I. **Purpose:** Brown University’s Institutional Animal Care and Use Committee (IACUC) has adopted the following policy to define the requirements of a Principal Investigator conducting animal research, teaching or testing on any protocol approved by Brown’s IACUC. Brown’s IACUC is charged with ensuring that all animal use procedures meet the criteria set by the federal regulations, including the Animal Welfare Act and Regulations (AWAR) and the Public Health Service Policy (PHS Policy). The PHS Policy requires that institutions to comply with the performance-based standards in the *Guide for the Care and Use of Laboratory Animals* (*The Guide*).

II. **Definition:** The Principal Investigator (PI) is defined as the person “responsible for a proposal to conduct research and for the design and implementation for research involving animals” (AWAR, p. 11). *The Guide* and PHS Policy 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, end of life/study judgments, etc.

III. **Policy:** This policy sets forth Brown’s requirements for a member of its research community to serve as a PI on an IACUC protocol and responsibilities when one serves as a PI.

A. **Qualifying Appointments**

   In order to serve as the PI on an IACUC protocol, the PI must have an affiliation with Brown University that satisfies one of the following conditions:

   1) Be employed by the University as a faculty member (all ranks), including “research” faculty.

   2) 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. Although generally employed by affiliated hospitals, medical faculty are considered University faculty for the purpose of serving as PIs and submitting proposals for external support, therefore, they may use Brown’s IACUC.

   3) Be employed by the university as the Director of Animal Care.
4) Adjunct faculty may be considered by the IACUC on a case-by-case basis.

The Brown IACUC does not require that the PI of an IACUC protocol also be the PI of all corresponding funding sources. For example, if an NIH award is funding, in whole or in part, the activities on an IACUC protocol, the PI of the IACUC protocol is not required to be the same PI name on the grant.

B. Protocol Oversight
The PI must ensure 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. In addition, the PI is responsible for amending his/her protocol as needed, submitting annual continuation(s), when required, and submitting a three-year de novo protocol when work extends beyond three years. The PI is expected to adhere to veterinary pre-consultation requirements and all submission deadlines.

C. Training Oversight
The PI is responsible for ensuring that all personnel listed on his/her IACUC protocol remain in compliance with the IACUC Policy on Training and Education of Personnel Working with Laboratory Animals. The PI must complete all of the “Required Core Training” outlined in this IACUC Policy, as well as any additional training that applies to work he/she will personally perform or directly supervise on the project.

D. Adverse events, Noncompliance, 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, 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 or a study sponsor), the PI is expected to review the IACUC’s draft report to the outside body and promptly respond with any suggested edits or factual corrections.

E. Participation in routine and for-cause Inspections
PIs are expected to engage in all IACUC semi-annual facility inspections. While it is preferred that the PI be present for semi-annual inspections whenever feasible, he/she may delegate a responsible party within the laboratory who is intimately familiar with the IACUC protocol(s) and the day-to-day work of the lab to be present instead. External regulatory bodies, such as the USDA and AAALAC (among others), may

---

1 While the PI retains responsibility for ensuring that these requirements are met, submission of these documents can be delegated to a responsible member of the laboratory.
inspect Brown’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.

F. Transfer of PI and/or delegation of a Co-Investigator
Transfer of an active protocol to a new PI is considered a significant modification that requires an amendment and approval by the IACUC. If the PI of an active IACUC protocol will not be physically present at Brown/an affiliated hospital for greater than 6 months, he/she must delegate a qualified Co-Investigator on his/her IACUC protocol to provide day-to-day oversight and adhere to the responsibilities outlined for PIs herein. This delegation can be accomplished via an amendment.

References: