

The Cleveland Clinic Foundation Consent to Participate in a Research Study

Study title: The PATHFINDER 2 Study: Evaluating the Safety and Performance of the GRAIL Multi-Cancer Early Detection Test in an Eligible Screening Population

Sponsor: GRAIL, LLC.

Principal Investigator: Dr. John Sedor, 216-445-7154

Study Coordinators: Lauren Grimm 216-444-4650

Pamela Lackner 216-636-9628

After hours phone contact#: If you have any emergencies after hours, please call 911 or go to the nearest emergency department. If you have questions related to scheduled procedures or tests that need to be addressed after business hours, please contact the number on your schedule or contact the CCF Operator at 1-800-223-2273 and they will connect you to the appropriate department.

KEY INFORMATION

The following is a short summary of this research study to help you decide whether or not to be a part of this research study. More detailed information is included later on in this document.

What should I know about a research study?

- Someone will explain this research study to you.
- You can choose whether or not to take part.
- You can agree to take part and then later change your mind.
- Your decision whether or not to participate will not be held against you.
- You can ask all the questions you want before you decide.

What is the purpose, procedures and duration of this study?

We invite you to take part in a research study because you are 50 years or older and do not have any exclusions to participating. Your participation in the study will last approximately 3 years. This study is sponsored by Grail, LLC.

This study is being done to find out more about how well a new screening test (called Galleri) can detect multiple different kinds of cancer earlier. The researchers would also like to find out how the Galleri test impacts patients and their doctors. This test is not approved or cleared by the Food and Drug Administration (FDA).

You will be asked to give a blood sample of 4 tubes of blood which is about 3 tablespoons (40mL). You will also be asked questions about your health and medical history and how you feel and receiving your test results back. You will also be asked to fill out questionnaires during the study.

If you receive a “cancer signal detected result” you will have another blood draw, additional questionnaires and additional testing.

More detailed information can be found under the section labeled: “Information on the Research.”

Why might you choose not to participate in this research study?

You might not want to participate due to the discomfort of the blood draw. You may be uncomfortable with the questions asked on the questionnaires. You might also experience stress associated with the risks of unnecessary procedures/tests if you receive a “cancer signal detected” result. If you receive a false negative result, this may delay additional evaluations and diagnosis for cancer.

More detailed information about the risks of this study can be found in the section labeled “Risks.”

Why might you choose to volunteer for this study?

You may or may not directly benefit from participating in this study. Some people who participate in this study will have a “cancer signal detected” test result. These participants will have further testing which may lead to a diagnosis of cancer, which could then be treated. In this case, the cancer may be diagnosed and treated earlier than if you were not part of this study. However, you may not experience any benefit from participation, but your participation may help others who may be evaluated for potential cancer in the future

The study will also allow GRAIL to further evaluate the usefulness of a multi-cancer early detection test, which may help future patients undergoing cancer screening.

More detailed information about the benefits of this study can be found in the section labeled “Benefits.”

What are my other choices if I do not take part in this study?

This is not a treatment study and it does not replace any cancer screening tests. There are no alternatives to a multi-cancer early detection test, although there are tests for some individual cancer types (mammography for breast cancer, colonoscopy for colon cancer, etc.). Your alternative is to not participate in this study.

More detailed information about the alternatives to this study can be found in the section labeled “Alternatives.”

Do the researchers or institution have any conflicts of interest relating to this study?

One or more of the Investigators conducting this study serve as consultants for the company that makes products used in this study. These financial interests are within permissible limits established by the local institutional Conflict of Interest Policy. If you have any questions regarding conflicts of interest, please ask your study doctor or call the Cleveland Clinic Institutional Review Board at (216) 444-2924.

DETAILED INFORMATION

The following is more detailed information about this study in addition to the information listed above.

1. INFORMATION ON THE RESEARCH

Why is the research being done?

The purpose of this study is to understand the performance of a multi-cancer early detection test called Galleri, and the impact of Galleri on patients and providers. Galleri is a new test that can be used for early detection of different types of cancers. This test is not approved or cleared by the Food and Drug Administration (FDA).

