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|  BROWN | Institutional Animal Care and use Committee (IACUC): Policy on Pilot Studies | POL 10.10.09 |
| | | Effective Date: June 28, 2019 |

1.0 Policy Purpose

The purpose of this policy is to establish expectations for animal researchers when proposing to conduct a pilot study using animals in research. This policy also applies when the IACUC requires that a pilot study be conducted based on proposed study procedures and/or based on proposed study personnel.

2.0 To Whom the Policy Applies

This policy applies to all persons involved in research using live vertebrate animals at Brown University under an IACUC-approved animal use protocol.

3.0 Policy Statement

When novel studies or techniques are proposed or when information for an alternative endpoint is lacking, the use of a pilot study is an effective method for identifying and defining humane endpoints and reaching consensus regarding such studies, techniques, or endpoints among the Principal Investigator (PI), IACUC, and veterinarians. A PI may also propose or the IACUC may require a pilot study to enable the PI to demonstrate his/her/their ability to perform a procedure or technique with which the PI and/or the research team do not have significant experience, as self-determined by the PI or as determined by the IACUC. The IACUC may also request and require, solely within its discretion, that a proposed animal use protocol include a pilot study. A system for communication with the IACUC must be in place both during and at the conclusion of any pilot study to ensure timely assessment of the pilot study's success.

It is the responsibility of the PI to submit a proposal for any pilot study as part of an IACUC animal use protocol, and to promptly provide the results of the pilot study to the IACUC once the pilot study is completed, or earlier if requested by the IACUC.

3.1 When a Pilot Study Is Necessary

The IACUC may request, at its sole discretion, that any proposed new animal use protocol or proposed modification to an approved animal use protocol be conducted initially as a pilot study for any reason.

For some new techniques, or when new endpoints are proposed, the IACUC may determine that a pilot study is necessary to show (a) that the technique can work on a small number of animals before the PI may request using the technique with a larger number of animals and/or (b) that new endpoints can be humanely achieved.

The IACUC may also require that a pilot study be designed to assess the effect of the procedure on the animals and to evaluate the skills of the research team. Using a pilot study to assess the skills of the research team may be done at any point in time, such as at the outset of a new proposed study or when experienced personnel leave a study or a laboratory, thereby altering the qualifications of the research team to perform certain techniques.

3.2 IACUC Animal Use Protocol Requirements

To request a pilot study, the PI may include the pilot study as part of the larger scope of the research project in the animal use protocol submitted to the IACUC. The pilot study should be clearly delineated in the protocol to describe its scope separate from the animal use activities the researchers intend to pursue if the pilot study is successful. Alternatively, the PI may submit a new animal use protocol with only the pilot study activities described and later amend the IACUC-approved protocol to expand the scope of the research project following confirmation by the IACUC that the pilot study was sufficiently successful.

In either event, the PI must submit the results of the pilot study to the IACUC prior to beginning the larger scope of the research project or amending the animal use protocol to expand the scope of the research project. Results must be reported to the IACUC via email to IACUC@Brown.edu. The PI may not proceed with a larger proposed study, extending beyond the activities described in the pilot, until the IACUC has granted approval in writing.

4.0 Definitions: N/A

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:** N/A

7.2 **Related Procedures:** N/A

7.3 **Related Forms:** N/A

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

7.5 **References:**

- Institute of Laboratory Animal Resources (U.S.). 2011. *Guide for the Care and Use of Laboratory Animals*. Washington, D.C.: National Academy Press.

8.0 Policy Owner and Contact

8.1 **Policy Owner:** Vice President for Research

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

8.3 **Subject Matter Contact:** Brown University Animal Research Protection Program

- Telephone: 401-863-3050
- Email: IACUC@Brown.edu

9.0 Policy History

9.1 **Policy Effective Date:** June 28, 2019

9.2 **Policy Last Reviewed:** June 24, 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 May 1, 2020.