

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

University Procedure 15.99.99.C1.01

Approved April 15, 2002; Updated November 27, 2006

1. GENERAL

Texas A&M University-Corpus Christi recognizes the scientific and ethical responsibility for the humane care and use of animals [for a definition of "animal" see NIH, PHS and USDA policy] involved in research and education and enjoins all individuals involved to the highest standards of care and consideration. The Institutional Animal Care and Use Committee (IACUC), as an agent for the University's obligations for humane care and use of animals, shall:

- 1.1 Assure all activities involving animals meet the ethical and legal requirements for the humane care and use of animals.
- 1.2 Maintain and promote an open and cooperative relationship with investigators, faculty and the greater University community.
- 1.3 Educate the University community concerning the ethical and regulatory considerations for the humane care of animals.
- 1.4 Review, at least every six (6) months, the University's program and all animal facilities using USDA Regulations/Guide as a basis.
- 1.5 Meet all federal requirements as defined in the Animal Welfare Act, the Public Health Service Policy on the Humane Care & Use of Laboratory Animals and the Guide for the Care and Use of Laboratory Animals.
- 1.6 This document may be amended by vote of the IACUC to meet changes in federal policy. The IACUC may amend other procedures in the document by vote of the committee.

2. COMMITTEE STRUCTURE

- 2.1 **Membership:** Members are appointed by the Provost and Vice President for Academic Affairs in consultation with the Chair of the Committee on Committees, Faculty Senate for staggered four-year terms. Membership must include a veterinarian, a community representative, a non-scientific representative from the University, and two scientific members from the University representing the wide diversity of activities utilizing animals on campus. The Chair is elected for a two-year term by the IACUC.
- 2.2 **Qualifications:** Members will possess a commitment to the ethical and

scientifically sound conduct of research, testing or teaching involving animals. A thorough review of pertinent documents concerning appropriate animal care for research, testing and teaching activities is mandatory prior to the first meeting.

- 2.3 Meetings: Matters concerning personnel, security arrangements, conferences with attorney, or issues required to be confidential by federal, state or local law may be held in executive session. Meetings will be scheduled not less than twice per year, with additional meetings called by the Chair as deemed necessary. While the committee actively works to reach consensus on issues presented for consideration, decisions will be based on majority rule. To further evidence diversity of opinion, minority opinions may be included in the minutes of all meetings as well as the Semi-Annual Report.

3. GENERAL IACUC APPROVAL PROCEDURES

- 3.1 New and renewal protocol applications are approved by the IACUC. Protocols that have been approved pending receipt of clarifications not involving major changes may be approved by the Chair plus one other IACUC member (preferably the Veterinarian) with notification of the IACUC. Clarifications involving major changes are returned to the full committee. The IACUC determines whether a clarification should come back to the committee at the time it grants approval pending clarification to the protocol. Regardless of the nature of the requested changes (i.e., 'non-major' or 'major'), such requested clarifications, responses to restrictions, or other requested changes shall be incorporated into a revised protocol with the revision(s) highlighted.
- 3.2 Annual Reviews of ongoing protocols are conducted administratively by two (2) committee members (one of which should be the Veterinarian) with notification of the IACUC unless full Committee review is either requested by an administrative reviewer or is mandated by other such policy (see 4.6. "Procedures for Conducting a Continuing Annual Review of Protocols").
- 3.3 Amendments to protocols (either alone or as part of an annual review) involving significant changes are approved by the full committee. Amendments (either alone or as part of an annual review) involving non-significant changes may be approved by two (2) committee members, usually the Chair and the veterinarian, with notification of the IACUC. Either reviewer may decide whether or not an amendment requires full IACUC review. Amendments that may be presented to the IACUC include a significant change in procedure(s), addition of new procedures, a significant change in administrative matters and/or the request for additional (greater than 10% of original approval) animals.
- 3.4 The Chair and two (2) Committee members may conduct an expedited protocol review on a "need" basis. The need for such a review will be determined by and

the review will be initiated by the Chair upon request from an investigator or IACUC member. Expedited review will be done through a convened subcommittee and approvals will be limited in terms of approval duration, animal numbers, and/or allowed procedures. Such expedited review shall be followed by full Committee review at the next IACUC meeting.

3.5 Closures of protocols are carried out by the Graduate Studies and Research Office with notification of IACUC. Certifications of current protocol approval are carried out by the Graduate Studies and Research Office with notification of IACUC. Reporting to the federal government will be carried out by the Graduate Studies and Research Office with notification of IACUC.

3.6 The transfer of animals from one approved protocol to another approved protocol will require action by the Veterinarian, one other member, and notification of the Committee.

