**APPROVED BY SALUS IRB: 25 JULY 2025**

**INFORMED CONSENT DOCUMENT**
**AGREEMENT TO BE IN A RESEARCH STUDY**

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|---|---|
| **NAME OF SPONSOR COMPANY:** | Prenuvo, Inc. |
| **PROTOCOL NUMBER AND TITLE:** | MA-001; A MULTI-SITE PROSPECTIVE, SINGLE-ARM, OBSERVATIONAL STUDY ON THE ACCURACY OF WHOLE BODY MAGNETIC RESONANCE IMAGING (WB-MRI) SCREENING TO PREDICT CLINICALLY SIGNIFICANT DIAGNOSES IN GENERAL POPULATION SUBJECTS INTERESTED IN PROACTIVE AND ADVANCED GENERAL PREVENTIVE HEALTHCARE. |
| **STUDY DOCTOR:** | Perry P. Kaneriya, MD, MBA |
| **ADDRESS OF STUDY SITE(S):** | Hercules Boston<br>118 Arsenal Yards Blvd.<br>Watertown, MA 02472 |
| **TELEPHONE NUMBER(S), DAYTIME AND AFTER HOURS:** | (833) 948-9981 |

**INTRODUCTION**
You are deciding if you would like to volunteer for a research study. You must read and sign this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. You should not sign this form if you have any questions that have not been answered.

You must be honest and complete in providing your medical history. Giving false, incomplete, or misleading information about your medical history, including past and present drug use, could have very serious health consequences.

**PURPOSE OF THE STUDY**
This is a research study that is investigating whether the use of whole-body magnetic resonance imaging (MRI) can detect significant disease in patients. An MRI is a medical imaging technique where the patient lays very still within a large tube that uses strong magnetic fields and radio waves to generate images of the organs in the body. The MRI machines and image acquisition protocols used in this study are cleared (approved) by the United States Food and Drug Administration (FDA) and the radiologists performing the radiology services are licensed by the Massachusetts Board of Medicine. However, the use of the specially-configured MRI machines, image acquisition protocols and radiology in a whole-body screening capacity (collectively the "Prenuvo whole body MRI") to predict certain significant diseases has not been previously evaluated prospectively (to discover what is likely to happen in the future) in a large general population cohort.

You are being asked to take part in this study to evaluate the abilities of Prenuvo whole body MRI in predicting clinically significant disease.

The decision, for you, to participate in this research study allows Prenuvo Inc. to use the findings of your MRI scan to evaluate whether the results can predict clinically significant diseases.

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The whole-body MRI images will be sent to a specifically trained radiologist (a medical doctor that specializes in medical imaging), who will evaluate the images and provide an interpretation. The investigational results from the radiologist will then be compared to any diseases you may be diagnosed with over the next 12-18 months by your health care provider.

You and your health care provider will receive the results from the whole-body MRI scan.

To qualify for this study, you must be 18 years or older and choosing on your own (and paying for) a screening whole body MRI as part of Prenuvo Inc. commercial services. You must also be willing to allow the sponsor or their representative access to your medical history and any diseases that you may be diagnosed with over the next 12-18 months.

MRI uses a strong magnetic field. For this reason, any imbedded medical device (for example stents, pacemakers, artificial joints, cochlear implants), external devices (for example continuous blood glucose monitoring devices, hearing aids), and material such as shrapnel, staples or clips can cause problems which may be severe. It is essential that you notify the study doctor before you enter the study if any of these conditions apply to you to determine if the device or implant is MRI safe or MRI conditional, or if you have any questions.