The main goals of this research are:

- To evaluate how doctors use the results of the Galleri test during your care
- To assess how doctors use the Galleri test to direct your care
- To understand what participants think about the risks and benefits of the Galleri test
- To understand how participants feel about their test results and future cancer screenings

How many people will take part in this study?

About 10,000 participants will take part in this study across North America and about 1500 at the Cleveland Clinic. Your participation will last about 3 years.

What is involved if you decide to take part in this research study?

					For Signal Detected Results Only			
Screening	Enrollment	Day 1	Day 15	Day 30	Months 1-6	If no cancer identified with diagnostic testing	Year 1	Year 2 + 3
Inclusion/Exclusion criteria	Sign consent form Questionnaire and medical history	Blood Draw	Results reported	Results Questionnaire	Diagnostic Evaluation and Resolution	PET-CT Scan Research Blood Draw	Follow up Questionnaire	Active Follow up

You will be asked to give 4 tubes of blood (about 3 tablespoons or 40mL). Your blood will be drawn at a scheduled lab visit.

Your sample will be tested with the Galleri test, which may detect multiple kinds of cancer early. A member of the study team will discuss the test results with you. Participants will either have a “cancer signal not detected” result or a “cancer signal detected” result.

This study test looks for small pieces of genetic material, also called DNA (deoxyribonucleic acid) in the blood that may indicate the presence of cancer. In addition to evaluating the use of a novel blood test in a clinical setting, the study will try to understand what types of tests and procedures are ordered by a healthcare provider when the test result findings require additional evaluation. This study will also evaluate how you feel about this blood test and other types of cancer screening tests.

Most participants will have a “cancer signal not detected” result indicating that no cancer signal has been detected by the test at this time. Even if you receive a “cancer signal not detected” result, this does not guarantee that you do not have cancer. You should continue to follow your healthcare provider’s recommendations about further testing.

Some participants will have a “cancer signal detected” result indicating that a cancer signal has been detected. In this case, additional testing needs to be done to confirm whether or not you

have cancer. Your study doctor or the healthcare provider will direct you to the appropriate tests. Having a test result that a signal has been detected and requires additional testing is not a diagnosis of cancer. Only additional testing can provide a cancer diagnosis. If the additional testing indicates a cancer diagnosis, the healthcare provider will discuss treatment options with you. The Galleri test results may not always be accurate. It is possible to get a false positive test result. Inaccurate results could lead to unnecessary testing, which could result in adverse events. For example, a false positive test result could result in unnecessary x-rays with unnecessary radiation exposure. These are described further below (see “Follow-Up Procedure-Related Risks”).

Inaccurate results could direct further evaluation to the wrong part of the body. For example, the test could indicate cancer in the breast that is not present in the breast but is instead in the colon. An inaccurate result could include a “false negative” result – meaning the test indicates no cancer signal when a cancer could be present or a “false positive” result – meaning the test indicates the presence of cancer when no cancer is present.. These possibilities are described further below (see “Test result risks”).

Genetic Testing:

This research includes genetic testing that studies the characteristics and genes that are found in the body’s cells. Genes are made of DNA. DNA (deoxyribonucleic acid) contains the instructions for your body’s development and function. This information determines traits that are passed on from parent to child, such as eye and hair color and the risk/chance you will get certain diseases. Genes also tells your cells to make substances (including proteins) that appear in your blood. RNA (ribonucleic acid) is made from DNA. RNA is a genetic material that has a major role in making proteins. Researchers are examining DNA, proteins (biomarkers) and RNA to look for genetic changes that cause cells not to work properly and cause disease. Some of the genetic changes that can cause disease are known. Researchers are working on finding other genetic changes causing disease.

Blood Sample Collection:

A trained healthcare professional will collect approximately 40 mL (3 tablespoons) of blood in four tubes from a vein in your arm during a scheduled lab appointment. You may be asked to come back for repeated blood draw of approximately 40 mL (3 tablespoons) of blood if there are technical issues with the initial samples.

