

Research Consent/Parental Permission/ Authorization Form

IRB #2018-0419

Study Name: PRoGRESS

Full Title: Pediatric Reporting of Genomic RESULTS Study

Lead Researcher: Adam Buchanan

Site(s): Geisinger

Study Phone Number: 1-866-910-6486, option 5

Funded by: National Human Genome Research Institute

We are asking you and your child to be in a health research study.

You and your child do not have to be in this study. You and your child's access to care at Geisinger will not change if you and your child say no. If you and your child join this study, you can both stop at any time.

This form tells you about the study and how you and your child's health information will be used.

What should I do?

- Read this form or have it read to you.
- Make sure we explain the study to you.
- Make sure we explain what is done for research and what is done as part of your routine care.
- Ask questions.
- Take time to think about this and talk to your and your child's family and friends.

During the study, we will tell you and your child if there is new information or changes to the study that could affect you and your child's health or you and your child's desire to stay in the study.

Why is this study being done?

We are asking you and your child to join this study because you and your child are currently members of the MyCode Community Health Initiative® (MyCode) at Geisinger. We would like to invite you and your child to join in a new research study. We want to learn more about the experience and health choices of children/teenagers who have DNA changes that increase their chances of diseases like cancer or heart disease as well as those who do not have these DNA changes.

Who will be in the study?

About 450 adults and children/teenagers will join at Geisinger.

- ~336 Adults
- ~114 Children/Teenagers

How long will I be in the study?

You and your child's active role in the study will last about 12 months. The study will last at least 5 years. You and your child's information will be kept for at least 5 years after the study is over.

What will I be asked to do?

As part of this study, you and your child may or may not receive a DNA result. If your child does have a DNA change and you would like to be tested for the DNA change, your genetic testing may be free within the first 90 days of receiving your child's result. After that, the cost for your genetic testing would go through your insurance. Your child's genetic testing would be paid for by the study. Any care that happens because of results of the testing will not be part of this study. You and your child will have the opportunity to meet with a Genetic Counselor for genetic testing and discussion of any genetic test results that are returned.

Note: Children between the ages of 11 and 17 (and their parent) will be asked to complete study surveys. Anyone under the age of 11 will not be asked to complete any study surveys.

- You and your child may be asked to complete up to 4 surveys that will measure psychosocial outcomes of interest, health behaviors, and beliefs (for example, how would you evaluate you and your child's mental, physical, and emotional health?).
 1. Baseline Survey – the baseline survey will last about 30 minutes and will be completed online after you and your child consent to participate in the study (if you and your child chose to do so).
 2. The second survey will be completed one month after you and your child's disclosure visit. This survey will last about 30 minutes and will be completed online via a REDCap survey or over the phone by a member of Geisinger's Survey Core Team.
 3. The third survey will be completed six months after you and your child's disclosure visit. This survey will last about 30 minutes and will be completed online via a REDCap survey or over the phone by a member of Geisinger's Survey Core Team.
 4. The fourth survey will be completed twelve months after you and your child's disclosure visit. This survey will last about 30 minutes and will be completed online via a REDCap survey or over the phone by a member of Geisinger's Survey Core Team.
- You and your child may also be asked to participate in an interview (lasting up to an hour) in which a study team member asks for more details about you and your child's experience of getting a DNA result.
- You and your child will be offered quarterly consults/appointments with a clinical psychologist to discuss any feelings of distress either of you may have from learning about you and/or your child's

result. These study visits will be covered/paid for by the study for the length of the study. Once the study is over, if you and/or your child decide to continue care with a psychologist, you and/or your child can do so but it will be considered part of your and/or your child's routine care and will no longer be covered by the study.

- If your child is old enough to agree to be in the study (age 7-17 years), we will help you tell him or her about the DNA result. As a parent, you will be asked for your guidance on how to give back information about a genomic condition to your child/teenager (for example, do you want this information given to your child/teenager at the initial disclosure or at a separate time with a genetic counselor?)
- If you do not want to participate and your child is suspected to have a DNA result that will not lead to increased disease risk until adulthood, their sample will be held for clinical confirmation until they reach the age of 18.
- If you do not want to participate and your child is suspected to have a DNA result that could lead to increased disease risk in childhood, we will proceed to clinical confirmation of the result outside of this study. We will tell you if the DNA result is confirmed clinically and help you take the next steps for your child's health care.
- Your child may be asked to give an additional MyCode blood sample. We may request this because there was not enough blood from their initial MyCode blood draw.

The Genetic Information Nondiscrimination Act of 2008 (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you and your child based on your genetic information. This protection does not apply to life insurance, disability insurance, or long-term care insurance.

What are the costs?

The items below are done for the study only. They will be done at no cost to you and your child or you and your child's insurance company.

- Surveys & interviews
- Office Visit with the Genetic Counselor and Clinical Psychologist
- Quarterly consults with the Clinical Psychologist
- Possible additional blood sample (if needed) which will be covered by the MyCode study.
- Genetic testing for child (if applicable)

If your child has a DNA result and you choose to have genetic testing for the same DNA change, this testing may be free within the first 90 days after receiving your child's result. After the 90 day mark has passed, your testing would be billed to insurance.

Any health care related to your genetic test results (such as extra office visits or tests) will not be paid for by the study. You will be responsible for any costs incurred and your insurance company will be responsible for the cost of the related health care.

Will I be paid?

You and your child will each get a \$25 check or gift card for every survey and/or interview you do. This is taxable income and reportable to the IRS.

If paid by check: You and your child's check will arrive in the mail up to 8 weeks after each of your interviews. To issue you and your child a check, you will be asked to complete a W-9 Form. This will include your name, address and Social Security Number. This form will be given to the Geisinger Research Finance and Accounts Payable Departments. If you or your child's total payments are \$600 or more in a calendar year, a 1099 form will be sent to you.

Can being in this study help me?

This study might or might not help you and your child. It is possible that finding a DNA result in your child will help alert you to risk for disease and help you and your child reduce that risk.

We hope that what is learned from this study will help other patients and families in the future.

What are the risks?

There are no physical risks expected with this study. There is a risk that your and your child's information could be seen by someone other than the study staff.

However, we will take steps to protect your information.

Risks Related to Surveys & Interviews

There is a chance that the questions asked during the surveys could make you sad or upset. You do not have to answer the questions if you do not feel comfortable doing so.

Risks Related to DNA Results

There is a chance that you could be surprised or upset by something we discover about your health during the study. Sometimes genetic testing of family members reveals information about biological relationships that not everyone in the family is aware of. Additionally, scientists do not know whether people found to have a DNA result through a program like MyCode have risks of disease as high as people found to have a DNA result because of their personal or family health history. This uncertainty could lead to people in this study having anxiety about their DNA result or having medical procedures that might not be necessary. If you become upset with your results at any time, you can contact the genetic counselor or clinical psychologists for support.

Privacy Risks

There is a chance that your information may be shared or used inappropriately. Geisinger takes the protection of your privacy very seriously and works hard to keep your information safe. Although we

cannot guarantee that your information will be kept private, we think the risk of your information being shared or used inappropriately is small.

Please recognize that using personal email may not be as secure as other forms of communication, such as the electronic health record patient portal. Email correspondence for this research study will not include sensitive information such as social security numbers or medical record numbers, but may include contact information such as addresses, names, and phone numbers.

Psychological Risks

There is a chance this study may have a negative impact on your child's self-esteem or body image. You or your child may experience increased anxiety, distress, or depression due to a genomic result. The study team will assess these feelings during the surveys. The study team psychologist will follow up with you or your child if there are any concerns about you or your child having significant distress or other negative feelings that may impact your health.

Risks of Effects on Family

There is a chance there can be negative impacts on family relationships or relationships between parents and their children (for example, viewing your child as incapable of being independent or of performing certain tasks). This can lead to stress and confusion for you and your child. The study team psychologist and social worker are professionally trained to assess family functioning and help improve functioning as able. They will follow up with you if there are concerns that the genomic result has negatively affected your family's functioning.

