



Albert Einstein College of Medicine

Grant/Proposal Application and IACUC Congruency Policy

I. Purpose

The NIH Grants Policy Statement defines contractual or legal obligations between the grantee institution and NIH. The Grant Policy Statement requires the institution to verify, before award, that the institution's IACUC has reviewed and approved the animal work outlined in the proposal. In particular, "It is an institutional responsibility to ensure that the description of animal studies included in the application is congruent with any corresponding protocol(s) approved by the IACUC." (NIH Policy Statement 10/12). Consequently, a congruency review is required for all funding that uses live vertebrate animals to ensure that the work outlined in the proposal is supported by an active, approved protocol.

II. Scope

This policy applies to all research experiments and programs at Einstein.

III. Policy

Albert Einstein College of Medicine elects to proceed according to Just-in-Time procedures for IACUC approval; and bears the responsibility for supporting the decisions of the IACUC. Einstein's IACUC should not be pressured to approve a protocol or be overruled on its decision to withhold approval.

In this case, the IACUC approval date is not required at the time of grant submission. At time of submission, the proposal can be submitted as "pending". NIH grants management staff will request the approval date as a Just-In-Time requirement in the pre-award stage. When NIH requests "Just in Time" information, it is the responsibility of the Principal Investigator to contact the IACUC office to obtain the information.

The IACUC office conducts a side-by-side direct comparison of the proposal and the IACUC protocol. Congruence will be evaluated for several important parts of protocols and proposals. Initially, The Vertebrate Animal Section and the Approach part of the Research Strategy Section are the areas of the grant to be compared with the protocol. However, other sections of the grant proposal may be reviewed. Information to be reviewed includes:

- General scope of work – disease area, target organs, etc.
- Species of animals
- Number of animals and sex
- Agents administered (including anesthetics, analgesics and experimental agents)
- Method to administer the agent
- Procedures to be conducted on animals
- Method of euthanasia
- Personnel involved in the animal studies
- Collaborative studies

It should be noted, that congruency will be established by review of all the studies described in the Grant Proposal, including: alternative studies and those proposed to be carried out at later time (years four and five). NIH will accept Animal Use protocols that are not more than three years old at the time of starting the Project. NIH considered that the ongoing work must stop if in fact an approved protocol expires.

The IACUC will work closely with investigators to clarify information or to help amend the protocol in a timely manner to ensure achieve congruency. In some cases, it might be necessary submit a new protocol to establish congruency. If at the JIT congruence review the PI decides not to perform specific procedures described in the grant a note should be filed, and the NIH should be informed of the change with verification of IACUC approval, as part of the JIT process.

It is essential to recognize that compliance with the PHS Policy is a term and condition of the Grants Policy Statement. More than just a set of rules, the Grants Policy Statement defines contractual or legal obligations between the grantee institution and NIH. If an institution accepts PHS funds and fails to meet the terms and conditions, there can be fiscal, civil, and/or criminal penalties.

For program consistency and to maintain the highest standards for compliance, Einstein applies these rules to all funding proposals regardless of source. Some sponsors require proof of IACUC congruency approval at the time of submission. In those cases, the IACUC will perform the congruence review before the Grant submission.

NOTE: The Congruency Letter for IACUC Review is different from the Protocol Approval letter. The Protocol Approval letter is not acceptable documentation to ensure compliance with NIH Policy.

General information: NIH Policy Statement 10/12 (4.1.1.2 Verification of IACUC Approval)
http://grants.nih.gov/grants/policy/nihgps_2012/nihgps_ch4.htm#iacuc_approval_verification

Grant Policy and Congruence (Webinar) [Grants Policy and Congruence - June 7, 2012 | grants.nih.gov](http://grants.nih.gov/grants/policy/nihgps_2012/nihgps_ch4.htm#iacuc_approval_verification)

IV. Definitions

None.

V. Effective Date

Effective as of: 23 February 2018.

VI. Policy Management and Responsibilities

Einstein's Institutional Animal Care and Use Committee (IACUC) is the Responsible Office under this Policy. The Institutional Official for the IACUC is the Responsible Executive for this policy. The IACUC Chairperson is the Responsible Officer for the management of this policy.

VII. Approved (or Revised)



Institutional Official



Date