

<b>TITLE:</b>	<b>Principal Investigator Status, Roles, Expectations &amp; Responsibilities</b>
<b>Policy Number:</b>	2014-013
<b>Responsible Department:</b>	Institutional Animal Care and Use Committee
<b>Policy Contact:</b>	<a href="mailto:IACUCOffice@westernu.edu">IACUCOffice@westernu.edu</a>
<b>Approval Date:</b>	7/9/14
<b>Reviewed:</b>	6/7/17; 2/12/2020
<b>Revised:</b>	10/15/15; 12/15/15; 6/7/17 (updated links; corrected and added titles under c)
<b>Legislation:</b>	Animal Welfare Act (Title 9 CFR Subchapter A, Part 1, § 1.1); 2/12/2020 (changed title to broaden scope; deleted reference to CRO; added list of PI responsibilities)

**Purpose of Policy:** To identify one person who will be ultimately accountable for any and all activities related to the work described in an approved animal care and use protocol.

**Policy Information:** The [Animal Welfare Act](#) defines Principal Investigator (PI) as “an employee of a research facility, or other person associated with a research facility, responsible for a proposal to conduct research and for the design and implementation of research involving animals.”

The PI on an animal care and use protocol is ultimately responsible for any and all activities related to the work described in an approved protocol. This includes, but is not limited to, responding to IACUC inquiries within the time frame stipulated by the IACUC, completion and submission of all annual reports, renewals, amendment requests and the actions and safety of all personnel identified in an approved protocol.

To be a PI on an animal care and use protocol, the person must either:

- a. hold regular faculty or research faculty status as defined in WesternU’s [Faculty Handbook](#),
- b. be an Attending Veterinarian *ex officio*,
- c. be the Director of Animal Resources (Pomona campus) or Coordinator of Animal Resources and Laboratory Management (Lebanon campus).

The IACUC has the responsibility to determine if the person named on a protocol as the PI meets the above criteria and if the person is qualified to assume the responsibilities of a PI as described above. Persons denied PI status may appeal the decision to the IACUC in writing for reconsideration but the IACUC shall make the final decision.

Only one person may be designated as the PI on a submitted animal care and use protocol. Only the PI may submit requests to amend an approved protocol or submit annual review forms, three-year renewals or protocols amended in response to IACUC concerns.

Being a PI on an animal care and use protocol does not convey any other privileges, other than those approved in the protocol, within any college or department of Western University.

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Responsibilities of the PI include, but may not be limited to:

- Ensuring that all members of the research team understand and have access to any approved IACUC protocol on which they are listed and that work does not commence until approval is received.
- Submitting annual progress reports when required and three-year *de novo* protocols when work extends beyond three years.
- Adherence to veterinary requirements and all submission deadlines.
- Ensuring that all personnel listed on his/her IACUC protocol have completed all training required by the IACUC and have enrolled in the Occupational Health & Safety Program.
- Promptly reporting to the IACUC any adverse events, noncompliance incidents and animal welfare concerns that may occur under his/her approved protocol. The PI is expected to cooperate with any investigation of any such incidents, self-reported or otherwise, by internal University personnel or by external regulators. If corrective actions are requested by the IACUC, the PI is responsible for ensuring that corrective actions are implemented and that all study personnel participate in any required re-training. When noncompliance incidents involve external reporting (i.e., to OLAW, USDA or a study sponsor), the PI is expected to review the IACUC's draft report to the outside body and promptly respond with any required edits or factual corrections.
- Engaging in all IACUC semi-annual facility inspections. The PI may delegate a responsible party within the laboratory who is familiar with the IACUC protocol(s) and the work of the lab to be present instead. External regulatory bodies, such as the USDA, may inspect WesternU's animal care facilities and animal laboratory spaces. It is expected that the PI will ensure that access is granted to enable inspection and promptly, accurately and courteously respond to any queries by the inspectors.