Permission to Take Part in a Human Research Study

Title of Research Study: A Prospective Dose-Escalation Study to Define an Ablative Dose of Yttrium-90 Transarterial Radioembolization Using Advanced Dosimetry and Functional MRI (MARGIN Study)

Principal Investigator: Andrew C. Gordon, MD PhD

Supported By This research is supported by Radiological Society of North America (RSNA).

Your doctor, who is also responsible for this research study is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Dr. Lewandowski, an investigator on this study, has been compensated by the manufacturer of the treatment procedure in this study, for consulting/advising services.

Key Information:
The first few pages of this document include a summary of this study to help you decide whether or not to participate. Detailed information is provided after the summary.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you have been diagnosed with a liver tumor that cannot be removed surgically or treated with standard ablation techniques, which are procedures that use heat or cold delivered through a needle to destroy tumors. This research involves studying how different doses of Yttrium-90 (Y90) radiation therapy affect liver tumors that cannot be treated with surgery or standard ablation. Using advanced imaging such as PET scans and MRI, the study aims to identify the most effective Y90 dose that can completely destroy the tumor while minimizing harm to the surrounding healthy liver tissue.

To allow you to make an informed decision as to whether or not you want to take part in this research study, this document, known as an informed consent, describes the purpose of the study, your rights and requirements, the procedures to be performed, and the possible benefits and risks of participating in the study. Before agreeing to participate in this study, please take time to read the following information carefully and ask your study doctor (also known as the principal investigator) or study staff as many questions about the study as you would like. This form may contain words that you do not understand. Please ask the study doctor or study staff to explain any words or information that is not clear to you. Joining a study is an important decision. You may have your primary doctor call the study doctor to ask any questions he/she feels are necessary to evaluate your participation. You may take home an unsigned copy of this informed consent for you to think about it or discuss it with your family and friends before making your decision. If you decide to take part in the research study, you must sign and date the end of this form before any procedures can be performed.

If you choose not to participate in this research study, your primary doctor will discuss all available options which regular medical care has to offer. When you decide to participate in this study, you are free to discontinue at any time and you will not incur any disadvantages in the further treatment of your disease.

Your participation in this study is entirely voluntary.

What should I know about a research study?

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

Why is this research being done?

This study is being done to help doctors improve how they treat liver tumors that cannot be removed by surgery or treated with standard ablation techniques. The researchers want to find out the best amount of radiation that needs to be delivered to completely destroy (or ablate) parts of the liver that have cancer. Currently, doctors use Yttrium-90 (Y90) radiation segmentectomy, a treatment that delivers tiny radioactive beads into the blood vessels feeding the liver tumor. These beads give off radiation that helps kill the cancer cells from the inside, right where the tumor is located. This approach allows doctors to target the tumor very precisely, while keeping the rest of the liver as healthy as possible. However, the exact dose needed to fully ablate a tumor without damaging healthy liver tissue is not well established.

To answer this, the study team will use specialized imaging before and after treatment to evaluate how the radiation is distributed in the liver and how the liver responds over time. These include PET/CT or PET/MRI scans*,* which are standard medical imaging tests that are not considered experimental. During these scans, a small amount of a safe radioactive substance is injected into your vein. This helps show where the Y90 beads are in your liver.

In a PET/CT scan, two types of imaging are performed during the same session. The PET scan detects signals from the radioactive substance and shows how your liver is functioning at a molecular level. The CT scan, which uses x-rays to create detailed cross-sectional images of the body, provides a precise anatomical map that helps localize these functional signals. Together, they give a clear picture of both the structure and activity within the liver.

PET/MRI works similarly but uses magnetic fields and radio waves instead of x-rays. It combines the functional information from the PET scan with the highly detailed soft-tissue images from MRI, which can be especially useful in evaluating the liver. Both imaging techniques are done during a single visit, with the PET component typically performed at the same time as the CT or MRI, depending on which machine is used.

You will also have a liver MRI with dual contrast (Eovist and extracellular gadolinium), another standard imaging procedure. MRI uses magnets and radio waves to take detailed pictures of your liver. Eovist is a special dye injected into your vein during the scan that helps highlight liver tissue and shows how well different parts of your liver are functioning. Extracellular gadolinium

is a more general contrast agent that enhances blood vessels and tissues, providing complementary information. This helps the doctors confirm whether the tumor area was completely treated.

The goal is to determine the safest and most effective dose of radiation to fully treat cancer while preserving healthy liver tissue. This information may help doctors treat future patients more precisely and safely.

Yttrium-90 and the imaging methods used in this study, including PET/CT, PET/MRI, and dual contrast MRI, are FDA-approved.

