# Title: National Cancer Institute/Division of Cancer Prevention

# Cancer Prevention Clinical Trials Network

# Genomic Data Sharing Guidance

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REVISION HISTORY (most recent first)

| Version | Effective Date | Summary of Changes |
|---|---|---|
| 2.0 | SEP-10-20 | Clarify LAO responsibility |
| 1.0 | AUG-17-2020 | Original version of document |

## 1. INTRODUCTION AND PURPOSE

The National Institutes of Health (NIH) Genomic Data Sharing (GDS) Policy sets forth expectations that ensure the broad and responsible sharing of genomic research data. Sharing research data supports the NIH mission, and is essential to facilitate the translation of research results into knowledge, products, and procedures that improve human health. NIH has longstanding policies to make data publicly available in a timely manner from the research activities that it funds.

## 2. SCOPE

The NIH Genomic Data Sharing (GDS) Policy applies to all NIH-funded research (e.g., grants, contracts, and intramural research) that generates large-scale human or non-human genomic data, regardless of the funding level, as well as the use of these data for subsequent research. Large-scale data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data.

The overarching NIH Genomic Data Sharing (GDS) policy applies to the collection of “large-scale” genomic data; however, DCP requires a Genomic Data Sharing Plan (GDSP) and Institutional Certificate (IC) for all CP-CTNet studies generating any genomic data (large or small).

For CP-CTNet studies that collect any human or non-human genomic data, a Genomic Data Sharing Plan (GDSP) and Institutional Certificate (IC) must be submitted.

## 3. LAO PRINCIPAL INVESTIGATOR RESPONSIBILITY

For each CP-CTNet study that generates any human or non-human genomic data, the Lead Academic Organization (LAO) is responsible for submitting to the DCP PIO:

a. The signed Genomic Data Sharing Plan (GDSP) and the provisional institutional approval with each concept (or first protocol iteration that identifies the need for the GDSP). If the institution performing the analysis is an AO, the AO should complete the GDSP and IC and forward them to the LAO for submission to the PIO.

- The PIO will forward the signed GDSP and provisional institutional approval to the DCP Medical Monitor, Scientific Lead, and Nurse Consultant, as well as to the CP-CTNet Director and CP-CTNet Program Official.
- The PIO will forward the signed GDSP, provisional institutional approval, and the concept or protocol to the DCP GDS Representative.

b. The final completed and signed Institutional Certificate after IRB approval of the protocol and GDSP.

- The PIO will forward the final institutional approval to the DCP Medical Monitor, Scientific Lead, and Nurse Consultant, as well as to the CP-CTNet Director, CP-CTNet Program Official, and the DCP GDS Representative.

NOTE: *Final DCP approval <u>will not</u> be delayed for receipt of Final Institutional Certification*

## 4. RESOURCES

NIH Genomic Data Sharing Policy
https://osp.od.nih.gov/wp-content/uploads/NIH_GDS_Policy.pdf

General information with step-by-step instructions
https://datascience.cancer.gov/data-sharing/genomic-data-sharing/extramural-grantees

GDSP template
https://datascience.cancer.gov/sites/default/files/2019-02/nci-dsp.pdf

Institutional Certificate template
https://osp.od.nih.gov/scientific-sharing/institutional-certifications/

## 5. APPENDICES

- None