DATE: July 31, 2015
TO: All NIH Principal Investigators
Research Protocol Principal Investigators
Research Protocol Associate Investigators
NIH IRB Chairs
FROM: Deputy Director for Intramural Research, NIH
SUBJECT: Your responsibilities as part of NIH Genomic Data Sharing Policy

This memorandum transmits the NIH Intramural Research Program's (IRP) new manual chapter, the *Human Data Sharing Policy* (HDS Policy). It is long-standing policy and practice within the IRP to make data available to other researchers. Many Institutes and Centers (ICs) have specific programs in place to advance data sharing already, and there are a number of initiatives on the horizon to further promote data sharing.

The HDS Policy applies to all research projects with human data that begin pre-research scientific review on or after October 1, 2015. Proposed studies that begin scientific review before October 1, 2015 are not required to comply, though, consistent with long-standing NIH rules, investigators are expected to share their results, whenever possible, through traditional channels for sharing, e.g., publication, collaboration, etc.

You may comply with the HDS Policy's call for data sharing in many ways. Sharing data benefits you because data are used and published more broadly than they otherwise would be, promoting more rapid translation, and you can satisfy publisher's requirements for data sharing as well as NIH-wide expectations and requirements. This memorandum describes some of the many resources that are available to assist you, and we will be developing more as our experience grows. Your feedback is very welcome. I want to emphasize the following points about the new policy:

Data Sharing and Scope

The HDS Policy does not create any new requirements to share data, though it encourages data sharing to the maximum extent possible consistent with applicable law and regulations, agreements covering use of the data, and individual informed consents. Other NIH policies, like NIH's *Genomic Data Sharing Policy* (GDS Policy), about which I wrote on June 29, 2015, may require data sharing and the requirements of these policies must be met. The HDS Policy does not alter the requirements or timelines of other policies for your research.

The HDS Policy applies to all data from research with humans or human data or material, including clinical and epidemiologic, interventional or natural history studies, that are used to validate published results, and NIH owned or jointly owned, meaning, that they are housed and used in IRP (except when there is no NIH ownership interest and no use of the data by NIH staff). Under the HDS Policy:

- Data should be collected in a manner that permits and promotes the broadest sharing possible.

- Investigators should share data broadly for secondary research purposes, in all cases consistent with applicable laws, regulations, policies, and agreements.
- Investigators are encouraged to deposit data in publicly accessible Research Repositories for sharing to the extent feasible and possible.

Data Sharing Plans

Like the GDS Policy, the HDS Policy requires investigators to plan for data sharing prior to the start of their research. A data sharing plan (DSP) must be developed for any project that collects, uses or stores human data or derivatives of human data. The DSP is not standardized. Subject to any limits imposed by IC Scientific Directors or other policies, like the GDS Policy, investigators are free to draft their plans in whatever form, style or format works best for them, depending on the nature of the research, the subject's consent, and the availability of tools for data sharing, e.g., existing public databases. These plans should describe, at least, what data will be shared, how and where data will be shared, and the anticipated timeframe for sharing.

Depending on the circumstances of a particular study, the DSP may be limited, saying for example that "data cannot be shared due to human subject objections" (a rare event, given that data is to be de-identified before sharing and, for data generated by Clinical Center systems at least, data are shared within the IRP automatically through the Biomedical Translational Research Information System (BTRIS)) to a multi-page description of various public databases through which data will be deposited and distributed to future researchers. Review of DSPs is delegated to the Scientific Director or their designee.

Individual Consents

The HDS Policy recognizes that in some cases individual human subjects may object to future data sharing. Nonetheless, NIH, as a public institution engaged in scientific discovery, favors broad sharing of de-identified data for future research activities. The HDS Policy imposes no new consent requirements, but IRP investigators are expected to develop consent processes and forms to promote data sharing of de-identified data whenever possible. The HDS Policy includes example language that may be used for this purpose, and more examples may be developed as needed.

Relationship to Other Policies

The HDS Policy does not supplant, replace or modify any existing policies or requirements for data sharing. A list of some these other data sharing policies at the NIH can be found at: http://www.nlm.nih.gov/NIHbmic/nih_data_sharing_policies.html

Existing Resources

Unlike genomic data sharing, there is not a single, standard database through with data are to be shared like NCBI's database of Genotypes and Phenotypes (dbGaP). However, a wide array of resources is available to assist you in identifying public databases through which data can be

shared. Resources are also available to assist you in identifying repositories and developing data sharing plans. These include:

- NIH-supported repositories that make data accessible for reuse list: http://www.nlm.nih.gov/NIHbmic/nih_data_sharing_repositories.html.

- NHLBI Data Sharing Page: http://www.nhlbi.nih.gov/research/funding/human-subjects/data-sharing

- NIAID Data Sharing Page: http://www.niaid.nih.gov/researchfunding/tool/pages/datasharingex.aspx

- IOM Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk (2015): http://books.nap.edu/openbook.php?record_id=18998&page=R1

- IOM Discussion Framework for Clinical Trial Data Sharing (2014): http://books.nap.edu/openbook.php?record_id=18610&page=R1

Additionally, the IRP Sourcebook will shortly be launching a webpage devoted to data sharing that will include this information as well as sample plans and other resources. I look forward to your support in this effort and welcome your comments.

Thank you for your attention to this matter and for your efforts to implement the HDS Policy.

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        NIH IRB Administrators
        NIH Principal Investigators
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Attachments: HDS Policy, Manual Chapter 3016
               Supplemental Information for the NIH Human Data Sharing Policy -- Guidance for Investigators Developing Data Sharing Plans (7/29/15)