Offsite Animal Use

This page covers guidance on offsite animal use. Researchers are encouraged to contact the <u>IACUC Office</u> with questions on this topic.

For an overview of the process for approving offsite animal use, please see the flow chart at the bottom of this document.

When do I need to submit a form for offsite animal use?

You must submit paperwork when offsite animal use involves **DFCI funds** and/or **DFCI-owned animals**. ("DFCI funds" includes, but is not limited to, DFCI-awarded grants, sub-awards of DFCI awards, internal funds, and gifts.) This extends to...

- All custom animal use at U.S. (domestic) animal facilities outside DFCI, such as
 custom generation of a monoclonal or polyclonal antibody. If the animal use will occur at
 your request, it is considered a custom project and paperwork must be submitted to and
 approved by the IACUC before work begins.
- All animal use at sites outside the United States. Please contact the <u>IACUC Office</u> for assistance with such projects.

What form do I need to submit?

For animal work at U.S. animal facilities, you must submit a Memorandum of Understanding (MOU) Request Form. Please email the completed form to the IACUC Office.

Please be advised that antibody generation in rabbits must be performed at sites that have both a USDA Registration and an Animal Welfare Assurance. (The IACUC will consider exemptions to this policy on a case-by-case basis.) Also, the IACUC recommends that investigators conduct antibody generation in rabbits at sites that are accredited with the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC).

Note that the Memorandum of Understanding replaces prior forms for off-site animal use, including the Inter-institutional Agreement and Off-Site Animal Project form.

For animal work at sites outside the U.S., you must submit a Review Form for Animal Use Outside the U.S.

How far in advance do I need to submit the form?

You are strongly encouraged to submit forms at least **1 month** before animal work is scheduled to start at the offsite facility.

For animal work at U.S. animal facilities, the timeline for approving DFCI-supported off-site animal work varies greatly depending on how quickly the parties involved respond, what DFCI funding sources will be used, and what type of animal work will be performed. If DFCI's IACUC has worked with the offsite facility before, the process may take as little as a few days or a couple weeks. In other cases, it may take 1 month or more to complete a Memorandum of Understanding (MOU).

Please see the flow chart below for an overview of the MOU process.

For animal work at sites outside the U.S., the timeline can also vary greatly depending for the same reasons outlined above. However, please be aware that there are cases where federal regulations would require DFCI's IACUC to review the animal protocol from the animal facility (i.e., if NIH funds will pay for animal work). This can increase the review timeframe significantly.

Why is a form required for offsite animal use?

When offsite animal use involves DFCI funds or DFCI-owned animals, federal regulations and other regulatory references (ex: *The Guide for the Care and Use of Laboratory Animals*) require the IACUC to create a document delineating DFCI's role and the offsite facility's role in the project. Also, the IACUC needs to confirm that the offsite facility has all applicable regulatory documentation, which varies depending on the project details (e.g., species used, funding used, animal ownership).

Failure to establish such a document and/or verify that the off-site animal facility has all applicable regulatory documentation can result in serious noncompliance and, especially when federal funding is involved, may be reportable to various regulatory agencies, including the USDA and OLAW (the animal regulatory arm of PHS/NIH). Use of federal funding to pay for animal work at an offsite facility without IACUC approval may necessitate return of some or all funds used.

Flow Chart for Offsite Animal Use

Only applies to animal facilities within the U.S. Contact the IACUC Office (dfci_iacuc@dfci.harvard.edu)
for information on working with an animal facility outside the U.S.

