# Institutional Certification Process for Genomic Data Sharing

**Summary:**

**•The NIH, many journals, and some non-federal sponsors require that PIs deposit genetic data into the NIH's database for Genotypes and Phenotypes (dbGaP). All data submissions must be accompanied by Institutional Certification (IC).**

**•The NIH may require a Provisional Institutional Certification (PIC) if the IRB has not completed its review of the protocol and the institution cannot attest to all the elements of the formal Institutional Certification. The funding agency can require it for Just-in-Time (JiT) submissions.**

**•The Office for Human Research Studies (OHRS) will provide the study team with a completed Institutional Certification, which will then need to be signed by the appropriate Institutional Signing Official (ISO).**

**•The DFCI ISO is the Office of Grants and Contracts. For all other DF/HCC institutions please inquire locally for the name of your ISO for Institutional Certifications.**

**•For multi-cohort studies in which samples are collected from multiple institutions, the NIH will accept either one Institutional Certification covering all the study or multiple certifications from the various contributing institutions.**

**Background:**
The NIH Genome Data-Sharing Policy applies to all NIH-funded research that generates large-scale human or non-human genomic data as well as the use of the data for subsequent research initiated after the effective date. Under this policy, an Institutional Certification outlining the data sharing provisions in a NIH-funded study must be provided by the Institutional Signing Official (ISO) of the submitting institution, prior to the award of funding.

The Institutional Certification assures that:

- The data submission is consistent with applicable national, tribal, and state laws and regulations, and institutional policies.
- Any limitations on the research use of the data, as expressed in the informed consent documents, are delineated.
- The identities of research participants will not be disclosed.
- The IRB has reviewed the investigator's proposal or data submission.

In the Institutional Certification, based on OHRS review, the ISO will assure the following:

- The protocol for the collection of genomic and phenotypic data is consistent with DHHS regulations on protection of human subjects.
- Data submission and sharing are consistent with the informed consent of study participants.

- IRB has considered risks to individual participants and their families.
- IRB has considered risks to groups or populations associated with the submission.
- The investigator's plan for de-identifying datasets is consistent with the standards outlined in the GDS Policy.

Provisional Institutional Certification

- Intended to be used as needed on a case by case basis.
- Is submitted at the time of JIT when the Institution is unable to provide assurance of the elements of the formal institutional certification.
- The Provisional Institutional Certification is submitted until the formal Institutional Certification can be provided.
- Examples of when a Provisional Institutional Certification may be used:
    - The institution cannot attest to all the elements of the Institutional Certificate because OHRS has not completed its review of the protocol.
    - Prospective studies

**Certification Requests – For Research Not Yet Approved**

*To avoid delays, begin working with OHRS as soon as you learn that your grant is likely to qualify for funding.*

If you have not obtained prior IRB approval, you will need to complete and submit the appropriate "New Project Application" form to the Office for Human Research Studies for IRB Review and Approval. OHRS forms and guidance are available on the website.

- If a Just in Time is requested by the NIH, and the protocol and consent are not fully developed a Provisional Certification form may be issued for a prospective study where the certification is a condition of the award or the IRB has not completed its review of the protocol and therefore cannot attest to all the elements of the formal Institutional Certification. Submit the Institutional Certification Request Form along with the grant and Provisional Certification to OHRS via Special Submission.
- If the protocol has been developed, and the research team is ready to submit to the IRB, ensure that the data sharing plan is specifically described in the research protocol and aligns with the data sharing plan (part of the Resource Sharing Plan in NIH grants) outlined in the funding application. Submit the Institutional Certification along with the grant and New Protocol Application for review.

Once OHRS completes its review, OHRS staff will route the Institutional Certification for signatures. OHRS will forward the completed Institutional Certification to the Office of Grants and Contracts for institutional signature.

**Certification Requests – Previously DFCI IRB Approved Research**

Submit an Institutional Certification Request Form via Special Submission. If a grant congruency has not been completed, please submit the grant as well. Using the definitions below select the appropriate Extramural Institutional Certification form(s) found on the NIH website. Include the appropriate form(s) with your submission:

- **Extramural Certification forms: Used for prospective or retrospective studies where the IRB's review of the protocol and associated data sharing plan has been provided approval or determined exempt or Not Human Subjects Research. Three different forms exist to account for when the GDS Policy became effective (January 25, 2015).**

  (1) For studies using data generated from cell lines created or specimens collected AFTER January 25, 2015.

  (2) For studies using data generated from cell lines created or specimens collected BEFORE January 25, 2015

  (a) That lack consent

  (b) That have consent

  Guidance for filling out each type of IC form can be found on the OHRS website.

**Disapproved Certification Requests:** In some cases, OHRS may determine that an Institutional Certification cannot be provided due to inadequate consent, or other reasons.

a) It may be possible to amend the protocol. In this case, an amendment should be submitted separate from the IC request. The amendment should update the following information in the protocol, if not currently included.
   i) Summary of the intent to contribute data to dbGaP or another repository
   ii) Specific sources of data to be submitted (e.g., all participants in the study, a specific subset of individuals, participants from all sites, etc.)
   iii) List of the genotypic data that will be provided
   iv) List of the phenotypic data that will be provided
   v) Statement of the proposed access restrictions (if any) for access
   vi) Plan for removing identifiers from the data to be provided
   vii) Plan for obtaining consent from previous participants using the revised consent form (if applicable)

b) For protocols where the informed consent form lacks the required sharing language, an IRB amendment will need to be submitted to revise the informed consent form. The consent form will need to be revised to include the NIH-required genomic data sharing language. Please note that the institutional expectation is that the default Data Use Limitation will be "Health/Medical/Biomedical," unless a more specific limitation is required by the consent form. This language is available in the resources below.

c) Alternatively, the NIH may grant an exception to the GDS Policy requirements if there is a compelling scientific reason. Please refer to the NIH GDS Policy for more information.

**Resources:**

**NIH Guidance on Institutional Certifications**

**NIH Guidance on Data Sharing Policy and Implementation**

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