For participants with a “cancer signal not detected” test result, the maximum amount of blood collected is approximately 40 mL (3 tablespoons) of blood or if repeated blood draw is needed due to technical issues, a total of up to approximately 80 mL (6 tablespoons) of blood.

For participants with a “cancer signal detected” test result, an additional research blood draw of approximately 40 mL (3 tablespoons) in four tubes may be ordered for research and the results will not be returned to you, your healthcare provider, PCP or any member of the study team. The results will be used for research purposes only, including for test development. The maximum amount of blood collected for participants with a “cancer signal detected” test result is up to approximately 80 mL (6 tablespoons) of blood or if repeated blood draw is needed due to technical issues with initial samples, a total of up to approximately 120 mL (8 tablespoons) of blood.

Questionnaire(s):

You will also be asked to complete questionnaires throughout the course of your participation in this study:

- Before your blood draw
- Following return of the Galleri test results
- After completion of additional testing for a “cancer signal detected” result
- 1 year after your blood draw

Each questionnaire is expected to take no more than 30 minutes on a computer or other electronic device. If you are unable to receive electronic questionnaires, a paper questionnaire may be provided. The questionnaires will ask you about:

- Your general health and well being
- Your level of worry and anxiety in general and about the multi-cancer early detect test
- Your experience receiving the multi-cancer early detection test
- Your level of worry and anxiety about being diagnosed with cancer or your risk of cancer
- How likely you are to follow currently recommended cancer screening tests and to receive a multi-cancer early detection test in the future

Blood Test and Results:

Your blood samples will be sent to the study sponsor (GRAIL) to be tested. The study staff or Dr. Sedor will contact you with the test results within 30 days of the blood draw. If you receive a test result of “cancer signal detected,” but do not get diagnosed with cancer, you may have a second blood draw. You will not receive the results of this second study test. The Galleri test is designed to return a result that indicates if a cancer signal is currently present as well as where in the body where the cancer may be located.

If your test result indicates “cancer signal not detected”, you will be notified via phone call, virtual visit, or at an in-person clinic visit. It is important that you continue to receive any recommended cancer screenings that the healthcare provider recommends as part of your routine standard of care.

If your test result indicates “cancer signal detected”, you will be notified via phone call, virtual visit, or at an in-person visit to the study site. You will then discuss with Dr. Sedor the appropriate tests to confirm the result. In the course of testing your samples, genetic information unrelated to cancer signal detection may be discovered, for example, Alzheimer’s disease. This information, also known as incidental findings, will not be shared with you or the healthcare provider.

Additional Tests and Procedures After a “Cancer Signal Detected” Test Result:

If you have a “cancer signal detected” test result, more tests and / or procedures may be recommended to confirm the presence of cancer. Dr. Sedor will decide what tests and / or procedures are needed and he will explain the blood test and your test results to your PCP or chosen healthcare provider. We will also collect information about the other tests and procedures ordered and the results of these tests and procedures.

Future Test Results:

The Galleri test will continue to be updated during the study. Once this updated version is approved for use in this study, your left over blood samples may be tested using the updated version. Results from this testing will be returned to Dr. Sedor and the research study team, and if the results indicate a “cancer signal detected”, Dr. Sedor may recommend additional tests for cancer. If you do not want to receive the results from the updated version of the test, you should notify Dr. Sedor and the research study team.

Tissue Collection:

If you are diagnosed with invasive cancer during the study, leftover tumor tissue obtained through standard of care biopsy or surgical procedure may be sent to the sponsor or to a designated location for storage until the time of testing. The tissue samples will be collected from the clinical pathology laboratory and will not require any additional biopsies or surgeries. The tissue samples are left over material that would normally be stored or thrown out after a diagnosis has been made. At the time of testing, genetic material will be separated from the tumor tissue sample and will undergo genetic testing.

Medical Record Review:

We will collect certain information about you during the course of this study. This information may include:

- Information such as your age, race, ethnicity and other descriptive information,
- Medical information such as your medical history, any current medical conditions you have, medications you take, your standard laboratory test results, and imaging results

PET-CT Scan:

A PET-CT Scan may be performed if no cancer is found using the standard diagnostic tests. This test gives more detailed information to determine where cancer may be in the body using x-rays that are combined to form a 3D picture.

