## CONSENT FORM AND HIPAA AUTHORIZATION

# Brain Health in the Time of COVID-19

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| Version Date | April 28, 2020 |
| Development Phase | Phase 4: Disease-Specific Investigation and Validation |
| Sponsor | Miro Health 260 King St.<br>San Francisco, CA 94107 |
| Principal Investigator | Miro Health:<br>Natasha Belfor, PhD |
| Collaborators | Argye Hillis, MD, Johns Hopkins<br>Neelesh Nadkarni, MD, UPMC |
| Sponsor Contact | Name: Shenly Glenn<br>Telephone: 415-655-3839 |

Name of Research Study: Brain Health in the Time of COVID-19
Study Number: Miro00102020
IRB Number: 20079
Sponsor: Miro Health
Principal Investigator: Natasha Belfor, PhD
Location: 260 King St., Unit 1505, San Francisco, CA 94107
24-Hour Contact: Staff member on call: 415-655-3839

### Disclosure of funding source and proprietary interests

This study is paid for by Miro Health. Miro Health owns the device being tested and thus has a financial interest in the outcome of the study. The primary investigator, Dr. Nataliya Belfor, is paid to perform her duties as P.I. on this study. Her compensation is not affected by nor tied to study outcomes.

## STUDY INFORMATION AND FAQ

What should you know about this research?

- Someone is available to explain this research to you by phone or email.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you.
- If you don't understand, ask questions by phone or email.
- Ask all the questions you want before you decide

**What is involved?**

What you'll do in three simple steps

Total Time: Up to 1 hour

1. Set-up and consent (15 minutes)
2. Health questionnaires (15 minutes)
3. Mobile device interactions (30 minutes)

**What is the purpose of this study?**

This study will collect data about your neurological health through questionnaires and interactive assessments.

This study is experimental. "Experimental" means that the study device has not yet been approved by the U.S. Food and Drug Administration (FDA) and is not yet intended to diagnose, treat or otherwise mitigate health conditions or influence health decisions.

**Why am I being asked to participate?**

You are an adult with a mobile device and Wi-Fi who has expressed interest in contributing to COVID-19 research. Participation in this study is voluntary.

**Am I eligible?**

You must be 18 years of age or older

You must have access to an iPad model from 2013 or later, iPhone 6 or later.

You must have access to stable Wi-Fi

You must have access to iTunes

**What is involved?**
Should you decide to participate, you will need to provide your email.

1. Read this consent form. Register and consent to the study by entering your email below (15 minutes). You will then receive an email. Click on the link. It will open Miro's online Questionnaires in your web browser.

2. In the web-browser, you will complete online health questionnaires (15 minutes).

- Demographic profile
- Medical History
- Modified Mayo Portland Adaptability Inventory: Questions about your current neurological status

3. You will download the Miro app from iTunes, answer questions about your current health status, interact with Miro Mobile Applications, and offer feedback (30 minutes).

    * Does your mobile device have more than 8GBs of free space? If not, delete items to free up 8GBs of memory to Download Miro App from the iTunes store.

By consenting to this study, you grant Miro permission to de-identify the data collected from you for future product development.

**How long will I be in the study?**
The study will take up to 1 hour.

**Where will the study take place?**
The study will be completed on your mobile device in a quiet setting of your choice that has a Wi-Fi connection.

**What are my responsibilities if I take part in this research?**

You will be responsible to complete the questionnaires and mobile interactions honestly and to the best of your abilities. Please do not skip any questions.

**Could participation hurt me?**

While answering these questions and performing these tasks though you may feel anxious, nervous, or become fatigued.

As with any study, there remains a data breach risk which could result in the loss of confidentiality. Technical security measures are in place to prevent this such as

encrypted data capture, transfer, and storage, key management systems, and data de-identification . And, importantly, minimal personally identifiable information is collected: email. Names and phone numbers are not collected.

**How will my personal information be protected?**
All data is encrypted and stored on secure databases. Only authorized Miro personnel with appropriate training can access data and files. Approved personnel are limited to research staff. All system access is logged for audit purposes. The FDA and the Institutional Review Board (IRB) will also have access to the data. The IRB is a research ethics oversight board whose role is to protect the rights and welfare of study participants.

