

Procedures for Research Data Management

I. Research Data Policy

Under Rice Policy 308 on Research Data Management¹ and applicable federal regulations governing federally sponsored research, Research Data is broadly defined as the information recorded or produced in any form or media during the course of a research investigation. To be a good steward of the research data, a researcher must understand ethical and regulatory issues of data management, best practices for creating data management plans, data collection, sharing, retention, storage, and transfer.

While responsible data management is important in all phases of the project, data management benefits research in a variety of ways.² First, responsible data management may allow for transparency and integrity of the research and published scientific findings. Second, as explained later in these procedures, certain federal agencies have data management requirements, so awareness of these issues will help researchers comply with grant terms. Finally, responsible data management has practical benefits, such as avoiding duplicated efforts, locating and sharing data easily. These benefits therefore include increased efficiency and easier collaboration between researchers and institutions.

It is the responsibility of the Principal Investigator (PI) to guide the research team in the methodology and practice of the team member's role in the design, collection, analysis, interpretation, maintenance and dissemination of the results from the data. At each stage of a project, PIs should be cognizant of issues relevant to data management. Planning for data management begins even before the launch of the project and continues after it is completed. At every stage, however, note that standards for properly handling data depend on, among other things:

- project terms and conditions;
- the type of data being generated;
- regulatory requirements; and
- research standards within the project's subject matter's academic or scientific community.

This guidance complements Rice Policy 308.

II. Definitions

- A. Research Data, under Rice Policy 308, is also referred to as research records. While the meaning of the term research data can vary from field to field, research data is broadly defined as information recorded or produced in any form or media during the course of a research investigation. Research data may be in hard-copy form (including research notes, laboratory notebooks, photographs) or in electronic form, such as in computer software, computer storage or digital images. Research data is not limited to raw experimental results and instrumental outputs, but also encompasses the associated protocols, numbers, graphs and charts used to collect and reconstruct the data. It also includes materials such as: original biological specimens, research animals, environmental samples, and materials and products generated by the research. Any reports, publications, correspondence, and summaries regarding research results are also part of the research records.

The definition of research data often comes into play when determining what types of data to retain for the five-year post-project period noted in Rice Policy 308. For example, a common

¹ <http://research.rice.edu/policies/>

² New England Data Management Curriculum, Module 1 (<http://library.umassmed.edu/necdmc/modules>)

question is whether PIs should retain all, or only certain, versions or drafts of a document. As noted several times in this document, standards for data management depend on, among other things, standards within the PI's particular academic or scientific community. The National Science Foundation (NSF) has also provided the following guidance in determining whether certain types of data (supporting documentation, metadata, validation protocols, field notebooks, etc.) are subject to data management and access protocol—and this guidance suggests that PIs should define, and thus retain, their research data in such a way as to allow them to defend their research results:

All researchers are expected to be able to explain and defend their results. Doing so usually entails maintaining complete records of how data was collected. The manner in which one maintains such records and makes them available to others will vary from project to project. What constitutes reasonable procedures will be determined by the community of interest through the process of peer review and program management. These standards are likely to evolve as new technologies and resources become available.³

- B. Principal Investigator (PI) means the individual officially responsible for the conduct of a sponsored project, or the individual officially responsible for the conduct of any funded project. On research projects, the PI is usually a faculty member; on other types of awards, the PI may have an administrative appointment.
- C. Research means a systematic investigation, study or experiment designed to develop or contribute to generalizable knowledge. The term encompasses basic and applied research (*e.g.*, a published article, book, or book chapter) and product development (*e.g.*, a diagnostic test or drug). The term includes any such activity for which sponsored funding is available such as a research grant, career development award, center grant, individual fellowship award, infrastructure award, institutional training grant, program project, research resources award, or other contractual mechanism.

III. Roles and Responsibilities

A. Principal Investigator (PI)

Typically, the PI of the grant or project is the data steward and has primary responsibility for ensuring:

- the use of appropriate ethical and responsible data collection methods;
- the validity, authenticity, and accuracy of the data;
- data quality control measures are in place and used;
- reasonable precautions to ensure the security of the data against theft or loss have been taken;
- all members of the research team are aware of any requirements pertaining to the data, including confidentiality and compliance; and
- requirements for the protection of human subjects' data are in place prior to data collection;
- appropriate methods for data storage, retrieval, archiving and disposal; and
- both data and its research interpretation are organized; documented properly; disseminated; and published appropriately.