Risks of Social Discrimination

There is a chance for insurance and employment discrimination. The Genetic Information Nondiscrimination Act (GINA), discussed on page 4 prohibits health insurance companies or employers from using genetic information against you. There is also a chance for educational discrimination. The study team psychologist will assess your child's

perceptions of their school performance and will follow-up with you and your child if there are any concerns and/or a need for intervention.

Other Risks

There is a potential risk that learning genomic information about your child will prevent him or her from making a future decision about whether to learn this information. That is why it is important to involve your child in deciding whether to be in this study. Also, there is a risk of your child misunderstanding the information we give them. The study team will make every effort to minimize this risk by having an experienced pediatric genetic counselor disclose your child's genetic result.

What if I am harmed?

If you or your child become ill or get injured during this study, call your doctor right away.

Medical treatment is available but will be provided at the usual charge. You or your child's insurance company will be charged for the medical care and/or hospitalization for you or your child's injury or illness. There is no money set aside to pay for you or your child's discomfort, disability, missed work, etc.

Your and your child's health insurance company may or may not pay for treatment of injuries as a result of your and your child's participation in this study.

How will Geisinger use and share my information?

The Geisinger study staff will look at and collect information that is in you and your child's medical record. We will collect information about you and your child during this study. These records will be kept for at least 5 years after the study ends and then information identifying you and your child will be removed. Any information placed in you and your child's medical record will be a permanent part of you and your child's medical record.

Certain information about you and your child will be shared with Bloomsburg University, including:

- Demographics (for example: age, race, education level)
- Information from interviews and surveys
- Genomic results

We are sharing this information with a researcher at Bloomsburg University who will help us learn more about how families talk about genetic results.

You and your child's primary care doctor or specialist may receive information about you and your child's participation in this study.

By signing this form, you are giving Geisinger permission to use and share you and your child's health information for purposes of this study for at least 5 years after the study is over. If you and your child change your mind, tell us in writing to stop using and sharing your information. Information already collected will still be used. We will only use and share new information if it is needed to protect you and your child's safety or follow with the law.

Write to:

Pediatric Return of Results (2018-0419)

Adam Buchanan

Geisinger - Genomic Medicine Institute

Mail Code: 38-59

190 Welles Street

Forty-Fort, PA 18704

If you or your child pass away while taking part in this trial, the study staff may get in touch with you and your child's emergency contacts for additional information.

How will others use and share my information?

The information shared with members of the study team will include:

- Name
- Date of Birth
- Study ID number
- Home Address
- Email Addresses
- Medical Record Number
- Social Security Number
- Telephone Number
- Medical history (including dates)
- Information about the medical care you receive during the study (including dates)
- Information from interviews and surveys

You and your child's research and medical record could be reviewed for quality and to make sure rules are followed. This review could be done by:

- Geisinger Institutional Review Board
- Geisinger staff
- Office for Human Research Protections (OHRP)
- National Institute of Health (NIH)
- National Human Genome Research Institute (NHGRI)

If information from this research study is included in an article published in a medical journal or presented at a medical or scientific meeting, it will be done in a way that does not identify you and your child.

Information from this study might be used for other, future research projects. Those projects can focus on any topic and might be unrelated to the goals of this study. Information we share with researchers at Geisinger, research institutions or companies around the world will not identify you and your child directly.

A description of this clinical trial will be available on www.clinicaltrials.gov as required by U.S. law. This website will not include information that can identify you and your child. At most, the website will include a summary of the results. You and your child can search this website at any time.

How is my information protected?

We will take steps to protect you and your child's information. The study team will make all efforts to keep Personal Health Information (PHI) confidential. We will store paper copies of documents as necessary in locked cabinets, in a locked office and any electronic documents will be kept on a password protected computer in a locked office. Any electronic information will be stored behind the Geisinger firewall and any data collected will be kept separate from information that can identify you and your child. Some laws that protect you and your child's information only applies to hospitals, doctors' offices, and other healthcare providers. When you and your child's information is shared outside of Geisinger, some federal privacy laws might not apply.

We will share you and your child's information with a court of law or the government, in the unlikely event this is required.

What if I have questions or problems?

Call the study team at 1-866-910-6486, option 5, if you have questions, concerns, or complaints about the study.

Call the Geisinger Institutional Review Board (IRB)
at: 844-542-3299 or 570-271-8663 (Danville, PA)
and identify study #2018-0419.

- If you have questions about your rights as a research participant.
- If you have questions, concerns or complaints about the research.

Signature Section

Signature Page: Adult Participants

Parents/Guardians/Adult Research Participants:

I give permission for my child to take part in this research study. I agree to take part in this research study and allow both my and my child's health information to be used for this research. My questions were answered. I will get a signed copy of this form.

Minor Participant's Printed Name

Print Name of Parent/Adult Research Participant

Signature of Parent/Guardian/Adult Research Participant

Date

Consenter

I confirm that the research study was thoroughly explained to the participant. I reviewed the consent form and answered all questions. The participant appeared to have understood the information.

Person Obtaining Consent Signature

Date

Research Consent/Parental Permission/ Authorization Form

IRB #2018-0419

Study Name: PRoGRESS

Full Title: Pediatric Reporting of Genomic REsults Study

Lead Researcher: Adam Buchanan

Site(s): Geisinger

Study Phone Number: 1-866-910-6486, option 5

Funded by: National Human Genome Research Institute

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You and your child do not have to be in this study. You and your child's access to care at Geisinger will not change if you and your child say no. If you and your child join this study, you can both stop at any time.

This form tells you about the study and how you and your child's health information will be used.

What should I do?

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- Make sure we explain the study to you.
- Make sure we explain what is done for research and what is done as part of your routine care.
- Ask questions.
- Take time to think about this and talk to your and your child's family and friends.

During the study, we will tell you and your child if there is new information or changes to the study that could affect you and your child's health or you and your child's desire to stay in the study.

Why is this study being done?

We are asking you and your child to join this study because you or one of your family members received a result through the MyCode Community Health Initiative® (MyCode) at Geisinger. This DNA result could be important for your child's health. We would like to invite you and your child to join in a new research study, which could include pursuing genetic testing for you and your child. We want to learn more about the experience and health choices of children/teenagers who have DNA changes that increase their chances of diseases like cancer or heart disease as well as those who do not have these DNA changes.

Who will be in the study?

About 450 adults and children/teenagers will join at Geisinger.

- ~336 Adults
- ~114 Children/Teenagers

How long will I be in the study?

You and your child's active role in the study will last about 12 months. The study will last at least 5 years. You and your child's information will be kept for at least 5 years after the study is over.

What will I be asked to do?

As part of this study, you and your child may or may not receive a DNA result. If you have not been tested for the DNA result that runs in your family, you may choose to be tested. You and your child may choose for your child to be tested for the DNA result that runs in your family. That genetic testing for you and your child would be paid for by the study. Any care that happens because of results of the testing will not be part of this study. You and your child will have the opportunity to meet with a Genetic Counselor before choosing to pursue genetic testing. If you decide to get genetic testing for you and your child, you will also meet with the Genetic Counselor after getting the genetic testing to review any genetic test results.

You and your child may be asked to complete up to 4 surveys that will measure psychosocial outcomes of interest, health behaviors, and beliefs

(for example, how would you evaluate you and your child's mental, physical, and emotional health?). Children between the ages of 11 and 17 (and their parent) will be asked to complete study surveys. Anyone under the age of 11 will not be asked to complete any study surveys.

1. Baseline Survey – the baseline survey will last about 30 minutes and will be completed online after you and your child consent to participate in the study (if you and your child chose to do so).
 2. The second survey will be completed one month after you and your child's disclosure visit. This survey will last about 30 minutes and will be completed online via a REDCap survey or over the phone by a member of Geisinger's Survey Core Team.
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- You and your child may also be asked to participate in an interview (lasting up to an hour) in which a study team member asks for more details about you and your child's experience of getting a DNA result.
 - You and your child will be offered quarterly consults/appointments with a clinical psychologist to discuss any feelings of distress either of you may have from learning about you and/or your child's result. These study visits will be covered/paid for by the study for the length

of the study. Once the study is over, if you and/or your child decide to continue care with a psychologist, you and/or your child can do so but it will be considered part of your and/or your child's routine care and will no longer be covered by the study.

