Outlook

NIH Genomic Data Sharing (GDS) Institutional Certifications - IRB Review Process

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To cuhs-irb@LISTS.CUMC.COLUMBIA.EDU <cuhs-irb@LISTS.CUMC.COLUMBIA.EDU>

Dear Colleagues,

Our office is pleased to announce the release of two new documents designed to support the IRB review of **NIH Genomic Data Sharing (GDS) Institutional Certifications**.

An **Institutional Certification** outlines the appropriate secondary uses of data submitted to an NIH-designated repository when genomic data will be generated. The certification ensures that data submission complies with the NIH GDS Policy and aligns with the informed consent provided by the original study participants.

The following two new documents are available on the HRPO website and can be accessed directly from the **Policy Guide** page under item 29:

1. CU HRPO Standard Operating Procedure (SOP) on Submitting and Reviewing Genomic Data Sharing (GDS) Institutional Certifications
2. CU GDS Institutional Certification Request Form

New Process (effective immediately):

The SOP describes the steps for preparing and submitting an NIH GDS Institutional Certification for IRB review. As part of this process, investigators must:

- Complete the CU GDS Institutional Certification Request Form, and the applicable NIH GDS Institutional Certification, and
- Attach both documents to the Rascal protocol submission (new protocol or modification, as applicable).

HRPO staff will conduct a congruency review to ensure compliance with GDS requirements. Once the IRB has reviewed and granted approval for the research/data sharing, a senior HRPO staff member will provide confirmation that the NIH GDS Institutional Certification may be signed. This confirmation will be sent to the Associate Vice President – Sponsored Projects Administration, who serves as the Institutional Signing Official.

If you have any questions regarding this process, please contact irboffice@columbia.edu. Any questions related to an IRB application should be directed to the HRPO team supporting your IRB protocol.

Additional Resources:

- NIH Extramural Institutional Certification Forms (downloadable): https://sharing.nih.gov/genomic-data-sharing-policy/institutional-certifications/completing-an-institutional-certification-form
- Sharing Data and Finding the Right Repository: https://research.columbia.edu/research-data-columbia

- NIH Genomic Data Sharing Policy: Frequently Asked Questions (FAQs): https://grants.nih.gov/faqs#/genomic-data-sharing-policy.htm?anchor=11832

Thank you.

HRPO Team

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Sincerely,

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