

May 29, 2002

Wendy Baldwin, Ph.D.
Deputy Director for Extramural Research
Office of Extramural Research
1 Center Drive, MSC 0152,
Building 1, Room 150
Bethesda, MD 20817

Dear Dr. Baldwin:

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to comment on the March 1, 2002 NIH proposed policy regarding the sharing of research data. FASEB is comprised of 21 societies with more than 60,000 members, making it the largest coalition of biomedical research associations in the United States. The mission of FASEB is to enhance the ability of biomedical and life scientists to improve, through their research, the health, well-being and productivity of all people.

The NIH proposed policy would require investigators submitting an NIH application to include a plan for data sharing or a statement within the application indicating why data sharing is not possible. As scientists, we recognize that we have an obligation to share data derived from publicly-supported studies and feel that, in most cases, this is accomplished by making one's data available through publication or posting in appropriate databases. An affirmation of that principle at the application process is appropriate. More detailed dissemination plans, however, are impractical at this stage.

The sharing of research data is a paramount concern to researchers. The American people have been extraordinarily generous in support of research, and we are privileged to pursue scientific opportunities at the behest of the public and for the benefit of the public. The sharing of data provides more effective use of public resources. Scientists, along with the public, are the principal beneficiaries of data sharing which lessens the duplication of expensive data collection activities and frees time and money for research into new areas of scientific inquiry.

NIH is correct to exclude "laboratory notebooks, partial data sets, preliminary analyses, drafts of scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as gels or laboratory specimens" from the proposed data sharing policy. While we recognize the worthy goal of also sharing unique research resources developed through NIH funding, such as specialized and/or genetically defined cell lines, monoclonal antibodies, microbial cells and products, viruses and viral

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products, recombinant nucleic acid molecules, DNA probes, nucleic acid and protein sequences, and certain types of animals such as transgenic mice, we feel strongly that no one rule or policy can be developed that adequately addresses the complexity of the sharing of physical resources. The costs of sharing some of these materials could be astronomical and could require an entire infrastructure to deal with making such resources available.

Notwithstanding our support of raising the science community's awareness of the obligation to share data generated by public funding, we have several comments about the workability of preparing a detailed plan *at the grant application* stage. This would require a formal agreement prior to the creation of the data. Certainly, it would be feasible to include a statement in the grant application indicating an intention to share data through publication. To a large extent the peer review system already regulates the sharing of data. If you don't publish, your grant renewal will not be ranked well by the Study Section. In addition, most journals require that types of data that are not published as part of a journal article, such as full sequences, NMR spectra, and crystallographic coordinates, be deposited in data banks. This existing control leverage over the sharing of data is at the publication level and is applicable to the majority of the data generated with NIH funding.

In general, publication works well to assure that data are shared. Science, however, by its very nature stumbles onto unanticipated discoveries, and one cannot envision all of the possible outcomes of a series of planned experiments. (In fact R01 grants do not even require that you follow your original experimental plan, if you can justify changing direction.) While it is important to promote the obligation to share data, it is crucial that a workable data-sharing plan afford maximum flexibility to accommodate evolving science. To afford this flexibility, we recommend that the plan be limited to a checklist that accompanies the grant application. A possible example is [attached](#).

Finally, grant rating by study sections should be blinded to the issue of data dissemination with the exception of confirming the applicant's intention to share data within a reasonable time and in a reasonable manner. A study section is not in a position to evaluate data sharing plans or the costs of such plans, and its job is to focus on the merits of the science. There is no reason why requests for additional funding to accommodate data dissemination costs, once they become apparent, should not be handled as an administrative matter by NIH staff.

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In summary, it is our goal to share the data we develop, as allowed by confidentiality and privacy protections, proprietary restrictions and resource availability. We recommend the use of a checklist in lieu of a detailed data-sharing plan at the grant application phase and would be happy to collaborate with the NIH representatives in designing an appropriate model. Again, thank you for giving us the opportunity to provide input into the data sharing policy prior to its adoption.

Sincerely,

Robert R. Rich, M.D.
FASEB President