BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC

EYETHREE, INC.
PARTICIPANT INFORMATION AND INFORMED CONSENT FORM

Protocol Title: Longitudinal Assessment of Neuroplasticity and Network Function Using Multi-Echo fMRI
Protocol #: 1000-001A
Sponsor: EyeThree, Inc.

Principal Investigator: Dr. Prantik Kundu
Institution: EyeThree, Inc.
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KEY INFORMATION ABOUT THIS RESEARCH STUDY

You are being asked to be a participant in a research study because you are a healthy adult interested in learning about your brain function and neural plasticity.

The following table is a concise and focused presentation of key information to assist you in understanding why you might or might not want to participate in the research.

Purpose	This is a research study to investigate normal brain function patterns in healthy adults for general wellness and educational purposes only. **IMPORTANT:** This study does NOT diagnose, treat, prevent, or cure any disease or health condition. This is **NOT** medical care. You will receive educational information about your brain function patterns for personal interest and wellness purposes only. You will **NOT** receive any experimental drugs, medical treatments, diagnostics or interventional procedures, nor anything that can be used in a medical context.
Voluntary Participation	Your decision to be in this study is voluntary.
Withdrawal	If you decide to be in this study and then change your mind, you can leave the study at any time without penalty.
Length of Participation	Your participation is expected to last up to 24 months, with a minimum of two and up to four Multi-echo functional MRI (ME-fMRI) scanning sessions spaced at least two months apart.
Procedures	The main procedures in the study include: • ME-fMRI scanning sessions (2-4 total) • Completion of basic demographic questionnaire and MRI safety screening • Virtual results discussion meetings (30-60 minutes) with trained EyeThree personnel after each scan Maintaining an activity log between scanning sessions at your own pace.
Risks	There are not expected to be any physical risks to you as part of this study beyond those normally associated with MRI scanning. These may include discomfort from loud noises for which you will receive

	hearing protection. If you are uncomfortable with tight spaces, you may experience claustrophobia from the MRI environment.
Benefit	Possible benefits may come from receiving comprehensive brain metrics through the E3Profile platform, enabling you to track changes in your brain function over time and gain insights into your unique cognitive profile, including personalized guidance from neuroscientists to help interpret your results. However, there is no guarantee that you will receive direct benefit as a result of your participation in this study. The study results may help people in the future.
Alternatives to Study Participation	Your alternative is to not take part in the study.
Costs	This is a participant-funded research study. You will be responsible for paying a fee ranging from $4,000 to $8,000 (i.e., for 2-4 scans) depending on the study site location and local scanning costs. There are payment options available to reduce the immediate financial burden of participation.
Confidentiality	**There are provisions in place by the study protocol and study site to help protect the privacy and confidentiality of your personal health information and study information.**

This overview does not include all of the information you need to know before deciding whether or not to take part. Additional detail is given in the full consent form, which can be found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.

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INFORMED CONSENT FORM

This consent form explains the research study. Before you decide to be a part of this study, you need to know why the research is being done, what it will involve and the risks and benefits. Ask the study doctor and study staff to explain anything in this form or if you want more information. Please take time to read this form carefully. Feel free to discuss it with your relatives, friends and your primary care physician. If you agree to take part in this research study, you must sign this consent form.

DISCLOSURE OF FINANCIAL INTERESTS

EyeThree, Inc., the sponsor of this study, is providing funds to the BioMedical Engineering and Imaging Institute at Icahn School of Medicine at Mount Sinai on a per participant basis for conducting the MRI scans for participants in this research study.

PURPOSE OF THE STUDY

This study helps us understand how individual brains naturally change and adapt over time. Everyone's brain works differently, and we want to learn more about these natural differences to provide you with personalized insights about your own brain function.

What We're Studying: We're looking at how your brain's activity patterns change over several months. Your brain has 16 major networks that handle different functions like attention, memory, problem-solving, and creativity. We want to evaluate techniques for measuring how these networks naturally change in healthy people like you in response to your strengths, where you have room for growth, and your optional self-reported activity.

