



BULLETIN

› NIH Data Sharing Policy

Contact Us:

For information about licensing to start-up companies
Tom Smerdon
tom.smerdon@cu.edu
phone: 303-735-0621
fax: 303-735-3831

For CU-Health Sciences Center inventors
Rick Silva
rick.silva@cu.edu
phone: 303-724-0222
fax: 303-724-0816

For CU-Boulder and Colorado Springs inventors
Ken Porter
ken.porter@cu.edu
phone: 303-735-1109
fax: 303-735-3831

For general information and CU System office
David Allen
david.allen@cu.edu
phone: 303-735-3711
fax: 303-735-3831

General Address for correspondence:
CU System Technology Transfer Office
4001 Discovery Dr., Suite 390C
588 SYS
Boulder, CO 80309-0588

Web site:
www.cu.edu/techtransfer

The National Institutes of Health (NIH) now requires that certain recipients of NIH awarded grants share their data in order to expedite the translation of research results into knowledge, products, and procedures to improve human health. This bulletin highlights key features and provides links to assist university investigators and administrators seeking NIH funds.

What Obligations Exist Under the NIH Data Sharing Policy?

Under the Data Sharing Policy, an investigator must share final, non-restricted research data in a timely manner, usually upon publication of the main findings from the final dataset. NIH grant applications should be formatted to include a data sharing plan, and the NIH expects that investigators and institutions will follow that plan.

To Whom Does the Policy Apply?

The Data Sharing Policy applies to all investigators* applying for NIH research grants subsequent to October 1, 2003 that request at least \$500,000 in direct funds in any single year.

* Some exceptions do exist, please see NIH website for details.

- Final research data – recorded factual material commonly accepted in the scientific community as necessary to document and support research findings.
- Non-restricted research data – datasets that may be introduced into the general public without concerns such as subject confidentiality; third-party funding, intellectual property protection, licensing, or use agreements; national security; and like concerns. Where the investigator expects restricted research data, the restricted data should be explained (e.g. restricted under third-party agreement until publication) in the data sharing plan and how the data will be shared or why it cannot be shared.

The investigator(s) and the university have the obligation to protect the rights and confidentiality of human subjects pursuant to university policy; local, state, and federal laws and regulations; and IRB rules. This may be accomplished through data redaction of all identifiers and deductive identifiers. The investigator also has a duty to meet the university's intellectual property policy and third-party contractual obligations, including:

- Complying with university policy requiring the disclosure of inventions to the Technology Transfer Office to allow the university to comply with federal law by reporting inventions made through federally-funded research to the appropriate agencies,
- Complying with third-party research agreements and material-transfer agreements, and
- Complying with the need to protect patentable or otherwise proprietary information.

While the NIH desires data and resources to be as widely and freely available as possible, investigators may seek funds from NIH for sharing, may charge for reasonable costs incurred while complying with a sharing request, and may seek restrictions on the use of data or resources such as "for academic or research purposes only." Patenting and licensing are also allowable methods of sharing so long as licensing/the licensed product is reasonably available and accessible to the research community. For investigators seeking publication of their research, consult with the journals that papers are submitted to as many have data sharing requirements as a condition for authorship. If questions about intellectual property arise when preparing sharing plans, please contact the Technology Transfer Office.

How to Include a Data Sharing Plan in NIH Grant Applications

Include a brief Data Sharing Plan immediately following the Research Plan section of the grant application. The plan may include the following:

- The expected schedule for sharing
- The format of the final dataset
- The documentation to be provided
- Whether or not any analytic tools also will be provided
- Whether or not a data-sharing agreement will be required and, if so, a brief description of such an agreement (including the criteria for deciding who can receive the data and whether or not any conditions will be placed on their use)
- The mode of data sharing (under the auspices of the investigator, through a data enclave or data archive, or through mixed methods).

The Data Sharing Plan section will not count towards NIH page limit requirements. If the investigator plans to seek NIH grant funds to pay data-sharing costs, he may do so and include such information in the Budget and Budget Justification sections. Also, if the research involves human subjects and datasets are to be shared, the investigator should address how the rights and confidentiality of participants will be protected in the Human Subjects Section. For complete Data Sharing information including guidelines and frequently asked questions, please see the NIH Data Sharing web site at http://grants.nih.gov/grants/policy/data_sharing/index.htm.

Sample Language for a Data Sharing Plan

The University of Colorado and the Investigators remain committed to the open and timely dissemination of research results. Investigators in this study recognize that promising new methods, technologies, and strategies may arise during the course of our research [tailor this statement and list to your particular research plan]. My institution and I are aware of and will adhere to the NIH Grants Policy on Sharing of Unique Research Resources, including the "[Sharing of Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Grants and Contracts](#)" issued in December, 1999.

While the Investigators expect that research data will be shared with the research community as widely and freely as possible, opportunities for technology transfer through commercialization will be explored as appropriate in conjunction with the University of Colorado Technology Transfer Office. The Technology Transfer Office serves the University community by commercializing inventions, ideas, and software developed at the University to ensure that new knowledge benefits society and continues to fund research and education. Further, where opportunities arise for third-party sponsored research related to the NIH-funded research programs, the University and I expect any agreements to conform to the principles described in the 1994 NIH policy "[Developing Sponsored Research Agreements: Consideration for Recipients of NIH Research Grants and Contracts](#)" and to allow for appropriate data sharing.

[If any restrictions on data sharing exist or may exist, explain them. (e.g., Following a third-party sponsored research agreement, research data will not be available until peer-reviewed publication of the main findings. Immediately following publication, the research data will be available as below.)]

The Investigators expect to share data with the scientific community by XXX method. With this method, data will be available to YYY through the following means: A, B, C, and D. (For a list of some current methods, an analysis of those methods, and specific sample text, see the Axiope Project Data Sharing White Paper at <http://www.axiope.org/datasharingwhite.html>.)

To download forms: <http://www.cu.edu/techtransfer/campus/idf.html>

To submit a disclosure, send emails to your campus TTO contacts.