4. PROCEDURES FOR PROCESSING ANIMAL USE PROTOCOLS AND AMENDMENTS

4.1 Procedures for Reviewing New Protocols: Prior to submission to the Graduate Studies and Research Office, protocols must be screened by the Veterinarian. Outcomes of this screening may be:

4.1.1 The Veterinarian approves and signs the protocol and it may be forwarded to the Graduate Studies and Research Office.

4.1.2 The Veterinarian does not approve and suggests the PI rewrite the protocol. The Veterinarian will notify the PI and indicate how the protocol should be modified. A modified protocol can then be presented to the Veterinarian and, if approved, he/she will sign the new protocol and it may then be submitted to the Graduate Studies and Research Office.

4.2 Protocol Receipt and Initial Processing: A protocol reviewed and approved by the Veterinarian may be submitted to the Graduate Studies and Research Office. It will be date stamped and assigned a protocol number. A file will be opened and the original will become the file copy. Copies of the protocol will be distributed to IACUC Chair for distribution to the IACUC members for review.

4.3 IACUC Review: At the next IACUC meeting, the Chair will give the Committee a short synopsis of the protocol and the protocol will be discussed. The committee will vote to approve, approve pending clarifications, defer action pending required modifications, or disapprove the protocol. In general, approval pending clarification will be given if the committee considers the clarification is sufficiently minor or straightforward so that the Chair and Veterinarian can certify the clarifications are adequate.

4.4 Outcomes of IACUC Actions:

- 4.4.1 If the protocol is approved, the IACUC chair will sign a notice of approval and forward it to the Graduate Studies and Research Office. A copy of the approval and a letter will be sent to the PI indicating the protocol may be initiated, e.g., animals may be purchased if needed and research covered by the protocol may begin pending availability of necessary resources.
- 4.4.2 If the protocol is approved pending clarification, a request for clarifications will be sent to the PI and he/she will be asked to respond by a prescribed time. A protocol will be considered withdrawn if a response is not received within 10 working days. Upon receipt of the clarifications the Chair and Veterinarian will review the response and either certify that it is adequate and proceed as in 4.4.1. or bring the response to the full committee.
- 4.4.3 Regardless of the nature of the changes or modifications requested, clarifications, responses to restrictions, or other requested changes shall be incorporated into a revised protocol with the revision(s) highlighted. This revised document will be the protocol of record.

4.5 Procedures for Reviewing Amendments to Active Protocols

Amendment Receipt and Initial Processing: Amendments will be received by the Graduate Studies and Research Office. There they will be copied for the protocol file and sent to a preliminary screener (usually the Veterinarian). The preliminary screener will indicate whether he/she believes the amendment is minor, not requiring committee action, or should be reviewed by the committee. He/she will indicate this judgment on the amendment, sign it, and return it to Graduate Studies and Research Office. The amendment will then be sent to a second screener (usually the Chair) who will indicate his/her judgment as to whether the amendment is minor or requires full committee action. He/she will indicate this decision on the original amendment, sign it, and return it to Graduate Studies and Research Office. If both Screeners agree that the amendment is minor and does not require committee action, the PI will be notified that the amendment is approved and in force. If either Screener believes the Committee needs to consider the amendment, it will be processed as in 4.1. "Procedures for Reviewing New Protocols."

4.6 Procedures for Conducting a Continuing Annual Review of Protocols

Information for Continuing Review: One month before the anniversary of a protocol, a continuing review questionnaire will be sent to the PI. The PI will be

asked for a timely response. If a response is not obtained the protocol will be inactivated after appropriate warning. Once information is received it will be reviewed by a member of the IACUC and the Veterinarian specifically for changes in the protocol or changes in regulations that require modification of the protocol. If there are no changes or minor changes then the protocol will be handled as a minor amendment (see 4.5. "Procedures for Reviewing Amendments to Active Protocols"). If the Veterinarian or IACUC member believes the committee should review the continuing review information, the protocol will be handled as an amendment would (see 4.5. "Procedures for Reviewing Amendments to Active Protocols").

5. FORMAT FOR SUBMITTED PROTOCOLS

Forms are available from the Graduate Studies and Research Office for research activities, teaching activities and amendments. Call for renewal protocols will be initiated by the Graduate Studies and Research Office and shall utilize the same forms as were used in the initial review. Requests and appropriate forms for continuing annual reviews will be sent from the Graduate Studies and Research Office.

