Children's Mercy
KANSAS CITY

Guide for Completing Genetic Sendout Consents

When sending testing to an outside genetics reference laboratory (Ref Lab) we will ask for both a CM consent form as well as the Ref Lab's consent form. In the case of an order for sponsored testing, an additional eligibility form may be required. CM Lab can be emailed to ask for these specific forms if needed.

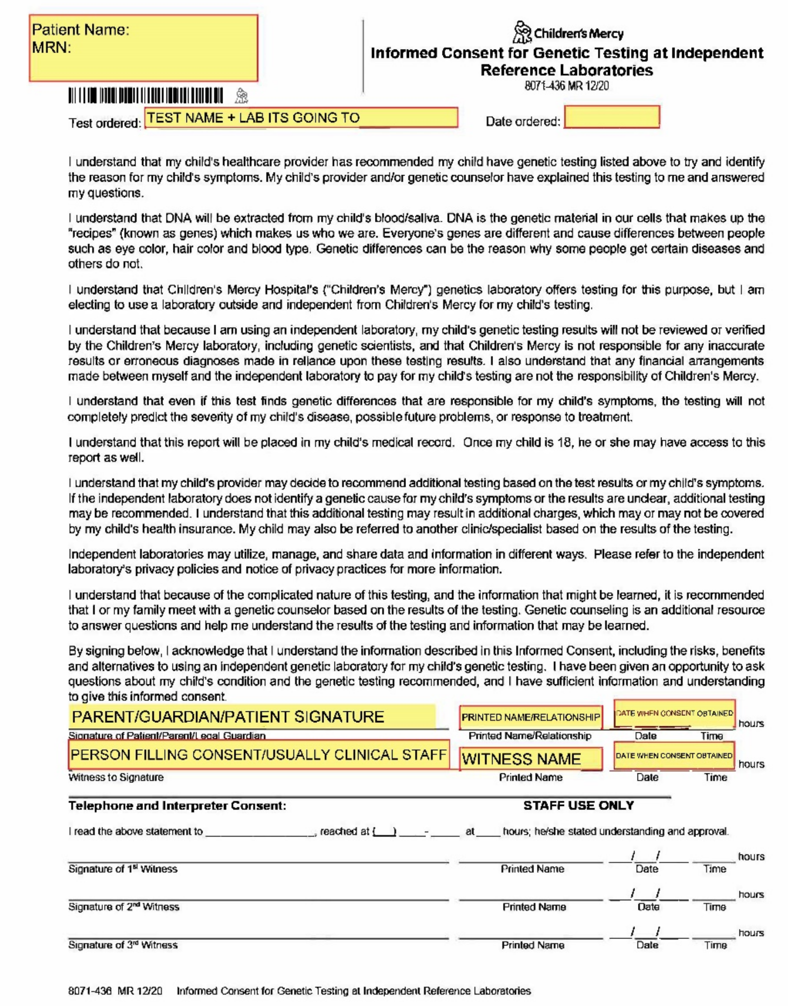
****Patient *must* have name *and* MRN on *all* pages of consents, CM and Ref Lab**

- CM providers should send all signed consents via Outlook to geneticslabconsents@cmh.edu and HIM at chart@cmh.edu.
- Please do not send via Cerner message.
- Please be sure that attached documents are able to be opened without a password.

STEPS FOR CONSENTS:

1) CM consents -- Must have test name and date ordered

   - Patient/Parent/Guardian signature - either mother or father.
     - Verbal consent can be obtained from them, please write down VERBAL CONSENT when it's the case.
   - Printed name & date.
   - Must have a witness signature/printed name/date (witness usually clinical staff member filling form).



Patient Name:
MRN:

Children's Mercy
Informed Consent for Genetic Testing at Independent Reference Laboratories
8071-436 MR 12/20

Test ordered: TEST NAME + LAB ITS GOING TO
Date ordered:

I understand that my child's healthcare provider has recommended my child have genetic testing listed above to try and identify the reason for my child's symptoms. My child's provider and/or genetic counselor have explained this testing to me and answered my questions.

I understand that DNA will be extracted from my child's blood/saliva. DNA is the genetic material in our cells that makes up the "recipes" (known as genes) which makes us who we are. Everyone's genes are different and cause differences between people such as eye color, hair color and blood type. Genetic differences can be the reason why some people get certain diseases and others do not.

I understand that Children's Mercy Hospital's ("Children's Mercy") genetics laboratory offers testing for this purpose, but I am electing to use a laboratory outside and independent from Children's Mercy for my child's testing.

I understand that because I am using an independent laboratory, my child's genetic testing results will not be reviewed or verified by the Children's Mercy laboratory, including genetic scientists, and that Children's Mercy is not responsible for any inaccurate results or erroneous diagnoses made in reliance upon these testing results. I also understand that any financial arrangements made between myself and the independent laboratory to pay for my child's testing are not the responsibility of Children's Mercy.

I understand that even if this test finds genetic differences that are responsible for my child's symptoms, the testing will not completely predict the severity of my child's disease, possible future problems, or response to treatment.

I understand that this report will be placed in my child's medical record. Once my child is 18, he or she may have access to this report as well.

I understand that my child's provider may decide to recommend additional testing based on the test results or my child's symptoms. If the independent laboratory does not identify a genetic cause for my child's symptoms or the results are unclear, additional testing may be recommended. I understand that this additional testing may result in additional charges, which may or may not be covered by my child's health insurance. My child may also be referred to another clinic/specialist based on the results of the testing.

Independent laboratories may utilize, manage, and share data and information in different ways. Please refer to the independent laboratory's privacy policies and notice of privacy practices for more information.

I understand that because of the complicated nature of this testing, and the information that might be learned, it is recommended that I or my family meet with a genetic counselor based on the results of the testing. Genetic counseling is an additional resource to answer questions and help me understand the results of the testing and information that may be learned.

By signing below, I acknowledge that I understand the information described in this Informed Consent, including the risks, benefits and alternatives to using an independent genetic laboratory for my child's genetic testing. I have been given an opportunity to ask questions about my child's condition and the genetic testing recommended, and I have sufficient information and understanding to give this informed consent.

PARENT/GUARDIAN/PATIENT SIGNATURE	PRINTED NAME/RELATIONSHIP	DATE WHEN CONSENT OBTAINED		hours
Signature of Patient/Parent/Legal Guardian	Printed Name/Relationship	Date	Time	
PERSON FILLING CONSENT/USUALLY CLINICAL STAFF	WITNESS NAME	DATE WHEN CONSENT OBTAINED		hours
Witness to Signature	Printed Name	Date	Time	

Telephone and Interpreter Consent: **STAFF USE ONLY**

I read the above statement to _________________, reached at (___) _____-______ at _____ hours; he/she stated understanding and approval.