³ <http://www.nsf.gov/bfa/dias/policy/dmpfaqs.jsp#7>.

B. Research Staff and Graduate Students

While research staff and graduate students often act under the guidance of their PIs, these individuals nevertheless have a responsibility to:

- assist their PI(s) in the use of ethical and responsible data collection methods;
- document research data accurately; and
- ensure the submission of their research data (*e.g.*, laboratory notebooks) to the University or their PI(s) prior to departing the University.

C. The University

The University is responsible for providing, among other things:

- general guidance regarding University and federal policy regarding data management;
- assistance in the transfer of incoming and outgoing research data;
- assistance in the storage and archiving of research data;
- coordination of data collection and retention in investigations and audits; and
- collection and retention of research data for departing personnel.

IV. Research Data and the Project Lifecycle



A. Proposal Stage

1. Developing the data management plan

Rice Policy 308 does not require data management plans for every project proposal. However, PIs should be aware when funding agencies require the submission of a data management plan at the proposal stage. During the proposal stage, the PI should estimate the storage and other resources required for data management and include this information in the proposed budget. The Research Computing Support Group (RCSG) and Digital Scholarship Services can work with the PI in determining the appropriate information to include in the proposal. [Appendix 1](#) (Data Management Check List) provides general questions to consider in drafting a data management plan.

Two major agencies that require a data management plan at the time of proposal submission are the NSF and, in certain cases, the National Institutes of Health (NIH). Both agencies have published guidelines for these requirements (See [Appendix 2](#), subject to change and current as of March 16, 2015). However, researchers should also refer to the guidelines for their particular proposal in case special data management requirements apply.

2. Resources

There are various university and online resources to help PIs with drafting data management plans:

- Rice's Research Data Management team (researchdata@rice.edu), a collaboration between Information Technology's Research Computing Support Group (RCSG) and Fondren Library's Digital Scholarship Services (DSS), assists researchers in preparing data management plans. Its main goal is to help researchers manage their data, whether by providing consulting, resources, or referrals. The team's website, <http://researchdata.blogs.rice.edu/>, provides an explanation of available services. Each partner in the Research Data Management team offers complementary expertise:
 - Rice's Research Computing Support Group (rcsg.rice.edu) is available to assist PIs who anticipate the use of sophisticated data storage, networking, and high performance computing. They also act as liaisons to local IT support.
 - Digital Scholarship Services (library.rice.edu/services/dss) can provide consulting expertise in digital curation, metadata creation, digital preservation, and copyright. It can also assist researchers with sharing datasets through the Rice Digital Scholarship Archive, provided that data meet criteria such as being publicly available, complete and final, in standard formats, and of small to medium size.
- The Data Management Planning Tool (DMPTool, <https://dmp.cdlib.org/>) is a free interactive tool developed by several universities and other contributing institutions in response to NSF and NIH data management requirements. The DMPTool can help researchers quickly compile a data management plan appropriate to their research. Rice researchers can create an account on DMPTool using their Rice login credentials (netid and password).

B. Project Initiation Stage

Upon notification that a project has been awarded, the PI should first coordinate with the Office of Sponsored Research (OSR), Office of the General Counsel, and the Office of Technology Transfer (OTT) to negotiate project terms. The PI should pay attention to terms and requirements relevant to data management such as intellectual property, copyright, licensing, and handling of sensitive data.

The PI is then responsible for the execution of the data management plan, and for informing/training Investigators on his/her research team. The PI should review the data management requirements developed during the planning stage to ensure the availability of needed resources in a timely manner.

Even if no formal data management plan is in effect, the PI should develop and implement procedures for managing data. Considerations include identifying the type and quantity of data to be generated; assigning roles and responsibilities for data management; developing file naming conventions and metadata strategies so that data can be located, understood and contextualized; understanding what data needs to be retained and for how long; and determining where and how data will be stored and backed up. For assistance with these decisions, PIs can consult with the Research Data Management team.

C. Research Stage

The PI is responsible for the continued execution and monitoring of data management plans.

Regardless of whether or not a formal plan is in place, the PI should implement procedures for tracking and storing data. Active management will help ensure the data remains accessible for the long term and support reuse or repurposing for continuing or future research. Research data storage needs to be appropriately allocated, which takes into consideration necessary compute cycles. The Research Data Management team can work with the PI to determine an appropriate data curation plan. Data curation involves the organization, description, cleaning, enhancing, and preservation of data. This process identifies what data will be archived long-term for compliance and replication of results, and what should be disposed of after meeting applicable federal mandates.

D. Project Wrap-Up Stage and Post-Project Stage

1. Initial considerations and PI responsibilities

At this stage, researchers should consider issues relating to managing and archiving data associated with a completed project, such as:

- data curation (if not already managed prior to this stage);
- choosing file storage formats (*e.g.*, choosing to archive documents in PDF vs. Microsoft Word) to ensure accessibility long-term and across different operating systems;
- determining whether to deposit and/or share the data, such as through a disciplinary or institutional repository (*e.g.*, Rice's Digital Scholarship Archive); and
- agreeing to rights and responsibilities for archiving and accessing the data post-project.

One of the responsibilities of a PI at this stage is to preserve data in accordance with a project's funding agency's terms, Rice policies, and federal requirements. Rice Policy 308 generally requires the retention of research data **for five years** following the conclusion of the research project, although this time period may be extended in certain cases (*e.g.*, litigation and investigations). Researchers should always consult with grant and agency guidelines for applicable data retention periods.

2. Storage options

The University is continuously reevaluating in-house storage options, and researchers are welcome to use whatever appropriate and convenient means to store their data. When choosing data storage, researchers must keep in mind the level of security needed for their data, especially with regard to confidential or sensitive information. Further, best practices suggest that researchers should keep three copies of critical data (ideally in different locations), implement appropriate version control, perform regular backups, and use reliable storage systems. Consult with the Rice Research Data Management team for more explicit guidance.

Options for storing electronic data include:

- Storage solutions managed by Rice's Information Technology (IT) department

Rice IT offers several storage solutions to accommodate different needs, including ongoing research projects, archival research data, and long-term file storage for departments and groups.

See <http://it.rice.edu/storageoptions/> for a comparison of these options, and contact the Help Desk with questions: 713.348.4357 or helpdesk@rice.edu.

- **Crate** provides Rice researchers 500GB (.5TB) of storage for ongoing projects per research award via a drive mounted on a computer; available upon request.
 - **Archive** supports long-term retention of completed work, offering 500GB (.5TB) of storage per research award, upon request. Data is accessible through a drive mounted on a computer.
 - **RNAS** is a private Rice long-term file storage solution purchased via a departmental or other fund and shared between all members in a group or department.
 - The Research Computing Support Group may also assist with providing access to the most current, state-of-the-art resources available at the University (additional charges may apply). These resources include **SPICE** (Shared Pool of Integrated Computing Environments), described as “a virtual machine farm, NFS Storage, and RSYNC Storage that is intended to be an efficient, manageable, and cost-effective replacement for standalone servers and moderate computational workloads.” SPICE is not a backup, archive, or preservation service. Rather, it is a shared hardware procurement. Every effort will be made to protect SPICE data, and disk redundancy is employed to protect against disk failure. However, any data that resides on SPICE hardware is subject to loss, so customers should take whatever steps necessary to preserve critical data via an archive or preservation service. More information is available at www.rcsg.rice.edu/spice
- Cloud solutions

While cloud-based storage such as Dropbox and Google Drive can be relatively inexpensive and convenient, it also comes with risks, including security concerns and the lack of complete control over data. As such, it should not be used for confidential or sensitive data. For cloud storage, consider using instead [Rice Box](#). Rice faculty and staff can get a free Rice Box account with 30GB. Box can be used in collaborating; it is encrypted and backed up, but it is not suitable for information defined as confidential or sensitive by Rice University [Policy 808](#).

- Consumer-grade storage solutions.

Commercially-available storage (external hard drives, portable flash memory drives, SD cards, etc) can provide a cheap and easy way to store data, but given the risk of hardware failure and varying degrees of mass-market production quality, they are best suited for short-term storage; furthermore, they do not facilitate sharing data among researchers. Optical media, such as burnable CDs and DVDs, are also not recommended, due to their instability and the risk of hardware obsolescence.

