

 <b>BROWN</b>	<b>Institutional Animal Care and Use Committee (IACUC): Policy on Principal Investigator Eligibility &amp; Responsibilities</b>	POL 10.10.18
		Effective Date: June 2, 2017

### 1.0 Policy Purpose

The purpose of this policy is to define the requirements to serve as a Principal Investigator (PI) of an Institutional Animal Care and Use Committee (IACUC) protocol and the associated responsibilities of the PI.

### 2.0 To Whom the Policy Applies

This policy applies to all individuals who will be listed as PI on an IACUC-approved animal use protocol at Brown University.

### 3.0 Policy Statement

In order to serve as the PI on an IACUC animal use protocol, the individual must have an employment relationship and/or affiliation with Brown University that satisfies one of the following conditions:

- Be employed by the University as a faculty member (all ranks), including “research” faculty;
- Be employed by a Brown-affiliated hospital and hold a full-time appointment in a section of the Program in Biology or in a department of the Program in Medicine, and require use of Brown’s animal care facility for the proposed animal work;
- Be employed by the University as the Director of the Center for Animal Resources and Education (CARE) or a delegate of the Director of CARE.

Adjunct faculty will be considered on a case-by-case basis, upon written request to the IACUC, and with written permission from the individual’s cognizant Dean.

The Brown IACUC does not require that the PI of an IACUC protocol be the PI of any or all corresponding funding sources cited on the protocol. For example, if a National Institutes of Health (NIH) award is funding, in whole or in part, the activities on an IACUC animal use protocol, the PI of the IACUC animal use protocol is not required to be the same PI named on the NIH grant.

#### 3.1 Protocol Oversight

The PI must ensure that all members of the research team have access to any IACUC approved animal use protocol on which they are listed as personnel, that they read and understand the IACUC protocol, and that work does not commence until IACUC approval is received. In addition, the PI is

responsible for amending the IACUC protocol as needed, submitting annual continuation(s) when required, and submitting a three-year de novo protocol when work extends beyond three years from the original approval date. The PI is expected to adhere to veterinary pre-consultation requirements when writing the animal use protocol, and to all protocol review-related deadlines.

### **3.2 Training Oversight**

The PI must ensure that all personnel listed on the IACUC protocol remain in compliance with the IACUC Policy on Training and Education of Personnel Working with Laboratory Animals (the “Training Policy”). The PI **must** complete all of the “Required Core Training” outlined in the Training Policy, as well as any additional training that applies to work the PI will personally perform or directly supervise on the project.

### **3.3 Reporting Adverse Events, Non-compliance, and Animal Welfare Concerns**

In accordance with the IACUC Policy on Adverse Events, Non-compliance, and Reporting Animal Welfare Concerns, the PI must promptly report to the IACUC any adverse events, non-compliance incidents, and animal welfare concerns that occur under the IACUC-approved animal use protocol. The PI must cooperate with any investigations of such incidents conducted by internal University personnel or by external regulatory agencies, and must implement or assist with implementing any recommendations resulting from such investigations. If the IACUC requests corrective actions, the PI must ensure that corrective actions are timely implemented and that study personnel participate in any required re-training. When non-compliance incidents involve external reporting (*i.e.*, to the Office of Laboratory Animal Welfare [OLAW] or to a study sponsor), the PI is expected to review the IACUC’s draft report to the external body and promptly respond with any factual corrections.

### **3.4 Participation in Routine and For-Cause Inspections**

PIs are responsible for ensuring their laboratory space(s) and associated personnel are available for routine IACUC semi-annual facility inspections. While it is preferred that the PI be present for semi-annual facility inspections and available to meet with inspectors whenever feasible, the PI may delegate a responsible party within the laboratory who is intimately familiar with the IACUC animal use protocol(s) and the day-to-day work of the lab to be present and available in the PI’s place. The PI must ensure that any inspection findings are rectified by the assigned date for correction.

External regulatory bodies, such as the USDA and AAALAC, routinely inspect Brown’s animal care facilities and animal laboratory spaces. The PI must be present for inspections by regulatory bodies, will ensure that access is granted to enable inspection, and will promptly, accurately, and courteously respond to any queries by the inspectors.

