Study Title: Mechanistic Assessment of N-Acetylcysteine as an Antioxidant Therapy for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS)

NCT#: NCT04542161

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APPROVED
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Weill Cornell Medical College

Informed Consent and HIPAA Authorization for Research

Project Title:	**Mechanistic Assessment of N-Acetylcysteine as an Antioxidant Therapy for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) Through Dose Response and Treatment Target Engagement**
Research Project/Protocol #:	**20-01021280**
Principal Investigator:	**Dikoma C. Shungu, Ph.D.**
Subject Name or number:	
MRN	

Please note, are you currently or have been (within the last 6 months) a participant in any other research study at Weill Cornell Medicine, New York Presbyterian Hospital or elsewhere? If so, please inform the research team.

INSTITUTION: **Weill Cornell Medical College**

STUDY SPONSOR/FUNDING AGENCY: Weill Cornell Medical College/ National Institute of Health

KEY INFORMATION ABOUT THIS RESEARCH STUDY	
We are asking you to choose whether to volunteer for a research study about N-acetylcysteine (NAC) dietary supplements' effect on glutathione (GSH) deficits in people with Myalgic Encephalomyelitis/ Chronic Fatigue Syndrome (ME/CFS). This page is designed to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.	
Purpose: **What is the study about and how long will it last?**	By doing this study, we hope to learn whether N-acetylcysteine (NAC) dietary supplements have an effect on glutathione (GSH) deficits in people with ME/CFS. By testing subjects before they take the drug, and again afterwards, we hope to find out the effect NAC supplements have on GSH levels in people with ME/CFS. This research is being done because currently, there is no effective treatment for this type of condition. Determining the effect of NAC supplement on GSH levels could help establish whether NAC supplementation has the potential to be used as a treatment for ME/CFS, as well as identify the optimal NAC dose. NAC is an

	unregulated dietary supplement. It is considered investigational and has not been approved by the U.S. Food and Drug administration (FDA). Your participation in this research will last about **up to five weeks**.
Benefits: **Key reasons you might choose to volunteer**	The study will not include a direct benefit to you. However, some participants appreciate knowing they have contributed to research that may benefit others in the future. For a complete description of benefits, refer to the Consent Document below.
Risks: Key reasons you might choose NOT to volunteer	NAC is an unregulated dietary supplement. It is considered investigational; it has not been approved by the U.S. Food and Drug administration (FDA). The most common side effects of NAC are GI disturbances, altered or metallic taste and skin rash, all of which will be thoroughly documented and monitored. For a complete description of risks and side effects related to the study drug- NAC, please refer to the Consent Document below. Other risks and side effects related to the study's procedures, which include study assessments/questionnaires, blood sampling, brain MRI/MRS, and the optional genetic testing, are described in detail in the Consent Document below.
Voluntary Participation: **Do you have to take part in the study?**	If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights or access to care you would normally have if you chose not to volunteer.
What if you have questions, suggestions, or concerns?	The person in charge of the study is **Dr. Dikoma C. Shungu**, the study Principal Investigator. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is**:** Dr. Dikoma C. Shungu at 646-265-0172 or the 24-hour for Department of Radiology: 212-746-2630. If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact staff in the Weill Cornell Medicine Institutional Review Board (IRB) between the business hours of 9am and 5pm EST, Monday-Friday at 646-962-8200 or send an e-mail to irb@med.cornell.edu.
This overview does not include all the information you need to know before deciding whether to take part in the study. Much additional detail is given in the full consent document, which can be	

found on the pages that follow. Be sure to review the rest of this consent form before deciding about participation.

INTRODUCTION

You are invited to participate in a research study. You were selected as a possible participant in this study because you are between the ages of 21-60 years old, and have a diagnosis of myalgic encephalomyelitis/ chronic fatigue syndrome (ME/CFS). Please take your time to make your decision. It is important that you read and understand several general principles that apply to all who take part in our studies:

(a) Taking part in the study is entirely voluntary.

