AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION

I authorize the laboratory that has conducted or will conduct my genetic testing under the *RPE65* Genetic Test Program and my physician to disclose to Spark Therapeutics and its affiliates, partners, collaborators, and others (collectively, "Spark") the following:

- my name;
- contact information;
- date of birth;
- information regarding my condition and diagnoses and the results of my genetic testing (collectively, "My Information") **so that Spark may use My Information for the purposes described in this form**.

I authorize Spark to use My Information for the following purposes:

- to contact me via mail, telephone, in electronic format or otherwise, to provide or offer information or services, including genetic counseling, that it believes to be of interest to me
- to help Spark develop programs and services that may be of interest to me or others with inherited retinal diseases (IRDs)
- to provide me with educational or marketing information about IRDs and their treatments.
- to contact my healthcare provider(s) about products and services that may be relevant for me, including contacting additional laboratories for further analysis

Spark will not sell My Information or use or disclose My Information for unauthorized purposes.

I understand that this Authorization is voluntary and that my ongoing medical care or eligibility for healthcare benefits will not be affected if I decline to sign this authorization form nor will it impact my ability to participate in Spark-sponsored programs in the future, but that I will not be able to participate in the ***RPE65* Genetic Test Program** if I decide not to sign this authorization.

I understand that I may revoke this Authorization at any time in writing by sending a letter to Spark at the address listed on the following page. Revoking this Authorization will prevent Spark from further using My Information, but will not affect uses and disclosures of My Information that were already made in reliance on this Authorization.

AUTHORIZATION TO USE AND DISCLOSE HEALTH INFORMATION

To revoke this Authorization or to change your contact information, submit a written request to:

Spark Therapeutics
3737 Market Street
Suite 1300
Philadelphia, PA 19104
Attn: Patient Services

I understand that once My Information has been disclosed, federal privacy laws may no longer apply or protect the information from further disclosure. Unless I expressly revoke this Authorization, it shall remain in effect for ten (10) years from the date I sign below. I may obtain a copy of this Authorization to keep for my records.

Signature of patient or parent/legal guardian of patient (if under the age of 18)

Date

Print name of patient or parent/legal guardian

Relationship to patient (if patient/legal guardian)

TERMS AND CONDITIONS

THE *RPE65* GENETIC TEST PROGRAM TERMS AND CONDITIONS

The *RPE65* GENETIC TEST PROGRAM is a genetic testing program ("the Program") that tests for the presence of *RPE65* gene mutations. The testing is supported by Spark Therapeutics, Inc. Your participation in the Program and use of Spark Therapeutics content and services is subject to the terms of the agreement between you and Spark Therapeutics set forth in these Program Terms and Conditions, which incorporate by reference the Spark Therapeutics general Terms of Use (sparktx.com/terms-of-use) and Privacy Policy (sparktx.com/privacy-policy). You may accept these Program Terms and Conditions by (1) clicking to accept or agree, where this option is made available to you, or (2) by signing this form at your physician's office when you agree to participate in genetic testing and share your genetic test results with Spark Therapeutics. You may not participate in the Program if you do not accept these Program Terms and Conditions.

To be eligible to participate in the Program, you must (1) be a US resident at the time you are tested and receive your test results; (2) have a type of inherited retinal disease (IRD) that makes you eligible for the Program as determined by your healthcare professional; (3) have the approval of your healthcare professional to have the genetic test; and (4) authorize in writing that your healthcare professional and the genetic testing laboratory selected by Spark Therapeutics may test the genetic sample you provide and share your name, contact information and information regarding your condition, diagnoses, and results of your genetic testing (collectively, "Your Information") with Spark Therapeutics. If you are under the age of 18, you must have the approval of your legal guardian to participate in the Program.

The genetic test provided under the Program requires you to provide a saliva or blood sample to your healthcare professional. Your sample will be analyzed by a genetic testing company selected by Spark Therapeutics, and the results will be provided to your healthcare professional and to Spark Therapeutics. The genetic testing company or companies that perform the test are independent from Spark Therapeutics and Spark Therapeutics has no control over or influence over how the test is conducted. Spark Therapeutics makes no warranty that the Program will meet your requirements, that it will be secure or error-free, that the results will be accurate or reliable, or that the quality of any of the services or information will meet your expectations. You understand and agree that by participating in the Program, Spark Therapeutics will process, use and disclose Your Information only as permitted by your written authorization and the Spark Therapeutics Privacy Policy.