How This Helps You: By understanding your unique brain patterns, we can provide you with educational insights about how your brain works. This information might help you better understand your cognitive strengths, areas with growth potential, and how your brain function changes over time.

What This Study Is: This research focuses on normal, healthy brain function and provides educational information for general wellness purposes only. We're not diagnosing, treating, or trying to cure any medical conditions. Think of it like getting insights about your fitness level or sleep patterns - it's information to help you better understand yourself.

The Science Behind It: We use advanced brain imaging (fMRI) to safely measure your brain activity while you rest comfortably in the scanner. This technology lets us see how different brain networks are working and create a personalized profile of your brain function.

ELIGIBILITY FOR THIS STUDY

You may be eligible if you:

- Are between 25-80 years old
- Are in generally good health (no untreated medical conditions)
- Can safely have MRI scans (no metal implants, not claustrophobic)
- Are interested in learning about your brain function for wellness purposes
- Are able to pay the study participation fee

You may not be eligible if you have any of the following:
Brain and Mental Health Conditions:

- Brain health conditions
- Suspected undiagnosed mental health conditions
- Newly diagnosed mental health condition (within the last year)
- Newly treated mental health condition (within the last year)
- History of schizophrenia, psychotic disorder, treatment-resistant depression, or bipolar type I disorder
- History of epilepsy
- History of neurodegenerative disease (such as Parkinson's disease or Alzheimer's disease)
- History of movement disorders (significant tremor, dystonia, dyskinesia)
- History of sleep disorders (such as narcolepsy)
- History of stroke
- History of brain cancer or metastatic disease affecting the brain
- History of brain surgery
- Diagnosis without treatment of bipolar type II disorder
- Diagnosis without treatment of Attention Deficit Hyperactivity Disorder (ADHD)

Current Medication and Substance Use:

- Current or regular use of benzodiazepines (anxiety medications such as Xanax, Valium, Ativan, Klonopin)
- Regular use of cannabis (marijuana)
- Use of illegal drugs

Physical Health Conditions:

- Cardiovascular disease or significant cardiovascular risk factors
- Neurological disorders, including history of traumatic brain injury

Pregnancy:

- Currently pregnant
- Planning to become pregnant during the study period (up to 24 months)

MRI Safety Exclusions:

- Claustrophobia or inability to tolerate MRI procedures
- Metallic implants or devices contraindicated for MRI (such as pacemakers, certain surgical clips, metal fragments)

Other Exclusions:

- Current participation in another research study involving neuroimaging

Important: By signing this consent form, you are formally attesting that you meet all eligibility requirements listed above and can safely undergo MRI scanning.

A separate MRI safety screening will be conducted prior to each scan to verify that you can safely receive the MRI scans as part of this study.

If you develop any excluded condition during the study, you must inform the study team immediately. You may need to withdraw from the study if you develop a condition that meets the exclusion criteria.

IMPORTANT: DEVICE CLASSIFICATION AND STUDY FOCUS

Software Classification: For research oversight purposes, the E3Profile platform is classified as Software as a Medical Device (SaMD) under a Non-Significant Risk determination. The MRI scanning procedures, whether performed on FDA-cleared 3T scanners or institutionally-cleared 7T scanners, also qualify as non-significant risk based on operating parameters that comply with FDA guidance. However, this classification is specific to the research context and regulatory framework.

This Study is NOT Medical Care: This study is designed exclusively for healthy volunteers seeking educational information about their brain function. Important distinctions:

What This Study IS:

- General wellness and performance insights about your brain function patterns
- Educational information for personal understanding and interest
- Brain performance optimization insights for everyday activities
- Scientific research to understand normal brain function variation, including change in neuroplasticity over time

What This Study is NOT:

- Medical diagnosis, treatment, or health assessment
- Clinical evaluation of brain health or disease
- Therapeutic intervention or medical care
- Substitute for professional healthcare services

Platform Purpose: The E3Profile platform provides educational brain function insights for general wellness and informational purposes only. These insights should not be used for medical decision-making. If you have any health concerns, consult with qualified healthcare providers.

