Center for Molecular & Behavioral Neuroscience
University Heights • 197 University Avenue • Newark • New Jersey 07102
Fax (973) 353-1760 • Telephone (973) 353-3184

# CONSENT TO TAKE PART IN A RESEARCH STUDY

**Title of Study: "Exercise to Improve Brain Health in Older African Americans"**

**Principal Investigator: Mark A. Gluck, Ph.D., ClinicalTrials.gov: NCT05597124**

**STUDY SUMMARY:** You have been asked to participate in a research study under the direction of Mark A. Gluck, Ph.D., Professor of Neuroscience and Public Health at the Center for Molecular and Behavioral Neuroscience, Rutgers University–Newark. Other persons who work with him as research study staff may assist. All research projects carried out in this lab are covered by the rules of both the Federal Government and Rutgers University.

The **purpose of the research** is to study changes over time in thinking skills, memory, and brain health following exercise interventions in African Americans.

**Possible harms or burdens** of taking part in the study may be the same as what you face every day and possible benefits of taking part may be improved physical and brain health.

Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

## Who is conducting this study?

Professor Mark A. Gluck, Ph.D. is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are other individuals who are part of the research team.

Professor Mark A. Gluck, Ph.D. may be reached at:
Rutgers University–Newark
Center for Molecular and Behavioral Neuroscience
197 University Avenue (Suite 209)
Newark, NJ 07102
Tel.: (973) 353-3298

The principal investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed Consent Form to keep.

**Sponsor of the Study**: National Institutes of Health-National Institute on Aging

**Why is this study being done?**
This study is being conducted to help us understand whether different types of exercise programs can improve thinking, memory skills, and brain health in older African Americans.

**Who may take part in this study and who may not?**
**INCLUSION CRITERIA:**

You *may* qualify to participate in this research study if you:

- identify as either African American or Black.
- are age 60 or older.
- are able to speak, read, and understand English.
- available over the study period.
- able to exercise without the assistance of walker or cane or other aid for one hour.
- are not physically exercising >60 minutes a week
- have clearance to participate from your primary care physician, with oversight of all participant health under the study physician.
- are willing to travel to a non-Rutgers site in the Newark area for exercise classes 3 times a week for 24 weeks (approximately 6 months).

**EXCLUSIONS:**

You will inform the researcher if you:

- are color-blind.
- have a diagnosis of any neurological disorders (including headaches and peripheral neuropathy).
- have a diagnosis of any non-neurological conditions such as, major depressive disorder, schizophrenia, delusional disorder, schizoaffective disorder or significant psychiatric symptoms that could impair the completion of the study (e.g., psychosis).
- have a diagnosis of a learning disability such as dyslexia or ADHD.
- are currently undergoing chemotherapy or radiation treatment for cancers.
- are planning to undergo general anesthesia.
- have any conditions that may be dangerous for exercise participation, such as a cardiac condition in the past year, current treatment for congestive heart failure, chest pain, irregular heartbeat, or another cardiovascular event (e.g., a heart attack), and uncontrolled high blood pressure with resting systolic or diastolic blood pressures > 180/110 mmHg.
- **Have any magnetic metal such as iron, nickel or cobalt implanted in or on your body or clothes including metal flakes or filings, surgical pins or plates, electrical devices such as a pacemaker, jewelry, or metal ink facial/ neck tattoos** *(optional MRI procedure).*
- **Are fearful in small, tight spaces, a.k.a., claustrophobia** *(optional MRI procedure).*
- **Decline participation in blood work/draw procedures.**
- **Are underweight and are unable to participate in blood work/draw procedures.**
- Have diabetes and are on insulin, sulfonylureas, or have poor uncontrolled Hemoglobin A1c levels (>8.5%).
- Unwilling to be randomized to either intervention group.
- Do not live in the Greater Newark area.
- Self-reported fall history—more than once in the past 6 months.
- Planned travel for 7+ consecutive days of travel after enrollment.

