv. Require a previously approved protocol be resubmitted.
v. Require increased oversight and/or retraining and unannounced inspections of animal related research areas.
vi. Suspension of part or all activity within relevant approved protocols as per III.D.4.c. Above, and III.D.10 below.

i. Actions to follow:

i. The Institutional Official (IO) shall receive a summary of the concerns, the IACUC subcommittee findings, and IACUC Committee actions.
ii. The IO will write a letter to the Office of Laboratory Animal Welfare concerning any serious violation or suspension of animal activity related to the concern. Relevant granting agencies will be informed as appropriate. If unsure whether the situation is reportable, the IACUC chair or IO will first call OLAW, National Institutes of Health (NIH) for clarification.
iii. The IO will inform the USDA if appropriate and will enforce all actions required, including but not limited to, suspension of research and submission of new or revised protocol(s) by a principal investigator.

iv. The complainant, if not anonymous, will receive a summary of the actions taken, absent any confidential information concerning protocols.

v. All documentation will be maintained by the Institutional Official (IO).

vi. The PI or responsible party will be provided the information contained in any letter to OLAW and also be provided a copy of the response from OLAW when received.

6. Recommendations to Institutional Official

The IACUC Ad-hoc Committee will **make written recommendations to the Institutional Official/Associate Dean** for Affiliated and Sponsored Programs regarding any aspect of the institution's animal program, facilities, or personnel training. The procedures for making recommendations to the Institutional Official are:

a. Recommendations resulting from the semi-annual program review and facilities inspection are transmitted via the semiannual report to the IO.

b. Any concerns arising between the semi-annual inspections are brought to the attention of the Institutional Official in writing, either by the Supervisor of Laboratory Animal Services or the IACUC Chair if needed. In addition, copies of all IACUC meeting minutes are given to the Institutional Official. The Institutional Official’s response is communicated back to the IACUC and a committee meeting is called to take further action if required.

7. Protocol review and approval

The IACUC will approve, require modifications (as needed to secure approval), or withhold approval of animal protocols related
to the care and use of animals as set forth in the PHS Policy at IV.C. The IACUC procedures for protocol review are as follows:

a. Principal investigators are required to electronically submit new, 3-year renewal protocols, required revisions, or amendments to an approved Protocol directly to the IACUC Chair. All investigators are provided the electronic standard protocol form to complete.

b. A pre-review of protocols is conducted by the IACUC Chair who works directly with the PI to make modifications and changes deemed necessary to meet anticipated committee concerns. Pre-review is also conducted by the Supervisor of Laboratory Animal Resources regarding animal and facility related issues.

c. A full IACUC committee meeting is scheduled as soon as possible (usually with 1 week). All new protocols are reviewed by a convened quorum of IACUC members (Full Committee Review, FCR). No designated member review of initial protocols occur at WVSOM. Review includes all relevant issues required by the PHS Animal Welfare Act and Guide for the Care and Use of Laboratory Animals. Following committee review, only three outcomes are permitted by majority vote on a formal motion;

i. approval

ii. modifications required to secure approval, or

iii. withholding of approval.

d. If the IACUC committee determines that modifications are required to secure approval, the chair provides the PI with written committee minutes spelling out all changes needed. The resubmitted protocol incorporating changes is eligible for designated member review (DMR). The IACUC Chair sends the protocol to all members and assigns a designated reviewer. Any member may then call for a new full committee review. If no member calls for full review, the designated reviewer may only approve, require further modification for approval, or request a full committee review of the revised protocol. If the
full committee requests more than one member to do the DMR, then identical copies of the revised protocol are sent to each reviewer and remaining committee members. When the designated reviewers do not agree on outcome, the protocol will require FCR. There is no Expedited Protocol Review process at WVSOM.

e. Full Committee review takes place when needed. Prior to the review, each IACUC member is provided an agenda with attached files of protocols to be reviewed. No member may participate in the IACUC review or approval of a protocol in which the member has a conflicting interest (e.g., a member is personally involved in the project), except to provide information requested by the IACUC. A person with a conflicting interest does not contribute to the constitution of a quorum or vote on that particular protocol.

f. PIs are informed of the IACUC meeting time and asked to be available to appear before the IACUC to clarify information in the written protocol. Information provided may be requested as part of a modified protocol.

g. The Committee reviews and approves, requires modifications (as needed to secure approval) or withholds approval of those activities related to the care and use of animals as set forth in the PHS Policy at IV.C. The criteria are:

i. Procedures with animals avoid or minimize discomfort, distress, and pain to the animals consistent with sound research design.

