

IACUC PI MANUAL

hsc  TM



TABLE *Of* CONTENTS

0 1 *Protocol / Amendment Review Process*

0 2 *Personnel Requirements*

0 3 *Congruence Checks, MOUs & IIAs*

0 4 *Post Approval Monitoring*

0 5 *Semi-Annual Inspections*

0 6 *Reporting Concerns*

0 7 *Noncompliance*

01: PROTOCOL/AMENDMENT REVIEW

PROTOCOL REVIEW:

- The IACUC meets monthly to review protocols and full committee review amendments.
- Generally, protocols are due the first Tuesday of the month. Exceptions may apply due to holiday schedules.
- The IACUC meets monthly, on the 4th Tuesday of the month. Exceptions may apply due to holiday schedules.
- You can find specific Submission Deadline and Meeting Date on the IACUC Website.



PROTOCOL PRE-REVIEW:

The IACUC Office pre-reviews the protocol:

- To ensure completeness.
- To ensure it meets the regulatory requirements.
- To ensure it is clear for the Committee Review.
- Comments sent to the PI within a week of the Submission Deadline, requests response within a week's time.

Ancillary Reviews:

The veterinarian, the Biosafety Manager, and the DLAM Facility Manager reviews every protocol during the pre-review. For departmentally funded protocols, the department chair conducts a peer review during the ancillary review period.



REVIEW TYPES:

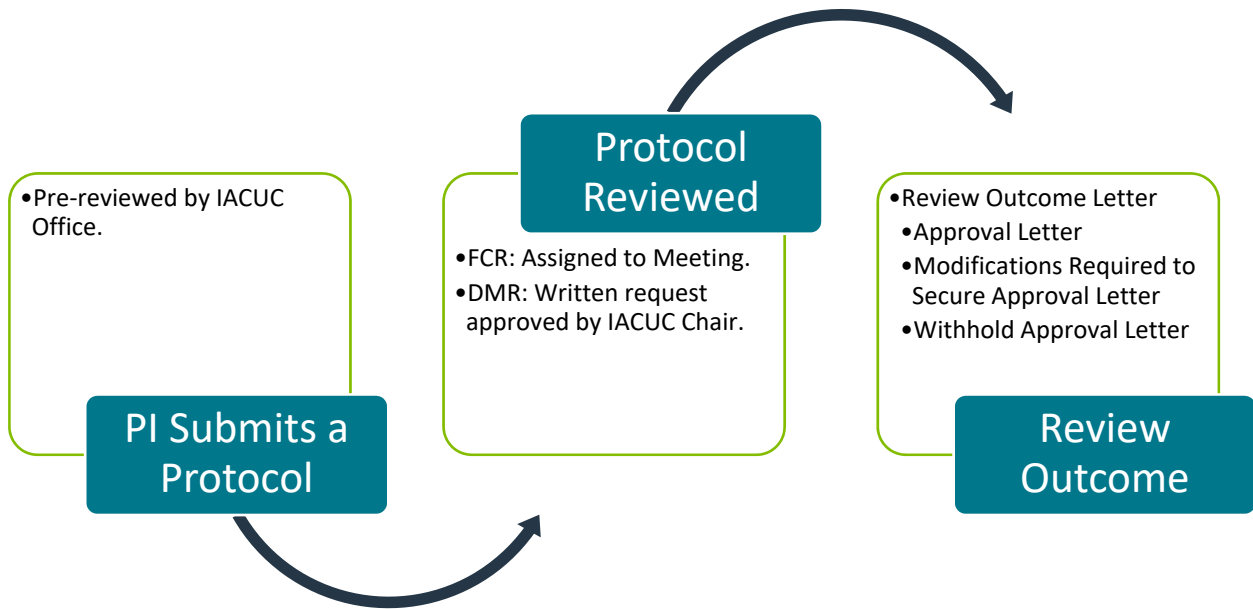
There are 2 ways to review a full protocol:

Full Committee Review (FCR):

- The default review method for full protocols.
- Review occurs during the IACUC monthly meeting.
- Requires a majority vote for approval.

