1. ­­Purpose

The purpose of this guideline is to define the criteria for permitting individuals to fulfill the roles and responsibilities of a Principal Investigator (PI).

1. Scope

This guideline applies to PIs, and management responsible for identifying a new or replacement PI.

1. Definitions

Principal Investigator (PI): An MSU employee responsible for a proposal (i.e.,“animal use protocol”) to conduct research and for the design and implementation of research involving animals.

1. Qualifications/Eligibility

To be a PI, an individual must meet the criteria as defined in the Office of Sponsored Programs Principal Investigator Guide, [Appendix D Who Can Serve as a PI](https://www.montana.edu/research/osp/documents/WhocanbeaPIReijoPera2015.pdf).

1. Accountability/Responsibility
2. The PI is accountable for:

The development and obtaining IACUC approval of a protocol describing required experimental procedures and associated animal care and use, and ensuring active protocols are current through amendments and annual renewals.

1. Consultation with the Attending Veterinarian regarding husbandry, handling, medical treatment, immobilization, sedation, analgesia, euthanasia, surgical planning, perioperative care and all procedures involving pain and/or distress for the development of protocols.
2. Consultation with the Attending Veterinarian for amendments involving pain and/or distress.
3. Ensuring the conduct of the research, testing and/or teaching involving the care and use of animals, following the methodologies described in the IACUC-approved protocol.
4. The care and use of animals in ways judged to be scientifically, technically and humanely appropriate (e.g., minimized pain and distress).
5. Reporting of events impacting or potentially impacting animal care, use and welfare to the AV or designee or IACUC.
6. Reporting deviations from approved protocols to the AV or designee, or IACUC.
7. The oversight of animal census associated with the approved IACUC protocol. This is accomplished in collaboration with the Animal Resources Center, the IACUC and/or any other appropriate Animal Resources personnel. Activities may include:

a. Transferring animals to another protocol (e.g., holding, training or active protocol).

b. Discontinuing, delaying or confirming standing orders for animal.s

c. Tracking animal numbers.

d. Updating cage cards.

e. Euthanizing animals.

1. PIs have the authority to provide the following assurances:
	* + 1. All activities proposed in the protocol:
2. Are in accord and consistent with the NRC Guide for the Care and Use of Laboratory Animals and the Animal Welfare Act regulations (as amended), as applicable.
3. Comply with MSU policies, procedures and guidelines regarding the humane care and use of laboratory animals in research; unless appropriately justified and approved by the IACUC.
	* + 1. No activities involving live vertebrate animals will begin without an approved IACUC animal use protocol, or amendment as applicable.
			2. All IACUC approved protocols will be kept accurate and up-to-date and will be submitted in a timely manner to ensure annual review and approval.
			3. All experiments involving live animals will be performed under the PI’s direct or delegated supervision. The PI may delegate hands-on animal work to qualified members of the research team. However, the PI remains ultimately accountable for the conduct of the research, testing and teaching procedures performed on animals as outlined in the IACUC-approved protocol.
			4. All personnel are adequately educated, trained and verified as competent prior to performing experimental procedures under a protocol with the exception of training procedures as applicable.
			5. All personnel conducting activities with the protocol must promptly report animals showing evidence of pain, distress or clinical health issues to the AV or designee.
			NOTE: PIs must recognize that emergency veterinary care may need to be administered to animals showing evidence of pain or illness, or that euthanasia may be ordered by the AV or designee for such animals.
			6. A good faith effort has been made to search for alternatives to painful procedures in research animals, the literature search has been examined for potential alternatives and a written analysis of the utility of any cited relevant alternatives is provided in the IACUC protocol.
4. The PI is also responsible for:
	* + 1. Ensuring maintenance of complete and current animal study records in a secure accessible location. Records must be available at all times for review by the Attending Veterinarian, the IACUC, the USDA, FDA, the funding agency and/or AAALAC.
			2. Assuring all animals in the protocol are identified using appropriate cage cards.
			3. Adhering to the IACUC Protocol Review Process.
			4. Justifying the specific need for the use of animals (species and numbers) in the IACUC approved protocol.
			5. Working with individual(s) during an internal audit of their protocol (e.g. IACUC Post Approval Monitoring). The PI is also responsible for completing any corrective action(s) assigned as a result of an audit within the given timeframe.
			6. Providing information requested by the IACUC during the semi-annual Facility Inspection/Program Review. The PI is also responsible for completing any corrective action(s) assigned to him/her within the given timeframe.
			7. Providing information requested by regulatory official(s) or AAALAC and answering questions if requested.