Shared Responsibility

At BU we are committed to the humane care and use of animals in accordance with high ethical and scientific standards.

All members of the research community including investigators, members of the IACUC, and staff of the Animal Welfare Program, Animal Science Center, Environmental Health and Safety and Research Occupational Health are partners in this mission.
AAALAC Accreditation

• BU’s animal care and use program is accredited by AAALAC International.

• AAALAC accreditation demonstrates that BU meets standards for the humane care and use of animals, and that we strive for excellence in our program.

• Maintaining accreditation includes submitting a description of our program every 3 years and an onsite review of our program.
Regulatory Oversight – OLAW & USDA

• BU has a Animal Welfare Assurance on file with the Office of Laboratory Animal Welfare (OLAW). Our Assurance provides a description of how our program complies with the PHS Policy, the Guide for the Care and Use of Laboratory Animals, and the Animal Welfare Act and Regulations.
  • This is required for BU to conduct PHS funded animal research.

• BU is registered with the United States Department of Agriculture (USDA) – the USDA conducts unannounced inspections of both campuses annually to ensure our program is operating in compliance with the Animal Welfare Regulations.
Institutional Animal Care and Use Committee (IACUC)

The IACUC provides oversight of BU’s animal care and use program. Responsibilities include:

- Semiannual review of our program for the humane care and use of animals;
- Semiannual review of our animal facilities;
- Review of animal welfare concerns and noncompliance;
- Initial and continuing review of animal use protocols;
- Making recommendations to BU’s Institutional Official (IO) regarding any aspect of the animal care and use program;
- Authorization to suspend an activity involving animals;
- Ensuring compliance with federal, state and local laws and regulations; and
- Reporting noncompliance.
Institutional Animal Care and Use Committee (cont.)

• The composition of the committees includes scientists from various disciplines, non-scientists, veterinarians and members of the community.

• Members are appointed by the Institutional Official (IO), BU’s Associate Vice President for Research Compliance.

• BU has two committees, one on each campus – both are part of the same animal care and use program supported by the Animal Welfare Program (AWP) staff.
Charles River Campus IACUC

• Meets monthly to review protocols submitted by investigators on the Charles River Campus.

• Meeting schedule and submission deadlines for protocol submissions can be accessed on the IACUC website.

• Application, amendment, and continuing review forms can also be accessed on the IACUC website.

• Any questions or requests for assistance should be directed to the Animal Welfare Program staff – we are here to help, please do not hesitate to contact us!
Medical Campus IACUC

• Meets monthly to review protocols submitted by investigators on the Medical School Campus.

• Meeting schedule and submission deadlines for protocol submissions can be accessed on the IACUC website.

• Protocols, amendments and continuing reviews are submitted through INSPIR, BUMC’s electronic IACUC system – information on accessing INSPIR is on the IACUC website.

• Any questions or requests for assistance should be directed to the Animal Welfare Program staff – we are here to help, please do not hesitate to contact us!
What requires IACUC review?

• All activities that propose to use live vertebrate animals require IACUC review and approval prior to implementation.
  • Animals cannot be obtained or used without valid IACUC approval, all animals must be obtained/ordered through the Animal Science Center (ASC).

• IACUC review and approval is sought through the submission of a animal use protocol.
  • Once approved, the animal use protocol documents how the research will be conducted in practice – strict adherence is required.

• It is the investigators responsibility to contact the IACUC whenever there may be questions about whether or not a planned activity requires IACUC review.
Activities that are Exempt

• There are certain activities that do not require IACUC review and approval and may be determined to be exempt.

• Please note that investigators do not have the authority to make a determination as to whether or not a proposed activity is exempt – a formal request for an exempt determination must be made.

• Exemption requests should be made utilizing the form on the IACUC website.

• Examples include: the use of only dead animals, animal tissues or fluids, invertebrate animals, and some field research.
Field Research

• Whenever an investigator is planning to conduct research in the field the AWP staff should be contacted to discuss whether or not the planned activity will require IACUC review and approval or a request for exemption should be filed.
  • Generally, IACUC review and approval is required if the activity involves invasive procedures or harms or materially alters the behavior of the animal under study.
  • Again, please note, that only the AWP staff have the authority to determine if IACUC review and approval is required.

• The potential impact to the health and safety of personnel must be considered in addition to wildlife permit requirements and compliance with pertinent wildlife regulations.
Interinstitutional Collaborations

• It is common for BU to collaborate with other institutions. Common scenarios include:
  • BU is the direct awardee on a grant or contract but all of the animal work will occur at another institution (also known as the performance site).
  • BU receives a subcontract to conduct research involving animals from an external institution.

• These collaborations have the potential to create ambiguities therefore, it is important that whenever these collaborations occur or are being contemplated that the investigator reach out to the AWP staff for guidance on how to proceed, a Off-Site Application form is also available on our website.
Interinstitutional Collaborations (cont.)

• There is no regulatory requirement for dual IACUC review meaning, in many cases it may be appropriate for only one IACUC to review the study however, this must be documented through a Memorandum of Understanding (MOU) between the collaborating institutions.

• The MOU addresses animal ownership, responsibilities for animal care and use, and IACUC oversight.

• BU investigators do not have the authority to sign MOU’s, they must be signed by the IO and any requests by other institutions to have BU sign a MOU for the purposes of collaborative research should be directed to the AWP.
Making Changes to an Approved Protocol

• All planned changes to an approved protocol (i.e., addition of personnel, increase in animal numbers, addition of experimental procedures) MUST receive IACUC review and approval prior to implementation.

