

April 24, 2013

RESEARCH STANDARD OPERATING PROCEDURES (SOP)
Handling of Research Non-Compliance and/or Reportable Incidents/ Unexpected Events
Involving Laboratory Animals

1. **PURPOSE:** To outline the procedures for handling of research non-compliance and/or reportable incidents/unexpected events related to research studies involving laboratory animals conducted at STVHCS.
2. **POLICY:**
 - a. The monitoring and reporting of research non-compliance and/or unexpected events are key components of the protection of laboratory animals in research and are critical to the function of the Animal Care and Use Program (ACUP) at STVHCS.
 - b. The Associate Chief of Staff (ACOS) for Research is responsible to ensure that all concerns or complaints related to research at STVHCS, received from any source, are promptly investigated.
 - c. **Definitions:**
 - (1) **Research Non-Compliance:** Conducting research in a manner that 1) disregards or violates federal regulations or institutional policies and procedures applicable to use of animals, or 2) failure to follow the research practices listed in the IACUC-approved proposal. Noncompliance is characterized by severity of the event (i.e., serious or not serious) and the pattern of like or similar events (continuing or not continuing). Noncompliance that is determined by the IACUC to adversely affect animal welfare is also considered a deviation.
 - (2) **Unanticipated or Unexpected Events.** The terms unanticipated and unexpected refer to an event or problem in VA research that is new or greater than previously known in terms of nature, severity, or frequency, given the procedures described in protocol-related documents and the characteristics of the study population. Examples presented in VHA Handbook 1058.01 include, but are not limited to: unanticipated loss of animal life, animal theft or potentially dangerous escape, work-related or research-related injury to any person requiring more than minor medical intervention or extended surveillance or leading to serious complications or death.
3. **ACTION:**
 - a. **IACUC Review of Reportable Incidents/Unexpected Events.** Within 5 business days of becoming aware of any reportable incident/unexpected event, members of the VA research community are required to ensure that the incident has been reported in writing to the IACUC. The IACUC must review any reportable incident/unexpected event at its next convened meeting.
 - (1) Incidents that present a significant risk to the safety of research personnel, animals, or the environment may require immediate attention and result in the need to convene an emergency session of the IACUC prior to the next scheduled meeting.

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- (2) Review of concerns involving the care and use of animals at the Institution.
- (a) Notices regarding reporting any misuse of animals are posted throughout the VMU. All allegations of improper animal care and use must be reviewed promptly by the IACUC and investigated if warranted.
 - (b) The chair is responsible for appointing fact finding committee members that will report their findings to the entire committee.
 - (c) If an activity requires immediate action, the concern will be reported to the veterinarian and the IACUC chair for review. After review, these individuals will agree upon and follow a course of action deemed to be in the best interest of the animals' welfare.
 - (d) A report of the action taken will be provided to the IACUC. The veterinarian, or his designee, unilaterally may decide to euthanize an animal in extreme distress or pain that cannot be alleviated if euthanasia is determined to be in the best interest of the animal.
 - (e) All reasonable attempts to seek advice from the above individuals and the principal investigator will be made. The veterinarian may require an investigator to cease procedures in process when the veterinarian determines the animal to be in extreme distress or pain if cessation of work in progress is determined to be in the best interest of the animal.
 - (f) Minor deficiencies discovered through inspections will be corrected on the spot or referred to the VMU staff for follow-up.
 - (g) Concerns of IACUC members, staff, or investigators are presented to the IACUC for review at the next scheduled meeting. The IACUC minutes will, in all cases, document action taken.
 - (h) Should the IACUC determine that a reportable incident or event occurred, the IACUC Chair, or designee must report the determination directly (without intermediaries) to the Medical Center Director, with a simultaneous copy to the ACOS for Research, the R&D Committee, and any other relevant research subcommittees, within 5 business days after the IACUC's determination regardless of whether the determination is preliminary.
 - (i) The Medical Center Director will report the IACUC's determination of a Research Event/Reportable Incident to the appropriate ORO review committee, with a simultaneous copy to the VISN Director, within 5 business days after receiving such notification.
 - (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, or if there are concerns regarding the safety or welfare of laboratory animals or the safety rights or welfare of research staff or others. The IACUC may suspend an activity only after review of the matter at a properly convened meeting (quorum) of the IACUC and with the suspension vote of a majority of members present. The following guidelines should be followed when suspending projects:
 - 1. No additional animals may be entered into studies.