3. Depositing and sharing data

By sharing data, researchers may be able to increase their citations, further research, and comply with funder and/or publisher requirements. As noted above, the NIH requires applicants requesting \$500,000 or more in direct costs to include a data sharing plan⁴, and the NSF expects that funded researchers will share their data with other researchers.⁵ Likewise, journals and publishers such as Nature,⁶ PLOS,⁷ and

⁴ http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm

⁵ www.nsf.gov/bfa/dias/policy/dmp.jsp

⁶ <http://www.nature.com/authors/policies/availability.html>

⁷ <http://www.plosone.org/static/policies#sharing>

Dryad Partner Journals⁸ require researchers to share or archive data associated with their publication. Options for sharing data include:

- Disciplinary data repositories

In some disciplines, researchers commonly deposit datasets through a disciplinary data repository, such as Dryad (biology), PubChem (chemistry), and ICPSR (social sciences; Rice is a member). See DataBib (<http://databib.org/>) and Registry of Research Data Repositories (<http://www.re3data.org/>) for comprehensive directories of research data repositories, or consult with Rice's Research Data Management team.⁹

- Rice Digital Scholarship Archive: scholarship.rice.edu

Through the Rice Digital Scholarship Archive (RDSA), researchers may deposit and share small and medium research datasets in standard formats. RDSA makes data publicly available (embargoes can be applied); it focuses on completed datasets rather than ongoing work. Managed by Fondren Library, RDSA follows best practices for the long-term preservation of data, such as frequent backup, archiving selected digital collections across geographically distributed storage, and using checksums to verify the integrity of data.

- Options for confidential data

Due to the sensitivity and necessity to protect confidential data, researchers should contact Information Technology to discuss the most current solutions for sharing this type of data. Information Technology has compiled a summary of options which outlines available storage solutions and the level of security available to each: it.rice.edu/storage options

IV. Common Events

Outside of the grant cycle, faculty and researchers should be cognizant of data management issues in the course of common University and other research-related events. Guidance below suggests that in some cases, researchers should refer to regulatory guidance. In other cases, however, researchers should refer to departmental or University policies.

A. New Faculty

Faculty are responsible for ensuring transfer of existing research data to Rice University. Coordination of this transfer generally occurs with the transfer of grant funds, and researchers should refer to their project's funding agency and University departmental policies to ensure proper data transfer.

B. Faculty, Graduate Student, and Personnel Departures

As noted in Policy 308, Rice holds legal title to research data, including laboratory notebooks. Generally, research data and laboratory notebooks (originals or duplicate originals) must be retained by the University. Researchers may make copies of their data, subject to grant sponsor restrictions.¹⁰ Collection and retention of laboratory notebooks and other research data is usually handled on the department level.

⁸ <http://datadryad.org/pages/jdap>

⁹ DataBib and re3data.org have announced plans to merge by the end of 2015.

¹⁰ Rice's copyright policy (Policy 334) provides that ownership of copyrights shall be governed by the terms of the governing sponsored research agreement.

The transfer of physical materials (*e.g.*, biological specimens) may require a Material Transfer Agreement (MTA). Questions regarding MTAs should be addressed to OTT.

Graduate students and research personnel must return their laboratory notebooks to their PIs. Departing research investigators may transfer their records to another institution, if approved by their PIs or the Vice Provost for Research, if the research investigator is a project's PI.

C. Collaborations and Data Sharing

Increasingly, researchers are encouraged to collaborate with investigators at other institutions, and to allow for public access of research data. Collaborations and public access provide for an opportunity to increase the visibility of Rice research, thereby enhancing scholarly reputation, recruitment of graduate students and faculty, and public impact.

PIs are responsible for determining the mechanisms and format of shared data, and to protect the security of this data. In this respect, PIs should check with grant sponsors and applicable federal agencies for specific guidelines and requirements as to data sharing between institutions.

The transfer of physical materials to a third party, such as to co-collaborators at another university or industry partner, may require an MTA. Questions regarding MTAs should be addressed to OTT.

Additionally, PIs should take note of the following issues relevant to data sharing.

1. International collaborations

According to the NSF, collaborations may also require additional data management considerations due to large international research consortia or formal science and technology agreements signed by the U.S. Government and foreign counterparts. Researchers should also check with OSR and their international research partner(s), if applicable, in these cases to ensure proper data handling.