When a for-cause inspection is necessary, the PI must be present and cooperative for the duration of the inspection and will ensure that any other study personnel listed on the IACUC-approved animal use protocol are present at the inspectors’ request.

### 3.5 Transfer of PI and/or Delegation of a Co-Investigator

Transfer of an IACUC-approved animal use protocol to a new PI is considered a significant modification that requires an amendment to the protocol and approval by the IACUC. If the PI of an IACUC-approved animal use protocol will not be physically present at Brown or at an affiliated hospital (as applicable) for six months or longer [six months or longer], the PI **must** delegate a qualified Co-Investigator on the animal use protocol to provide day-to-day oversight of the laboratory.

The Co-Investigator must meet the PI eligibility criteria outlined herein and will assume the associated responsibilities of the PI for the duration of the PI's absence. The Co-Investigator delegation request must be submitted as an amendment to the IACUC-approved protocol for the IACUC's review and consideration sufficiently in advance of the PI's expected absence to ensure that approval is received before the PI's departure.

### 4.0 Definitions

For the purpose of this policy, the terms below have the following definitions:

**Principal Investigator (PI):** The person “responsible for a proposal to conduct research and for the design and implementation for research involving animals” (AWAR, p. 11). *The Guide for the Care and Use of Laboratory Animals, 8th edition* and the *Public Health Service Policy on Humane Care and Use of Animals* also refer to the PI as the person who is able to make or take part in decisions regarding important topics such as managing a vivarium, disaster planning, and end of life/study judgments.

### 5.0 Responsibilities

All individuals to whom this policy applies are responsible for becoming familiar with and following this policy. University supervisors are responsible for promoting the understanding of this policy and for taking appropriate steps to help ensure compliance with it.

### 6.0 Consequences for Violating this Policy

Violation of this policy may be considered a serious event of noncompliance that is reportable to the IACUC, funding and accrediting agencies, as well as other regulatory agencies. Violation of this policy is a serious matter that may adversely affect both the ability to perform animal work and acquire funding sources.

Failure to comply with this and related policies is subject to disciplinary action, up to and including suspension without pay, or termination of employment or association with the University, in accordance with applicable (*e.g.*, staff, faculty, student) disciplinary procedures.

## 7.0 Related Information

Brown University is a community in which employees are encouraged to share workplace concerns with University leadership. Additionally, [Brown's Anonymous Reporting Hotline](#) allows anonymous and confidential reporting on matters of concern online or by phone (877-318-9184).

The following information complements and supplements this document. The information is intended to help explain this policy and is not an all-inclusive list of policies, procedures, laws and requirements.

### 7.1 Related Policies:

- [Training and Education of Personnel Working with Laboratory Animals](#)
- [Adverse Events, Non-compliance, and Reporting Animal Welfare Concerns](#)

### 7.2 Related Procedures: N/A

### 7.3 Related Forms: N/A

### 7.4 Frequently Asked Questions (FAQs): N/A

### 7.5 Other Related Information: References

- Animal Welfare Act. United States Department of Agriculture Animal and Plant Health Inspection Service. November 2013. USDA-APHIS
- Institute for Laboratory Animal Research, National Research Council. 2011. The Guide for the Care and Use of Laboratory Animals, 8th edition. Washington, DC: National Academies Press.

## 8.0 Policy Owner and Contact

### 8.1 Policy Owners: Vice President for Research

### 8.2 Policy Approved by: Vice President for Research

### 8.3 Subject Matter Contact: Brown University Animal Research Compliance

- Telephone: 401-863-3050
- Email: [IACUC@Brown.edu](mailto:IACUC@Brown.edu)

## 9.0 Policy History

### 9.1 Policy Effective Date: June 2, 2017

### 9.2 Policy Last Reviewed: December 1, 2020

### 9.3 Policy Update/Review Summary: This policy is not new; it was converted to the University's new policy template and re-reviewed by the IACUC at its convened meeting on July 10, 2020. Prior version of this policy was:

- IACUC Policy Principal Investigator Eligibility & Responsibilities, date of IACUC review and approval: June 2, 2017