DATE: June 29, 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 is to clarify the NIH Intramural Research Program's (IRP) requirements for implementation of the *NIH Genomic Data Sharing (GDS) Policy* (GDS Policy).

The GDS Policy applies to all research projects generating "large-scale" genomic data on or after August 31, 2015, whether the projects are new or ongoing at that time. Final decisions about which studies are subject to the Policy, including some "smaller" research projects, are determined by the Institute or Center (IC) in light of the state of the science, the needs of the research community and the IC's programmatic priorities. Each IC generating covered data must appoint, or engage through another IC, a Genomic Program Administrator (GPA) to assist with implementation and serve as a resource for questions about the Policy. **Please contact your IC Scientific Director (SD) or GPA to get additional information about whether the genomic data you are producing is covered by GDS Policy.**

Also, please review the attached GDS Policy and the *Supplemental Information to the NIH GDS Policy* (Supplemental Information) if you have not done so already. They provide important information about the GDS Policy and examples of the types of studies covered. You may also want to review additional resources on the NIH Office of Science Policy website, found at https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/. Sharing data under the GDS Policy benefits you because data are used and published more broadly than they otherwise would be and because you can satisfy publisher's requirements for data sharing. I want to emphasize the following points:

Data Sharing Plans

All investigators doing research covered by GDS Policy must develop and have in place an approved data sharing plan prior to start of the research. If research is already underway, you should submit a data sharing plan by **August 31, 2015**. These plans should describe, at least, what data will be shared, how and where data will be shared, the timeframe for sharing and other details described in the GDS Policy. As a default, submission to an NCBI database will usually suffice. **The IC Scientific Directors, or their delegates, will provide further information about the format for data sharing plans, the name of your GPA, and will review and approve individual plans. Many ICs will be developing standardized plan formats, to be distributed shortly.**

Timelines

The GDS Policy and the Supplemental Information include required timelines for genomic data sharing. Generally, non-human data should be made publicly available no later than the date of initial publication and human genomic data six months after the initial data submission to NIH begins or at the time of the first publication, whichever occurs first. Each IC may establish shorter data release timelines to enhance public availability of data.

Sharing Human Data under the GDS Policy

While the GDS Policy applies to human and non-human data, there are several important considerations to emphasize for human data.

IRP investigators must submit covered human genomic data and associated data (e.g., phenotype and exposure data) to an NIH-designated repository, meaning a repository maintained or supported by the NIH either directly or through collaboration, unless the IC grants an exception. As has been the long-standing practice under the NIH Genome Wide Association Studies (GWAS) Policy, NCBI's database of Genotypes and Phenotypes (dbGaP) will be the repository in most cases.

Exceptions to deposit in an NIH-designated repository may be granted by the IC with review and approval by the DDIR when the IC cannot meet the NIH-required assurances for protecting the interests of individuals who are the subject of the data required in the "Institutional Certification" described below. When exceptions are made, investigators should share data, if at all possible, through alternative channels approved by the IC.

Registration
All human genomic data studies covered by the GDS Policy must be registered in dbGaP by the time that data cleaning and quality control measures begin, regardless of which NIH-designated data repository (e.g., dbGaP, GEO, SRA, the Cancer Genomics Hub) or alternative will ultimately house and distribute the data. NIH-designated data repositories need not be the exclusive source for facilitating the sharing of genomic data; investigators may also submit data to a non-NIH-designated data repository. Each PI should work with his or her IC's GPA to initiate the registration process.

De-identification
Before sharing, data should be de-identified according to the standards set forth in the HHS Regulations for the Protection of Human Subjects, at 45 CFR 46, and stripped of direct identifiers according to the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR 164.512. Data should be coded by the investigator and the key retained within the IRP.

Informed Consent and IRB Review
An IRB will review available informed consent materials to determine whether it is appropriate for data to be shared for secondary research use. Additionally, an IRB, or other appropriate body if designated by the IC, should review data submission plans for compliance with the Institutional Certification criteria set forth in the GDS Policy.

- *For studies using data or specimens collected after August 31, 2015*: IRP investigators should obtain participants' consent for their genomic and phenotypic data to be used for future research purposes and to be shared broadly, even if the data will be de-identified and even when data is from cell lines or clinical specimens if they are created or collected after August 31, 2015. ICs may allow exceptions to this requirement, on a case-by-case basis, for compelling scientific reasons.

- *For studies using data or specimens collected before August 31, 2015*: An IRB must assess whether data submission is not inconsistent with the informed consent provided by the research participant at the time of collection.

When broad sharing is not consistent with the informed consent of the research participants whose data are included in the dataset, IRP investigators should note any data use limitations in their data sharing plans and Institutional Certification.

Institutional Certification
As has been the practice for many years under the NIH GWAS Policy, each IC must complete an Institutional Certification as part of the data submission process. This document identifies whether human genomic data are being submitted for unrestricted- or controlled-access use and assures that certain provisions to protect the interests of research participants are satisfied. The requirements of the Institutional Certification should be considered in developing data sharing plans prior to the start of research. An Institutional Certification memorandum should be completed and sent from the Scientific Director, or delegate, to the IC GPA before research is begun whenever possible.

The details described above are not meant to be exhaustive. Please work closely with contacts in your IC for further information.

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

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CC: Dr. John Gallin, the NIH Clinical Center
Dr. Carrie D. Wolinetz, the NIH Office of Science Policy
NIH IRB Administrators
NIH Principal Investigators
Institute Directors
Clinical Directors
Scientific Directors

Attachments: GDS Policy
GDS Supplemental Information Sheet