Title: NIH Controlled Access Data, Institutional Certificates, and the IRB - SOP 27
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27.1. Executive Summary

This unit standard contains expectations outlining the responsibilities of the NC State University investigator, the IRB, and the Institutional Official or their designee in requesting access to, submitting, reviewing, or providing data from studies generating large-scale human genomic data, including NIH's required Institutional Certification for a submission or receipt of data to and from NIH's Controlled Access Data Repositories (opens in a new window) dbGaP or other repositories from NIH subject to the GDS policy (opens in a new window).

27.2. Standard Operating Practice

All submissions to, or receipt of data from the National Institutes of Health (NIH) data repository dbGaP (database of Genotypes and Phenotypes) or other Controlled Access Data repositories from NIH are subject to the NIH Genomic Data Sharing Policy (GDS Policy) (opens in a new window). This includes researchers proposing to submit data from studies generating large-scale human genomic data, including genome-wide association studies (GWAS).

NIH requires submissions for accessing "Controlled Access Data to include review by an IRB and institutional certification (opens in a new window). At NC State, the IRB's Institutional Official or their designee provides this certification (REG 01.20.02, section 4.2).

All requests for access to the Controlled Access Genomic Data must submit an IRB application including a "Data Access and Security Plan" created with NC State Security and Compliance, to the NC State University IRB. Once approved, submit a Data Use Certification to the appropriate NIH Data Access Committee for approval and adhere to all data security controls and data management requirements.

27.3. Operational Procedures

NIH's database of Genotypes and Phenotypes (dbGaP) was developed to archive and distribute the results of studies that have investigated the interaction of genotype and phenotype. The following procedures detail expectations for NC State stakeholders submitting or receiving controlled data from dbGap or other repositories from NIH subject to the GDS policy.

27.3.a. Definitions

1. **Controlled Access Genomic Data** is considered sensitive, identifiable human genetic information protected by privacy regulations or requiring authorized access that can only be obtained if a user has been given authorization. At NC State, Controlled Access Genomic Data is considered "highly sensitive" and in rare cases "ultra-sensitive" and requires IRB approval for use and sharing.

2. **Data Access Committee (DAC):** Data Access Committees are established based on programmatic areas of interest as well as technical and ethical expertise. All DACs will operate through common principles and under similar mechanisms to ensure the consistency and transparency of the controlled-data access process.

3. **Data Use Certification (DUC):** A Data Use Certification is the application a user submits to a particular study's Data Access Committee (DAC) for consideration for authorized use of controlled dbGaP data. The Data Use Certification should include a list of the controlled data set(s) required by the user and a brief description of the proposed research use of the requested data.

4. **Data Access and Security Plan from NC State:** This plan details the data security controls required for a research protocol involving human subjects that access, collect, or generate highly or ultra-sensitive data (opens in a new window) or require a NIH data sharing plan (NIH DMSP) related to genomic data.

5. **Data Use Limitations** are based on language in the informed consent forms as well as any additional considerations deemed necessary by an IRB or equivalent review body committee. Data Use Limitations (opens in a new window) restrict how the submitted data will be used or how the accessed data can be used.

6. **Genomic Data Sharing Plan:** Genomic Data Sharing (GDS) plans (opens in a new window) describe how the research will meet the expectations of NIH's GDS Policy. This plan is now combined into the NIH's "Data Management and Sharing Plan." NIH's Data Management and Sharing Plan (DMSP) is required by the NIH and describes the data management, preservation, and sharing of scientific data and accompanying metadata.

7. **Implementation Update for Data Management and Access Practices Under the Genomic Data Sharing Policy,** NOT-OD-24-157 (opens in a new window), which includes additional IT security requirements.

8. **Institutional Certification** is provided by the submitting investigator and a signing official (SO) at the investigator's institution, assures NIH that submission of large-scale human genomic data to an NIH-designated data repository is consistent with the NIH GDS Policy, the informed consent of the original study participants, and/or the preferences of the original study population. The institutional certification also states whether, after IRB review, research use limitation is deemed necessary. This certification is signed by the NC State University Institutional Official or their designee.