Signature of 1st Witness	Printed Name	__/__/__ Date	Time	hours
Signature of 2nd Witness	Printed Name	__/__/__ Date	Time	hours
Signature of 3rd Witness	Printed Name	__/__/__ Date	Time	hours

8071-436 MR 12/20 Informed Consent for Genetic Testing at Independent Reference Laboratories

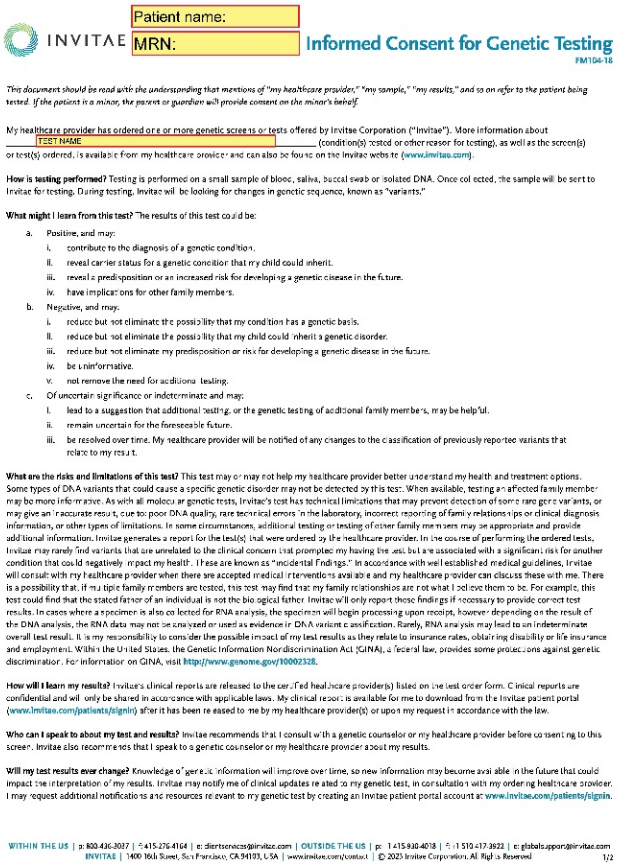
2) REF LAB INSTRUCTIONS:

For our Ref Labs, instructions will basically be the same regarding their consent forms.

In general:

- Must have name + MRN/DOB on all pages.
- Patient/Parent/Guardian signature - either mother/father/guardian AND dated.
  - ▪ For MOST Ref Labs, verbal consent can be obtained.Please write down VERBAL CONSENT in the signature line when it's the case.
- Provider/clinical staff signature - dated.

Example:



INVITAE

Patient name:

MRN:

Informed Consent for Genetic Testing

FM104-18

This document should be read with the understanding that mentions of "my healthcare provider," "my sample," "my results," and so on refer to the patient being tested. If the patient is a minor, the parent or guardian will provide consent on the minor's behalf.

My healthcare provider has ordered one or more genetic screens or tests offered by Invitae Corporation ("Invitae"). More information about TEST NAME (condition(s) tested or other reason for testing), as well as the screen(s) or test(s) ordered, is available from my healthcare provider and can also be found on the Invitae website (www.invitae.com).

How is testing performed? Testing is performed on a small sample of blood, saliva, buccal swab or isolated DNA. Once collected, the sample will be sent to Invitae for testing. During testing, Invitae will be looking for changes in genetic sequence, known as "variants."

What might I learn from this test? The results of this test could be:

a. Positive, and may:
   i. contribute to the diagnosis of a genetic condition.
   ii. reveal carrier status for a genetic condition that my child could inherit.
   iii. reveal a predisposition or an increased risk for developing a genetic disease in the future.
   iv. have implications for other family members.
b. Negative, and may:
   i. reduce but not eliminate the possibility that my condition has a genetic basis.
   ii. reduce but not eliminate the possibility that my child could inherit a genetic disorder.
   iii. reduce but not eliminate my predisposition or risk for developing a genetic disease in the future.
   iv. be uninformative.
   v. not remove the need for additional testing.
c. Of uncertain significance or indeterminate and may:
   i. lead to a suggestion that additional testing, or the genetic testing of additional family members, may be helpful.
   ii. remain uncertain for the foreseeable future.
   iii. be resolved over time. My healthcare provider will be notified of any changes to the classification of previously reported variants that relate to my result.

What are the risks and limitations of this test? This test may or may not help my healthcare provider better understand my health and treatment options. Some types of DNA variants that could cause a specific genetic disorder may not be detected by this test. When available, testing an affected family member may be more informative. As with all molecular genetic tests, Invitae's test has technical limitations that may prevent detection of some rare gene variants, or may give an inaccurate result, due to: poor DNA quality, rare technical errors in the laboratory, incorrect reporting of family relationships or clinical diagnosis information, or other types of limitations. In some circumstances, additional testing or testing of other family members may be appropriate and provide additional information. Invitae generates a report for the test(s) that were ordered by the healthcare provider. In the course of performing the ordered tests, Invitae may rarely find variants that are unrelated to the clinical concern that prompted my having the test but are associated with a significant risk for another condition that could negatively impact my health. These are known as "incidental Findings." In accordance with well established medical guidelines, Invitae will consult with my healthcare provider when there are accepted medical interventions available and my healthcare provider can discuss these with me. There is a possibility that, if multiple family members are tested, this test may find that my family relationships are not what I believe them to be. For example, this test could find that the stated father of an individual is not the biological father. Invitae will only report these findings if necessary to provide correct test results. In cases where a specimen is also collected for RNA analysis, the specimen will begin processing upon receipt, however depending on the result of the DNA analysis, the RNA data may not be analyzed or used as evidence in DNA variant classification. Rarely, RNA analysis may lead to an indeterminate overall test result. It is my responsibility to consider the possible impact of my test results as they relate to insurance rates, obtaining disability or life insurance and employment. Within the United States, the Genetic Information Nondiscrimination Act (GINA), a federal law, provides some protections against genetic discrimination. For information on GINA, visit http://www.genome.gov/10002328.

How will I learn my results? Invitae's clinical reports are released to the certified healthcare provider(s) listed on the test order form. Clinical reports are confidential and will only be shared in accordance with applicable laws. My clinical report is available for me to download from the Invitae patient portal (www.invitae.com/patients/signin) after it has been released to me by my healthcare provider(s) or upon my request in accordance with the law.