The Program does not test for gene mutations other than *RPE65*, nor are the results of the testing performed in connection with the Program intended to be comprehensive. The results of the genetic test provided to your healthcare provider by the testing company may be: (1) positive (if the gene associated with the IRD has been identified by the test); (2) negative (if no genetic cause of the IRD has been identified by the test); or (3) inconclusive (if the test identified a genetic mutation, but it is unknown whether the identified mutation causes an IRD). You should consult with your own healthcare professionals about your diagnoses, genetic testing, and genetic

testing results. Spark Therapeutics does not provide medical advice, and the results of the Program are not intended to be used by you for any diagnostic purpose or as a substitute for professional medical advice. Spark Therapeutics does not endorse, warranty, or guarantee the effectiveness of any specific course of action, resources, tests, physicians or other healthcare professionals, drugs, biologics, medical devices, products, procedures, opinions, or other information that may be offered to you or become available to you through the Program. Reliance on any information provided by Spark Therapeutics is solely at your own risk.

Through the Program, you may be offered an optional opportunity to discuss your genetic test results by telephone with a genetic counselor, in the case of certain types of results that may not be conclusive as to your *RPE65* mutation. If you choose this option, any advice provided by the counselor is independent of Spark.

If you choose to participate in the Program, you will not be responsible for the costs of the genetic test itself or the genetic counseling described in the previous paragraph. Please be aware, however, that you will be responsible for any other costs that may be incurred as a result of participating in the Program, including but not limited to the costs of visits or consultations with your healthcare professional in connection with the genetic test or the testing results.

By participating in the Program, you understand and agree that you acquire no rights in any research or commercial products that may be developed by Spark Therapeutics and/or its collaborating partners. You specifically understand that you will not receive compensation for any research or commercial products that include or result from Your Information.

DISCLAIMER OF WARRANTIES. You expressly acknowledge and agree that your participation in the Program is at your sole risk, and the Program is provided on an “as is” and “as available” basis. Spark Therapeutics expressly disclaims all warranties of any kind, whether express or implied, including but not limited to the implied warranties of merchantability, fitness for a particular purpose, and non-infringement.

LIMITATION OF LIABILITY. Spark Therapeutics does not control or endorse any actions resulting from your participation in the Program, and therefore, SPARK THERAPEUTICS SPECIFICALLY DISCLAIMS ANY LIABILITY WITH REGARD TO ANY ACTIONS RESULTING FROM YOUR PARTICIPATION IN THE SERVICES, TO THE EXTENT PERMITTED BY APPLICABLE LAW. YOU EXPRESSLY ACKNOWLEDGE AND AGREE THAT SPARK THERAPEUTICS SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL, OR EXEMPLARY DAMAGES ARISING OUT OF OR RELATED TO YOUR PARTICIPATION IN THE SERVICES.

These Program Terms and Conditions, which incorporate by reference the Spark Therapeutics general Terms of Use and Privacy Policy, constitute the entire agreement between you and Spark Therapeutics and govern your participation in the Program.

PREVENTION GENETICS

PREVENTIONGENETICS USE ONLY

Testing must be ordered by a qualified Healthcare Provider

THIS FORM MUST ACCOMPANY SIGNED SPARK CONSENT FORM AND PATIENT SPECIMEN

TEST REQUISITION FORM
SP047 - SPARK

PERSON COMPLETING FORM	CONTACT (PHONE OR EMAIL)	DATE OF REQUEST
		____ / ____ / ____ MONTH / DAY / YEAR

PATIENT INFORMATION

LAST (FAMILY) NAME	FIRST NAME	MI	DATE OF BIRTH
			____ / ____ / ____ MONTH / DAY / YEAR

STREET ADDRESS	CITY	STATE	ZIP

PATIENT ID CODE (i.e. EMR #)	PHONE NUMBER	EMAIL ADDRESS

SPECIMEN COLLECTION DATE	SPECIMEN SOURCE	GEOANCESTRY / ETHNICITY	SEX
MONTH ____ / DAY ____ / YEAR ____	☐ Whole Blood ☐ Saliva ☐ Other ____		☐ Male ☐ Female ☐ Other ____ SPECIFY KARYOTYPE

HAS PATIENT BEEN TESTED PREVIOUSLY AT PreventionGenetics?
- ☐ NO
- ☐ YES
  PG ID# ____