9. **Institutional Certification (Provisional)** is a provisional certification provided to the NIH pending submission of the Institutional Certification and is to accompany the Just-in-Time (JIT) information submitted. This provisional certification (opens in a new window) serves as an assurance that future data sharing outlined in the NIH data management and sharing plan addresses genomic data sharing and will be consistent with the elements delineated in the Institutional Certification.

10. **Institutional Signing Official (SO):** The label, "Institutional Signing Official" refers to the individual that has institutional authority to legally bind the institution in administrative matters. The individual fulfilling this role may have any number of titles in the institution but is typically located in its Office of Sponsored Research or equivalent.

11. **NIH Genomic Data Sharing (GDS) Policy,** NOT-OD-14-124 (opens in a new window), which sets forth NIH's expectations for the broad and responsible sharing of large-scale human and

non-human genomic data.

12. **Open Access Data** front the NIH can be browsed online or downloaded from dbGaP without prior permission or authorization. Unless analysis of this data will lead to re-identification of a living individual, IRB approval through NC State is not required for the use of this data.

13. **Scientific Data:** The recorded factual material commonly accepted in the scientific community as of sufficient quality to validate and replicate research findings, regardless of whether the data are used to support scholarly publications.

27.3.b. Applicability

27.3.a.i. The NIH GDS Policy applies to all NC State University investigators who:

1. Have funding by the NIH and generate large-scale human or non-human genomic data;

2. Generates small-scale genomic data that NIH or the funding Institutes or Centers (ICs) (opens in a new window) determines should be shared because of the state of the science, programmatic priorities, utility, and/or value of the data for the research community.

3. Plan to voluntarily submit any genotype/phenotype data into dbGaP or other repositories from NIH subject to the GDS policy, or

4. Plan to access controlled data from dbGaP or other repositories from NIH subject to the GDS policy, regardless of funding source.

27.3.a.ii. The NIH GDS Policy does not apply to:

1. NIH-funded research submitted prior to January 25, 2015, though the NIH strongly encourages all NIH-funded research to comply with the expectations outlined in the GDS Policy.

2. A project that generates genomic data but it is not within the GDS policy's intended scope including: instrument calibration, statistical or technical methods development, use of genomic data for control purposes such as assay development.

27.3.c. Responsibilities for Submission a Controlled Access Data repository subject to the GDS policy.

27.3.b.i. Investigators are responsible for developing a data sharing plan for the NIH in accordance with the NIH's Data Management and Sharing (DMS) Policy that describes:

1. The consistency of informed consent with submission to the NIH GDS repository and subsequent sharing with other researchers for other research projects;
    a. Study participants must be informed in the consent process that their study-related materials will be submitted to public, scientific databases such as dbGaP or other repositories from NIH subject to the GDS policy.
    b. NIH expects that informed consent for future research use and broad data sharing will have been obtained even if the cell lines or clinical specimens are de-identified. This data sharing requirement may be addressed in the Informed Consent form with the required NIH statements in it or via seeking Broad Consent from participants.

2. How informed consent was or will be obtained for prospectively collected samples or data; and

3. How data will be subsequently de-identified prior to submission to the Controlled Access Data repositories from NIH subject to the GDS policy. NIH recommends that the data provided to Controlled Access Data repositories from NIH subject to the GDS policy are
    a. coded, and
    b. participants are/were informed that they are free to withdraw their data from the NIH database (although data that have been distributed for approved research cannot be retrieved).

4. When applying for IRB approval for the use of the controlled access data, the Data Management and Sharing plan (DMSP) must be uploaded to the IRB application with a correlating “Data Security and Access Plan” created with NC State’s Security and Compliance.