Important Reminder: If you are seeking medical evaluation or treatment for any health concerns, this research study is not appropriate for you.

NUMBER OF PARTICIPANTS AND LENGTH OF STUDY PARTICIPATION

Up to 2,000 participants are expected to participate in this study at multiple research sites in the United States.

Your participation in this study is expected to last up to 24 months, with a minimum of two and up to four ME-fMRI scanning sessions spaced at least two months apart.

STUDY PROCEDURES

REMINDER: All procedures are for research and educational purposes only, NOT for medical diagnosis or treatment.

All participants will be asked to:

1. Complete an initial eligibility questionnaire and MRI safety screening.
2. Complete baseline assessments including:
   - Demographic questionnaire (age, biological sex, education)
   - MRI safety screening prior to each scan
3. Undergo a minimum of two and up to four ME-fMRI scanning sessions over a period of up to 24 months, with at least two months between sessions. Each scanning session will include:

   Scanner Information: You will be scanned on either an FDA-cleared 3T MRI scanner or an investigational 7T MRI research system. Which scanner you receive will be determined based on two factors:

   - **Scanner availability** at the imaging location serving you
   - **Discussion with you about claustrophobia concerns**

   The 7T scanner has a smaller opening (bore) than the 3T scanner. During your MRI safety screening before each scan, you will be asked about any concerns regarding claustrophobia or discomfort in enclosed spaces. If you indicate any concerns about claustrophobia, you will be assigned to a 3T scanner, which has a larger bore and is generally more comfortable for individuals with concerns about enclosed spaces. If you do not have claustrophobia concerns, you will be assigned to whichever scanner type is available at your imaging location.

   Both scanner types operate within non-significant risk parameters as defined by FDA guidance and provide equivalent safety profiles. The 7T scanner offers enhanced signal quality for more precise brain measurements, but both scanners produce scientifically valid and clinically equivalent results for this study.

   Scans Performed:
   - T1-weighted MPRAGE anatomical scan (1mm isotropic) (approximately 5 minutes)
   - Multi-echo fMRI scanning (approximately 10 minutes)
   - Other additional short scans for imaging adjustments

   Important: No contrast agents (dyes) will be administered during any of your scans. All imaging will be conducted without intravenous contrast.

4. Maintain a free-form activity journal between scanning sessions using the E3Profile platform. There is no mandatory usage requirement, but using this portal may provide you with more informative insights regarding your brain capabilities and performance. You will have access to a digital journal where you can record:
   - Cognitive activities (work, learning, problem-solving)
   - Physical activities (exercise, sports, movement practices)
   - Creative pursuits (arts, music, writing)
   - Social interactions (meaningful conversations, group activities)
   - Restorative practices (meditation, sleep quality, relaxation techniques)

- Unusual or notable experiences

5. Complete follow-up assessments after each scanning session including:
   - Experience questionnaire regarding the scanning process
   - Virtual results discussion meeting (30-60 minutes) with trained EyeThree personnel to review your brain function insights

INCIDENTAL FINDINGS

What You Should Know About the Brain Scans in This Study:

Research Scans vs. Medical Scans: The brain images we take are designed for research purposes to measure brain function patterns, not to detect medical conditions or diseases. These research scans are different from medical scans your doctor might order.

Limited Medical Information: Our research scans cannot detect or diagnose medical conditions. They are not intended for medical purposes and should not be used for health decisions.

If We Notice Something Unusual: During routine quality checks of your brain images, if imaging site staff notice any obvious abnormalities, they will:

- Contact you directly
- Recommend that you discuss the finding with your healthcare provider
- Provide you with information about how to obtain your scan images if you want to share them with your doctor

Important Limitations:

- We cannot provide medical interpretation of any findings
- We cannot diagnose medical conditions based on these research scans
- Any health concerns should be addressed through appropriate medical care, not this research study

Your Options: If you want copies of your brain imaging, you can request them directly from the scanning site after your scan.