**Why have I been asked to take part in this study?**
You are a healthy African American, over the age of 60.

**How long will the study take and how many subjects will take part?**
You will be one of about 300 individuals who will participate in this study.

The overall study will last about five years.

Your individual participation will take about six months including two baseline visits, a six-month exercise program, and two post-intervention testing visits.

**What will I be asked to do if I take part in this study?**

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| YES___ NO ___ | You will be asked to answer general information questions, fill out questionnaires, reproduce or identify simple drawings or photographs, and remember words, stories or pictures. |
| YES___ NO ___ | You will sit in front of a computer and make observations, judgments and keyboard responses as instructed by on-screen directions or verbal directions from the experimenter. |
| YES___ NO ___ | You will be asked to give a sample of your genetic material for analysis. This will be done by taking a sample of your saliva by spitting into a small vial designed for saliva collection. The saliva collection will take place at the Rutgers NJ Medical School, Clinical Research Unit, Doctors Office Center, located at 90 Bergen Street (Suite 1200), Newark, NJ 07103. The researchers will then test your genetic material to look for naturally occurring variations in several genes. (If you would like to see a list of the names of the specific genes being tested, you may request the list from the experimenter.) Naturally occurring variations in these genes may contribute to different learning and memory abilities in people. We are also interested in investigating whether these gene variations can be implicated in the development of Alzheimer's disease. |
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| YES___ NO ___ | You will provide a sample of blood which will be analyzed to test for new experimental markers which may reflect the changes in the brain that occur in people with very early stages of Alzheimer's disease. The blood draw will be scheduled at the Rutgers NJ Medical School, Clinical Research Unit, Doctors Office Center, located at 90 Bergen Street (Suite 1200), Newark, NJ 07103. |
| YES___ NO ___ | You will be asked to have your height, weight, body mass index (a measure of obesity), heart rate and blood pressure measured, and you will be given a short physical performance test. |
| YES___ NO ___ | You will be invited to participate in an optional MRI (Structural and Functional Magnetic Resonance Imaging) study. The procedure will involve lying on your back for approximately one hour inside an MRI chamber that is open on either end, with a projector screen on the opposite end. You will be required to keep still and avoid moving for this one-hour period during which time an image of your brain will be recorded. You will be given earplugs to block out the noise of the machine while it is operating, during the imaging process. You will hear background noise and feel some vibrations of the machine during this process. During scanning, you will have open verbal communication with the experimenter outside the scanner through an intercom system. |

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| YES___ NO ___ | You will be asked to wear three monitoring devices that track your physical activity and/or sleep over the course of the study. The first device (an Actigraphy bracelet) is an electronic monitoring device that tracks activity and sleep and should be worn at all times throughout the day. The second device (Sleep Profiler™) is a headband that will monitor your sleep in more detail. These two devices will be used for the duration of 1 week after the first study visit, repeated at 6-month post-assessment. The third device (Fitbit Versa) is a smart watch designed to measure heart rate and should be worn during the 60-min exercise classes. |
| YES___ NO ___ | You will be asked to participate in an exercise program three times a week for 24 weeks (approximately 6 months). The exercise program will be completed in groups of 15-20 persons and led by a certified fitness instructor. The instructor will provide all necessary exercise equipment as part of this program. During this program, you may find some exercises easy and some to be challenging. We ask that you do the best you can. |

**Duration of your participation:**

Baseline Testing

- Your participation in the *baseline testing* portion of this study will last for 2 sessions.
    - At the first baseline study visit, you will provide a genetic and blood sample and then complete tests of your vision, thinking skills, and physical function. You will also complete questionnaires about your mood, health, and everyday activities. This first visit will last approximately 2 to 2.5 hours.
    - At the second baseline study visit, you will participate in the optional MRI procedure for a brain scan (approximately 1 hour).