Who can I speak to about my test and results? Invitae recommends that I consult with a genetic counselor or my healthcare provider before consenting to this screen. Invitae also recommends that I speak to a genetic counselor or my healthcare provider about my results.

Will my test results ever change? Knowledge of genetic information will improve over time, so new information may become available in the future that could impact the interpretation of my results. Invitae may notify me of clinical updates related to my genetic test, in consultation with my ordering healthcare provider. I may request additional notifications and resources relevant to my genetic test by creating an Invitae patient portal account at www.invitae.com/patients/signin.

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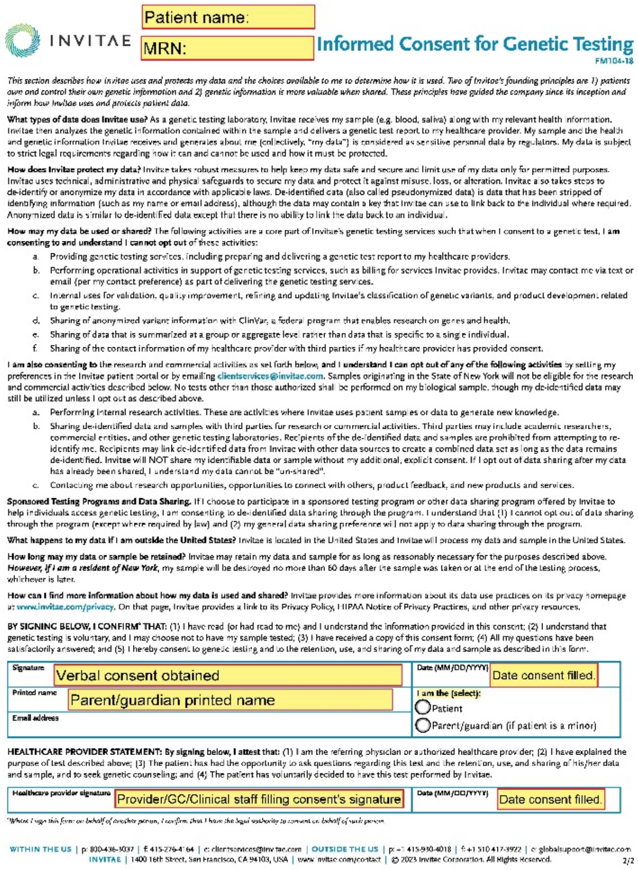
INVITAE | 1400 16th Street, San Francisco, CA 94103, USA | www.invitae.com/contact | © 2023 Invitae Corporation. All Rights Reserved. 1/2



INVITAE

Patient name:

MRN:

Informed Consent for Genetic Testing

FM104-18

This section describes how Invitae uses and protects my data and the choices available to me to determine how it is used. Two of Invitae's founding principles are 1) patients own and control their own genetic information and 2) genetic information is more valuable when shared. These principles have guided the company since its inception and inform how Invitae uses and protects patient data.

What types of data does Invitae use? As a genetic testing laboratory, Invitae receives my sample (e.g. blood, saliva) along with my relevant health information. Invitae then analyzes the genetic information contained within the sample and delivers a genetic test report to my healthcare provider. My sample and the health and genetic information Invitae receives and generates about me (collectively, "my data") is considered as sensitive personal data by regulators. My data is subject to strict legal requirements regarding how it can and cannot be used and how it must be protected.

How does Invitae protect my data? Invitae takes robust measures to help keep my data safe and secure and limit use of my data only for permitted purposes. Invitae uses technical, administrative and physical safeguards to secure my data and protect it against misuse, loss, or alteration. Invitae also takes steps to de-identify or anonymize my data in accordance with applicable laws. De-identified data (also called pseudonymized data) is data that has been stripped of identifying information (such as my name or email address), although the data may contain a key that Invitae can use to link back to the individual where required. Anonymized data is similar to de-identified data except that there is no ability to link the data back to an individual.

How may my data be used or shared? The following activities are a core part of Invitae's genetic testing services such that when I consent to a genetic test, **I am consenting to and understand I cannot opt out** of these activities:

a. Providing genetic testing services, including preparing and delivering a genetic test report to my healthcare providers.
b. Performing operational activities in support of genetic testing services, such as billing for services Invitae provides. Invitae may contact me via text or email (per my contact preference) as part of delivering the genetic testing services.
c. Internal uses for validation, quality improvement, refining and updating Invitae's classification of genetic variants, and product development related to genetic testing.
d. Sharing of anonymized variant information with ClinVar, a federal program that enables research on genes and health.
e. Sharing of data that is summarized at a group or aggregate level rather than data that is specific to a single individual.
f. Sharing of the contact information of my healthcare provider with third parties if my healthcare provider has provided consent.

I am also consenting to the research and commercial activities as set forth below, **and I understand I can opt out of any of the following activities** by setting my preferences in the Invitae patient portal or by emailing clientservices@invitae.com. Samples originating in the State of New York will not be eligible for the research and commercial activities described below. No tests other than those authorized shall be performed on my biological sample, though my de-identified data may still be utilized unless I opt out as described above.

a. Performing internal research activities. These are activities where Invitae uses patient samples or data to generate new knowledge.
b. Sharing de-identified data and samples with third parties for research or commercial activities. Third parties may include academic researchers, commercial entities, and other genetic testing laboratories. Recipients of the de-identified data and samples are prohibited from attempting to re-identify me. Recipients may link de-identified data from Invitae with other data sources to create a combined data set as long as the data remains de-identified. Invitae will NOT share my identifiable data or sample without my additional, explicit consent. If I opt out of data sharing after my data has already been shared, I understand my data cannot be "un-shared".
c. Contacting me about research opportunities, opportunities to connect with others, product feedback, and new products and services.

Sponsored Testing Programs and Data Sharing. If I choose to participate in a sponsored testing program or other data sharing program offered by Invitae to help individuals access genetic testing, I am consenting to de-identified data sharing through the program. I understand that (1) I cannot opt out of data sharing through the program (except where required by law) and (2) my general data sharing preference will not apply to data sharing through the program.

What happens to my data if I am outside the United States? Invitae is located in the United States and Invitae will process my data and sample in the United States.

How long may my data or sample be retained? Invitae may retain my data and sample for as long as reasonably necessary for the purposes described above. ***However, if I am a resident of New York***, my sample will be destroyed no more than 60 days after the sample was taken or at the end of the testing process, whichever is later.

How can I find more information about how my data is used and shared? Invitae provides more information about its data use practices on its privacy homepage at www.invitae.com/privacy. On that page, Invitae provides a link to its Privacy Policy, HIPAA Notice of Privacy Practices, and other privacy resources.