Bottom Line: These research scans are for understanding brain function patterns, not for medical diagnosis. If you have health concerns about your brain, please consult with appropriate medical professionals.

PARTICIPANT RESPONSIBILITIES

As a participant in this study, you will have certain responsibilities, including the following:

- Attend all study visits and, if needed, reschedule appointments as soon as possible
- Follow the instructions of the study staff

- Tell the study staff any time you do not feel well during or after imaging or if you have any unpleasant experiences from the scanning process
- Complete the optional activity journal between scanning sessions
- Provide optional feedback on the E3Profile platform

RISKS AND DISCOMFORTS

The risks associated with this study are primarily related to the MRI scanning procedure:

- **Claustrophobia**: Some people may feel anxious or claustrophobic in the MRI scanner. If you experience claustrophobia, you can stop the scan at any time.
- **Noise**: MRI scanners produce loud noises during operation. You will be provided with ear protection to minimize discomfort.
- **Metallic objects**: You cannot bring metal objects into the scanning room as they may have attraction to the magnetic field of the MRI machine, and therefore could move or experience heating during the scan. You will be thoroughly screened for metallic objects before each scan.
- **Discomfort**: You may experience some discomfort from lying still for an extended period during the scan.
- **Confidentiality risks**: Several measures are taken to protect the confidentiality of your information and imaging data. If there is a compromise to your data or data confidentiality, you will be notified as soon as possible.

Scanner Platform: You may be scanned on either an FDA-cleared 3T MRI scanner or an investigational 7T MRI research system. Which scanner you receive depends on scanner availability at your imaging location and discussion with you about any claustrophobia concerns during your MRI safety screening. The 7T scanner has a smaller bore (opening) than the 3T scanner. If you have any concerns about claustrophobia or enclosed spaces, you will be assigned to a 3T scanner.

The word "investigational" for 7T scanners refers to the scanner not being FDA-cleared for clinical diagnostic use. However, both 3T and 7T scanners in this study operate within the same non-significant risk safety parameters as defined by FDA guidance. All safety protocols, including contraindication screening, hearing protection, and monitoring procedures, are equivalent across both platforms. The primary difference is that 7T provides enhanced signal quality for more precise brain function measurements.

NEW INFORMATION

You will be notified in a timely way if important new findings become known that may affect your willingness to continue in the study.

Clinically Relevant Research Results

As the results obtained during the research study are not for medical diagnosis or treatment, you will not receive individual clinical information.

BENEFITS

We cannot promise any benefit to you or others from your participation in this research.

Possible Personal Benefits (Educational and Informational Only):

You may receive educational insights about your brain function through the E3Profile platform, including:

- **Brain Function Patterns**: Visualization of how your 16 major brain networks show activity and connectivity patterns
- **Neuroplasticity Insights**: Educational information about your brain's potential for adaptation and change over time
- **Network Information**: Learning about which brain networks support different everyday activities and functions
- **Personal Tracking**: If you complete multiple scans, you can see how your brain function patterns (neuroplasticity) change over time
- **Brain Age Information**: Educational comparison of your brain activity patterns to population averages
- **Growth Areas**: Information about brain networks that show potential for development or optimization
- **Expert Guidance**: Personal consultation with trained EyeThree personnel to help you understand and interpret your brain function patterns

Important Reminders About These Benefits:

- All insights are for **educational and wellness purposes only**
- These are **NOT medical assessments** or health evaluations
- Results should **NOT be used for medical decision-making**
- Information is for **personal interest and understanding only**
- You will **own and retain access** to your insights permanently through the secure platform

Benefits to Science and Society:
Your participation may help advance scientific understanding by:

- Establishing foundational data on normal brain function variation in healthy adults
- Contributing to research that may inform future brain wellness and performance approaches
- Supporting development of personalized approaches to improving brain function
- Helping validate methods for measuring individual differences in brain function

No Guaranteed Benefits: There is no guarantee that you will find the brain function insights useful or meaningful for your personal goals. The value of these educational insights will depend on your individual interests and how you choose to use the information.

