**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*