6. REPORTING THE MISTREATMENT OF ANIMALS AND DEFICIENCIES IN THEIR CARE

It is the policy of Texas A&M University-Corpus Christi that the care, use and treatment of University-owned laboratory animals should be of high quality and in compliance with all federal, state, and local regulations. The law requires that all persons involved or in any way associated with the use of animals in research know how to report deficiencies in animal care and treatment. There are no restrictions on who can report an alleged incident. Anyone who has knowledge of such a deficiency is obligated to report it immediately. Under no circumstances will reporting such incidences in good faith be detrimental to an individual's standing within the organization.

- 6.1 Definition: Allegations of animal mistreatment and deficiencies in care include the wrongful or abusive physical or psychological treatment of an animal and non-compliance with established procedures, policies or protocols.
- 6.2 Procedures: Any person with knowledge of deficiencies or with reasonable suspicions of deficiencies or mistreatment involving University laboratory animals is obligated to report them directly to the Chair of the IACUC, any member of the IACUC, or the Graduate Studies and Research Office.
- 6.3 Reporting: There are no restrictions on who can report an alleged incident. Timely reporting is essential to protect the animals involved and to aid the investigation of the allegations. Reports of suspected deficiencies should be made in writing and should include, but need not be limited to, the nature and the place of the occurrence, the person or persons alleged to be delinquent, the date, the

time, and any supporting facts. If a person actually witnesses mistreatment or abuse, the witness will immediately notify the Veterinarian, the IACUC Chair or the Graduate Studies and Research Office so that the animal or animals involved can be evaluated and receive medical treatment if necessary. The person should then report the incident through channels as described above. The IACUC will investigate allegations and report its findings and recommendations to the Graduate Studies and Research Office in a timely fashion.

- 6.4 Details of any reports or allegations of deficiencies, findings or recommendations of the IACUC, as well as administrative or legal actions taken by the committee are considered privileged information and may be released only through official channels, or as required by law.
- 6.5 Willful mistreatment or abuse of animals may be grounds for suspension of all animal use activities or protocols involved, or other disciplinary actions. Disciplinary action may be appealed through existing procedures.
- 6.6 This policy will be distributed to all personnel involved in any way in animal research at TAMU-CC. Personnel will be required to sign a document indicating that they have received and understand this information. Principal investigators will be responsible to assure that all personnel involved in research activities under their direction are aware of the above procedures. Instructions for reporting allegations will be posted on bulletin boards in each building where research animals are used.
- 6.7 Statutory authority for this instruction is found in the 1985 Amendment to The Animal Welfare Act Title 7, United States Code, Section 2131-2156, PL-99-198. The act requires that "...training for scientists, animal technicians, and other personnel involved with animal care...shall include...methods whereby deficiencies in animal care and treatment should be reported."

7. IACUC PROCEDURES FOR THE INVESTIGATION OF A COMPLAINT

The IACUC Chair is responsible for the receipt and disposition of all complaints. All allegations will remain confidential to the extent possible until proven or disproved. The IACUC, however, will not formally investigate anonymous complaints. When the complainant wishes to be openly identified, the IACUC Chair will acknowledge receipt of the allegation to the complainant in writing. The IACUC Chair will present all allegations to the IACUC during its next meeting. The IACUC will then determine if the complaint has sufficient substance to warrant a full investigation. The IACUC will determine the procedures by which it will carry out an investigation. All persons involved in the investigation will be informed in writing of the purpose of the investigation and the manner in which it will be conducted. If there is indication of serious noncompliance, the IACUC may suspend an activity pending the outcome of a full investigation. The IACUC will examine all pertinent documents, animals, procedures, and interview involved

personnel during its investigation. Persons against whom the complaint is made will be given the opportunity to appear before the committee. The final results of the investigation will be presented during a formal meeting of the IACUC and all committee members will be given the opportunity to present minority views. The IACUC will inform all parties involved, including the complainant, of the committee's findings. The results will be forwarded to the Graduate Studies and Research Office with appropriate recommendations.

- 7.1 If following an investigation of the alleged incident the IACUC finds no evidence of animal mistreatment or noncompliance, the report of the investigation will be forwarded to the Graduate Studies and Research Office with the recommendation that no further action be taken.
- 7.2 If allegations of animal mistreatment are substantiated, the Provost will be advised of the committee's findings and recommendations and take appropriate action after consulting with the IACUC and reviewing the results of the IACUC investigation. The Provost has the power to impose sanctions on an investigator found responsible for mistreatment or noncompliance. The decision of the Provost is final.
- 7.3 IACUC is empowered by USDA Regulation and PHS policy to suspend a previously approved project pending review by the Provost. In this case, and whenever IACUC suspends an activity involving animals (for example when activities are suspended pending the outcome of an investigation), the Graduate Studies and Research Office must report the action with a full explanation to any Federal funding agency involved in the project.

Contact for Interpretation: Associate Vice President for Research and Scholarly Activity