

(v) The procedures which the IACUC will follow to fulfill the requirements set forth in this subpart;

(vi) The health program for personnel who work in laboratory animal facilities or have frequent contact with animals;

(vii) The gross square footage of each animal facility (including satellite facilities), the species housed therein and the average daily inventory, by species, of animals in each facility; and

(viii) Any other pertinent information requested by OPRR.

(2) *Institutional status.* Each institution must assure that its program and facilities are in one of the following categories:

(i) *Category 1—Accredited* by the American Association for the Accreditation of Laboratory Animal Care (AAALAC). All of the institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated and accredited by AAALAC, or another accrediting body recognized by PHS.²

(ii) *Category 2—Evaluated* by the Institution. All of the institution's programs and facilities (including satellite facilities) for activities involving animals have been evaluated by the IACUC and will be reevaluated by the IACUC at least once each year. The IACUC shall use the *Guide* as a basis for evaluating the institution's program and facilities.

A report of the IACUC evaluation shall be submitted to the institutional official and updated on an annual basis.³ The initial report shall be submitted to OPRR with the Assurance. Annual re-

ports of the IACUC evaluation shall be maintained by the institution and made available to OPRR upon request. The report must contain a description of the nature and extent of the institution's adherence to the *Guide* and this policy.⁴ The report must identify specifically any departures from provisions of the *Guide* and this policy, and state the reasons for each departure. If program or facility deficiencies are noted, the report must contain a reasonable and specific plan and schedule for correcting each deficiency. The report must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one which, in the judgment of the IACUC and the institutional official, is or may be a threat to the health or safety of the animals. Failure of the IACUC to conduct an annual evaluation and submit the required report to the institutional official may result in PHS withdrawal of its approval of the Assurance.

(3) *Institutional Animal Care and Use Committee (IACUC).* (i) Each institution shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through experience and expertise of its members, to oversee the institution's animal program, facilities and procedures.

(ii) The Assurance must include the names, position titles and credentials of the IACUC chairperson and the members. The committee shall consist of not less than five members, and shall include at least:

(A) One 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 institution;

(B) One practicing scientist experienced in research involving animals;

(C) One member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy); and

(D) One individual who is not affiliated with the institution in any way

care and use of animals in PHS-supported activities is appropriate and humane in accordance with this policy. However, each institution may identify the committee by whatever name it chooses. Membership and responsibilities of the IACUC are set forth in PHS 380.205(d).

²As of the issuance date of this policy the only accrediting body recognized by PHS is the American Association for Accreditation of Laboratory Animal Care (AAALAC).

³The IACUC may, at its discretion, determine the best means of conducting an evaluation of the institution's programs and facilities. The IACUC may invite ad hoc consultants to conduct or assist in conducting the evaluation. However, the IACUC remains responsible for the evaluation and report.

⁴If some of the institution's facilities are accredited by AAALAC or other accrediting body recognized by PHS, the report should identify those facilities and need not contain any further information about evaluation of those facilities.

other than as a member of the IACUC, and is not a member of the immediate family of a person who is affiliated with the institution.

(iii) An individual who meets the requirements of more than one of the categories detailed in PHS 380.205(d)(2)(i)-(iv) above, may fulfill more than one requirement. However, no committee may consist of less than five members.

(b) *Functions of the Institutional Animal Care and Use Committee.* As an agent of the institution, the IACUC shall, will respect to PHS-supported activities:

(1) Review at least annually the institution's program for humane care and use of animals;

(2) Inspect at least annually all of the institution's animal facilities, including satellite facilities;

(3) Review concerns involving the care and use of animals at the institution;

(4) Make recommendations to the institutional official regarding any aspect of the institution's animal program, facilities or personnel training;

(5) Review and approve, require modifications in (to secure approval), or withhold approval of those sections of PHS applications or proposals related to the care and use of animals, as specified in PHS 380.205(f) of this subpart;

(6) Review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities; and

(7) Be authorized to suspend an activity involving animals in accord with specifications set forth in this subpart.

