

IACUC12 TITLE: Offsite Animal Use & Memoranda of Understanding (MOUs)

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- 1.0 Purpose**
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1.0 Purpose:

To establish when an MOU is executed for offsite animal use and to delineate the process for executing an MOU. MOUs are executed to meet requirements in the Guide for the Care and Use of Laboratory Animals and in guidance from the Office of Laboratory Animal Welfare.

2.0 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.
- Memorandum of understanding (MOU): An agreement between two sites defining each site's responsibilities regarding animal use for collaborative research.
- Performance site: The site at which offsite animal use will occur.
- Vendor: A site offering off-the-shelf and/or custom materials and/or services for animal research.
- Well-defined service: A service performed by a vendor on a fee-for-service basis where the vendor has expertise, the outcome is predictable, and adverse events are unlikely to occur. Examples include (but are not limited to) strain rederivation and cryopreservation.

3.0 Policy:

An MOU is executed before offsite animal use begins in cases where DFCI funds (e.g., DFCI-awarded grants, subawards on DFCI-awarded grants, internal funds, gift funds) and/or animals legally owned by DFCI will be used in animal work for collaborative research. The requirement to execute an MOU does not apply when offsite animal use will occur at a vendor providing a well-defined service.

Regardless, DFCI researchers should notify the IACUC Office in advance of all planned offsite animal use. The IACUC may have a regulatory obligation to establish oversight of offsite animal use and may need to execute other regulatory responsibilities, such as grant-to-protocol congruency review for NIH and NSF grants.

4.0 Procedure:

1. Researchers notify the IACUC Office of planned offsite animal use by submitting an MOU Request Form.
2. The IACUC Office reviews each MOU Request Form for completeness. Review typically takes 2-3 business days. The IACUC Office may then require the DFCI researcher to clarify the request or to provide more information. For example:
 - Justification is required if the performance site is not AAALAC-accredited, even if DFCI does not own the animals used at the performance site.
 - A copy of the animal protocol at the performance site is required if DFCI-awarded grants fund from sponsors where congruency review must be performed (e.g., NIH/NSF).
3. The IACUC Office determines if a new MOU is needed, including whether a site-wide or project-specific MOU is appropriate, or if a previously executed MOU covers the new project. Step 3 is often completed concurrent to step 2, but may take a further 1-2 business days in cases where more information is required.
4. If the MOU Request Form involves one or more of the following, the Attending Veterinarian or IACUC Chair will review the form and decide whether the IACUC Office may continue processing the form, whether more information is required, or whether the form must be reviewed by the IACUC by one of the methods described in policy ACUC04.
 - Category E animal work
 - USDA-covered species except rabbits
 - A performance site that does not have applicable regulatory coverage (e.g., performance site is not accredited with AAALAC but DFCI legally owns the animals used at the site)

Step 4 typically takes 2-5 business days. If the form is submitted for IACUC review, the process will be extended depending on review method (4-6 business days minimum and potentially several weeks or more).

5. If a new MOU needs to be executed, the IACUC Office will work with the performance site to draft one. New MOUs may be executed by Associate Director of IACUC and Compliance, Senior Director of the ARF, or the Institutional Official.

Step 5 may take anywhere from 1-2 business days to several weeks (or longer).

6. The IACUC Office will inform the DFCI researcher within 1-2 business days once the MOU review process is complete, all other reviews (such as grant congruency review) are complete, and the project may begin.

5.0 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.8, <https://grants.nih.gov/grants/olaw/faqs.htm#621>, last updated 7/12/2017, accessed 11/21/2017.