**SCOPE:** This policy applies to all facility-run Institutional Animal Care and Use Committees (IACUCs).

**PURPOSE:** The purpose of this policy is to guide the appropriate care and use of all animals involved in research, research training, and biological testing activities.

**POLICY:** This policy applies to institutions that own or engage in research with live, vertebrate non-human animals used or intended for use in research, research training, experimentation, or biological testing or for related purposes (henceforth “animals”). Engagement is defined as assuming responsibility for compliance with federal guidelines and law, both with and without direct Office of Laboratory Animal Welfare (OLAW) oversight through an active Assurance. Simply providing diagnostic examinations for researchers (i.e., MRIs, x-ray etc.) does not engage facilities in the conduct of research.

1. **SCOPE OF POLICY AND PROGRAM**
   a. Advance written permission from the corporate Responsible Executive for Clinical Research must be obtained for the ownership and/or use of species regulated by the Office of Laboratory Welfare or United States Department of Agriculture.
   b. For all animal research conducted or supported by the United States Public Health Service (PHS), a current written assurance must be approved by the OLAW prior to research activity taking place.
      i. The Assurance identifies an Institutional Official (IO) as the individual who signs, and has the authority to sign the institution’s Assurance, making a commitment on behalf of the institution that the PHS Policy requirements will be met.
      ii. The Assurance must be updated according to PHS/OLAW policy (i.e., every five years).
      iii. A copy of this Assurance and each of its updates shall be forwarded to the HCA Corporate Responsible Executive for Clinical Research.
   c. For all animal research that is conducted through non-PHS funding (private, state and other funding), an Assurance is not required.
      i. These projects are ineligible to have an active OLAW Assurance until such time that federal funding is procured. When federal funding is obtained, the OLAW Assurance is then required at the site.
      ii. Non-Assurance sites are required to follow all current and applicable OLAW and/or USDA guidelines including:
         1. Active IACUC
         2. Regular reporting within institution and HCA
         3. Same standards are used to assess the animal program as if an Assurance is in place
   d. The institution endorses the following documents:
      i. The 9 principles put forth in the *U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training* developed by the United States’ Interagency Research Animal Committee.
ii. The “Three Rs” (Replacement, Reduction and Refinement) as put forth by the 1959 report by Russell and Burch entitled *The Principles of Humane Experimental Techniques*.

iii. *Error! Hyperlink reference not valid.* The most current OLAW endorsed edition of the *Guide for the Care and Use of Laboratory Animals* published by the National Research Council of the National Academies (a.k.a. “The Guide”) as the basis for developing and implementing an institutional program for activities involving animals.

2. IACUC MEMBERSHIP AND FUNCTIONS
   a. IACUC Membership Requirements
      i. The IACUC must be comprised of at least 5 members, appointed by the CEO (or CEO’s designee as evidenced in writing by the CEO).
      ii. IACUC members must include at least one of the following (note, one member can fulfill more than one requirement, with the exception of being both a scientist and a non-scientist, but the committee must still consist of a minimum of 5 members):
         1. a Doctor of Veterinary Medicine, with training or experience in laboratory animal science and medicine, who has direct or delegated program authority and responsibility for activities involving animals at the institution;
         2. a practicing scientist experienced in research involving animals;
         3. a member whose primary concerns are in a nonscientific area (for example, ethicist, lawyer, member of the clergy);
         4. an individual who is not affiliated with the institution in any way 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.
   b. The IACUC must be documented as being responsible for oversight and evaluation of institution’s program.
   c. The IACUC reports to the IO as evidenced by organizational charts.
   d. The institution provides training and resources to assist IACUC members in understanding and evaluating issues brought before the committee.
   e. At least once every six months, the IACUC reviews the institution’s program for humane care and use of animals, using the Guide as a basis for evaluation.
   f. At least once every six months, the IACUC inspects all of the institution's animal facilities (including satellite facilities) using “The Guide” as a basis for evaluation.
   g. The IACUC reviews and investigates concerns about animal care and use at the institution.
   h. The IACUC makes recommendations to the Institutional Official regarding any aspect of the institution's animal program, facilities, or personnel training.
   i. The IACUC has procedures in order to review and approve, require modifications in (to secure approval) or withhold approval of activities related to the care and use of animals.
   j. The IACUC has procedures in order to review and approve, require modifications in (to secure approval), or withhold approval of proposed significant changes regarding the use of animals in ongoing activities.
   k. The IACUC is authorized to suspend an activity involving animals.
### IACUC RECORDS AND REPORTING REQUIREMENTS