BY SIGNING BELOW, I CONFIRM* THAT: (1) I have read (or had read to me) and I understand the information provided in this consent; (2) I understand that genetic testing is voluntary, and I may choose not to have my sample tested; (3) I have received a copy of this consent form; (4) All my questions have been satisfactorily answered; and (5) I hereby consent to genetic testing and to the retention, use, and sharing of my data and sample as described in this form.

Signature Verbal consent obtained	Date (MM/DD/YYYY) Date consent filled.
Printed name Parent/guardian printed name	I am the (select): ○ Patient ○ Parent/guardian (if patient is a minor)
Email address	

HEALTHCARE PROVIDER STATEMENT: By signing below, I attest that: (1) I am the referring physician or authorized healthcare provider; (2) I have explained the purpose of test described above; (3) The patient has had the opportunity to ask questions regarding this test and the retention, use, and sharing of his/her data and sample, and to seek genetic counseling; and (4) The patient has voluntarily decided to have this test performed by Invitae.

Healthcare provider signature Provider/GC/Clinical staff filling consent's signature	Date (MM/DD/YYYY) Date consent filled.

**Where I sign this form on behalf of another person, I confirm that I have the legal authority to consent on behalf of such person.*

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INVITAE | 1400 16th Street, San Francisco, CA 94103, USA | www.invitae.com/contact | © 2023 Invitae Corporation. All Rights Reserved. 2/2

For WES testing:

GeneDx:

For XomeDx Duo/Trio/etc: One consent can be used for patient and parent(s).

- Same rule applies for Names and MRNs which MUST be on top of all pages of consent forms.
- Only proband's name/MRN is required for consent.
- Parent signature/verbal consents can be documented as Relative A and Relative B.

Please also specify if secondary findings will be wanted with testing. For this, both parents must agree to secondary findings to request them.

Ambry:

Each family member must have their own CMH AND Ambry consent.

1) Names and MRNs must be on top of all pages of consent forms.
2) Must initial the bottom of page 1.
3) If verbal consent, must hand write the addition 'verbal consents' manually at bottom of page 2.

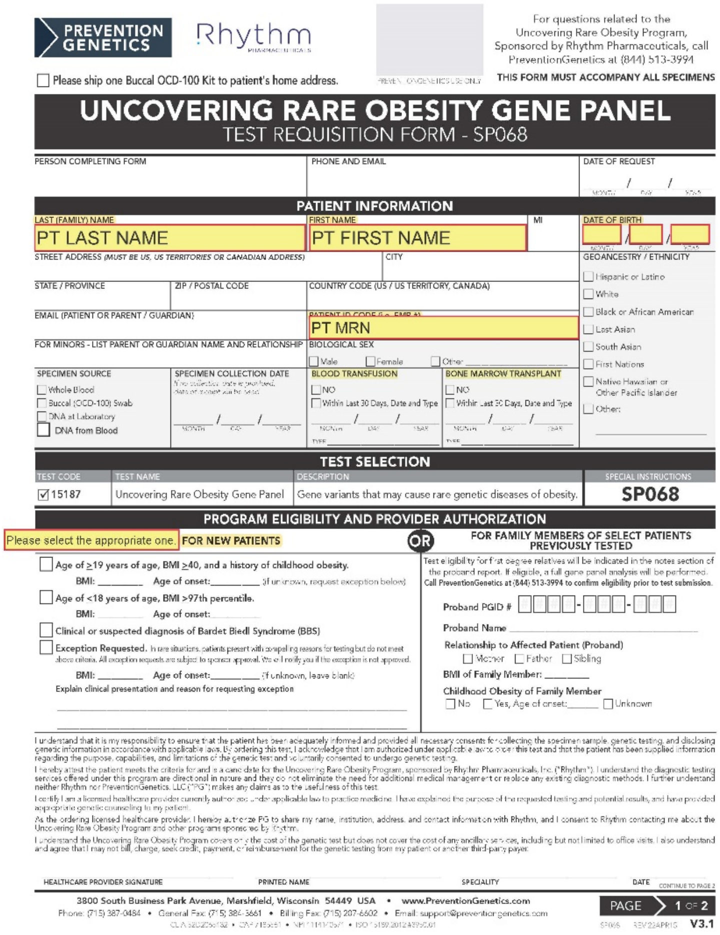
***Also, please remember to circle what specific test option is wanted. This will be found in the first page of Ambry's consent form.

Special consents:

Some labs might be a bit more specific with what they want in their consents. Updates will be added here as we become aware.

Prevention:

Prevention actually requires parent/guardian's <u>physical</u> signatures in the consent forms for all their tests.



PREVENTION GENETICS | Rhythm PHARMACEUTICALS

PREVENTIONGENETICS USE ONLY

For questions related to the Uncovering Rare Obesity Program, Sponsored by Rhythm Pharmaceuticals, call PreventionGenetics at (844) 513-3994

THIS FORM MUST ACCOMPANY ALL SPECIMENS

☐ Please ship one Buccal OCD-100 Kit to patient's home address.

UNCOVERING RARE OBESITY GENE PANEL
TEST REQUISITION FORM - SP068

PERSON COMPLETING FORM | PHONE AND EMAIL | DATE OF REQUEST ___ / ___ / ___ MONTH DAY YEAR

PATIENT INFORMATION

LAST (FAMILY) NAME: PT LAST NAME
FIRST NAME: PT FIRST NAME
MI
DATE OF BIRTH ___ / ___ / ___ MONTH DAY YEAR
STREET ADDRESS *(MUST BE US, US TERRITORIES OR CANADIAN ADDRESS)*
CITY
STATE / PROVINCE
ZIP / POSTAL CODE
COUNTRY CODE (US / US TERRITORY, CANADA)
EMAIL (PATIENT OR PARENT / GUARDIAN)
PATIENT ID CODE (i.e., EMR #): PT MRN
FOR MINORS - LIST PARENT OR GUARDIAN NAME AND RELATIONSHIP
BIOLOGICAL SEX ☐ Male ☐ Female ☐ Other ______

GEOANCESTRY / ETHNICITY
☐ Hispanic or Latino
☐ White
☐ Black or African American
☐ East Asian
☐ South Asian
☐ First Nations
☐ Native Hawaiian or Other Pacific Islander
☐ Other: ______

SPECIMEN SOURCE
☐ Whole Blood
☐ Buccal (OCD-100) Swab
☐ DNA at Laboratory
☐ DNA from Blood

SPECIMEN COLLECTION DATE
If no collection date is provided, date of receipt will be used.
___ / ___ / ___ MONTH DAY YEAR