**HOW LONG THE STUDY WILL LAST AND HOW MANY PEOPLE WILL BE IN THE STUDY**

If you qualify, you may be in the study for up to 18 months, or longer up to 4 years if you elect to participate in the optional follow-up visit(s), which are described below. Your participation will begin after you provide informed consent and complete your screening whole body MRI scan. The MRI scan will take approximately 60 minutes, and the entire visit may take up to 2-3 hours. Following this, you will be contacted approximately 15 months later for a follow-up telephone visit. Your participation may end at the completion of your follow-up telephone visit, or you will be offered the ability to participate in an optional part of the study, where you will return to the study site at approximately 2 years and 3 years after your initial whole body MRI scan to perform additional scans. If you elect to participate in the 2$^{nd}$ whole body MRI scan at year 2, you will again be contacted approximately 15 months after that scan for a follow-up telephone call. If you further choose to participate in the 3$^{rd}$ whole body MRI scan at year 3, you will again be contacted approximately 15 months after that scan for a follow-up telephone call.

Approximately 100,000 adult subjects will participate in the study. The study will include adult men and women.

**WHAT WILL HAPPEN DURING THE STUDY**

After providing informed consent to participate in this research study, each subject will provide their demographic information, medical history, and socioeconomic information (this type of information includes income and education levels, occupation, insurance information, social support, and your residential zip code). Following this, you will be prepared for your screening whole body MRI scan, which will include instructions on breathing technique and how to limit body motions within the MRI machine.
Following the scan, the images will be sent to a trained radiologist for assessment. The radiologist will forward their findings to your health care provider for further assessment and discussion with you. Any further testing or assessments you may encounter due to the results of the screening whole body MRI will be up to the discretion of you and your health care provider.

You will be contacted approximately 15 months after your scan. At this contact, you will be asked about any diseases you may have been diagnosed with since the screening whole body MRI scan (which may include dates, name of disease(s), treatments, outcome). If necessary the study doctor may also ask you to provide any new medical records from doctor visits that have occurred to you since the previous screening

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whole body MRI. You will also be asked to complete a survey on the whole body MRI. It is important you answer all questions truthfully.

**SUMMARY OF STUDY PROCEDURES:**

***Visit 1***

***During Visit 1 the following study-specific procedures will occur:***

1. The study will be explained to you, and you may be asked questions to see if you qualify.
2. You will read and sign this Informed Consent Form.
3. You will be assigned a subject identification number.
4. You will provide demographic information (age, race, ethnicity), medical history, smoking history, medication information, and socioeconomic information (household income level, education level, occupation, type of health insurance provider, access to primary care provider, social support systems, and residential zip code).
5. You will undergo a whole-body MRI scan.
6. Results will be interpreted and provided to your health care provider

***During the Visit 1 follow-up telephone visit the following procedures will occur:***

1. You will be contacted approximately 15 months after your initial MRI scan to answer questions about your recent medical history.
2. You will be asked to complete a survey about the whole-body MRI.
3. You will be asked to participate in an optional second whole-body MRI scan at Year 2
4. If you elect not to participate in an additional whole-body MRI scan, you will complete the research study.

***Optional Visit 2***

***During Optional Visit 2 the following study-specific procedures will occur:***

1. You will be asked questions to confirm you still qualify for the study.
2. You will undergo a whole-body MRI scan.
3. Results will be interpreted and provided to your health care provider.

***During the Visit 2 follow-up telephone visit the following procedures will occur:***

1. You will be contacted approximately 15 months after your 2nd MRI scan to answer questions about your recent medical history.
2. You will be asked to complete a survey about the whole-body MRI.
3. You will be asked to participate in an optional second whole-body MRI scan at Year 3.
4. If you elect not to participate in an additional whole-body MRI scan, you will complete the research study.

***Optional Visit 3***

***During Optional Visit 3 the following study-specific procedures will occur:***

1. You will be asked questions to confirm you still qualify for the study.
2. You will undergo a whole-body MRI scan.
3. Results will be interpreted and provided to your health care provider.

***During the Visit 3 follow-up telephone visit the following procedures will occur:***

1. You will be contacted approximately 15 months after your 3rd MRI scan to answer questions about your recent medical history.
2. You will be asked to complete a survey about the whole-body MRI.
3. You will complete the research study.

