Study ID #: IRB 18-00497 **Form Version Date: 10 May 2019**

TITLE OF RESEARCH STUDY:

Title: N-of-1 Brain Boost Study

PRINCIPAL INVESTIGATOR (HEAD RESEARCHER) NAME AND CONTACT INFORMATION:

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WHAT IS A RESEARCH STUDY?

A research study is when scientists try to answer a question about something that we don't know enough about. Participating may not help you or others.

People volunteer to be in a research study. The decision about whether or not to take part is totally up to you. You can also agree to take part now and later change your mind. Whatever you decide is okay. It will not affect your ability to get medical care within the Mount Sinai Health System.

Feel free to ask all the questions you want before you decide. If you have any questions, you can contact the research team at info@n1app.org or via the "Contact" button in the N-of-1 app. Any new information that develops during this research study that might make you change your mind about participating will be given to you promptly.

PURPOSE OF THIS RESEARCH STUDY:

The purpose of this study is to see whether certain supplements affect your ability to think more than others.
The supplements being tested are:

- Caffeine (50-400mg)
- Caffeine (50-400mg) + L-theanine (250mg)

You may qualify to take part in this research study if you are:

1. Over 18 years old
2. A caffeine drinker
3. Live in the United States
4. Not pregnant or breastfeeding
5. Have no reason to believe that consuming caffeine may be harmful to your health

Funds for conducting this research are provided by the Institute for Next Generation Healthcare at the Icahn School of Medicine at Mount Sinai.

LENGTH OF TIME AND NUMBER OF PEOPLE EXPECTED TO PARTICIPATE

Your participation in this research study is expected to last a maximum of 1 month.

The total number of people expected to take part in this research study is 500.

DESCRIPTION OF WHAT'S INVOLVED:

If you agree to participate in this research study, the following information describes what may be involved.

You will spend up to one week without any prescribed treatment, in which you will take up to 3 cognitive assessments daily. This will be your "baseline" study arm. Next, you will be assigned a study arm length that determines how long you will consume each treatment. During each study arm, you will either consume the:

"Experimental supplement": 1 caffeinated beverage or supplement (50-400mg), + L-theanine (250mg)

OR

"Comparator supplement": 1 caffeinated beverage or supplement (50-400mg), alone

You can choose either a caffeinated beverage or a caffeine supplement (pill) for the study. If you choose a beverage, the type of caffeinated beverage is up to you. You should choose something that you are comfortable drinking every day for about 3 weeks and have experience drinking in the past. Examples of typical caffeinated beverages are coffee, tea, and soda. Only choose a caffeine supplement (e.g. pill) if you have used it before.

1 cup of black tea (8 oz.) = 50mg caffeine
1 large Starbucks coffee (20 oz.) = 400mg of caffeine
Pure caffeine (e.g. pill) = 200mg

Each day, you will be informed of which study arm you are in, and you will be alerted when you are supposed to consume the supplement(s). You get to choose when to do the study each day based on the time of day that you want to be most productive and alert.
You will also take up to 3 cognitive tests 1 hour after consuming the supplement(s) each day. These tests will be taken using the N-of-1 app, and they will check your creative cognition, reaction time, visual attention, and task-switching ability.

To make it easier to keep track during the study, you have the option of turning notifications on in the app so that you will be reminded of when to switch study arms and take the cognitive tests.

We do not know what study details affect a person's ability to adhere to the study directions and participate for the whole duration of the study. To investigate this, we have randomized study length and the frequency of notifications that each study participant will have.

At the end of the study, you will be able to view your study results to learn about your cognitive outcomes during each arm of the study. You will also have the option of extending your study upon completion, with your choice of study length. You will have to sign another consent form if you choose to extend your study. The only difference is that we are not assigning your study length – you are choosing for yourself.

When you get your results, you may share your study results outside of the app on social media channels. You may also choose to share your data with researchers around the world. These options are provided within the N-of-1 app settings. If you choose to share data socially or with researchers, it will never include identifiable information like your name or email address. Sharing the data in any way is totally up to you.

YOUR RESPONSIBILITIES IF YOU TAKE PART IN THIS RESEARCH:

If you decide to take part in this research study, you will be responsible for the following things:

--choosing when you want to start the study

--choosing what time of day to consume the supplements

--taking up to 3 cognitive assessments, daily

--obtaining caffeinated beverages/supplements and L-theanine for the entire duration of the study

--logging completed activities in the N1 app daily for the duration of the study

COSTS OR PAYMENTS THAT MAY RESULT FROM PARTICIPATION:

You will not be paid for participating in this research study.

Taking part in this research study may lead to added costs to you. These costs may include the cost of each caffeinated beverage consumed, and the cost of L-theanine supplements. The total cost of this study may be between $25 and $75 depending on your beverage choices. There may also be a cost involved in using the N-of-1 iPhone app because of cellular data usage.

