Animal and Plant Health Inspection Service, USDA

§ 2.31 Institutional Animal Care and Use Committee (IACUC).

(a) The Chief Executive Officer of the research facility shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members to assess the research facility’s animal program, facilities, and procedures. Except as specifically authorized by law or these regulations, nothing in this part shall be deemed to permit the Committee or IACUC to prescribe methods or set standards for the design, conduct, or performance of research or experimentation by a research facility.

(b) IACUC membership. (1) The members of each Committee shall be appointed by the Chief Executive Officer of the research facility;

(2) The Committee shall be composed of a Chairman and at least two additional members;

(3) Of the members of the Committee:

(i) At least one shall be a Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or
delegated program responsibility for activities involving animals at the research facility:

(ii) At least one shall not be affiliated in any way with the facility other than as a member of the Committee, and shall not be a member of the immediate family of a person who is affiliated with the facility. The Secretary intends that such person will provide representation for general community interests in the proper care and treatment of animals;

(4) If the Committee consists of more than three members, not more than three members shall be from the same administrative unit of the facility.

(c) IACUC functions. With respect to activities involving animals, the IACUC, as an agent of the research facility, shall:

(1) Review, at least once every six months, the research facility’s program for humane care and use of animals, using title 9, chapter I, subchapter A—Animal Welfare, as a basis for evaluation;

(2) Inspect, at least once every six months, all of the research facility’s animal facilities, including animal study areas, using title 9, chapter I, subchapter A—Animal Welfare, as a basis for evaluation; Provided, however, That animal areas containing free-living wild animals in their natural habitat need not be included in such inspection;

(3) Prepare reports of its evaluations conducted as required by paragraphs (c)(1) and (2) of this section, and submit the reports to the Institutional Official of the research facility; Provided, however, That the IACUC may determine the best means of conducting evaluations of the research facility’s programs and facilities; and Provided, further, That no Committee member wishing to participate in any evaluation conducted under this subpart may be excluded. The IACUC may use subcommittees composed of at least two Committee members and may invite ad hoc consultants to assist in conducting the evaluations, however, the IACUC remains responsible for the evaluations and reports as required by the Act and regulations. The reports shall be reviewed and signed by a majority of the IACUC members and must include any minority views. The reports shall be updated at least once every six months upon completion of the required semiannual evaluations and shall be maintained by the research facility and made available to APHIS and to officials of funding Federal agencies for inspection and copying upon request. The reports must contain a description of the nature and extent of the research facility’s adherence to this subchapter, must identify specifically any departures from the provisions of title 9, chapter I, subchapter A—Animal Welfare, and must state the reasons for each departure. The reports must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, with reference to Subchapter A, and, in the judgment of the IACUC and the Institutional Official, is or may be a threat to the health or safety of the animals. If program or facility deficiencies are noted, the reports must contain a reasonable and specific plan and schedule with dates for correcting each deficiency. Any failure to adhere to the plan and schedule that results in a significant deficiency remaining uncorrected shall be reported in writing within 15 business days by the IACUC, through the Institutional Official, to APHIS and any Federal agency funding that activity;

(4) Review, and, if warranted, investigate concerns involving the care and use of animals at the research facility resulting from public complaints received and from reports of noncompliance received from laboratory or research facility personnel or employees;

(5) Make recommendations to the Institutional Official regarding any aspect of the research facility’s animal program, facilities, or personnel training;

(6) Review and approve, require modifications in (to secure approval), or withhold approval of those components of proposed activities related to the care and use of animals, as specified in paragraph (d) of this section;

(7) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the care and use of animals in ongoing activities; and
(8) Be authorized to suspend an activity involving animals in accordance with the specifications set forth in paragraph (d)(6) of this section.