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**POSSIBLE SIDE EFFECTS AND RISKS**

The risks for a whole-body MRI are similar to any conventional MRI procedure, which may include anxiety, claustrophobia, and body discomforts due to not being able to move for approximately 60 minutes. MRI machines do not use ionizing-radiation, and therefore there is no related future risk of radiation-induced malignancy.

Severe adverse health effects including death from exposure to magnetic fields have occurred in people who have certain magnetic metallic objects attached to their clothing or skin or implanted in their bodies. You should not volunteer for an MRI scan in this study if you answer yes to any of the questions regarding non-removable metal.

You should not volunteer for an MRI scan if you wear a cardiac pacemaker or a biostimulation device, if you have ever had surgery which may have involved the insertion of aneurysm clips, if you may have other medical implants such as a plate or pin, or if you are wearing cosmetics or jewelry such as eyeliner or pierced earrings which may contain ferrous metal.

The FDA has not established the safety of magnetic resonance imaging for scanning an unborn baby or pregnant women. You should not volunteer for an MRI scan in this study if you know or suspect that you may be pregnant.

Side effects from exposure to radiofrequency energy in rare cases include warming of the skin and burns. These burns may occur with MRI systems if your body touches the bore of the magnet during an MRI scan, or if conductive cables or leads are positioned so that they cross one another in close proximity to you. While you are scanned you will be appropriately protected from touching cables. You should not volunteer for an MRI scan unless your body can fit comfortably within the magnet bore without touching its surface.

Mild neurological sensations such as tingling and nerve stimulation have been reported with certain rapid MRI scanning techniques in certain parts of the body including, but not limited to, the arms, legs, fingertips, and nose while the scan is occurring. This sensation is not lasting and is typically not painful. Your body will be positioned with your arms and legs uncrossed and hands unclasped which will lessen or eliminate this tingling sensation. If you notice this sensation and it is uncomfortable for you, please notify the MRI technician.

If you do experience any pain or discomfort during your participation, it is important to notify your study doctor.

You must tell the study doctor or study staff about all side effects that you have. If you are not honest about your side effects, it may not be safe for you to stay in the study.

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***Results***
The Prenuvo whole body MRI is a medical screening evaluation that may cause you to discover sensitive information about your health or disease status, including for diseases that currently have no treatment. The results provided may also be found to be inaccurate. If the results falsely note a possible disease that is later found to be inaccurate, this may lead you to anxiety and unnecessary further dedicated diagnostic testing as part of your follow-up. The results may also report no abnormal findings, even though an abnormal disease may be present.

***Pregnancies***
Although there are no known proven risks to a pregnant woman or unborn babies from MRI exams, if you are known to be pregnant or thought to be pregnant, you cannot participate in this study. Please notify the study doctor or nurse if you believe you are pregnant.

***Confidentiality***
There is a risk of loss of confidentiality of your information that is used in this study. A loss of confidentiality may result in your whole-body MRI findings and personal health information (PHI) being seen by others. This information could lead to discrimination by insurance companies for life, disability, or long-term care insurance. You will read more about the protection of your information later in this form. Please ask the study doctor or another member of the study team if you would like to know more about how this information will be protected while you are in this study.

There may be risks to being in this study that we do not know about now or cannot predict. For more information about any of the risks above, you can ask the study doctor**.**

**POSSIBLE BENEFITS OF THE STUDY**
Your results may indicate you have certain medical conditions, the early diagnosis of which may or may not have a material impact on treatment outcomes. Your results may also show benign features (tumors or disease that are not cancerous), the knowledge of which may or may not prevent an incorrect medical diagnosis in the future. Your results might show that you have disease precursors or risk factors, the knowledge of which may or may not help you make lifestyle changes that alter how the future disease may progress. This knowledge may or may not help you and your healthcare provider make more informed healthcare decisions.

**ALTERNATIVES TO PARTICIPATING IN THE STUDY**
Your alternative is to not participate. If you elect not to participate you will be unable to continue with the Prenuvo whole-body MRI scan at this facility.

Some people do not want to take part in this kind of research study. If you feel that way, you should elect NOT to take part in this study.

