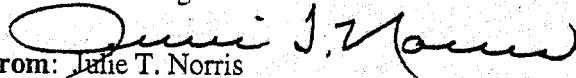


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To: NIH Investigators

From: Julie T. Norris



Subject: NIH Policy on Sharing of Model Organisms for Biomedical Research

NIH has published a new policy on the sharing of model organisms in the NIH Guide (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>). While NIH has always supported timely sharing and distribution of biomedical resources developed with NIH funding, this policy now requires that investigators anticipating the development of model organisms include a plan for sharing and distributing such resources in applications beginning with the October 1, 2004 deadline.

Highlights of the new policy include the following:

- 1) Model organisms include but are not restricted to mammalian models, such as the mouse and rat; and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. [See NIH Model Organism for Biomedical Research Website at <http://www.nih.gov/science/models/> for information about NIH activities related to these resources].
- 2) Unlike the NIH Data Sharing Policy, the submission of a model organism sharing plan is not subject to a cost threshold of \$500,000 or more in direct costs.
- 3) Adequacy of plans will be considered by reviewers when a competing evaluation is evaluated, however, reviewers will not include their assessment in the overall priority score. For some special initiatives such as Request for Applications (RFA) and Request for Proposals (RFP) specifically directed to the development of model organisms, reviewers may be asked to integrate their evaluation of the distribution plan with other review criteria and factor their assessment into the overall evaluation of the scientific merit.
- 4) At a minimum, the plan should address the following questions in a clear and concise manner:
 - ◆ Will material transfers be made with no more restrictive terms than in a sample letter agreement as detailed at http://ott.od.nih.gov/NewPages/Rtguide_final.html#sla or the Uniform Biological Material at <http://ott.od.nih.gov/NewPages/UBMTA.pdf>?
 - ◆ How would inappropriate "reach through" requirements as specified in the Bayh-Dole Act on materials transferred be addressed?
 - ◆ How will technologies remain widely available and accessible to the research community, for example, if any intellectual property rights arise for which a patent application may be filed?

Investigators are responsible for preparing their own plans for sharing of model organisms, and should contact their NIH program office with questions. Your OSP contract officer or the Office of the Intellectual Property Counsel at x8-8327 are available as additional resources.