(b) If you choose not to participate in the study or if your decision changes, your regular care will not be affected. In addition, you will not lose any of the benefits to which you are entitled.

(c) Personal benefit to you may or may not result from taking part in the study, but knowledge gained from your participation may benefit others.

(d) Genetic material contains information about many different traits, like a personal diary. The traits being tested are heritable, which means that they may be passed on from generation to generation within families. Because genetic testing can have consequences for you as well as your family members, please read this consent form carefully before making a decision about whether or not to participate.

The purpose and nature of the study, possible benefits, risks, and discomforts, other options, your rights as a participant, and other important information about the study are discussed below. Any new information discovered which might affect your decision to participate or remain in the study will be provided to you while you are a participant in this study. You are urged to ask any questions you have about this study with members of the research team. Please take whatever time you need to discuss the study with your physician and family/loved ones/friends. The decision to participate or not to participate is yours. If you decide to participate, please sign and date where indicated at the end of this form. Participation in the genetic analysis component of the study is optional, which means that you can participate in the drug treatment study even if you opt out of the genetic study. If you decide to participate in the genetic analysis component, please check the box below the signature line at the end of this form.

The research study is being funded by National Institute of Health (NIH). The NIH is providing a research grant for this study. Dikoma C. Shungu, Ph.D. is the primary investigator. If you choose to participate in the genetic analysis component, an additional blood sample will be collected which will also be analyzed by collaborators at Cornell University in Ithaca, NY.

The study will take place at the Citigroup Biomedical Imaging Center (CBIC) of Weill Cornell Medical College (WCMC), 516 E. 72nd Street, New York, NY 10021. Some portions of the study may take place at facilities of NewYork-Presbyterian Hospital, where the investigators are members of the medical staff.

NewYork-Presbyterian Hospital is neither a sponsor nor an investigator for this study. Processing of blood samples for the genetic analysis component will be conducted at Cornell University in Ithaca, NY.

WHY IS THE STUDY BEING DONE?

The purpose of this study is to investigate whether N-acetylcysteine (NAC) dietary supplements have an effect on glutathione (GSH) deficits in people with ME/CFS. GSH is an important antioxidant in the body, which is often very low in people with ME/CFS. Since GSH cannot cross the blood-brain barrier, the only way to increase levels is by causing the body to create more; we think that this can be done by administering NAC dietary supplements. By testing subjects before they take the drug, and again afterwards, we hope to find out the effect NAC supplements have on GSH levels in people with ME/CFS. This research is being done because currently, there is no effective treatment for this type of condition. Determining the effect of NAC supplement on GSH levels could help establish whether NAC supplementation has the potential to be used as a treatment for ME/CFS, as well as identify the optimal NAC dose.

If you choose to participate in the genetic analysis component, we will analyze your blood sample for genes that we believe may be associated with oxidative stress in people with ME/CFS. If an association is found between these genes and oxidative stress, this could help identify which ME/CFS subjects would potentially benefit from higher doses of antioxidants.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Participants in the study are referred to as subjects.
About 95 subjects will take part in this study worldwide; 95 subjects will be recruited at this site.

WHAT IS INVOLVED IN THE STUDY?

On your first study visit, you will undergo a baseline brain MRS screening scan to determine whether your brain glutathione levels are within the range that is required for you to participate in this study. If your glutathione is not within this required range, you cannot participate and your involvement in the study will end at that point. If your baseline brain MRS screening scan confirms your eligibility to participate, then you will be "randomized" into one of the study groups where you will be administered NAC capsules to ingest daily, over approximately four weeks. Depending on which group you are assigned, your capsules may have a dose of 0 mg/day, 900mg/day, or 3600mg/day. Randomization means that you are put into a group by chance. It is like flipping a coin. Neither you nor the researchers will choose what group you will be in. You will have a one in three chance of being placed in any group. Neither you nor the investigator will know what group you are in but the study doctor can find out if medically necessary. You will be given a study drug and it will either contain NAC or, if you are assigned to the 0mg/day dose group, a placebo (pills with no study drug)

