Adopted 12/3/13

**Non-Compliance Procedures**

The use of live vertebrate animals is an important component of the Institution’s research and teaching missions and the FSHU community is committed to conducting this use in a humane manner.  The use of live vertebrate animals in research is a privilege, and carries with it the responsibility to follow applicable law, policies, and procedures developed by the federal government and the Institution.  Noncompliance with the law, policies and procedures of a single individual can place this privilege at risk for the entire FHSU community.  Consequently, the IACUC takes the position that the welfare of animal subjects has priority when there is a conflict between the welfare of animal subjects and the rights and interests of an individual.

 To help ensure that animals receive humane care, use or treatment in accordance with the highest ethical standards, laws, regulations and policies governing animal research, the IACUC must review and, if warranted, address any animal-related concerns raised by the public or institutional employees. Procedures must be established to ensure that concerns are communicated to the IACUC. The Committee must review each concern in a timely and systematic manner and, when necessary, take prompt, appropriate corrective actions

The FHSU IACUC has adopted the following guidelines for the investigation of allegations of noncompliance in the animal care program.  Noncompliance includes animal use activities that are not reviewed and approved by the IACUC, go beyond the scope of an approved protocol, as well as other activities that unnecessarily increase risks to animal subjects.

Protocol non-compliance occurs when procedures or policies approved by the IACUC are not being followed. Examples include conducting studies or any procedures that were not reviewed or approved by the IACUC, performing experimental surgery, unauthorized persons participating in a research project, or treating animals with any drugs that are not approved by the IACUC (aside from medical treatments administered by the licensed veterinarian).

When faced with protocol noncompliance, the IACUC’s first step, if possible, should be to find a way to bring the protocol into compliance. If allegations of animal mistreatment or protocol non-compliance are verified, the IACUC can apply sanctions. The IACUC reserves the rights to decide whether as to impose sanctions or not. A case where minor or unintentional misinterpretation of an IACUC policy that has created problem with animal care and use is an example of where a verified allegation of protocol non-compliance might lead to an explanation and correction of the issues rather than a sanction.

Under the AWAR (9 CFR § 2.32 ( c ) (4), no facility employee, Committee member or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of regulations or standards under the act. Therefore, the FHSU IACUC is obligated to protect the rights of any employee who has made allegations of impropriety.

 Requests for anonymity should be honored to the extent possible. This includes protecting the confidentiality of those who report concerns as well as anyone against whom allegations are directed, while allegations are under investigation. The policy of the University is to prohibit unlawful retaliation against employees as a consequence of good faith actions in the reporting of, or the participation in an investigation pertaining to, allegations of wrongdoing.

Concerns may include situations or activities that cause immediate, actual, or perceived danger/harm to animals, as well as actual and perceived violations of the AWRs or institutional Animal Welfare Assurance (with or without endangering animals). Concerns also may focus on allegations of past policy and procedure violations or protocol non-compliance.

The course of action taken by the IACUC should be driven by the potential significance of the alleged situation. Conditions that reportedly jeopardize the health or well-being of animals should be evaluated immediately. In such case, the FHSU IACUC authorizes the Attending Veterinarian to halt any procedures that are perceived to be not in compliance with institutional policies until the IACUC can be convened and consider the matter formally. Similarly, situations that may involve potential criminal activity or human safety should be reported promptly to the institution's law enforcement or occupational health and safety officials.  Allegations of other ongoing policy or procedural matters may not require such same-day attention, but should not be deferred merely as a matter of convenience. Emergency meetings may be necessary in these cases to ensure prompt consideration of concerns.

**General Principles**

* Confidentiality will be maintained throughout the investigation.  This will be achieved by:

(a) Restricting the dissemination of information about the allegation, the course of the investigation and its outcome, to the following individuals involved in the process:  members of the IACUC, other appropriate FHSU officials, and individuals who may have information regarding the allegation.  Should the allegation be found to have merit, it is possible that sponsoring agencies may also have to be notified.