Exercise

- After completing the two baseline visits, if you are eligible, you will be asked to complete an exercise program three times a week for 24 weeks (approximately 6 months). Each session will be about 60 minutes in duration. At each session, you will have 5 minutes of warm up, 50 minutes of exercise (with a short break halfway), and 5 minutes of cool down. (If you would like to take other breaks, you can notify the instructor.)

Post-Testing

- After completing the exercise program, we will ask you attend **two post-testing sessions**; each session will last approximately 2 hours.
    - At the first post-testing session, you will provide a blood sample and repeat tests of your thinking skills and physical function from your baseline visits. You will also repeat questionnaires about your mood, health, and everyday activities (approximately 2 to 2.5 hours).
    - At the second post-testing session, you will participate in the optional MRI procedure for a brain scan (approximately 1 hour)

Alumni Exercise Classes

- After you complete your 6-month participation in the study, you will be invited to attend free exercise classes.

**What are the risks of harm or discomforts I might experience if I take part in this study?**

This research is considered to be minimal risk. That means that the risks associated with this study are the same as what you face every day.

For participants who will be providing a **saliva sample** for genetic analysis, please be informed of the following:

- Psychological or Social Risks Associated with Loss of Privacy:
  Although your genetic information is unique to you, you do share some genetic information with your children, parents, brothers, sisters, and other blood

relatives. Consequently, it may be possible that genetic information from them could be used to identify you. Similarly, it may be possible that genetic information from you could be used to help identify them. Further, patterns of genetic variation also can be used by agencies to identify a person or their blood relatives (for example, to establish relationships between parents and their children).

- Economic Risks of Harm: Since some genetic variations can help to predict the future health problems of you and your relatives, this information might be of interest to health providers, life insurance companies, and others. Therefore, your genetic information potentially could be used in ways that could cause you or your family economic distress.

There is a federal law call the Genetic Information Nondiscrimination Act (GINA) that helps protect against genetic discrimination. In general, this law makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways: (1) health insurance companies and group health plans may not request your genetic information that we get from this research; (2) health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums; and (3) employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

For participants undergoing optional **MRI scanning**, the following risks and/or discomforts are possible:

- Feelings of being fearful in small, tight spaces can occur in the scanner. If you experience these fears, please alert the researcher and you will be removed from the scanner immediately.

- There is considerable background noise and vibrations generated by the magnet which are harmless. You will be given earplugs to reduce the noise, but you should alert the researcher if you find the noise too uncomfortable and you will be removed from the scanner immediately.

For participants undergoing **Blood work** procedures, the following risks and/or discomforts are possible:

- Removal of blood by a needle and syringe may cause temporary discomfort or bruising at the site of the needle stick and may pose a small risk of infection. Some people may experience fainting or dizziness. To minimize these risks, experienced medical personnel will handle all the blood drawing procedures and sterile conditions will be maintained. In total, approximately 3 tablespoons of blood may be drawn which your body will replenish.

**Are there any benefits to me if I choose to take part in this study?**
The study results will benefit the theoretical understanding of how exercise may contribute to healthy aging among African Americans. You will be encouraged to engage in healthier lifestyle behaviors and will receive a pamphlet describing how to improve brain health including information regarding risk factors associated with Alzheimer's disease, as well as a guide to local brain health resources. You will also be provided with a summary of your current health information for your own use, including height, weight, BMI and blood pressure. However, it is possible that you may not receive any direct benefit from taking part in this study.

**What are my alternatives if I do not want to take part in this study?**
There are no alternative treatments available. Your alternative is not to take part in this study.

**How will I know if new information is learned that may affect whether I am willing to stay in the study?**
During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

**Will I receive the results of the research?**
If a report of this study is published, or the results are presented at a professional conference, only group results will be stated. Neither you nor any other participant will be identified by name. If your data are used in a published paper, and if you would like to receive a copy of this paper, you may inform the experimenter. You understand that it may take several years before any data appear in a published form.

You will **not** be informed of any research results obtained from analysis of your individual genetic analyses or blood work.