- If your child is old enough to agree to be in the study (age 7-17 years), we will help you tell him or her about the DNA result. As a parent, you will be asked for your guidance on how to give back information about a genomic condition to your child/teenager (for example, do you want this information given to your child/teenager at the initial disclosure or at a separate time with a genetic counselor?)
- You and your child will be asked to give a blood sample or saliva sample if you choose to proceed with genetic testing. There is no cost for you or your child to have this sample drawn.

The Genetic Information Nondiscrimination Act of 2008 (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you and your child based on your genetic information. This protection does not apply to life insurance, disability insurance, or long-term care insurance.

What are the costs?

The items below are done for the study only. They will be done at no cost to you and your child or you and your child's insurance company.

- Surveys & interviews
- Office Visit with the Genetic Counselor and Clinical Psychologist
- Quarterly consults with the Clinical Psychologist
- Blood sample or saliva kits
- Genetic testing for parent (if applicable)
- Genetic testing for child (if applicable)

If you or your child choose to have genetic testing for the DNA change that runs in your family, you may choose to have additional screenings or pursue additional appointments related to the result. Although the study

will pay for the cost of genetic testing for you and your child, you or your insurance company will be responsible for any costs incurred for related health care.

Will I be paid?

You and your child will each get a \$25 check or gift card for every survey and/or interview you do. This is taxable income and reportable to the IRS.

If paid by check: You and your child's check will arrive in the mail up to 8 weeks after each of your interviews. To issue you and your child a check, you will be asked to complete a W-9 Form. This will include your name, address and Social Security Number. This form will be given to the Geisinger Research Finance and Accounts Payable Departments. If you or your child's total payments are \$600 or more in a calendar year, a 1099 form will be sent to you.

Can being in this study help me?

This study might or might not help you and your child. It is possible that finding a DNA result in your child will help alert family members to risk for disease and help them and your child reduce that risk.

We hope that what is learned from this study will help other patients and families in the future.

What are the risks?

There are no physical risks expected with this study. There is a risk that your and your child's information could be seen by someone other than the study staff.

However, we will take steps to protect your information.

Risks Related to Surveys & Interviews

There is a chance that the questions asked during the surveys could make you sad or upset. You do not have to answer the questions if you do not feel comfortable doing so.

Risks Related to DNA Results

There is a chance that you could be surprised or upset by something we discover about your health during the study. Sometimes genetic testing of family members reveals information about biological relationships that not everyone in the family is aware of. Additionally, scientists do not know whether people found to have a DNA result through a program like MyCode have risks of disease as high as people found to have a DNA result because of their personal or family health history. This uncertainty could lead to people in this study having anxiety about their DNA result or having medical procedures that might not be necessary. If you become upset with your results at any time, you can contact the genetic counselor or clinical psychologists for support.

Privacy Risks

There is a chance that your information may be shared or used inappropriately. Geisinger takes the protection of your privacy very seriously and works hard to keep your information safe. Although we cannot guarantee that your information will be kept private, we think the risk of your information being shared or used inappropriately is small.

Please recognize that using personal email may not be as secure as other forms of communication, such as the electronic health record patient portal. Email correspondence for this research study will not include sensitive information such as social security numbers or medical record numbers, but may include contact information such as addresses, names, and phone numbers.

Psychological Risks

There is a chance this study may have a negative impact on your child's self-esteem or body image. You or your child may experience increased anxiety, distress, or depression due to a genomic result. The study team will assess these feelings during the surveys. The study team psychologist will follow up with you or your child if there are any concerns about you or your child having significant distress or other negative feelings that may impact your health.

Risks of Effects on Family

There is a chance there can be negative impacts on family relationships or relationships between parents and their children (for example, viewing your child as incapable of being independent or of performing certain tasks). This can lead to stress and confusion for you and your child. The study team psychologist and social worker are professionally trained to assess family functioning and help improve functioning as able. They will follow up with you if there are concerns that the genomic result has negatively affected your family's functioning.

Risks of Social Discrimination

There is a chance for insurance and employment discrimination. The Genetic Information Nondiscrimination Act (GINA), discussed on page 4 prohibits health insurance companies or employers from using genetic information against you. There is also a chance for educational discrimination. The study team psychologist will assess your child's perceptions of their school performance and will follow-up with you and your child if there are any concerns and/or a need for intervention.

Other Risks

There is a potential risk that learning genomic information about your child will prevent him or her from making a future decision about whether to learn this information. That is why it is important to involve your child in deciding whether to be in this study. Also, there is a risk of your child misunderstanding the information we give them. The study team will make every effort to minimize this risk by having an experienced pediatric genetic counselor disclose your child's genetic result.

What if I am harmed?

If you or your child become ill or get injured during this study, call your doctor right away.

Medical treatment is available but will be provided at the usual charge. You or your child's insurance company will be charged for the medical care and/or hospitalization for you or your child's injury or illness. There is no money set aside to pay for you or your child's discomfort, disability, missed work, etc.

Your and your child's health insurance company may or may not pay for treatment of injuries as a result of your and your child's participation in this study.

How will Geisinger use and share my information?

The Geisinger study staff will look at and collect information that is in you and your child's medical record. We will collect information about you and your child during this study. These records will be kept for at least 5 years after the study ends and then information identifying you and your child will be removed. Any information placed in you and your child's medical record will be a permanent part of you and your child's medical record.

Certain information about you and your child will be shared with Bloomsburg University, including:

- Demographics (for example: age, race, education level)
- Information from interviews and surveys
- Genomic results

We are sharing this information with a researcher at Bloomsburg University who will help us learn more about how families talk about genetic results.

You and your child's primary care doctor or specialist may receive information about you and your child's participation in this study. By signing this form, you are giving Geisinger permission to use and share you and your child's health information for purposes of this study for at least 5 years after the study is over. If you and your child change your mind, tell us in writing to stop using and sharing your information. Information already collected will still be used. We will only use and share new information if it is needed to protect you and your child's safety or follow with the law.

Write to:

Pediatric Return of Results (2018-0419)

Adam Buchanan

Geisinger - Genomic Medicine Institute

Mail Code: 38-59

190 Welles Street

Forty-Fort, PA 18704

If you or your child pass away while taking part in this trial, the study staff may get in touch with you and your child's emergency contacts for additional information.

If you live outside of the state of Pennsylvania and wish to participate in this study, the study team would share your information with our partner, Genome Medical™. Genome Medical™ is a nationwide medical practice that can order genetic testing and provide virtual, secure genetic counseling to help you understand your test results. For this study, Geisinger would enter your information (name, date of birth, and contact information) into Genome Medical's secure patient portal. Geisinger study staff would also schedule you for a telehealth visit with a Genome Medical genetic counselor at that time. Genome Medical would then meet with you virtually, order genetic testing, and later review any results from that testing.

How will others use and share my information?

The information shared with members of the study team will include:

- Name
- Date of Birth
- Study ID number
- Home Address
- Email Addresses
- Medical Record Number
- Social Security Number
- Telephone Number
- Medical history (including dates)

- Information about the medical care you receive during the study (including dates)
- Information from interviews and surveys

You and your child's research and medical record could be reviewed for quality and to make sure rules are followed. This review could be done by:

- Geisinger Institutional Review Board
- Geisinger staff
- Office for Human Research Protections (OHRP)
- National Institute of Health (NIH)
- National Human Genome Research Institute (NHGRI)

If information from this research study is included in an article published in a medical journal or presented at a medical or scientific meeting, it will be done in a way that does not identify you and your child.

Information from this study might be used for other, future research projects. Those projects can focus on any topic and might be unrelated to the goals of this study. Information we share with researchers at Geisinger, research institutions or companies around the world will not identify you and your child directly.