ii. Procedures that may cause more than momentary, or slight pain or distress to the animals are performed with appropriate sedation analgesia, or anesthesia, unless that procedure is justified for scientific reasons in writing by the investigator.

iii. Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved are painlessly sacrificed at the end of the procedure or, if appropriate, during the procedure.
iv. The living conditions of animals are appropriate for their species and contribute to their health and comfort. The housing, feeding, and non-medical care of animals is approved by the Veterinarian.

v. Medical care for animals is available at WVSOM’s location and provided as necessary by a qualified, contracted Veterinarian.

vi. Personnel conducting procedures on the species being maintained or studied are appropriately qualified and trained in those procedures by the Supervisor of Laboratory Animal Services or our veterinarian.

vii. Methods of euthanasia used are consistent with the most recent recommendations in the AVMA Guidelines on Euthanasia, or if not, are justified for scientific reasons in writing by the investigator.

i. Approved protocols are maintained by the PI, IACUC Chair and Supervisor of Laboratory Animal Resources. In addition, committee members, consulting Veterinarian, and IO have access to this information.

j. The IACUC may invite consultants to assist in the review of complex animal protocols and other issues. Consultants may not approve or withhold approval of an activity or vote as an IACUC member.

k. In accordance with PHS Policy, the Institutional Official or another authorized official is not precluded from unilaterally suspending, terminating, or imposing sanctions on any activity involving animals, regardless of previous approval by the IACUC. However, no institutional official may approve animal activities or reinstate animal activities that were suspended by the IACUC.

l. The IACUC conducts continuing review of activities covered by this Policy at appropriate times as determined by the IACUC, but not less than once every three years. The duration of protocol approval can be for one to three years from the date of approval, and is determined in part by classification of the protocol by USDA pain or distress level, which correspond to a
level of discomfort incurred by an animal. Classification E protocols are only eligible for 1 year approval. However, all protocols using animals covered by the Animal Welfare Act receive only a one year approval irrespective of the pain or distress classification. All protocols for teaching receive a one year approval irrespective of the classification. The IACUC may determine to give a shorter than three year period of approval for a protocol, but never a longer one. Several months prior to the date of expiration, a principal investigator is sent a Notice of Continuing Review.

m. Designated Member Review (DMR) – The WVSOM does not have DMR for new or continuing protocols.


Protocol revisions will be reviewed and approved or will require modifications (as needed to secure approval). Approval may be withheld with recommended and/or proposed significant changes regarding the use of animals in ongoing activities as set forth in the PHS Policy at IV.C. The IACUC procedures for reviewing proposed significant changes in ongoing research projects are:

a. Requested changes in an approved protocol are submitted electronically to the IACUC Chair. The Chair then determines which method of approval is appropriate based on our Policy: Approval Process for Changes to Animal Activities at WVSOM which follows NOT-OD-14-126, Guidance on Significant Changes to Animal Activities and outlined in 7.b., 7.c., and 7.d. above. If required under 7.b., full committee review (FCR) is handled in the same manner as a newly submitted protocol following procedures in section III.D.6. Specific significant changes described in 7.c. are assigned DMR by the Chair. The DMR reviewer then conducts the review with veterinary consultation. The WVSOM IACUC Veterinarian serves as subject matter expert to determine if the proposed changes comply with IACUC-reviewed and approved policy. The veterinary consultation is documented and made a part of the DMR. WVSOM’s Consulting Veterinarian has authority to
refer any DMR protocol change for FCR and must refer for FCR any request that does not meet the criterion of the IACUC-reviewed and approved policies. If the veterinary consult is satisfactory, the designated reviewer can only approve the requested changes, require modification of the changes for approval, or request a FCR. The IACUC Chair then informs the PI in writing their review and proposed changes to an existing Protocol. Any Veterinarian or administrative DMR approval of changes will be made in writing and entered into minutes of the subsequent IACUC meeting.

b. The IACUC can review, approve, require amendments or withholds approval of written proposed changes, described in b. i-vii below, in the use of animals in ongoing protocols. The IACUC considers significant changes to be as follows:

i. from non-survival to survival surgery
ii. resulting in greater pain, distress, or degree of invasiveness
iii. in housing and or use of animals in a location that is not currently part of the animal program overseen by the IACUC
iv. in species
v. in study objectives
vi. in Principal Investigator (PI), and
vii. a protocol that impacts personnel safety.