BLOOD TRANSFUSION
☐ NO
☐ Within Last 30 Days, Date and Type
___ / ___ / ___ MONTH DAY YEAR
TYPE ______

BONE MARROW TRANSPLANT
☐ NO
☐ Within Last 30 Days, Date and Type
___ / ___ / ___ MONTH DAY YEAR
TYPE ______

TEST SELECTION

TEST CODE	TEST NAME	DESCRIPTION	SPECIAL INSTRUCTIONS
☑ 15187	Uncovering Rare Obesity Gene Panel	Gene variants that may cause rare genetic diseases of obesity.	SP068

PROGRAM ELIGIBILITY AND PROVIDER AUTHORIZATION

Please select the appropriate one. **FOR NEW PATIENTS** OR **FOR FAMILY MEMBERS OF SELECT PATIENTS PREVIOUSLY TESTED**

FOR NEW PATIENTS

☐ Age of ≥19 years of age, BMI ≥40, and a history of childhood obesity.
BMI: ______ Age of onset: ______ (if unknown, request exception below)
☐ Age of <18 years of age, BMI >97th percentile.
BMI: ______ Age of onset: ______
☐ Clinical or suspected diagnosis of Bardet Biedl Syndrome (BBS)
☐ Exception Requested. In rare situations, patients present with compelling reasons for testing but do not meet above criteria. All exception requests are subject to sponsor approval. We will notify you if the exception is not approved.
BMI: ______ Age of onset: ______ (if unknown, leave blank)
Explain clinical presentation and reason for requesting exception

FOR FAMILY MEMBERS OF SELECT PATIENTS PREVIOUSLY TESTED

Test eligibility for first degree relatives will be indicated in the notes section of the proband report. If eligible, a full gene panel analysis will be performed. Call PreventionGenetics at (844) 513-3994 to confirm eligibility prior to test submission.

Proband PGID # ☐☐☐☐-☐☐☐-☐☐☐
Proband Name ______
Relationship to Affected Patient (Proband)
☐ Mother ☐ Father ☐ Sibling
BMI of Family Member: ______
Childhood Obesity of Family Member
☐ No ☐ Yes, Age of onset: ______ ☐ Unknown

I understand that it is my responsibility to ensure that the patient has been adequately informed and provided all necessary consents for collecting the specimen sample, genetic testing, and disclosing genetic information in accordance with applicable laws. By ordering this test, I acknowledge that I am authorized under applicable law to order this test and that the patient has been supplied information regarding the purpose, capabilities, and limitations of the genetic test and voluntarily consented to undergo genetic testing.

I hereby attest the patient meets the criteria for and is a candidate for the Uncovering Rare Obesity Program, sponsored by Rhythm Pharmaceuticals, Inc. ("Rhythm"). I understand the diagnostic testing services offered under this program are directional in nature and they do not eliminate the need for additional medical management or replace any existing diagnostic methods. I further understand neither Rhythm nor PreventionGenetics, LLC ("PG") makes any claims as to the usefulness of this test.

I certify I am a licensed healthcare provider currently authorized under applicable law to practice medicine. I have explained the purpose of the requested testing and potential results, and have provided appropriate genetic counseling to my patient.

As the ordering licensed healthcare provider, I hereby authorize PG to share my name, institution, address, and contact information with Rhythm, and I consent to Rhythm contacting me about the Uncovering Rare Obesity Program and other programs sponsored by Rhythm.

I understand the Uncovering Rare Obesity Program covers only the cost of the genetic test but does not cover the cost of any ancillary services, including but not limited to office visits. I also understand and agree that I may not bill, charge, seek credit, payment, or reimbursement for the genetic testing from my patient or another third-party payer.

HEALTHCARE PROVIDER SIGNATURE | PRINTED NAME | SPECIALITY | DATE
CONTINUE TO PAGE 2

3800 South Business Park Avenue, Marshfield, Wisconsin 54449 USA • www.PreventionGenetics.com
Phone: (715) 387-0484 • General Fax: (715) 384-3661 • Billing Fax: (715) 207-6602 • Email: support@preventiongenetics.com

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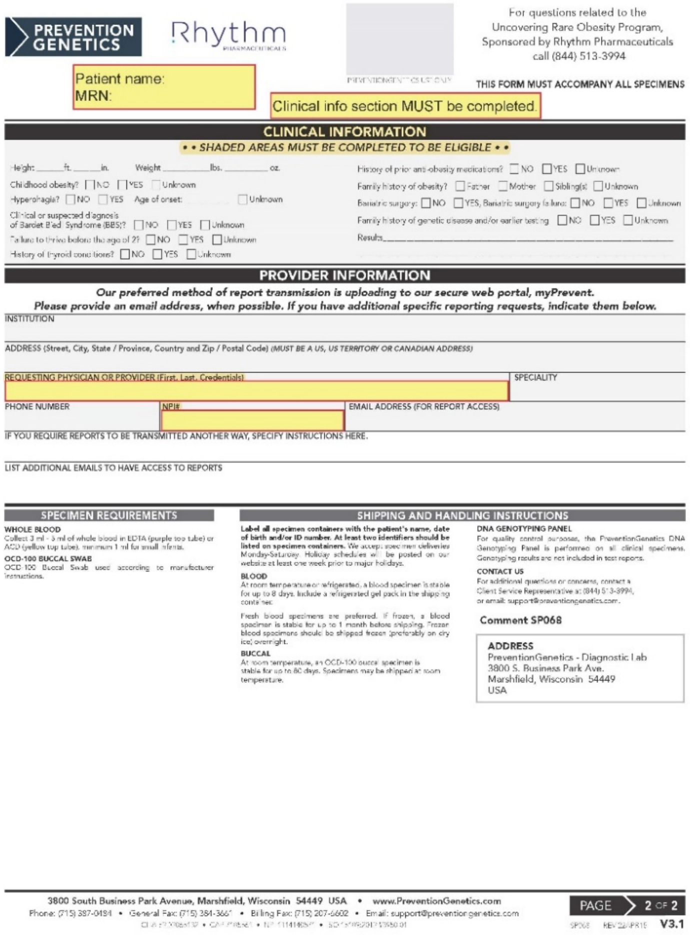

PREVENTION GENETICS | Rhythm PHARMACEUTICALS

Patient name:
MRN:

PREVENTIONGENETICS USE ONLY

For questions related to the Uncovering Rare Obesity Program, Sponsored by Rhythm Pharmaceuticals call (844) 513-3994

THIS FORM MUST ACCOMPANY ALL SPECIMENS

Clinical info section MUST be completed.