27.3.c.ii. The IRB must review the investigator’s plans for data submission and verify that:

1. The submission of data to Controlled Access Data repositories from NIH subject to the GDS policy and subsequent sharing for research purposes is consistent with the informed consent of study participants from whom the data were obtained

2. The investigator’s plan for de-identifying datasets is consistent with the standards outlined in the NIH GDS policy

3. The risks of further research on the GDS data to particular individuals, their families, and groups or populations (e.g., stigmatization) has been considered and minimized, and

4. The genotype and phenotype data to be submitted were collected in compliance with 45.CFR.46.

5. Researchers have the appropriate data security training completed.

6. Researchers are handling this data within the scope of their appointment at NC State and have the appropriate credentials to manage this type of data.

7. Researchers have access to appropriate resources to ensure adherence to required security controls.

8. The IRB informs the NC State Institutional Official or their designee that all human subjects concerns, including consistency with the approved protocol and Informed consent, have been addressed and are consistent with the proposal to submit data to the controlled access data repositories subject to the GDS policy.

27.3.c.iii. The Institutional Official or their Designee is responsible for providing a certification letter or approval in the NIH Controlled Access Data system, verifying that:

1. The data submission is in compliance with all applicable laws and regulations, as well as institutional policies;

2. The appropriate research uses of the data and the uses that are specifically excluded by the consent documents are delineated; and

3. The identities of research participants will not be disclosed to the Controlled Access Data

repositories from NIH subject to the GDS policy.

4. The NC State Institutional Official or their designee is responsible for approving the submission to the NIH data repository.

5. Certification must be provided for all sites contributing samples to the Controlled Access Data repositories from NIH subject to the GDS policy.
    a. The lead site may submit one institutional certification on behalf of all collaborating sites.
    b. Alternatively, each site providing data may provide its own institutional certification.

27.3.d. Procedures for Submitting Data

27.3.d.i. For Institutional Certification of a data submission to Controlled Access repositories from NIH subject to the GDS policy, an NC State University investigator must provide the following information to the NC State IRB:

1. An NC State IRB protocol number where the protocol includes:
    a. A description of all data fields (genotype and phenotype) being submitted to Controlled Access Data repositories from NIH subject to the GDS policy
    b. A copy of the consent form(s) used to enroll participants and collect their samples and phenotype data. This includes all versions used with participants.
    c. A description of the method(s) used to code identifiers associated with the data for transmission to Controlled Access Data repositories from NIH subject to the GDS policy and how the key linking the identity of each study participant will be maintained.
    d. A written statement by the NC State University investigator that the key to identifiers of study participants will never be shared by the NC State University investigator with NIH.

2. Submission of the NIH Data Management and Sharing Plan that the researchers submitted the NIH.

3. Submission of a Data Access and Security Plan made with NC State University's Security and Compliance which operationalizes the NIH Data Management and Sharing Plan.

4. Proof of completion of the appropriate data security training.

5. Confirmation that handling this data is within the scope of their appointment at NC State and that the researchers have the appropriate credentials to manage this type of data.

6. Confirmation that researchers have access to appropriate resources to ensure adherence to required security controls. This can be completed through the IRB’s Data Access and Security Plan.

7. For data submissions where the NC State University investigator is submitting data to a Controlled Access repository where NC State University was not the IRB of record on the protocol under which the original samples and phenotype data were collected:
    a. The NC State IRB will request certification from the IRB of record,
    b. If there was no review completed by an IRB of record with an FWA, the NC State University IRB will review the consent forms and other materials in accordance with the procedures outlined below, in the section 27.3.d.ii “IRB Review and Verification.”

27.3.d.ii. IRB Review and Verification: For any proposed submission of phenotype data and genotype data to Controlled Access Data **repositories from NIH subject to the GDS policy, the NC State University IRB will review the research protocol and consents provided by the PI via the IRB application to determine whether:**

1. Specimens and data were, or will be, collected in compliance with 45 CFR 46 and any other applicable federal or state law, including informed consent;

2. The risks of further research on the genomic data to particular individuals, groups, or populations (e.g., stigmatization) has been considered and minimized; and

3. Data are appropriately de-identified:
    a. The deidentified data meets the standards for de-identification under 45 CFR 46 and HIPAA Privacy Rule;
    b. The de-identified data is assigned a random, unique code and the code key will not be shared with NIH.

