

Definitions of Model Organisms and Research Resources

Model organisms include but are not restricted to:

Non-Human Mammalian Models, such as:

- Mouse
- Rat

Non-Mammalian Models, such as:

- Budding yeast
- Social amoebae
- Roundworm
- Arabidopsis
- Fruit fly
- Zebrafish
- Frog

New genetically modified model organisms developed with NIH funding may be shared as mature organisms, sperm, eggs, embryos, or even the vectors used to generate transgenic or knockout organisms. The term “resources” includes materials and data necessary for the production and understanding of model organisms, such as vectors, non-human embryonic stem cells, established cell lines, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

Genetically modified organisms are those in which mutations have been induced by chemicals, irradiation, transposons, or transgenesis (e.g., knockouts and injection of DNA into blastocysts), those in which spontaneously occurring mutations have occurred, and congenic or consomic strains.

Visit the following Web sites for additional guidance including links to relevant NIH Guide notices, Frequently Asked Questions, and Sample Sharing Plans

NIH Model Organisms for Biomedical Research

<http://www.nih.gov/science/models/>

NIH Grants Policy Statement (2003)

http://grants1.nih.gov/grants/policy/nihgps_2003/index.htm

NIH iEdison

<https://s-edison.info.nih.gov/iEdison>

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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<http://grants.nih.gov/grants/oer.htm>

The National Institutes of Health (NIH), part of the Department of Health and Human Services (DHHS), is the principal health research agency of the U.S. Federal Government. The Office of Extramural Research (OER) provides policies and guidelines for extramural research grants administration. OER has primary responsibility for developing and implementing NIH Grants Policy, including policies related to data and safety monitoring and protection of human subjects; monitoring compliance with humane use and care of laboratory animals policy; coordinating program guidelines; compliance with invention reporting requirements; and developing and maintaining the information systems for grants administration. OER works in conjunction with the NIH Office of Technology Transfer (OTT) which has primary responsibility for extramural technology transfer policy matters.



NIH Policy on the Sharing of Model Organisms for Biomedical Research

“Progress in science depends upon prompt access to the unique research resources that arise from biomedical research laboratories throughout government, academia, and industry.”

—*Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, December 1999*

All NIH applications and proposals that will produce new, genetically modified variants of model organisms and related resources are expected to include a sharing plan or to state why such sharing is restricted or not possible.

Why an NIH Policy on the Sharing of Model Organisms?

Advances in science depend on the timely sharing and distribution of biomedical research resources. The National Institutes of Health (NIH), a public sponsor of biomedical research, is committed to supporting national and international efforts that encourage the sharing and dissemination of important research resources. The timely sharing of biomaterials, reagents, and data, which has been essential to the rapid progress in research on many model organisms, avoids duplication of very expensive efforts and permits NIH to support more investigators and a greater variety of model organisms. To further ensure that NIH-funded research resources are made available to the research community for future research efforts and to accelerate the development of products and knowledge to benefit the public, NIH has reaffirmed its policy on the sharing of model organisms for biomedical research and provided additional guidelines for applicants seeking funding beginning with the October 1, 2004, application receipt date.

To Whom Does This Policy Pertain?

This policy statement applies to extramural investigators funded by NIH grants, cooperative agreements, and contracts, including Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) mechanisms.

The model organism sharing plan is expected to be addressed by **all** investigators and is **not** subject to a cost threshold.

Preparing an Application for NIH Funding

Investigators submitting an application or contract proposal beginning with the October 1, 2004, receipt date are expected to include a sharing plan for distributing unique model organism research resources generated using NIH funding, or to state appropriate reasons for why such sharing is restricted or not possible.

The adequacy of model organism sharing plans will be considered by reviewers at the start of each competitive funding cycle for new and renewal applications. As the expectations and tools available to facilitate model organism sharing continue to evolve, maximum flexibility is encouraged to allow renegotiation during the project period at the request of either the NIH Institute/Center or the funded institution in response to materially new and/or unforeseen developments. Applicants responding to a Request for Applications (RFA) or a Request for Proposals (RFP) may find additional requirements related to resource or data sharing in the specific announcement or solicitation.

Sharing plans may vary, depending on the organism, the nature of the resources that will be shared, the extent to which intellectual property issues may be considered in sharing, and plans for distributing the resources. The sharing plan should specify:

- How the novel strains will be made available to the scientific community, including:
 - The form in which the organisms will be provided (e.g., adults, embryos, sperm);
 - A reasonable time frame for periodic deposition of material and associated data;
 - Whether a repository will be used; and
 - If relevant, how risks of infection or contamination will be minimized.

- How technology transfer and intellectual property issues will be handled, including:
 - How the institution plans to make 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 under the NIH award; and
 - A description of the mechanisms that will be used to distribute organisms and related research resources, e.g., material transfer agreements (MTAs).

Applicants are encouraged to confer with their institutional offices of technology transfer and other relevant institutional offices to address these issues.

Funds for Research Resource Sharing

Investigators may request funds in their applications to defray reasonable costs associated with the sharing of model organisms and related research resources. Investigators are encouraged to confer with their institutional offices of technology transfer and/or offices of sponsored programs for guidance.

Compliance with Research Resource Sharing Guidelines

When evaluating non-competing continuation applications, NIH program staff may consider, as part of the criteria for continued funding, adequate progress in model organism sharing as well as a demonstrated willingness to make research resources developed during the project widely available to the research community. Failure to comply with NIH research resource sharing policies and the accepted plan may also be considered by NIH program staff in future funding decisions for the investigator and the investigator's institution.