Follow-Up (approximately 3 years):

We will request your test results of additional evaluations, diagnoses and treatments and information about your general health during this study. We may also contact you via phone, mail, text messaging or email to ask you additional questions about your health annually for the next three years. You can select the method of communication that you prefer in the Method of Contact section below.

How will my data/specimens be used?

Your samples will be sent to researchers outside of the Cleveland Clinic for testing by GRAIL, LLC. Your blood and tissue samples will be labeled with your name, date of birth, and participant ID. Identifiable information is being sent so that your test results may be returned to you accurately.

Your samples collected for this research will be analyzed for the study. As part of the analysis, the research may undergo genetic testing which may include whole or targeted genetic sequencing with the intent to sequence either the DNA that makes up your healthy cells, or the DNA that might be coming from abnormal cells in your body. Genetic testing includes research that studies the characteristics and genes that are found in the body’s cells. Genes are made of DNA (deoxyribonucleic acid) which contains the instructions for your body’s development and function.

Cancer cells release small pieces of DNA (genetic material) into the bloodstream. The DNA from cancer cells is different from the DNA from non-cancer cells. This blood test looks for DNA from cancer cells in the blood and identifies the most likely location in the body the DNA may be coming from (type of cancer).

Two tubes of blood are needed for the blood test. If there are issues with processing the two tubes of blood provided, your additional samples will be used. Any unused samples will have your personal information removed and may be used for laboratory process improvements, quality assessment and improvement activities, proficiency testing, and future research relevant to this blood test. Therefore, while your active participation in this study will be approximately 3 years, your samples, and the data resulting from their analysis, may be used and studied for many years.

If it is determined after you are enrolled in this study that you are no longer eligible for participation, any samples that you provided during your participation will be destroyed.

You may request that your samples be withdrawn / destroyed from further study at any time. Your request should be in writing to Dr. Sedor who will inform the study Sponsor. This request will eliminate any further testing of your samples. If your samples have already been processed or de-identified, the data generated cannot be withdrawn / destroyed.

The results of the research carried out for this study may be presented at scientific meetings or in scientific publications; however, any directly identifying information about you will be removed so that no results can easily be associated with you.

The research done with your tissue/blood may lead to the development of new products in the future. You and your family will not receive, either now or in the future, any compensation, royalty, or other financial benefits resulting from any product, procedure, or other items developed from studying your sample(s).

Will I be notified of the results of the tests on my samples?

Your Galleri test results will be provided to Dr. Sedor and the research study team and communicated to you. You will not receive any results from tests run on leftover tumor tissue collected as part of a biopsy or surgical procedure.

When samples are collected and analyzed, there is the chance of finding something that may be important for your care. You will be informed of any results that are relevant to your clinical care

2. ALTERNATIVES

What are the alternatives to participation in the research study?

This is not a treatment study and it does not replace any cancer screening tests. There are no available alternatives to the Galleri multi-cancer early detection test, although there are tests for some individual cancer types (mammography for breast cancer, colonoscopy for colon cancer, etc.). Your alternative is not to participate in this study.

3. RISKS

What are the risks of participating in the research study?

You may experience risks and discomforts associated with the study procedure(s) and / or the blood test.

Blood Draw:

The insertion of the needle to draw blood can be painful; however, the discomfort is brief. For most people, needle punctures to get blood samples do not cause any serious problems; however, they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting.

Questionnaires:

Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

PET-CT Scan

One of the risks associated with radiation exposure is cancer. The natural incidence of fatal cancer in the U.S. is about a 1 chance in 5 (18%). In this research study, you may receive one (1) PET-CT Scan in addition to any radiographic tests you will receive as standard of care.

The amount of additional radiation you will receive for the research scans is 10.3 mSv over 1 year which is too low to accurately estimate your additional risk of cancer, but is approximately equal to 3.4 years of background radiation.