4. The NIH Data Management and Sharing Plan and the NC State Data Access and Security Plan are in place and account for data sharing.

27.3.d.iii. IRB determination: After reviewing the research protocol, data sharing plan, data access and security plan, and the relevant consents, the NC State University IRB may determine the following:

1. That the consent form(s) and information reviewed (including all relevant materials) is consistent with the proposal to submit to repositories from NIH subject to the GDS policy;

2. That the consent form(s) and information reviewed (including all relevant materials) is not consistent with the proposal to submit to repositories from NIH subject to the GDS policy;
    a. reasons supporting this would include, but not be limited to, the fact that original consent was obtained where no data sharing information was provided or a waiver of informed consent was granted.

3. That the consent form(s) and information reviewed (including all relevant materials) is not consistent with the proposal to submit to repositories from NIH subject to the GDS policy, but that an attempt to cure the deficiency is appropriate. Therefore, as a condition for submission, the IRB may:
    a. Require revision of the consent form(s) to be consistent with a submission of data to repositories from NIH subject to the GDS policy with re-consent of the research participants;
    b. Permit the submission, but subject to certain restrictions or limitations on use, as the relevant NC State University IRB may specify; or
    c. Request additional information, as necessary.

27.3.d.iv. Cooperative Research

1. Data from studies using secondary data or specimens in which NC State University is the IRB of record: the NC State University IRB will determine whether each relevant version of the consent forms are consistent with submission of genotype and phenotype information into the repository. In reviewing this requirement, the IRB may consider the following questions:
    a. Do the consent documents identify future research use of the specimens or data?

   b. Do the consent documents address disposal of the specimens or data?
   c. Do any of the consent forms contain statements such as “your data/specimens will not be shared” or “will only be seen by the research team?”
   d. Were any of the contributors of specimens children?
   e. Did the original consent forms limit future use to specific projects, conditions, disease states, or to non-commercial research?
   f. Were any of the phenotype data (e.g., medical record information) collected under a waiver of consent?
   g. Was Broad consent for future unspecified research sought

2. Data from Prospective studies in which NC State University is the IRB of record: In addition to the considerations listed above in section 27.3.d.iv.1, for the submission of genomic data on prospectively collected specimens the NC State University IRB may consider:
   a. Whether the consent documents adequately explain genetic testing, heritable traits, DNA, genes, or genotyping.
   b. Additionally, the consent form(s) for prospective studies must:
      i. Describe the repository, broad data sharing, and the risks associated with these research activities; and
      ii. Describe the likelihood of re-identification in the future.

27.3.d.v. Provisional Institutional Certification

The Provisional Institutional Certification is a specific type of certification used for data submission to Controlled Access Data repositories from NIH subject to the GDS policy, often requested by NIH during the Just-in-Time process before a grant is officially awarded.

1. The Provisional Institutional Certification is typically used for a prospective study where the IRB review of the protocol and consent form(s) is not complete or has not been submitted.
   a. The PI is responsible for obtaining a Provisional Institutional Certification form from the NIH and providing it to the NC State Institutional Official for review and sign-off.
   b. The researcher must complete the Provisional Institutional Certification, including signing the form before it is sent to NC State’s signing official.

2. A final, formal Institutional Certification is submitted to the NIH once IRB review and approval are finalized.
   a. The PI is responsible for obtaining the Institutional Certification form from the NIH and providing it to the NC State Institutional Official for review and sign-off.
   b. The researcher must complete the Institutional Certification, including signing the form before it is sent to NC State’s signing official.

27.4. Procedures for Receiving Data

As a Principal Investigator, accessing Controlled Access Data from NIH repositories subject to the GDS policy involves two distinct processes, depending on whether the data is Open Access or Controlled Access.

27.4.a Accessing Open Access Data

Open Access data contains summary-level information, study documentation, and frequently asked questions. This information is generally not considered sensitive and does not require authorization.

These data can be accessed by navigating to the dbGaP website. IRB review and approval is not required.

