UW MEDICINE CENTER FOR PRECISION DIAGNOSTICS
NORTHWEST CLINICAL GENOMICS LABORATORY
1959 NE PACIFIC AVE., LAB H-561, SEATTLE, WA 98195
PHONE: 206-543-0459; FAX: 206-616-1899 www.uwcpdx.org

EXOME AND GENOME TEST REQUISITION

PATIENT INFORMATION

Name:		
Address:		
City:	State:	ZIP:
Phone (home):		
Phone (other):		
Date of birth:	MRN:	
Gender: ☐ Male ☐ Female ☐ Unknown		

Ethnic background (select all that apply):

☐ African American ☐ Hispanic
☐ Caucasian (White) ☐ Asian
☐ Ashkenazi Jewish ☐ Native American
Other:

ORDERING PHYSICIAN

Name:		
Organization:		
Address:		
City:	State:	ZIP:
Phone:	FAX:	
Email:		

OTHER REPORT RECIPIENT

Name:		
Address:		
City:	State:	ZIP:
Phone:	FAX:	
Email:		

SAMPLE INFORMATION

Date of collection:	Collected by:

Specimen type: ☐ Whole blood (lavender top - EDTA tube) ☐ Extracted DNA Other:

FAMILIAL (BIOLOGICAL) SAMPLES

Mother:		Father:	
Date of birth:	Date of collection:	Date of birth:	Date of collection:
☐ Whole blood	☐ Extracted DNA	☐ Whole blood	☐ Extracted DNA
☐ Asymptomatic	☐ Symptomatic	☐ Asymptomatic	☐ Symptomatic
Other:		Other:	
Date of birth:	Date of collection:	Date of birth:	Date of collection:
☐ Whole blood	☐ Extracted DNA	☐ Whole blood	☐ Extracted DNA
☐ Asymptomatic	☐ Symptomatic	☐ Asymptomatic	☐ Symptomatic

TEST TO BE PERFORMED

☐ Exome Sequencing and Interpretation

☐ Trio-Exome Sequencing and Interpretation

Trio Proband
Trio Mother
Trio Father

Other family member for support of proband testing

Relationship to Proband:
Proband Name:

☐ Reflex Exome Sequencing - (only after completion of exome "panel")

☐ Genome Sequencing and Interpretation

☐ Trio-Genome Sequencing and Interpretation

Trio Proband
Trio Mother
Trio Father

Other family member for support of proband testing

Relationship to Proband:
Proband Name:

☐ RAPID Exome Sequencing and Interpretation (additional charges apply)

☐ RAPID Trio-Exome Sequencing and Interpretation (additional charges apply)

REQUISITION FORM

Patient name: _____ Date of birth: _____ (MM/DD/YYYY)

CLINICAL INFORMATION

Indication for Study and Pertinent Clinical Information (provide any suspected clinical diagnoses or state if unaffected):

_____

_____

Previous Genetic Testing: ☐ **No** ☐ **Yes - Provide results:** _____

Suspected Mode of Inheritance: ☐ **Dominant** ☐ **Recessive** ☐ **X-linked** ☐ **De novo** ☐ **Mitochondrial**

Medical History: For any section marked "Abnormal" please provide additional information

ICD-9 Code(s): _____

Perinatal / Prenatal History:
☐ Abnormal ☐ Normal ☐ Unknown

In Utero Abnormalities of Proband:
☐ Abnormal ☐ Normal ☐ Unknown

Growth and Build:
☐ Abnormal ☐ Normal ☐ Unknown

Head and Neck:
☐ Abnormal ☐ Normal ☐ Unknown

Voice:
☐ Abnormal ☐ Normal ☐ Unknown

Chest and Thorax:
☐ Abnormal ☐ Normal ☐ Unknown

Cardiovascular:
☐ Abnormal ☐ Normal ☐ Unknown

Respiratory:
☐ Abnormal ☐ Normal ☐ Unknown

Abdomen:
☐ Abnormal ☐ Normal ☐ Unknown

Genital System:
☐ Abnormal ☐ Normal ☐ Unknown

Urinary System:
☐ Abnormal ☐ Normal ☐ Unknown

Skeletal:
☐ Abnormal ☐ Normal ☐ Unknown

Muscle, Soft Tissue:
☐ Abnormal ☐ Normal ☐ Unknown

Neurologic:
☐ Abnormal ☐ Normal ☐ Unknown

Skin, Nails, Hair:
☐ Abnormal ☐ Normal ☐ Unknown

Immunology:
☐ Abnormal ☐ Normal ☐ Unknown

Endocrine System:
☐ Abnormal ☐ Normal ☐ Unknown

Hematology:
☐ Abnormal ☐ Normal ☐ Unknown

Metabolic:
☐ Abnormal ☐ Normal ☐ Unknown

Neoplasia:
☐ Abnormal ☐ Normal ☐ Unknown

Abnormal Laboratory Results:
☐ Abnormal ☐ Normal ☐ Unknown

Please list any genes for which you are requesting specific analysis or note any special requests here. (Please note: The lab will also generate a list of genes and variants based on clinical features and indication of study unless directed otherwise):