How long will the research last, and what will I need to do?

We expect that you will be in this research study for 12 months. You will be asked to undergo a baseline MRI of your liver within one month prior to treatment. After receiving Y90 radiation segmentectomy, you will have a PET/CT or PET/MRI scan within 72 hours to measure the radiation dose delivered. This scan is for research purposes. To monitor your liver function and how well the treatment worked, you will have standard of care follow-up MRI scans with dual contrast at 1 month, between 4 and 9 months, and at again 12 months to monitor liver function and treatment response. You will also have routine blood tests and clinical evaluations during each visit.

If you undergo liver transplant or surgery during the study period, your removed liver tissue may be examined for research purposes.

You can find more detailed information about the study procedures in the **What happens if I say, "Yes, I want to be in this research"?** section.

Is there any way being in this study could be bad for me?

Yes, being in this study could involve some risks. The most important risks relate to the imaging procedures and the contrast agents used. Although these are generally safe, there is a small chance you could have an allergic reaction to the contrast dye used during MRI or PET/CT scans. This could include symptoms like rash, itching, or more serious but rare reactions that require medical treatment. You may also feel uncomfortable during MRI scans due to loud noises or the enclosed space, especially if you are claustrophobic. You can find more detailed information about the risks of this study in the **Is there any way being in this study could be bad for me? (Detailed Risks)** section.

Will being in this study help me in any way?

We cannot promise any direct benefit to you from taking part in this research. However, the imaging studies done as part of this research may give your care team additional information about how your liver is functioning and how your tumor responds to treatment, which could help guide your future care.

There may also be benefits to others in the future. The information learned from this study may help doctors better understand how to safely and effectively deliver Y90 radiation to treat liver tumors, improving treatment for future patients.

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What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose not to participate, there will be no penalty to you or loss of benefit to which you are entitled.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

Whom can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, you can talk to the research team:

PRINCIPAL INVESTIGATOR:
Andrew C. Gordon MD, PhD
Assistant Professor of Radiology
Department of Radiology Northwestern University
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This research has been reviewed and approved by an Institutional Review Board (IRB). You may talk to them at (312) 503-1376 or irbcompliance@northwestern.edu if:

- The research team is not answering your questions, concerns, or complaints.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 30 people will be in this research study. This is a single-site study.

What happens if I say, "Yes, I want to be in this research"?

If you agree to take part in this research study, you will be followed for about 12 months. All research procedures in this study involve imaging to help researchers understand how your liver and tumor respond to Yttrium-90 (Y90) radiation segmentectomy.

The research will take place at Northwestern Medicine in Chicago, Illinois.

Here's what you can expect:

Before treatment: Your case will be reviewed by a multidisciplinary tumor board as part of routine clinical care. If the board determines that you are a potential candidate for Y90 treatment and this research study, you may then be contacted by the study team and asked to provide consent. If you agree to participate, you will be formally enrolled in the study. It is important to note that the review of your medical records and imaging by the tumor board is part of standard clinical workflow and does not constitute a separate study visit. Within one month prior to the Y-90 treatment, you will undergo a liver MRI with contrast, including both Eovist and extracellular gadolinium. Eovist is a special contrast agent that is taken up by functioning liver cells, helping to highlight liver tumors and healthy tissue. Extracellular gadolinium is a more general contrast agent that enhances blood vessels and tissues, providing complementary information. The scan takes approximately 60 minutes and will be scheduled only after you have provided consent to participate in the study.

On the day of treatment: You will receive Y90 radiation segmentectomy, minimally invasive outpatient procedure used to treat liver tumors. During this procedure, a specially trained doctor (called an interventional radiologist) inserts a thin, flexible tube called a catheter through a small incision in your groin or wrist and guides it through your blood vessels to reach the arteries that supply blood to your liver tumor. Once in position, tiny radioactive beads—known as Yttrium-90 or Y90—are released through the catheter into the blood vessels feeding the tumor. These beads become lodged in the tumor's blood supply, where they give off radiation directly to the tumor cells while sparing most of the healthy liver tissue around it. The goal is to destroy the tumor or stop it from growing. Within 72 hours of the procedure, you will undergo a PET/CT or PET/MRI scan (lasting about 60–90 minutes) to assess how much radiation was delivered to the tumor and nearby tissue. Please note that this scan is done as part of the research study and is not considered standard clinical care.

