SHARING OF MODEL ORGANISMS

BACKGROUND

As a public sponsor of biomedical research, the NIH is committed to supporting national and international efforts that encourage the sharing and dissemination of important research resources. Restricted availability of unique research resources, upon which further studies are dependent, can impede the advancement of research. Conversely, sharing biomaterials, reagents, and data in a timely manner has been an essential element in the rapid progress of research on many model organisms for biomedical research. The NIH is interested in continuing to ensure that the research resources developed with NIH funding are made readily available in a timely fashion to the research community for further research, development, and application. This is done in the expectation that this will further the research enterprise and accelerate the development of products and knowledge of benefit to the public.

According to the NIH, model organisms include, but are not restricted to:

- Nonhuman mammalian models, such as:
  - mouse
  - rat

- Non-mammalian models, such as:
  - budding yeast
  - social amoebae
  - roundworm
  - 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. 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.

The term “resources” includes materials and data necessary for the production and understanding of model organisms, such as vectors, nonhuman embryonic stem cells, established cell lines, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

MODEL ORGANISM SHARING PLAN REQUIREMENTS

All grant applications or contract proposals in which the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms and research resources that are generated using NIH funding. If
sharing of the model organism(s) or resources is not possible, the applicant or offeror must state why such sharing is restricted or not possible. The need for the inclusion of a model organism sharing plan is not subject to a cost threshold of the application’s or proposal’s budget.

Model organism 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 the 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, or sperm)
  - A reasonable time frame for periodic deposition of material and associated data
  - Whether a repository will be used
  - 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 the appropriate dissemination of model organisms under the NIH award
  - A description of the methods that will be used to distribute organisms and related research resources, e.g. material transfer agreements

International Collaborations and Foreign Grants/Contracts
If the US institution is the primary grantee or offeror, then the domestic institution is responsible for its sub-grantee or subcontract arrangements and is expected to ensure that this policy is adequately addressed in the application.

Model Organism Sharing Plan Evaluation for Grants
The reviewer will address whether the application’s model organism sharing plan is “Acceptable” or “Unacceptable,” if applicable. The reviewer should not include their assessment of the plan in the determination of the application’s Overall Impact/Priority score. If the plan is deemed “Unacceptable,” a brief explanation of why it was unacceptable should be provided.

However, some special initiatives may contain additional requirements related to model organism sharing; in these cases, the adequacy of the model organism sharing plan may be an additional review criterion, and the reviewers would then factor their evaluation of the plan into the overall evaluation of scientific merit, i.e. the Overall Impact/Priority score.

Model Organism Sharing Plan Evaluation for Contracts
The reviewer will address whether the proposal’s model organism sharing plan is “Acceptable” or “Unacceptable,” if applicable. The reviewers should not include their assessment of the plan
in the determination of whether the overall proposal is “Acceptable” or “Unacceptable.” If the plan is deemed “Unacceptable,” a brief explanation of why it was unacceptable should be provided.

However, some Requests for Proposals or Broad Agency Announcements may contain special requirements related to model organism sharing; in these cases, the adequacy of the model organism sharing plan may be factored into the score of the respective Technical Evaluation Criteria and into whether the proposal is “Acceptable” or “Unacceptable.”

For more information, see the following NIH web site: http://grants.nih.gov/grants/policy/model_organism/