A description of this clinical trial will be available on www.clinicaltrials.gov as required by U.S. law. This website will not include information that can identify you and your child. At most, the website will include a summary of the results. You and your child can search this website at any time.

How is my information protected?

We will take steps to protect you and your child's information. The study team will make all efforts to keep Personal Health Information (PHI) confidential. We will store paper copies of documents as necessary in locked cabinets, in a locked office and any electronic documents will be kept on a password protected computer in a locked office. Any electronic information will be stored behind the Geisinger firewall and any data collected will be kept separate from information that can identify you and

your child. Some laws that protect you and your child's information only applies to hospitals, doctors' offices, and other healthcare providers. When you and your child's information is shared outside of Geisinger, some federal privacy laws might not apply.

We will share you and your child's information with a court of law or the government, in the unlikely event this is required.

If you live out of the state of Pennsylvania and will be seeing a genetic counseling from Genome Medical™, your data will be protected to the same degree that Geisinger patient data is protected. Genome Medical™ has signed an attestation form stating that they have similar strict security measures in place to protect their patient data. You will have access through their online patient portal to contact Genome Medical™ providers at any time. The Geisinger study staff will also have access to your study data by logging into the Genome Medical portal.”

What if I have questions or problems?

Call the study team at 1-866-910-6486, option 5, if you have questions, concerns or complaints about the study, call the Geisinger Institutional Review Board (IRB) at: 844-542-3299 or 570-271-8663 (Danville, PA) and identify study #2018-0419.

- If you have questions about your rights as a research patient.
- If you have questions, concerns, or complaints about the research.

Signature Section**Signature Page: Adult Participants****Parents/Guardians/Adult Research Participants:**

I give permission for my child to take part in this research study. I agree to take part in this research study and allow both my and my child's health information to be used for this research. My questions were answered. I will get a signed copy of this form.

Minor Participant's Printed Name

Print Name of Parent/Adult Research Participant

Signature of Parent/Guardian/Adult Research Participant

Date

Consenter

I confirm that the research study was thoroughly explained to the participant. I reviewed the consent form and answered all questions. The participant appeared to have understood the information.

Person Obtaining Consent Signature

Date

Research Assent

IRB #2018-0419

Study Name: P^RoG^RESS

Full Title: Pediatric Reporting of Genomic **RES**ults **St**udy

Lead Researcher: Adam Buchanan

Site(s): Geisinger

Study Phone Number: 570-214-4747

Funded by: National Human Genome Research Institute

In this consent form, “you” always refers to the person taking part in the research study.

Why Am I Here?

You are here because we would like you to help us with a new study. We would like you to help us learn more about how you feel when you visit with doctors who take care of you and how healthy you feel.

Why are we doing this study?

We want to learn how children respond to hearing about their chances of getting cancer or heart disease.

What will I be asked to do?

- You might learn information about chances for diseases like cancer and heart disease that can be passed through families. We call this information a DNA result. As part of this study, you may or may not get a DNA result.
- You will be a part of this project for about 1 year.
- You will be asked to answer questions about your feelings and

experiences. These questions are called surveys. You will do 4 surveys during this project. Each survey will last about 30 minutes.

- You will be offered to meet with a Psychologist every 3 months to check in and see how you are doing.
- You may be asked to give some extra blood because there was not enough when you gave some for MyCode.

Will I be paid?

You and your parent will each get a \$25 check or gift card for every survey and/or interview you do.

Can being in this study help me?

This study might or might not help you. It is possible that you will learn health information that will help your parents and doctors take care of you better. We hope that what is learned from this study will help other kids like you and their families in the future.

Note: As part of this study you may or may not get a result back.

What are the risks?

There are no physical risks expected with this study. There is a risk that what you tell us could be seen by someone other than the study team. However, we will take strong steps to keep your information safe.

There is a chance that the questions asked during the surveys could make you sad or upset. You do not have to answer the questions if you do not feel comfortable doing so. Members of the study team can help you if you get sad or upset.

There is a chance that you could be surprised or upset by something we learn about you or your family during the study. Scientists do not know exactly how likely it is that people found to have a DNA result through a program like MyCode will develop a disease. This could lead to people having medical care that might not be necessary. If you become upset

with your DNA results at any time, you can talk to the genetic counselor or psychologist for help.

What if I am harmed?

If you become sick or get injured during this study, call your doctor right away.

Medical treatment is available but will be provided at the usual charge. You or your insurance company will be charged for the medical care and/or hospitalization for your injury or illness. There is no money set aside to pay you for discomfort, disability, missed work, etc.

Your health insurance company may or may not pay for treatment of injuries as a result of your participation in this study.

What if I have questions or problems?

You can ask questions at any time. You can ask now. You can ask later. You can ask your parents or anyone from the study team any questions you have about being in this study.

Do I have to be in the study?

No. No one will be mad at you if you do not want to do this. If you do not want to be in the study, you can just tell someone. You can say yes now and change your mind later. It is up to you. Your parents know you are being asked to be a part of this study.

Signature Page: Participants 7 to 14 years of age

Participants 7 to 14 years old:

I agree to take part in this study. My questions were answered. I will get a signed copy of this form.

Research Participant's Printed Name

Research Participant's Signature

Date

Consenter:

For children 7 years of age and older, I confirm that this research study was discussed with the minor participant using language and concepts appropriate to this child's developmental ability. The participant was encouraged to ask questions and voice concerns. The parent/guardian of this child were invited to participate in this engaged discussion.

The participant **agrees** to participate.

The participant **does not agree** to participate.

The participant is less than 7 years of age or does not have the capacity to assent.

The research study was thoroughly discussed with the parent/guardian. We reviewed the consent form and I answered all questions and discussed all concerns. The parent/guardian appeared to have understood the information.

Person Obtaining Consent Signature

Date

Research Assent

IRB #2018-0419

Study Name: PРоGRESS

Full Title: Pediatric Reporting of Genomic RESULTS Study

Lead Researcher: Adam Buchanan

Site(s): Geisinger

Study Phone Number: 1-866-910-6486, option 5

Funded by: National Human Genome Research Institute

In this consent form, “you” always refers to the person taking part in the research study.

We are asking you to be in a health research study.

You do not have to be in this study. Your care at Geisinger will not change if you say no. If you join this study, you can stop at any time.

This form tells you about the study and how your health information will be used.

What Should I do?

- Read this form or have it read to you.
- Make sure we explain the study to you.
- Make sure we explain what is done for research and what is done as part of your normal care.
- Ask questions
- Take time to think about this, and talk to your family and friends

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. law. This website will not include information that can identify

you. At most, the website will include a summary of the results. You can search this website at any time.

During the study, we will tell you if there is new information or changes to the study that could affect you, your health or your desire to stay in the study.

Why is this study being done?

We are asking you to join this study because you are currently a member of the MyCode Community Health Initiative (MyCode) at Geisinger. We would like to invite you to join a new research study. We want to learn more about the experience and health decisions of children/adolescents who have DNA changes that increase their chances of diseases like cancer or heart disease as well as those who do not have these DNA changes.

Who will be in the study?

About 450 adults and children/adolescents will join at Geisinger.

- ~336 Adults
- ~114 Children/Adolescents

How long will I be in the study?

Your role in the study will last about 12 months. The study will last at least 5 years. Your information will be kept for at least 5 years after the study is over.

What will I be asked to do?

As part of this study, you may or may not receive a DNA result. If you receive a DNA result, your parent may choose to be tested for the same result. That DNA testing for you will be paid for by the study. Any extra doctor visits or test that you (or your parent) choose to have done because of the test results will not be paid for by the study.

- You will be asked to take up to 4 surveys that will help us to

understand your experience with having a DNA change (or not having a DNA change) and how you feel about your mental, physical, and emotional health.

