**PROTOCOL REVIEW REQUIREMENTS: PROCESS**

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<td>I. This Policy is intended to implement and supplement [The US Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research &amp; Training]. II. All institutions are required to comply, as applicable, with the Animal Welfare Act, and other Federal statutes and regulations relating to animals.</td>
<td>IV.C.2. Prior to the review, each IACUC member shall be provided with a list of proposed research projects to be reviewed.</td>
<td>a4.b.(4) all VA facilities conducting animal research must comply with the Health Research Extension Act and the PHS Policy. a4.b.(4) (a) All VA animal research must be covered by a PHS Assurance. a4.b.(5) all VA animal research must comply with the Animal Welfare Act.</td>
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<td>2.31(d)(2) Prior to the review, each IACUC member shall be provided with a list of proposed research projects to be reviewed.</td>
<td>2.31(d)(2) Written descriptions of all proposed activities that involve the care and use of animals shall be available to all IACUC members.</td>
<td>IV.C.2. Written descriptions of research projects that involve the care and use of animals shall be available to all IACUC members.</td>
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<td>2.31(d)(2) If full Committee review is not requested, at least one member of the IACUC, designated by the chairman and qualified to conduct the review, shall review those activities, and shall have the authority to approve, require modifications in (to secure approval), or request full Committee review of any of those activities.</td>
<td>2.31(d)(2) 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.</td>
<td>a8.f.(2)(c-d) The designated review system may be used... all IACUC members receive complete copies of all protocol forms to aid them in deciding whether or not to request full committee review. a8.f.(2)(d)1. The research office must provide packets to IACUC members no later than 3 business days before the IACUC meeting.</td>
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<td>2.31(d)(2) If full Committee review is requested for a proposed activity, approval of that activity 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.</td>
<td>2.31(d)(2) 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.</td>
<td>a8.f.(2) All research projects involving animals must be approved by the IACUC and then by the R&amp;D Committee. The IACUC must review proposed research at convened meetings at which a quorum ...is present.</td>
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<td>2.31(d)(2) No member may participate in the IACUC review or approval of an activity in which that member has a conflicting interest (e.g., is personally involved in the activity), except to provide information requested by the IACUC, nor may a member who has a conflicting interest contribute to the constitution of a quorum</td>
<td>2.31(d)(2) 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.</td>
<td>a8.e.(2),(3) no IACUC member may participate in the IACUC review, or in the approval of a research project in which the member is personally involved in the project/[has a financial conflict], except to provide information requested by the IACUC.</td>
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<td>2.31(d)(3) The IACUC may invite consultants to assist in the review of complex issues arising out of its review of proposed activities. Consultants may not approve or withhold approval of an activity, and may not vote with the IACUC unless they are also members of the IACUC;</td>
<td>2.31(d)(3) 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.</td>
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Lorinda.Wright2@va.gov, megreene@msu.edu
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### USDA

2.31.(d)(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 decision and give the principal investigator an opportunity to respond in person or in writing.

2.31(d)(5) The IACUC shall conduct continuing reviews of activities covered by this subchapter at appropriate intervals as determined by the IACUC, but not less than annually;

2.31.(d)(6) The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of that activity provided by the principal investigator and approved by the Committee.

2.31(d)(6) 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;

2.31(d)(8) Proposed activities and proposed significant changes in ongoing activities that have been approved by the IACUC may be subject to further appropriate review and approval by officials of the research facility. However, those officials may not approve an activity involving the care and use of animals if it has not been approved by the IACUC.

2.35(a)(1) Minutes of IACUC meetings, including records of attendance, activities of the Committee, and Committee deliberations;

(2) Records of proposed activities involving animals and proposed significant changes in activities involving animals, and whether IACUC approval was

### PHS

IV.C.4. 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.

IV.C.5. 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 in accordance with IV.C.1.-4. at least once every three years.

IV.C.6. 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 IV.C.1.a.-g. of this Policy.

IV.C.6. 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.

IV.D.1,2. Applications or proposal …covered by this Policy…shall include verification of approval …by the IACUC of those components related to the care and use of animals. [Protocols must match grant proposal].

IV.C.8. 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.

IV.E.1.b. The awardee institution shall maintain: minutes of IACUC meetings, including records of attendance, activities of the committee, and committee deliberations c. records of applications, proposals, and proposed significant changes in the care and use of animals and whether IACUC approval was given or withheld;

### VA Handbooks

8.f.(2) Research and Development Committee must approve the protocol and the Principal Investigator must receive notification from the ACOS prior to initiating the research.

8.g. The IACUC must review the conduct of all animal protocols annually.

8.g.(2) Prior to the third anniversary, the IACUC must conduct a complete re-review of the protocol.

8.j. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of that activity provided by the PI and approved by the IACUC.

8.j. Unless the IO has granted additional authority, the IACUC may suspend an activity only after review of the matter at a properly-convened IACUC meeting and with the suspension vote by a majority of a quorum.

8.f.(2)(e) Responses to all ACORP review items found in Appendix D must be provided in the given sequence when applications selected for ORD funding include an ACORP.

8.f.(2) Research and Development Committee must approve the protocol and the Principal Investigator must receive notification from the ACOS prior to initiating the research.

14.d. Each subcommittee must maintain adequate records. (1) Copies of all research proposals and their amendments … and any accompanying materials; (2) All continuing or final reports; (3) Minutes of its meetings; (4) Copies of all written correspondence; (5) A membership list of all voting, non-voting, and ex-officio members; (6) Written records

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Lorinda.Wright2@va.gov, megreene@msu.edu

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<td>given or withheld;</td>
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<td>documenting actions taken to carry out the subcommittee’s responsibilities; (7) Standard Operating Procedures; and (8) All communications to and from investigators, other committees, subcommittees, and other entities or individuals.</td>
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2.31.(d)(7) If the IACUC suspends an activity involving animals, the Institutional Official, in consultation with the IACUC, shall review the reasons for suspension, take appropriate corrective action, and report that action with a full explanation to APHIS and any Federal agency funding that activity;

IV.C.7. If the IACUC suspends an activity involving animals, the Institutional Official 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.

a8.i(1) (b) 1-5. Suspensions of protocols previously approved or suspensions of procedures or studies never given approval. The report needs to include: When and how the IACUC became aware of the problem. When the investigation was performed to determine facts and detail circumstances that lead to the non-compliance. The results of that investigation. When the IACUC convened a quorum to suspend the activity. What corrective actions the IACUC approved to prevent recurrences.

### References:
- PHS Policy on Humane Care and Use of Laboratory Animals (2002)
- VA Handbooks Referenced:
  - aVHA Handbook 1200.07 “Use of Animals in Research” (2011)
  - bVHA Handbook 1200.01 “Research and Development (R&D) Committee” (6-16-09)