ALTERNATIVES TO STUDY PARTICIPATION

Your alternative is to not take part in the study

COSTS OF PARTICIPATION

This is a participant-funded research study designed to evaluate brain wellness services while establishing foundational scientific data.

Why You Pay for Participation:

Direct Personal Benefit: Unlike traditional research studies where participants test experimental treatments with uncertain outcomes, you receive personalized brain function insights immediately. You own these insights and retain access to them permanently through the E3Profile platform.

Service Validation: This study validates whether brain wellness services can be delivered sustainably to broader populations in the future. Your participation helps determine if these services can be made more widely accessible.

Research Independence: Participant funding ensures that research findings reflect true brain function patterns without influence from external sponsors who might bias study design or results interpretation.

Cost Recovery Only: EyeThree's fee is strictly designed to recover the direct costs of providing brain function insights to you. There is no profit margin built into the study fees.

Study Fees: You will pay a fee ranging from $4,000 to $8,000 depending on:

- Study site location and local MRI scanning costs
- Number of scanning sessions you complete (minimum 2, maximum 4)

Your Fee Covers:

- MRI scanner time and technical support at current market rates
- Advanced multi-echo fMRI data processing and analysis
- Maintenance of secure E3Profile platform access
- Virtual consultations with trained EyeThree personnel to discuss your results
- Quality control and data security measures

Payment Options:

- Full payment upfront, OR
- Installment plans (pay per scanning session before each scan)
- Extended payment window (up to 30 days) between enrollment and first scan

Important: This fee structure enables the study to operate independently while providing you with valuable brain function insights that you will own and can access indefinitely.

REIMBURSEMENT

There will be no reimbursement for this study.

COMPENSATION FOR INJURY

For medical emergencies, call 911. If you become ill or are hurt while you are in this study, contact your imaging site personnel immediately. Neither EyeThree nor Mt. Sinai will be responsible for the costs of treatment caused by the properly performed study procedures.

No other compensation will be offered by the sponsor or Mt. Sinai or Biomedical Research Alliance of New York, including for things such as lost wages or discomfort. You are not waiving any legal right to seek additional compensation through the courts by signing this form.

PARTICIPANT ELIGIBILITY CONFIRMATION AND ATTESTATION

By signing this consent form, I confirm, attest, and declare that:

Study Understanding:

☐ I am NOT seeking medical diagnosis or treatment through this study

☐ I understand this study provides educational information only, not medical care

☐ I have realistic expectations that this study is for wellness and personal interest, not health assessment

☐ I will consult healthcare providers for any medical concerns, not rely on study insights

☐ I am participating to learn about my brain function for educational and wellness purposes only

Eligibility Attestation:

☐ I am between 25 and 80 years old

☐ I do NOT have any of the brain health, mental health, or neurological conditions listed in the exclusion criteria above, including but not limited to: schizophrenia, psychotic disorder, treatment-resistant depression, bipolar type I disorder, epilepsy, neurodegenerative disease, movement disorders, sleep disorders (such as narcolepsy), stroke, brain cancer, brain surgery, or untreated bipolar type II or ADHD

☐ I do NOT currently use or regularly use benzodiazepines, cannabis, or illegal drugs

☐ I do NOT have cardiovascular disease, significant cardiovascular risk factors, or other neurological disorders including traumatic brain injury

☐ I am NOT currently pregnant and do NOT plan to become pregnant during my participation in this study (up to 24 months)

☐ I do NOT have claustrophobia or any metallic implants or devices that would prevent me from safely undergoing MRI scanning

☐ I am NOT currently participating in another neuroimaging research study

☐ I understand that I may be scanned on either FDA-cleared 3T MRI equipment or institutionally-cleared 7T MRI scanner, and that both operate within non-significant risk parameters

Ongoing Obligations:

☐ I understand that if I develop any excluded condition during the study, I must inform the study team immediately and may need to withdraw from the study

☐ I confirm that all information I have provided regarding my eligibility is true and accurate to the best of my knowledge

☐ I understand that providing false information about my eligibility could result in my withdrawal from the study and may pose risks to my safety during MRI scanning

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate, or you may stop your participation at any time, without penalty or loss of benefits or medical care that you would otherwise receive. If you decide to leave the study, please contact the Principal Investigator using the contact information at the top of this form.