27.4.b. Accessing Controlled Access Data

Controlled Access data includes the individual-level genotype and phenotype data (e.g., individual-level health records and genomic files). Access to this data requires a formal application that is co-signed by NC State's Institutional Official or their designee and subsequently approved by the NIH Data Access Committee.

1. Before submitting to the NIH, researchers wanting to access Controlled Data must work with their department research office or Associate Dean for Research to ensure that there are adequate IT resources available to work with this type of data. At NC State accessing and working with this data requires access to an "HPC" or "SURE" environment.

2. Researchers wanting access to controlled data must submit a Data Use Certification to the appropriate NIH Data Access Committee for approval.

3. Data Access Committee approval for controlled data access will be dependent upon completion of the Data Use Certification, and confirmation that the proposed research use is consistent with participant consent forms and any constraints identified by the institutions that submitted the dataset to repositories from NIH subject to the GDS policy.

27.4.c IRB Review for Controlled Access Data

For most requests to receive controlled-access data from Controlled Access Data repositories from NIH subject to the GDS policy, IRB review falls into one of three categories, depending on the nature of the data.

1. Not Human Subjects Research (NHSR): The primary data that is accessed is not considered "about a living individual" since all identifiers are removed and the investigator has no access to the code key nor is the investigator completing analysis that will lead to re-identification of an individual.
   a. An IRB application is not required for data eligible for an NHSR determination, but NC State data sensitivity standards and subsequent controls apply.

2. Exempt Research: The use of coded, non-identifiable private information or biospecimens may be considered exempt under 45.CFR.46.
   a. An IRB application is required for an exemption determination.
   b. Privacy and Confidentiality requirements as detailed in 45.CFR.46 and NC State University data sensitivity standards and subsequent controls are applicable to studies eligible for an exemption determination made by the IRB office.
   c. An Exemption determination that uses data from a repository subject to the NIH GDS policy will be required to submit a Data Access and Security plan made with NC State's Security and Compliance.
   d. An Exemption determination that uses data from a repository subject to the NIH GDS policy will have an annual approval expiration date and approval must be renewed yearly.
   e. An Exemption determination that uses data from a repository subject to the NIH GDS policy will be required to submit closure information to the IRB office.

3. Expedited Approval: The use of coded, identifiable or re-identifiable private information or biospecimens may be eligible for expedited review under 45.CFR.46.
    a. An IRB application is required for studies reviewed and approved via expedited procedures.
    b. All requirements for approval as detailed in 45.CFR.46 and NC State University data sensitivity standards and subsequent controls are applicable to studies approved at the expedited level.
    c. In some cases, the original submitting institution may have placed a specific restriction on the data that requires IRB approval at the expedited level. This is often noted on the dbGaP study page itself under Data Use Limitations.
    d. A study reviewed via expedited procedures that uses data from a repository subject to the NIH GDS policy will be required to submit a Data Access and Security plan made with NC State's Security and Compliance.
    e. A study reviewed via expedited procedures that uses data from a repository subject to the NIH GDS policy will have an annual approval expiration date and approval must be renewed yearly.
    f. A study reviewed via expedited procedures that uses data from a repository subject to the NIH GDS policy will be required to submit closure information to the IRB office.

4. Full Board Approval: The use of coded, identifiable or re-identifiable private information or biospecimens may require Full Board review and approval under 45.CFR.46.
    a. An IRB application is required for studies reviewed and approved by the convened Full Board.
    b. All requirements for approval as detailed in 45.CFR.46 and NC State University data sensitivity standards and subsequent controls are applicable to studies approved by the convened Full Board.
    c. In some cases, the original submitting institution may have placed a specific restriction on the data that requires IRB approval by the convened Full Board. This is often noted on the dbGaP study page itself under Data Use Limitations.
    d. A study reviewed by the convened Full Board that uses data from a repository subject to the NIH GDS policy will be required to submit a Data Access and Security plan made with NC State's Security and Compliance.
    e. A study reviewed by the convened Full Board that uses data from a repository subject to the NIH GDS policy will have an annual approval expiration date and approval must be renewed yearly.
    f. A study reviewed by the convened Full Board that uses data from a repository subject to the NIH GDS policy will be required to submit closure information to the IRB office.