_____

_____

BILLING INFORMATION AND AUTHORIZATION

Insurance Billing Pre-Authorization (not offered for tests <$500)

☐ **Do insurance preauthorization; PROCEED if approved (PREAUTH FORM and sample required)**
☐ **Do insurance preauthorization; CONTACT PROVIDER before proceeding (PREAUTH FORM and sample required)**
☐ **PROCEED to testing without preauthorization (add billing information below)**

1. BILL INSTITUTION			
Institution:	Tax ID #:	PO#:	
Claims Billing Address:	City:	State:	Zip:
Billing Contact Name:	Phone:	FAX:	

2. BILL INSURANCE (SEE PRE-AUTH ABOVE)			
Policyholder Name:	Relationship to Patient: ☐ Self ☐ Parent ☐ Spouse	Other (specify):	
Policyholder DOB:	Dates of Coverage:		
Patient Policy ID#:	Group Name:	Group #:	
Insurance Company Name:			
Claims Billing Address:	City:	State:	Zip:
Phone:	FAX:		
ICD9 Diagnosis Code(s):			

3. SELF-PAY			
Payment Method: ☐ Cashier Check / Money Order (Payable to *UW Physicians*)			
☐ Visa ☐ MasterCard ☐ AmEX ☐ Discover			
Amount (USD):	(Amount authorized to be charged)		
Card #:	Expiration Date:	CVV#:	
Name of Cardholder:			
Billing Address:	City:	State:	Zip:
Electronic Funds Transfer (EFT) (See website for details)			
EFT Amount (USD):			

4. MEDICAID
For Medicaid billing, the following is <u>required</u>:
1. Medicaid claims address
2. Copy of Medicaid card (attach to requisition form)
3. Letter of necessity from referring physician (attach to requisition form)

SAMPLE & SHIPPING REQUIREMENTS

Blood samples should be collected in lavender top (potassium EDTA) tubes: 7mL (3-5mL for infants). All samples must be labeled with two unique identifiers: 1) the patient's full name and 2) date of birth. If possible please include the patient's medical record number. Please contact the laboratory for more details and test kits.

Samples must be accompanied by a requisition form and signed consent forms (when applicable).
Sample (with forms) should be shipped overnight at room temperature to:

Center for Precision Diagnostics
Northwest Clinical Genomics Laboratory
1959 NE Pacific St., HSC H-561
Seattle, WA 98195

For more detailed information about shipping requirements and procedures, please contact the lab at 206-543-0459.

CONSENT FOR
CLINICAL EXOME OR GENOME (GENOMIC) SEQUENCING

Patient Name: _____ Date of Birth: _____ (MM/DD/YYYY)

Test ordered: _____ Exome sequencing (sequencing of the coding portions of the genome)
_____ Genome sequencing (sequencing of the coding and non-coding portions of the genome)

Exome and genome sequencing tests are referred to as "genomic sequencing" throughout the following consent form. The technical limitations and caveats are applicable to both.

Please read this form carefully. You are being offered a blood test that examines your genetic material. This testing may help us better understand your/your child's medical condition. This consent form will explain the testing, how results are released and potential risks and benefits of doing the test and possible costs. In addition, this form will describe what is known and not known about genomic sequencing (GS) at present. GS is a new lab technique that is changing quickly. Your healthcare provider will help you understand the information on the consent form and answer any questions that you have.

You should keep your healthcare provider updated with your current contact information. This will make it possible for us to contact you if we learn important information from this testing now or in the future.

1. **What is the purpose of the genomic sequencing (GS) test ?**
   The purpose of this test is to examine the DNA sequence of each gene in the body to try to find genetic changes that might play a role in the cause of your/your child's health with respect to the following conditions(s):
   _____

2. **What must be provided for GS testing ?**
   You/your child will be asked to provide a blood or other tissue sample for testing. Medical history and family history information will be requested to assist in interpreting the test results. Once testing is completed, additional medical or family history information, or further medical tests may be recommended to better interpret the test results. At times we may request similar testing samples from relatives for comparison. If a comparator sample is submitted, the relative should also fill out and submit a Comparator Consent Form.

