

Subject: Protocol Review outside Normal IACUC Meeting Schedule

Source: Institutional Animal Care and Use Committee (IACUC)
Effective Date: 02/08/21
Replaces: 08/11/14
Applies to: Research or teaching studies involving animals
Reference: AWA; PHS Policy on Humane Care & Use of Laboratory Animals;
Guide for the Care & Use of Laboratory Animals



Introduction

The Institutional Animal Care and Use Committee (IACUC) maintains oversight review for federally mandated rules and regulations with regard to animal research, ethics, misconduct and biomedical research for the University of Colorado Denver | Anschutz Medical Campus (CU Denver | Anschutz).

The IACUC Office facilitates the animal care and use protocol process for all CU Denver | Anschutz research faculty; advises researchers and maintains a repository of regulatory information; provides support for the IACUC and maintains oversight review for federally mandated rules and regulations with regard to animal research, ethics, misconduct and biomedical research.

Policy Statement

This policy is intended to provide information on requests for review of protocols outside the normal timeline under which protocol review would normally occur i.e. "emergency" review by designated member of protocols and to establish the procedures to be followed.

Procedures

Accelerated i.e. outside the normal Committee meeting schedule, new protocol or amendment review by designated member is discouraged and used sparingly. The IACUC Chair may grant permission for review of protocols by designated member for issues that are determined by the Chair to be of an emergency nature. Examples are: protocol deviations, facility disasters or life threatening incidents. To be determined on a case by case basis.

- Investigators requesting a review of their protocol outside the Committee schedule and process are required to submit justification for the request.
- The request is reviewed by the IACUC Chair. If the Chair decides that adequate justification exists for the requested review of the submitted protocol, review is conducted by the Designated Reviewer Process.
- The investigator is required to submit the completed protocol submission form.
- The protocol is distributed as an e-mail attachment or assigned online to all IACUC members. All Committee members are given the opportunity to review the protocol and to request a full committee review. If no member calls for full Committee review within three business days, then the designated review process proceeds.
- If no full committee review is requested, the designated reviewers are requested to review the protocol within five business days.
- The IACUC Chair has determined that the designated reviewers for protocol review will consist of a scientist member, a veterinarian and a scientific support member, collectively serving as designated reviewers. The IACUC Chair has determined that designated reviewers be selected sequentially from the IACUC roster
- Documentation that each IACUC member has been afforded the opportunity to review and request full committee review of each protocol undergoing accelerated review is retained in the IACUC Office; automatic e-mail return receipts are received in the IACUC Office or access is recorded online, verifying that all committee members have received the protocol submission.
- Each designated reviewer may approve, require modifications to the protocol (to secure approval) or request full committee review of the protocol submission (designated reviewers do not vote).
- Using this procedure of review all three designated reviewers must approve the protocol for it to be approved. If the designated reviewers cannot agree on an outcome, then the protocol is forwarded to the next scheduled meeting of the IACUC. If modification of the protocol occurs at any stage of the review, all designated reviewers must review and approve the changes.