## Data Sharing and Scoring

Reviewers will not use the data sharing plan in determining scientific merit or priority score for applications. Program staff are responsible for overseeing the data sharing policy and for assessing the appropriateness and adequacy of the data sharing plan. Program concerns must be resolved prior to making an award.

## Cost of Data Sharing

Applicants may request funds for data sharing and archiving. The financial issues should be addressed in the budget section of the application. If the data have been collected already, a competitive or administrative supplement may be available.

> We placed our National Survey of Adolescent Males data in the Data Archive on Adolescent Pregnancy and Pregnancy Prevention where it has been accessed for analysis and classroom projects. The advantage of this approach is that the Archive provides technical assistance and publicity on data availability to the research and education communities.
>
> *Freya Sonenstein, The Urban Institute*

## NIH Staff Can Help

Instructions related to data sharing can be found in the specific Request for Proposal (RFP), Request for Application (RFA), or Program Announcement (PA). However, NIH encourages investigators to consult with NIH program staff prior to submitting an application to determine the appropriateness of data sharing and a suitable mechanism for disseminating data.

For more information on the NIH Data Sharing Policy, including a link to the Final NIH Statement on Sharing Research Data, visit the NIH Office of Extramural Research Website on Data Sharing Policy:

**http://grants2.nih.gov/grants/policy/data_sharing**


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The National Institutes of Health (NIH), part of the Department of Health and Human Services (DHHS), is the principal health research agency of the 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; and developing and maintaining the information systems for grants administration.

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# NIH Data Sharing Policy

"Data should be made as widely and freely available as possible while safeguarding the privacy of participants, and protecting confidential and proprietary data."

*— Final NIH Statement on Sharing Research Data February 26, 2003*

## *What You Need to Know for Successful Funding*

## NIH Data Sharing Policy

Scientific research depends on the free flow of information and ideas. To ensure that future research can build on previous efforts and discoveries, the National Institutes of Health (NIH) has developed a data sharing policy that goes into effect beginning **October 1, 2003**, for applicants seeking NIH funding of $500,000 or more in direct costs in any one year.

The policy expects final research data, especially unique data, from NIH-supported research efforts to be made available to other investigators. It includes data from:

- Basic research
- Clinical studies
- Surveys
- Other types of research

Data sharing applies to human subjects and laboratory research. In some instances, it may include data not produced with NIH funding but used in an NIH-supported activity.

> Unrestricted access to the mouse sequence should enhance efforts to identify causative genes in mouse models of diseases as well as identify human genes responsible for various disorders. The rapid progress toward making these data widely available will in turn speed the research for new ways to treat or even prevent disease.
>
> *Arthur Holden, Chairman of the Mouse Sequencing Consortium*

## Data Sharing Methods

Data sharing can be accomplished through:

- ***Publishing***–articles in scientific publications
- ***Researcher's Efforts***–investigator responds directly to data requests (mailing a CD-ROM containing data or posting data on a Web site)
- ***Data Enclave***–controlled, secure environment in which eligible researchers can perform analyses using data resources
- ***Data Archive***–place where machine-readable data are acquired, manipulated, documented, and distributed
- ***Mixed Mode***–more than one version of a dataset, each providing a different level of access

When making data available, researchers cannot place limits on questions or methods nor require coauthorship as a condition for receiving data. Proper documentation is needed to ensure that others can use the dataset and to prevent misuse, misinterpretation, or confusion.

> Overall, I found the benefits of sharing to greatly outweigh the bother of pulling together the data and annotating them. I have also benefited from receiving data from colleagues along with programs vital to appropriate analyses. I truly believe that data sharing is an important component of the research enterprise.
>
> *Peter Killeen, Department of Psychology, Arizona State University*

## Privacy Concerns

Protecting the rights and privacy of human subjects should be the first priority of any researcher. Investigators, Institutional Review Boards, and research institutions have an obligation to protect participants' rights and confidentiality. However, data sharing is possible without compromising these efforts because identifiers can be removed from data. In addition, data sharing agreements can be used to restrict the transfer of data to others and to require that data be used only for research purposes.

Investigators also should take into consideration possible restrictions from local, State, and Federal laws, such as the Privacy Rule, a Federal regulation under the Health Insurance Portability and Accountability Act (HIPAA). There also may be proprietary information or patent issues when research is co-funded by private sources. Any restrictions should be discussed in the data sharing plan section of the funding application. Researchers should carefully plan the study design, informed consent documents, and structure of resulting dataset prior to initiating the study.

> We placed our cleaned files on the Web for free dissemination. There is a vast group of users, particularly for our China and Russia surveys. The culture of empirical research is new to Russia, and our surveys have helped to revolutionize social science training in that country.
>
> *Barry Popkin, Department of Nutrition and Carolina Population Center, University of North Carolina at Chapel Hill*

## Timeframe for Data Sharing

Data sharing should be timely and no later than the acceptance for publication of the main findings from the final dataset. Data from large studies can be released in waves as data become available or as they are published.

> The data were placed in the public domain, free of charge, 6 months after completing the last interview. Within a year, researchers at over 100 institutions were using the data. Over 300 published articles have used these data.
>
> *Larry Bumpass and James Sweet, Center for Demography and Ecology, University of Wisconsin at Madison*

## Preparing an Application for NIH Funding

Researchers submitting grant, cooperative, or contract applications will be required to include a data sharing plan or an explanation of why data sharing is not possible. Data sharing plans or an explanation should be addressed in a brief paragraph placed after the research plan. The precise content of the data sharing plan will vary depending on the data being collected. The following may be included:

- Schedule for data sharing
- Format of final dataset
- Documentation to be provided
- Analytical tools to be provided, if any
- Need for data sharing agreement
- Mode of data sharing

Additional information may be included in other sections of the application, such as the significance, budget, and human subjects sections. Investigators who incorporate data sharing in the initial design of the study may more readily and economically establish adequate procedures for confidentiality and sharing a useful dataset.