Regulatory background:

*PHS Policy* mandates that the Institutional Animal Care and Use Committee must “conduct a review of those components related to the care and use of animals and determine that the proposed research projects are in accordance with this Policy. In making this determination, the IACUC shall confirm that the research project will be conducted in accordance with the *Animal Welfare Act* insofar as it applies to the research project, and that the research project is consistent with the *Guide* unless acceptable justification for a departure is presented.”

The Office for Laboratory Animal Welfare (OLAW) states: “When the grantee is a domestic institution (i.e., domestic grant with a foreign component), PHS animal welfare requirements are applicable. Accordingly, the grantee remains responsible for animal activity conducted at a foreign site and must provide verification of IACUC approval. That approval certifies that the activity, as conducted at the foreign performance site, is acceptable to the grantee. The grantee IACUC may accept, as its own, the approval of a foreign entity's IACUC; however, the grantee IACUC remains responsible for the review. Additionally, the foreign entity must complete the Animal Welfare Assurance for Foreign Institutions available from OLAW.”

Implementation at USA:

**Domestic subcontracts**

The following† must be submitted to the USA IACUC office, by the USA PI, for administrative review by the Chair or Vice-Chair of the IACUC:

1. A memo containing the following information:
   a. The title of the project,
   b. A brief description of the project,
   c. The name of the institution where the work will be completed,
   d. The name of the investigator who will complete the work,
   e. The PHS Assurance number of the institution,
   f. The AAALAC Accreditation number (if applicable), and
   g. A brief statement explaining why the work must be completed outside the grantee institution;

2. A copy of the approval letter from the site’s IACUC; and

3. Certification of completion by the USA investigator of the CITI training module *Information Specific to Subcontracts Involving Animal Use.*

†The IACUC reserves the right to request additional supporting documentation.

**Foreign subcontracts**

Along with the above requested information*, the following additional documentation must be submitted to the USA IACUC office for full IACUC committee review:

4. A copy of the protocol as submitted to the IACUC (or equivalent review board);
5. A letter from the foreign site’s veterinarian certifying veterinary oversight; and
6. A description of the training the foreign investigator has completed.

*The Foreign Assurance number should be substituted for the PHS Assurance number. In cases where there is no IACUC, the approval letters from the equivalent licensing or review board must be submitted.

Once the above information has been submitted to the IACUC Office, the IACUC Compliance Specialist will add the item to the agenda for the next IACUC meeting. The IACUC will review and verify the submitted documents (administratively for domestic subcontracts and by full committee for foreign subcontracts). Post-review, the IACUC will provide the USA PI with a letter certifying review and acceptance of the subcontracted animal work. Record of review will be included in the IACUC meeting minutes and filed in the IACUC office.

All subcontracted animal work will be monitored semi-annually during the semi-annual program review using the *Guide* and the *Animal Welfare Act* as the basis for evaluation.

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