After treatment: You will return for three follow-up visits:

- 1 month (±2 weeks): MRI with dual contrast, and a clinical exam (~2–3 hours)
- 4–9 months: Repeat MRI and clinical evaluation (~2 hours)

- 12 months (+1 Month): Final MRI, labs, and comprehensive health assessment (~2–3 hours)

All research activities in this study involve advanced imaging. These scans are designed to measure liver function, tumor response, and radiation dose distribution over time.

If you undergo liver surgery or transplantation during the study, any removed liver tissue may be reviewed for research to evaluate how well the treatment worked.

The research-related post-treatment PET scan is done specifically for this study. Your Y90 treatment, lab tests, and dual contrast MRIs are part of your regular medical care. This study does not involve any experimental drugs or devices beyond the investigational use of Y90 dosimetry.

Your participation is voluntary, and you may be contacted in the future to ask if you'd like to join related research studies, but that is entirely optional.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for:

- Attending all scheduled study visits and imaging appointments.
- Informing the study team of any changes in your health, medications, or medical care.
- Following the instructions provided by your study doctor and staff.
- Telling the study doctor if you experience any side effects or unexpected issues.
- Letting the study team know if you undergo any new procedures, such as liver surgery or transplant, during the study period.
- Using reliable contraception during your participation if you or your partner could become pregnant.

What happens if I say "Yes" but I change my mind later?

You can leave the research at any time; it will not be held against you.

Choosing not to be in this study or deciding to leave the study later will not result in any penalty or loss of benefits to which you are entitled. Specifically, your decision will not affect your current or future medical care, your class standing (if you are a student at Northwestern University), or your employment (if you are an employee of Northwestern University or its affiliates).

If you decide to leave the research, please contact the study doctor so they can ensure your participation ends safely. You may be asked to complete a final visit or test, if needed, to help transition your care and ensure no unresolved medical issues remain.

Because this study is regulated by the U.S. Food and Drug Administration (FDA), any data that has already been collected about you before you withdraw will remain part of the study and cannot be removed. You may also be asked whether the study team can continue collecting data from your routine medical care after you stop participating. If you agree, this information

will be handled the same way as all other research data. If you do not agree, no additional data will be collected from your medical record or through direct contact.

Your decision to stop participation will not affect your access to care or any services you are otherwise entitled to receive.

Detailed Risks: Is there any way being in this study could be bad for me?

Physical risks:
You may experience mild side effects related to contrast agents used during MRI or PET scans, such as nausea, a metallic taste, or a rare allergic reaction (e.g., rash or shortness of breath). The MRI may cause discomfort from noise or claustrophobia (fear of small or enclosed spaces), and some people may find it uncomfortable to lie still in the scanner.

Background radiation is present on Earth (soil, air, water, food) and includes cosmic radiation. Exposure to radiation from natural sources is a feature of everyday life. Your participation in this study will involve additional exposure to radiation. the radiation dose received from the CT portion of the PET/CT scan is approximately equal to 2 months of background radiation(~50 mrem). Health risks from medical imaging studies at effective doses below 10,000 mrem (100 mSv) are too low to be detectable and may be nonexistent (Health Physics Society Policy statement PS010-3).

Psychological risks:
Some people may feel anxious or uncomfortable during imaging procedures, especially if they are claustrophobic. You may also feel stressed or worried when waiting for scan results.

Privacy and confidentiality risks:
This study uses identifiable, personal health information (such as your medical records and imaging). There is a small chance of a breach of confidentiality, meaning someone could access your information without permission. We have safeguards in place to minimize this risk, but it cannot be completely eliminated. **See the section titled "What happens to the information collected for the research?" for more details**.

Unknown risks:
In addition to the known risks listed above, this research may carry unknown risks. These could range from minor inconvenience to serious complications, although such events are highly unlikely. The imaging procedures used in this study, including dual contrast MRI and PET/CT or PET/MRI, are FDA-approved and have been extensively studied and safely used in clinical practice. While the use of these scans to analyze radiation effects is investigational in this context, no new or experimental imaging agents or procedures are being introduced.

Possible complications may include:

- Minor risks:
    - Discomfort from lying still for a long time in the scanner
    - Claustrophobia (feeling of being closed in) during MRI
    - Mild allergic reaction to contrast dye (e.g., rash or itching)
    - Bruising or discomfort at the IV injection site
    - Temporary metallic taste or warmth sensation from contrast agents

- Moderate risks:
    - Headache or nausea after contrast injection
    - In rare cases, delayed allergic reactions to contrast
    - Anxiety during scan procedures
- Serious (rare) risks:
    - Severe allergic reaction to contrast (anaphylaxis)
    - Kidney complications in people with pre-existing kidney disease (related to contrast use)
    - Radiation exposure from PET/CT (very low, but cumulative exposure over time could increase risk)

Use of identifiable information:
This study involves the use of your identifiable health information, including imaging data and medical history. While we will take steps to protect your identity, there is a small risk that your information could be accessed or misused.