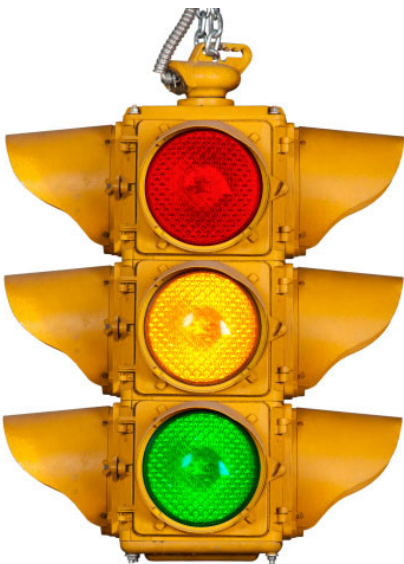
Designated Member Review (DMR):

- PI Submits a written request to the IACUC Office.
- The IACUC Chair must give approval to the request before proceeding with this review type.
- IACUC Members are provided with the protocol, and given 5 business days to call for FCR.
- If no one calls for FCR, the Designated Reviewers review the protocol, and may approve, require modifications, or call for FCR.



REVIEW OUTCOMES:

- **Full Approval:**
 - The IACUC determines protocol meets all review criteria.
- **Modifications Required to Secure Approval:**
 - The IACUC determines the protocol requires modifications before granting approval. The review of the protocol after modifications are made can occur in one of three ways:
 - Administrative Review (AR): Reviewed by IACUC Office.
 - Designated Review: Reviewed by IACUC Members (generally the original reviewers).
 - Full Committee Review: Reviewed by the full committee during the IACUC Meeting.
- **Withhold Approval:**
 - The IACUC determines that the protocol cannot be approved in its current state.
 - May only occur during a fully convened meeting.
 - PI will receive a written letter as to why approval is withheld.
 - PI may choose to take into account the written response, and create a new protocol for review.



AMENDMENT REVIEW:

- There are times when a protocol requires changes, i.e. changes in personnel, funding, procedures, timing, dosing, lab locations, euthanasia, etc...
- Prior to initiating any changes to a protocol, IACUC approval must first be secured. This is done through an amendment.
- Amendments must be submitted through GRAMS.
- All amendments must provide a justification for the changes made.
- If Changing/ Adding a procedure, the PI should address whether this change/ addition of a procedure would cause a need to adjust the number of animals needed for the project.



REVIEW TYPES:

There are 4 ways to review an amendment:

- **Administrative Review (AR):**
 - Administrative changes, such as personnel, title, funding, etc... qualify for the administrative review process.
- **Veterinary Verification and Consultation (VVC):**
 - Amendments for minor procedures, as outlined in our IACUC SOP 002: Amendments to Approved Protocols, may qualify for VVC review, which authorizes the veterinarian to review and approve the amendment.
- **Designated Member Review (DMR):**
 - Amendments containing moderate procedural changes qualify for Designated Member Review. Like DMR for full protocols, amendments that qualify for this review process, members are provided with a 5-day grace period to call for FCR. If no one calls for FCR, the Designated Reviewer reviews the amendment, and may approve, require modifications, or call for FCR.
- **Full Committee Review (FCR):**
 - Amendments containing significant changes qualify for full committee review. This review type is also reserved for amendments that are called to full committee review during the designated member review process. These amendments are assigned to the next IACUC meeting, attended by a quorum of IACUC members. The proposal must receive a majority vote of member present in order to receive full approval.

02: PERSONNEL REQUIREMENTS

OCCUPATIONAL HEALTH ENROLLMENT:

We care about the safety of all personnel working with or around laboratory animals. Therefore, it is important for these individuals to enroll in our Occupational Health Program.

- **Complete** the [Medical History Questionnaire Form](#).
- **Acquire** a copy of Td/Tdap Record. Be sure to have an electronic copy ready to upload when filling out the form.
 - *If a vaccination or mask fit test is needed, feel free to schedule an appointment with Priority Care 817-735-5051.*

CITI TRAINING:

In effort to help maintain a culture of compliance, we want to ensure that all personnel working with animals are aware of the regulations and guidelines that govern laboratory animal research, as well as, ensuring an understanding of the importance of maintaining animal welfare. Therefore, we require all personnel working with laboratory animals to complete the following online CITI training modules:

Required Courses:

- Working with the IACUC (Investigators, Staff and Students)
- Minimizing (Reducing) Pain and Distress
- Post-Approval Monitoring (PAM)
- Species Specific (based on species used)

Additional Courses (based on work performed):

- Antibody Production
- Aseptic Surgery
- Essentials for IACUC Members (IACUC Chairs, Members and Coordinators)
- Refresher Course (reserved for special circumstances)

DLAM TRAINING:

In addition to the CITI Training, we have our in house training through the Department of Laboratory Animal Medicine (DLAM), which provides training for conducting laboratory animal research at UNTHSC.

