UH Office of Research Compliance

Policy for Animal Use and Biological Materials Activities with Collaborating Organizations

(Previously IACUC Policy 45.1)

I. Policy Statement

The purpose of this policy (previously IACUC Policy 45.1) is to ensure IACUC/IBC coverage of collaborative projects in which the University of Hawaii is engaged in research, teaching, manufacturing, or testing with live vertebrate animals and/or biological materials. This policy applies to all UH faculty and personnel engaged in collaborative projects with at least one or more collaborating organizations.
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1. UH is engaged in a collaborative project when UH faculty, personnel, space facilities, equipment or funds are involved in the design or conduct of the activity. Collaborative projects that involve teaching, testing, manufacturing, or research with live vertebrate animals and/or biological materials must meet all applicable regulations and University policies regarding the humane care and use of animals and/or use of biological materials These projects are subject to the review and approval of the UH IACUC/IBC.

2. For the purpose of Policy, a *Collaborating Organization* is defined as a non-UH entity where teaching, testing, manufacturing, or research with live vertebrate animals and/or biological materials is conducted using UH resources such as faculty or staff, space, facilities, equipment or funds.

3. In the majority of cases, the UH IACUC/IBC may elect to not conduct a duplicate review of the work. Should this be the situation, the UH IACUC/IBC will rely upon the collaborating Organization's IACUC/IBC to provide oversight for the care and use of animals and/or use of biological materials. Procedures for this review are outlined in the UH Office of Research Compliance Policy *Guidance*, part 1.3 and 1.4 *Requirements for Review of Protocols*. Alternatively, the collaborating organization may request that the UH IACUC/IBC serve as the IACUC/IBC of record for both organizations.

4. In cases where no local IACUC/IBC exists or if the UH IACUC/IBC has concerns of appropriate oversight, the UH IACUC/IBC will decide whether it will assume responsibility for providing oversight for the work.

5. During the course of the project, if the UH IACUC/IBC has significant concerns about the welfare or treatment of animals and/or safety at the *Collaborating*

Organization, if there is evidence which jeopardizes UH status such as the loss of accreditation, citations by regulatory agencies or other such significant events, UH may require additional details from the *Collaborating Organization*, or revoke its approval of the *Authorization Ceding Agreement*.

II. Guidance and Procedures

1. Guidance

Conditions to which this Policy is applied:

1.1 When animal use and/or biological materials activities are being conducted with live vertebrate animals at any UH campus, community college, farm, or at field or client site locations by a UH representative (faculty or staff), a complete IACUC and/or IBC protocol must be submitted, reviewed, and approved by either the UH IACUC/IBC or collaborating Organization's IACUC/IBC before initiation of research protocol activities.

1.2 When animal use activities that involve live vertebrate animals and/or biological materials activities are being conducted externally by collaboration through a sub-award or sub-contract, and the UH is the awardee Organization, the terms and conditions of the grant flow through to the sub-awardee. The UH is responsible for ensuring that the animal use and/or biological materials activity is being conducted is compliant with applicable regulations and guidelines pertinent to the type of proposed activity. Such activities are subject to the review and approval by the UH IACUC/IBC. The extent of the IACUC's review is determined by the accreditation and the Assurance status of the collaborating Organization.

1.3 Requirements for Review of IACUC Protocols:

1.3.1. When the sub-awardee maintains an Assurance with the *Office of Laboratory Animal Welfare* (OLAW), which covers the use of vertebrate animals proposed in the animal use activity, is *Association for Assessment and Accreditation for Laboratory Animal Care International* (AAALAC) accredited, and/or in some cases *American Veterinary Medical Association* (AVMA) accredited, and the activity has been approved by the IACUC at the sub-awardee Organization, the UH IACUC may decide to not perform a duplicate review of an animal use protocol, but instead elects to enter into an Administrative Ceding Authorization agreement with the sub-awardee Organization.

1.3.2. When the sub-awardee Organization maintains an Assurance with OLAW, but is not AAALAC and/or AVMA accredited, the UH IACUC will determine

whether the committee will perform a full protocol review or may defer to the other Organization IACUC to oversee the animal care and use on protocol.

1.3.3 When the sub-awardee Organization does not maintain an Assurance with OLAW, the UH IACUC will decide whether or not research at such an Organization will be permitted, and if allowed, must define the terms and conditions for which the research is performed.