If you take part in this study, your involvement would include two visits. Your first visit would include a review of your medical and medication history, height and weight, clinical assessments including surveys/questionnaires, as well as blood and urine collection for testing. You will also have your vital signs taken (temperature, pulse, blood pressure, breathing rate) and undergo brain Magnetic Resonance Imaging (MRI) and Magnetic Resonance Spectroscopy (MRS). These scans will last up to two hours in total, during which time you will have to lie down flat in the scanning machine without moving. The MRI/MRS will be used to help confirm your eligibility. Depending on the results, you may be assigned to one of the study groups and

provided with a supply of either NAC or placebo capsules. NAC is an unregulated dietary supplement. It is considered investigational and has not been approved by the U.S. Food and Drug administration (FDA).

If following your baseline brain MRS screening scan you are found to be eligible to participate in 4-week trial, you will be assigned to a study group and be asked to self-administer the NAC capsules daily as instructed,, for up to 32 days. Additionally, you will also be asked to self-administer a weekly questionnaire, at home, during that time. At the end of four weeks, you will be asked to return for a follow-up visit where all the study procedures from your first visit will be repeated. You will also be asked to return your completed weekly questionnaires either at your follow-up visit, or by mail within one week of your follow-up visit.

Visit 1: Baseline (Approx. 4-5 hours)

- Informed consent
- Medical history
- Medication history
- Height and weight
- Urine collection
- Baseline brain MRS screening scan to establish trial eligibility

The following items will happen only if baseline brain MRS scan confirms participation eligibility

- Clinical assessments
- Blood collection
- Vital Signs
- Brain MRI/MRS

Week 1: Self –administration

- Take capsules daily
- Complete weekly questionnaire at home

Week 2: Self –administration

- Take capsules daily
- Complete weekly questionnaire at home

Week 3: Self –administration

- Take capsules daily
- Complete weekly questionnaire at home

Week 4: Self –administration

- Take capsules daily
- Complete weekly questionnaire at home

Visit 2: Follow-up (Approx. 4-5 hours**)**

- Height and weight
- Clinical assessments
- Blood collection
- Urine collection
- Vital Signs
- Brain MRI/MRS

Please advise the researchers of any medications you are taking. In addition, if you are taking any over-the-counter drugs or herbal supplements which you have obtained from the drug store, grocery store, etc., you should advise the researchers.

HOW LONG WILL I BE IN THE STUDY?

We think you will be in the study for up to five weeks.
You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the researcher and your regular doctor first. If you choose to leave the study, your regular care will not be affected, nor will you lose any benefits to which you are entitled. In addition your relations with WCMC, NewYork-Presbyterian Hospitals, your physicians, or other personnel will not be affected.

Withdrawal by investigator, physician, or sponsor

The investigators, physicians or sponsors may stop the study or take you out of the study at any time if they feel it is in your best interest, if you experience a study-related injury, if you need additional or different medication, or if you do not follow the study plan. They may remove you from the study for various other administrative and medical reasons. They can do this without your consent.

WHAT ARE THE RISKS OF THE STUDY?

For trials of drugs, there may be risks. These risks will be discussed with you by the research doctor.
Risks and side effects related to the drugs we are studying include:

1. **Clinical assessments:** The subject may feel embarrassed to give or discuss private information. Participants may become fatigued or bored from filling out the questionnaires, but rest breaks will be provided as needed.
2. **Blood Sampling:** Possible adverse effects are pain, infection and bruising at the needle insertion site, dizziness and feeling faint.
3. **Study Drug:** NAC is an unregulated dietary supplement. It is considered investigational; it has not been approved by the U.S. Food and Drug administration (FDA). The most common side effects are GI-disturbances, altered or metallic taste and skin rash, all of which will be thoroughly documented and monitored. Risks and side effects related to the study drug include the following (depending on dose and excipient):

 Gastrointestinal disturbances: nausea, vomiting, constipation, diarrhea

 Altered or metallic taste

 Skin: rashes, itching, swelling

□ Lung: bronchial irritation, bronchoconstriction (asthma attack)

□ Heart and circulation: low blood pressure, increased heart rate, chest tightness

□ Other possible effects: anaphylaxis, fever, headache, drowsiness/fatigue, liver problems

4. **Brain MRI/MRS:** The MRI/MRS scan involves the use of a magnet and radiofrequency waves (much like an ordinary shortwave radio.) There are no known risks or adverse effects resulting directly from exposure to the magnetic fields and radiofrequency signals that will be used in this study, other than the potential risks associated with the scanning procedure summarized below.