Required Courses:

- DLAM Policy Training
- DLAM Animal Handling Techniques Training

Additional Courses:

- Aseptic Surgical Techniques Training
- Required for anyone performing procedures requiring aseptic handling (such as survival surgery).
- Anesthesia Techniques Training
- For using volatile anesthetics.
- Additional Handling Techniques Training
- Injections
- Blood Collection Procedures
- Other training by request.

Training Registration:

Please complete the [Training Request Form](#) to register for this training.

These requirements must be met before adding personnel to the protocol. Refer to our [Personnel Requirements](#) Page on the website or [IACUC SOP 012: Personnel Training for Research Staff](#) for more information.

03: CONGRUENCE CHECKS, MOU's & IIA's

CONGRUENCE CHECKS:

Why does the IACUC want to see my grant application? According to the PHS Policy and the NIH Grants Policy Statement, Institutions are responsible for ensuring that the information the IACUC reviews and approves is congruent with the grant application/ proposal. This does not require a side-by-side comparison.

To fulfill this requirement, UNTHSC IACUC Office conducts a congruence check on PHS funded projects:

- When submitting an IACUC protocol that will be funded by PHS, in the funding section, a copy of the Vertebrate Animal Section and Research Strategy Section should be attached to the protocol.
- If receiving funding to be added to an existing protocol, please submit an amendment to the protocol to add the funding (regardless of funding source). For PHS funded projects, when submitting this amendment to add the funding, please include a copy of the Vertebrate Animal Section and Research Strategy Section by attaching this in the funding section.
- The IACUC Office uses a checklist to conduct the congruence check. Depending on the outcome of the congruence check, the PI may be asked for clarifications.
 - If the protocol is found to be incongruent with the grant, the PI may either amend the protocol, or work with OSP to amend the grant.
- The IACUC Administrator conducting the congruence check will attach the checklist to the protocol through the Manage Tags function.

Refer to [IACUC SOP 047: Protocol to Grant Congruence Verification](#) for more information.

MOU:

When collaborating with another institution for your animal studies, a Memorandum of Understanding (MOU) may need to be in place to ensure that responsibilities for animal care and use, ownership, and IACUC review and oversight are addressed.

- **UNTHSC Owned Animals/ External Performance Site:** Contact the UNTHSC IACUC Office to initiate an MOU with the other site.
- **Externally owned animals/ UNTHSC Performance Site:** Contact the UNTHSC IACUC Office to initiate an MOU with the other site.
- When animals are owned by the performance site, there is no need for an MOU.

Refer to [IACUC SOP 052: Institutional Collaboration](#) for more information.

IIA:

The PHS Policy requires that institutions have an OLAW-approved Animal Welfare Assurance before carrying out any activities involving live vertebrate animals. If the awardee institution does not have an OLAW Assurance, but plan to have UNTHSC named as the performance site, an IIA will need to be in place

- Contact the IACUC Office, by sending a draft of the [Inter-institutional Assurance form](#) to IACUC@unthsc.edu.
- The IACUC Administrators will process the form for signatures, and return to the PI.
- It is the PI's responsibility to work with the Awardee institution for submitting the form to OLAW.

For more information, refer to the [OLAW Guidance Page for Institutional Assurance](#).

04: POST-APPROVAL MONITORING

Once a protocol is approved and the project begins, that is not the end of your relationship with the IACUC Office. Every month (with the exceptions of the Semi-Annual Inspection months), the IACUC performs Post-Approval Monitoring Audits.

As we have eliminated the need for annual reviews of protocols, we have replaced these with the post-approval monitoring audits. Therefore, do not be surprised your protocol is selected for an audit, more than once during the protocol life cycle.

The IACUC Office is now doing three types of audits: Document Review Audit, Laboratory Audit, and Procedure Observation Audit.

- The IACUC Administrator selects the protocol(s) for the audit, along with the audit type.
- The PI will be notified their protocol was selected for an audit, along with the audit type. The PI will then have an opportunity to respond with dates of availability for the audit.
- Once scheduled, the IACUC Administrator will send a calendar invite.
- The audit type will determine the checklist used for the audit.
- Once completed, a memo will be sent to the PI, along with any findings from the Audit.

Document Review:

This audit is reserved for reviewing of documentation associated with the protocol. This audit may be conducted virtually.

- A list of documents may be requested for the PI to provide prior to the audit for review.
- A meeting with the PI may occur after the document review to discuss the records, seek clarifications, or discuss any findings.

Laboratory Audit:

This audit is a more traditional audit. The Auditors will visit the laboratory, thus this is conducted in person.

