**DATA USE LIMITATION RECORD**

(For biospecimens collected before January 25, 2015)

* Title of Specimen Collection Protocol:
* Protocol Number:
* Consent Form Title:
* Principal Investigator Listed on Consent Form:

The Institutional Review Board (IRB) or Ethics Committee (EC) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ has reviewed all relevant informed consent forms for the above referenced protocol. The permissible research uses of the data are noted below. [Note that if data use restrictions in the consent have changed over time, please use separate forms to document these time-specific restrictions.]

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)

**[If “no,” do not complete the remainder of this form, as data deposition may not be permissible. Please return the form to the Program for the Protection of Human Subjects at IRB@mssm.edu. The PPHS staff will work with the researchers involved on possible alternatives.]**

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

* Use by commercial entities
* Methods research (analytic/software/technology development)
* Aggregate level data for general research use

1. The display of variant alleles and/or frequencies from the study (e.g., study wide summary data on the frequency of particular genetic variants in the study population) in **open access** variation archives (i.e., dbSNP and dbVAR) is not inconsistent with the informed consent. [[For more information about dbSNP and dbVar, visit:](http://www.ncbi.nlm.nih.gov/variation/dbSNP_dbVar_FAQ) <http://www.ncbi.nlm.nih.gov/> variation/dbSNP\_dbVar\_FAQ.]

* Yes, display of variant alleles or frequencies is **not inconsistent** with the consent. (It is permitted)
* No, display of variant alleles or frequencies is **inconsistent** with the consent. (It is not permitted)

1. Permissible future uses of the data are as follows:
   * **No restrictions,** general research use is permitted

## Future use is restricted to health/medical/biomedical research (any type)

* + Future research is **restricted to the following area(s):** [*Please note that checking any of these boxes precludes all future research outside of the indicated disease or population.*

|  |  |
| --- | --- |
| □Cancer (all types) | □ Mental health |
| □ Cardiology | □ Cognition |
| □ Dermatology | □ Neurology |
| □ Endocrinology | □ Obstetrics and Gynecology |
| □ Gastroenterology | □ Orthopedics |
| □ Immunology | □ Pulmonology |
| □ Infectious disease | □ Rheumatology |
| □ Other (please describe): | □ Urology |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |

* Future research is **restricted to following populations**:

### No population restrictions

### Research in children under 18 years of age

### Research in adults over 18 years of age

### Research in men only

### Research in women only

### Research in the following ethnic or geographic population: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

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

* Data submission and subsequent data sharing for research purposes are not inconsistent with the informed consent of study participants from who the data were obtained.
* 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. 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.

#### **Institutional Review Board/ Ethics Committee Official**

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Institution Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Please return this form to your primary point of contact at ISMMS.*