This is not an exhaustive list. The IACUC may consider an amendment for other activities which the IACUC regards as significant for submission for full IACUC review.

c. The specific significant changes in c. i-iii, below, may be handled by DMR according to IACUC in consultation with contracted Veterinarian.

i. anesthesia, analgesia, sedation, or experimental substances.
ii. euthanasia to any method approved in the American Veterinary Medical Association’s (AVMA) Guidelines for the Euthanasia of Animals, and/or
iii. duration, frequency, type, or number of procedures performed on an animal.
d. A significant change that may be handled by the IACUC Chair utilizing the existing IACUC-reviewed and approved policy without additional consultation or notification, is an increase in previously approved animal numbers. Our policy states that a full explanation of why more animals are needed than in the original protocol must be provided and justified based on new statistical power analysis or other relevant explanations, consistent with the original rationale. The chair has the authority to refer any request for increased number of animals for FCR if insufficient reason is provided.

e. Changes that may be handled administratively according to our IACUC–approved policy, without consultation, or notification include:

   i. correction of typographical errors,
   ii. correction of grammar,
   iii. contact information updates,
   iv. change in personnel, other than the PI, with documentation of adequate, and/or
   v. qualifications and training, enrollment in occupational health and safety programs and other IACUC requirements that may be required by the IACUC.

f. Principal investigators must submit an amendment in writing to the IACUC chair at any time for any change from the approved protocol. The investigator is to refer to the protocol form to address the relevant questions. If the amendment requires IACUC consideration and is approved, the approval date is updated, but the protocol expiration date is not extended. Additional conditions may be added to the Notice of Approval.

g. The IACUC Committee may also determine that the proposed amendment, while related to the protocol, is so involved, that the amendment should be incorporated directly into the protocol and the entire revised protocol be submitted for approval.

9. **Principal investigator/s and institution** notification regarding protocol review decisions:
a. Shortly following the IACUC meeting. Principal investigators are sent notification of the status of their protocol by email from the IACUC Chair.

b. The IACUC Chair notifies 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, as set forth in the *PHS Policy* at IV.C.4. If the IACUC decides to withhold approval of an activity, it includes in its written notification a statement of the reasons for its decision, recommendations for changes that can meet the requirements and gives the investigator an opportunity to respond in person or in writing.

c. If a new investigator does not have approval from Occupational Health or has not taken the Animal Training Orientation class, approval may not be issued until he or she has done so. If an investigator did not renew their Occupational Health approval, a two month approval may only be given for the protocol, in order to encourage him or her to do so. Once the Occupational Health status is updated, the full term of protocol approval will be provided beginning with the original approval date. All current investigators with approved protocols have taken our Animal Training Orientation Course unless waived by the IACUC.

d. The Associate Dean for Affiliated and Sponsored Programs is the Institutional Official (IO). No activity involving the use of animals can occur until the IO has given final approval. Our Supervisor of Laboratory Animal Resources can only order animals after the IO has provided final written approval for the activity. Any questions regarding the status of the protocols are directed to the Office of Affiliated and Sponsored Programs.

10. **Continuing Protocol Review.**

All previously approved activities undergo an annual continuing review regardless of species, including a complete review in accordance with the *PHS Policy* at IV.C. 1-4 at least once every three years. The IACUC procedures for conducting continuing review and post approval
monitoring (PAM) are:

a. The IACUC protocol approval letter includes due dates for annual reports. The IACUC provides a reminder to the PI of the annual report date at least one month in advance. Upon receipt of the annual protocol update, the Chair determines if changes have occurred. If major changes are proposed, (see 7b. above), the full IACUC conducts annual continuing protocol review of protocol using the same procedures for Initial Committee Review or three year renewals. Every three years, the principal investigator is required to rewrite the protocol (de novo submission) in its entirety on the current protocol form. Investigators are sent notification several months prior to the expiration. The new protocol may be as simple as copying with addition of new experiments to a fully rewritten version. The literature review and Search for Alternatives must be from current searches. The IACUC reviews the new protocol as an initial review.

b. Acceptance of annual report as submitted or committee review results are provided to the PI and IO in writing. Any required protocol changes must be made by the assigned date or the IACUC will recommend to the IO that activity be suspended (as in 10 below) until such time that changes are submitted and found acceptable by Committee review.

c. Post approval monitoring (PAM), is accomplished in multiple ways as described below. PAM is completed with keeping in mind that the review is a learning experience and should be a positive process for all involved.