#### a. Contents of the Semi-Annual Report to the IO

- Reports of semiannual program reviews & facility inspections are to be submitted to the IO every six months.
- Reports are to describe departures (and reasons for departure) from either or both the most current edition of the *Guide for the Care and Use of Laboratory Animals* published by the National Research Council of the National Academies (a.k.a. “Guide”) and the most current Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (a.k.a. “PHS Policy”).
- The report must distinguish significant from minor deficiencies (a “significant deficiency” being one which, consistent with PHS Policy, and, in the judgment of the IACUC and the IO, is or may be a threat to the health or safety of the animals).
- The report is to include a reasonable and specific plan for correction of each deficiency identified.
- Reports are to include minority IACUC views.
- Copies of these reports are to be sent to the corporate Responsible Executive for Clinical Research.

#### b. Reports to OLAW

- Annual Reports: At least once every 12 months, the IACUC, through the IO, shall submit its annual report in writing to OLAW. The report shall contain all legally required elements. If there are no changes to the program, the report is still due to OLAW and must specify that there were no changes.
- AD-HOC Reports: The IACUC, through the IO, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to:
  1. any serious or continuing noncompliance with PHS Policy;
  2. any serious deviation from the provisions of “The Guide”; or
  3. any suspension of an activity by the IACUC.
- Annual Reports and AD-HOC reports must include any minority views filed by members of the IACUC.
- Copies of these reports are to be sent to the corporate Responsible Executive for Clinical Research.

#### c. Records

- Minutes of IACUC meetings (including records of attendance, activities of the committee, and committee deliberations) and semiannual reports are to be maintained for 3 years.
- IACUC review documentation is to be maintained for 3 years after the end of the activity. Specifically:
  1. records of any applications/forms;
  2. proposals/protocols;
  3. proposed significant changes in the care and use of animals;
  4. whether IACUC approval was given or withheld;
  5. correspondence with investigators.
iii. IACUC rosters are to be dated (including month, date and year) and maintained for 3 years, as is any documentation of qualification and training of members.

iv. Copies of minutes and changes of roster are to be sent to the corporate Responsible Executive for Clinical Research.

v. All records shall be accessible for inspection and copying by authorized OLAW or other PHS representatives at reasonable times and in a reasonable manner.

4. IACUC OVERSIGHT OF PROTOCOLS
   a. Prior to the review, each IACUC member shall be provided with a list of proposed research projects to be reviewed. Written descriptions of research projects that involve the care and use of animals shall be available to all IACUC members, and any member of the IACUC may obtain, upon request, full committee review of those research projects. If full committee review is not requested, at least one member of the IACUC, designated by the chairperson and qualified to conduct the review, shall review those research projects and have the authority to approve, require modifications in (to secure approval) or request full committee review of those research projects. If full committee review is requested, approval of those research projects may be granted only after review at a convened meeting of a quorum of the IACUC and with the approval vote of a majority of the quorum present. No member may participate in the IACUC review or approval of a research project in which the member has a conflicting interest (e.g., is personally involved in the project) except to provide information requested by the IACUC; nor may a member who has a conflicting interest contribute to the constitution of a quorum.

   b. The IACUC may invite consultants to assist in the review of complex issues. Consultants may not approve or withhold approval of an activity or vote with the IACUC unless they are also members of the IACUC.

   c. The IACUC shall notify investigators and the institution 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 decision and give the investigator an opportunity to respond in person or in writing.

   d. The IACUC shall conduct continuing review of each previously approved, ongoing activity covered by this Policy at appropriate intervals as determined by the IACUC, including a complete review at least once every three years (or one year for USDA governed species).

   e. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with applicable provisions of the Animal Welfare Act, the Guide, the institution's Assurance, or PHS Policy. 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.
f. If the IACUC suspends an activity involving animals, the IO, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to OLAW. A copy of this report shall also be sent to the corporate Responsible Executive of Clinical Research.

g. Applications and proposals that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the institution. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC.