

**THE NATIONAL HUMAN GENOME RESEARCH INSTITUTE
MEDICAL SEQUENCING PROGRAM**

Applicant Agreement Policy

By submitting this application to submit samples, or by accepting an invitation to submit samples, to the NHGRI Medical Sequencing Program (MSP), the Primary Contributing Investigator, all Major Co-investigators, and their respective institutions certify their agreement with the approved operating policies and procedures established by NHGRI and approved by the National Advisory Council for Human Genome Research, as summarized here and fully described on the NHGRI Medical Sequencing website (Policies and Procedures).

- It is the responsibility of the Primary Contributing Investigator and Major Co-investigators to obtain approval for participation in MSP from the appropriate institutional officials and/or committees at all sites at which data and samples being submitted for sequencing were collected according to applicable federal, state, and local laws and regulations and any relevant institutional policies. This explicitly includes obtaining appropriate local IRB approval.
- Coded phenotype and exposure data (if any) associated with the DNA samples that are proposed for sequencing will be submitted to the MSP Database managers according to the requirements defined in the MSP Dataset Submission instructions. Because the MSP has a range of distinct programs, conditions for submitting data will vary between those programs, depending on how each is implemented. In essentially all cases, submission of data must occur before sequencing will begin. In some cases, NHGRI will ask that data be submitted at the time of application to allow the review process to assess the range of phenotypic measures, the amount of effort required to put these data into the web resource database, and the completeness of the data submitted. In rare cases, submission of phenotype data may be waived. It is the responsibility of the Primary Contributing Investigator and his/her institution to ensure that all data are submitted in accordance with applicable federal, state, and local laws and regulations. In the event that an application is not approved or samples are not sequenced, MSP will destroy all data submitted.
- Should sequence data be produced from the submitted samples, it is understood that the MSP sequence data will be deposited into publicly available databases maintained at The National Center for Biotechnology Information (NCBI), as follows:
 - Individual sequence trace data will be made available through the NCBI Trace repository. Traces will not be associable with each other (i.e., as coming from the same individual) beyond a 1 Mb extent. Traces will be annotated with ancillary information to include the name of the study, the affected status (if known), and other non-identifying information.
 - Phenotype data, and the information linking all sequence traces to a particular (anonymous or de-identified) individual, and linking sequence data to phenotype data, will be made available through a controlled-access database maintained by

NCBI, beginning at the same time sequence depositions are made. This dataset will be made available to any researcher who, along with his/her institution, has certified agreement to the statements within the Data Use Certification and acknowledged the intent of the NHGRI that users of MSP Datasets follow the posted NHGRI policies on data access and intellectual property.

- Links to the postings will be made available through the NHGRI Web Site. Depending on the program within the MSP, NHGRI may also post summary information such as allele frequencies and descriptive information such as variables measured and protocols used. Summary information may also be posted on dbSNP.

- Investigators contributing data and DNA samples to the MSP will access MSP Datasets through the same procedures and Data Use Certification document as other investigators. Because of the unique position of the investigators who retain the code to the data within a given MSP Project Dataset, Primary Contributing Investigators and Major Co-investigators will additionally be responsible for compliance with any applicable federal, state, and local laws and regulations (e.g., 45 CFR Part 46) and any institutional policies relevant to their future research use of that particular MSP Project Dataset. For some MSP programs, it is possible that samples will be completely anonymous, that is, no code will be maintained.

By signing and dating this Applicant Policy Agreement, the Primary Contributing Investigator and his/her Institutional Official represent and warrant their authority to submit for MSP participation the proposed phenotype dataset and DNA samples for sequencing, and certify their agreement to the NHGRI/MSP principles, policies and procedures as articulated in this document. The Institutional Business Official further acknowledges that he/she has shared this document and the relevant MSP policies and procedures with appropriate institutional organizations, such as the Office of Technology Transfer and the Office for Human Subjects Research.

Investigator:

Name: _____ Title: _____

Signature: _____ Date: _____

Institutional Business Official:

Name: _____ Title: _____

Signature: _____ Date: _____