i. All first time surgical procedures are required to be performed under Veterinarian supervision. Final surgical SOPs are then written prior to PIs or technicians performing routine surgeries without our Veterinarian. The Laboratory Animal Supervisor (LAS) reviews the SOP and observes all recovery surgeries at least quarterly. A report is provided to the IACUC chair after each observation. The LAS also observes non-recovery surgeries at least once each year, compares
procedures to approved protocols and reports findings in writing to the IACUC. The LAS observes all animals housed in our facility multiple times during the normal work week. Animal caretakers are taught to observe individual animals in cages and report any concerns to the LAS. Any observed problem during weekends is reported to the LAS, laboratory technician or PI.

ii. All research technicians are made aware that approved animal use protocols must be followed at all times and that any modifications needed must go to the PI and be approved by the IACUC. They are encouraged to be continuously vigilant of animal health and welfare and to report any suspect issues to their PI and/or the LAS.

iii. The IACUC Chair does PAM of each recovery surgery protocol at least once annually. The Chair meets with the PI, reviews the protocol and any SOPs, gets a current update on number of animals utilized and observes at least one recovery surgery with the PI. The Chair writes a summary of the review for the PI and full IACUC. Any minor deviation from surgical SOP is given a fix by date for the PI to update in consultation with the Veterinarian for approval at the subsequent IACUC meeting. Any significant deviation from approved Protocol or SOP is handled as in 3.D.7 above.

iv. All animals are purchased by our LAS who keeps track of numbers ordered relative to numbers approved by the IACUC. No animal order is placed which would exceed protocol approval. The PI is notified that a protocol revision is required prior to continued animal usage.

v. Annual reports for each approved Protocol are to include discussion of animal usage, unexpected results or unanticipated animal related issues that form the basis for protocol revision. If needed, PIs are invited to subsequent meetings to further discuss relevant issues in order for the IACUC to pass judgment on requested protocol changes.

11. Suspension of Activity Involving Animals: As set forth in the PHS Policy at IV.C.6, the IACUC procedures for suspending an ongoing activity following A.5. above are:
a. Instructions and forms for reporting concerns about inappropriate use of animals are posted in the Animal Facility, available from the Offices of the President and the Associate Dean Affiliated & Sponsored Programs, and on the WVSOM website.

b. The IACUC may vote to suspend an ongoing activity if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide or the Assurance as stated in section IV.C.PHS Policy. The activity may be suspended only after review by a convened meeting of a quorum of the IACUC and with a majority of the quorum present voting for suspension. The Institutional Official, after consulting with the IACUC to review reasons for suspension, will take appropriate corrective action acceptable to the IACUC, and report that action with a full explanation to OLAW.

C. OCCUPATIONAL HEALTH.

The WVSOM’s Occupational Health Program for Personnel Working with Animals is based on guidance provided in the NRC publication, Occupational Health and Safety in the Care and Use of Research Animals (1997) and is under the direction of a WVSOM clinician assigned as the Occupational Health Physician and Program Director. The occupational health program applies to all animal care personnel, new investigators, medical students, summer students and others who have access to the animal facility and have contact with animals housed in the facility including housekeeping and maintenance assigned to the facility. When needed an occupational health physical exam will be provided by the Occupational Health Physician as appropriate. WVSOM contracts for all campus security, including the animal facility. The contractor covers their own personnel for occupational health. Each person enrolled in WVSOM’s occupational health program fills out a pre-exam questionnaire which is focused on previous and current health status issues relevant to employment. The exam covers only medical issues of concern to animal workers based on patient questionnaire and job requirements including, but not limited to; a structural exam, allergies, tetanus, appropriate vaccinations, vision, and hearing issues. Tetanus status and all relevant
vaccinations are reviewed and updated as required. WVSOM is not designed for housing non-human primates. Individuals who may utilize captured wild species and USDA covered species will have their occupational health physical reviewed and/or revised as appropriate. WVSOM has no farm animal facility, but some farm species appropriate for housing within our animal facility is possible. If this occurs, appropriate additions to the Occupational Health Program will include relevant zoonotic disease surveillance, training and vaccination as needed and/or available. Mandatory training on safe handling and interaction with animals, training on use of work clothing provided, and training in workplace hazards including zoonotic diseases also must be completed and reported to the Office of Affiliated and Sponsored Programs, prior to initiating animal activities.

