OBJECTIVE - The purpose of this policy and procedure is to describe the process for submitting and the reviewing protocols for review by the Institutional Animal Care and Use Committee (IACUC).

GENERAL DESCRIPTION - IACUC conducts initial review for all research conducted at Texas Southern University during a convened meeting. Investigators are responsible for submitting planned research studies for IACUC review and approval prior to study initiation.

RESPONSIBILITY - The parties responsible for implementing this policy and procedure include the following: Principal Investigators (PI)/Study Personnel, IACUC Chair, IACUC Members, and Department of Research Enhancement and Compliance Services (DRECS) Director, and DRECS Staff.

PROCEDURES

The PI or designee is responsible for completing an application for IACUC review of a research protocol for initial review, including all study related documents to the DRECS.

DRECS staff will schedule the IACUC application on the agenda for the next available meeting. The IACUC usually meets at least once per semester, but may meet more often (i.e. monthly) if the demand for review exists. If requested by the IACUC Chair or IACUC Member, DRECS staff will send the PI a request for the PI or designee to attend the meeting.

Upon receipt, DRECS staff screen the submitted application for initial review to determine whether it is complete and all pertinent forms and signatures were provided. If the initial review submission is not complete, DRECS staff will return the submitted documents to the investigator or, in cases where only a few minor items are missing, the DRECS staff will call or write the investigator to request additional items.

DRECS staff will screen the protocol to determine whether additional expertise is necessary to conduct the review. If so, DRECS staff will consult the DRECS Director to identify an individual who has appropriate expertise in the discipline or with the study population to participate in the review. The DRECS Director may contact the IACUC Chair, IACUC members, TSU faculty, or department chairs for advice in identifying consultants.

DRECS staff will ensure that reviewing consultants do not have a conflict of interest, as per the IACUC Conflict of Interest Policy and Procedure. Participating consultants will receive the same information as voting IACUC members, including the IACUC application and study protocol.

DRECS staff will assign a primary reviewer based on the IACUC member’s background and expertise. Approximately 10 days prior to a scheduled IACUC meeting, DRECS staff will electronically forward initial review submission materials to all IACUC members for review.
All IACUC members will review all information placed on the agenda in advance of the meeting, including those protocols for which the IACUC member is not the primary reviewer, in enough depth to be familiar with the protocol, to be prepared to discuss the protocol at the meeting, and to be prepared to determine whether the research meets the regulatory criteria for approval.

Selected consultants will be asked to provide comments or recommendations in writing to the IACUC prior to the meeting or attend the convened meeting to participate in the review. IACUC staff will maintain documentation of written comments or reports in the protocol file. In cases where the consultant participates in the meeting, the minutes of the meeting will document the information provided by the consultant.

Questions the IACUC will consider while reviewing an animal care and use application or a request for modification of a previously approved protocol include:

- Do the procedures proposed avoid or minimize discomfort, distress or pain, yet conform to sound research design or teaching objectives?
- If momentary or slight pain is likely to result from the procedure, is appropriate pain relief provided?
- Are the living conditions of the animals appropriate for their species?
- Is medical care available and will it be provided by qualified veterinary staff?
- Are the personnel conducting the study appropriately qualified for the procedures listed and the species to be included?
- Are euthanasia methods consistent with the American Veterinary Medical Association recommendations, unless exceptions are approved by the IACUC?
- Is the animal model appropriate for the proposed study?
- Does the number of animals planned to be used seem appropriate?
- Has the investigator considered alternatives to using animals?

In order for the IACUC to approve proposed research projects, the study must receive the approval of a simple majority of those members present at the meeting. IACUC members or consultants with a conflict of interest will not participate in the voting of a discussed study and will leave the room during the actual voting process.

During the meeting and following the discussion of a submitted research study, a IACUC member will make a motion and another member will second the motion. The convened IACUC will vote for, against, or abstain from one of the following four actions:

- **APPROVED**: The IACUC motion for approval will signify that the committee has concluded that the research meet the federal criteria for approval and no additional information or revisions are requested.
- **APPROVED PENDING**: The IACUC motion for approval pending will signify that the committee has concluded that minor revisions or clarifications are needed prior to the initiation of the research study.
- **DEFERRED**: The IACUC motion for deferral will signify that the committee has concluded that major revisions and/or additional information are needed prior to the initiation of the research study.
- **DISAPPROVED**: The IACUC motion for disapproval will signify that the committee has concluded that the risk of the procedures outweighs any benefit to be gained or the proposed research does not meet the federal criteria for IACUC approval.
DRECS staff will send the investigator an outcome letter following the IACUC meeting. The approval letter will include the approval period (not to exceed 3 years) and a reminder that the IACUC must approve any changes to the protocol prior to initiation of the changes.

The investigator of a research study receiving approval pending status following a convened meeting will receive a letter describing the revisions requested by the IACUC. Once the PI responds to the IACUC’s suggested revisions in writing, DRECS staff will give the response to all members of the IACUC. The IACUC may request additional information or approve the study. If the research study is determined to be approvable, DRECS staff will follow the process for sending the approval letter to the investigator as previously described.

The investigator of a research study receiving deferral status following a convened meeting will receive a letter describing the revisions requested by the IACUC. Once the PI responds to the IACUC questions and revisions in writing, DRECS staff will give the response to the IACUC and place the submission on the next agenda for discussion.

The investigator of a research study receiving disapproval status following a convened meeting will receive a letter describing the reasons for disapproval.

Before issuing the IACUC approval letter, DRECS staff will ensure that all study personnel have completed the required training. If the PI and study personnel have not completed training, DRECS staff will notify the PI in writing.

If the PI has concerns regarding the IACUC decision and/or recommendations for changes in the study, he/she may submit them to the IACUC via a written document that includes a justification for the request to change the IACUC decision. The IACUC will review the request using the standard IACUC review procedures.

REFERENCES
