



Timetable for IACUC and PI Responses to Submissions Policy

I. Purpose

This policy outlines timetables for the Institutional Animal Care and Use Committee (IACUC) and Principal Investigator (PI) responses to protocol and modification submissions and requests for revisions.

II. Scope

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

III. Policy

A. Incomplete Protocols or Modifications

Protocols or modifications that are incomplete at the time of submission will be returned to the Principal Investigator (PI) for completion within one (1) week of submission. No further review of the protocol will take place until a completed protocol form is submitted. Criteria for incompleteness include:

1. Items in protocol or modification are left blank
2. Required appendices are not attached
3. No Attachments of procedure or methodology referred except Core approval letter, Approval from the chair of the department, and funding documents to be deleted in the protocol.

B. Triage

When complete protocol or modification is received, it will be assigned to either a Review Subcommittee (RSC), with a final review/approval by members of the full IACUC or designated to a Reviewer (Reviewer) as per the IACUC review policy. Any protocol or modification not requiring full review can be reassigned to a full review by any member of the IACUC including the Reviewer. Assignment of the submitted protocol or modification will take place within two (2) weeks of receipt of the completed protocol or modification

C. IACUC Response

1. Full Review

A protocol or modification assigned to full review will be discussed at a RSC meeting. RSC meetings are typically held two-three times a month and comments are immediately sent to the PI through eSirius. The protocol and comments from reviewers are discussed at the full committee meeting. Comments

compiled from the RSC meeting and the full committee meeting will be sent to the PI within one week of the full committee meeting.

2. Delegated Review

A protocol or modification assigned to delegated review will be reviewed and any requests for revisions sent to the PI within two (2) weeks of assignment to a Reviewer.

D. Response by PI

The PI is expected to respond to requests for revisions by either the RSC or the Reviewer within two (2) weeks of such request. The office of the IACUC or the Reviewer will remind the PI of this responsibility if no response is received by the end of this period. If a PI has not responded to a request for revision within one (1) month, a final reminder will be sent indicating that the protocol or modification will be considered withdrawn if revisions are not provided within two (2) more weeks.

E. Subsequent Revisions

Any requests for further revisions should be made within two (2) weeks of receipt of the revised protocol or modification. The PI is expected to respond to such request within two (2) weeks, or the protocol or modification will be considered withdrawn. The elapsed time between the submission of an initial protocol or modification and the receipt of a final revised version should be no longer than three (3) months.

F. Inquiries

Inquiries regarding the status of a submitted protocol or modification may be addressed to: iacuc@einsteinmed.edu or the Reviewer.

IV. Definitions

None.

V. Effective Date

Effective as of: 19 February 2018.

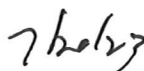
VI. Policy Management and Responsibilities

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

Revision dates: 4/20/2005, 6/15/2011, 4/29/2014, 2/19/18

20 July 2023

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