Future use of data:
If your data or tissue samples are stored or shared for future research, there is a small risk that someone could potentially identify you, even though your information will be coded and de-identified as much as possible. Despite these precautions, we cannot guarantee that the risk of re-identification is zero.

What do I need to know about reproductive health and/or sexual activity if I am in this study?

Yttrium-90 (Y90) radioembolization poses significant risks to pregnant women and their fetus because the ionizing radiation can damage rapidly dividing fetal tissues. Exposure during early pregnancy may interfere with organ development and result in congenital malformations, growth restriction, or miscarriage. Radiation exposure in later stages of pregnancy can impair brain development and lead to long-term neurodevelopmental problems, as well as increase the lifetime risk of cancer for the child. For these reasons, Y90 treatment is contraindicated during pregnancy, and strict contraception is required before, during, and for several months after therapy.

You or your partner should not be or become pregnant while participating in this research study. The radiation used in this study, including Y90 treatment and imaging procedures such as PET/CT, may harm a pregnancy or fetus. Although no new investigational drugs or imaging agents are being used, radiation exposure is known to pose potential risks during pregnancy. For this reason, pregnant individuals may not take part in the study.

If you are sexually active, you and your partner should use at least one effective means of birth control while participating in this research study. According to the World Health Organization and the United States Center for Disease Control and Prevention, the most effective forms of birth control include complete abstinence, surgical sterilization (both male and female), intrauterine devices (IUDs), and the contraceptive implant. The next most effective forms of birth control include injectables, oral contraceptive pills, the contraceptive ring, or the contraceptive

patch. Acceptable but least effective methods of birth control include male condoms (with or without spermicide) and female condoms.

If you or your partner becomes pregnant while participating in the study or within 3 months of completing it, contact the study doctor or research staff immediately. You may be asked to stop participation in the study. Your care team will discuss alternative options with you if needed.

If you or your partner [are/is] considered to be postmenopausal, you are not required to use contraception while participating in this research study. Postmenopausal people rarely become pregnant. If you or your partner become pregnant while participating in this research study or for 3 months after you complete the study, it is important that you tell the study doctor or other research team member immediately. You may be required to stop participation in this study; however, other treatment options will be discussed with you at that time if necessary.

Will it cost me anything to participate in this research study?

Taking part in this research study may lead to added costs to you.

The research-related post-treatment PET/CT or PET/MRI will be covered by the study and provided to you at no cost.

However, you and your insurance company will be charged for health care services that are part of your regular medical care, including the Y90 treatment itself, dual contrast MRIs, routine clinic visits, blood tests, and other standard imaging or procedures that would occur even if you were not in this study. You may also be responsible for co-pays, deductibles, or other out-of-pocket costs required by your insurance plan.

In some cases, your insurance may not cover services performed as part of a research study. You should check with your insurance provider to understand what will be covered and what your financial responsibility may be.

Will being in this study help me in any way?

We cannot promise any direct benefits to you from your taking part in this research.

However, participating in this study may give your doctors additional information about how your liver responds to Y90 treatment through advanced imaging. This information might help guide your future care, but it is not guaranteed to change your treatment plan or outcome.

There may also be benefits to others in the future. The knowledge gained from this study could help doctors better understand how to safely and effectively deliver Y90 radiation to treat liver tumors, which may improve treatment strategies for future patients.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose not to participate, there will be no penalty to you or loss of benefit to which you are entitled.

If you decide not to take part in this research study, you will still have all of the usual options available for the treatment of your liver tumor. These may include the standard of care use of Yttrium-90 (Y90) transarterial radioembolization (TARE) at non-escalated, clinically established doses, or other locoregional therapies such as transarterial chemoembolization (TACE), microwave or radiofrequency ablation, external beam radiation therapy, or systemic therapy as determined appropriate by your treating physicians. Supportive care, including best medical management without liver-directed procedures, is also an option. Your doctors will discuss these options with you to determine the best plan of care for your specific situation, regardless of your decision about participating in this study

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including your research data and medical records, to only those people who need to see it for research, regulatory, or oversight purposes. However, we cannot guarantee complete confidentiality.

- Organizations that may inspect or copy your research records include:
- The Institutional Review Board (IRB)
- Northwestern University’s Office for Research Integrity
- The U.S. Food and Drug Administration (FDA)
- The study sponsor, the Radiological Society of North America (RSNA), and its representatives
- Contract research organizations and monitors involved in overseeing the study
- The U.S. Department of Health and Human Services (DHHS)

The research imaging portion of your medical care is paid for by the sponsor, we may be required to share identifying information (such as your name, date of birth, and Medicare ID or Social Security Number) with the sponsor for billing or compliance purposes.