1. OHSP participants are identified thru the hiring process or through approved IACUC protocols. The Office of the Associate Dean for Affiliated and Sponsored programs maintains an active database of approved IACUC protocols which list the individuals with contact with research animals. Protected Occupational Health Records are maintained in a secure patient files. The Occupational Health Physician provides status of approval/non-approved status of each individual to work with animals, as well as the presence/absence of restrictions, to WVSOM Human Resources office. Initial training includes recognizing possible allergies if none are present. Human Resources then forwards animal use status for those working with animals to the employee and their supervisor. No involvement with animals is allowed until the employee and their supervisor receives clearance notification from the Human Resource Office and in turn, provides the Supervisor of Laboratory Animal Resources with final approval.

2. All WVSOM PIs, faculty and staff are given written directions to contact the Occupational Health Physician/Director if there is a change in their health status, including but not limited to illness, decreased immune-competence and pregnancy. All employees with research animal contact are provided allergy recognition information on a yearly basis. All injuries in the work place, including animal
related bites, animal fluid contamination etc., must be reported. Initial first aid is available in the Animal Facility or, if the injury is more severe, the employee is sent to Med Express of Lewisburg and/or transported to Greenbrier Valley Medical Center emergency room. All PIs, faculty and staff involved in the incident must complete an online WVSOM Incident Report form. The form needs to be printed and submitted to WVSOM Human Resources within 24 hours of the incident/accident or as soon as physically able to do so. Paper copies of the form are also available in the animal facility, the Office of Affiliated and Sponsored Programs, and online under Human Resources. If the incident involves infectious materials the PI, faculty and/or staff member must also complete the online Blood Borne Pathogen Exposure form and return a print a copy along with the Incident Report form to Human Resources within 24 hours or when feasible.

3. All personnel new to working with animals at the WVSOM must undergo a mandatory orientation program provided by the Supervisor of Laboratory Animal Resources. Training includes education on the Occupational Health program and a thorough discussion of the WVSOM Safety manual as it pertains to animal users. First aid treatment and reporting requirements for bites, scratches, or other injuries are included, as are discussions of proper gowning, use of hand and eye washing stations, and provision of lockers in the shower facilities. Gowning is required in all animal rooms. Signs are posted and appropriate protection is available outside of the animal rooms. If specific personnel protection beyond gowning is required, the Laboratory Animal Supervisor will work with the PI, Veterinarian, and others to determine what is required and will make appropriate purchases and lead training on usage for all personnel needing the protection. Signage will clearly indicate access requirements for areas requiring any special personnel protection. Eating, drinking, and applying cosmetics are prohibited in the animal facility. Standard American Association for Laboratory Animal Science (AALAS) approved Animal Care and Use Training, as well as species specific training, via CITI (Collaborative Institutional Training Initiative).
4. Use of hazardous substances (e.g. chemicals, carcinogens, biological agents, ionizing radiation, etc.) in animal studies is part of the IACUC animal protocol review process. All research with issues of any hazard must have WVSOM Institutional Biosafety Committee (IBC) approval, as well as IACUC Protocol approval, provided to the Office of Affiliated and Sponsored Programs before the activity can be initiated. At this time a determination is made regarding research related hazards, the education and training required, and a plan is written for proper education and training. Training is provided by the school safety officer, LAS and/or any other identified authority as needed. Final Protocol approval by the Associate Dean of Sponsored and Affiliated Programs is withheld until all required training of involved personnel is completed. No new person is allowed to participate in known hazard research until training is completed. An annual safety inspection of the Frederick Smith Science Building is conducted by the IACUC and the WVSOM Safety Officer, which includes a review of the animal facility and adjacent research labs. Any deficiencies noted, whether facility related or human performance related, are subject to having deadlines imposed for correction of the deficiency. Follow up is provided by the Safety Officer and the Director of Occupational Health.

D.TRAINING

Training or instruction is available to scientists, animal technicians, and other personnel involved in animal care, or use is as follows:

1. **Sources** for training in the use of research animals at WVSOM is provided by completing CITI online programs and with hands-on training. All training is provided by, documented, and kept on file by the Supervisor of Laboratory Animal Resources who is both a CMAR and RLATG.

2. **Online Training:** The Collaborative Institutional Training Initiative (CITI) at the University of Miami is used by WVSOM for its online training program. The CITI Program’s Animal Care and Use (ACU)
series offers courses for IACUC members, researchers, research assistants, animal workers and staff. Their basic courses and animal-specific courses are utilized. The components of the ACU series is customized to meet the specific needs of each WVSOM learner.

