Requesting Release of Exome Data Instructions

The FASTQ data files (text-based format for storing nucleotide sequences) from the exome sequencing tests can be requested by an Institution. For FASTQ files to be released by Baylor Miraca Genetics Laboratories to the requesting institution the following information is required for each patient:

1) Institutional Whole Exome/Genome Data Release Form - To be filled out by requesting Institution, and signed by the investigator and patient. The investigator will need to attest that the patient/patient's guardian has been provided with an informed consent document and that this informed consent document specifically authorizes the receipt and analysis of whole exome raw data.

2) Request for and Consent to Release of Information from Individual's Records Form - To be filled out by requesting institution and patient. Required for every patient.

Once all information is compiled, please fax all documentation in its entirety to (713) 798-2787. Please allow up to 6 weeks for data receipt. There is currently no additional charge for this service.

For any questions, please contact us at 1-800-411-GENE (4363).

Disclaimer: Our results are reported based on our method, which has been validated using our criteria, and results are interpreted by Board Certified Directors. Given that variability exists in bioinformatics pipelines used to analyze sequence data and generate variant lists, it is possible that other pipelines will uncover potentially "clinically relevant" discoveries not included in the clinical report.

Baylor Miraca Genetics Laboratories is not involved with analysis performed outside of the analysis included in the clinical report and is not responsible for disclosures of genetic information beyond those included in the clinical report issued by the Baylor Miraca Genetics Laboratories.
The Baylor Miraca Genetics Laboratories will provide raw sequencing data in the form of FASTQ data files.

To release of raw data, this form and a copy of the "Request for and Consent to Release of Information from Individual's Records Form" for each specific patient are required. Once all required documentation is received, please allow up to 6 weeks for receipt of data.

Given that variability exists in bioinformatics pipelines used to analyze sequence data and generate variant lists, it is possible that research pipelines will uncover potentially “clinically relevant” discoveries not included in the BMGL clinical report. Institutions receiving raw sequence data are strongly encouraged to share any new discoveries with our laboratory.

The BMGL is not involved in the research and are not responsible for disclosures of genetic information beyond those included in the clinical report issued by the Baylor Miraca Genetics Laboratories. It is the responsibility of the institution receiving the data and their clinical personnel to appropriately inform patients of research discoveries.

**Institution(s) Requesting Raw Data:**

- Institution
- IRB or other Protocol # (Optional)
- Person Responsible for Receipt of Raw Data
- Email Address of Person Responsible for Receipt of Raw Data
- Phone # of Person Responsible for Receipt of Raw Data
- Signature
- Date

**Patient Information:**

- Proband Name
- Proband DOB (MM/DD/YY)
- BMGL Lab Number(s)*
- BMGL Family Number

*NOTE: For Cancer Exome Sequencing, please provide lab numbers for both the tumor and nontumor specimens.

As the Investigator, I attest that the patient/patient's guardian has been provided an informed consent document for this research and that the informed consent document specifically authorizes the receipt and analysis of whole exome raw data.

- Investigator (Print Name)
- Signature of Investigator
- Date

- Patient/Patient's Legal Guardian (Print Name)
- Signature of Patient/Patient's Legal Guardian
- Date

**Checklist of required documentation:**

- Request for and Consent to Release of Information from Individual's Records Form (to be signed by patient or legal guardian)
- Completed copy of this form
REQUEST FOR AND CONSENT TO RELEASE OF INFORMATION FROM INDIVIDUAL'S RECORDS

Note: The execution of this form does not authorize the release of information other than that specifically described below. This form authorizes the release of information that you specify in accordance with 5 U.S.C., Section 5701 and 7332; and 45 C.F.R., parts 160 and 164.

Name of Individual/Patient: ____________________________

Date of Birth: ____________________________

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

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

Information Requested: FASTQ data files from clinical exome sequencing

Purpose(s) or Need for which Information is to be used by Organization or Individual to whom information is to be released:

________________________________________________________________________

Authorization and Certification:
I certify that this request has been made freely, voluntarily, and without coercion and that the information given above is accurate and complete to the best of my knowledge. I understand this release may not be obtained or offered as condition for treatment, payment, or other eligibility for benefits upon my signing this authorization. I may revoke this authorization at any time in writing, except to the extent that this action has already been taken to comply with it. Written revocation is effective upon receipt by the facility housing the records. Upon release, my records will no longer be protected, and re-disclosure by those receiving the information may be accomplished without my further authorization. Without my express revocation, the authorization will automatically expire upon satisfaction of the need for disclosure, under the conditions listed below, or upon this date ____________________________ (supplied by individual/patient).

Signature of Individual/Patient ____________________________ Date ____________________________

Signature of Personal Representative, if not signed by patient* ____________________________ Date ____________________________

*[NOTE: Attach documents demonstrating your authority to act on behalf of the patient.]

PLEASE FAX COMPLETED FORM TO: 713-798-2787

OP.FR 6 Authorization For Release of Protected Health Information