v.1 dated 3/11/2026

Columbia University Human Research Protection Office
Standard Operating Procedure (SOP) for submitting and reviewing GDS Institutional Certifications

Background

The National Institutes of Health (NIH) Genomic Data Sharing (GDS) Policy became effective on January 25, 2015.

- ➢ The GDS policy applies to all NIH-funded research that generates large-scale human or non-human genomic data and its use for subsequent research, specifically:
  - Competing grant applications that are submitted to the NIH for the January 25, 2015, due date or subsequent due dates;
  - Proposals for contracts that are submitted to the NIH on or after January 25, 2015; and
  - NIH intramural research projects generating genomic data on or after January 25, 2015.

  Please refer to the NIH description of the application of the GDS policy for further information: https://sharing.nih.gov/genomic-data-sharing-policy/about-genomic-data-sharing/does-gds-apply-to-my-research#when-does-the-nih-gds-policy-apply?

- ➢ The policy also applies when submitting large-scale human genomic datasets from non-NIH funded research to one of the NIH-designated data repositories.

Institutions and their IRBs are responsible for ensuring compliance with NIH's Genomic Data Sharing (GDS) Policy through review of data sharing plans and assurance that submission of data and subsequent sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained.

This assurance is conveyed through Institutional certifications signed by the Signing Official at the Investigator's institution.

Effective January 25, 2023, genomic data sharing considerations are expected to be addressed in the Data Management and Sharing (DMS) plans. Additional information about DMS plans is available on the NIH website: https://sharing.nih.gov/genomic-data-sharing-policy/developing-genomic-data-sharing-plans#after

Institutional Certifications:

Institutional certifications will be requested by the NIH in the following situations:

- For NIH funded studies that generate human or non-human genomic data: as part of the Just-In-Time additional grant application information, prior to funding.

- For non-NIH funded studies: At the time of submission of a human genomic data set to one of the following NIH-designated data repositories: dbGaP, dbSNP, dbVar, GenBank, GEO, SRA.

Columbia University (CU) Process for Review of Institutional Certifications

At Columbia, the signing official is the Assistant Vice President for Sponsored Projects Administration (AVP-SPA). The certification will be signed by the AVP-SPA upon confirmation from an appropriate HRPO staff member, e.g., Senior IRB Specialist, Director or HRPO unit head, that the protocol and the consent process approved by the IRB are compliant with the GDS policy.

In accordance with the policy, investigators who intend to use research or clinical specimens collected, or cell lines created, for projects initiated after January 25, 2015 (as described above), to generate genomic data **may generally only do so when informed consent processes explicitly discuss future research use and broad data sharing**, even if the data are generated from specimens that are de-identified.

1. Request to review an institutional certification form

1.1. Principal Investigators (PIs) who need to provide an institutional certification to NIH should complete and sign:
- the applicable Institutional Certification available on the NIH website
- the GDS Institutional Certification Request Form

1.2. Submit both completed forms in Rascal with the original review of the protocol/grant, as applicable, a new protocol or for already approved studies, a modification]. At the time of submission, send an email to notify the HRPO staff (IRB Senior Specialist, i.e., Manager or Senior Manager, supporting the IRB that has reviewed the protocol. The protocol overview page in Rascal will provide the IRB assignment. The HRPO directory provides the staff associated with each IRB.

Note that certification templates are based on whether data generated from specimens/cell lines were collected for research initiated on or after January 25, 2015 and, for specimens collected for research initiated before January 25, 2015, whether they were collected with consent or waiver of consent.

The email should provide the IRB approved protocol number associated with the certification.

2. HRPO Staff review

HRPO staff will conduct a congruency review to check the GDS requirements, with the scope of the review determined by whether the research is covered by the GDS policy.

2.1 Research not covered by the GDS policy:
HRPO staff will assess whether specimens were collected for research initiated before January 25, 2015. If so, and consent was obtained from subjects who donated their specimens, HRPO staff will confirm that either: the consent document does not preclude sharing, i.e., is silent with respect to sharing; or the consent form overtly permits sharing.

2.2. Research covered by the GDS policy:

2.2.1. Review of protocol:

HRPO staff will check that the protocol:

- includes the plan to share/submit data to NIH-designated data repositories, data submitted will be coded, and the key to the code that links the data to specific individuals will be held by the institution, or the data will be de-identified;
- specifies the sources of the data to be submitted (e.g., all participants in the study, a specific subset of individuals, participants from all sites, etc.;
- includes the list of the genotypic and/or phenotypic data that will be provided to the NIH;
- includes proposed restrictions (if any) for access.

2.2.2. Review of Consent forms:

The following elements will be checked:

- The protocol requires written consent from subjects if specimens were collected for research initiated after January 25, 2015.