Test Result Risks:

There is a potential risk of a test result indicating a signal is detected when no cancer is present (sometimes referred to as “false positive”). A participant with this result may be recommended for unnecessary additional diagnostic procedures and could experience physical and psychological risks that are associated with those procedures, as well as additional anxiety.

There is also a potential risk of receiving a test result indicating no signal is detected when cancer is actually present (sometimes referred to as “false negative”). A participant with a false negative result might experience a delay in additional diagnostic procedures and possible delay in a potential cancer diagnosis. A “cancer signal not detected” test result should not be interpreted as cancer not being present and should not replace any guideline-recommended screenings or other standard of care diagnostic or treatment options. Failure to adhere to guideline-recommended screening or other standard of care modalities could also lead to a delay in a potential cancer diagnosis.

There is also a potential risk of an incorrect test result about the location of the cancer, for example indicating cancer present in one location when it is not present there and is present elsewhere or not. A participant with an incorrect location result might be recommended for unnecessary additional diagnostic procedures associated with the incorrect location and could incur physical and psychological risks that are associated with those procedures. An incorrect location result could also result in delayed identification of the correct tumor location, which could result in delayed treatment and reduced effectiveness of treatment.

Follow-Up Procedure-Related Risks:

Potential risks include those from additional evaluation (procedure or imaging, [e.g. endoscopy, colonoscopy, biopsy, CT with or without intravenous (IV) contrast, magnetic resonance imaging ultrasound, mammography] as part of the additional evaluation for a “cancer signal detected” test result. Additional evaluation may include multiple sequential procedures (e.g. CT scan followed by biopsy), each with its own potential risks. It is expected that the potential risks of any additional evaluation determined appropriate by Dr. Sedor and the research study team, which will be administered as part of standard of care, will be explained to you. This informed consent form (ICF) does not describe all potential risks for additional evaluation. All diagnostic testing will be paid for by the sponsor, GRAIL, LLC.

For example, potential risks include, but are not limited to:

1. If you need surgery as part of the additional evaluation, surgeries requiring anesthesia can cause allergic reactions, abnormal heart rates, breathing problems, and other serious complications. Each type of surgery will have its own risks which are dependent on the organ site and the type of surgical procedure as well as your general health and the capabilities of the institution where the procedure is performed. These risks may be serious and may be life-threatening.
2. If you need biopsy or a scope inserted as part of the additional evaluation (e.g. of your colon, esophagus, bladder, or stomach), this can cause perforation of the organ, which can lead to additional complications such as prolonged or severe bleeding, infection, or permanent damage to the organ that may interfere with its function. In rare instances, surgical complications or anesthetic reactions can lead to death.
3. If you require imaging as part of the additional evaluation, this could result in exposure to radiation, acute allergic or severe contrast reactions including acute kidney failure, and in rare instances death from procedures using imaging contrast agents.

Follow-up procedures may also result in incidental findings (e.g., malignant or benign tumors, physical malformations, masses or lesions that may be medically unimportant or may be evidence of other cancers or diseases other than cancer, gallstones, pancreatic lesions, colonic diverticulosis, or other abnormalities or findings of major, moderate, minor, or indeterminate clinical significance), which are findings unrelated to the test result that may have little impact on your health. The healthcare provider will determine how to address incidental findings related to diagnostic testing. It may not be possible to determine whether or not a finding is incidental prior to undergoing surgery or biopsy.

Dr. Sedor may recommend procedure(s) or imaging as a result of a “cancer signal detected” test result which might include additional imaging and/or biopsy and/or surgery as part of your diagnostic workup. All tests done as part of the diagnostic workup will be covered by the study.

Confidentiality Risks

There is a potential risk of loss of confidentiality of your data. Efforts will be made to keep your information confidential. The information collected about you will not directly identify you by your name, medical record number, social security number, address, or telephone number. Instead, you will be assigned a study identification number. The principal investigator will keep a link that identifies you to your coded information, but this link will be kept secure and available only to the principal investigator or selected members of the research team. Any information that can identify you will remain confidential. Any personal information that could identify you will remain confidential. Any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public.

Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. While the chance that someone could access and misuse your information is believed to currently be very small, it is possible that the risk may increase in the future as people find new ways to access information.

