

IACUC Guideline 03-01: IACUC Holding Protocol

Purpose: The purpose of this guideline is to provide information on when and how an IACUC Holding Protocol is utilized at UW, as well as describe the typical conditions of the protocol.

Roles & Applicability.

UW has implemented a means to establish 'just-in-time' protocols in an effort to ensure that all animals used for research and/or teaching are on an approved protocol at all times. It does not replace a timely renewal of a protocol, nor does it absolve the original Principal Investigator (PI) of their responsibilities to ensure their animals' wellbeing. When a Holding Protocol is created, the UW Attending Veterinarian will be named the PI of the Holding Protocol, with the original protocol's PI assigned all responsibilities related to ***maintaining*** the animals' care. If a Holding Protocol is created in response to a suspended or expired protocol, and/or if the original PI violates conditions of the Holding Protocol, the IACUC may take corrective actions to remedy any non-compliance that has occurred. The IACUC is not compelled to utilize a Holding Protocol for any reason, and it is the original PI's responsibility to ensure that their protocols are approved and/or renewed in a timely manner without lapse.

Background.

Federal regulations require that all animals involved in research, testing, teaching, or for related purposes must be on a reviewed and approved IACUC protocol at all times. Current UW policies require annual updates on all IACUC protocols and a complete *de novo* review at least every three years. When an IACUC approval expires, the research protocol is no longer valid, and continuation of research activities is a violation of the UW IACUC Policy, the Animal Welfare Regulations, and the PHS Policy on Humane Care and Use of Laboratory Animals. Additionally, lapses in IACUC approval may violate terms and conditions of grant funding agencies and may result in mandatory reporting and/or losses of funding. Other examples of animals associated with inactive protocols may include the arrival of new faculty members with research animals, faculty departing UW without proper removal of animals, or situations that arise during research non-compliance that must halt experimentation. To avoid euthanasia of valuable research animals, and to remain in compliance with University and federal regulatory requirements, the UW IACUC has been empowered with the use of Holding Protocols when the Committee deems it appropriate to do so.

Procedures.

1. Whenever a scenario arises in which research animals at UW may be without an approved and/or compliant IACUC proposal, the IACUC Chair and Attending Vet (AV) will be immediately notified.
2. The original PI must complete and return copies of the UW Animal Transfer Form as well as an IACUC Holding Protocol Form for each protocol ***with at least*** 10 business days prior to the protocol lapse.
3. These forms will be shared with the entire IACUC and the Chair will designate at least two Committee members to serve as designated reviewers. Any IACUC member may call for a full board review of the protocols but must do so within 48 hours of the forms being sent out. If a full board review is called for an emergency meeting may be called to discuss the protocols and situation. Otherwise the forms will be assessed via Designated Member Review.
4. Approved Holding Protocol and Animal Transfer Forms will transfer ownership and authority of the animals to the AV, **though day-to-day animal care costs and responsibilities will still be the sole responsibility of the original PI.**

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Approved by:



Dr. R. Scott Seville, IACUC Chair, University of Wyoming



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5. Once animals are transferred to the Holding Protocol, the **original PI will no longer be allowed to perform ANY experimental procedures or non-critical husbandry**. This includes data collection, sample collection, surgery, administering test substances, new breeding pairings, or any other procedures that have been previously approved.
6. The IACUC Chairperson has the authority to amend the Holding Protocol to include procedures necessary to maintain valuable animals or breeding stock (e.g. transgenic, knockout, or mutant mice) as well as procedures required to minimize pain and/or suffering in animals (e.g. removing or collecting tumors, sacrificing unthrifty animals, etc.). In these instances the original PI must provide scientific justification, and a detailed plan of what will be done and by whom.
7. After a resolution has been reached, the animals will be transferred to the original PI and the Holding Protocol will be closed.
8. If a resolution has not been reached after 60 days on the Holding Protocol, the animals will be euthanized by an American Veterinary Medical Association (AVMA)-approved method, or, when appropriate, offered by the IACUC for transfer to appropriate, approved animal protocols maintained by other investigators. The Institutional Official will be notified, as well as any reporting agencies (when appropriate). The IACUC Chair may grant an extension to the Holding Protocol when appropriate.

References.

Code of Federal Regulations, Title 9, Chapter 1, Part 2, Subpart C, §2.31(c)(6)(7).

Public Health Service. *Policy on Humane Care and Use of Laboratory Animals* (US Department of Health and Human Services, Washington, DC, 1986, amended 2002). <<https://olaw.nih.gov/policies-laws/phs-policy.htm>>

Office of Laboratory Animal Welfare. Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals. Notice NOT-OD-05-034. (National Institutes of Health, Washington, DC, 24 February 2005, updated 15 April 2010).

Office of Laboratory Animal Welfare. Guidance Addressing the NIH Policy on Allowable Costs for Grant Activities Involving Animals when Terms and Conditions are not Upheld. Notice NOT-OD-07-044. (National Institutes of Health, Washington, DC, 26 January 2007)

History of Revisions.

03-01 – new guideline approved 07/01/2020

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