- All approved **consent form** versions include the elements of consent required by the NIH. The consent form requirements under the GDS policy and NIH suggested language for each element are provided below.
  - **Consent form requirements under the GDS policy**
    To meet the expectations for future research use and broad sharing under the GDS policy, the consent form should provide research subjects with information addressing the following elements:
    - ✓ Genomic and phenotypic data, and any other data relevant for the study (such as exposure or disease status) will be generated and may be shared broadly and used for future research in a manner consistent with the participant's informed consent and all applicable federal and state laws and regulations.
    - ✓ Prior to submitting the data to an NIH-designated data repository, data will be stripped of identifiers such as name, address, account and other identification numbers and will be deidentified by standards consistent with the Common Rule and HIPAA. Safeguards to protect the data according to Federal standards for information protection will be implemented.

- ✓ Access to de-identified, individual-level participant data will be controlled, unless participants explicitly consent to allow unrestricted access to and use of their data for any purpose.
- ✓ Aggregate study information (including genomic summary results) and study analyses may be shared in the scientific literature or through other public scientific resources, such as data repositories or other data sharing resources that provide broad or unrestricted access to the information.
- ✓ Because it may be possible to re-identify de-identified genomic data, even if access to data is controlled and data security standards are met, confidentiality cannot be guaranteed, and reidentified data could potentially be used to discriminate against or stigmatize participants, their families, or groups. In addition, there may be unknown risks due to computational methods, analytic technologies, or techniques (e.g., generation of information that could allow participants' identities to be readily ascertained).
- ✓ No direct benefits to participants are expected from any secondary research on de-identified individual-level data or genomic summary results that may be conducted.
- ✓ Participants may withdraw consent for research use of genomic or phenotypic data at any time without penalty or loss of benefits to which the participant is otherwise entitled. In this event, data will be withdrawn from any repository, if possible, but data already distributed for research use will not be retrieved.
- ✓ The name and contact information of an individual who is affiliated with the institution and familiar with the research and will be available to address participant questions.
- ✓ The privacy protections, and limitations of those protections, afforded by a Certificate of Confidentiality to individual-level data do not apply to summary results.

If the HRPO review identifies the protocol and/or consent are not compliant with the GDS policy, the PI will be advised to update the protocol and/or consent form and bring the protocol/consent in compliance with the policy which may include re-consenting subjects for broad use of the data. Alternatively, the PI may provide justification for use of the data, if applicable, and re-consent is not feasible.

2.2.3. Review of the Institutional Certification Form:

The following elements will be checked:

- The **Data Use Limitations** listed on the certification are consistent with the consent form.

  Data Use Limitations are developed based on the informed consent that was obtained from the participants and the NIH expects that one of the four following main categories of consent groups will be selected in the Data Use

Limitations table, on page 3 of the institutional certification: General Research Use, Health/Medical/Biomedical, Disease-Specific or Other (for customized data use limitation).

Example: If the consent form specifies that data will only be used for research on a specific disease (e.g., lung cancer), that disease (i.e., "lung cancer") will need to be added as a data use limitation, next to the "Disease-specific" selection.

Additional Data Use Limitation modifiers can be added based on the information in the consent form: IRB Approval Required, Publication Required, Collaboration Required, Not-for-Profit Use Only, Methods, Genetic Studies Only.

For additional information on the interpretation of the standard data use limitations and modifiers, please refer to Points to Consider in Developing Effective Data Use Limitation Statements Following review, the HRPO staff member will confirm review of the certification and compliance with GDS via email to the AVP-SPA or designee.

When the HRPO review is able to confirm that the protocol and consent form are compliant with the GDS requirements, an email will be sent to the AVP-SPA for confirmation that the Institutional Certification can be signed.

3. Specific cases

3.1. A provisional certification may sometimes be used in a situation such as for a prospective study where the IRB has not completed its review of the protocol and therefore the institution cannot attest to all elements of the formal Institutional Certification. If a modification to the protocol is required, the HRPO will work with the PI to ensure the protocol and consent form are compliant with the GDS policy before final IRB approval. Congruency review will be re-confirmed before the final certification is signed.

3.2. Multicenter studies: The PI should check with their NIH project officer to determine which institution will certify. If CU certifies on behalf of other institutions, CU will first ask each collaborative site to provide a certification.

3.3. For studies that are reviewed by an external IRB: The PI should provide documentation of assurances from the reviewing IRB that the following GDS requirements are met before HRPO confirms the GDS certification can be signed.

- The appropriate research uses of the data and the uses that are specifically excluded by the informed consent documents are delineated;
- The identities of research participants will not be disclosed to the NIH GWAS data repository; and
- An IRB and/or Privacy Board, as applicable, reviewed and verified that:

- The submission of data to the NIH GWAS data repository and subsequent sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained;
- The investigator's plan for de-identifying datasets is consistent with the standards outlined above;
- It has considered the risks to individuals, their families, and groups or populations associated with data submitted to the NIH GWAS data repository; and
- The genotype and phenotype data to be submitted were collected in a manner consistent with 45 C.F.R. 46.