3. **What does the GS test look for ?**
   This test looks for gene sequence (DNA) changes that are associated with specific genetic disorders. The test may find changes in one gene or in many that cause or contribute to your/your child's condition. It is possible that this test will not find any changes that explain your/your child's condition. This "normal GS result" would not mean that you/your child do not have or will not develop a genetic disorder, only that with the current technology we cannot find the exact cause

4. **What other information can the GS test tell me ?**
   The test may find genetic changes that tell us that you/your child are at risk for disorders other than your/your child's condition, such as cancer risk. These changes are referred to as "incidental" or secondary findings. If incidental findings are thought to be medically important for you/your child, the NCGL will report the results to your/your child's healthcare provider. Your/your child's healthcare provider will talk to you about how these findings may change your/your child's risk for this additional condition and/or its medical use.

5. **What are the limits of the genomic sequencing test ?**
   Although, the GS test method will find a large number of genetic changes, there remain a small number of DNA changes that it will not detect. For the changes that we find, we may not know whether they lead to the disorder or are normal changes in gene sequence. It may be many years before we understand what all of the changes mean and are able to find a change that causes or contributes to your/your child's condition.

6. **How will I learn the results of my genomic sequencing test ?**
   You will learn the results of this test from: _____ . This healthcare provider will receive a laboratory report that discusses the results that may be relevant to the reason you/your child had testing. Your/your child's healthcare provider will share this information with you and a genetic counselor may assist in explaining the results.

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Phone: 206-616-4115 206-221-9364
www.uwcpdx.org cpdx@uw.edu

7. **How long will it take to get my results ?**
   The Northwest Clinical Genomics Lab (NCGL), the laboratory performing this test, expects to complete GS in 3 months time. Factors such as the need to repeat some part of the test or to test other family members to help with interpretation may extend the timeline. We will get the results to your healthcare provider as quickly as possible.

8. **Will I get all of my results at once ?**
   All results that we find (that you have agreed to receive) will be reported in the initial report. Because the understanding of DNA changes will improve over time, it is likely that more will be understood about your results later, after you get your initial report. If new information is discovered that is thought to be important to your/your child's health and/or the health of your relatives, your/your child's healthcare provider will be re-contacted If you would like an updated report, you should contact your healthcare provider or the NCGL. There may be a charge for a new interpretation of your results.

9. **What are the risks of the genomic sequencing test to you and your family ?**
   You may learn medical information about yourself/your child that you did not expect. Learning that you/your child are at risk for a condition other than your/your child's condition for which the test is done, and which may not be preventable or treatable, could lead to emotional or psychological distress.
   You may discover things about yourself/your child that trouble you and that you may not have the ability to control or change. For example, unexpected parental relationships or other information about your ancestry could be uncovered.
   Your relatives may be upset to learn that they may be at risk for a disease.
   The test will give us a lot of information, but we might not know what all of it means right away. It is possible that this test will not find the cause of your/your child's condition, or the test may not tell us your/your child's chance of developing specific disorders. This could be frustrating or upsetting.
   Although there are laws to prevent employment and health insurance discrimination based upon genetic findings, there are currently no laws to prevent the use of genetic information to alter the ability to obtain life, disability or long-term insurance or their cost.

10. **How could the genomic sequencing test affect my family members ?**
    This test could reveal information about the health of your relatives, such as their chances of developing certain disorders. Such information could be unexpected, or it could explain a medical condition in your family. If the test finds a genetic change that may be important to your family's health, you/your child's healthcare provider will ask you to tell your family members about it.
    This test will find many changes that we cannot interpret. In this case, testing your parents or other family members to see if they have the same change may help understand certain results. Your/your child's healthcare provider may ask you if your family members would be willing to have genetic testing. Certain follow-up testing may be performed free of charge.

11. **Will my genetic information become part of my medical record ?**
    Your/your child's genomic sequencing report will list medically important genetic changes that were found by the genomic sequencing test. The report that contains your/your child's test results as well as any updates to those results will become part of your/your child's permanent electronic medical record and can be made available to any healthcare provider who treats you now or in the future. Your protected health information will be used in accordance with the terms of the UW Medicine Healthcare Privacy policies. As we understand more about genetic changes, your/your child's report and medical record may be updated. The laboratory will not initially deposit your complete genome sequence into your/your child's medical record. However, it is possible that this policy will change in the future in which case your/your child's complete genetic sequence may be incorporated into your/your child's permanent medical records.

