

**Title:** **CP-CTNet Genomic Data Sharing Guidance**

Document ID: CP-CTNet REFGD05

Version: 8.0

Version Date: November 26, 2025

REVISION HISTORY (most recent first)

Version	Effective Date	Summary of Changes
8.0	NOV-26-2025	Updated Section 6 <i>Instructions for Submission of Genomic Data</i> to include instructions for obtaining the <i>Basic Study Information Form</i> . Updated links and changed DMACC to DMASC throughout the document.
7.0	FEB-07-2025	Added Section 4 <i>Institutional Certification (IC)</i> and Section 6 <i>Instructions for Submission of Genomic Data</i> . Updated Section 7 <i>Resources</i> to include new links associated with Section 6. Made minor editorial updates throughout the document.
6.0	MAY-24-2024	Updated resource links, made minor editorial clarifications.
5.0	FEB-21-2023	Added Definitions and Resources tables, replaced the resource links, and made updates throughout the document to align with the latest guidance from NIH.
4.0	JAN-24-2022	Clarification of who completes the GDSP.
3.0	SEP-02-2021	Clarification of LAO responsibility.
2.0	SEP-10-2020	Clarification of LAO responsibility.
1.0	AUG-17-2020	Original version of the 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 GDS Policy applies to all NIH-funded research (e.g., extramural (grants and contracts) and intramural) 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 genomic data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNPs) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data.

The overarching NIH GDS Policy applies to the generation of large-scale genomic data; however, the Division of Cancer Prevention (DCP) requires a Genomic Data Sharing Plan (GDSP) and Institutional Certification (IC) for all Cancer Prevention Clinical Trials Network (CP-CTNet) studies generating any genomic data (large or small).

For CP-CTNet studies that generate any human or non-human genomic data, a GDSP must be submitted. In addition, for CP-CTNet studies that generate any human genomic data, an IC must also be submitted.

**Note:** CP-CTNet members should consult the latest guidance on the GDSP provided by NIH when preparing the GDSP: *Instructions for Developing Genomic Data Sharing Plans*. They should consult the latest guidance on the IC and access the most recent IC template provided by NIH when preparing the IC: *Institutional Certification Instructions* and *Institutional Certification Template*.

## 3. DEFINITIONS

Term	Definition
AO	Affiliated Organization
CIRB	Central Institutional Review Board
CP-CTNet	Cancer Prevention Clinical Trials Network
dbGaP	database of Genotypes and Phenotypes
DCP	Division of Cancer Prevention
DMASC	Data Management, Auditing, and Statistical Center
DUL	Data Use Limitation
GDS	Genomic Data Sharing
GDSP	Genomic Data Sharing Plan
GPA	Genomic Program Administrator
GWAS	Genome-Wide Association Studies
IC	Institutional Certification
IRB	Institutional Review Board
LAO	Lead Academic Organization
M-SOP	Manual of Standard Operating Procedures
MM	Medical Monitor
NC	Nurse Consultant
NIH	National Institutes of Health

Term	Definition
PI	Principal Investigator
PIO	Protocol Information Office
SL	Scientific Lead
SNP	Single Nucleotide Polymorphism
SO	Signing Official
SOP	Standard Operating Procedure

#### 4. INSTITUTIONAL CERTIFICATION (IC)

The IC assures that institutions planning to submit human genomic data to NIH meet the expectations of the NIH GDS Policy. The IC, provided by the PI and SO of the submitting institution, clearly delineates any DULs on the research use of the data, as expressed in the informed consent documents signed by study participants.

For multi-site studies (with samples collected at several institutions), NIH understands that the submitting institution is not necessarily the local institution or IRB of record for all accruing LAOs and AOs. However, the submitting institution should assure NIH that it believes, based on either its own review or assurance from other institutions, that the expectations of the policy are met for the entire dataset. Institutions may choose to collect and submit a single-site IC from each accruing LAO and AO contributing samples or submit a multi-site IC. Single and multi-site ICs for both extramural and intramural studies can be found in the NIH GDS Policy.