1.4 Requirements for Review of IBC Protocols:

1.4.1 When the sub-awardee maintains an IBC Registration with the *NIH Office of Science Policy* (OSP), which covers the use of biological materials proposed in the activity, and the activity has been approved by the IBC at the sub-awardee Organization, the UH IBC may decide to not perform a duplicate review of a biological materials use protocol, but instead elects to enter into an Administrative Ceding Authorization agreement with the sub-awardee Organization.

1.4.2 When the sub-awardee Organization does not maintain an IBC Registration with the NIH OSP, the UH IBC will decide whether or not research at such an Organization will be permitted, and if allowed, must define the terms and conditions for which the research is performed.

1.5 Requirements for Facility Inspections

1.5.1 In situations where the UH IACUC and/or IBC decide to assume responsibility for providing oversight for the work, regular, semi-annual/annual facility inspections will be performed by the committee(s). On a case-by-case basis, the IBC may accept a memo from the collaborator's Organizational Official indicating the facilities meet the minimum biosafety level requirements according to the activity and have been inspected by an alternative IBC who is registered with NIH.

1.5.2 In the event that the Collaborating Organization's space where animal use and/or biological materials activity will occur is a secured area and committee members may not be able to enter, the IACUC/IBC may require a virtual inspection format in lieu of an in-person inspection.

1.5.3 If deficiencies are identified during a regular inspection by the UH IACUC/IBC, it is the responsibility of the UH Principal Investigator (PI) to

work with the Collaborating Organization to correct the deficiencies. Deficiencies that are not corrected result in a “Does Not Meet” inspection status and the work will not be approved to start.

1.5.4 A fee schedule is not applied for inspections conducted by the UH IACUC/IBC at a Collaborating Organization that uses UH resources such as faculty or staff, space, facilities, equipment or funds.

2. Administrative Procedures

2.1 UH PI on the protocol submits a completed UH IACUC and/or IBC protocol, or the PI provides a copy of the fully-approved IACUC/ and/or IBC protocol from the collaborating Organization, with the animal use and/or biological materials activity as described in the grants/proposal (if applicable). In addition, the PI provides:

- Provide documentation of the collaborating Organization’s Animal Welfare Assurance (AWA) status and AAALAC and/or AVMA Accreditation information and dates of approval (if applicable).

- Provide documentation of the collaborating Organization’s NIH Office of Science Policy registration status (if applicable).

- Provide a copy of the approval letter that recognizes the UH PI as a collaborating partner and the role of the UH PI in the scope of the animal use and/or biological materials activity.

2.2 Protocol is reviewed by the UH IACUC and/or IBC Administrator(s) and Director of the Office of Research Compliance (ORC), Office of the Vice President for Research and Innovation.

2.3 UH IACUC and/or IBC Administrator(s) contacts the UH PI and collaborating Organization to initiate the authorization agreement.

2.4 Once the Authorization Ceding Agreement is signed by all parties, the protocol may be administratively approved. The Authorization Ceding Agreement is part of the electronic record of the protocol.

2.5 If the UH IACUC and/or IBC relies on an approved protocol from the collaborating Organization, an abbreviated protocol record is entered into the UH protocol management system (Topaz) by the protocol Administrator in order to enable information tracking and verification of personnel training. The record shall contain the PI name, protocol title, start/end date, protocol associates and training, attachment of the Ceding

agreement, and attachment of collaborating Organization's approved protocol.

2.6 Status of the protocol is reported to the UH IACUC and/or IBC at a convened meeting of the committee.

2.7 Reports (if any) from the collaborating Organization related to the protocol are shared with the UH IACUC and/or IBC.

2.8 Agreements and their status are reported to the Organizational Official.

2.9 UH PI is solely responsible for submitting or providing copies of approved annual reviews and three-year renewals to the UH IACUC and/or three-year renewals to the UH IBC.

2.10 Failure to comply with this policy will effectively void and terminate the Authorization Ceding Agreement between UH and collaborating Organization.

3. Reference: Federal regulations, Refer to http://grants.nih.gov/grants/notice-files/NOT-OD-01-017.html Subject - “Duplicative Review”

4. Refer to **Authorization Ceding Agreement Form**

5. UH Office of Research Compliance Policy (previously 45.1)
IACUC approved 11/18/2021, IBC approved 11/24/2021