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2. Investigator's access to the animals will be removed.
 3. All animals under the suspended protocol will be transferred to the holding protocol.
 4. Breeding of valuable animals should not be interrupted, but the entry of new animals into research studies is prohibited.
- (k) Should the IACUC determine to terminate or suspend a protocol, the IACUC Chair, or designee must report the determination directly (without intermediaries) to the Medical Center Director, with a simultaneous copy to the ACOS for Research, the R&D Committee, and any other relevant research subcommittees, within 5 business days after the IACUC's determination.
- (l) The Medical Center Director will report the IACUC's determination of a protocol termination or suspension to the appropriate ORO review committee within 5 business days after receiving such notification.
- (m) Any employee who believes that an allegation of improper animal care and use was not investigated properly at the local level may contact the CVMO directly to express concerns without seeking local permissions.

b. IACUC Review of Research Non-Compliance

- (1) Non-compliance can be identified as any of the following:
- (a) Activity of animal use prior to written IACUC, SRS, and R&D approval.
 - (b) Proceeding with changes in activities without written IACUC approval or failure to adhere to the activities as described in an approved protocol.
 - (c) Research activity involving animals that is not associated with an approved and current ACORP.
 - (d) Any violation of the animal care and use provisions of the Animal Welfare Act, the PHS Policy on Humane Care and Use of Laboratory Animals, the NIH Guide for the Care and Use of Laboratory Animals, or any applicable VA policies or SOP's.
 - (e) Procedures conducted past the approval period or by unauthorized or untrained personnel.
- (2) Review of Research non-compliance may be identified through any number of ways, including but not limited to:
- (a) A report by any individual to the IACUC, SRS, R&D Committee, or R&D Office
 - (b) Continuing review of ongoing research by the IACUC, SRS or R&D Committee
 - (c) Compliance audits conducted by the UTHSCSA or STVHCS compliance offices
 - (d) A report by another committee, department, or official.
 - (e) A report from the study sponsor or sponsor's monitoring entity
- (3) Noncompliance identified as deviation from an approved protocol may be reported in a number of ways including but not limited to:
- (a) Self-reporting by the Principal Investigator.
 - (b) Reporting by other committees, departments or officials.
 - (c) Reporting by other faculty/staff.
 - (d) The IACUC may learn of noncompliance as a result of continuing review of ongoing research.
 - (e) Reporting by the study sponsor or a monitoring entity.
 - (f) As a result of Semi-Annual Inspection findings.

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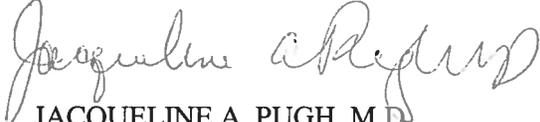
- (4) IACUC may determine the following:
 - (a) Not noncompliance
 - (b) Noncompliance that is neither Serious nor Continuing
 - (c) Noncompliance that is Serious and/or Continuing
 - (d) Not enough information available to make a determination (Deferred)
 - (e) If a possible noncompliance is Deferred, additional information may be requested from the investigator or the issue may be sent to a subcommittee to further investigate the allegation. The subcommittee will report the findings of the investigation to the IACUC for determination.
- (5) Issues or events that are reported are possible noncompliance until a final determination is made by the IACUC.
- (6) Should the IACUC determine serious and/or continuing noncompliance, the IACUC Chair, or designee must report the determination directly (without intermediaries) to the Medical Center Director, with a simultaneous copy to the ACOS for Research, the R&D Committee, and any other relevant research subcommittees, within 5 business days after the IACUC's determination.
- (7) The Medical Center Director will report the IACUC's determination of serious and/or continuing noncompliance to the appropriate ORO review committee, with a simultaneous copy to the VISN Director, within 5 business days after receiving such notification.
- (8) Final determination is sent to the PI with a corrective action plan if appropriate.

c. Reporting to ORO

- (1) Notification to ORO will include any official correspondence from the IACUC, and will include the following information when not included in any IACUC correspondence:
 - (a) The nature of the event (serious or continuing non-compliance) including when and how the IACUC became aware of the problem.
 - (b) Name of the institution conducting the research.
 - (c) Title of the research project or grant proposal in which the problem occurred.
 - (d) Name of the principal investigator on the protocol.
 - (e) Identification numbers of the research project as assigned by the IACUC and the STVHCS R&D Office and the identification number of any applicable federal award(s), grant, contract, or cooperative agreement.
 - (f) A detailed description of the problem including the findings of the organization and the reasons for the decision of the IACUC.
 - (g) Actions that IACUC or STVHCS has taken or plans to take to address the problem.
 - (h) Plans, including a timetable for completion of the investigation and/or corrective action if appropriate, for the IACUC or STVHCS to send a follow-up or final report.
 - (i) The name of any agencies or organization external to VA that were notified or need to be notified, of the event.
- (2) Interim and final reports will be provided as directed by ORO.
- (3) Reports to external regulatory agencies by the STVHCS or the UTHSCSA IACUC will be communicated to the reciprocal office.

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4. **REFERENCES:** VHA Handbook 1058.01
5. **RESPONSIBILITY:** Associate Chief of Staff for Research (151)
6. **RECISSION:** None
7. **RECERTIFICATION:** April 2018



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