

BULLETIN

› NIH Model Organism Sharing Policy

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NIH Model Organism Sharing Policy

In May 2004, the National Institutes of Health (NIH) issued the [NIH Policy on Sharing of Model Organisms for Biomedical Research](#). The goal of the policy is to enable progress in science through prompt access to the unique research resources that arise from biomedical research laboratories. This bulletin highlights key features of the policy statement and provides resources for the university investigators and administrators seeking NIH Funds.

The Policy Applies to You If...

You are an investigator* applying for NIH research grants subsequent to October 1, 2004.

* Some exceptions do exist, please see NIH website for details.

What Obligations Exist

Under the Model Organism Sharing Policy?

Under the Model Organism Sharing Policy, investigators that plan to produce new, genetically-modified variants of model organisms are expected to share the organism and related resources in a timely way, generally at least upon publication of the primary results that announce the development of the genetically modified model organism(s). A plan for sharing organisms and related resources should be included in an NIH research grant application, and the NIH expects that the investigator and the institution will abide by the proposed plan. For a list of model organisms included under this policy, see <http://www.nih.gov/science/models/>.

The investigator and the university maintain an obligation to protect the rights and confidentiality of possible human subjects pursuant to university policy; local, state, and federal laws and regulations; and IRB rules. The investigator also maintains a duty to meet the university's intellectual property and third-party obligations, including

- ❖ Complying with university policy requiring the disclosure of inventions to the Technology Transfer Office to allow the university to comply with federal law by reporting inventions made through federally-funded research to the appropriate agencies,
- ❖ Complying with third-party research agreements and material-transfer agreements, and
- ❖ Complying with the need to protect patentable or otherwise proprietary information.

While the NIH seeks for organisms and related resources to be as widely and freely available as possible, investigators may seek funds from the NIH for sharing, may charge for reasonable costs incurred while complying with a sharing request, and may seek restrictions on the use of organisms and resources. Patenting and licensing are allowable methods of sharing so long as licensing/the licensed product is reasonably available and accessible to the scientific research community. For investigators seeking publication of their research, consult with the appropriate journals as many have sharing requirements as a condition for authorship. If questions about intellectual property arise when preparing sharing plans, please contact the Technology Transfer Office.

Formatting NIH Grant Applications to Include a Model Organism Sharing Plan

A brief statement of a sharing plan or an explanation as to why sharing would not be possible should be included in the Research Plan section (i.e., immediately after PHS 398 Section F. Vertebrate Animals, Rev. May 2001). The sharing plan will not count

towards the page limit. The plan should address the following:

- ❖ How novel strains will be made available to the scientific community
 - The form in which the organisms will be provided (e.g., adults, embryos, sperm)
 - Related research resources and data that you will provide
 - A reasonable time frame for periodic deposition of material and associated data
 - Whether sharing will occur under investigator's auspices, through a repository, or both [if a repository, state which one]
 - For vertebrate animals and species for which pathogens/contaminants are potential problems, maintenance plans to minimize the risks of infection or contamination
- ❖ How technology transfer and intellectual property issues will be handled
 - How the institution plans to make the organisms and resources widely available to the research community
 - How the institution plans to make certain any rights or obligations to third parties are consistent with the terms and conditions of the NIH award to ensure appropriate dissemination of model organisms or reagents under the NIH award
 - A description of the mechanisms that will be used to distribute organisms and related research resources (e.g., materials transfer agreements, UBMTA, etc.)

Sample Language for a Model Organism Sharing Plan

The University of Colorado and the Investigators are committed to the open and timely dissemination of research results, information, and tools that facilitate further research and scientific progress. It is the expectation and goal of the University and the Investigators that all "[model organisms](#)" defined by the NIH that are created during the course of NIH funded research, are shared with the research community. In accordance with these efforts the University of Colorado and the Investigators will use the [NIH Grant Policy on Sharing of Unique Research Resources](#) and the [NIH Policy on Sharing of Model Organisms for Biomedical Research](#) as guidance.

Should intellectual property arise which requires a patent or other protection, we would work with the University of Colorado Technology Transfer Office to ensure that the technology remains widely available to the research community in accordance with NIH policy. Following University policy, we will disclose newly created model organisms in a timely manner. If the University decides to patent the model organism, the Technology Transfer Office will take steps to ensure that the protection of rights shall not interfere with the distribution of the organism to the scientific community. If the University decides to patent and license the model organism, it will negotiate license(s) that promote widespread distribution of the organism. The University will also make every effort to reserve rights to the licensed material to the University and other non-profit institutions. If third party obligations exist, the University and Investigators will seek to minimize possible restrictions affecting the availability of model organisms.

Following the characterization and peer-reviewed publication of the transgenic XXX strain generated, XXX will be distributed to investigators at academic institutions wanting XXX for non-commercial research. Individual requests for shipment of XXX generated by this program project funding to AAALAC accredited institutions will be honored. The recipient investigators would provide written assurance and evidence that animals will be used solely in accord with their local IACAC review, that animals will not be further distributed by the recipient without consent of our Program, that animals will not be used for commercial purposes. Material transfers would be made with no more restrictive terms than in the Simple Letter Agreement or the UBMTA and without reach through requirements.

Requests for XXX from for-profit corporations to use the XXX commercially will be negotiated by the University of Colorado Technology Transfer Office. The technology transfer office will report an invention disclosure submitted to them to the appropriate federal agency. All licensing shall be subject to revenue distribution pursuant to my institution's policies and procedures on royalty income.

In addition, the transgenic XXX generated may/will be deposited in at an NIH supported XXX repository [see Section IV for list of XXX repositories and database]. NIH supported repositories cryopreserve embryos or sperm and distribute the frozen embryos or XXX to researchers. For the XXX I generate, I will use standard nomenclature and receive approval from the XXX Genome Governing Body.

To facilitate sharing and distribution of the transgenic/knockout XXX and associated resources developed under this grant, XXX will be maintained in a specific pathogen-free facility. This facility will maintain the XXX free of the following micro-organisms and pathogens: *M*, *N*, *O*, and *P*. Should the transgenic/knockout XXX become infected with any of these micro-organisms, the XXX will be (recreated from embryos, etc.)

"Other Research Resources" generated with funds from this grant will include *G*, *H*, *I*, etc. As available, these resources would also be distributed upon request to qualified academic investigators for non-commercial research.