Your participation in this study may be stopped without your consent at any time and for any reason by study personnel, the sponsor, or the FDA and other regulatory authorities. Reasons you may be withdrawn from the study include determination that you may represent a harm to yourself or others in connection to the procedures of the study or feedback from EyeThree, you need treatment not allowed in this study, you do not follow the study instructions, the study is stopped, or for other administrative reasons.

CONFIDENTIALITY

To the extent allowed by law, every effort will be made to keep your personal information confidential. The consent form signed by you along with other documents and information that you provide will be stored and analyzed by Eyethree or its authorized representatives. As part of oversight for this study, your data may be inspected by authorized members of Institutional Review Boards, and the Biomedical Research Alliance of New York, to ensure adherence to ethical and safety guidelines. In such processes, while these parties are aware of the need to keep your information confidential, total confidentiality cannot be guaranteed. The results of this research project may be presented at meetings or in publications; however, you will not be identified in these presentations and/or publications.

If you take part in this study, you will be assigned a unique participant code to help protect your privacy. Your study records will be labeled with this code that does not directly identify you. The study site staff securely stores the linking code between your name and study information.

The E3Profile platform provides HIPAA-compliant data storage and transmission with secure user authentication and data encryption at rest and in transit. EyeThree will store your name and email address on EyeThree's servers or data systems, which will be stored separately from your brain function metrics. You will have access to your own data through the secure E3Profile platform using OAuth Identity Provider APIs, from whence no identifying information will be collected by EyeThree.

<u>AUTHORIZATION TO USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION</u>
Medical health information here includes medical records, phone calls with physicians, diagnostic imaging, treatment records, etc. The imaging data acquired in this study, whether from FDA-cleared 3T scanners or institutionally-cleared 7T scanners, are not being used to develop any diagnostic capability or therapeutic application. All scanning protocols operate within non-significant risk parameters regardless of scanner platform. This study is not a clinical trial, as defined by the Food & Drug Administration. We will not acquire any information related to HIV diagnosis or treatment. Any interactions you have with the imaging site regarding matters of personal health information and confidentiality will be governed by the policies and procedures specific to that imaging site. The imaging data that is stored on EyeThree’s systems are anonymized and cannot be de-anonymized without information from the imaging site where the data was acquired. Identifying data is managed and removed according to the policies and procedures put into place between EyeThree and the imaging site. Any subsequent re-identification of your imaging data and your identifying information will require your explicit consent. All further interaction with your data through the E3Profile platform will be based on a

username that you can define according to your preferences. Otherwise, you will have ongoing access to your E3Profile data based on an anonymized key that is managed by a third-party identity provider that you have an existing account with (Gmail, Apple, etc.), which is a standard practice for cloud-based commercial services.

PERSONAL HEALTH INFORMATION COLLECTED IN THIS STUDY

This study collects only limited personal information necessary for participation and platform access.

Information We Collect:

- **Email address** - for secure access to the E3Profile platform and study-related communications
- **Basic demographics** – name, month and year of birth, biological sex, and education level only
- **MRI safety information** - standard safety screening responses required for all MRI procedures
- **Activity log entries** - voluntary journal entries you choose to record about your daily activities

Information We Do NOT Collect:

- Your home address, or phone number
- Medical records, health history, or treatment information
- Laboratory test results or diagnostic information
- Insurance information or billing records
- Information from your doctors or healthcare providers

How We Protect Your Information:

- Email addresses are stored in encrypted, HIPAA-compliant systems separate from your brain imaging data
- Your brain scans are processed using anonymous study codes, not your email or name
- Only authorized study personnel can access personal information
- All data transmission uses secure, encrypted connections
- You control what information you share in your voluntary activity logs

Important: While we collect your email address, your actual brain imaging data and research insights are processed using anonymous identifiers to maximize your privacy protection.