12. **Will anyone else have access to my genome sequence, shared medical history or interpreted results ?**
    Test results and submitted clinical information may be shared with other clinical laboratories to improve our understanding of the relationship between genetic changes and clinical symptoms and findings. Sharing data in this manner may enable us to provide better interpretations of your genetic findings as well as assist other patients with similar results. We will protect your privacy/confidentiality by replacing your name and other direct identifiers, such as date of birth or medical record number, with a code. The key to the code numbers will be stored securely in the testing laboratory. We will share only de-identified information with outside clinical laboratories.

13. **Who besides my physician can I talk to if I have more questions about the genomic sequencing test ?**
    You may request the name and phone number of a genetic counselor who can answer your questions about the genomic sequencing test and help you understand your/your child's results.

Patient Name: _____ Date of Birth: _____ (MM/DD/YYYY)

14. **How will my blood sample and genetic information be used after testing is completed?**
    After performing your test, the laboratory may use your/your child's remaining sample to do quality control checks and/or develop new and better laboratory tests. Your/your child's name and other identifying information will be removed from the sample before it is used in these ways. In addition, your de-identified sample may be used in accordance with the research policies stated in the following section. There will be no additional charge to you for using your/your child's sample in these ways.

15. **Will I have to pay for the genomic sequencing test?**
    Your health insurance may not cover the cost of this test. You will need to pay any portion of this test that is not covered by your health insurance. You may also have medical visits to follow up on the results of this test. Insurance coverage for such tests will be subject to current medical practice and your insurance policy coverage.
    If you seek insurance coverage for this test, you may be required to release your/your child's results to your health insurance company for payment purposes.

Optional Disclosure

Diagnostic Findings Not Related to the Target Clinical Condition in Adult-onset Medically Actionable Disorders: Medically actionable conditions are those for which there is current recommended treatment or preventative actions that can be taken to reduce risk of developing the complications of an adult-onset disorder. An example would be hereditary cancer syndromes where periodic medical screening may identify the cancer early. You can choose whether you want us to report the presence of such DNA changes in adult-onset disorders. Because an individual may have a DNA change of a medically actionable gene that will not be detected by the GS method, based on one's family history, additional testing for health purposes should be discussed with your doctor or genetic counselor.

☐ YES, report information regarding adult-onset actionable conditions. _____ Patient/Guardian Initials
☐ NO, DO NOT report information regarding adult-onset actionable conditions. _____ Patient/Guardian Initials

Comparators - Testing of a relative for Comparison

If a comparator sample is submitted, the relative should also fill out and submit a Comparator Consent Form.

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Patient Name: _____ Date of Birth: _____ (MM/DD/YYYY)

RESEARCH POLICIES & OPPORTUNITIES

Blood or other samples sent to the Northwest Clinical Genomics Laboratory (NCGL) may be used by UW Medicine, by medical organizations affiliated with UW Medicine, or by educational or business organizations approved by UW Medicine, for research, education and other activities that support UW Medicine's mission, without your/your child's specific consent. Other types of research performed in association with the NCGL require that we obtain consent from the patient (below).

PATIENTS – Please check off and initial below whether we can contact you to let you know about research studies requiring consent in which you/your child may be able to participate. These research studies may include: 1) a request for additional clinical records about your condition, 2) studies to find new causes for your condition, and 3) studies to evaluate newly developed treatments for your condition.

Patient Name: _____ Date of Birth: _____ / _____ / _____ (MM/DD/YYYY)

Please check one:

☐ Yes, you can contact me _____ (Patient/Guardian initials)
If yes, please provide your contact information on the first page of the requisition form.

☐ No, please do not contact me _____ (Patient/Guardian initials)

PATIENT / GUARDIAN SIGNATURE

I have carefully reviewed the above. I have had my questions answered to my satisfaction. I consent to provide a sample for genetic testing by genomic sequencing.

_____	_____	_____ AM / PM
Patient/Guardian Signature	Date	Time
_____	_____	
Patient Name (Print)	Guardian, if applicable (Print)	

_____ I agree that my family history information and my/my child's personal medical information, including results of the exome sequencing test, may be shared among all of my/my child's family members.

PROVIDER SIGNATURE

I, _____ (print name), as ordering provider, confirm that I understand and accept that the patient being tested and/or their legal guardian have been informed of the risks, benefits, expectations and limitations of the testing ordered, as well as the policies of the NCGL listed above. I have obtained informed consent, as required by my own state and/or federal laws. In addition, I assume responsibility for returning the results of genetic testing to my patient and/or their legal guardian and for ensuring that my patient receives appropriate genetic counseling to understand the implications of their test results.

___ Other
NP
PA
_____ MD _____ _____ _____ AM / PM

Signature NPI # Date Time