- The checklist, provided to the PI prior to the audit, will be used by the audit team to conduct the audit.
- At the conclusion of the audit, the audit team will discuss any findings or recommendations with the PI. The PI will also be given an opportunity to ask any questions.

Procedure Audit:

This audit is reserved for the observation of procedures. The audit team will visit the location of the procedure, thus this is conducted in person.

- The Audit team will coordinate with the PI on the best time to conduct this audit.
- The Auditors will observe the procedure in the appropriate PPE, and will follow any guidance provided by the PI.

05: SEMI-ANNUAL INSPECTIONS

The PHS Policy & Animal Welfare Act charges the IACUC with inspecting the facilities (animal use areas) every six months. At UNTHSC we conduct these inspections every **April** and **October**.

- A notice from the IACUC Chair, announcing the inspections is sent to the Principal Investigators at the beginning of the month.
- The IACUC and DLAM office works together to compile a list of all of the animal use areas for the inspections.
- Investigators are encouraged to contact the IACUC Office if they are not available during the inspection time, in order to reschedule the inspection. It is also an opportunity for Investigators to inform the IACUC Office if a laboratory area has become inactive.
- A checklist (provided to the investigators) is used for inspecting the areas.
- Inspection teams provides the IACUC Office a list of any findings during the inspections.
- At the conclusion of the inspections, the IACUC administrators compile a list of all findings, and draft inspection outcome letters.
- Investigators are to respond to the inspection outcome letter with their corrective action plan and any resolution to the findings.
- The IACUC Office then drafts a report to present to the IACUC and IO, which includes the inspection findings, and date of correction.

Laboratories:

The UNTHSC IACUC inspects all laboratories in which animals are taken to for procedures, such as: surgical procedures, non-surgical procedures, behavioral studies, and euthanasia.



Vivarium:

The UNTHSC IACUC inspects all areas within the vivarium. Including, but not limited to, animal housing areas, procedural areas, euthanasia and necropsy areas, surgical suites, quarantine areas, storage areas, and even the van used to transport animals.

06: REPORTING CONCERNS

"Using Animal in research is a privilege granted by society to the research community with the expectation that such use will provide either significant new knowledge or lead to improvement in human and animal well being."
- The Guide (Pg. 4)

Responsibility

UNTHSC IACUC takes seriously any reported concern for the care and use of animals. "The IACUC must review and, if warranted, address any animal-related concerns raised by the public or institutional employees." (IACUC Guidebook, Page 159)

Noncompliance:

Violation of federal or University procedures and policies.

Allegations:

The complaint made about the alleged mistreatment or noncompliance.

Mistreatment:

Any action which results in wrongful treatment of an animal.

Ways to Report:

Office:	Contact:
IACUC Office	IACUC@unthsc.edu
DLAM Office	HSCDLAM.Office@unthsc.edu
Ethics Point:	(844) 692-6025

Remain Anonymous:

- ✓ Anyone may report a concern.
- ✓ Anyone who reports has the right to remain anonymous.
- ✓ Anyone who reports has Whistle-blower Protection.
- ✓ Anyone who reports retains the protection of no threat of reprisal.

07: NON-COMPLIANCE

In the event of potential non-compliance:

- The IACUC Office is informed.
- A subcommittee may be formed to conduct an investigation.
- If non-compliance is confirmed, it is reported to the IACUC during a convened IACUC Meeting.
- The IACUC Chair drafts a letter to the PI indicating the non-compliance, along with any recommendations of a corrective action plan from the committee.
- The committee determines if it is reportable. If so, then either the Attending Veterinarian or the IACUC Office reports the non-compliance.

Examples of Reportable Situations:

- Conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals.
- Conduction of animal-related activities without appropriate IACUC review and approval.
- Failure to adhere to IACUC-approved protocols.
- Implementation of any significant changes to IACUC-approved protocols without prior IACUC approval.
- Conduction of animal-related activities beyond the expiration date established by the IACUC (Three Year Anniversary).
- Participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained.
- Failure to monitor animals post-procedurally as necessary to ensure well-being (e.g., during recovery from anesthesia or during recuperation from invasive or debilitating procedures).
- Failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry).
- Failure to ensure death of animals after euthanasia procedures (e.g., failed euthanasia with CO₂).
- IACUC suspension or other institutional intervention that results in the temporary or permanent interruption of an activity due to non-compliance with the Policy, Animal Welfare Act, the Guide, or the institution's Animal Welfare Assurance.