2. Health Insurance Portability and Accountability Act (HIPAA)

HIPAA's Privacy Rule protects Protected Health Information (PHI): all individually identifiable health information (*e.g.*, individual's physical or mental health or condition, the provision of health care to the individual) in any form or media (electronic, paper, or oral). The Privacy Rule's disclosure provisions can affect the way research is conducted and shared and the way data is stored and secured.

3. Research Involving Human Participants: Institutional Review Board (IRB)

Data sharing involving IRB-approved projects may involve requirements regarding participant consent and de-identification of data. Researchers should determine whether data can be shared, even with researchers and students at the University, by referring to their approved IRB protocols. For questions regarding IRB, contact Stephanie Thomas, Compliance Administrator.

4. Export Controls

Researchers must comply with any agreed upon restrictions from sponsors pertaining to U.S. laws and regulations controlling the export of technical data, computer software, laboratory prototypes and other commodities in connection with the results of their research. Such restrictions may include publication and sharing with non-U.S. citizen collaborators and/or students if the data is controlled under the

International Traffic in Arms Regulations (ITAR) or Export Administration Regulations (EAR). While certain exceptions apply to the ITAR and EAR, questions should be addressed to Melissa Gambling, Compliance Manager, or the University's Office of the General Counsel.

5. Industry Sponsored Research

Many times agreements with industry include confidentiality or non-disclosure agreements. Researchers should refer to those terms and, if necessary, discuss any questions with OSR and OTT prior to data sharing involving industry sponsored research.

D. Investigations and Audits

At times the University or an outside entity, such as the grant sponsor or a U.S. government agency, will request research records for purposes of an investigation (*e.g.*, research or financial misconduct) or audit. As noted by the NSF, all researchers (and, accordingly, the University itself) are expected to be able to explain and defend research results. This principle underlines the need for the University to require the five-year retention period for research data.

The University, through the Office of the General Counsel, OSR, and OTT, will coordinate with the PI to ensure data preservation and collection.

E. Research Data Associated with Theses and Dissertations

Generally, departing graduating students must turn in research data (*e.g.*, laboratory notebooks) to their PIs or department if the research associated with their theses or dissertations was supported by grant. Research data may be considered supplementary files that can be submitted with a thesis and stored in the Rice Digital Scholarship Archive. In cases where graduate students' work is unfunded, students should confer with their assigned faculty advisor and department to determine whether any of their generated research data should be retained by the University.

Appendix 1: Data Management Check List

Scope and Responsibilities

- ☐ Who is responsible for which part of the data management?
- ☐ Who has access to which data during and after the research? Who will control access to the data? Who will use the data?
- ☐ How much data will be produced? Do you need extra resources to manage data, such as people, time or hardware?

Data Collection and Description

- ☐ Are you using standardized and consistent procedures to collect, process, check, validate and verify data?
- ☐ Are your structured data self-explanatory in terms of variable names, codes and abbreviations used?
- ☐ Which descriptions are contextual? Can documentation explain what your data means, how it was collected and the methods used to collect it?
- ☐ How will you label and organize the data, records, and files?
- ☐ How will data be consistently catalogued, transcribed and organized, *e.g.* standard template or input forms?

Data Formats

- ☐ Which data formats will you use? Do formats and software enable sharing and long-term validity of data, such as non-proprietary software and software based on open standards?
- ☐ When converting data across formats, do you check that no data or internal metadata has been lost or changed?

Data Storage, Confidentiality and Security

- ☐ Are your digital and non-digital data, and copies, held in a safe and secure location?
- ☐ Do you need to securely store personal or sensitive data?
- ☐ Do you know what the master version of your data file is?
- ☐ Does your data contain confidential or sensitive information? If so, have you discussed data sharing with the respondents from whom you collected the data?
- ☐ Are you gaining (written) consent from the respondents to share data beyond your research? Are there any privacy rules pertaining to the data?
- ☐ Do you need to de-identify the data, during research or in preparation for sharing?

- ☐ If data is collected with mobile devices, how will you transfer and store the data?
- ☐ Have you ensured that you retained the copyright to your data?
- ☐ If data is held in various places, how will you keep track of versions?
- ☐ Are your files backed up sufficiently and regularly and are back-ups stored safely?
- ☐ Have you made provisions to maintain long term storage of your data?