   A. Metallic Foreign Body Risks. You may not be able to undergo MRI scanning if you have a pacemaker, an implanted defibrillator or certain other implanted electronic or metallic devices. It is important for you to advise the MRI staff if you have had brain surgery for a cerebral aneurysm, or if you have implanted medical or metallic devices, shrapnel, or other metal fragments or objects in your body, such as metal in your eye.

   B. Collision Hazard. Because of the strong magnetic field associated with the scanner, there is a risk that a metal object could fly through the air towards the scanner and hit you. To reduce this risk, the scanning room does not contain metal objects that could come loose. All people involved with this study will remove all metal from themselves, their clothing, and their pockets when in the scanning environment.

   C. Claustrophobia. Some people feel claustrophobic in the MR scanner. If this happens, we will stop the scan immediately.

   D. Hearing Protection. The MR scanner produces tapping sounds during operation, which may reach very loud levels. To minimize any discomfort from this noise, you will be provided with disposable earplugs that suppress external noise levels, but do not eliminate voice communication with the scanner operator. If you find the noise from the scanner objectionable, you may stop the study at any time.

   E. Neurostimulation. In some cases, it is possible that you might experience neurostimulation effects, such as muscle twitches and tingling sensations, due to the rapid switching of magnetic field gradients used in these examinations. There are no known risks associated with these effects. Stimulation of the muscles of the heart, causing abnormal heart rhythms is much less likely to occur.

5. **Incidental Findings:** The MRI scans will be interpreted by a WCMC Department of Radiology faculty radiologist. The report of the findings will be provided to the study PI. The MRI scans could show unexpected findings that seem unusual. These findings could suggest that we may have accidentally found a disease that you didn't know you had. If this situation occurs, we might recommend that you have these findings examined further in collaboration with a physician who is not involved in this study. This could result in anxiety, risks unrelated to the research procedures, and health care costs. These costs are not covered by the study or WCMC, and therefore will be your sole responsibility and/or of your insurance company.

6. **Risks and side effects related to study questionnaires**: The study questionnaires may involve probing of information which might be considered personal or sensitive. You may feel embarrassed to give or

discuss private information. You may become fatigued or bored from filling out the questionnaires, but rest breaks will be provided as needed.

7. **Risks and side effects related to the genetic testing procedures include the following:** Genetic testing in general can generate information about a subject's personal health risks and can cause or increase anxiety, damage family relationships, and/or compromise insurability, employability and can even lead to social discrimination. Since the genetic information we obtain will be for research purposes only, the results will not be made available to you.

   There is a new Federal law called the Genetic Information Nondiscrimination Act (GINA). 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. However, it does not protect you against discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

There may also be side effects, other than listed above that we cannot predict. Other drugs may be given to make side effects that occur less serious and less uncomfortable. Many side effects go away shortly after the drug is stopped, but in some cases side effects can be serious, long lasting or permanent.

Considerations for Pregnancy and Sexual Activity

You will be asked to provide a urine sample for pregnancy testing on days of assessments. Females of reproductive age will be asked to utilize an effective birth control method for the duration of their study participation. You will not be able to undergo any imaging procedures or continue your participation in the study in the event of a positive pregnancy test.