5. IRB Applications for the Use of Controlled Access Data from the NIH must include:
    a. A justification that the proposed research is consistent with the dataset's specific Data Use Limitations.
    b. Research Use Statement: Copy and paste or upload the Research Use Statement you submitted and had approved in the dbGaP Authorized Access System.
    c. Variables/Data Elements: Provide a list of the general types of data that will be analyzed.
    d. The completed NIH Data Management and Sharing Plan required by the NIH
    e. An NC State University "Data Access and Security plan"
        i. NC State IT personnel will ensure that the study meets the requirements of the NIH Data Use Certification and NIST SP 800-171 as applicable.

        ii. Researchers can request this plan before submitting the IRB application or as part of the IRB review process.
    f. Researchers must provide proof of completion for appropriate data security training.
    g. Researchers must describe how handling this data is within the scope of their appointment at NC State.
    h. Researchers must describe how they have the appropriate credentials to manage this type of data (often demonstrated through the NC State Data Access and Security Plan).
    i. Researchers must describe how they have access to appropriate resources to ensure adherence to required security controls detailed in the NC State Data Access and Security Plan.

6. Regardless of the human subjects' determination or approval level, the Institutional Signing Official will certify the Data Use Certification.

Appendix A

Additional Definitions and Terms

A GENOME WIDE ASSOCIATION STUDY (GWAS) is defined as any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits or the presence or absence of a disease or condition.

dbGaP is NIH's GWAS databank for genotypic and phenotypic data. dbGaP contains only data, not specimens.

The human genome is all the DNA contained in an organism or a cell, including both the DNA comprising chromosomes within the nucleus and the DNA in mitochondria.

Institutional Official: At NC State University, the Institutional Officials include the University Chief Research Compliance Officer for the University Area IRB and the Institutional Officials for the HSPH and HMS IRBs.

Phenotype data are data on health conditions, behavioral characteristics, or measurable observable traits (such as blood pressure, alcohol consumption, cholesterol, or eye color) that are obtained during physical or psychological examinations and maintained in a medical or research record. Phenotype data may also include information about medical treatments, drug tolerance, and family medical history as well as responses to questionnaires.

NIH GWAS DATA SHARING POLICY: ("GWAS Policy") is the policy that GWAS data obtained with NIH support should be shared through a central repository when such data sharing is compatible with the consent provided by the participant.

Retrospective studies: Studies that are using pre-existing genetic materials and previously collected data. IRBs are expected to determine whether the initial consent process under which the pre-existing genetic materials and data were obtained is consistent with the submission of data to the NIH GWAS repository and sharing of data, and also is in accordance with the GWAS policy.

Prospective studies: Studies performed in which GWAS was part of the study design at the time research and participants provided their consent for phenotype data and samples to be collected for the study.

The consent form and process must comply with the requirements of 45 CFR, Part 46 and any other applicable law. The informed consent process and document should state that participants' DNA will undergo genome-wide analysis and that genotype and phenotype data will be shared for research purposes through the NIH GWAS data repository.

Appendix B

Reviewer Checklist for Data subject to the GDS Policy at NIH

Studies involving human genomic data, such as GWAS, sequencing, genotyping, epigenomics, gene expression, and phenotypic data, need to be registered and submitted to dbGaP if they are NIH-funded or fall under NIH Genomic Data Sharing Policy. For studies where data will be submitted to dbGap or other repositories subject to the GDS policy, the IRB will include the following in their review:

Informed Consent and Broad Consent

- Broad Sharing: Does the consent form explicitly state that data will be shared with other researchers, NIH databases, or a national repository?
- Genomic Specifics: Does the consent explain that DNA/RNA/genomic analysis will be performed?
- Withdrawal Policy: Does it explain that while a participant can withdraw from the primary study, data already shared in dbGaP cannot be retrieved once distributed?
- Commercial Use: Does the consent allow for-profit or commercial entities to access the data?

