**RCIGM-CGC Whole Genome Sequencing** 

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Childrens
Institute
Genomic Medicine

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Patient Last Name, First Name

DOB (MM/DD/YYYY)

Patient ID/MRN

## **RCIGM-CGC** Notice of Use and Disclosure of Samples & Information; Incidental Findings

Samples will be sent to RCIGM laboratories in California for testing. RCIGM acknowledges the confidentiality and privacy rights of the patient, parents and other family members tested. In accordance with its policies and applicable law, RCIGM will retain samples, the results of testing, associated data and reports. Identifiable samples and information will be kept confidential and accessible only to RCIGM clinical staff. Unless required or permitted by law, RCIGM will not disclose identifiable samples or information to any person or entity without your written authorization. For the limited purposes of treatment, payment, healthcare operations and on a restricted need-to-know basis, RCIGM may share your samples and/or data with your provider(s).

Additional Use of De-identified Information and/or Samples. RCIGM may use De-identified Information and Samples for research, scientific and technical development, and internal statistical and program operations analysis ("Additional Use"). De-identified data may be submitted to rare disease databases such as GeneMatcher to help identify new disease causing genes and aid in the ability to identify a genetic diagnosis in the individual. Additionally, samples may be sent de-identified, or as otherwise permitted by HIPAA, to external clinical laboratories, providers, and specialists for consultation on complex, rare, and difficult cases and/or to resolve any analytical discrepancies that occur during testing at the discretion of RCIGM. Additional Use of De-identified Information and Samples for the purposes of research, development, and analysis may improve identification and development of therapies for existing and new diseases now or in the future. At the time of placing an order and prior to testing, RCIGM offers patients/guardians and/or individuals tested the ability to prohibit RCIGM additional use of De-identified information and samples. No response will be treated as Opt-In (except for New York residents).

For New York Residents: If no selection is marked below, RCIGM laboratory will select Opt-Out by default. If Opt-In for additional use is not selected, New York law requires that no tests other than those authorized shall be performed on the biological sample and RCIGM is required to destroy samples no more than sixty (60) days after sample collection or at the end of the testing process. If Opt-In is selected for Additional Use, De-Identified samples may be stored and used longer than 60 days.

Data Release: RCIGM can provide the release of raw sequence data from WGS for patients and/or family members to the healthcare provider on record, upon request. Data will be provided as BAM and/or VCF files. For data release requests, the ordering provider can contact RCIGM\_rWGS@rchsd.org.

Incidental Findings. In rare cases, RCIGM may also report an incidental finding during routine analysis. Incidental findings are pathogenic variants identified in genes not related to the patient's phenotype that are considered medically actionable and the results are significant for the health of the patient or family members tested.

What will be reported for relatives: The presence of any incidental findings reported for the proband may be provided for relatives included in this testing, unless they opt-out of receiving such results.

Limitations: Pathogenic variants that may be present in a relative, but not present in the proband, will not be identified or reported.

## Please mark the appropriate boxes below to Opt-In or Opt-Out.

If no selection is marked, RCIGM laboratory will select Opt-In by default (except for New York residents).

Use of De-identified Information and/or Samples		Incidental Findings		Proband and Family Member Names	
Opt-In	Opt-Out	Opt-In	Opt-Out	Relationship	Print Name
				Proband	
				Mother	
				Father	
				Sibling	
				Other	

By signing below you are acknowledging that you have reviewed the WGS test information and authorize the completion of the described test. Your signature(s) confirm that you Opt-In or Opt-Out of incidental findings and sharing of de-identified data for each participant as selected above. Print the name of the person signing. Parent/Guardian(s) must sign below for minors. Each adult (age 18 and older) must sign for themselves. If parent is under 18, parent guardian signature may be required.

Proband/Proband Guardian Name (Print)	Proband/Proband Guardian Signature	Date (MM/DD/YYYY)
Mother/Mother Guardian Name (Print)	Mother/Mother Guardian Signature	Date (MM/DD/YYYY)
Father/Father Guardian Name (Print)	Father/Father Guardian Signature	Date (MM/DD/YYYY)
Sibling/Sibling Guardian Name (Print)	Sibling/Sibling Guardian Signature	Date (MM/DD/YYYY)
Other Family Member Name (Print) ∖}Á+ÐੰB2€GIÁ KÍ FÁÚT Á⊈ÚÙ∨DĚÁÚæt^Á Á	Other Family Member Signature	Date (MM/DD/YYYY)