If there are any unsuspected, incidental laboratory or pathological findings that you should know about, the Principal Investigator will share the findings with you or a physician who you may designate. Incidental findings noted on the MRI/MRS study might or might not have clinical significance and might or might not lead to further medical tests or treatments. It will be up to you and your designated physician to determine if any further testing or treatment is necessary on the basis of this information. However, you should know that the limited MRI/imaging that is done in conjunction with this study is not meant to be a comprehensive examination, therefore we may not detect abnormalities or diseases which may be present and might be detected in a full clinical and diagnostic MRI examination. Should we find abnormalities in our limited MRI examination of your brain, your doctor might recommend that you undergo the full diagnostic MRI, which would then no longer be considered a part of this study.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

We cannot and do not guarantee that you will receive any benefits from this study. However, knowledge gained from this study may eventually help improve our understanding of ME/CFS. We hope the information learned from this study will benefit other patients with ME/CFS in the future.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you have these options:
You may choose not to participate in this study.

WHAT ABOUT CONFIDENTIALITY?

Efforts will be made to protect your medical records and other personal information to the extent allowed by law. However, we cannot guarantee absolute confidentiality. Records of study participants are stored and kept according to legal requirements and may be part of your medical record. You will not be identified personally in any reports or publications resulting from this study. Organizations that may request to inspect and/or copy your research and medical records for quality assurance and data analysis include groups such as:

- Weill Cornell Medical College and NewYork-Presbyterian Hospital
- Cornell University at Ithaca
- The WCMC Institutional Review Board (IRB)
- The Office of Human Research Protection (OHRP)
- Department of Health and Human Services
- National Institutes of Health
- The Food and Drug Administration (FDA) and/or their representatives

By signing this consent form, you authorize access to this confidential information. You also authorize the release of your medical records to WCMC by any other hospitals or institutions where you might receive medical care of any kind while you are participating in this study.

If information about your participation in this study is stored in a computer, we will take the following precautions to protect it from unauthorized disclosure, tampering, or damage by requiring a unique ID and password to log into the database: Data will be stored on a password protected computer in a locked office. Only personnel who are associated with the study will have access to the study specific records in the database. We must also document in your medical record chart that you are participating in this study. After your participation in this study is over, the FDA may continue to use your health information that is collected as part of this study.

In addition, only personnel who are associated with the study will have access to the study specific records in the database.

Please also note that your brain *MR imaging* that is done as part of this study will be read and interpreted by a WCMC Department of Radiology radiologist and the report will be provided to the Principal Investigator. If there are any unsuspected, incidental findings that you should know about, the Principal Investigator will share the findings with you or a physician who you may designate. Incidental findings noted on the *MR imaging* study might or might not have clinical significance and might or might not lead to further medical tests or treatments. It will be up to you and your designated physician to determine if any further testing or treatment is necessary on the basis of this information. However, you should know that the limited MRI/imaging that is done in conjunction with this study is not meant to be a comprehensive examination, therefore we may not detect abnormalities or diseases which may be present and might be detected in a full clinical and diagnostic MRI examination. Should we find abnormalities in our limited MRI examination of your brain, your doctor might recommend that you undergo the full diagnostic MRI, which would then no longer be considered a part of this study.

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

HIPAA AUTHORIZATION TO USE or DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

Purposes for Using or Sharing Protected Health Information: If you decide to join this study, WCMC researchers need your permission to use your protected health information. If you give permission, WCMC researchers may use your information or share (disclose) information about you for their research that is considered to be protected health information.

Voluntary Choice: The choice to give WCMC researcher's permission to use or share your protected health information for their research is voluntary. It is completely up to you. No one can force you to give permission. However, you must give permission for WCMC researchers to use or share your protected health information if you want to participate in the study. If you decline to sign this form, you cannot participate in this study, because the researchers will not be able to obtain and/or use the information they need in order to conduct their research. Refusing to give permission will not affect your ability to get usual treatment, or health care from WCMC.

