

PROVISIONAL INSTITUTIONAL CERTIFICATION

Date: [MM/DD/YYYY]

Name of GPA

Genomic Program Administrator (GPA)

_____, National Institutes of Health (NIH), U.S. Department of Health and Human Services (HHS)

RE :Provisional Institutional Certification of _____ [NAME OF INSTITUTION]
for _____ [NAME OF STUDY/TITLE OF GRANT, GRANT OR PROPOSAL
NUMBER] as part of an expectation of the NIH Genomic Data Sharing (GDS) Policy

To the National Institutes of Health (NIH), U.S. Department of Health and Human Services (HHS):

This Provisional Certification is being provided pending submission of the Institutional Certification and is to accompany the Just-in-Time (JIT) information submitted for the above referenced _____ from _____ [NAME OF PI], as part of an expectation of the [NIH Genomic Data Sharing \(GDS\) Policy](#) (NIH Guide Notice Number NOT-OD-14-124) because [REASON CERTIFICATION ELEMENTS CANNOT BE MET, E.G., IRB HAS NOT GRANTED FINAL APPROVAL]ⁱ

This document serves as an assurance from _____ that future data sharing outlined in the data management and sharing plan addressing genomic data sharing submitted by _____ for _____ will be consistent with the elements delineated in an Institutional Certification³ that will be submitted to the NIH by _____ [MM/DD/YYYY].ⁱⁱ

SIGNATURE PAGE FOR THIS PROVISIONAL INSTITUTIONAL CERTIFICATION

SUBMITTED AND AGREED TO BY:

Investigator:

Name: _____ Title: _____

Signature: _____ Date: _____

Institutional Signing Officialⁱⁱⁱ

By signing below, I certify on behalf of _____ that the investigator and our institution are unable to provide assurances to the criteria of the Institutional Certification at Just-in-Time and will follow-up with a completed Institutional Certification at the appropriate time.

Name: _____ Title: _____

Signature: _____ Date: _____

Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this Certification are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) and/or imprisonment).

OMB Control Number: 0925-0670

Expiration Date: May 31, 2029

Public reporting burden for this collection of information is estimated to vary from 15 to 45 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-0670). Do not return the completed form to this address.

ⁱ This document is intended to be used as needed on a case-by-case basis where the submitting institution, at the time of Just-in-Time, is unable to provide assurance to the elements of the formal Institutional Certification. An example of when a provisional Institutional Certification would be used would be for a prospective study where the Institutional Review Board (IRB) has not completed its review of the protocol and therefore the institution cannot attest to all of the elements of the formal Institutional Certification. In such situations, this provisional Institutional Certification will be submitted until a formal Institutional Certification can be provided.

ⁱⁱ <https://sharing.nih.gov/genomic-data-sharing-policy/institutional-certifications/about-institutional-certifications>

ⁱⁱⁱ Under the NIH Genomic Data Sharing (GDS) Policy, an Institutional Signing Official is generally a senior official at an institution who is credentialed through the NIH eRA Commons system and is authorized to enter the institution into a legally binding contract and sign on behalf of the institution and the investigator who has submitted data or a data access request (DAR) to NIH.