- Baseline Survey – the baseline survey will last about 30 minutes and will be done online after you consent to participate in the study (if you chose to do so).
 - The second survey will be completed one month after your disclosure visit. This survey will last about 30 minutes and will be done online or over the phone by a member of Geisinger’s Survey Core Team.
 - The third survey will be completed six months after your disclosure visit. This survey will last about 30 minutes and will be done online or over the phone by a member of Geisinger’s Survey Core Team.
 - The fourth survey will be completed twelve months after your disclosure visit. This survey will last about 30 minutes and will be done online or over the phone by a member of Geisinger’s Survey Core Team.
- You may also be asked to participate in an interview (lasting up to an hour) in which a study team member asks for more details about your experience of getting a DNA result.
 - You will be offered quarterly consults/appointments with a clinical psychologist to discuss any feelings of distress you may have from learning about your result. These study visits will be covered/paid for by the study for the length of the study. Once the study is over, if you decide to continue care with a psychologist, you can do so but it will be considered part of your routine care and will no longer be covered by the study.

- You may be asked to give an additional MyCode blood sample. We may request this because there was not enough blood from your initial MyCode blood draw.

The Genetic Information Nondiscrimination Act of 2008 (GINA), makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This protection does not apply to life insurance, disability insurance, or long-term care insurance.

What are the costs?

The items below are done for the study only. They will be done at no cost to you or your insurance company.

- Surveys & interviews
- Office Visit with the Genetic Counselor and Clinical Psychologist
- Quarterly consults with the Clinical Psychologist
- Possible additional blood sample (if needed) which will be covered by the MyCode study
- Genetic testing for you

Will I be paid?

You and your parent will each get a \$25 check or gift card for every survey and/or interview you do. This is taxable income and reportable to the IRS.

If paid by check: Your check will arrive in the mail up to 8 weeks after your interview. In order to issue you a check, you will be asked to complete a W-9 Form. This will include your name, address and Social Security Number. This form will be given to the Geisinger Research Finance and Accounts Payable Departments. If your total payments are \$600 or more in a calendar year, a 1099 form will be sent to you.

Can being in this study help me?

This study might or might not help you. It might lead to finding a DNA change that could guide your healthcare or the healthcare of family members. We hope that what is learned from this study will help other patients and families in the future.

What are the risks?

There are no physical risks expected with this study. There is a risk that your information could be seen by someone other than the study staff. However, we will take steps to protect your information.

Risks Related to Surveys & Interviews

There is a chance that the questions asked during the surveys could make you sad or upset. You do not have to answer the questions if you do not feel comfortable doing so.

Risks Related to DNA Results

There is a chance that you could be surprised or upset by something we discover about your health or health risks during the study. Sometimes genetic testing of family members reveals information about biological relationships that not everyone in the family is aware of. Additionally, scientists do not know whether people found to have a DNA result through a program like MyCode have risks of disease as high as people found to have a DNA result because of their personal or family health history. This uncertainty could lead to people in this study having anxiety about their DNA result or having medical procedures that might not be necessary. If you become upset with your results at any time, you can contact the genetic counselor or clinical psychologists for help.

Privacy Risks

There is a chance that your information may be shared or used inappropriately. Geisinger takes the protection of your privacy very seriously and works hard to keep your information safe. Although we cannot guarantee that your information will be kept private, we think the risk of your information being shared or used inappropriately is small. You should know that using your personal email to talk to the study team may not be as secure as other forms of communication. Correspondence

for this research study will not include sensitive information such as social security numbers or medical record numbers, but may include contact information such as addresses, names, and phone numbers.

Psychological Risks

There is a chance this study may have a negative impact on your self-esteem or body image. You may experience increased anxiety, distress, or depression. The study team will ask you about these feelings during the surveys. The study team psychologist will follow-up with you if there are any concerns about you having significant distress or other negative feelings that may impact your health.

Risks of Effects on Family

There is a chance there can be negative impacts on family relationships or relationships between parents and their children (for example, your parent viewing you as incapable of being independent or of performing certain tasks). This can lead to stress and confusion for you and your parent. The study team psychologist and social worker are well trained to identify potential dysfunctions and assess family functioning. They will follow-up with you if there are any concerns about the risk of dysfunction within your family.

Risks of Social Judgement

There is a chance for insurance and employment discrimination. The Genetic Information Nondiscrimination Act (GINA), discussed on page 4, prohibits health insurance companies or employers from using genetic information against you. The study team psychologist will ask you about how you feel about your school performance and will follow-up with you and your parent if there are any concerns or a need for intervention related to a DNA result.

Other Risks

There is a risk of you misunderstanding the information we give you. The study team will make every effort to minimize this risk by having an experienced pediatric genetic counselor disclose your genetic result.

What if I am harmed?

If you become sick or get injured during this study, call your doctor right away.

Medical treatment is available but will be provided at the usual charge. You or your insurance company will be charged for the medical care and/or hospitalization for your injury or illness. There is no money set aside to pay you for discomfort, disability, missed work, etc.

Your health insurance company may or may not pay for treatment of injuries as a result of your participation in this study.

How will Geisinger use and share my information?

The Geisinger study staff will view and collect information that is in your medical record. We will collect information about you during this study. These records will be kept for at least 5 years after the study ends and then information identifying you will be removed. Any information placed in your medical record will be a permanent part of your medical record.

Certain information about you will be shared with Bloomsburg University, including:

- Demographics (for example: age, race, education level)
- Information from interviews and surveys
- Genomic results

We are sharing this information with a researcher at Bloomsburg University who will help us learn more about how families talk about genetic results.

Your primary care doctor or specialist may receive information about your participation in this study.

By signing this form, you are giving Geisinger permission to use and share your health information for at least 5 years after the study is over. If you change your mind, tell us in writing to stop using and sharing your information. Information already collected will still be used. We will only use and share new information if it is needed to protect your safety or follow with the law.

Write to:

Pediatric Return of Results (2018-0419)
Adam Buchanan
Geisinger - Genomic Medicine Institute
Mail Code: 38-59
190 Welles Street
Forty-Fort, PA 18704

If you pass away while taking part in this study, the study staff may get in touch with your emergency contacts for additional information.

How will others use and share my information?

The information shared with members of the study team will include:

- Name
- Date of Birth
- Study ID number
- Home Address
- Email Addresses
- Medical Record Number
- Social Security Number
- Telephone Number
- Medical history (including dates)
- Information about the medical care you receive during the study (including dates)
- Information from interviews and surveys

Your research and medical record could be reviewed for quality and to make sure rules are followed. This review could be done by:

- Geisinger Institutional Review Board
- Geisinger staff
- Office for Human Research Protections (OHRP)
- National Institute of Health (NIH)
- National Human Genome Research Institute (NHGRI)

If information from this research study is included in an article published in a medical journal or presented at a medical or scientific meeting, it will be done in a way that does not identify you.

Information from this study might be used for other, future research projects. Those projects can focus on any topic and might be unrelated to the goals of this study. Information we share with researchers at Geisinger, research institutions or companies around the world, will not identify you directly.

How is my information protected?

We will take steps to protect your information. The study team will make all efforts to keep Personal Health Information (PHI) confidential. We will store hard copies of documents as necessary in locked cabinets, in a locked office and any electronic documents will be kept on a password protected computer in a locked office. Any electronic information will be stored behind the Geisinger firewall and any data collected will be kept separate from information that can identify you. Some laws that protect your information only apply to hospitals, doctors' offices, and other healthcare providers. When your information is shared outside of Geisinger, some federal privacy laws might not apply.

We will share your information with a court of law or the government, in the unlikely event this is required.

What if I have questions or problems?

Call the study team at 1-866-910-6486, option 5, if you have questions, concerns or complaints about the study.

Call the Geisinger Institutional Review Board (IRB) at:
844-542-3299 or 570-271-8663 (Danville, PA) and
identify study #2018-0419.

- If you have questions about your rights as a research participant.
- If you have questions, concerns or complaints about the research.

Signature Page: Participants 15 to 17 years of age**Participants 15 to 17 years old:**

I agree to take part in this study. My questions were answered. I will get a signed copy of this form.