POSSIBLE BENEFITS:

It is important to know that you may not get any benefit from taking part in this research. Others may not benefit either. However, possible benefits may be learning about what cognitive enhancement options work best for you and your lifestyle.

REASONABLY FORESEEABLE RISKS AND DISCOMFORTS:

Caffeine & L-theanine risk

Consuming caffeine may cause health risks if you have a sleeping disorder, migraines or chronic headaches, or if you have fast/irregular heart rhythms. If you consume too much caffeine, you may

feel shaky, you may get a headache, and/or you might feel your heart beat unusually fast. If you have any concerns about how caffeine may affect your health, you should talk to your doctor or another available health professional before doing this study. Again, you should only consume a dose of caffeine that you are comfortable with and that has not caused significant side effects to you before. There are no known adverse effects of L-theanine.

Protecting your data

There is a risk of loss of private information. This risk always exists, but there are procedures in place to reduce the risk. We will work hard to protect your information. However, we do not guarantee anonymity. Improper access to your account is possible, including hacking or other activities outside of our authorized access procedures.

We will take reasonable steps to keep your account information private and secure. The research team will never sell, rent, or lease your account information. Your information will be transmitted and stored using secure systems.

Storing your data

As described elsewhere in the consent form, during the study, data pertaining to your participation will be generated and recorded. We refer to such data as your "study data." We will store your study data attached to a study ID (code) that is unique to you. We will store your account information (e.g. name and email address) separately from your coded study data. In order to improve the study app, the researchers may track some information automatically, including information about your mobile device, app version, and operating system, which pages in the app you view, and the date and time you view them. This information will also be attached to your study ID. It will not affect your study results in any way.

Using your study data

We limit the access of your study data. Future modules will provide you more options for sharing your study data more broadly, if you choose. Only the following entities and organizations may use your Study Data by default:

- you

- the study team, including other people who, and organizations that, assist the study team;

- the ethics committee or institutional review board that approved this study;

- regulatory agencies and government officials who have a duty to monitor or oversee studies like this one.

If data, results, or other information from this study is published or presented at scientific meetings, your name will not be used without your permission.

Other possible risks or discomforts

Economic risks; you are responsible for paying the cost of each caffeinated beverage and for paying L-theanine for the length of the study.

OTHER POSSIBLE OPTIONS TO CONSIDER:

You may decide not to take part in this research study without any penalty. The choice is totally up to you.

IN CASE OF INJURY DURING THIS RESEARCH STUDY:

If you believe that you have suffered an injury related to this research as a participant in this study, you should contact the research team and study doctor via email at health@n1app.org or through the "health-related" option when you press "contact us" on the app.

ENDING PARTICIPATION IN THE RESEARCH STUDY:

You may stop taking part in this research study at any time without any penalty. This will not affect your ability to receive medical care or to receive any benefits to which you are otherwise entitled.

If you decide to stop being in the research study, please contact the Principal Investigator or the research staff through info@n1app.org or via the "Contact" button on the N-of-1 app.

You may also withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page or via email at the address provided within the N-of-1 app. Even if you withdraw your permission, the Principal Investigator for the research study may still use the information that was already collected if that information is necessary to complete the research study. Your health information may still be used or shared after you withdraw your authorization if you have an adverse event (a bad effect) from participating in the research study.

Withdrawal without your consent: The study team, the sponsor or the institution may stop your involvement in this research study at any time without your consent. This may be because the research study is being stopped, the instructions of the study team have not been followed, the investigator believes it is in your best interest, or for any other reason. If specimens or data have been stored as part of the research study, they too can be destroyed without your consent.

CONTACT PERSON(S):

If you have any questions, concerns, or complaints at any time about this research, or you think the research has hurt you, please contact the office of the research team and/or the Principal Investigator through the Contact Us button on the N-of-1 app or by sending an email to the study team at info@n1app.org.

If you experience an emergency during your participation in this research, call 911 or go to the nearest hospital.

This research has been reviewed and approved by an Institutional Review Board. You may reach a representative of the Program for Protection of Human Subjects at the Icahn School of Medicine at Mount Sinai at telephone number (212) 824-8200 during standard work hours for any of the reasons listed below. This office will direct your call to the right person within the Mount Sinai Health System:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You are not comfortable talking to the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

DISCLOSURE OF FINANCIAL INTERESTS:

Sometimes, physicians/researchers receive payments for consulting or similar work performed for industry. Effective September 2014 Mount Sinai reviews only payments to an individual totaling more than $5,000 a year per entity when determining potential conflicts of interest. If you have questions regarding industry relationships, we encourage you to talk your physician/researcher or visit our website at http://icahn.mssm.edu/ where Mount Sinai publicly discloses the industry relationships of our faculty.

MAINTAINING CONFIDENTIALITY – HIPAA AUTHORIZATION:

As you take part in this research project it will be necessary for the research team and others to use and share some of your private protected health information. Consistent with the federal Health Insurance Portability and Accountability Act (HIPAA), we are asking your permission to receive, use and share that information.