Risk and Benefit Assessment

- Individual/Family Risk: Consider the risk of re-identification (rare diseases or small, isolated populations)?
- Group/Population Risk: For studies involving specific ethnic or geographically defined groups, has the risk of stigmatization or group harm been evaluated?
- Benefit: Do the societal benefits of broad genomic sharing outweigh the risks of re-identification?

Accessing Data

- IRB review is not required for Open Access Data.
- Some Controlled Access data requires IRB review before submission of data or to receive data from the repository.
  - If the data are identifiable or re-identifiable to the researcher
  - If the submitting IRB required IRB approval for future use
- A study can be eligible for an NHSR determination, exemption determination, or expedited review and approval.
- All dbGaP datasets can be reviewed as secondary research with the following addressed:
  - Data Access and Security Plan: This must be completed before approval.
  - Data Use Limitations (DUL): The PI should include the DUL from the dataset and a justification that the proposed research is consistent with the DUL.
  - Research Use Statement: The PI must provide the “Research Use Statement” they submitted and had approved in the dbGaP Authorized Access System.
  - Variables/Data Elements: Provide information about the general types of data they will be analyzing.
  - Waivers of Consent: In order to be submitted to the dbGap database or other repositories subject to the GDS policy, all data must be accompanied by consent for future research.

Appendix C

Signing Official Certification Instructions

1. Certifying a Data Submission (Institutional Certification)

When an investigator wants to submit a dataset to dbGaP, the institutional official or their designee needs to certify that the data were collected ethically and match the consent and IRB approved information.

1. The PI prepares the Institutional Certification form.
2. The PI signs the Institutional Certification form and submits it to the institutional official or their designee.
3. Before signing, the the institutional official or their designee confirms:
   - The submission is consistent with applicable laws and institutional policies.
   - The risks of genomic data sharing have been considered.
   - The IRB has reviewed and approved the data sharing.
4. The signed certification is typically sent to the Genomic Program Administrator at the NIH.
5. Once the Genomic Program Administrator approves the certification, they will initiate the study registration in dbGaP, allowing the PI to begin uploading data.

2. Provisional Institutional Certification (PIC)

1. The PI is responsible for providing the Provisional Institutional Certification form.
2. The PI signs the Provisional Institutional Certification form and submits it to the institutional official or their designee.
3. Before signing, the institutional official or their designee must confirm that the document contains the following assurances, even if the final consent is pending:
   - Intent to Comply: The institution intends to adhere to the Genomic Data Sharing Policy.
   - Future Consent: For prospective studies, the informed consent documents will be designed to permit sharing through the controlled-access section of dbGaP.
   - Data Use Limitations : Any planned limitations on future use are clearly outlined and will be incorporated into the final Institutional Certification.
4. The institutional official or their designee electronically signs the form.
5. The Provisional Institutional Certification acknowledges the intent to comply before IRB approval, while the Full Institutional Certification is the final, verified assurance of compliance post-IRB review.

3. Approving a Data Access Request

When a researcher wants to use existing data from a repository subject to the GDS policy, the request is automatically routed to the institutional official or their designee for electronic sign-off.

1. The PI completes a Data Access Request in the dbGaP Authorized Access System.
   - They will select the institutional official's or their designee's name from a pre-populated list of registered signatories from NC State.
2. The institutional official or their designee will receive an automated email from dbGaP stating that a request is Awaiting Approval.
3. The institutional official or their designee will login to the eRA Commons.
   - On the dashboard the signing official can view the PI's research use statement, the IT Director's information, and the specific datasets requested.
   - If it meets NIH and institutional requirements, the signing official electronically signs the request. This moves it to the NIH Data Access Committee for final review.
   - If changes are needed, the signing official can send it back to the PI for revision.

4. Every year, the signing official must also approve the PI’s Project Renewal or Project Closeout report, which includes confirming that data destruction protocols were followed if the project is ending.