**IN CASE OF STUDY RELATED INJURY**
If you have serious side effects, complications, or are injured because of a direct result of the research procedures required in this study, please contact and notify the study doctor promptly.

Medical care for injuries occurring as a direct result of your participation in this study may be provided or you may be directed to an emergency facility and will be billed to your health insurance company.

Some insurance companies and third-party payers may not pay for treatment of injuries that result from participation in a research study, including hospitalization costs. You may be billed for the expenses of medical care resulting from injury if your insurance company or third-party payer does not pay for those

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costs.

No payment is offered to you for lost wages or other damages or losses or for medical expenses. No other form of compensation is offered.

**LEGAL RIGHTS**
You will not lose any of your legal rights by signing this consent form.

**COSTS TO PARTICIPATE**
The study participants will pay a charge in order to reimburse the sponsor for study-related costs. The participant cost will be set annually by taking into account estimated costs at the time a participant is enrolled and could change year to year.

The cost to you for enrolling and receiving the first scan will be between $2000 and $3000.

In some instances, if you are unable to pay some or all of the amount required for the whole-body MRI and you meet a health equity enrollment criteria, the sponsor may be able to assist with some of the costs. Participants in certain target groups may also be eligible for a discounted cost. The study staff will discuss this with you.

If you agree to follow-up scans (i.e. optional visit 2 and beyond) the cost to you will be an additional $2,000 per scan and follow-up.

It is allowable for you to make special arrangements to have your costs for participating in the study paid by someone else (a third party). An agreement for a third party to pay for your participation would be your responsibility to arrange. Please discuss this with the study staff. Study staff can also provide you with an invoice to use in seeking outside financial help with the study costs.

**PAYMENT FOR BEING IN THE STUDY**
You will not receive compensation for your participation in this research study.

The study doctor is being paid to conduct this study.

**CONFIDENTIALITY**
Your personal information will be kept confidential to the extent permitted by law. We cannot guarantee absolute confidentiality. By signing this document, you give permission to access your medical records, including after withdrawal, to check the information being used.

Any and all personal data provided within the context of this study are available to the study doctors, their deputies and authorized persons (such as representatives of the sponsor of the study or of the appropriate regulatory agencies), who all are bound to confidentiality. Personal identifiable data will not be published (including in publication of the study results such as in a scientific publication). With the exception of disclosures to the sponsor in order to facilitate the delivery of necessary and important parts of the Prenuvo Whole Body MRI clinical service, data will be passed on to third parties anonymized. This means that your name will be assigned a number by your study doctor and the information we collected about you will only be passed on using that number to such other third parties.

For billing and invoicing of the whole-body MRI, a third party representative of the sponsor will be provided with your necessary contact information.

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The sponsor may make your whole-body MRI results available to you on a secure website and/or mobile-device application. This may allow you to view your results, and interact with the sponsor or their representative regarding your findings. Any personal information available will only be accessible via a secure, password protected website. Only the sponsor or their representative personnel bound with confidentiality, and specifically granted access, may view your information.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as:

- The study doctor
- Prenuvo Inc. (Sponsor of this study) or those who work for or represent the Sponsor
- The United States Food and Drug Administration (FDA)
- Other state or federal regulatory agencies
- Salus IRB

Salus IRB and accrediting agencies may inspect and copy your records, which may have your name on them. Therefore, total confidentiality cannot be guaranteed. If the study results are presented at meetings or printed in scientific publications, your information would only be presented by a de-identified number and your name would not be available nor used. By signing this document, you give permission to use the information you provide, including after withdrawal.

In the rare event that your information is required to be disclosed by law to another entity, privacy laws may not apply, and neither the Sponsor nor the IRB can protect your information.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

**WHO CAN YOU CALL IF YOU HAVE QUESTIONS OR IN CASE OF AN EMERGENCY**

You may contact the study doctor or study staff at the phone number listed on the first page of this consent document:

- for answers to questions, concerns, or complaints about this research study,
- to report a research related injury, or
- for information about study procedures.

