Supplemental Information for the NIH Human Data Sharing Policy Guidance for Investigators Developing Data Sharing Plans
7/29/2015

In accordance with the NIH Human Data Sharing Policy (HDS Policy), data sharing plans must be developed for all studies generating human data. This document offers intramural researchers preliminary guidance on developing these plans. It will be updated periodically.

Your Scientific Director or delegate will review and approve your plan.

Your data sharing plan (DSP) should describe, at least, what data will be produced and shared, how and where data will be shared, and the timeframe for sharing (generally, no later than the time of publication of the main findings). It should include a commitment to share, at a minimum, the data underlying any publications resulting from the research or an explanation of why sharing is not possible, e.g., informed consent limits, intellectual property issues (e.g., patent filings) or contractual obligations that would preclude sharing. When additional funds/resources will be needed, e.g., to prepare data for submission to an intramural or public repository, include those also.

The DSP format is not dictated by the Office of Intramural Research and your Institute or Center (IC) may develop or have a specific format to be used. Please consult with your Scientific Director for more specific guidance on the form and content that may be required within your IC. Please remember also that the form and content of your DSP may be affected by other policies applicable to your research, such as the NIH's *Genomic Data Sharing Policy* (2014).

DRAFT EXAMPLE DATA SHARING PLANS

Example 1 −Checklist with or without sharing

Data Sharing Plan for _____

What data will be shared?

I will share human data generated in this research for future research as follows (*check all that apply*):

- ☐ De-identified data in an NIH-funded or approved public repository.
- ☐ De-identified data in another public repository.
- ☐ Identified data in BTRIS (automatic for activities in the Clinical Center)
- ☐ De-identified or identified data with approved outside collaborators under appropriate agreements.
- ☐ I will not share human data generated in this research for future research. If checked, explain:

How and where will the data be shared?

Data will be shared through (*check all that apply*):

- ☐ An NIH-funded or approved public repository. Insert name or names:
_____.

- ☐ Another public repository. Insert name or names: _____.
- ☐ BTRIS (automatic for activities in the Clinical Center)
- ☐ Approved outside collaborators under appropriate individual agreements.
- ☐ Publication and/or public presentations.

When will the data be shared? (*check all that apply*)

- ☐ Before publication.
- ☐ At the time of publication or shortly thereafter.

Example 2 – Narrative with no data sharing

The proposed research will involve a small sample (less than 20 subjects) recruited from clinical facilities in the Baltimore area with Williams syndrome. This rare craniofacial disorder is associated with distinguishing facial features, as well as mental retardation. Even with the removal of all identifiers, we believe that it would be difficult if not impossible to protect the identities of subjects given the physical characteristics of subjects, the type of clinical data (including imaging) that we will be collecting, and the relatively restricted area from which we are recruiting subjects. Therefore, we are not planning to share the data.

Example 3 – Narrative with limited data sharing through individual agreements

The proposed research will include data from approximately 500 subjects being screened for three bacterial sexually transmitted diseases (STDs) at an inner city STD clinic. The final dataset will include self-reported demographic and behavioral data from interviews with the subjects and laboratory data from urine specimens provided. Because the STDs being studied are reportable diseases, we will be collecting identifying information. Even though the final dataset will be stripped of identifiers prior to release for sharing, we believe that there remains the possibility of deductive disclosure of subjects with unusual characteristics. Thus, we will make the data and associated documentation available to users only under a specific data-sharing agreement that provides for: (1) a commitment to using the data only for research purposes and not to identify any individual participant; (2) a commitment to securing the data using appropriate computer technology; and (3) a commitment to destroying or returning the data after analyses are completed. No additional funds are needed for this plan.

Example 4 – Narrative with data sharing through public, controlled-access database

We are collecting public-use data from a survey of more than 22,000 Americans over the age of 50 every 2 years. De-identified data products from this study will be made available without cost to researchers and analysts through _____ [database]. User registration is required in order to access or download files. As part of the registration process, users must agree to the conditions of use governing access to the public release data, including restrictions against attempting to identify study participants, destruction of the data after analyses are completed, reporting responsibilities, restrictions on

redistribution of the data to third parties, and proper acknowledgement of the data resource. Registered users will receive user support, as well as information related to errors in the data, future releases, workshops, and publication lists. Additional funds for data cleaning and upload in the amount $_____ are needed for this plan.