



**Duke University
Animal Care & Use Program
Policy**



**ADMINISTRATIVE ACTION ON TERMINATION OF
REVIEWED (NOT APPROVED) PROTOCOLS
AND AMENDMENTS**

PERFORMANCE STANDARD: Animal use applications and amendments to approved protocols will be processed rapidly, providing faculty with the maximum amount of time possible to address Committee concerns and clarifications.

BACKGROUND: The IACUC has the responsibility to require modifications to requests for animal use prior to approving the application for use (or amendment of an existing protocol). To prevent development of a very large collection of unapproved protocols (or unapproved amendments) in the IACUC files, which results in slower service to all researchers, complicates the oversight process, and interferes with support of active research, the IACUC has established a process for protocol review and approval (and amendment review and approval). This policy specifically addresses the duration of time until the IACUC will administratively inactivate an application for failure to respond to questions.

ROLES:

1. **Researcher:** The investigator should respond to the IACUC inquiries in a timely manner.
2. **OAWA Staff:** The OAWA (IACUC support) shall distribute the proposed activity (protocol or amendment) to the OESO, the EHOW within 3 business days of receipt. The OAWA staff will communicate the IACUC instructions and required clarifications within 7 days of the IACUC meeting (decision) to the Principal Investigator. The OAWA will receive Principal Investigator correspondence when provided and forward to the appropriate IACUC activity (Designated Member, Chair, Vice Chair, Sub-Committee,) within 48 hours of receipt. This policy focuses on the time after these steps have occurred (details below).

PROTECTION POSTURES REQUIRED: None

PROCESS: The process for PI notification of administrative applications for animal use is as follows (counting from the day the IACUC [either full Committee or Sub Committee] meets as day 0):

1. **Day 0 -7:** OAWA staff will provide IACUC communication to Principal Investigator detailing the requirements for approval (including specific IACUC clarifications, required training, and absence of OESO / EHO clearance). Email is preferred and should have a Return Receipt to assure receipt by the PI. If there is no Email address, then a FAX or hard copy mailed letter may be used.

2. Day 25-30: If no response from the PI is received by this milestone, then the OAWA staff will send a second correspondence to the PI requesting a response to the IACUC's previous correspondence. Email is preferred and should have a Return Receipt to assure receipt by the PI. A template letter is attached to this policy.
3. Day 40-45: If no response from the PI is received by this milestone, then the OAWA staff will send a third correspondence to the PI requesting a response to the IACUC's previous correspondence. Email is preferred and should have a Return Receipt to assure receipt by the PI. A template letter is attached to this policy.
4. Day 50-55: If no response from the PI is received by this milestone, then the:
 - a. OAWA Protocol Specialist will send a fourth correspondence to the PI requesting a response to the IACUC's previous correspondence. Email is preferred and should have a Return Receipt to assure receipt by the PI.
 - b. OAWA Protocol Specialist will place a phone call to the PI, and if the PI is not available, a message will be left on the voice messaging system.A template letter is attached to this policy.
5. Day 60: If no response by the PI is received by this milestone, then the OAWA staff member will forward the application package with the referenced Emails, to the IACUC Chairperson for a signature to authorize administrative termination of the application.
6. Day 60+: OAWA will send an Email (FAX or hard copy letter) to the PI advising them of the action and advising them that a new protocol / amendment must be submitted to the IACUC if they wish to pursue this proposed activity. A template letter is attached to this policy.

LETTER SENT 25-30 DAYS POST IACUC CONSIDERTION

DATE: Date
TO: PI NAME
FROM: Office of Animal Welfare Assurance (OAWA)
APPLICATION TITLE:
REGISTRY NUMBER:

Re: Final action on the above referenced animal use application / amendment to an existing protocol was deferred by the IACUC on (INSERT DATE) pending receipt of additional information for review by the IACUC.

As of the date of this letter, the information required to complete the review has not been received.

No animals may be ordered or housed, and no procedures involving animals may take place until this application has been approved by the IACUC.

Should you have any questions about this action, please contact the Office of Animal Welfare Assurance at 668-6720.

The IACUC procedure policy on this matter is available on the Animal Program Web Site at the following address: <http://vetmed.duhe.duke/xxxxxxxxxxx.pdf>

LETTER SENT 40-45 DAYS POST IACUC CONSIDERTION

DATE: Date
TO: PI NAME
FROM: Office of Animal Welfare Assurance (OAWA)
APPLICATION TITLE:
REGISTRY NUMBER:

Re: Final action on the above referenced animal use application / amendment to an existing protocol was deferred by the IACUC on (INSERT DATE) pending receipt of additional information for review by the IACUC.

As of the date of this letter, the information required to complete the review has not been received.

This is the second and final alert.

Failure to respond with the IACUC's requested clarification will result in an administrative termination of further review of this application by the IACUC.

None of the procedures proposed under this application can be performed until the requested clarifications have been approved by the IACUC.

Should you have any questions about this action, please contact the Office of Animal Welfare Assurance at 668-6720.

The IACUC procedure policy on this matter is available on the Animal Program Web Site at the following address: <http://vetmed.duhe.duke/xxxxxxxxxxx.pdf>

LETTER SENT 50-55 DAYS POST IACUC CONSIDERTION

DATE: Date
TO: PI NAME
FROM: Office of Animal Welfare Assurance (OAWA)
APPLICATION TITLE:
REGISTRY NUMBER:

Re: Final action on the above referenced animal use application / amendment to an existing protocol was deferred by the IACUC on (INSERT DATE) pending receipt of additional information for review by the IACUC.

As of the date of this letter, the information required to complete the review has not been received.

Accordingly to policies of the institution's animal care and use program, failure to respond with the IACUC's requested clarification within 60 days of the IACUC's initial review will result in an administrative termination of further review of this application by the IACUC. Termination of consideration will occur on <DATE>. After this date, a new proposal must be received by the IACUC for further review.

A copy of the application / amendment for animal use that was originally submitted to the IACUC is enclosed. Should you wish to perform this study in the future, a new animal use application / amendment to an existing protocol must be submitted for IACUC review and approval.

Should you have any questions about this action, please contact the Office of Animal Welfare Assurance at 668-6720.

The IACUC procedure policy on this matter is available on the Animal Program Web Site at the following address: <http://vetmed.duhe.duke/xxxxxxxxxxxx.pdf>