Research Participant's Printed Name

Research Participant's Signature

Date

Consenter:

I confirm that the research study was thoroughly discussed with this minor participant and parent/guardian. We reviewed the consent form. I answered all questions and discussed all concerns. The participant appeared to be engaged and indicated that he/she understands what the research study involves. The parents/guardians of this participant were invited to participate in all discussion of this research study. Both the participant and parent/guardian appeared to have understood the information.

Person Obtaining Consent Signature

Date

Research Assent

IRB #2018-0419

Study Name: PRoGRESS

Full Title: Pediatric Reporting of Genomic RESULTS Study

Lead Researcher: Adam Buchanan

Site(s): Geisinger

Study Phone Number: 1-866-910-6486, option 5

Funded by: National Human Genome Research Institute

In this consent form, “you” always refers to the person taking part in the research study.

We are asking you to be in a health research study.

You do not have to be in this study. Your care at Geisinger will not change if you say no. If you join this study, you can stop at any time.

This form tells you about the study and how your health information will be used.

What Should I do?

- Read this form or have it read to you.
- Make sure we explain the study to you.
- Make sure we explain what is done for research and what is done as part of your normal care.
- Ask questions
- Take time to think about this, and talk to your family and friends

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

During the study, we will tell you if there is new information or changes to the study that could affect you, your health or your desire to stay in the study.

Why is this study being done?

We are asking you to join this study because one of your family members got a DNA result through the MyCode Community Health Initiative (MyCode) at Geisinger. This DNA result could be important for your health. We would like to invite you to join a new research study. We want to learn more about the experience and health decisions of children/adolescents who have DNA changes that increase their chances of diseases like cancer or heart disease as well as those who do not have these DNA changes.

Who will be in the study?

About 450 adults and children/adolescents will join at Geisinger.

- ~336 Adults
- ~114 Children/Adolescents

How long will I be in the study?

Your role in the study will last about 12 months. The study will last at least 5 years. Your information will be kept for at least 5 years after the study is over.

What will I be asked to do?

As part of this study, you may or may not receive a DNA result. If your parent has not been tested for the DNA result that runs in your family, they may be tested before you are tested. That DNA testing for you and your parent will be paid for by the study. Any extra doctor visits or tests that you (or your parent) choose to have because of the test results will not be paid for by this study.

- You will be asked to take up to 4 surveys that will help us to understand your experience with having a DNA change (or not having a DNA change) and how you feel about your mental, physical, and emotional health.

- Baseline Survey – the baseline survey will last about 30 minutes and will be done online after you consent to participate in the study (if you chose to do so).
- The second survey will be completed one month after your disclosure visit. This survey will last about 30 minutes and will be done online or over the phone by a member of Geisinger's Survey Core Team.
- The third survey will be completed six months after your disclosure visit. This survey will last about 30 minutes and will be done online or over the phone by a member of Geisinger's Survey Core Team.
- The fourth survey will be completed twelve months after your disclosure visit. This survey will last about 30 minutes and will be done over online or over the phone by a member of Geisinger's Survey Core Team.
- You may also be asked to participate in an interview (lasting up to an hour) in which a study team member asks for more details about your experience of getting a DNA result.
- You will be offered quarterly consults/appointments with a clinical psychologist to discuss any feelings of distress you may have from learning about your result. These study visits will be covered/paid for by the study for the length of the study. Once the study is over, if you decide to continue care with a psychologist, you can do so but it will be considered part of your routine care and will no longer be covered by the study.
- You will be asked to give a blood sample or saliva sample if you decide to get DNA testing.

The Genetic Information Nondiscrimination Act of 2008 (GINA), makes it illegal for health insurance companies, group health plans, and most

employers to discriminate against you based on your genetic information. This protection does not apply to life insurance, disability insurance, or long-term care insurance.

What are the costs?

The items below are done for the study only. They will be done at no cost to you or your insurance company.

- Surveys & interviews
- Office Visit with the Genetic Counselor and Clinical Psychologist
- Quarterly consults with the Clinical Psychologist
- Possible additional blood sample (if needed) which will be covered by the MyCode study.
- Genetic testing for your parent (if applicable)
- Genetic testing for you (if applicable)

Will I be paid?

You and your parent will each get a \$25 check or gift card for every survey and/or interview you do. This is taxable income and reportable to the IRS.

If paid by check: Your check will arrive in the mail up to 8 weeks after your interview. In order to issue you a check, you will be asked to complete a W-9 Form. This will include your name, address and Social Security Number. This form will be given to the Geisinger Research Finance and Accounts Payable Departments. If your total payments are \$600 or more in a calendar year, a 1099 form will be sent to you.

Can being in this study help me?

This study might or might not help you. It might lead to finding a DNA change that could guide your healthcare or the healthcare of family members. We hope that what is learned from this study will help other patients and families in the future.

What are the risks?

There are no physical risks expected with this study. There is a risk that your information could be seen by someone other than the study staff. However, we will take steps to protect your information.

Risks Related to Surveys & Interviews

There is a chance that the questions asked during the surveys could make you sad or upset. You do not have to answer the questions if you do not feel comfortable doing so.

Risks Related to DNA Results

There is a chance that you could be surprised or upset by something we discover about your health or health risks during the study. Sometimes genetic testing of family members reveals information about biological relationships that not everyone in the family is aware of. Additionally, scientists do not know whether people found to have a DNA result through a program like MyCode have risks of disease as high as people found to have a DNA result because of their personal or family health history. This uncertainty could lead to people in this study having anxiety about their DNA result or having medical procedures that might not be necessary. If you become upset with your results at any time, you can contact the genetic counselor or clinical psychologists for help.

Privacy Risks

There is a chance that your information may be shared or used inappropriately. Geisinger takes the protection of your privacy very seriously and works hard to keep your information safe. Although we cannot guarantee that your information will be kept private, we think the risk of your information being shared or used inappropriately is small. You should know that using your personal email to talk to the study team may not be as secure as other forms of communication. Correspondence for this research study will not include sensitive information such as social security numbers or medical record numbers, but may include contact information such as addresses, names, and phone numbers.

Psychological Risks

There is a chance this study may have a negative impact on your self-esteem or body image. You may experience increased anxiety, distress, or depression. The study team will ask you about these feelings during the surveys. The study team psychologist will follow-up with you if there are any concerns about you having significant distress or other negative feelings that may impact your health.

Risks of Effects on Family

There is a chance there can be negative impacts on family relationships or relationships between parents and their children (for example, your parent viewing you as incapable of being independent or of performing certain tasks). This can lead to stress and confusion for you and your parent. The study team psychologist and social worker are well trained to identify potential dysfunctions and assess family functioning. They will follow-up with you if there are any concerns about the risk of dysfunction within your family.

Risks of Social Judgment

There is a chance for insurance and employment discrimination. The Genetic Information Nondiscrimination Act (GINA), discussed on page 4, prohibits health insurance companies or employers from using genetic information against you. The study team psychologist will ask you about how you feel about your school performance and will follow-up with you and your parent if there are any concerns or a need for intervention related to a DNA result.

Other Risks

There is a risk of you misunderstanding the information we give you. The study team will make every effort to minimize this risk by having an experienced pediatric genetic counselor disclose your genetic result.

What if I am harmed?

If you become sick or get injured during this study, call your doctor right away.

Medical treatment is available but will be provided at the usual charge. You or your insurance company will be charged for the medical care and/or hospitalization for your injury or illness. There is no money set aside to pay you for discomfort, disability, missed work, etc.

Your health insurance company may or may not pay for treatment of injuries as a result of your participation in this study.

How will Geisinger use and share my information?

The Geisinger study staff will view and collect information that is in your medical record. We will collect information about you during this study. These records will be kept for at least 5 years after the study ends and then information identifying you will be removed. Any information placed in your medical record will be a permanent part of your medical record.

Certain information about you will be shared with Bloomsburg University, including:

- Demographics (for example: age, race, education level)
- Information from interviews and surveys
- Genomic results

We are sharing this information with a researcher at Bloomsburg University who will help us learn more about how families talk about genetic results.

Your primary care doctor or specialist may receive information about your participation in this study.