(d) IACUC review of activities involving animals. (1) In order to approve proposed activities or proposed significant changes in ongoing activities, the IACUC shall conduct a review of those components of the activities related to the care and use of animals and determine that the proposed activities are in accordance with this subchapter. Unless acceptable justification for a departure is presented in writing, provided, however, that field studies as defined in part 1 of this subchapter are exempt from this requirement. Further, the IACUC shall determine that the proposed activities and significant changes in ongoing activities meet the following requirements:

(i) Procedures involving animals will avoid or minimize discomfort, distress, and pain to the animals;

(ii) The principal investigator has considered alternatives to procedures that may cause more than momentary or slight pain or distress to the animals, and has provided a written narrative description of the methods and sources, e.g., the Animal Welfare Information Center, used to determine that alternatives were not available;

(iii) The principal investigator has provided written assurance that the activities do not unnecessarily duplicate previous experiments;

(iv) Procedures that may cause more than momentary or slight pain or distress to the animals will:

(A) Be performed with appropriate sedatives, analgesics or anesthetics, unless withholding such agents is justified for scientific reasons, in writing, by the principal investigator and will continue for only the necessary period of time;

(B) Involve, in their planning, consultation with the attending veterinarian or his or her designee;

(C) Not include the use of paralytics without anesthesia;

(v) Animals that would otherwise experience severe or chronic pain or distress that cannot be relieved will be painlessly euthanized at the end of the procedure or, if appropriate, during the procedure;

(vi) The animals' living conditions will be appropriate for their species in accordance with part 3 of this subchapter, and contribute to their health and comfort. The housing, feeding, and nonmedical care of the animals will be directed by the attending veterinarian or other scientist trained and experienced in the proper care, handling, and use of the species being maintained or studied;

(vii) Medical care for animals will be available and provided as necessary by a qualified veterinarian;

(viii) Personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in those procedures;

(ix) Activities that involve surgery include appropriate provision for preoperative and post-operative care of the animals in accordance with established veterinary medical and nursing practices. All survival surgery will be performed using aseptic procedures, including surgical gloves, masks, sterile instruments, and aseptic techniques. Major operative procedures on non-rodents will be conducted only in facilities intended for that purpose which shall be operated and maintained under aseptic conditions. Non-major operative procedures and all surgery on rodents do not require a dedicated facility, but must be performed using aseptic procedures. Operative procedures conducted at field sites need not be performed in dedicated facilities, but must be performed using aseptic procedures;

(x) No animal will be used in more than one major operative procedure from which it is allowed to recover, unless:

(A) Justified for scientific reasons by the principal investigator, in writing;

(B) Required as routine veterinary procedure or to protect the health or well-being of the animal as determined by the attending veterinarian; or

(C) In other special circumstances as determined by the Administrator on an individual basis. Written requests and supporting data should be sent to the Animal and Plant Health Inspection Service, Animal Care, 4700 River Road, Unit 84, Riverdale, Maryland 20737-1234;

(xi) Methods of euthanasia used must be in accordance with the definition of
the term set forth in 9 CFR part 1, §1.1
of this subchapter, unless a deviation is
justified for scientific reasons, in writ-
ing, by the investigator.

(2) Prior to IACUC review, each mem-
ber of the Committee shall be provided
with a list of proposed activities to be
reviewed. Written descriptions of all
proposed activities that involve the
care and use of animals shall be avail-
able to all IACUC members, and any
member of the IACUC may obtain,
upon request, full Committee review of
those activities. If full Committee re-
view is not requested, at least one
member of the IACUC, designated by
the chairman and qualified to conduct
the review, shall review those activi-
ties, and shall have the authority to
approve, require modifications in (to
secure approval), or request full Com-
mittee review of any of those activi-
ties. If full Committee review is re-
quested for a proposed activity, ap-
proval of that activity may be granted
only after review, at a convened meet-
ing of a quorum of the IACUC, and with
the approval vote of a majority of the
quorum present. No member may par-
ticipate in the IACUC review or ap-
proval of an activity in which that
member has a conflicting interest (e.g.,
is personally involved in the activity),
except to provide information re-
quested by the IACUC, nor may a mem-
ber who has a conflicting interest con-
tribute to the constitution of a
quorum;

(3) The IACUC may invite consult-
ants to assist in the review of complex
issues arising out of its review of pro-
posed activities. Consultants may not
approve or withhold approval of an ac-
tivity, and may not vote with the
IACUC unless they are also members of
the IACUC;