(b) Good faith efforts to maintain the confidentiality of the identity of the Complainant, if requested.  Although, due to the nature of the investigation, confidentiality cannot always be assured, whenever possible, the Complainant will be notified prior to the revelation of his or her identity.

* Initial investigations will be a collegial process.  The investigator, IACUC chair, Institutional Officer, and the academic unit supervisor will be notified of any allegation that has been made.  Both the individual reporting the concern and the responsible party will be requested to provide information relevant to the report.  It is the obligation of the respondent(s) to cooperate with the committee during this process.
* The responsible party will be informed if and when their superiors are being made aware of the existence and nature of the allegations of impropriety and the course of any inquiry concerning them.
* Following completion of the investigation, the IACUC may take actions deemed necessary or appropriate.  Some of these are listed in the following section.

**Specific Guidelines for Investigating Allegations of Noncompliance**

The IACUC Chairperson will appoint a subcommittee consisting of the at least 2 IACUC members without conflict of interest. Typically the subcommittee includes the IACUC Chairperson and at least one other IACUC member.  The subcommittee will communicate with the principal investigator and/or other responsible parties and the individual(s) making the allegation and gather information relevant to the issue.

The subcommittee can either meet in person, or via email discussion. After initial review of the complaint, the subcommittee will determine whether it requires further investigation and any subsequent actions deemed necessary. Once this decision has been made, the subcommittee will determine the individuals and offices being notified.

If immediate action appears warranted due to immediate harm to animal or human welfare, the IACUC will notify the IO and proceed accordingly. Veterinary medical intervention, suspension of a research activity, and/or notification of appropriate safety, occupational health, or other officials, are examples of actions that may be taken immediately to protect animal or human welfare. In accordance with the AWRs, if an activity is suspended, the IO shall report that action to APHIS and any agencies (federal, state, and/or private) that are funding that activity. If the PHS supports the activity in any way, the IACUC, through the IO, must promptly notify OLAW.

The subcommittee is authorized to require and institute immediate changes necessary to prevent further unnecessary activities that are harmful (actual and perceived) to animals, to protect animal welfare, and to preserve FHSUs regulatory compliance.  These actions may include ordering a temporary cessation of activities involving the animals at risk, while maintaining normal appropriate husbandry.  The subcommittee is not authorized to suspend the protocol.

If the investigator does not respond in a timely manner or refuses to address the subcommittee’s concerns, the subcommittee will inform the responsible party’s immediate superiors of the problem and may request their assistance in resolving the matter.

The subcommittee will report their findings together with their recommendations at a convened meeting of the full IACUC.  The IACUC will determine whether or not the allegation has merit.  It may also ask the subcommittee to continue its investigation and gather further information and report back to the full committee before final disposition.

Should the IACUC determine that further investigation is required, the subcommittee will conduct the investigation and report back to the IACUC without prejudice.

The IACUC should charge the designated person or group with its requirements for information gathering and impose a completion date. The assigned completion date will depend on the IACUC’s determination of whether immediate remedial action may be required. The nature of the information required will vary depending on the circumstances, but often involves:

* Interviewing complainants (if known), any persons against whom allegations were directed, and pertinent program officials;
* Observing the animals and their environment; and
* Reviewing any pertinent records, (e.g., animal health records, protocol, and other documents).

The subcommittee should provide a report to the IACUC, which summarizes:

* The concern(s),
* The results of interview(s),
* The condition of animals and their environment, and
* The results of records and other document reviews.

The report should also contain:

* Any supporting documentation such as correspondence, reports, and animal records,
* Conclusions regarding the substance of the concerns vis-à-vis requirements of the AWRs, the PHS Policy, the Guide, and institutional policies and procedures, and
* Recommended actions, if appropriate

Upon receipt and evaluation of the report, the IACUC may request further information or find that:

* There was no evidence to support the concern or complaint,
* The concern or complaint was not sustained, but
  + related aspects of the animal care and use program requires further review or
  + other institutional programs may require review, or
* The concern or complaint was valid.

If the IACUC determines that an allegation is without merit and cannot be substantiated, the responsible party and any FHSU officials who have been informed of the allegation will be so notified in writing.