Genetic Risks

Your medical and genetic information is unique to you. There is a risk that someone outside of the research study could get access to your study records or trace information in a database back to you. They could use that information in a way that could harm you. While the chance that someone could access and misuse your information is believed to be very small currently, it is possible that the risk may increase in the future as people find new ways to access information.

A federal law called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information obtained during this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information obtained during this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

Unknown Risks

There may be risks or side effects related to the study tests that are unknown at this time. You will be notified of any significant new findings that become known that may affect your willingness to continue in the study.

4. BENEFITS

What are the possible benefits of participating in the research?

You may or may not directly benefit from participating in this study. It is anticipated that some participants will have a “cancer signal detected” test result and subsequent work-up will lead to a diagnosis of cancer, which could be treated. This may result in an earlier diagnosis than if the participant were not involved in the study. However, you may not experience any benefit from participation, but your participation may help others who may be evaluated for potential cancer in the future

The study will also allow GRAIL to further evaluate the feasibility and acceptability of a multi-cancer early detection test, which may help future patients undergoing cancer screening or evaluation.

5. COSTS

Are there any costs to you if you participate in this study?

The multi-cancer early detection test will be provided to you at no cost. If you receive a test result of “cancer signal detected”, the study sponsor will cover the costs of the tests ordered by Dr. Sedor until a cancer diagnosis or it is determined that no additional diagnostic procedures are needed.

Participants will be financially responsible for any treatments in the event of a cancer diagnosis.

You and / or your insurer must provide payment for standard medical care and medical costs unrelated to this study. Standard medical care is the care that you would receive regardless of whether or not you were enrolled in this study.

6. PAYMENT

Are there any payments to you if you participate in this study?

You will receive compensation for taking part in this research study.

You will receive a \$10 gift card certificate after you complete each study follow-up questionnaire for a total of \$30:

- Following return of the Galleri test results
- After completion of additional testing for a “cancer signal detected” result
- 1 year after your blood draw

If any new products, tests, or discoveries that result from this research, or the use of your samples or data, have potential commercial value or are used for commercial profit, you will not share in any financial or commercial benefits or profits.

The IRS requires CCF to report payments to an individual of \$600 or greater (in a calendar year) on a Form 1099-MISC. Your name, address and social security number will be collected to track the payments made to you and, if you receive \$600 or greater, will be used to process a Form 1099-MISC.

7. RESEARCH RELATED INJURY

What will happen if you are injured as a result of taking part in the research?

In the event you suffer a research related injury as a result of being in this study, Cleveland Clinic will provide appropriate medical treatment for such injury in a timely manner. Provision of such medical treatment does not imply any negligence or other wrongdoing on the part of Cleveland Clinic or any of the physicians or other personnel involved in the study. If you believe that you have been injured as a result of participating in the study, please immediately contact your Cleveland Clinic study doctor even if you may have already been seen or treated by another doctor. If you are seen or treated by a doctor other than the study doctor, you should inform such doctor that you are in this study and, if possible, take this document with you as it may help such doctor treat you.

In the event you suffer a research related injury as a result of being in this study, the costs for medical treatment may be billed to you or your medical insurance plan, if applicable. Medical

insurance plans may or may not cover costs for medical treatment of research-related injuries. If you have insurance, you should check with your medical insurance plan before deciding to participate in this research study. In the event your medical insurance plan covers some or all of the treatment costs, you may still be responsible for co-pays or deductibles as required by your medical insurance plan.

Cleveland Clinic has not set aside any money to pay you or to pay for your treatment if you suffer a research related injury as a result of being in the study. There are no plans for Cleveland Clinic to provide other forms of compensation (such as lost wages, pain and suffering, or other direct or indirect losses) to you for research related injuries. You are not waiving any legal rights by signing this form, including the right to seek compensation for an injury. Further information about research related injury is available by contacting the Institutional Review Board at (216) 444-2924.

8. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected for this research?

Cleveland Clinic may share your study information, without anyone knowing that it is related to you specifically, with others or use it to research projects not listed in this form. Your samples may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your samples, we will no longer be able to identify and destroy them.