**Will there be any cost to me to take Part in this study?**

No.

**Will I be paid to take part in this study?**
You have been informed that you will receive the following as cash compensation:

Baseline Testing

___ $50.00 upon completion of the baseline cognitive testing portion of the study.

___ $50.00 upon completion of the saliva and blood draw.

___ $100.00 upon completion of the MRI portion of the study (optional).

___ $50.00 upon completion of the Physical Activity Tracking.

___ $50.00 upon completion of the sleep portion of the study (optional).

Exercise

___ $100 if you complete 80% or more of exercise classes.

Post-Testing

___ $50.00 upon completion of the cognitive testing portion of the study.

___ $50.00 upon completion of the blood draw.

___ $100.00 upon completion of the MRI portion of the study (optional).

___ $50.00 upon completion of the Physical Activity Tracking.

___ $50.00 upon completion of the sleep portion of the study (optional).

You will also be offered up to $20.00 per testing visit as a reimbursement if you have used public transportation to come to the testing site. Further, free parking will be provided at the testing and exercise program site.

**How will information about me be kept private or confidential?**
All efforts will be made to keep your personal information and your research record confidential, but total confidentiality cannot be guaranteed. No one but senior researchers will have access to any information that identifies you personally. All your data will be de-identified using a code to replace your name. This information will be

kept in a locked cabinet, in a locked room, in a locked office suite. The research team, that National Institutes of Health (study sponsor), and the Institutional Review Board at Rutgers University are the only parties that will be allowed to see the data, except as may be required by law.

If a report of this study is published, or the results are presented at a professional conference, only group results will be stated. Neither you nor any other participant will be identified by name. If your data are used in a published paper, and if you would like to receive a copy of this paper, you may inform the experimenter. You understand that it may take several years before any data appear in a published form.

You will **not** be informed of any research results obtained from analysis of your individual genetic material.

The research team may use or share your information collected or created for this study with the following people and institutions:

- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- The National Institutes of Health, the study sponsor

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

**Certificate of Confidentiality:** This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require, such as laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example,

you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

**What will happen to my information—data, recordings and/or images—and biospecimens collected for this research after the study is over?**
All genetic material derived from any saliva samples provided by a participant will be stored to be used for future additional analysis. All genetic data will be used in a completely anonymous fashion by our research team and collaborators and never linked back to, or associated with, an individual's name or identity.

In addition, blood samples will be stored to be used for future additional analyses of Alzheimer's disease risk and pathology, including those that may not yet be discovered at of the time of blood draw.

**What will happen if I am injured during this study?**
This study is deemed to be of minimal risk to participants. The risks associated with participation in the exercise intervention include minor physical discomfort such as fatigue and muscle soreness. If you experience shortness of breath, you may be referred to a cardiologist for follow-up. Similarly, if you fall, you may be referred to a physical therapist for a basic gait/balance exam to make sure you are stable/safe to continue the exercise program.

In addition, it is possible that during the course of this study, new adverse effects of exercise may occur that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University. However, by signing this form, you are not giving up any legal rights to seek further compensation.

**What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?**
It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

If you decide to withdraw from the study at any point, you will be compensated for your participation on a pro-rated basis.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to:

Professor Mark Gluck, Ph.D., Center for Molecular and Behavioral Neuroscience, Rutgers University–Newark, 197 University Avenue (Suite 209), Newark, NJ 07102 Tel.: (973) 353-3298

However, any data collected from saliva samples already sent for processing/analysis cannot be withdrawn because there may not be any identifiers with the data.