(c) *Review of applications and proposals.* In order to approve applications and proposals or proposed changes in ongoing activities, the IACUC shall conduct a review of those sections related to the care and use of animals and determine that the proposed activities are in accordance with this policy. In making this determination, the IACUC shall confirm that the activity will be conducted in accordance with the Animal Welfare Act insofar as it applies to the activity, and that the activity is consistent with the *Guide*, unless the IACUC determines that acceptable justification for a departure is

presented. Furthermore, the IACUC shall determine that the activity conforms with the institution's Assurance and meets the following requirements:

(1) Procedures with animals will avoid or minimize discomfort, distress and pain to the animals, consistent with sound research design.

(2) Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesia, or anesthesia, unless the procedure is justified for scientific reasons in writing by the investigator.

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

(4) The living conditions of animals will be appropriate for their species and contribute to their health and comfort. The housing, feeding and non-medical care of the animals will be directed by a veterinarian or a scientist trained and experienced in the proper care, handling and use of the species being maintained or studied.

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

(6) Personnel conducting procedures on the species being maintained or studies will be appropriately qualified and trained in those procedures.

(7) Methods of euthanasia used will be consistent with the recommendations of the American Veterinary Medical Association (AVMA) Panel of Euthanasia⁵, unless a deviation is justified for scientific reasons in writing by the investigator.

PHS 380.206 Public Health Service implementation.

(a) *Responsibility of the Office for Protection from Research Risks (OPRR).* OPRR is responsible for the general administration and coordination of this policy and will:

(1) Request and negotiate, approve or disapprove, and, as necessary, withdraw approval of Assurances;

⁵ Journal of the American Veterinary Association (JAVMA), 1978, Vol. 143, No. 1, pp. 59-72, or succeeding revised editions.

(2) Distribute to executive secretaries of initial review and technical evaluation groups, and to PHS contracting offices, lists of institutions that have an approved Assurance;

(3) Advise contracting offices and awardee institutions concerning the implementation of this policy;

(4) Evaluate allegations of non-compliance with this subpart;

(5) Have the authority to review and approve or disapprove waivers of this subpart (see paragraph (d) of this section); and

(6) With other PHS officials, conduct site visits to selected institutions.

(b) *Responsibilities of PHS contracting offices.* PHS contracting offices shall not make an award for an activity involving animals unless the institution submitting the application or proposal is on the list of institutions that have an approved Assurance of file with OPRR, and the institutional official has provided verification of approval by the IACUC of those sections of the application or proposal related to the care and use of animals. If an institution is not listed, the contracting office shall ask OPRR to negotiate an Assurance with the institution before an award is made. No award shall be made until the Assurance has been submitted by the institution, approved by OPRR, and the institution has provided verification of approval by the IACUC of those sections of the application or proposal related to the care and use of animals in PHS-supported activities.

(c) *Conduct of special reviews/site visits.* Each awardee institution is subject to review at any time by PHS staff and advisors, which may include a site visit, to assess the adequacy of the institution's compliance with this policy.

(d) *Waiver.* Institutions may request a waiver of a provision of this policy by submitting a request to OPRR. No waiver will be granted unless sufficient justification is provided, and the waiver is approved in writing by OPRR.

Subpart PHS 380.3—Acquisition of Drugs and Medical Supplies

PHS 380.301 Scope of subpart.

This subpart provides policies and procedures pertaining to the acquisition

of drug products and medical supplies by PHS or PHS's contractors.

PHS 380.302 Acquisition of drugs.

PHS 380.302-1 Policy.

(a) Drugs shall be acquired at the lowest possible price consistent with acceptable standards of identity, strength, quality, purity, safety and effectiveness, and with due regard for the welfare of the patient and the professional judgment of the prescriber.

(b) Contracting activities shall ensure that drugs are acquired by generic name on a competitive basis whenever it is possible to obtain therapeutically effective drugs of established quality. However, the professional judgment of the prescriber to request drugs by brand name or house designation must be recognized when the best interest of the patient requires it. Similarly, scientific investigators have the prerogative to request drugs having end-product characteristics considered necessary for the conduct of research or investigations.