#### 5. LAO PRINCIPAL INVESTIGATOR (PI) RESPONSIBILITY

For each CP-CTNet study that generates any human or non-human genomic data, the LAO PI is responsible for submitting to PIO:

1. The GDSP and provisional IC with the first protocol iteration that identifies the need for the GDSP (the GDSP and provisional IC may also be submitted with the concept). The institution performing the data analysis should complete the GDSP. If the institution performing the data analysis is an accruing LAO or AO, then the accruing LAO or AO should complete the GDSP and forward it, along with the provisional IC, to the LAO for submission to PIO.
  - 1.1. PIO forwards the GDSP and provisional IC to the DCP Study Team, as well as to the CP-CTNet Director and CP-CTNet Program Official.
  - 1.2. The DCP Study Team forwards the GDSP, provisional IC, and concept or protocol to the DCP GPA and works with the DCP GPA should any questions arise. Once any questions are resolved, the DCP Study Team sends the GDSP back to PIO and PIO sends the LAO either an approval letter or a pending letter.
2. The final completed and signed IC after CIRB approval of the protocol.
  - 2.1. The final IC should be sent to PIO within 60 days of CIRB approval of the protocol. Failure to send the final IC could affect future grant funding.
  - 2.2. PIO forwards the final IC to the DCP Study Team, as well as to the CP-CTNet Director and CP-CTNet Program Official.
  - 2.3. The DCP Study Team forwards the final IC to the DCP GPA and works with the DCP GPA should any questions arise. Once any questions are resolved, the DCP Study Team sends the final IC back to PIO and PIO sends the LAO either an approval letter or a pending letter.

**Note:** Final DCP approval will not be delayed for receipt of the final IC.

## 6. INSTRUCTIONS FOR SUBMISSION OF GENOMIC DATA

To comply with the NIH GDS Policy, CP-CTNet investigators must follow the steps below when submitting genomic data to DCP.

1. Complete data generation and cleaning
  - 1.1. The LAO contacts the DCP GPA (Claire Zhu, [zhucla@mail.nih.gov](mailto:zhucla@mail.nih.gov)) to request the *Basic Study Information Form*.
  - 1.2. Once data generation and cleaning are complete, the LAO prepares the *Basic Study Information Form*.
  - 1.3. The LAO submits the completed *Basic Study Information Form* to PIO for distribution to the DCP Study Team (i.e., MM, SL, and NC).
  - 1.4. The DCP Study Team forwards the *Basic Study Information Form* to the DCP GPA (Claire Zhu, [zhucla@mail.nih.gov](mailto:zhucla@mail.nih.gov)).
  - 1.5. The DCP GPA registers the study in the dbGaP system.
2. Upload data
  - 2.1. The dbGaP system sends the study PI an automated email on how to submit files to the repository using the submission portal. Assignment of an accession number generally takes a few days once the required fields have been received by dbGaP staff.
3. dbGaP study release
  - 3.1. Data is released to the public as soon as the data is accepted by the dbGaP system. There is no publication embargo.

## 7. RESOURCES

**Note:** All CP-CTNet SOPs are included in the [CP-CTNet Manual of Standard Operating Procedures \(M-SOP\)](#), which is available on the [CP-CTNet DMASC public website](#).

Resource	ID	Location
Institutional Certification Instructions	Reference	<a href="https://sharing.nih.gov">Sharing.nih.gov</a>
Institutional Certification Template	Template	<a href="https://sharing.nih.gov">Sharing.nih.gov</a>
Instructions for Developing Genomic Data Sharing Plans	Reference	<a href="https://sharing.nih.gov">Sharing.nih.gov</a>
NIH Genomic Data Sharing Policy	Reference	<a href="https://grants.nih.gov">grants.nih.gov</a>

## 8. APPENDICES

None