If you need medical attention, please go to the nearest emergency room.

You may contact Salus IRB if you:

- would like to speak with someone unrelated to the research,
- have questions, concerns, or complaints regarding the research study, or
- have questions about your rights as a research participant.

Salus IRB
Phone: 855-300-0815 between 8:00 AM and 5:00 PM Central Time
Email: salus@salusirb.com

If you would like additional information about your rights, research in general, or IRBs, you may visit www.salusirb.com.

**VOLUNTEERING TO BE IN THE STUDY**

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It is your choice if you want to be in the study. Taking part in this study is voluntary. No one can force you to be in the study. You may choose not to take part, and you may leave the study at any time for any reason. Leaving the study will not result in any penalty or loss of benefits to which you are otherwise entitled. If you choose to leave the study however, it is encouraged that you speak with your study doctor first.

The study doctor, the sponsor company, Salus IRB, or the FDA, if applicable, may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the study doctor's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health

If you leave the study or if you are taken out of the study, if the information generated from this study is published or presented, your identity will not be revealed. If you leave the study, no more information about you will be collected for this study. However, all of the information you gave us before you left the study will still be used.

**Inclusion of Sedative Administration and Monitoring Procedures for Patients with Anxiety**

1. **Sedative Option for Anxiety**
   Patients who express concern that they may experience anxiety during imaging may request assistance with a sedative if they desire. If you choose this option, your information will be reviewed by a Nurse Practitioner (NP) to determine the appropriateness of prescribing Hydroxyzine as a sedative option to assist with scan-related anxiety and undergoing the WB-MRI.
2. **Prescribing and Usage of Sedative**
   - If approved, the NP will prescribe Hydroxyzine 25 mg (3 tablets).
   - You will be instructed to take 2–3 tablets prior to your arrival at the clinic.
   - Your medical chart will be flagged to indicate that you have taken a sedative.
3. **Voluntary Disclosure of Sedative Use**
   If you have been prescribed a sedative by your own healthcare provider, you may voluntarily inform us during check-in that you have taken a sedative.
4. **Sedative Monitoring Protocol**
   If you have taken a sedative, you will be monitored according to the Sedative Monitoring Protocol to ensure your safety:
   - Before the scan: Vital signs will be measured.
   - During the scan: Your alertness and any nausea will be assessed.
   - After the scan: Vital signs will be rechecked, and a final assessment will determine your readiness for discharge.
5. **Discharge and Transportation**
   - You are advised not to drive yourself after taking the sedative medication. You should arrange for other transportation in advance, such as coordinating a ride from a friend or family member or taking a taxi/ride-share service.
   - If you decline transportation guidance, you will be required to sign a waiver acknowledging your decision.

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**Risks and Benefits**

The use of sedatives may help reduce anxiety and improve your comfort during the scan. However, sedatives may cause drowsiness, nausea, or other side effects, and additional monitoring is required to ensure your safety. By signing this consent, you acknowledge your understanding of these potential risks and agree to participate in the Sedative Monitoring Protocol if you choose to take a sedative.

**YOUR RESPONSIBILITIES AS A RESEARCH SUBJECT**
You will be asked to follow all instructions issued by the study doctor and other study staff and to arrive on time for your appointment. You should also answer all asked questions truthfully.

If you are not able to follow the study instructions, the study doctor may stop your study participation. Your study doctor may also exclude you from this study if it is beneficial for your health, or if you do not meet the study requirements. Your participation in this study may end if the Sponsor stops the study for any reason.

**NEW FINDINGS**
If there is new information or any significant new findings that could relate to your willingness to continue your participation in the study, we will tell you. You can then decide if you still want to be in the study.

**AUTHORIZATION TO USE AND DISCLOSE YOUR PERSONAL HEALTH INFORMATION**

**INTRODUCTION**
**This authorization may have words that you do not understand. Please ask the study doctor or staff to explain any words or information that you do not understand.**

The purpose of this form is to explain how details about your health **and your personal information** that you give us during this study will be used and shared with others.