By signing this form, you are giving Geisinger permission to use and share your health information for at least 5 years after the study is over. If you change your mind, tell us in writing to stop using and sharing your information. Information already collected will still be used. We will only use

and share new information if it is needed to protect your safety or follow with the law.

Write to:

Pediatric Return of Results (2018-0419)

Adam Buchanan

Geisinger - Genomic Medicine Institute

Mail Code: 38-59

190 Welles Street

Forty-Fort, PA 18704

If you pass away while talking part in this study, the study staff may get in touch with your emergency contacts for additional information.

If you live outside of the state of Pennsylvania and wish to join this study, we would share your information with our partner, Genome Medical™. Genome Medical™ is a nationwide medical practice that can order genetic testing and provide virtual, secure genetic counseling to help you understand your test results. For this study, Geisinger would enter your information (name, date of birth, and contact information) into Genome Medical's secure patient portal. Geisinger study staff would also schedule you for a telehealth visit with a Genome Medical genetic counselor at that time. Genome Medical would then meet with you virtually, order genetic testing, and later review any results from that testing.

How will others use and share my information?

The information shared with members of the study team will include:

- Name
- Date of Birth
- Study ID number
- Home Address
- Email Addresses
- Medical Record Number
- Social Security Number
- Telephone Number

- Medical history (including dates)
- Information about the medical care you receive during the study (including dates)
- Information from interviews and surveys

Your research and medical record could be reviewed for quality and to make sure rules are followed. This review could be done by:

- Geisinger Institutional Review Board
- Geisinger staff
- Office for Human Research Protections (OHRP)
- National Institute of Health (NIH)
- National Human Genome Research Institute (NHGRI)

If information from this research study is included in an article published in a medical journal or presented at a medical or scientific meeting, it will be done in a way that does not identify you.

Information from this study might be used for other, future research projects. Those projects can focus on any topic and might be unrelated to the goals of this study. Information we share with researchers at Geisinger, research institutions or companies around the world, will not identify you directly.

How is my information protected?

We will take steps to protect your information. The study team will make all efforts to keep Personal Health Information (PHI) confidential. We will store hard copies of documents as necessary in locked cabinets, in a locked office and any electronic documents will be kept on a password protected computer in a locked office. Any electronic information will be stored behind the Geisinger firewall and any data collected will be kept separate from information that can identify you. Some laws that protect your information only apply to hospitals, doctors' offices, and other healthcare providers.

When your information is shared outside of Geisinger, some federal privacy laws might not apply. We will share your information with a court of law or the government, in the unlikely event this is required.

If you live out of the state of Pennsylvania and will be seeing a genetic counselor from Genome Medical™, your data will be protected to the same degree that Geisinger patient data is protected. Genome Medical™ has signed a form stating that they have strict security measures to protect their patient data. You will have access through their online patient portal to contact Genome Medical™ providers at any time. The Geisinger study staff will also have access to your study data by logging into the Genome Medical portal.

What if I have questions or problems?

Call the study team at 1-866-910-6486, option 5, if you have questions, concerns or complaints about the study.

Call the Geisinger Institutional Review Board (IRB) at: 844-542-3299 or 570-271-8663 (Danville, PA) and identify study #2018-0419.

- If you have questions about your rights as a research participant.
- If you have questions, concerns or complaints about the research.

Signature Page: Participants 15 to 17 years of age**Participants 15 to 17 years old:**

I agree to take part in this study. My questions were answered. I will get a signed copy of this form.

Research Participant's Printed Name

Research Participant's Signature

Date

Consenter:

I confirm that the research study was thoroughly discussed with this minor participant and parent/guardian. We reviewed the consent form. I answered all questions and discussed all concerns. The participant appeared to be engaged and indicated that he/she understands what the research study involves. The parents/guardians of this participant were invited to participate in all discussion of this research study. Both the participant and parent/guardian appeared to have understood the information.

Person Obtaining Consent Signature

Date

Research Re-consent Authorization Form

IRB #2018-0419

Study Name: PProGRESS

Full Title: Pediatric Reporting of Genomic RESULTS Study

Lead Researcher: Adam Buchanan

Site(s): Geisinger

Study Phone Number: 1-866-910-6486, option 5

Funded by: National Human Genome Research Institute

****This form is to be reviewed and signed by participants when they turn 18 years of age and are now an adult participant in this study.**

We are asking you to be in a health research study.

You do not have to be in this study. Your access to care at Geisinger will not change if you say no. If you join this study, you can stop at any time.

This form tells you about the study and how your health information will be used.

What should I do?

- Read this form or have it read to you.
- Make sure we explain the study to you.
- Make sure we explain what is done for research and what is done as part of your routine care.
- Ask questions.
- Take time to think about this and talk to your family and friends.

During the study, we will tell you if there is new information or changes to the study that could affect your health or desire to stay in the study.

Why is this study being done?

We are asking you to join this study because you or one of your family members received a result through the MyCode Community Health Initiative® (MyCode) at Geisinger. This DNA result could be important for your health. We would like to invite you to join in a new research study, which could include pursuing genetic testing. We want to learn more about the experience and health choices of children/teenagers who have DNA changes that increase their chances of diseases like cancer or heart disease as well as those who do not have these DNA changes.

Who will be in the study?

About 450 adults and children/teenagers will join at Geisinger.

- ~336 Adults
- ~114 Children/Teenagers

How long will I be in the study?

Your active role in the study will last about 12 months. The study will last at least 5 years. Your information will be kept for at least 5 years after the study is over.

What will I be asked to do?

As part of this study, you may or may not receive a DNA result. If you have not been tested for the DNA result that runs in your family, you may choose to be tested. That genetic testing for you would be paid for by the study. Any care that happens because of results of the testing will not be part of this study. You will have the opportunity to meet with a Genetic Counselor before choosing to pursue genetic testing. If you decide to get genetic testing, you will also meet with the Genetic Counselor after getting the genetic testing to review any genetic test results. You may be asked to complete up to 4 surveys that will measure psychosocial outcomes of interest, health behaviors, and beliefs (for example, how would you evaluate your mental, physical, and emotional health?). Children between the ages of 11 and 17 (and their parent) will be asked to complete study surveys. Anyone under the age of 11 will not be asked to complete any study surveys.

1. Baseline Survey – the baseline survey will last about 30 minutes and will be completed online after you consent to participate in the study (if you choose to do so).
 2. The second survey will be completed one month after your disclosure visit. This survey will last about 30 minutes and will be completed online via a REDCap survey or over the phone by a member of Geisinger’s Survey Core Team.
 3. The third survey will be completed six months after your disclosure visit. This survey will last about 30 minutes and will be completed online via a REDCap survey or over the phone by a member of Geisinger’s Survey Core Team.
 4. The fourth survey will be completed twelve months after your disclosure visit. This survey will last about 30 minutes and will be completed online via a REDCap survey or over the phone by a member of Geisinger’s Survey Core Team.
- You may also be asked to participate in an interview (lasting up to an hour) in which a study team member asks for more details about your experience of getting a DNA result.
 - You will be offered quarterly consults/appointments with a clinical psychologist to discuss any feelings of distress either of you may have from learning about your result. These study visits will be covered/paid for by the study for the length of the study. Once the study is over, if you decide to continue care with a psychologist, you can do so but it will be considered part of your routine care and will no longer be covered by the study.
 - You may be asked to give a blood sample or saliva sample if you choose to proceed with genetic testing. There is no cost for you to have this sample drawn.

The Genetic Information Nondiscrimination Act of 2008 (GINA), makes it illegal for health insurance companies, group health plans, and most

employers to discriminate against you and your child based on your genetic information. This protection does not apply to life insurance, disability insurance, or long-term care insurance.

What are the costs?

The items below are done for the study only. They will be done at no cost to you or your insurance company.

- Surveys & interviews
- Office Visit with the Genetic Counselor and Clinical Psychologist
- Quarterly consults with the Clinical Psychologist
- Blood sample or saliva kits
- Genetic testing for parent (if applicable)
- Genetic testing for child (if applicable)

If you choose to have genetic testing for the DNA change that runs in your family, you may choose to have additional screenings or pursue additional appointments related to the result. Although the study will pay for the cost of genetic testing for you, you or your insurance company will be responsible for any costs incurred for related health care.