RELEVANT CLINICAL INFORMATION *(INDICATE ALL THAT APPLY)*

DIAGNOSIS
- ☐ Retinitis Pigmentosa
- ☐ Leber Congenital Amaurosis
- ☐ Other: ____

SIGNS / SYMPTOMS
- ☐ Nyctalopia
- ☐ Nystagmus
- ☐ Abnormal ERG
- ☐ ERG Not Performed
- ☐ Decreased Visual Fields
- ☐ Poor Dark Adaptation
- ☐ Light Seeking Behavior
- ☐ Decreased Visual Acuity
- ☐ Other: ____

AGE OF ONSET OF DISEASE
- ☐ 0 - 10 years
- ☐ 11 - 17 years
- ☐ over 18 years

TEST SELECTION

TEST CODE	TEST NAME	DESCRIPTION	SPECIAL INSTRUCTIONS
☐ 7371	Spark *RPE65* Sequencing and Deletion / Duplication	*RPE65* testing is covered by the Spark Testing Initiative. Any requests for reflex testing to a broader vision panel will be discounted 10%, but will be the responsibility of the patient and/or institution (complete a separate Add On Test Requisition Form). For any questions or additional information about the Spark Testing Program, please visit www.luxturna.com.	SP047

PROVIDER INFORMATION

Our preferred method of report transmission is secure email (via ZixCorp).
Please provide an email address when possible. If you have additional specific reporting requests, indicate them below.

PROVIDER INFORMATION

INSTITUTION

ADDRESS (City, State, Country and Postal Code)

REQUESTING PHYSICIAN OR PROVIDER (First, Last, Degree)

PHONE NUMBER	NPI#	EMAIL

GENETIC COUNSELING

You acknowledge that if a patient's results are INDETERMINATE, Spark sponsors a program through which the patient may be offered genetic counseling by InformedDNA.

TEST REPORTING INSTRUCTIONS

SECURE EMAIL VIA ZIXCORP ☐ *Use above email address*

☐ DO NOT USE ZIXCORP. EMAIL RESULTS VIA SHAREFILE TO: ____

☐ DO NOT EMAIL RESULTS. Send via fax (provide fax number): (____) ____-____

N-UNBD-US-470003

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.

DNA
Send in screw cap tube at least 5 µg -10 µg of purified DNA at a concentration of at least 20 ng/µL for NGS and Sanger tests and at least 5 µg of purified DNA at a concentration of at least 100 ng/µL for gene-centric aCGH, MLPA, and CMA tests, minimum 2 µg for limited specimens. Indicate concentration on tube label. For requests requiring more than one test, send an additional 5 µg DNA per test ordered when possible.

SALIVA
Oragene™ or GeneFiX™ Saliva Collection kit used according to manufacturer instructions.

SHIPPING AND HANDLING INSTRUCTIONS

Please 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 for all specimen types except cell cultures, direct amniotic fluid, or direct chorionic villi. Cell culture deliveries are routinely accepted Monday-Thursday and require advance notice of arrival. If a Friday or Saturday delivery is necessary, please contact us to make arrangements. Saturday delivery should especially be avoided when possible as prenatal specimens are not processed over the weekend. Holiday schedules will be posted on our home page at least one week prior to major holidays.

BLOOD
DO NOT FREEZE. During hot weather, include a frozen ice pack in the shipping container. Place a paper towel or other thin material between the ice pack and the blood tube. In cold weather include an unfrozen ice pack in the shipping container as insulation. At room temperature, blood specimen is stable for up to 48 hours. If refrigerated, blood specimen is stable for up to one week.

DNA
DNA may be shipped at room temperature. Label the tube with the composition of the solute, DNA concentration as well as the patient's name, date of birth, and/or ID number. We only accept genomic DNA for testing. We do not accept products of whole genome amplification reactions or other amplification reactions.

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.

DNA BANKING
DNA Banking has a reduced price of $98 for patients if clinical testing is also being performed at PreventionGenetics. Visit our website at www.PGDNABank.com for information about the process and forms. For questions related to PGDNABanking, contact our DNA Banking Director at (715) 387-0484, ext. 151, or email: dnabanking@preventiongenetics.com.

CONTACT US
For additional questions or concerns, please contact our Client Service Representatives at (715) 387-0484, ext. 0, or our Genetic Counseling Team at option 2, or email: clinicaldnatesting@preventiongenetics.com.

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

TESTING KITS
Clinical testing kits with prepaid return shipping are available for U.S. Clients.

Comment SP047

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