Protected Health Information To Be Used or Shared: Government rules require that researchers get your permission (authorization) to use or share your protected health information. Your medical information may be disclosed to authorized public health or government officials for public health activities when required or authorized by law. If you give permission, the researchers could use or share with the entities identified above any protected health information related to this research study from your medical records and from any test results, which includes *clinical assessments, vital signs, blood tests (including genetic testing if you participate in the genetic analysis component), urine tests, neuroimaging (MRI/MRS).*

Other Use and Sharing of Protected Health Information: If you give permission, the researchers could also use your protected health information to develop new procedures or commercial products. They could share your protected health information with the study sponsor, the WCMC Institutional Review Board, inspectors who check the research, government agencies and research study staff. The researchers could also share your protected health information with the National Institutes of Health (NIH)**.**

The information that may be shared with the sponsor and/or government agencies could include your medical record and your research record related to this study. They may not be considered covered entities under the Privacy Rule and your information would not be subject to protections under the Privacy Rule.

Future Research

By signing this form, you agree to allow your data, and blood sample(s) to be used for future research within WCMC or at outside institutions and private companies. If information goes to an outside entity then WCMC cannot ensure the privacy rule is followed.

GENETIC TESTS AS PART OF THIS RESEARCH STUDY

A genetic test will be done using the blood samples. By signing this consent form, you agree to give these samples to collaborators at Cornell University in Ithaca, NY for research purposes. Your information will be kept confidential in accordance with State and Federal law. You will not be notified of the results of the genetic testing and the results will not be placed in your medical record.

DISCLOSURE OF TEST RESULTS

To the extent permitted by law, under no circumstances will any information linking you to specific test results be disclosed to any individual or organization without your written consent. The results from the genetic test we perform may be disclosed to the following individuals or groups:
o Weill Cornell Medical College and New York-Presbyterian Hospital

o Cornell University at Ithaca

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

• Health insurance companies and group health plans may not request your genetic information that we get from this research.

• Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.

• Employers with 15 or more employees may not use your genetic information that we get from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. Nor does this Federal law prohibit discrimination on the basis of an already manifest genetic disease or disorder.

RESEARCH REPOSITORY

What is a Research Repository? A research repository (database) is a collection of information from the health and medical records of many individuals and can sometimes include identifiable specimens (like your tissue). The repository (database) may share the information with researchers who study medical conditions and diseases.

The repository (database) includes codes that identify each person whose information is collected. However, the repository does not share information with researchers unless the researchers promise to keep the information confidential.

RESEARCH PARTICIPANT: Please check the box below that describe your wishes:

☐ The WCMC and NIH Repositories may keep my protected health information and/or specimens and share it with qualified researchers studying the research described above **AND** for unspecified research to be done in the future. I understand that the samples will be stored for an indefinite period of time and will be destroyed after the research is completed. By signing this consent form, you agree to give these samples to WCMC for research purposes. If information goes to an outside entity then the Privacy Rule may not apply.

☐ The WCMC and NIH Repositories may not keep my protected health information for a research repository.

CANCELING AUTHORIZATION

Canceling Permission: If you give the WCMC researchers permission to use or share your protected health information, you have the right to cancel your permission whenever you want. However, canceling your permission will not apply to information that the researchers have already used or shared.

If you wish to cancel your permission, you may do so at any time by writing to:

Privacy Office
1300 York Avenue, Box 303
New York, NY 10065
Email: privacy@med.cornell.edu

If you have questions about this and would like to discuss, call (646) 962-6930.

End of Permission: Unless you cancel it, permission for WCMC researchers to use or share your protected health information for their research will never end.

ACCESS TO RESEARCH RECORDS

During the course of this study**, you will not have access** to see or copy certain parts of your protected health information that contains research information as described in this authorization form, in accordance with WCMC policies. This is done to prevent knowledge of study results affecting the reliability of the study. The part of your private information that you will not have access to are the clinical assessments and blood tests results, genetic results if you choose to participate in the genetic

analysis component, as well as which dosage of the study drug you will receive (0 mg/day, 900mg/day, or 3600mg/day). Your information will be available should an emergency arise that would require the treating physician to know this information in order to best treat you. Your right to access this information will not be reinstated at any time. If you wish to appeal this suspension at any time, please write to the Privacy Officer at the address on this form. By signing this form, you are agreeing to this suspension of your rights to access protected health information.

