

MCO Requirements For Activities Involving Animal Subjects / Materials

This memorandum restates established institutional policies regarding the requirement that all use of live animal subjects for research and/or training must receive prior review and approval by the Medical College of Ohio Institutional Animal Care and Use Committee (IACUC), as described below, before any project can begin. These policies reflect the regulations and requirements found in MCO's Federal Animal Assurance filed with and approved by the NIH Office for the Protection from Research Risks (OPRR) and our responsibilities to abide by USDA Animal Welfare Act (9 CFR Ch. I) and requirements of the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International). A copy of the OPRR Assurance is available on reserve in the Mulford Library. It may also be obtained from MCO Research & Grants Administration or via the Internet from the "Research Regulatory Assurance" section of the MCO Research Office Web site at the URL noted in the header of this document.

Requirement That All Research or Training Involving Live Animals Be Reviewed and Approved by the IACUC:

All MCO-related use of live vertebrate animal subjects must be reviewed by the MCO IACUC prior to initiation. In addition, all projects involving invertebrate species housed in the Department of Laboratory Animal Medicine must be reviewed and approved by the MCO IACUC. Projects not supported by external funding must be reviewed by the same procedures as grant-supported projects.

"MCO-related use" means research or training carried out on or off campus (including in other states or countries) by MCO faculty, students, or employees, and all studies using MCO facilities.

1. This requirement will, at times, entail review of projects by the IACUC of two or more institutions, for example, when an MCO faculty member is involved in studies using animals at another institution while on sabbatical leave. This also applies when MCO people go to other labs to train other people in techniques and/or procedures utilizing live animals.
2. It is the responsibility of faculty advisors to ensure that research done by students, as part of their MCO degree program or whenever any student is involved in a research project, also has prior approval from the MCO IACUC and all other appropriate IACUCs.
3. Arrangements to reduce unnecessary duplication of paper work may be made, when appropriate, with the approval of the MCO IACUC chairperson.

Requirement That All Changes In Personnel and/or Procedures Receive Prior Review and Approval by the IACUC:

Animal Welfare Regulations and PHS policy require that any addition of personnel and/or changes in species, procedures, and substances to be used must receive IACUC approval prior to initiating the addition or change.

1. Prior approval ensures that all personnel handling animals have been or will be properly trained and that significant changes in ongoing research meet the same requirements as the originally proposed and approved activities.
2. Examples of changes in "substances to be used" would include addition of a new drug, adjuvant, or use of a different antigen or method of euthanasia. To be sure of providing all needed information about the change, refer to the relevant question(s) on the original protocol application form. For example, to add personnel,

refer to the personnel question on the application form. That question requests name, position, specific procedures to be performed by that person, and experience and training with each specific procedure in the species used for the study; therefore provide the same information in the amendment memo.

3. If a requested change to an IACUC protocol requires review/approval by one of the other regulatory committees, ABC (biological and chemical hazards) and/or IBC (recombinant DNA), such review/approval must be finalized and reported to the IACUC before the IACUC will grant approval of the requested change to the IACUC protocol.

Procurement of Custom Antibodies

The Office for Protection from Research Risks (OPRR) has issued guidelines for procuring “**custom**” antibodies. “**Custom**” antibodies are those produced by an outside organization, specifically for an investigator from antigens provided by that investigator. The organization producing the antibodies must either have on file with OPRR an approved Animal Welfare Assurance or be included as a component of the “procuring” organization’s Assurance. In addition, if species covered by the Animal Welfare Act are utilized, the producer must be registered as a “Research Facility” with the U.S. Department of Agriculture (USDA). The guidelines are as follows:

“When procuring custom antibody production services from non-institutional sources:

- a) Contact the proposed producer to determine its Assured status, and if Assured, obtain the Assurance number. Alternatively, consult with OPRR for information on the Assured status of the preferred antibody producer. If the producer is Assured, the procurement action may proceed without additional actions.
- b) If the producer is not Assured, at least two options are available:
 - i) Antibodies may be procured from other producers that are assured; or
 - ii) The producer or the applicant organization may request that OPRR negotiate an Assurance with the producer’s organization. Upon successful completion of negotiations with the proposed producer and approval of an assurance, which usually can be accomplished expeditiously, antibodies may be procured in accord with a) above.”

If your research involves use of standard, commercially available antibodies , i.e., ordered out of a catalog (“off the shelf”) as opposed to an order for “custom” antibodies as discussed above, please state that on your purchase requisitions to avoid any possible delay in the processing of your order.

Requirements for Submitting a Protocol Application for IACUC Review and Approval

1. Protocols requiring IACUC review and approval should be submitted on the most current MCO protocol form (11/97) **by the first working day of each month** for consideration at the monthly meeting of the IACUC on the 2nd Wednesday of each month. An original protocol and **19** copies should be submitted by 5:00 PM to Research and Grants Administration, Room 148, Block Health Science Building, Attention IACUC.

2. The responsible party (i.e., principal investigator) on an MCO IACUC protocol must be a salaried MCO faculty member or other salaried MCO contract personnel.

Note: Animal tissues obtained from slaughterhouses or excess tissues obtained from animals which were killed for some purpose other than to provide tissues for the project on which you are working do not require MCO IACUC approval. For example, if a colleague sacrifices an animal to obtain the heart for use in a study for which he has MCO IACUC approval and you get the liver from that animal for use in your study, you do not need IACUC approval for your study. On the other hand, should you use or sacrifice an animal to obtain any fluid, tissue, or organ for your study, you must have an approved IACUC protocol.

For information on any of the above issues, contact William E. Jacobus, Ph.D., MCO IACUC Chair, at extension 4118, Andrew Beavis, Ph.D., Vice Chair, at extension 4125, or Kathi Hinrichs, Research and Grants Administration, at extension 4252. In addition, general information regarding MCO policies and federal regulations governing the use of animal subjects may be obtained from the “Research Regulatory Assurance” section of the MCO Research Office Web site at the URL noted in the header of this document.