

# Provisional Institutional Certification

Date: [MM/DD/YYYY]

Name of GPA

Genomic Program Administrator

\_\_\_\_\_, NIH, HHS

9000 Rockville Pike

Bethesda, MD 20892-7395

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 Genomic Data Sharing Policy

Dear

This provisional certification<sup>1</sup> is being provided pending submission of the Institutional Certification and is to accompany the Just in Time Information submitted for the above referenced

\_\_\_\_\_ from \_\_\_\_\_ [NAME OF PI], as  
part of an expectation of the Genomic Data Sharing Policy,<sup>2</sup> because [REASON CERTIFICATION ELEMENTS CANNOT BE MET,  
E.G., IRB HAS NOT GRANTED FINAL APPROVAL]

This document serves as an assurance from \_\_\_\_\_ that future data sharing outlined in the genomic data sharing plan submitted by \_\_\_\_\_ for \_\_\_\_\_ will be consistent with the elements delineated in an Institutional Certification<sup>3</sup> that will be submitted to the NIH by \_\_\_\_\_ [MM/DD/YYYY].

Sincerely,

Investigator:

Name: \_\_\_\_\_ Title: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Authorized Institutional Official:<sup>4</sup>

Name: \_\_\_\_\_ Title: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

<sup>1</sup> 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 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.

<sup>2</sup> <http://gds.nih.gov/03policy2.html>

<sup>3</sup> [http://gds.nih.gov/Institutional\\_Certifications.html](http://gds.nih.gov/Institutional_Certifications.html)

<sup>4</sup> A senior official at an institution who is authorized to enter the institution into a legally binding contract and sign on behalf of an investigator who plans to submit data to NIH, e.g., Dean, Vice President for Research.