We may publish the results of this study in scientific journals or present them at conferences, but your identity will not be revealed in any publication or presentation.

A description of this clinical trial will be posted on ClinicalTrials.gov, as required by U.S. law. The website will not include information that can identify you. You may search the website at any time to view a summary of the study and its findings.

If identifiers are removed from your data or samples collected during this study, those de-identified materials may be used for future research or shared with other investigators without additional informed consent**. See the section "Will my data or samples be used for future research?" for more details.**

Will my data or samples be used for future research?

This study is collecting data from you, including imaging and clinical information. We would like to make your data available for other research studies that may be done in the future. These studies may focus on similar diseases or conditions, or they may involve unrelated health topics. Future research could be conducted by researchers at Northwestern or other academic or commercial institutions, including groups in other countries. Our goal is to make more research possible that could benefit patients in the future.

We plan to keep your data for up to 15 years after the completion of this study, in accordance with institutional policy. Researchers who want to use your data will need to request approval through this institution, and their projects may require review by an Institutional Review Board (IRB).

We will protect the confidentiality of your information to the extent possible. Your data will be coded to protect your identity before being shared with other researchers. Only the study team will have the code key that links the data back to your name or other identifying information. This code key will be stored securely and separately from your study data.

Participating in this study means you agree to allow your data and samples to be shared for future research. You can change your mind later by contacting the study doctor, but researchers may still use data that has already been shared before your request. If you do not want your data used in future studies, you should not participate in this study.

Can I be removed from the research without my OK?

The person in charge of the research study or the study sponsor may remove you from the study at any time, without your permission. Possible reasons for removal include changes in your medical condition, safety concerns, noncompliance with study procedures, or if the study is stopped by the sponsor, institution, or regulatory authorities.

We will tell you about any new information that may affect your health, welfare, or decision to continue in the research.

What else do I need to know?

If you become ill or are injured as a result of participating in this research study (for example, from imaging procedures or radiation exposure), you should seek medical treatment through

your doctor or treatment center of choice. You should promptly tell the study doctor about any illness or injury you experience during the study.

Northwestern University, the hospital and the researchers will not pay for medical care required because of a bad outcome resulting from your participation in this research study. This does not keep you from seeking to be paid back for care required because of a bad outcome.

You will not be paid for your participation in this study.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- Results of physical examinations
- Medical history
- Lab tests and imaging related to this study
- Records about study medication or drugs
- Records about study devices
- Billing information
- Records related to your Y90 procedure and follow-up imaging
- Records about study procedures and outcomes

During this study, you may be coming to a Northwestern Memorial HealthCare/Northwestern Medicine entity for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the NMHC computer system. When a clinical exam or lab is done by NMHC or one of its employees for the purpose of this research study, that information will be kept in both NMHC's clinical records and in the study records.

The following clinical providers may give the researchers information about you: all current and previous health care providers, including but not limited to the Shirley Ryan AbilityLab (SRALAB) and Northwestern Memorial HealthCare/Northwestern Medicine entities and its current and future affiliates.

Once we have the health information listed above, we may share some of this information with the following offices or entities outside of Northwestern University and its clinical partners (or affiliates): the Northwestern University Institutional Review Board Office and Office for

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Research Integrity; the US Office of Research Integrity; the US Office for Human Research Protections; the US Food and Drug Administration.

Any research information shared with outside entities will not contain your name, address, telephone or social security number or any other personal identifier unless disclosure of the identifier is necessary for review by such parties or is required by law or University policy [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigator's office].

The following entities may receive your health information:

Authorized members of the Northwestern University and the Shirley Ryan AbilityLab workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board.

- Clinical affiliates, including but not limited to the Shirley Ryan AbilityLab (SRALAB), Northwestern Memorial HealthCare, and the Ann & Robert H. Lurie Children's Hospital of Chicago (Lurie Children's). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Memorial HealthCare, for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- RSNA, who is sponsoring the study, and that company's contractors and partners.
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Unless you revoke your consent, it will not expire.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing.

To revoke your authorization, write to:

Principal Investigator: Dr. Andrew C. Gordon
Institution: Northwestern University
Department: Department of Radiology
Address: 676 N St Clair St, Suite 800, Chicago, IL 60611

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You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Signature Block for Adults Capable of Providing Consent:

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

_____ _____

Signature of Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

_____

Printed Name of Person Obtaining Consent