Will I be paid?

You will each get a \$25 check or gift card for every survey and/or interview you do. This is taxable income and reportable to the IRS.

If paid by check: Your check will arrive in the mail up to 8 weeks after each of your interviews. To issue you a check, you will be asked to complete a W-9 Form. This will include your name, address and Social Security Number. This form will be given to the Geisinger Research Finance and Accounts Payable Departments. If your total payments are \$600 or more in a calendar year, a 1099 form will be sent to you.

Can being in this study help me?

This study might or might not help you. It is possible that finding a DNA result in you will help alert family members to risk for disease and help them reduce that risk.

We hope that what is learned from this study will help other patients and families in the future.

What are the risks?

There are no physical risks expected with this study. There is a risk that your information could be seen by someone other than the study staff.

However, we will take steps to protect your information.

Risks Related to Surveys & Interviews

There is a chance that the questions asked during the surveys could make you sad or upset. You do not have to answer the questions if you do not feel comfortable doing so.

Risks Related to DNA Results

There is a chance that you could be surprised or upset by something we discover about your health during the study. Sometimes genetic testing of family members reveals information about biological relationships that not everyone in the family is aware of. Additionally, scientists do not know whether people found to have a DNA result through a program like MyCode have risks of disease as high as people found to have a DNA result because of their personal or family health history. This uncertainty could lead to people in this study having anxiety about their DNA result or having medical procedures that might not be necessary. If you become upset with your results at any time, you can contact the genetic counselor or clinical psychologists for support.

Privacy Risks

There is a chance that your information may be shared or used inappropriately. Geisinger takes the protection of your privacy very seriously and works hard to keep your information safe. Although we cannot

guarantee that your information will be kept private, we think the risk of your information being shared or used inappropriately is small.

Please recognize that using personal email may not be as secure as other forms of communication, such as the electronic health record patient portal. Email correspondence for this research study will not include sensitive information such as social security numbers or medical record numbers, but may include contact information such as addresses, names, and phone numbers.

Psychological Risks

There is a chance this study may have a negative impact on your self esteem or body image. You may experience increased anxiety, distress, or depression due to a genomic result. The study team will assess these feelings during the surveys. The study team psychologist will follow up with you if there are any concerns about you having significant distress or other negative feelings that may impact your health.

Risks of Effects on Family

There is a chance there can be negative impacts on family relationships or relationships between parents and their children (for example, viewing your child as incapable of being independent or of performing certain tasks). This can lead to stress and confusion. The study team psychologist and social worker are professionally trained to assess family functioning and help improve functioning as able. They will follow up with you if there are concerns that the genomic result has negatively affected your family's functioning.

Risks of Social Discrimination

There is a chance for insurance and employment discrimination. The Genetic Information Nondiscrimination Act (GINA), discussed on page 4 prohibits health insurance companies or employers from using genetic information against you. There is also a chance for educational discrimination. The study team psychologist will assess your perceptions

of your school performance and will follow-up with you if there are any concerns and/or a need for intervention.

Other Risks

There is a risk that you may misunderstand the information we give you. The study team will make every effort to minimize this risk by having an experienced pediatric genetic counselor disclose your genetic result.

What if I am harmed?

If you become ill or get injured during this study, call your doctor right away.

Medical treatment is available but will be provided at the usual charge. Your insurance company will be charged for the medical care and/or hospitalization for your injury or illness. There is no money set aside to pay for your discomfort, disability, missed work, etc.

Your health insurance company may or may not pay for treatment of injuries as a result of your participation in this study.

How will Geisinger use and share my information?

The Geisinger study staff will look at and collect information that is in your medical record. We will collect information about you during this study. These records will be kept for at least 5 years after the study ends and then information identifying you will be removed. Any information placed in your medical record will be a permanent part of your medical record.

Certain information about you will be shared with Bloomsburg University, including:

- Demographics (for example: age, race, education level)
- Information from interviews and surveys
- Genomic results

We are sharing this information with a researcher at Bloomsburg University who will help us learn more about how families talk about genetic results.

Your primary care doctor or specialist may receive information about your participation in this study.

By signing this form, you are giving Geisinger permission to use and share your health information for purposes of this study for at least 5 years after the study is over. If you change your mind, tell us in writing to stop using and sharing your information. Information already collected will still be used. We will only use and share new information if it is needed to protect your safety or follow with the law.

Write to:

Pediatric Return of Results (2018-0419)

Adam Buchanan

Geisinger - Genomic Medicine Institute

Mail Code: 38-59

190 Welles Street

Forty-Fort, PA 18704

If you pass away while taking part in this trial, the study staff may get in touch with your emergency contacts for additional information.

If you live outside of the state of Pennsylvania and wish to participate in this study, the study team would share your information with our partner, Genome Medical™. Genome Medical™ is a nationwide medical practice that can order genetic testing and provide virtual, secure genetic counseling to help you understand your test results. For this study, Geisinger would enter your information (name, date of birth, and contact information) into Genome Medical's secure patient portal. Geisinger study staff would also schedule you for a telehealth visit with a Genome Medical genetic counselor at that time. Genome Medical would then meet with you virtually, order genetic testing, and later review any results from that testing.

How will others use and share my information?

The information shared with members of the study team will include:

- Name
- Date of Birth
- Study ID number
- Home Address
- Email Addresses
- Medical Record Number
- Social Security Number
- Telephone Number
- Medical history (including dates)
- Information about the medical care you receive during the study (including dates)
- Information from interviews and surveys

Your research and medical record could be reviewed for quality and to make sure rules are followed. This review could be done by:

- Geisinger Institutional Review Board
- Geisinger staff
- Office for Human Research Protections (OHRP)
- National Institute of Health (NIH)
- National Human Genome Research Institute (NHGRI)

If information from this research study is included in an article published in a medical journal or presented at a medical or scientific meeting, it will be done in a way that does not identify you.

Information from this study might be used for other, future research projects. Those projects can focus on any topic and might be unrelated to the goals of this study. Information we share with researchers at Geisinger, research institutions or companies around the world will not identify you directly.

A description of this clinical trial will be available on www.clinicaltrials.gov as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

How is my information protected?

We will take steps to protect your information. The study team will make all efforts to keep Personal Health Information (PHI) confidential. We will store paper copies of documents as necessary in locked cabinets, in a locked office and any electronic documents will be kept on a password protected computer in a locked office. Any electronic information will be stored behind the Geisinger firewall and any data collected will be kept separate from information that can identify you. Some laws that protect you only applies to hospitals, doctors' offices, and other healthcare providers. When your information is shared outside of Geisinger, some federal privacy laws might not apply.

We will share your information with a court of law or the government, in the unlikely event this is required.

If you live out of the state of Pennsylvania and will be seeing a genetic counseling from Genome Medical™, your data will be protected to the same degree that Geisinger patient data is protected. Genome Medical™ has signed an attestation form stating that they have similar strict security measures in place to protect their patient data. You will have access through their online patient portal to contact Genome Medical™ providers at any time. The Geisinger study staff will also have access to your study data by logging into the Genome Medical portal.”

What if I have questions or problems?

Call the study team at 1-866-910-6486, option 5, if you have questions, concerns or complaints about the study, call the Geisinger Institutional Review Board (IRB) at: 844-542-3299 or 570-271-8663 (Danville, PA) and identify study #2018-0419.

Signature Section

Signature Page: Adult Participants

Adult Research Participants:

I give permission to take part in this research study. I agree to take part in this research study and allow my health information to be used for this research. My questions were answered. I will get a signed copy of this form.

Print Name of Adult Research Participant

Signature of Adult Research Participant

Date

Consenter

I confirm that the research study was thoroughly explained to the participant. I reviewed the consent form and answered all questions. The participant appeared to have understood the information.

Person Obtaining Consent Signature

Date