(4) The IACUC shall notify principal
investigators and the research facility
in writing of its decision to approve or
withhold approval of those activities
related to the care and use of animals,
or of modifications required to secure
IACUC approval. If the IACUC decides
to withhold approval of an activity, it
shall include in its written notification
a statement of the reasons for its deci-
sion and give the principal investigator
an opportunity to respond in person or
in writing. The IACUC may reconsider
its decision, with documentation in
Committee minutes, in light of the in-
formation provided by the principal in-
vestigator;

(5) The IACUC shall conduct con-
tinuing reviews of activities covered by
this subchapter at appropriate inter-
vals as determined by the IACUC, but
not less than annually;

(6) The IACUC may suspend an activ-
ity that it previously approved if it de-
termines that the activity is not being
conducted in accordance with the de-
scription of that activity provided by
the principal investigator and approved
by the Committee. The IACUC may
suspend an activity only after review
of the matter at a convened meeting of
a quorum of the IACUC and with the
suspension vote of a majority of the
quorum present;

(7) If the IACUC suspends an activity
involving animals, the Institutional Of-
official, in consultation with the IACUC,
shall review the reasons for suspension,
take appropriate corrective action, and
report that action with a full expla-
nation to APHIS and any Federal agen-
cy funding that activity; and

(8) Proposed activities and proposed
significant changes in ongoing activi-
ties that have been approved by the
IACUC may be subject to further ap-
propriate review and approval by offi-
cials of the research facility. However,
those officials may not approve an ac-
tivity involving the care and use of
animals if it has not been approved by
the IACUC.

(e) A proposal to conduct an activity
involving animals, or to make a sig-
nificant change in an ongoing activity
involving animals, must contain the
following:

(1) Identification of the species and
the approximate number of animals to
be used;

(2) A rationale for involving animals,
and for the appropriateness of the spe-
cies and numbers of animals to be used;

(3) A complete description of the pro-
posed use of the animals;

(4) A description of procedures de-
signed to assure that discomfort and
pain to animals will be limited to that
which is unavoidable for the conduct of
scientifically valuable research, includ-
ing provision for the use of analgesic,
anesthetic, and tranquilizing drugs
where indicated and appropriate to minimize discomfort and pain to animals; and

(5) A description of any euthanasia method to be used.


§ 2.32 Personnel qualifications.

(a) It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel.

(b) Training and instruction shall be made available, and the qualifications of personnel reviewed, with sufficient frequency to fulfill the research facility’s responsibilities under this section and §2.31.

(c) Training and instruction of personnel must include guidance in at least the following areas:

(1) Humane methods of animal maintenance and experimentation, including:

(i) The basic needs of each species of animal;

(ii) Proper handling and care for the various species of animals used by the facility;

(iii) Proper pre-procedural and post-procedural care of animals; and

(iv) Aseptic surgical methods and procedures;

(2) The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress;

(3) Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility;

(4) Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act;

(5) Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information:

(i) On appropriate methods of animal care and use;

(ii) On alternatives to the use of live animals in research;

(iii) That could prevent unintended and unnecessary duplication of research involving animals; and

(iv) Regarding the intent and requirements of the Act.

§ 2.33 Attending veterinarian and adequate veterinary care.

(a) Each research facility shall have an attending veterinarian who shall provide adequate veterinary care to its animals in compliance with this section:

(1) Each research facility shall employ an attending veterinarian under formal arrangements. In the case of a part-time attending veterinarian or consultant arrangements, the formal arrangements shall include a written program of veterinary care and regularly scheduled visits to the research facility;

(2) Each research facility shall assure that the attending veterinarian has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use; and

(3) The attending veterinarian shall be a voting member of the IACUC; Provided, however, That a research facility with more than one Doctor of Veterinary Medicine (DVM) may appoint to the IACUC another DVM with delegated program responsibility for activities involving animals at the research facility.

(b) Each research facility shall establish and maintain programs of adequate veterinary care that include:

(1) The availability of appropriate facilities, personnel, equipment, and services to comply with the provisions of this subchapter;

(2) The use of appropriate methods to prevent, control, diagnose, and treat diseases and injuries, and the availability of emergency, weekend, and holiday care;

(3) Daily observation of all animals to assess their health and well-being;