Your test results will be provided to the Dr. Sedor or a member of the research study team. Only trained site study personnel and the healthcare provider will have password-protected access to the secure electronic results portal used to return test results, or it will be sent directly to the healthcare provider via fax.

Research data from the study will be stored separately from your medical records.

Study results may be shared in medical journals, at scientific meetings, and in other media without your identifying information. Your records will be confidential and your identity will not be shared in medical journals, at scientific meetings, and in other media without your express consent.

Authorization to Use/Disclose Protected Health Information

Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.

The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth, Social Security number, and other identifying information.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

People outside Cleveland Clinic may see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and the sponsor of the research (GRAIL) and their agents. Cleveland Clinic will take steps to ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your information may not be covered by this promise.

You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing.

Dr. John Sedor
9500 Euclid Ave – Q7
Cleveland, OH 44195

If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

May I review or copy my information?

You will always have access to your medical record. You will not have access to research data that is not part of your medical record.

Clinical Trials Language

A description of this clinical trial will be available on <http://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 the Website at any time.

9. QUESTIONS

Who do you call if you have any questions or problems?

If you have any questions or concerns about the research, or develop a research-related problem, you should contact Dr. John Sedor at 216-445-7154 or Lauren Grimm at 216-444-4650. If you have any emergencies after hours, please call 911 or go to the nearest emergency department. If you have questions related to scheduled procedures or tests that need to be addressed after business hours, please contact the number on your schedule or contact the CCF Operator at 1-800-223-2273 and they will connect you to the appropriate department. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at (216) 444-2924.

10. VOLUNTARY PARTICIPATION

What are your rights as a research participant?

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Withdrawal will not change your standard medical care. Your decision will not result in any penalty or loss of benefits to which you are entitled. If you withdraw from the study, information and samples that have already been collected may still be used by the study researchers, but no new information will be collected.

Your participation in this study may be stopped at any time by the healthcare provider, the site, the Sponsor, the reviewing IRB or a regulatory authority without your consent for any reason, including:

- if it is in your best interest or for safety reasons,
- if you fail to comply with the procedures of the study, or
- if the clinical information collected from your medical record is insufficient, incomplete, or your blood sample is unable to be processed.

If you leave the study early, Cleveland Clinic may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

Can I withdraw my samples?

If you agree to allow your tissue/blood to be kept for future research with identifying information that could link your sample to you, you are free to change your mind at any time. We ask that you contact the Principal Investigator in writing and ask to withdraw your permission for your identifiable tissue/blood to be used for future research.

The mailing address is 9500 Euclid Ave. Q-7) Cleveland, OH. 44195.

At that time we will ask you to indicate in writing if you want the unused identifiable tissue/blood destroyed or if your samples (having all identifying information removed that would link the sample to you) could be used for other research.

Method of Contact

With your consent, you agree to future contact by authorized study research personnel at the enrolling site by email, phone, mail, or SMS / text messaging. Contact may be made for the following reasons:

- to ask you about your current health status
- to ask whether you have completed the questionnaires
- to ask whether you would be willing to provide another blood sample

To stop being contacted by the site or to change the type of communications that you receive, please contact your study site personnel.

Please indicate communication preference(s) below. If you do not select a method of communication, the study site will use the contact information it has in its files to contact you.

1. I agree to receive study communications through email.

Yes ____

No ____

2. I agree to receive study communications through phone calls.

Yes ____

No ____

3. I agree to receive study communications through SMS messaging (standard rates apply; message rates differ from carrier to carrier, so please contact your wireless phone provider to ask about the details of your plan).

Yes ____

No ____

Optional Future Contact

You may be asked to be re-contacted in the future to provide additional feedback on this study. If you decide not to be re-contacted, you can still participate in this study.

I agree to be re-contacted in the future to provide additional feedback on this study.

Yes ____

No ____

Initials _____

11. SIGNATURES

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

Printed name of Participant

Participant Signature

Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

Printed name of person obtaining consent

Signature of person obtaining consent

Date