

IACUC14 TITLE: IACUC Review of Animal Work at Sites Outside the U.S.

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1. Purpose

This policy describes when offsite animal use at sites outside the United States needs IACUC review and how that review is conducted. Please see [policy IACUC12](#) for information about how offsite animal use at sites within the U.S. is handled.

At minimum, some IACUC oversight of animal use at sites outside the U.S. is required when DFCI funds and/or DFCI-owned animals are used. This is to ensure applicable regulatory requirements for the humane care and use of animals are met, both by the performance site and by DFCI.

2. Definitions

- Animal use: All experimental and breeding projects or services where a live, vertebrate animal is manipulated at the request of a DFCI investigator and/or specifically for a DFCI investigator's study. Purchasing an off-the-shelf antibody from a vendor is not animal use because animals are not manipulated on request; however, ordering a custom antibody from a vendor is animal use because live animals are manipulated on request to produce the antibody.
- Performance site: The site at which offsite animal use will occur.
- Memorandum of understanding (MOU): An agreement between two sites defining each site's responsibilities regarding animal use for collaborative research.

3. Policy

When animal use will be done at a performance site outside the U.S. **and** will involve DFCI funds **and/or** DFCI-owned animals, researchers will submit the following to the IACUC (dfci_iacuc@dfci.harvard.edu):

- A completed [Review Form for Animal Use Outside the U.S.](#)
- The most recent internal facility inspection results (or equivalent) for the performance site
- A letter from the performance site stating the laws, regulations, and policies of the jurisdiction in which the research will be conducted

These documents should be submitted well in advance of the planned animal use start date to allow sufficient time for IACUC review. If the performance site has questions about any of the above, please contact the IACUC.

The IACUC Office will then vet the performance site to confirm it meets all applicable regulatory criteria:

- If animal use involves federal funding (e.g., NIH, NSF, NASA), the performance site must have an active Foreign PHS Assurance.
- If animal use involves DFCI-owned animals, the performance site must have AAALAC accreditation.

If the performance site does not meet applicable regulatory criteria **and/or** the proposed animal use would be prohibited in the U.S., the IACUC Office will consult with the IACUC and discuss alternative sites with the researcher. Animal use cannot proceed if the performance site does not meet applicable criteria.

The IACUC will then review the planned animal use. Animal use should not begin until IACUC review is complete.

- **If animal use will be paid for with federal funding (e.g., NIH, NSF, NASA)**, the IACUC must review the animal protocol from the performance site before animal work begins. Animal protocols from sites outside the U.S. are handled by Designated Member Review (DMR) – please see [policy IACUC04](#) for details. The DFCI researcher responsible for the project must provide a copy of the animal protocol from the performance site that has been, if necessary, translated into English.

If the IACUC determines that the animal protocol from the performance site is acceptable, the committee can either issue its own approval for the protocol or accept the approval of the performance site's IACUC-equivalent ethics committee before animal work can begin.

Following IACUC approval of the animal protocol from the performance site, amendments to that protocol that affect DFCI-supported animal use must also be reviewed and approved by the IACUC before the changes in those amendments take effect. Amendments will be handled as described in [policy IACUC05](#).

- **If animal use will involve USDA-covered species**, the IACUC will review the Foreign Site Animal Protocol Review Form by Designated Member Review (DMR) in the same manner as animal protocols from sites outside the U.S. when federal funding is used.
- **In all other cases**, a subcommittee comprised of the Attending Veterinarian, IACUC Chair, and Associate Director for IACUC and Compliance will administratively review the Foreign Site Animal Protocol Review Form. Subcommittee members may escalate review to DMR or FCR.

During the review process, the committee may ask for additional information or documentation.

If the request to conduct animal use at a site outside the U.S. is approved by the IACUC **and** involves a research project, the IACUC Office will execute an MOU with the IACUC-equivalent ethics committee at the performance site. When the MOU is executed, animal use can proceed. An MOU is not executed for fee-for-service animal use.

4. References

1. National Research Council. Guide for the Care and Use of Laboratory Animals. Eighth edition, 2011, pg. 15.
2. Frequently Asked Questions. Office of Laboratory Animal Welfare, FAQ D.13, <https://olaw.nih.gov/faqs#/guidance/faqs?anchor=50328>, last accessed 4/19/2023.

3. Frequently Asked Questions, AAALAC International, FAQ B.1, <https://www.aaalac.org/accreditation-program/faqs/#A1>, last accessed 4/19/2023.