**Who can I contact if I have questions?**
If you have questions, concerns or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the Principal Investigator:

Professor Mark Gluck, Ph.D., Center for Molecular and Behavioral Neuroscience, Rutgers University–Newark, 197 University Avenue (Suite 209), Newark, NJ 07102 Tel.: (973) 353-3298

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB or the Rutgers Human Subjects Protection Program via phone at (973) 972-3608 or (732) 235-2866 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

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**Who May Use, Share or Receive My Information?**
The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University Investigators involved in the study.
- The Rutgers University Institutional Review Board and Compliance Boards.
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services.
- The National Institutes of Health, the study sponsor
- Yanille Traveras, Research Program Manager; on-site contact for the Clinical Research Unit at Rutgers NJMS.
- Maria Laura Gennaro, M.D., M.Sc., Professor, Dept. of Medicine – Division of Infectious Diseases, NJ Medical School (Co-Investigator).

- Patricia Fitzgerald-Bocarsly, Dept. of Pathology & Laboratory Medicine, Rutgers NJMS (Co-Investigator); preparation of blood samples for shipment to Sweden for analysis.
- Sukhwinder Singh, PhD, Assistant Professor, Dept. of Pathology & Laboratory Medicine, Rutgers NJMS; preparation of blood samples for shipment to Sweden for analysis.
- Henrik Zetterberg, MD, PhD and Kaj Blennow, MD, PhD, Professors at the Clinical Neurochemistry Lab, Institute of Neuroscience and Physiology, Mölndal Hospital, Mölndal, Sweden who will analyze de-identified blood samples. Non-Rutgers Co-Investigators on the Study Team.

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

**Will I Be Able To Review My Research Record While The Research Is Ongoing?**
No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

**Do I Have To Give My Permission?**
No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

**If I Say Yes Now, Can I Change My Mind And Take Away My Permission Later?**
Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell them of your decision:

Professor Mark Gluck, Ph.D.,
Center for Molecular and Behavioral Neuroscience,
Rutgers University–Newark
197 University Avenue (Suite 209)
Newark, NJ 07102
Tel.: (973) 353-3298

**How Long Will My Permission Last?**

There is no set date when your permission will end. Your health information may be studied for many years.

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## AGREEMENT TO TAKE PART IN RESEARCH

**Subject Consent:**

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print):_____

Subject Signature:_____ Date:_____

**Signature of Investigator/Individual Obtaining Consent:**

To the best of my ability, I have explained and discussed all the important details about the study including all of the information contained in this consent form.

Investigator/Person Obtaining Consent (Print):_____

Signature:_____ Date: _____

Center for Molecular & Behavioral Neuroscience
University Heights • 197 University Avenue • Newark • New Jersey 07102
Fax (973) 353-1272 • Telephone (973) 353-3668

## ADDENDUM: CONSENT TO AUDIO-/VISUALLY RECORD OR PHOTOGRAPH SUBJECTS

You have already agreed to take part in a research study entitled: Exercise to Improve Brain Health in Older African Americans conducted by Dr. Mark Gluck. We are asking your consent to allow us to:

Photograph you and/or your property for the purposes of inclusion on recruitment materials as well as community wellness event presentations. Images taken of you will be used for recruitment flyers, instructional videos specifically regarding the MRI study and the Gluck Lab website: www.brainhealth.rutgers.edu.

You do not have to consent to be photographed or recorded in order to take part in the main research.

Any recordings and/or photographs taken of you during this research study will have no commercial value. Audio recordings and photographic records will be kept on a password-protected computer in the Gluck Lab at CMBN, Rutgers University–Newark.

After information that could identify you has been removed, de-identified recordings and/or photographs as described above may be used by the Gluck Lab research staff for future **recruitment and instructional material**s or distributed to investigators for other research without obtaining additional informed consent from you.

Your signature on this form permits the investigator named above to photograph or record you as described above during participation in the above-referenced study. The investigator will not use any materials for any other reason than that/those stated in the consent form without your written consent.

You do not have to consent to be specifically photographed or video recorded in order to take part in the main research.

**AGREEMENT TO BE RECORDED**

Subject Name (Print):_____

Subject Signature _____ Date _____

Investigator/Person Obtaining Consent Name (Printed):_____

Signature _____ Date _____