CLINICAL INFORMATION

• • SHADED AREAS MUST BE COMPLETED TO BE ELIGIBLE • •

Height: ___ ft. ___ in. Weight ______ lbs. ______ oz.
Childhood obesity? ☐ NO ☐ YES ☐ Unknown
Hyperphagia? ☐ NO ☐ YES Age of onset: ______ ☐ Unknown
Clinical or suspected diagnosis of Bardet Biedl Syndrome (BBS)? ☐ NO ☐ YES ☐ Unknown
Failure to thrive before the age of 2? ☐ NO ☐ YES ☐ Unknown
History of thyroid conditions? ☐ NO ☐ YES ☐ Unknown
History of prior anti-obesity medications? ☐ NO ☐ YES ☐ Unknown
Family history of obesity? ☐ Father ☐ Mother ☐ Sibling(s) ☐ Unknown
Bariatric surgery: ☐ NO ☐ YES, Bariatric surgery failure: ☐ NO ☐ YES ☐ Unknown
Family history of genetic disease and/or earlier testing ☐ NO ☐ YES ☐ Unknown
Results ______

PROVIDER INFORMATION

Our preferred method of report transmission is uploading to our secure web portal, myPrevent. Please provide an email address, when possible. If you have additional specific reporting requests, indicate them below.

INSTITUTION
ADDRESS (Street, City, State / Province, Country and Zip / Postal Code) *(MUST BE A US, US TERRITORY OR CANADIAN ADDRESS)*
REQUESTING PHYSICIAN OR PROVIDER (First, Last, Credentials) | SPECIALITY
PHONE NUMBER | NPI# | EMAIL ADDRESS (FOR REPORT ACCESS)
IF YOU REQUIRE REPORTS TO BE TRANSMITTED ANOTHER WAY, SPECIFY INSTRUCTIONS HERE.
LIST ADDITIONAL EMAILS TO HAVE ACCESS TO REPORTS

SPECIMEN REQUIREMENTS

WHOLE BLOOD
Collect 3 ml - 5 ml of whole blood in EDTA (purple top tube) or ACD (yellow top tube), minimum 1 ml for small infants.

OCD-100 BUCCAL SWAB
OCD-100 Buccal Swab used according to manufacturer instructions.

SHIPPING AND HANDLING INSTRUCTIONS

Label all specimen containers with the patient's name, date of birth and/or ID number. At least two identifiers should be listed on specimen containers. We accept specimen deliveries Monday-Saturday. Holiday schedules will be posted on our website at least one week prior to major holidays.

BLOOD
At room temperature or refrigerated, a blood specimen is stable for up to 8 days. Include a refrigerated gel pack in the shipping container.

Fresh blood specimens are preferred. If frozen, a blood specimen is stable for up to 1 month before shipping. Frozen blood specimens should be shipped frozen (preferably on dry ice) overnight.

BUCCAL
At room temperature, an OCD-100 buccal specimen is stable for up to 80 days. Specimens may be shipped at room temperature.

DNA GENOTYPING PANEL
For quality control purposes, the PreventionGenetics DNA Genotyping Panel is performed on all clinical specimens. Genotyping results are not included in test reports.

CONTACT US
For additional questions or concerns, contact a Client Service Representative at (844) 513-3994, or email: support@preventiongenetics.com.

Comment SP068

ADDRESS
PreventionGenetics - Diagnostic Lab
3800 S. Business Park Ave.
Marshfield, Wisconsin 54449
USA

3800 South Business Park Avenue, Marshfield, Wisconsin 54449 USA • www.PreventionGenetics.com
Phone: (715) 387-0484 • General Fax: (715) 384-3661 • Billing Fax: (715) 207-6602 • Email: support@preventiongenetics.com

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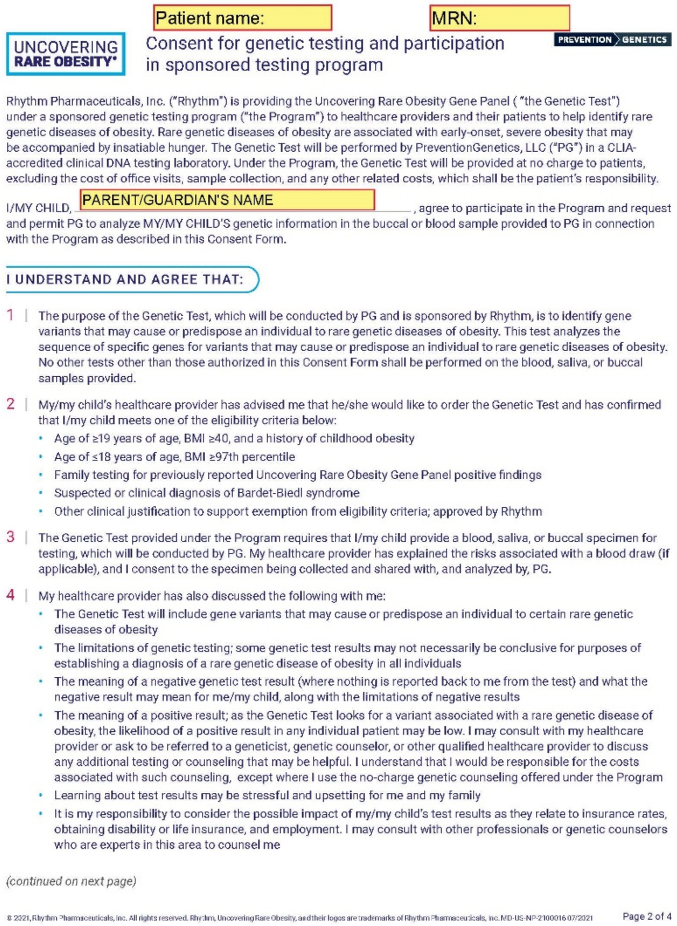
Guide for Completing Genetic Sendout Consents



Patient name: MRN:

UNCOVERING RARE OBESITY®

Consent for genetic testing and participation in sponsored testing program

PREVENTION GENETICS

Rhythm Pharmaceuticals, Inc. ("Rhythm") is providing the Uncovering Rare Obesity Gene Panel ("the Genetic Test") under a sponsored genetic testing program ("the Program") to healthcare providers and their patients to help identify rare genetic diseases of obesity. Rare genetic diseases of obesity are associated with early-onset, severe obesity that may be accompanied by insatiable hunger. The Genetic Test will be performed by PreventionGenetics, LLC ("PG") in a CLIA-accredited clinical DNA testing laboratory. Under the Program, the Genetic Test will be provided at no charge to patients, excluding the cost of office visits, sample collection, and any other related costs, which shall be the patient's responsibility.