**What are the possible benefits of the study?**

There will be no immediate personal benefit to you.

Your participation may help researchers to understand the neurological effects of COVID-19 on brain health.

At the conclusion of the study, you will receive non-medical information on your brain function. This summary will not provide any indication of your medical status. You will also receive information about study findings and publications made possible by your participation.

Miro Health cannot provide you with any health-related information. However, at the conclusion of the study, Miro Health can release the results of your Miro assessment to your physician with your permission. In order for Miro Health to do this, you will be required to confirm your identity online, sign a HIPAA agreement to share the information with your physician, and to enter your physician's name, email, and contact information.

**How many other people will be in the study?**
It is expected that over 15,000 participants will be enrolled in the study.

**Can I leave the study after I've agreed to participate?**
You may leave the study at any time, for any reason. There is no need to provide a reason. You are free to refuse to participate or withdraw at any time without penalty or loss of benefits to which you are otherwise entitled.

To withdraw, send Miro Health an email with the following information. Be sure to email Miro Health from the email address that you used for the study.

Email: research@mirohealth.com

Subject: Withdrawal from COVID-19 study
Body: Please withdraw me from your study

Should you withdraw, the de-identified data collected from you during the study will remain as part of the study. Any data that personally identify you will be deleted (e.g., email).

Your de-identified data will be used by Miro for group analyses to find markers that might indicate disease. These de-identified data sets may be shared with:

- Miro authorized research staff
- Academic collaborators who work with Miro on this study
- Government agencies, such as the FDA
- Regulatory agencies
- Ethical and Independent Review Services (E&I), the IRB for this study

The sponsor, the FDA or the IRB may also decide to stop the study at any time.

**What other choices do I have if I do not participate?**
The alternative is not to participate.

**Will I be paid for my participation?**
You will not be paid for your participation.

**Will I have to pay for anything?**
You will need access to a mobile device and Wi-Fi in order to participate. Data from the mobile device will be uploaded. Carrier charges, if applicable, will apply.
**Note:** Your participation will not entitle you to rights to Miro's product or to intellectual property developed by Miro Health.

**Can this research study replace my medical assessment?**
No. This research does not provide any medical care.

**What happens if I am injured from participation in this study?**
This is a minimal risk study with a low likelihood of injury and Miro Health has no plans for payment for potential injuries.

Should you face a medical emergency during the study, contact:
911 Emergency Services.

If you think you may have been injured as a result of participation, please contact:
phone: 415-655-3839

**What if new information becomes available about the study?**
During the course of this study, we may discover relevant public health information. Should this be the case, we will notify you of our findings via email.

**Who can see or use my information?**
Your study records may be reviewed by the following:

- Miro authorized research staff
- Academic collaborators who work with Miro on this study
- Government agencies, such as the FDA
- Regulatory agencies
- E&I Review Services IRB

The IRB is a research ethics oversight board whose role is to protect the rights and welfare of study participants. Your information will not be shared with insurance companies, employers, nor doctors.

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

**How will my information be used?**
The sponsor and the groups above will use your health information:

- To evaluate the results of the study
- To ensure that the study is being done properly
- To obtain FDA approval for findings that may result from this research

**What data is de-identified?**
Demographics
Questionnaires
Touchscreen data
Data extracted from spoken interactions

**Who do I call if I have questions?**
If you have any questions about this research study, please call or email the study

staff to ensure that all of your questions have been answered before you consent to the study. Study staff will respond within 24 hours.

If you have concerns, complaints, to offer input or if you think that you may have been harmed by this study, please contact the study staff:

Email: research@mirohealth.com
Phone: 415-655-3839

Please call EandI Review Services IRB at 1-800-472-3241 or email subject@eandireview.com if:

- You want to talk to someone other than the study doctor or study staff
- You have a hard time reaching the study doctor or study staff
- You have questions about your rights as a research participant
- You have other questions, concerns or complaints about this study

Please reference study 20079.

**I consent to participate in the study, Brain Health in the Time of COVID-19**
This study is voluntary and I can withdraw at any time.