3. **The Three R’s**: One IACUC meeting each year has a training session on Reduction, Replacement and Refinement. All PI’s, laboratory animal technicians, students involved with animal research, the Laboratory Animal Supervisor, and animal caretakers join the IACUC for a discussion of the three R’s, emphasizing that everyone has a role to play in reduction of animal pain and distress. Examples will be discussed, showing that all involved with animal research have a responsibility and are encouraged to come forward with ideas that might further the welfare and wellbeing of animals in our facility.

4. **Hands-on training**: Individual training is provided on specific techniques for investigators and research technicians as needed basis. The training is conducted by the Supervisor of Lab Animal Resources (LAR), Attending Veterinarian and/or a senior Research Technician. This may come about as a condition of protocol approval or as a request from the investigator. Written policies or Standard Operating Procedures are in place, or developed, for each research protocol. Compliance with relevant policies is a condition of protocol approval. New rodent surgery protocols require that at least one person be observed and approved by the Attending Veterinarian. All hands on training is documented in writing and maintained by the LAR Supervisor.

5. **New IACUC member training**: New members are given a hard copy of the PHS Policy, the Animal Welfare Act regulations, the Guide, the OLAW/ARENA IACUC Handbook, a copy of the PHS Animal Welfare Assurance and other related documents. They take the online CITI IACUC training described above with completion recorded in the Office of Sponsored and Affiliated Programs. New members then are provided a protocol to review and perform a mock meeting with the IACUC chair. The new member presents the protocol and
goes thru each section trying to articulate the appropriate requirements and issues involved. The Chair interacts with the new member to reinforce their learning and clarify issues needing further understanding. At each IACUC meeting new members are provided specific training on issues before the committee, including group re-reading of Guide and/or Act statements. Thus, each IACUC meeting is ongoing training for all members as well as conducting official business. Each year one or more members of the IACUC attends an IACUC 101 training and the Chair attends either the National SCAW meeting or an IACUC 101-201. The consulting Veterinarian attends laboratory animal sessions at the AVMA meeting, national AALAS, or NCABR meeting at least once yearly as a component of our consulting contract. The Supervisor of Laboratory Animal Resources attends the national AALAS or a LAMA meeting annually.

6. Protocol Development: Assistance to Faculty is available when needed. All new Protocols are first submitted to and reviewed by the IACUC Chair who provides feedback. When the Chair deems protocols to be adequate they are put on an agenda for full IACUC review. Those needing assistance in searching for alternatives are directed to the WVSOM Librarian who has AWIC training. A full time Statistician is also on staff. Any new investigator is provided one on one instruction by our Statistician on mathematical methods used to determine the minimum number of animals needed to obtain valid results and limit animal pain or distress. If a Protocol is presented to the IACUC without appropriate statistical basis for number of animals requested, the PI is asked to undergo training with our statistician and modify their protocol appropriately before the final IACUC protocol approval can be given. Our statistician gives the IACUC Training on minimum numbers when requested.
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AALAS</td>
<td>American Association for Laboratory Animal Science</td>
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<tr>
<td>ACU</td>
<td>Animal Care and Use</td>
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<tr>
<td>ADASP</td>
<td>Associate Dean for Affiliated and Sponsored Programs</td>
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<td>AVMA</td>
<td>American Veterinary Medical Association</td>
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<td>AWA</td>
<td>Animal Welfare Act</td>
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<td>DMR</td>
<td>Designated Member Review</td>
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<td>FCR</td>
<td>Full Committee Review</td>
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<td>IACUC</td>
<td>Institutional Animal Care and Use Committee</td>
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<td>IO</td>
<td>Institutional Official</td>
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<tr>
<td>LAMA</td>
<td>Laboratory Animal Management Association</td>
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<td>LAR</td>
<td>Laboratory Animal Resources</td>
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<td>LAS</td>
<td>Laboratory Animal Supervisor</td>
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<td>NCABR</td>
<td>North Carolina Association for Biomedical Research</td>
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<td>OHSP</td>
<td>Occupational Health and Safety Program</td>
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<td>OLAW</td>
<td>Office of Laboratory Animal Welfare</td>
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<td>PAM</td>
<td>Post Approval Monitoring</td>
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<td>PHS</td>
<td>Public Health Service</td>
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<td>PI</td>
<td>Principle Investigator</td>
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<td>SCAW</td>
<td>Scientist Center for Animal Welfare</td>
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<td>SOP</td>
<td>Standard Operating Procedure</td>
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<td>RLATG</td>
<td>Registered Laboratory Animal Technologist Group</td>
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<tr>
<td>USDA</td>
<td>United States Department of Agriculture</td>
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