I/MY CHILD, PARENT/GUARDIAN'S NAME, agree to participate in the Program and request and permit PG to analyze MY/MY CHILD'S genetic information in the buccal or blood sample provided to PG in connection with the Program as described in this Consent Form.

I UNDERSTAND AND AGREE THAT:

1 | The purpose of the Genetic Test, which will be conducted by PG and is sponsored by Rhythm, is to identify gene variants that may cause or predispose an individual to rare genetic diseases of obesity. This test analyzes the sequence of specific genes for variants that may cause or predispose an individual to rare genetic diseases of obesity. No other tests other than those authorized in this Consent Form shall be performed on the blood, saliva, or buccal samples provided.

2 | My/my child's healthcare provider has advised me that he/she would like to order the Genetic Test and has confirmed that I/my child meets one of the eligibility criteria below:

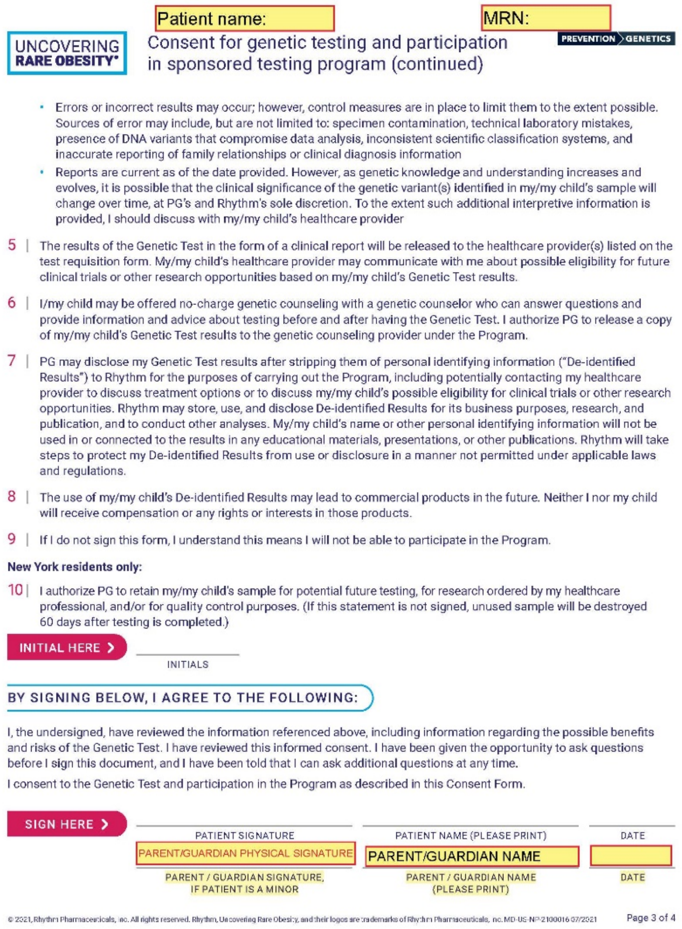
- Age of ≥19 years of age, BMI ≥40, and a history of childhood obesity
- Age of ≤18 years of age, BMI ≥97th percentile
- Family testing for previously reported Uncovering Rare Obesity Gene Panel positive findings
- Suspected or clinical diagnosis of Bardet-Biedl syndrome
- Other clinical justification to support exemption from eligibility criteria; approved by Rhythm

3 | The Genetic Test provided under the Program requires that I/my child provide a blood, saliva, or buccal specimen for testing, which will be conducted by PG. My healthcare provider has explained the risks associated with a blood draw (if applicable), and I consent to the specimen being collected and shared with, and analyzed by, PG.

4 | My healthcare provider has also discussed the following with me:

- The Genetic Test will include gene variants that may cause or predispose an individual to certain rare genetic diseases of obesity
- The limitations of genetic testing; some genetic test results may not necessarily be conclusive for purposes of establishing a diagnosis of a rare genetic disease of obesity in all individuals
- The meaning of a negative genetic test result (where nothing is reported back to me from the test) and what the negative result may mean for me/my child, along with the limitations of negative results
- The meaning of a positive result; as the Genetic Test looks for a variant associated with a rare genetic disease of obesity, the likelihood of a positive result in any individual patient may be low. I may consult with my healthcare provider or ask to be referred to a geneticist, genetic counselor, or other qualified healthcare provider to discuss any additional testing or counseling that may be helpful. I understand that I would be responsible for the costs associated with such counseling, except where I use the no-charge genetic counseling offered under the Program
- Learning about test results may be stressful and upsetting for me and my family
- It is my responsibility to consider the possible impact of my/my child's test results as they relate to insurance rates, obtaining disability or life insurance, and employment. I may consult with other professionals or genetic counselors who are experts in this area to counsel me

(continued on next page)



Patient name: MRN:

UNCOVERING RARE OBESITY®

Consent for genetic testing and participation in sponsored testing program (continued)

PREVENTION GENETICS

- Errors or incorrect results may occur; however, control measures are in place to limit them to the extent possible. Sources of error may include, but are not limited to: specimen contamination, technical laboratory mistakes, presence of DNA variants that compromise data analysis, inconsistent scientific classification systems, and inaccurate reporting of family relationships or clinical diagnosis information
- Reports are current as of the date provided. However, as genetic knowledge and understanding increases and evolves, it is possible that the clinical significance of the genetic variant(s) identified in my/my child's sample will change over time, at PG's and Rhythm's sole discretion. To the extent such additional interpretive information is provided, I should discuss with my/my child's healthcare provider

5 | The results of the Genetic Test in the form of a clinical report will be released to the healthcare provider(s) listed on the test requisition form. My/my child's healthcare provider may communicate with me about possible eligibility for future clinical trials or other research opportunities based on my/my child's Genetic Test results.

6 | I/my child may be offered no-charge genetic counseling with a genetic counselor who can answer questions and provide information and advice about testing before and after having the Genetic Test. I authorize PG to release a copy of my/my child's Genetic Test results to the genetic counseling provider under the Program.

7 | PG may disclose my Genetic Test results after stripping them of personal identifying information ("De-identified Results") to Rhythm for the purposes of carrying out the Program, including potentially contacting my healthcare provider to discuss treatment options or to discuss my/my child's possible eligibility for clinical trials or other research opportunities. Rhythm may store, use, and disclose De-identified Results for its business purposes, research, and publication, and to conduct other analyses. My/my child's name or other personal identifying information will not be used in or connected to the results in any educational materials, presentations, or other publications. Rhythm will take steps to protect my De-identified Results from use or disclosure in a manner not permitted under applicable laws and regulations.