CERTIFICATE OF CONFIDENTIALITY

A Certificate of Confidentiality has been granted by the Department of Health and Human Services (DHHS). This Certificate will protect the investigators (research/study staff) from being forced to release any research data in which the subject is identified even under a court order or subpoena. This protection is not absolute. For instance, it does not override any state requirement to report child abuse to the appropriate authorities.

WHAT ARE THE COSTS?

You will not have to pay for the investigational drugs or any research only procedures, including the MRI scan.

If unsuspected, incidental findings are noted in the review of the MRI study and further medical tests and/or treatments are considered, such tests and/or treatments are no longer considered part of the study and therefore would be billed to you or your insurer. You should expect no compensation or reimbursement for these costs or any risks and anxieties associated with any such follow up care. You or your insurance company will also be charged for any continuing medical care and/or hospitalization that are not a part of the study.

POLICY/PROCEDURES FOR RESEARCH RELATED INJURY

The Policy and Procedure for Weill Cornell Medical College **are as follows:**
We are obligated to inform you about Weill Cornell Medical College's policy in the event injury occurs. If, as a result of your participation, you experience injury from known or unknown risks of the research procedures as described, immediate medical care and treatment, including hospitalization, if necessary, will be available at the usual charge for such treatment. No monetary compensation is available from Weill Cornell Medical College. Further information can be obtained by calling the Institutional Review Board at (646) 962-8200.

COMPENSATION FOR PARTICIPATION

You *will* receive compensation for participating in this study as follows: (a) if your baseline brain MRS screening scan finds that you are ineligible to participate in the 4-week trial, you will receive a stipend of $100 and your involvement in the study will end at that point; or (b) if you are confirmed by baseline brain MRS screening scan to be eligible to participate in the 4-week trial, you will receive a stipend of $200 for each of 2 successfully completed study visits, for a total of $400. The stiped will be given to you in the form of a check approximately six weeks after you complete each visit.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. You may choose to not take part in the study or to leave the study at any time. If you choose to not participate in the study or to leave the study, your regular care will not be affected nor

will your relations with Weill Cornell Medical College, your physicians, or other personnel. In addition, you will not lose any of the benefits to which you are entitled.

We will tell you about new information that may affect your health, welfare, or participation in this study.

A Data Safety and Monitoring Board, an independent group of experts, will be reviewing the data from this research throughout the study. We will tell you about the new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study, a research-related injury, any problems, unexpected physical or psychological discomforts, or if you think that something unusual or unexpected is happening, call Dr. Dikoma C. Shungu, the study PI at 646-265-0172 or the 24-hour for Department of Radiology: 212-746-2630. Be sure to inform the physician of your participation in this study.

If you have questions about your rights as a research participant, contact the WCMC IRB Office. Direct your questions to:

Institutional Review Board at: (646) 962-8200
1300 York Avenue
Box 89
New York, New York 10065

Consent for Research Study

Project Title: Mechanistic Assessment of N-Acetylcysteine as an Antioxidant Therapy for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) Through Dose Response and Treatment Target Engagement

Principal Investigator: Dikoma C. Shungu, Ph.D.

RESEARCHER'S STATEMENT

I have fully explained this study to the subject. As a representative of this study, I have explained the purpose, the procedures, the benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

_____	_____	_____
Signature of person obtaining the consent (Principal Investigator or Co-investigator)	Print Name of Person	Date

SUBJECT'S STATEMENT

I, the undersigned, have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to participate in this study. I am free to withdraw from the study at any time without need to justify my decision. This withdrawal will not in any way affect my future treatment or medical management and I will not lose any benefits to which I otherwise am entitled. I agree to cooperate with *Dikoma C. Shungu, Ph.D.* and the research staff and to inform them immediately if I experience any unexpected or unusual symptoms.

_____	_____	_____
Signature of Subject	Print Name of Subject	Date

PARTICIPATION IN GENETIC ANALYSIS COMPONENT

☐ I have opted to participate in the optional genetic analysis component. I understand that this will involve collection of an additional blood sample, which will be used for gene analysis.

☐ I have opted to NOT participate in the optional genetic analysis component.