**dbGaP CERTIFICATION REQUEST FORM**

**(Emory submitting data directly to public repository (e.g. dbGAP)**

**Overview:**

* Use this form when Emory University will be the institution submitting the data to dbGaP or other national repository
* This information helps the IRB prepare/review the required “Institutional Certification” (or “Provisional Certification) stating that the proposed (genomic) data sharing complies with NIH policy and ethical principles, including adequate informed consent.
* The Institutional Certification also states what limitations should be placed on data to be shared (e.g. types of research, requirements for co-authorship…)
* NOTE: Consent requirements for *genomic* data sharing differ pre- and post-January 25, 2015. **Two** Institutional Certifications are required if samples come from both periods. Guidance for post-January 25, 2015 consent forms is **at the end of this document.**
* **What if I don’t have some of the below information, and the deadline is soon? *An option is “Provisional Certification*.”** If the study protocol and consent forms have not yet been drafted, OSP can sign a *“*Provisional Certification.” The final certification will need to be completed as soon as those documents are complete (but not necessarily fully IRB-approved).

**For reference: NIH Institutional Certification Forms**

* [For Studies Using Data Generated from Cell Lines Created or Clinical Specimens Collected AFTER January 25, 2015](http://osp.od.nih.gov/wp-content/uploads/GDS_Extramural_Certification.pdf)
* For Studies Using Data Generated from Cell Lines Created or Clinical Specimens Collected BEFORE January 25, 2015
	+ [That Lack Consent](http://osp.od.nih.gov/wp-content/uploads/GDS_Clinical_Specimen_Certification.pdf)
	+ [That Have Consent](http://osp.od.nih.gov/wp-content/uploads/GDS_Extramural_Certification_Pre2015.pdf)
* [Provisional Institutional Certification](http://osp.od.nih.gov/wp-content/uploads/GDS_Provisional_Institutional_Certification.pdf) – to be used in a situation such as 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

**Steps**

1. Complete **each** of the following items as applicable.
2. Once completed, please submit this document and any attachments to irb@emory.edu.
	1. ***Note:*** *If your study does not have an approved eIRB application, please attach the protocol, data sharing plan (within grant application if applicable) and draft consent form(s) to your email request.*
3. You may copy the Director and/or Team Leads if urgent handling is required.

**Questions**

1. What is [or will be] the original source of the samples?

*Check all that apply*

* 1. [ ] Collected under the current study (**IRB number** if already submitted; say “not yet submitted” if not: Click or tap here to enter text.)
	2. [ ] Collected under other studies conducted at Emory

Enter IRB #: Click or tap here to enter text.

* 1. [ ] Obtained from an outside institution

 List the institutions: Click or tap here to enter text.

1. Will any of the data be generated from samples collected prior to January 25, 2015?

 [ ] Y [ ] N

1. Will any of the data be generated from samples collected after January 25, 2015?

[ ] Y [ ] N

1. What genotypic data will be shared with dbGAP (or other repository)?

 *Check all that apply*

[ ] Whole Genome Sequencing (WGS)

[ ] Exome Sequencing

[ ] Genome-Wide Association Studies (GWAS)

[ ] Single Nucleotide Polymorphism (SNP) Arrays

[ ] Transcriptome Sequencing

[ ] Other: Click or tap here to enter text.

1. The Institutional Certification Forms include the following question. Please propose an answer and explain reasoning.

“The National Center for Biotechnology Information is authorized to upload the display of **variant** [ ]  **alleles and/or** [ ]  **frequencies** from this study in public variation archives (i.e., dbSNP and dbVar).”

**Your reasoning**: Click or tap here to enter text.

1. List the phenotypic data that will be provided to dbGAP (e.g., clinical variables, demographic information). Be sure to provide enough information to allow the IRB to determine if any of the information or combination of the information would be considered identifiable. Click or tap here to enter text.

***Note:*** *Please be aware that if age will be a submitted demographic variable, you need to specify that ages greater than 89 will not be individually reported as they are identifiers. Please be aware that dates (e.g., dates of birth, death, dates of tests, admission or discharge) including elements other than just the year cannot be included as they are identifiers.*

1. The identities of research participants cannot be disclosed to the NIH GWAS data repository. As such, please select the following statement that is true of your study.

[ ]  The data set to be submitted is anonymous (no member of the research team, or anyone else, is able to identify the participant connected to the data).

[ ]  The data set to be submitted is coded (with a key or master list in existence). However, only the coded data set and not the key or master list will be shared.

[ ]  N/A, submitting to a repository that does include identifiers. Please include a link to repository information, or attach a document: Click or tap here to enter text.

*[If this is a request for samples that have not yet been collected, please skip item 6]*

1. For samples collected at Emory (Items 1a and/or 1b were selected).
	1. Please attach copies of all consent form versions that were actually used (and/or will be used) to obtain consent from participants to collect the samples. *Please attach* ***only*** *the consent documents. Do not attach other materials such as IRB approval letters, questionnaires, etc. that were approved with the consents.*

Please **DO NOT submit signed consent forms**. Provide only a copy of the versions used to obtain consent.

1. For samples that have been/will be collected at an outside institution (Item 1c was selected), please attach a letter/email/institutional certification from each applicable site assuring Emory University that the samples used were/will be collected in accordance with NIH requirements.

*\*Please refer to our website for a sample assurance letter. If our template letter is not used, please be sure your alternate letter or form of documentation includes all required elements.*

1. Please attach the Genomic Data Sharing Plan from your NIH grant application.

[**Guidance for Consent under the NIH GDS Policy**](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidance_on_Elements_of_Consent_under_the_GDS_Policy_07-13-2015.pdf) **(Direct quote):**

***Emory IRB provides sample language that meets these requirements in our “Modular Language for Consent Forms” document in our*** [***Consent Toolkit***](http://irb.emory.edu/forms/consent_toolkit/index.html)***.***

In order to meet the expectations for future research use and broad sharing under the GDS Policy, the consent should capture and convey in language understandable to prospective participants information along the following lines:

* Genomic and phenotypic data, and any other data relevant for the study (such as exposure or disease status) will be generated and may be used for future research on any topic and shared broadly in a manner consistent with the consent and all applicable federal and state laws and regulations.
* Prior to submitting the data to an NIH-designated data repository, data will be stripped of identifiers such as name, address, account and other identification numbers and will be deidentified by standards consistent with the Common Rule. Safeguards to protect the data according to Federal standards for information protection will be implemented.
* Access to de-identified participant data will be controlled, unless participants explicitly consent to allow unrestricted access to and use of their data for any purpose.
* Because it may be possible to re-identify de-identified genomic data, even if access to data is controlled and data security standards are met, confidentiality cannot be guaranteed, and reidentified data could potentially be used to discriminate against or stigmatize participants, their families, or groups. In addition, there may be unknown risks.