By signing this form, you allow the study doctor to use and share your personal health information collected during the course of this study. Please read this with the Informed Consent for the above-mentioned study. All participation information is explained in that consent form.

You do not have to sign this form. However, if you choose not to sign this authorization, you may not participate in the study.

**INFORMATION THAT MAY BE USED AND SHARED**
Information that may be used and given to others may include past, present, and future health information collected during this study. Your personal information includes but is not limited to the results of study related procedures as described in the informed consent and other study-related materials that are unique and specific to your participation in this clinical study.

Your personal health information will be used to carry out the research, to review records on the information collected in this study, to check how the study was carried out, or for other uses permitted by law.

**THIS INFORMATION MAY BE SEEN BY:**
- The study doctor and staff
- The study sponsor or their representative
- Salus IRB
- The U.S. Food and Drug Administration

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- The Department of Health and Human Services
- Government agencies that require reporting of reportable diseases
- Governmental agencies in other countries and
- Individuals or companies that monitor the quality of research practice

There may be other information that may be used and given to others that has not been stated above. You should discuss this with the study doctor or a member of the staff and ask any questions that you may have about the sharing of your health information.

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**HOW LONG IS THIS AUTHORIZATION IN EFFECT**

This authorization to use and disclose your personal health information will expire December 31, 2073. You must notify the study doctor in writing that you no longer want to share your information.

To revoke your authorization, please write to the study doctor at the address on page 1 of this informed consent.

Information collected before the termination of your authorization may still be used for study purposes.

If you decide that you no longer wish to have your personal health information shared, you may withdraw it at any time. However, once you do so, you can no longer continue to participate in the study.

In addition:

- You must provide a written request to the study doctor, listed on page 1, and tell him or her that you no longer want to share your information. Revoking your authorization and choosing to no longer participate in this study does not affect your treatment or any other benefits to which you would otherwise be entitled.
- You will no longer be a part of this research study.
- The study doctor and staff can continue to share any of the information that they already have.

Once the study doctor has shared your information with someone outside the study, it may no longer be protected. There is a chance that your information will be shared with others in ways that are not listed here and released without your permission.

You have a right to see and copy your information. However, you will not be able to see it while the research study is going on.

If you have questions or concerns about your privacy and the use of your personal medical information, contact the study doctor at the telephone number listed on page 1 of the consent form.

**AUTHORIZATION**

**I agree to share my information as described in this form and I have received a signed and dated copy of my records.**

_____
PRINTED NAME OF SUBJECT

_____
SIGNATURE OF SUBJECT CAPABLE OF CONSENT DATE

**The information contained in this document was fully and carefully explained to the study participant.**

_____
PRINTED NAME OF PERSON OBTAINING AUTHORIZATION

_____
SIGNATURE OF PERSON OBTAINING AUTHORIZATION DATE

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**AGREEMENT TO BE IN THE STUDY**

This consent document contains important information to help you decide if you want to be in this study. If you have any questions that are not answered in this consent document, please ask one of the study staff.

By signing this informed consent document, you are acknowledging the following:

A. This document is in a language you understand.

B. You understand the information in this consent form.

C. You have been given enough time to ask questions and talk about the study.

D. All of your questions have been answered to your satisfaction.

E. You think you received enough information about the study.

F. You volunteer to be in this study of your own free will and without being pressured by the study doctor or study staff.

G. You know that you can leave the study at any time without giving a reason and without affecting your health care

H. You know that your health records from this study may be reviewed by the sponsor company and by government authorities.

**IF YOU DO NOT AGREE OR ARE UNABLE TO AGREE WITH ANY OF THE ABOVE STATEMENTS, YOU SHOULD NOT SIGN THIS CONSENT FORM.**

**SIGNATURE PAGE**

_____
Printed Name of Study Subject

_____
Signature of Study Subject Date

_____
Printed Name of Person Explaining Consent Form

_____
Signature of Person Explaining Consent Form Date

You will receive a signed and dated copy of this consent form to keep.