**(Genomic) Data Sharing Institutional Certification Request Form**

**Emory not submitting data directly to public repository (e.g. dbGAP)**

**Instructions:**

* Use this form when an outside institution is submitting data to an NIH repository that are generated from samples collected at Emory University.
* This information helps the IRB prepare/review an “Institutional Certification” (or “Provisional Certification) stating that the (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 allowed, non-profit status…)
* 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.**

**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](mailto: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](mailto:rrouss2@emory.edu?subject=Institutional%2520Certification%2520request%2520for%2520data%2520sharing) and/or [Team Leads](mailto:maria.davila@emory.edu%253Bshara.karlebach@emory.edu%253Bcarol.corkran@emory.edu) if urgent handling is required.

**Questions**

1. Identify the original source of the samples (or what the source will be), e.g. research studies, repostiories, pathology lab…: Click or tap here to enter text.
   * Please provide all applicable eIRB approval numbers: Click or tap here to enter text.
2. What genotypic data will be shared with dbGAP?

*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. For specimens that have already been collected only: please provide copies of all consent form versions that were actually used to obtain consent from participants to create the genetic/genomic data). *Attach with this document. Please attach only the consent documents. Do not attach other materials such as IRB approval letters, questionnaires, etc. that were approved with the consents, unless waiver of consent was granted by IRB, in which case provide documentation.*

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

1. If samples are from post-mortem tissue: Explain under what consent (if any) the post-mortem tissue was stored/used, if not under an IRB-approved protocol: Click or tap here to enter text.

[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):**

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.

***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)***.***