

ClinGen Data Sharing Program

You have the option to watch a short video that summarizes the information in this form (link).

Throughout this form, “**YOU**” will refer to the person who is signed up for this registry. For example, if you enrolled your child in this registry, every time it says “**YOU**” we mean “your child.”

This Patient Insights Network (PIN) is partnering with the Clinical Genome Resource (ClinGen) to give you the option share your de-identified genetic and health information. Participation is voluntary. With your permission, we would like to de-identify and share information you have provided to the registry, including:

- All the information about your genes from your **genetic test results**
- **Health information** you have provided through surveys to this registry

What is ClinGen?

[ClinGen](#) is a National Institutes of Health (NIH)-funded project aiming to build a resource that defines the impact of genes and genetic changes on health. Data sharing is vital to this resource.

What will I be asked to do?

- You will be asked to upload a copy of your genetic testing report to your existing registry account. This allows ClinGen to learn about the genetic change(s) that were found. If you do not have a copy of your results, the ClinGen team can help you try to get one.
- The ClinGen team will also have access to your email address. The ClinGen team may contact you with questions about your test results and health surveys. You also have the option to receive updates to your test results from the ClinGen team.
- The PIN coordinator may send you information about additional, optional health surveys or research studies that may apply to you.

How will information be shared?

If you decide to allow ClinGen to share your data, your information would be shared with others from who will use it to improve patient care and genetic testing. Your information could be shared with other groups and databases, including:

- **Open-access databases:** These are available to anyone with internet access. General information, such as the de-identified health and genetic information, age, race, or sex may be shared with these types of databases. One example is [ClinVar](#), a National Center for Biotechnology Information database of genetic changes and their relationship to human health.
- **Controlled-access databases:** These are only available to approved users. More detailed information such as a complete list of all changes found in your genes during testing, may be found in these databases.
- **Clinical Genome Resource (ClinGen):** ClinGen may have access to this de-identified data for ClinGen related activities which may be displayed on our [website](#).
- **Geisinger Institutional Review Board:** The committee that oversees this project.

To learn more where data is shared, click [here](#).

Because nature of this data sharing, it is unlikely that you will be notified if your information is used. You will have the option to receive updates about your genetic test results from the ClinGen team. Most participants will not receive any results.

You will not be paid for your participation.

Can being in this study help me?

Your information can help doctors and scientists understand how genes impact health. You may not personally benefit from this data sharing, but data sharing helps:

- **Doctors** provide better care for their patients
- **Laboratories** improve genetic testing

Sharing your genetic and health information can also help you connect with other patients and families, researchers, and doctors.

You will also have the option to receive updates about your genetic test results from the ClinGen team

What are the risks and how is my information protected?

Your privacy is important to us. We will take all appropriate measures to protect your privacy. We do not share any identifiable information such as email address, name, or contact information. All personal information is replaced with a unique code. Sharing information can help improve medical care and genetic testing.

Risks include the possibility that you could be identified based on your genetic and health information and that it could be used for insurance or employment discrimination. We believe that this is unlikely. The risk is greater if you have already shared your genetic or health data with public resources, such as genealogy websites.

[Federal legislation](#) is in place to protect against some types of genetic discrimination.

What if I have questions or problems?

For questions about the research study, call or email the study team.

- ClinGen at datashare@clinicalgenome.org or 570-214-1721 (toll free 855-322-7683)
- The PIN Coordinator at coordinator@pin.invitae.com

Geisinger has a group of people who are not part of this study that review research to protect your safety, rights, and welfare. If you would like to obtain more information, offer input or discuss problems or concerns about your rights as a research participant, you can call Geisinger Institutional Review Board (IRB) at:

- 844-542-3299 or 570-271-8663 (Danville, PA)

Who is being consented to participate in this data sharing: *
(dropdown)

- Yourself
- Your child (ages newborn - 9 years)
- Your child (10 - 17 years old)
- Adult (age 18 or older for whom you have authority to consent)
- A deceased individual whose information you have the authority to share
- Unsure

Please check one box below that describes your choice.

Your decision is voluntary. If you check “**YES**” below, your information will be shared indefinitely.

You can change your mind at any time. If you no longer wish to participate, we can stop your data from being shared in the future. Data that has already been shared cannot be removed. If you change your mind, contact:

- ClinGen at datashare@clinicalgenome.org or 570-214-1721 (toll free 855-322-7683)
 - The PIN Coordinator at coordinator@pin.invitae.com
- **Yes** - I agree to give ClinGen access to my individual genetic and health information. ClinGen will then share my de-identified data with other approved users and open and controlled-access databases. NO personal identifying information will be shared.
 - **No** - I DO NOT agree to give ClinGen access to my individual genetic and health information. I DO NOT want my genetic and health information to be de-identified and shared with other registered users and databases.

Explanation of assent for 10-17 year olds:

Children ages 10 through 17-years old need to agree to participate in data sharing to be enrolled. This is called “assent.” If the child is not able to understand the details of the study for reasons like a cognitive impairment, the child’s assent is not needed (i.e. it is “waived”).

Please have the child (ages 10-17) read or listen to the following:

You are being asked to take part in the ClinGen Data Sharing Program because you have had genetic testing. The reason for this program is for doctors to learn more about genetic reasons for health problems.

This study may not benefit you personally, but doctors might find out something from your genetic and health information that may help other patients in the future. This may also help you in the future. You might be able to connect with other researchers or doctors.

Your parent or another adult who cares for you will be sharing your health information and genetic test results with us. The people who run the study will see your name, your age, and some other details about you. When we share your health and genetic information with researchers and doctors, we won’t give out those personal details about you.

There is a chance someone could get your information out of our computer system or use your genetic information to figure out who you are, but the ClinGen staff does everything they can to make sure this does not happen.

You do not have to be in the study, and it is okay if you don’t want to be or if you change your mind. You and your parent/guardian need to let us know if you want to stop participating.

By checking the box below, you are agreeing to participate in the ClinGen Data Sharing Program.

- **Yes** - I agree to participate in the ClinGen Data Sharing Program.

What is your relationship to the participant: * (dropdown)

- Self
- Parent (biological or adoptive)
- Stepparent
- Spouse
- Grandparent
- Aunt/Uncle
- Brother/Sister
- Other Relative
- Legal Guardian
- Foster Parent
- Medical Caregiver
- Other non-relative

If the ClinGen team learns about any potential updates about your genetic testing results, would you like ClinGen to contact you via email about these updates? *

Answering “Yes” means that you may be contacted by the ClinGen team if we learn about any potential updates to your genetic testing results.

Genetic test results may list one or more genetic changes, each with an interpretation. An interpretation is what the laboratory thought the change meant for your health. As we learn more about genetic changes, interpretations may change. Some updates impact your medical care while others do not.

If ClinGen learns there may be a possible update, we would email you and refer you back to your doctor or another healthcare provider in your area to discuss this more.

- Yes**, I would like to hear about potential updates to my genetic test results from the ClinGen team.
- No**, I DO NOT want to hear about potential updates to my genetic test results from the ClinGen team