**Instructions:**

This form is to accompany all requests to certify data or samples for submission into a large repository or database with the intent for broad sharing in the research community. This form should be used for submission of **human data only**.

Complete each of the following items. Once completed, please attach this form and accompanying documentation to your email request.

**Basic Request Information:**

1. List the name/owner of the repository or database:

dbGaP

Other NIH

Other (please name):

1. Name of the Individual to whom the letter should be addressed:

If an NIH repository/database, this individual may be your Genomic Program Administrator (GPA)

1. Are you requesting an institutional certification as part of a JIT request?

Yes

No

If Yes, list is your anticipated date of award:

**Sample Information**

1. Samples were collected: (Check all that apply)

Before January 25, 2015

After January 25, 2015

Samples not yet collected

1. What is (or will be) the original source of the samples? (Check all that apply)
   1. Collected under this study and/or another approved study(ies):

List the myIRB ID# for other studies and/or state “Current Study”:

* 1. Obtained from an outside entity

List the entities:

* 1. Collected without consent\*

*\*Note this applies only to samples collected before January 25, 2015*

**Required Attachments:**

1. Attach a copy of the JIT request documenting that a certification is required.

Not Applicable

1. Attach a copy of the complete grant (individual salary may be redacted).

Not Applicable (e.g., study is not funded or grant has already been provided)

1. Attach copies of **all** consent form versions that were actually used to obtain consent from participants to create the genetic/genomic data.

*Consent documents must be attached as pdf documents*

*Consent documents should be attached as a single “bundled” pdf file with documents going in order from oldest to newest.*

*Attach* ***only*** *consent documents. Do not attach IRB approval letters, brochures, etc.*

***DO NOT*** *attach signed consent documents.*

***DO NOT*** *attach consent documents that were never used to obtain consent.*

1. Attach a completed spreadsheet for certification request

*Template is located on the HRPO website*

*List the consent versions on this document in the same order as the scanned documents*

Not Applicable

1. Attach institutional certification letters from each outside entity listed above in 5b

Not applicable

*These certification letters should be on the current NIH template whenever possible*

*Two certification letters may be required, if samples are collected before and after January 25, 2015*

*If the institution is not using the NIH template, the letter (at minimum) must include the following details:*

* *Name of original study*
* *Project title for data to be submitted*
* *Whether data will be made available through unrestricted or controlled-access*
* *Whether variant alleles and/or frequencies may be uploaded from this study in public variation archives (i.e., dbSNP and dbVar), if applicable*
* *Any data use limitations placed on the data/samples that are submitted (e.g., general research use, may be used for only health/medical/biomedical research, disease-specific research)*
  + *For any limitation other than general research use, the letter should specify (indicate all that apply):*
    - *IRB – whether the institution would require users of the data to provide IRB approval*
    - *PUB – user must agree to make results of studies using the data available to the larger scientific community*
    - *COL – user must provide letter of collaboration with primary study investigator(s)*
    - *NPU – data/samples may only be used for not-for-profit organizations*
    - *MDS – data/samples includes methods development research (e.g., development of software or algorithms)*
    - *GSO – use of data is limited to genetic studies only*