Data Retention, Depositing, Sharing and Disposal

- ☐ Is there a scientific or discipline specific standard for data sharing/integration?
- ☐ How long does the data need to be retained after the conclusion of the project?
- ☐ Have you made provisions for the appropriate disposal of the data?

Appendix B: NSF and NIH Data Management Guidelines

NSF Guidelines

Proposals must include a supplementary document of no more than two pages labeled “Data Management Plan.” This supplement should describe how the proposal will conform to NSF policy on the dissemination and sharing of research results (see AAG Chapter VI.D.4), and may include:

- the types of data, samples, physical collections, software, curriculum materials, and other materials to be produced in the course of the project;
 - the standards to be used for data and metadata format and content (where existing standards are absent or deemed inadequate, this should be documented along with any proposed solutions or remedies);
 - policies for access and sharing including provisions for appropriate protection of privacy, confidentiality, security, intellectual property, or other rights or requirements;
 - policies and provisions for re-use, re-distribution, and the production of derivatives; and
 - plans for archiving data, samples, and other research products, and for preservation of access to them.
- Data management requirements and plans specific to the Directorate, Office, Division, Program, or other NSF unit, relevant to a proposal are available at: <http://www.nsf.gov/bfa/dias/policy/dmp.jsp>. If guidance specific to the program is not available, then the requirements established in this section apply.
 - Simultaneously submitted collaborative proposals and proposals that include subawards are a single unified project and should include only one supplemental combined Data Management Plan, regardless of the number of non-lead collaborative proposals or subawards included. Fastlane will not permit submission of a proposal that is missing a Data Management Plan. Proposals for supplementary support to an existing award are not required to include a Data Management Plan.

NIH Guidelines

Investigators seeking \$500,000 or more in direct costs in any year should include a description of how final research data will be shared, or explain why data sharing is not possible. It is expected that the data sharing discussion will be provided primarily in the form of a brief paragraph immediately following the Research Plan Section of the PHS 398 application form (i.e., immediately after I. Letters of Support), **and would not count towards the application page limit.**

- **Data Sharing Plan (to follow immediately after the Research Plan Section)** The precise content of the data-sharing plan will vary, depending on the data being collected and how the investigator is planning to share the data. Applicants who are planning to share data may wish to describe briefly the expected schedule for data 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), and the mode of data sharing (*e.g.*, under their own auspices by mailing a disk or posting data on their institutional or personal website, through a data archive or enclave). Investigators choosing to share under their own auspices may wish to enter into a data-sharing agreement.

References to data sharing may also be appropriate in other sections of the application, as discussed below.

Budget and Budget Justification Sections

Applicants may request funds in their application for data sharing. If funds are being sought, the applicant should address the financial issues in the budget and budget justification sections. Some investigators have more experience than others in estimating costs associated with preparing the dataset and associated documentation, and providing support to data users. As investigators gain experience with the process, their ability to estimate costs will improve. Investigators working with archives can get help with data preparation

- A valid Data Management Plan may include only the statement that no detailed plan is needed, as long as the statement is accompanied by a clear justification. Proposers who feel that the plan cannot fit within the supplement limit of two pages may use part of the 15-page Project Description for additional data management information. Proposers are advised that the Data Management Plan may not be used to circumvent the 15-page Project Description limitation. The Data Management Plan will be reviewed as an integral part of the proposal, coming under Intellectual Merit or Broader Impacts or both, as appropriate for the scientific community of relevance.

Source:

http://www.nsf.gov/pubs/policydocs/pappguide/n sf11001/gpg_2.jsp#dmp.

and cost estimation. Investigators who are concerned about paying for data-sharing costs at the end of their grant can make prior arrangements with archives. Investigators facing considerable delays in the preparation of the final dataset for sharing should consult with the NIH program about how to manage this situation, such as requesting a no-cost extension.

Background and Significance Section (PHS 398 Research Plan Section B) If support is being sought to develop a large database that will serve as an important resource for the scientific community, the applicant may wish to make a statement about this in the significance section of the application.

Human Subjects Section (PHS 398 Research Plan Section E) If the research involves human subjects and the data are intended to be shared, the application should discuss how the rights and confidentiality of participants would be protected. In the Human Subjects section of the application, the applicant should discuss the potential risks to research participants posed by data sharing and steps taken to address those risks.

Source:

http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm