



Joslin Diabetes Center

Institutional Animal Care and Use Committee

Maintaining humane animal care in research is a dynamic endeavor and requires conscientious interpretation of animal welfare regulations. The Joslin Diabetes Center has established an Institutional Animal Care and Use Committee (IACUC), which is qualified through the experience and expertise of its members to oversee the institution's animal program, facilities and procedures.

The IACUC is based out of the Office of Sponsored Research and is managed by the Senior Research Programs Administrator who reports to the Institutional Official (IO), the Director of the Office of Sponsored Research. The Senior Research Programs Administrator and Research Programs Coordinator receives information from Investigators on the use of animals at the institution and facilitates the review of this information by the IACUC to verify compliance with applicable animal welfare regulations. In addition, the Senior Research Programs Administrator is a resource to Investigators and research staff seeking advice on regulatory and animals welfare issues and is available to assist Investigators in maintaining compliance with federal, granting agency and institutional animal welfare regulations.

IACUC Responsibilities

The IACUC shall:

1. Review at least once every six months the institution's program for humane care and use of animals, using the *Guide for the Care and Use of Laboratory Animals (Guide)*, NRC 1996; as a basis for their evaluation.
2. Inspect at least once every six months the institution's animal facilities using the *Guide* as a basis for their evaluation.
3. Prepare reports of the IACUC evaluations conducted and submit reports to the Institutional Official outlining the nature and extent of adherence to the *Guide* and NIH/USDA Policy and identifying any departures from the *Guide* and NIH/USDA Policy and the reasons for the each departure. The reports will also outline any deficiencies (significant or minor) along with a reasonable and specific plan and schedule for correcting each deficiency.
4. Review concerns involving the care and use of animals at the institution.
5. Make recommendations to the IO regarding any aspect of the institution's animal program, facilities, or personnel training.
6. Review and approve, require modifications in (to secure approval) or withhold approval of activities related to the care and use of animals.
7. Review and approve, require modifications in (to secure approval) or withhold approval of proposed significant changes regarding the use of animals in ongoing activities.
8. Be authorized to suspend an activity involving animals. If the IACUC suspends an activity involving animals, the IO, in consultation with the IACUC, will review the reasons for suspension, take appropriate corrective actions, and report that action to the NIH Office of Laboratory Animal Welfare (OLAW).
9. Ensure that all personnel involved with animal care, treatment or use are provided with training on humane practices and the concept, availability and use of research, teaching or testing methods that replace, reduce, or refine the use of animals or animal distress.
10. Ensure that all personnel involved with animal care, treatment or use are provided with training on occupational health and safety programs, their implementation and function in promoting employee well-being.

IACUC Membership

IACUC members are appointed for their experience and expertise to oversee the institution's animal program, facilities and procedures. In accordance with federal regulations, the Committee must consist of no less than five members, and shall include at least:

- One doctor of Veterinary Medicine, with training or experience in laboratory animal sciences and medicine, who has direct or delegated program authority and responsibility for activities involving animals at the institution.
- One practicing scientist experienced in research involving animals.
- One member whose primary concerns are in a non-scientific area.
- One member who is not affiliated with the institution in any way other than as a member of the IACUC.

IACUC Meetings

The IACUC meets monthly on the third Tuesday of the month. Quorum is needed to for the Committee to conduct business. Quorum consists of one more than half the regular voting members.

The agenda of meetings consists of review of the minutes from the previous meeting, review of new protocols, review of protocol rewrites and annual renewals, followed by any other business needing the Committee's review and/or input. All members are provided with the material to be reviewed at the meeting 7-10 days prior to the scheduled meeting.

Minutes of the IACUC meetings are kept by the Senior Research Programs Administrator in the Office of Sponsored Research and are made available for review by regulatory agencies, as required by regulation.

IACUC Records Retention

The IACUC is responsible to maintaining the following records:

- assurance approved by OLAW
- minutes of IACUC meetings
- records of IACUC activities and deliberations
- minority IACUC views
- documentation of protocols reviewed by the IACUC, and proposed significant changes to protocols
- IACUC semi-annual program reviews and facility inspections (including deficiencies found and correction plans)
- USDA determinations

All records are kept of a minimum of 3 years, with the exception of records that relate directly to protocols which must be kept for the duration of the research and for an additional 3 years after the completion of the research.

Records documenting such activities as the provision of adequate veterinary care, training, and occupational safety, are expected to conform with the recommendations of the Guide and with commonly accepted professional standards.

IACUC Protocol Submission and Approval Process

The IACUC has the responsibility for assuring that the research involving animals at the Joslin Diabetes Center provide for animal welfare and comply with the regulations. To fulfill this responsibility with IACUC reviews **all** animal research and use. **No animal experimentation or use is permitted at the Joslin Diabetes Center without written approval by the IACUC.**

Investigators must submit the completed IACUC “Application for Approval of Protocol for Animal Experimentation” for review and approval before any research activity can be initiated. This application is available from the Senior Research Programs Administrator or Research Programs Coordinator. The completed application must be submitted to the Senior Research Programs Administrator by the appropriate deadlines in order to be reviewed by the Committee at its scheduled meetings.

Once the completed application is received, it is given a four-digit protocol number (first two digits designate the year submitted, the last two identify the protocol) and placed on the agenda for the next scheduled meeting.

After review of the completed application at the scheduled IACUC meeting, one of the following actions will be taken:

- *Approval (as submitted)*
The IACUC consider that all significant points have been addressed by the Investigator and that no question has been raised by any elements of the proposed study. The Research Programs Administrator will inform the Investigator of the Committee’s determination in writing. This action grants the Investigator permission to conduct the experiments on the number of animals as specified in the submitted proposal.
- *Approval (pending modifications/clarifications)*
The IACUC consider that all significant points have been addressed by the Investigator, yet requires minor modifications and/or clarifications to the proposed study. The Senior Research Programs Administrator will inform the Investigator of the Committee’s determination in writing along with an outline of the Committee’s requested modifications and/or clarifications. The Investigator must address all the requested modifications and/or clarifications by submitting a revised application for administrative review by the IACUC chairperson and/or designated members. This process will continue until all the requested information is received and approved. Once this is completed the Investigator will be granted permission to conduct the experiments on the number of animals as specified in the submitted proposal.
- *Deferral*
The IACUC has found that insufficient information has been submitted to review the proposed study at this time or found that substantial modifications and/or clarifications are needed to the proposed study. The Research Programs Administrator will inform the Investigator of the Committee’s determination in writing along with an outline of the Committee’s requested modifications and/or clarifications. The Investigator must address all the requested modifications and/or clarifications by submitting a revised application for re-review by the full Committee at a scheduled meeting.
- *Disapproval*
This is rare due to the on-going discussions, which usually occur between Investigators and the IACUC. However, if an Investigator refused to modify their proposed study or fail to supply the appropriate information to address the Committee’s questions or concerns, this may be the only option. The Senior Research Programs Administrator will inform the Investigator of the Committee’s reasons for this action in writing. The disapproved proposed study **cannot** be administratively approved by a higher institutional authority.

Annual Protocol Renewal Process

The IACUC is required to annual monitor ongoing, approved activities that involve the use of animals. To fulfill this requirement, each active protocol must go through an annual renewal process. The purpose of this review is to ensure that no changes have inadvertently taken place in the approved activity and to ensure that any new requirements have been addressed and are in compliance.

Investigators are sent a reminder approximately 4-6 weeks before their protocol needs to be reviewed, along with a copy of the current approved version of the protocol and the “*Annual Protocol Review*” form. The renewal form provides the IACUC with basic and current information on the status of the project.

The completed form must be submitted to the Senior Research Programs Administrator by the appropriate deadlines in order to be reviewed by the Committee at its scheduled meetings.

Once the completed form is received, the protocol renewal is placed on the agenda for the next scheduled meeting.

After review of the protocol renewal at the scheduled IACUC meeting, one of the following actions will be taken:

- *Continuation Approved (as submitted)*
The IACUC found that based on the information provided there has been no questions or concerns regarding the conduct of the study and determined that the study can continue as submitted. The Senior Research Programs Administrator will inform the Investigator of the Committee’s determination in writing.
- *Continuation Approved (modifications/clarifications requested)*
The IACUC found that based on the information provided that there are some minor modifications/clarifications needed. The Senior Research Programs Administrator will inform the Investigator of the Committee’s determination in writing along with an outline of the Committee’s requested modifications and/or clarifications. The Investigator must address all the requested modifications and/or clarifications by submitting the requested information for administrative review by the IACUC chairperson and/or designated members. This process will continue until all the requested information is received and accepted.
- *Suspension of Study*
This is rare due to the on-going discussions, which usually occur between Investigators and the IACUC. However, if the Committee has questions or concerns regarding the conduct of the study, this may be the only option. The Senior Research Programs Administrator will inform the Investigator of the Committee’s reasons for this action in writing. If the IACUC suspends an activity involving animals, the IO, in consultation with the IACUC, will review the reasons for suspension, take appropriate corrective actions, and report that action to the NIH Office of Laboratory Animal Welfare (OLAW).

Every three years after initial review and approval, every protocol must be submitted for *de novo* review. At this time Investigators will follow the process for protocol submission and approval (*see IACUC Protocol Submission and Approval Process*).

Modifications to Approved Protocols

The IACUC is required to review and approve, prior to initiation, proposed modifications to ongoing activities using animals.

The Investigator must submit the proposed changes in writing to the Senior Research Programs Administrator for review clearly stating why the modification is being requested. Administrative and minor modifications to the protocol may be reviewed by expedited review by the IACUC chairperson and/or designated members. Major modifications must be reviewed by the full Committee at a scheduled meeting since new issues related to animal welfare may arise.

Examples of Administrative Modifications

- adding and/or removing study staff
- protocol title change
- change in funding source

Examples of Minor Modifications

- changes in anesthetic or analgesic being used
- changes in the method of euthanasia
- changes in any surgical procedures/addition of a surgical procedure
- changes in the animal strain
- change in the number of animals to be used (< 25% of the previously approved number)
- changes in non-surgical procedures/addition of non-surgical procedure
- addition of tests that can be related to the specific aims of the protocol

Examples of Major Modifications

- changes in the species used
- adding procedures that do not relate to the specific aims of the protocol
- an unrelated change in the scientific aims of the original protocol
- changing from non-survival to survival surgery
- changing from single to multiple survival surgeries

Semi-Annual Program Review and Facility Inspections

Under PHS policy and USDA Regulations, the IACUC is required to conduct a semi-annual review of the IACUC Program and an inspection of the animal facilities. This review and inspection provides an ongoing mechanism for insuring the Institution maintains compliance with the applicable animal care and use policies, guidance and laws.

The program review takes place at a convened meeting (usually the June and December meetings). The Committee uses the sample semi-annual program review checklist found on the OLAW web-site as a guide for this review.

The facility inspection is scheduled for the morning on the day of the IACUC meeting (usually the June and December meetings), though it can be done at another time agreed on by the Committee. All IACUC members are invited to take part in the inspection and additional ad hoc consultants may be included if needed. The Committee uses the sample semi-annual facilities inspection checklist found on the OLAW web-site as a guide for this inspection.

After the program review and facilities inspection is completed, the IACUC Program Administrator drafts a report, which is reviewed by the IACUC to verify that all comments have been reported and any corrective actions planned are adequate. Once the Committee accepts this report, it is forwarded to the Institutional Official as an update on the status of the animal care and use program and animal facility.

Receiving and Handling Animal Care or Concerns

The Joslin Diabetes Center requires all animal care and use to conform to all applicable Federal and State laws and regulations. The *Guide* is the principal document providing standards of care and use of animals at Joslin. It is the responsibility of Investigators to ensure that their staff uses proper procedures and techniques and that training is provided. By signing the "Application for Approval of Protocol for Animal Experimentation", this responsibility is acknowledged and accepted by the Principal Investigator.

Any employee of the Joslin Diabetes Center who has a concern regarding an observed animal care or use activity is encouraged to report such activity to the IACUC Chairperson, Attending Veterinarian, Research Programs Administrator, Animal Resources Manager or any IACUC member.

Center Policy, as well as Federal law, protects individuals from any discriminatory or reprisal measures being taken for reporting animal care or use deficiencies. The Joslin Diabetes Center will also take all steps possible to protect the anonymity of any person who, in good faith, reports such a deficiency.

An initial evaluation of all reports shall be conducted under the direction of the Chair of the IACUC or her/his designee. If it is determined that the activity was within the parameters of the approved protocol, the results will be recorded in the IACUC minutes and no further action is necessary. If further action is indicated, the incident will be investigated by the IACUC and disciplinary actions may be taken which could include temporary or permanent restrictions on the use of animals by the personnel involved. The individual who made the initial complaint will be notified of the decision of the IACUC and, if there is evidence of a serious noncompliance, appropriate Federal agencies need and will be notified.