Genomic Data Release Liability and Disclosure Form

Stanford Medicine Clinical Genomics Laboratory

The data file(s) requested for release by the signator(s) below include information on germline genetic variation observed during patient testing. Family member data files may also be released if they (or their legal guardian) complete an independent Genomic Data Release Liability and Disclosure Form. Details on data generation can be found within the clinical report(s) provided by the Clinical Genomics Laboratory.

Importantly, there are limits to the data present in the released files. Data in these files should not be used for clinical decision-making purposes. Discussion with appropriately trained healthcare providers is strongly recommended prior to taking any action based on information in these files.

By signing this form, I recognize that I understand the following:

- The Clinical Genomics Laboratory will not release data until clinical testing is completed and a final clinical report has been delivered.
- Stanford Health Care (SHC) and/or Lucile Packard Children's Hospital (LPCH) are not responsible for analysis and/or interpretation of raw genomic data performed outside of the SHC/LPCH clinical laboratories.
- Data file(s) released to the recipient contain 'raw' genomic data. As such, the released file(s) will include: benign variants, previously unreported rare variants, false positive variants, and/or potential secondary/incidental findings. Only the genetic variants described in the original clinical report issued by the Clinical Genomics Laboratory have been confirmed for accuracy.
- Specialized software may be required to access, analyze, or process the released data files.
- Data present in the released data file(s) may contain information relevant to individual predisposition to genetic disease. In addition, the released data may have implications related to the health of family members.
- Deidentified raw genomic data has a risk of unauthorized re-identification of the sequenced individual.

- Raw genomic data can include information that patients or family members declined to receive at the time testing was initiated. The data recipient should discuss any questions or concerns with a qualified care provider prior to receiving the raw genomic data interrogated by the original clinical test.
- Information about genomic data in public online databases can be incorrect or outdated. Therefore, no clinical decisions should be made based purely on any entries in these public databases at any given time.
- There are many reasons why genomic data in the released files may not have been included in the clinical report provided by the Clinical Genomics Laboratory, including but not limited to:
    - Genomic data in these files may include variants relevant to individual health, but that were not related to the primary reason for clinical genomic testing.
    - Genomic data in these files may not have met the standardized laboratory criteria required for interpretation as part of the test.
    - Genomic data may not have been located within the interrogated region of interest (ROI) of the clinical test.
    - Understanding and interpretation of genomic data changes over time. As such, some data present in these files may not have had enough evidence supporting a gene or genetic variant's role in disease at the time of testing to warrant reporting.
    - Genomic data provided by family members to assist with interpretation of patient data is not independently analyzed or reported by the Clinical Genomics Laboratory.
- Authorization for genomic data release may be withdrawn by submitting a written request to the Clinical Genomics Laboratory prior to the data being released to the designated recipient. However, once genomic data is released to the designated recipient, authorization cannot be withdrawn.

For genomic data on family members included as part of the proband/patient's test, please note:

- VCF (unfiltered variant file) and/or BAM (aligned sequencing file) files from all family members included in the genomic test analysis can be provided upon request. However, a signed form is required for **each individual** authorizing release of their individual genomic data.

Information to be released:

☐ VCF

☐ BAM files [note: not readable without specialized software]

Name, Address, and Fax number of Organization or Individual to whom information is to be released (data recipient):

Name of Person/Entity: _____

Phone #: _____

E-mail address (if needed for VCF file delivery): _____

Street Address, City, State, Zip Code (if data will be shipped):

_____

_____

_____

By signing below, I confirm that I understand the limitations regarding this unprocessed raw genomic data as described above and have discussed any questions pertaining to this request with my healthcare provider(s).

DATE TIME SIGNATURE (Patient/Legal Designated Representative)

PRINT NAME RELATIONSHIP TO PATIENT

If an interpreter participated in the informed consent discussion:

PRINT SHC in-person interpreter name Video or TEL Interpreter ID# Language