**Your email will function as your signature.**
When you enter your email, you are agreeing to take part in this research study. . If you do not want to take part in this study, do not enter your email.

This means that you have read this consent form, your questions have been answered, and you have decided to participate. Your email entry also means that you permit Miro Health to use information collected about you for research purposes, publication of study findings (no personal information is included in publications, only group-based analyses), and to share anonymized data with the FDA and IRB

<email entry>

A copy of the consent, HIPAA Authorization, and Bill of Rights may be downloaded for your records.

**By electronically signing this form, you have not waived any of your legal rights.**

## Health Insurance Portability and Accountability Act (**HIPAA) Authorization Q&A**

Federal regulations give you certain rights related to your health information. These include the right to know who will receive the information and how it will be used. The study must obtain your authorization (permission) to use or release any health information that might identify you. This information shall be released to Miro Health. This authorization for release of information includes your neurological or psychiatric diagnosis and medication information up to the present.

**What information may be used and shared?**
I will share with Miro Health my medical history, specifically as it relates to neurological and psychiatric health.

**What if I decide not to allow the use of my health information?**
You do not have to sign this form. If you do not sign this form, you cannot take part in this research study.

**May I withdraw or revoke (cancel) my permission?**
Yes, you may withdraw your permission to use and disclose your health information at any time. You can do this by emailing:

**What happens if I want to withdraw my authorization?**
No new health information will be gathered, but de-identified information may still be used.

**Will my authorization expire?**
This authorization will expire on December 31, 2060.

**May I review or copy the information obtained or created about me?**
Yes, you will enter your own psychiatric and / or neurological conditions, if any.

## HIPAA AUTHORIZATION

I understand that:

- My health information may be used by Miro Health only for research purposes.
- This Release of Information shall be in effect until terminated by me in writing.
- I have the right to revoke this authorization at any time.
- This authorization does not permit Miro Health to share my health information with anyone other than Miro staff, the FDA, and the IRB.
- All items on this form have been read and my questions about this form have been answered.
- I will be provided a copy of the form.

### HIPAA Authorization Agreement

O By checking this box, I allow Miro to use provided health information as described in this consent form.

**EXPERIMENTAL RESEARCH SUBJECT'S BILL OF RIGHTS**

California law, under Health & Safety Code Section 24172, requires that any person asked to take part as a subject in research involving a medical experiment, or any person asked to consent to such participation on behalf of another, is entitled to receive the following list of rights written in a language in which the person is fluent.

This list includes the right to:

1. Be informed of the nature and purpose of the experiment.
2. Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
3. Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
4. Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
5. Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
6. Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
7. Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
8. Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.
9. Be given a copy of the signed and dated written consent form.
10. Be given the opportunity to decide whether or not to consent to participate.

**BRIEF DECISIONAL CAPACITY ASSESSMENT**

A potential participant must have a perfect score of 8 to be eligible to be included in the study. The participant may attempt a perfect score over 3 trials.

1. Are you 18 years or older?
   - YES
   - NO
2. Is the purpose of this study is to find brain health markers for COVID-19?
   - YES
   - NO
3. Is the purpose of this study is to develop a vaccine for COVID-19?
   - YES
   - NO
4. Select the **FALSE** statement ( multiple choice )
   - I will provide details about my health information to the researchers.
   - I will give a blood sample.
   - The data from my tests will be used for research.
5. Select the **RISK** of participation ( multiple choice )
   - Loss of confidentiality
   - Bruising from blood draws
   - Nausea
6. Will you benefit from study participation? ( multiple choice )
   - There is no direct benefit to my participation in this study, but my participation may contribute to improving science or helping research.
   - I will benefit from the study because my brain health will improve.
7. I can contact the researchers with questions any time before, during, or after my participation in this study.
   - YES
   - NO
8. This study is voluntary and I can withdraw at any time.
   - YES
   - NO

## CONSENT TO BE CONTACTED FOR FUTURE RESEARCH

I am interested in learning about future research and you may contact me regarding (check all that apply):

- COVID-19 studies
- Neurobehavioral research studies