If the full IACUC determines that the allegation has merit and has been substantiated, the IACUC will require the responsible party to rectify the situation and the matter may be referred to the appropriate FHSU officials for further action.

The IACUC may take actions that are deemed necessary.  These may include but are not limited to:

* In cases in which the protocol deviation is justifiable, requirement for the submission of a protocol amendment or new protocol depending on the nature or extent of the change,
* Written reminders of IACUC procedures and policies,
* Require completion of specific training aimed at preventing future incidents.
* Notify direct superiors and other FHSU officials,
* Monitor an investigator's research activities involving animal subjects,
* Suspend or terminate such activities,
* Report to the USDA or funding agency,
* Refer the matter to the FHSU Research Misconduct Committee.

Subsequent actions of the IACUC may include:

* Implementing measures to prevent recurrence;
* Notifying the IO and the AV of its actions;
* Notifying funding or regulatory agencies, as required; and/or
* Notifying the complainant, any persons against whom allegations were directed, and pertinent program officials (appropriate supervisory and management staff, the public affairs office, institutional attorneys, etc.).

### Institutional Sanctions

Examples of institutional sanctions include sanctions include:

* Counseling;
* Issue letters of reprimand;
* Monitoring by the IACUC or IACUC-appointed individuals of research, testing, or training that involving animals;
* Temporary revocation of privileges to provide animal care or to conduct research, testing, or training that involves animals, pending compliance with specific, IACUC-mandated conditions;
* Permanent revocation of privileges to provide animal care or to conduct research, testing, or training that involves animals; and
* Recommend to the IO that institutional (e.g., reassignment, termination of employment) sanctions be imposed.

### Suspension of Animal Activities

The IACUC is empowered to suspend a project if the activity is in violations of University policy, PHS Policy, the Guide, Assurance, or Animal Welfare Regulations. Suspension may occur only after review of the matter at a convened meeting of a quorum of the IACUC, and a vote for suspension by a majority of the quorum present. Further, the IACUC must consult with the Institutional Official regarding the reasons for the suspension. The Institutional Official is required to take appropriate corrective action, and report the action and the circumstances surrounding the suspension to OLAW. Because an IACUC action to suspend a project is a serious matter, the action must be reported to OLAW promptly.

If the violation is verified by the IACUC, the IACUC is empowered under [USDA Regulations](http://www.nal.usda.gov/awic/legislat/usdaleg1.htm) and [PHS Policy](http://grants.nih.gov/grants/olaw/references/phspol.htm) to suspend a previously approved project.  If the activity is supported by PHS funds, the IACUC, through the Institutional Official, must file a full report to the National Institutes of Health, [Office of Laboratory Animal Welfare (OLAW)](http://grants.nih.gov/grants/olaw/olaw.htm).  In cases where there is sufficient evidence of serious noncompliance, it may be prudent for the IACUC to suspend an activity pending the outcome of a full investigation.  In these cases, a preliminary report will be sent to OLAW and the USDA, through the Institutional Official, on the understanding that a full report will be submitted upon completion.

The Institutional Official, in consultation with the IACUC, has the power to impose further sanctions on an investigator found to be responsible for mistreatment or noncompliance.  Each case must be considered individually and all cases will result in precedents being set, and the implications of these should be considered.  The institution must also consider whether to announce its findings publicly.

## Reporting Requirements

Failure by research personnel to follow Federal and/or University regulations, guidelines, policies and/or procedures may require reporting to the appropriate institutional, local, state and/or Federal agencies.  Violations may include, but not limited to

* Serious or continuing non-compliance with the [PHS Policy](http://grants.nih.gov/grants/olaw/references/phspol.htm);
* Serious deviations from the [*Guide for the Care and Use of Laboratory Animals*](http://www.nap.edu/readingroom/books/labrats/); and
* IACUC suspensions.

If the responsible party wishes formally to contest this finding, he will be referred to the Institutional Official, who has been delegated the obligation of enforcing FHSU’s regulations pertaining to the use of animal subjects in research.

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