<u>What protected health information is collected and used in this study, and might also be disclosed (shared) with others?</u>

As part of this research project, the research team at the hospital(s) involved in the research will collect your name, email address, and year of birth.

During the study, the researchers will gather information by:

- completing the tests, procedures, note logs, and questionnaires explained in the description section of this consent.

<u>Why is your protected health information being used?</u>

Your personal contact information is important to be able to contact you during the study. Your health information and the results of any tests and procedures being collected as part of this research study will be used for the purpose of this study as explained earlier in this consent form. The results of this

study could be published or presented at scientific meetings, lectures, or other events, but would not include any information that would let others know who you are, unless you give separate permission to do so.

The research team and other authorized members of The Mount Sinai Health System ("Mount Sinai") workforce may use and share your information to ensure that the research meets legal, institutional or accreditation requirements. For example, the School's Program for the Protection of Human Subjects is responsible for overseeing research on human subjects and may need to see your information. If you receive any payments for taking part in this study, the Mount Sinai Finance Department may need your name, address, social security number, payment amount, and related information for tax reporting purposes. If the research team uncovers abuse, neglect, or reportable diseases, this information may be disclosed to appropriate authorities.

Who, outside Mount Sinai, might receive your protected health information?

As part of the study, the Principal Investigator, study team and others in the Mount Sinai workforce may disclose your protected health information, including the results of the research study tests and procedures, to the following people or organizations: (It is possible that there may be changes to the list during this research study; you may request an up-to-date list at any time by contacting the Principal Investigator.)

- Approved external researchers who want to study data related to this project. This will only happen if you choose to opt in to share your data with researchers globally via the N-of-1 app.
- The United States Department of Health and Human Services and the Office of Human Research Protection.
- The United States Food and Drug Administration

In all disclosures outside of Mount Sinai, you will not be identified by name, email address, or any other direct personal identifier unless disclosure of the direct identifier is required by law. Some records and information disclosed may be identified with a unique code number. The Principal Investigator will ensure that the key to the code will be kept in a locked file or will be securely stored electronically. The code will not be used to link the information back to you without your permission, unless the law requires it, or rarely if the Institutional Review Board allows it after determining that there would be minimal risk to your privacy. It is possible that a sponsor or their representatives, a data coordinating office, a contract research organization, may come to inspect your records. Even if those records are identifiable when inspected, the information leaving the institution will be stripped of direct identifiers. Additionally, when applicable, the monitors, auditors, the IRB, the Office of Human Subjects Protection (OHRP) of the Department of Health and Human Services as well as the Food and Drug Administration (FDA) will be granted direct access to your medical records for verification of the research procedures and data. OHRP and FDA are authorized to remove information with identifiers if necessary to complete their task. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

For how long will Mount Sinai be able to use or disclose your protected health information?

Your authorization for use of your protected health information for this specific study does not expire.

Will you be able to access your records?

During your participation in this study, you will have access to your medical record and any study information that is part of that record. The investigator is not required to release to you research information that is not part of your medical record.

Do you need to give us permission to obtain, use or share your health information?

NO! If you decide not to let us obtain, use or share your health information you should not sign this form, and you will not be allowed to volunteer in the research study. If you do not sign, it will not affect your treatment, payment or enrollment in any health plans or affect your eligibility for benefits.

Can you change your mind?

You may withdraw your permission for the use and disclosure of any of your protected information for research, but you must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, the Principal Investigator for the research study may still use your protected information that was already collected if that information is necessary to complete the study. Your health information may still be used or shared after you withdraw your authorization if you should have an adverse event (a bad effect) from being in the study. If you withdraw your permission to use your protected health information for research that means you will also be withdrawn from the research study, but standard medical care and any other benefits to which you are entitled will not be affected. You can also tell us you want to withdraw from the research study at any time without canceling the Authorization to use your data.

It is important for you to understand that once information is disclosed to others outside Mount Sinai, the information may be re-disclosed and will no longer be covered by the federal privacy protection regulations. However, even if your information will no longer be protected by federal regulations, where possible, Mount Sinai has entered into agreements with those who will receive your information to continue to protect your confidentiality.

If as part of this research project your medical records are being reviewed, or a medical history is being taken, it is possible that HIV-related information may be revealed to the researchers. If that is the case, the following information concerns you. If this research does not involve any review of medical records or questions about your medical history or conditions, then the following section may be ignored.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the recipient(s) is (are) prohibited from re-disclosing any HIV-related information without your authorization unless permitted to do so under federal or state law. You also 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 New York State Division of Human Rights at (888) 392-3644 or the New York City Commission on Human Rights at (212) 306-5070. These agencies are responsible for protecting your rights.

****If you agree to participate in this research study, please exit this screen and print and sign your name on the consent review screen****