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your authorization (permission) to use or give out any health information that might identify you. If you choose to be in this study, the study doctor will get personal information about you. This may include information that might identify you. The study doctor may also get information about your health, including:

- Past and present medical records
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about laboratory test results
- Results from diagnostic and medical procedures including but not limited to X-rays,

physical examinations and medical history
- Billing records

Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study. Your information may be given to the sponsor of this research. “Sponsor” includes any persons or companies that are working for or with the sponsor or are owned by the sponsor. Information about you and your health which might identify you may be given to:

- The U.S. Food and Drug Administration
- Department of Health and Human Services agencies
- Governmental agencies in other countries
- Biomedical Research Alliance of New York (BRANY)
- The Institutional Review Board
- Accrediting agencies
- Data safety monitoring boards
- Health insurers and payers
- Other individuals and organizations that analyze or use your information in connection with these research activities, including laboratories, contract research organization and study sites (if you transfer to another study site)

Your personal health information may be further shared by the groups listed above. If shared by them, the information will no longer be covered by the U.S. federal privacy laws. However, these groups are committed to keeping your personal health information confidential. If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. There is a risk that your information will be released to others without your permission.

Information about you and your health that might identify you may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will review your information for this purpose. The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

This authorization does not have an expiration date. If you do not withdraw this authorization in writing, it will remain in effect indefinitely.

By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. You do not have to sign this consent form. If you choose not to sign this consent form, you will not be able to be in this research study. Your decision not to sign this consent form will not have any effect on your medical care, and you will not lose any benefits or legal rights to which you are entitled. You have the right to review, correct and copy your health information. However, if you decide to be in this study and sign this permission form, you may not be allowed to look at or copy your information until after the research is completed.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor at the address on the front of this informed consent form. If you withdraw your permission, you will not be able to continue

being in this study, but you will not have any penalty or loss of access to treatment or other benefits to which you are entitled. When you withdraw your permission, no new health information which might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Notice Concerning HIV-Related Information: HIV-related information that either is collected as part of the research or that may already exist in your medical record might be accessed for the research by the research staff and the study sponsor, but will not be shared with others without your authorization, unless federal or state law requires the disclosure. You have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the agencies that are responsible for protecting your rights.

Collection of Identifiable Private Information or Identifiable Biospecimens:

Your information and biospecimens collected as part of this research study, even if identifiers are removed, will not be used or distributed for future research studies.

CONTACTS FOR QUESTIONS, COMPLAINTS, CONCERNS

If you have any questions or requests for information relating to this research study or your participation in it, or if you want to voice a complaint or concern about this research, or if you have a study related injury, you may contact Dr. Prantik Kundu at (646) 220-5755.

If you have any questions about your rights as a research participant or complaints regarding this research study, or you are unable to reach the research staff, you may contact a person independent of the research team at the Biomedical Research Alliance of New York Institutional Review Board at 516-318-6877. Questions, concerns or complaints about research can also be registered with the Biomedical Research Alliance of New York Institutional Review Board at www.branyirb.com/concerns-about-research. The IRB is a committee that reviews research studies to help protect the rights and welfare of study participants.

STATEMENT OF CONSENT - SIGNATURES

By signing this form, I confirm the following:

- I have read all of this consent form.
- All of my questions have been answered to my satisfaction.
- I can leave the study at any time without giving a reason and without penalty.
- I agree to the collection, use, sharing and analysis of my imaging data, study information, collected as part of this study by the sponsor and other authorized persons as described in this form.
- I will be given a copy of this signed and dated consent form to keep.
- I do not give up any legal rights that I would otherwise have if I were not in this study.

I voluntarily agree to participate in this study.

Participant: Name (Print)	Signature	Date

BIOMEDICAL RESEARCH ALLIANCE OF NEW YORK LLC

Participant Date of Birth: _____

I have explained this research study to the study participant named above, answered all their questions to the best of my ability, believe they understand what has been explained and have consented voluntarily.

_____

Person Obtaining Consent: Name (Print) Signature Date