• Amendments can be filed on the CRC using the form on the IACUC website or on the BUMC by filing an amendment through INSPIR.

• Failure to adhere to IACUC approved protocols is considered noncompliance and in some cases must be reported to our oversight bodies – if you have any questions about amending an existing protocol, please ask, we are here to help!
Continuing Review

• Some protocols must receive IACUC review at least annually – the Principal Investigator (PI) will be notified if a protocol requires continuing review, and how often.

• If a protocol requires continuing review it is important from a compliance perspective that this review is timely – the PI will receive reminders from the AWP but ultimately it is the PI’s responsibility to ensure information is submitted in a timely fashion.

• If the PI needs to file an amendment to an approved protocol this should be done as needed – please do not wait until the time of continuing review unless they happen to coincide.

• Every protocol must be reviewed as new at least every 3 years.
Keeping the IACUC Informed

• In general, any event resulting in unexpected harm or death to an animal must be reported to the Attending Veterinarian (AV) and the IACUC immediately.

• The IACUC and the AV must be immediately notified of any unanticipated pain or distress, morbidity or mortality.

• The IACUC must also be notified of any unexpected study results that impact animals.

• When in doubt please contact the IACUC or seek guidance from AWP staff.
Compliance – Maintaining IACUC Approval

*The approved protocol must be available to all personnel
Reporting Noncompliance

• The IACUC is required to report serious and continuing noncompliance, any serious deviation from the provisions of the Guide, and any suspension of an activity by the IACUC to our oversight bodies.

• Therefore, it is critically important that any noncompliance be promptly reported to the IACUC for inquiry and if warranted, investigation.

• When questions arise, please contact the AWP for more information and to seek guidance on whether or not something is reportable.
Reporting Noncompliance (cont.)

- Examples of reportable situations include:
  - Conditions that jeopardize the health or well-being of animals;
  - Conduct of animal-related activities without IACUC review and approval;
  - Failure to adhere to IACUC-approved protocols;
  - Implementation of changes to IACUC-approved protocols without prior IACUC approval;
  - Conduct of animal-related activities beyond the expiration date;
  - Participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified;
  - Inappropriate euthanasia techniques and/or failure to confirm euthanasia; and
  - Lack of veterinary care.
Postapproval Monitoring (PAM)

- Continuing oversight of protocols is required by our oversight bodies.

- PAM includes various types of monitoring after a protocol is initially approved by the IACUC to ensure that procedures are consistent with the approved protocol.

- PAM also provides an opportunity to refine procedures and improve competency through education and training.
Postapproval Monitoring (cont.)

• Methods include: continuing review of protocols, semiannual facility inspections and observation of procedures by qualified members of the IACUC, veterinary and animal care staff.

• PAM is a cooperative and collegial effort to benefit the research and promote the well-being of the animals.
Policies, Procedures & Guidelines

• The IACUC and Animal Science Center (ASC) have numerous polices, procedures, and guidelines that govern how animal activities are conducted at BU.

• Please spend some time on the website ensuring that you are familiar with all IACUC policies, procedures and guidelines.

• Investigators are responsible for knowing which policies apply to their work and for complying with all institutional polices and procedures.
Reporting Animal Welfare Concerns

• Please review our Violation and Compliant Resolution Policy on the IACUC website.

• Everyone at BU has an obligation to report animal welfare concerns.

• Whistleblower protection - Under no circumstances will reporting in good faith be detrimental to an individual’s standing within the organization. No person will be discriminated against or be subject to any reprisal for reporting, in good faith, a concern or violation of any animal care and use regulations or standards.
Research Occupational Health Program (ROHP)

• Clearance is required for all personnel working with animals.

• After initial clearance, updates are required annually.

• Visit the ROHP website for more information or contact ROHP@bu.edu
Working with Hazardous Agents

• If you are working with potentially hazardous chemicals review of the Chemical Containment Levels (CCL) and the general practices that must be followed for each level is important – see EH&S’s website or contact EH&S at OEHS@bu.edu

• Please note that Institutional Biosafety Committee (IBC) approval is a condition of IACUC approval – if you have questions about whether your proposed work requires IBC approval contact the IBC, IBC@bu.edu

• If you are using radioactive agents, Radiation Safety Committee approval may be required.
Use of Controlled Substances

• Please familiarize yourself with the requirements for working with controlled substances on the EH&S website – registration with the Controlled Substances Program (CSP) is required.

• Please review the IACUC’s policy on the Use of Pharmaceutical – Grade Chemicals and Other Substances and Expired Medical Materials Policy.
  • Expired anesthetic, analgesic, or emergency drugs cannot be used on live animals under any circumstances.
Available Training & Resources

• In addition to this training there are other online trainings available.
• Note: to access the animal facilities additional training is required.
• Hands-on training is available – please contact the ASC Training Coordinator for more information.
• Please visit the IACUC website for a list of resources including the Guide for the Care and Use of Laboratory Animals (8th ed.) which can also be accessed online for free in its entirety.
• Please contact the AWP or ASC with requests for training and resources – we are here to connect you with the training and resources you need to be successful in your work.
Please contact us – we are here to help!

The Animal Welfare Program (AWP) staff support the activities of the IACUC.

Please contact us with questions, concerns or if you need assistance – we want to hear from you!

Email: IACUC@bu.edu

Phone: 617-638-4533
References