(c) Prior to taking any acquisition action, the contracting officer shall ensure that the requested drug products are not available from mandatory sources such as Federal Supply Schedules. Part 103-26 of the HHS Material Management Manual describes sources of supply for drugs.

PHS 380.302-2 Solicitation and contract requirements.

The contracting officer should consider including statements similar to the following in solicitations and resultant contracts pertaining to drug products:

(a) The offeror (contractor) guarantees that all requirements established by the Food and Drug Administration, HHS, have been met. These requirements include: plant sanitation, manufacturing, packaging, labeling, identification, strength, quality, purity, safety, and effectiveness.

NOTE: The contracting officer may want to cite the applicable reference(s) pertaining to the FDA requirements.

(b) The offeror (contractor), by signing this document, guarantees/warrants that any applicable shelf-life requirements have been met and the furnished drugs are free from defects.

(c) The Government reserves the right to inspect the manufacturer's plant and premises during normal operating hours.

NOTE: FDA will normally conduct the inspection when requested, but may request to be reimbursed for the services.

(d) The offeror (contractor) agrees to submit either a comprehensive, certified analysis on each lot of drugs at the time of delivery of the drugs, or a comprehensive list of specifications met by the drugs along with a certificate of analysis, or other suitable documentation, verifying that the drugs meet the appropriate standards.

(e) The offeror (contractor) claims it is not currently listed as a disqualified bidder or offeror for drugs by any Federal agency or department.

(f) The offeror must set forth full, accurate, and complete information as required by this solicitation (including attachments). The penalty for making false statements in offers is prescribed in 18 U.S.C. 1001.

(g) If the offeror (prime contractor) plans to use (or uses) a subcontractor or secondary manufacturer for the furnishing of any or all the drug products under the resultant contract, the name and address of the subcontractor or secondary manufacturer is to be furnished the contracting officer, along with the drug lots affected. The prime contractor shall ensure that the subcontractor or secondary manufacturer complies with the above stated requirements.

PHS 380.303 Acquisition of controlled drugs.

(a) Controlled drugs include narcotics and dangerous drugs identified by the Drug Enforcement Administration (DEA), Department of Justice, in the regulations implementing the Comprehensive Drug Abuse Prevention and Control Act of 1970 (Title 21 CFR Chapter II).

(b) The DEA issues a Controlled Substances Inventory List which provides general information pertaining to the ordering of controlled drug products

and the use of specific order forms. The local DEA regional office should be contacted to receive the list and instructions regarding registering and ordering forms, as well as other matters concerning the handling and processing of controlled drugs. Sections 103–27.6204(a)(2) and 103–27.6302(b) of the HHS Material Management Manual provide information on issuing, shipping, and safeguarding controlled drugs.

(c) Contracting officers shall ensure that requests for contracts or purchase requests are supported by the required DEA form prior to initiation of any action.

PHS 380.304 Effectiveness of drug products.

PHS 380.304–1 General.

(a) The National Academy of Sciences National Research Council (NAS-NRC) has established effectiveness classifications for the indication of drug products, based upon the following criteria:

(1) Factual information that is freely available in scientific literature;

(2) Factual information that is available from the Food and Drug Administration, the manufacturer, or other sources; and

(3) Experience and informed judgment of the members of NAS-NRC panels.

(b) The indications mentioned in the following categories refer to "the effect the drug purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling." That is, the indications are the claims noted in the labeling of a given drug product.

(1) *Category A—Effective.* For the presented indication, the drug is effective on the basis of the criteria cited in PHS 380.304–1(a) above.

(2) *Category B—Probably Effective.* For the indication presented, effectiveness of the drug is probable on the basis of the criteria cited in PHS 380.304–1(a) but additional evidence is required before it can be assigned to Category A.

(3) *Category C—Possibly Effective.* In relation to the indication in question, there is little evidence of effectiveness under any of the criteria cited in PHS