

## RESEARCH SUBJECT CONSENT FORM

**Title:** Voice Biomarkers predictive of Depression and Anxiety: an Observational study

**Protocol No.:** 2021/08/25

**Sponsor:** Kintsugi Mindful Wellness, Inc.

**Investigator:** Mei-Hsin Cheng, PhD  
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**Study-Related Phone Number(s):** (415) 754-9129

You are being invited to take part in a research study.

### What should I know about this research?

- Taking part in this research is voluntary.
- There is no penalty if you do not join.
- You can always opt out.
- Feel free to ask questions anytime.
- Ask any questions before making your decision.

### Why is this research being done?

Depression affects 30% of people every year, and early detection can make a big difference.

Artificial intelligence can help doctors find depression early and get people to the right level of care . Many researchers are working on ways to increase screening, and voice biomarkers have early promise. The purpose of this study is to find correlations between voice and how people sound with clinical diagnoses.

1,000 people will take part in this research.

### How long will I be in this research?

The study will last 45 minutes or less:

1. You will be asked to complete a web-based survey similar to the one you participated in prior (15 min)
  - Voice recorded section: 3 questions that are up to 60 seconds each.
  - 16 multiple choice questions that ask a range of how you're feeling.
2. A clinical assessment from a licensed mental health professional immediately following the survey above (30 min)
  - You will be scheduled to meet with a mental healthcare professional who will evaluate your mental state.
  - This will only be a clinical assessment and will not involve treatment of any kind.

## **What happens to me if I agree to take part in this research?**

### **Part I**

If you decide to join, you'll be asked to take the online survey.

The survey will ask if you're able to record your voice, and if you are, you'll answer the following questions aloud:

1. *How are you feeling today? Please speak for 1 minute about your day, if there was anything special about it and overall, how you felt.*
2. *What is your biggest source of stress and why?*
3. *What or who are you grateful for today?*

The above recordings will be analyzed for pitch, tone, and other traits. If you do not agree to be recorded, you will be unable to join the study.

After 3 recorded sections you will complete 2 self-assessments: PHQ-9 and GAD-7. The Patient Health Questionnaire and Generalized Anxiety Disorder tests have 16 questions in total. These assessments will immediately follow the recorded section.

### **Part II**

Shortly thereafter, you will be asked to follow a link to start a video conference call for you and a mental health professional (MHP). The MHP will evaluate your current mental health status, including asking for your current medications. Some medications affect voice biomarkers and for our study we want to be able to separate the effect of depression and anxiety vs the effect of medication from the voice biomarkers. The information is stored on a password protected location only accessible to the PI and the research coordinators. When the study is over, the Personal Health Information (the email addresses) will be deleted, and coding will be used to match the records going forward.

## **Potential risks**

The most important risks or discomfort you may expect from taking part in this research include:



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- There is always the potential for breach of confidentiality. To minimize this risk, all entries are encrypted. Researchers will store all data in a secure, password protected Google Cloud Platform bucket. Researchers will also use Named Entity Recognition (NER) and scripts to take out names, locations, and numbers.
- Participation may bring up emotional content which could temporarily impact your mood. To minimize this risk, everyone will be emailed a list of mental health resources.

## **Will it cost me money to take part in this research?**

There is no cost to you for participation.

## **Will being in this research benefit me?**

There may be no direct benefit from participation. Possible indirect benefits include:

- Reduction in anxiety.
- Reduction in stress.

## **What other choices do I have besides taking part in this research?**

You can choose not to participate.

## **What information will you collect during this research?**

We will only collect personal information about you which is directly related to the research or as required to provide you with your participation payment, including:

- Email address
- Voice samples
- Demographic information

## **What happens to the information collected for this research?**

Your private personal information including audio recordings, email address, survey responses and other information will only be shared with a third party as necessary to perform the study. These parties include the following:

- The research sponsor.
- Research study personnel.
- The Institutional Review Board (IRB) that reviewed this research.

No other groups will have access to this study data. We take data privacy seriously and protect your information to the full-extent required by the law. We cannot 100% guarantee that data will remain secure. The audio recordings and survey responses will be maintained for at least three years

following the completion of the study in case of FDA audits. This is only accessible by the PI and

**Solutions**

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Research Coordinator. After the study has finished, the names, phone numbers, and emails will be deleted. Participants will only be referenced by the unique ID.

## **Who can answer my questions about this research?**

The Research team is here to answer any questions, issues, or complaints. The phone number is at the top of this form. In the event of a research-related injury, please contact:

Alice Kim  
Research Coordinator  
(415) 275- 0116  
[alice@kintsugihello.com](mailto:alice@kintsugihello.com)

If you have questions about your rights as a participant in the study, please contact:

Solutions IRB  
(855) 226-4472  
[participants@solutionsirb.com](mailto:participants@solutionsirb.com)

## **Can I be removed from this research without my approval?**

You may be removed without approval for the following reasons:

- It is in your best interest.
- The research is canceled by the sponsor.

We will provide any information that may affect your decision to stay in this research study.

## **What happens if I agree to be in this research, but I change my mind later?**

If you decide to leave before completion, please let the Research Coordinator know by phone, text, or email. There is no penalty if you choose to leave the study anytime. All data collected up to that point, will be discarded and not used for analysis.

## **Will I be paid for taking part in this research?**

Yes, you will receive a \$50 USD Amazon Gift card, PayPal or Visa card via email. Partial or fraudulent completions will not be paid. \$50 will be for 3 voice entries, two tests (PHQ-9 and GAD-7) and a clinical assessment with the MHP. Everyone who finishes the steps of the study will be emailed the Gift cards within 6 days.

You may also download the Kintsugi voice journaling app for free (normally, \$19.99 in the Apple App Store). Kintsugi app support, [support@kintsugihello.com](mailto:support@kintsugihello.com) will be available anytime for questions or feedback.

## **Conflict of Interest Disclosure**

The PI and Research coordinators of this study are employed by Kintsugi Mindful Wellness, Inc. The Research Associates of this study are contractors of Kintsugi Mindful Wellness, Inc. The National Science Foundation supports Kintsugi's research and development but does not fund this study. This disclosure is provided so that you can decide if this affects your decision to join.

## **Statement of Consent:**

By clicking 'I consent', you agree to take part in this research.

I consent to being audio recorded as part of this research study.

I understand that if I do not consent to being audio recorded, I cannot participate in this study.

I understand that you may disclose my personal information to a third party solely for the purposes of conducting this study.