8 | The use of my/my child's De-identified Results may lead to commercial products in the future. Neither I nor my child will receive compensation or any rights or interests in those products.

9 | If I do not sign this form, I understand this means I will not be able to participate in the Program.

New York residents only:

10 | I authorize PG to retain my/my child's sample for potential future testing, for research ordered by my healthcare professional, and/or for quality control purposes. (If this statement is not signed, unused sample will be destroyed 60 days after testing is completed.)

INITIAL HERE ❯ ____________
INITIALS

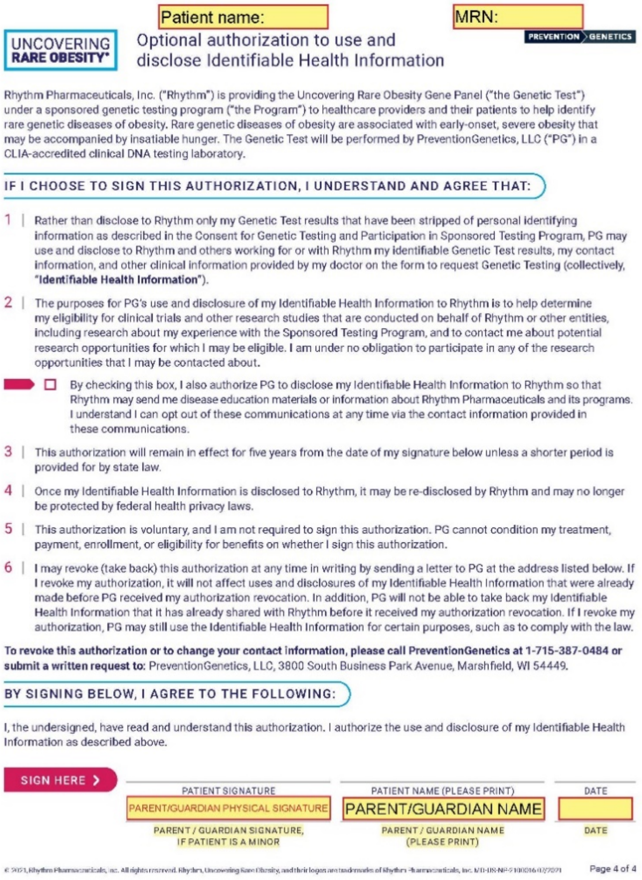
BY SIGNING BELOW, I AGREE TO THE FOLLOWING:

I, the undersigned, have reviewed the information referenced above, including information regarding the possible benefits and risks of the Genetic Test. I have reviewed this informed consent. I have been given the opportunity to ask questions before I sign this document, and I have been told that I can ask additional questions at any time.

I consent to the Genetic Test and participation in the Program as described in this Consent Form.

SIGN HERE ❯

PATIENT SIGNATURE	PATIENT NAME (PLEASE PRINT)	DATE
PARENT/GUARDIAN PHYSICAL SIGNATURE	PARENT/GUARDIAN NAME	
PARENT / GUARDIAN SIGNATURE, IF PATIENT IS A MINOR	PARENT / GUARDIAN NAME (PLEASE PRINT)	DATE



Patient name: MRN:

UNCOVERING RARE OBESITY®

Optional authorization to use and disclose Identifiable Health Information

PREVENTION GENETICS

Rhythm Pharmaceuticals, Inc. ("Rhythm") is providing the Uncovering Rare Obesity Gene Panel ("the Genetic Test") under a sponsored genetic testing program ("the Program") to healthcare providers and their patients to help identify rare genetic diseases of obesity. Rare genetic diseases of obesity are associated with early-onset, severe obesity that may be accompanied by insatiable hunger. The Genetic Test will be performed by PreventionGenetics, LLC ("PG") in a CLIA-accredited clinical DNA testing laboratory.

IF I CHOOSE TO SIGN THIS AUTHORIZATION, I UNDERSTAND AND AGREE THAT:

1 | Rather than disclose to Rhythm only my Genetic Test results that have been stripped of personal identifying information as described in the Consent for Genetic Testing and Participation in Sponsored Testing Program, PG may use and disclose to Rhythm and others working for or with Rhythm my identifiable Genetic Test results, my contact information, and other clinical information provided by my doctor on the form to request Genetic Testing (collectively, "**Identifiable Health Information**").

2 | The purposes for PG's use and disclosure of my Identifiable Health Information to Rhythm is to help determine my eligibility for clinical trials and other research studies that are conducted on behalf of Rhythm or other entities, including research about my experience with the Sponsored Testing Program, and to contact me about potential research opportunities for which I may be eligible. I am under no obligation to participate in any of the research opportunities that I may be contacted about.

☐ By checking this box, I also authorize PG to disclose my Identifiable Health Information to Rhythm so that Rhythm may send me disease education materials or information about Rhythm Pharmaceuticals and its programs. I understand I can opt out of these communications at any time via the contact information provided in these communications.

3 | This authorization will remain in effect for five years from the date of my signature below unless a shorter period is provided for by state law.

4 | Once my Identifiable Health Information is disclosed to Rhythm, it may be re-disclosed by Rhythm and may no longer be protected by federal health privacy laws.

5 | This authorization is voluntary, and I am not required to sign this authorization. PG cannot condition my treatment, payment, enrollment, or eligibility for benefits on whether I sign this authorization.

6 | I may revoke (take back) this authorization at any time in writing by sending a letter to PG at the address listed below. If I revoke my authorization, it will not affect uses and disclosures of my Identifiable Health Information that were already made before PG received my authorization revocation. In addition, PG will not be able to take back my Identifiable Health Information that it has already shared with Rhythm before it received my authorization revocation. If I revoke my authorization, PG may still use the Identifiable Health Information for certain purposes, such as to comply with the law.

To revoke this authorization or to change your contact information, please call PreventionGenetics at 1-715-387-0484 or submit a written request to: PreventionGenetics, LLC, 3800 South Business Park Avenue, Marshfield, WI 54449.

BY SIGNING BELOW, I AGREE TO THE FOLLOWING:

I, the undersigned, have read and understand this authorization. I authorize the use and disclosure of my Identifiable Health Information as described above.

SIGN HERE ❯

PATIENT SIGNATURE	PATIENT NAME (PLEASE PRINT)	DATE
PARENT/GUARDIAN PHYSICAL SIGNATURE	PARENT/GUARDIAN NAME	
PARENT / GUARDIAN SIGNATURE, IF PATIENT IS A MINOR	PARENT / GUARDIAN NAME (PLEASE PRINT)	DATE