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DATA USE LIMITATION RECORD

- Title of Specimen Collection Protocol: _____

- Protocol Number: _____

- Consent Form Title: _____

- Principal Investigator Listed on Consent Form: _____

- Data Manager *(individual responsible for communicating future decisions regarding data access and transfer)*

Data Manager Name: _____

Data Manager Email: _____

- Sample collection date range *(e.g. 2/18/2012-ongoing)***.** *This information is needed because NIH consent requirements changed after 1/25/2015.*

Sample collection start date: _____

Sample collection end date: _____ ☐ Ongoing process

- Data is intended for repository deposition?

◯ Yes

◯ No

Samples from the above referenced protocol have been or will be part of a genomic research collaboration with the Broad Institute.

In order to be responsible stewards of the genomic data that is generated, we are asking your IRB/Ethics Committee to identify appropriate use and sharing limitations based on a review of the consent form research participants signed when the samples were collected.

Identification of these data use limitations will ensure that future use is aligned with the commitments made to research subjects in the consent. The data use limitations may be used in one of two ways to identify use restrictions: 1) to facilitate data management, and/or 2) if appropriate, for data deposition into a controlled-access or open-access repository.

Please answer the following questions to describe data use limitations based on the consent form interpretation.

Section 1: Information for required for data management

For all data (regardless of whether intended for repository sharing or not), permissible future uses of the data are as follows (please choose only one primary option):

1. Primary restrictions

- [ ] No restrictions
- [ ] General research use *(Data can be used for any research purpose but would not be made available for non-research purposes. These data would generally be made available to any qualified investigator, irrespective of the specific research purpose for which the data are requested.)*
- [ ] Future use is restricted to health/medical/biomedical research *(any type)*
- [ ] Future research is restricted to (a) specific disease(s): *Please note that checking any of these boxes precludes all future research outside of the indicated disease.*
  - [ ] Infectious and parasitic diseases
  - [ ] Cancer
  - [ ] Endocrine, nutritional and metabolic diseases
    - [ ] Diabetes mellitus
  - [ ] Mental, Behavioral and Neurodevelopmental disorders
  - [ ] Nervous system diseases
  - [ ] Eye diseases
  - [ ] Ear and mastoid process diseases
  - [ ] Circulatory & Cardiovascular system diseases
  - [ ] Respiratory system diseases
  - [ ] Digestive system diseases
    - [ ] Inflammatory bowel disease
  - [ ] Skin and subcutaneous tissue diseases
  - [ ] Musculoskeletal system & connective tissue diseases
  - [ ] Genitourinary system diseases
  - [ ] Pregnancy, childbirth and the puerperium
  - [ ] Congenital malformations, deformations and chromosomal abnormalities
  - [ ] Blood and blood-forming organs and certain disorders involving the immune mechanism diseases
  - [ ] Other *(please describe below)*

2. Does the informed consent form or the IRB/EC prohibit any of the following?

☐ Use by commercial entities or for commercial purposes

☐ Methods research *(analytic/software/technology development)*

3. Future research is restricted to the following populations:

☐ No population restrictions

☐ Research in children under 18 years of age only

☐ Research in adults 18 years of age and older only

☐ Research in men only

☐ Research in women only

☐ Research in the following ethnic or geographic population:

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4. Other restrictions: *(Please describe below. For example: future research use requires review by the data recipient's IRB/EC; no data deposition from samples collected using consent forms before 1992)*

Section 2: Information required for data sharing via a repository

(Please see final bullet on page one to ascertain if data is intended for repository deposition)

If data is intended for data deposition into a repository, please answer the following, depending on sample collection date (see sample collection dates on page 1). These date range specific questions are needed because NIH consent requirements changed after 1/25/2015. If samples were collected both before and after 1/25/2015, please answer both sets of questions.

For samples collected BEFORE 1/25/2015	For samples collected AFTER 1/25/2015
1. Is data submission not inconsistent with (not prohibited by) the informed consent provided by the research participant? ◯ Yes, data submission is **not inconsistent** with the consent. *(Data submission is permitted)* ◯ No, data submission is **inconsistent** with the consent. *(Data submission is not permitted)*	**1. Did participants consent to the use of their genomic and phenotypic data for future research and broad sharing?** ◯ Yes ◯ No *(if No, do not answer questions 2 & 3 below)* **2. Is data deposition into a repository described in the consent form?** ◯ Yes ◯ No **3.** *If yes to #2 above (data deposition into a repository is described),* **what type of repository is permitted?** ◯ Controlled-access *(researchers are required to apply for access, e.g. dbGaP, EGA)* ◯ Open-access *(data publicly available without application or restrictions)* ◯ Both controlled-access and open-access are permitted

NIH provides genomic summary results (GSR) from most studies submitted to NIH-designated data repositories through unrestricted access. However, data from data sets considered to have particular 'sensitivities' related to individual privacy or potential for group harm (e.g., those with populations from isolated geographic regions, or with rare or potentially stigmatizing traits) may be designated as "sensitive" by. In such cases, "controlled-access" should be checked below and a brief explanation for the sensitive designation should be provided. GSR from any such data sets will only be available through controlled-access.

4. Are the genomic summary results (GSR) from this study to be made available only through controlled-access?

◯ No, controlled-access for GSR is *not* required

◯ Yes, controlled-access for GSR is required

Explanation if controlled-access was selected for GSR (required):

Note: If an answer is not provided to the question below, the NIH default will be 'No'. If 'Yes' is selected, an explanation is required. If 'Yes' is selected and no explanation is provided, the NIH default of 'No' will persist regardless of the answer selected.

Section 3: Assurances *(by signing this form, you are also attesting):*

Consideration was given to risks to individual participants and their families associated with data submitted to the data repository and subsequent sharing.

- To the extent possible, consideration was given to risks to groups or populations associated with data submitted to the data repository and subsequent sharing.

The protocol for the collection of genomic and phenotypic data is consistent with the U.S. Code of Federal Regulations, 45CFR46 (or your equivalent national human subjects research standards, if outside the US). This means that in the above referenced protocol:

- Risks to subjects are minimized

- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result.

- Selection of subjects is equitable.

- Informed consent is sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by applicable national and local laws and regulations.

- Informed consent is appropriately documented, in accordance with, and to the extent required by applicable national and local laws and regulations.

- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

- When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.

Please note if the data use restrictions for this protocol change at any time the IRB/EC is responsible for contacting Broad's Office of Research Subject Protection at orsp@broadinstitute.org in order to update the restrictions accordingly in dbGaP (when applicable) and Broad's data management systems.

Institutional Review Board/ Ethics Committee Official
I hereby attest that I am qualified to sign this agreement on behalf of the Institution listed below:

Signature: _____

Printed Name: _____

Position/Title in your Institution: _____

Institution: _____

Date: _____

Please return this form to your primary point of contact at the Broad Institute, or directly to the Broad's Office of Research Subject Protection: orsp@broadinstitute.org.