RESEARCH SUBJECT CONSENT FORM

Title:	**Kintsugi Voice Device API Pilot Study**
Protocol No.:	2022/02/12
Sponsor:	Kintsugi Mindful Wellness, Inc. (“Kintsugi”)
Investigator:	Grace Chang Kintsugi Mindful Wellness, Inc. 1569 Solano Avenue, No. 365 Berkeley, CA 94707 USA
Study-Related Phone Number(s):	341-529-1188

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 opt out at any time.
- Feel free to ask questions anytime.
- Ask any questions before making your decision.

Why is this research being done?

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

Artificial intelligence can help doctors find depression and/or anxiety early and get people to the right level of care earlier. Many researchers are working 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.

Up to 100 people will take part in this research.

How long will it take for me to participate in this research?

The time required for your participation in the study will be approximately 2 hours or less and includes an eligibility screening call. After the initial screening call, you will be scheduled for a structured clinical interview with a psychiatrist (up to 90 minutes) and also asked to complete online self-assessments (approximately 15 minutes).

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

You will complete two self-assessment surveys that ask a total of 16 questions about your mental health: the Patient Health Questionnaire (PHQ-9) and Generalized Anxiety Disorder (GAD-7).

The Research Coordinator will set up a teleconference with a doctor to evaluate your current mental health status using the Structured Clinical Interview for DSM-5. The interview will be videotaped and the audio will be recorded. If you do not agree to be videotaped and recorded, you will be unable to join the study. The video recording is for quality assurance purposes.

The results of the SCID-5 will be shared with you. As described in more detail below, the diagnosis that is shared with you is for general information purposes only and is not intended for treatment purposes. The doctor will also share your personal information, including without limitation the results of the SCID-5, your diagnosis and treatment history with the Research Coordinator and other members of the research team.

You will be randomly assigned to either complete the self-assessment surveys or the SCID-5 first.

The audio recorded during the clinician SCID-5 assessment will be inputted to the Kintsugi Voice Device to receive a prediction for risk of depression and anxiety. The Kintsugi Voice Device prediction will not be shared with you.

Will I receive any treatment or diagnosis as part of this research?

This study is intended for research purposes and is <u>not</u> intended for treatment and/or diagnostic purposes. Any results or diagnoses that are shared with you are for your general information purposes only. Based on the episodic nature of your participation in the research, there are limitations to its study and that it may not represent your overall well being. Your participation in this research, including any communications with the doctor, is not intended to create an ongoing physician-patient relationship between you and the doctor.

Although you will be provided with the results of the evaluation, all such information is provided as a courtesy and does NOT constitute any formal diagnosis, nor is the information part of any formal medical record. If you feel you need further evaluation you should follow-up through your regular physician or how you would regularly access medical care. If the clinician who evaluates you believes that you will benefit from formal medical evaluation or treatment, they will refer you to your regular physician or how you would regularly access medical care. In the rare circumstance that the doctor believes there is an emergency or that your health is in imminent danger, the clinician may opt to call 911 or refer you to your closest emergency department. If the clinician feels you present an imminent risk to yourself or others, necessary steps will be taken. You should not view this study as an opportunity to receive diagnosis and treatment for any medical condition, as the study is only to provide results to the study, and does not establish any medical relationship between you and either the physician evaluator nor with Kintsugi the sponsor of this study. If you are seeking or otherwise in need of treatment,

including for depression or other clinical conditions, we recommend that you contact your health care provider for such treatment or any other questions that you may have regarding your health.

If you are experiencing, or think you may be experiencing, a medical emergency, call 911 or seek other immediate medical attention.

Potential risks

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

- Given the episodic nature of your participation in the research, there is the risk that the results that are shared with you may not accurately reflect your overall wellbeing.
- There is always the potential for breach of confidentiality. To minimize this risk, all entries are encrypted. Researchers de-identify personal information using IDs. Researchers will store all data in a secure, password protected REDCap Cloud and Google Cloud Platform bucket.
- 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 stress.
- Learning more about mental health.

Benefits are not guaranteed.

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

You can choose not to participate. Refusing to participate or withdrawing from the study does not incur any penalties or loss of benefits to which the subject is otherwise entitled.

What identifiable information will be collected during this research?

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

- Name
- Phone Number
- Email address
- Voice recordings of Structured Clinical Interview for DSM-5 (SCID-5)
- Video recordings of SCID-5
- Demographic information
- Emergency contact and physical location during study
- Basic medical history
- Results of Structured Clinical Interview for DSM-5 (SCID-5)

Identifiable data will be kept for 7 years. De-identified data will be kept indefinitely.

What happens to the information collected for this research?

Your private personal and health information including video and 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:

- Research study personnel of Kintsugi and its vendors assisting on the research, including but not limited to the doctor conducting the SCID-5 and SCID reviewer
- Regulatory bodies (e.g. the US Food and Drug Administration (FDA))
- The Institutional Review Board (IRB) that reviewed this research.

Kintsugi may conduct additional research activities in connection with the development of its artificial intelligence products. To the extent I consent, the information that is collected as part of this research can be used and disclosed by Kintsugi with its research study personnel, regulatory bodies, and relevant IRB oversight bodies, in connection with such future research.

No other groups will have access to this study data. We take data privacy seriously and protect your information by the law. We cannot 100% guarantee that data will remain secure. The video and audio recordings and survey responses will be stored accordingly in case of FDA or other applicable audits. Participant confidentiality will be protected by using a uniquely generated ID.

Who can answer my questions about this research?

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

Do Hyung Kim
Research Coordinator
(341) 529-1188
david@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

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 of all study steps, please let the Research Coordinator know by phone, text, or email. There is no penalty if you choose to leave the study anytime. To the extent not already relied upon, all data collected up to that point, will be discarded and not used for further analysis.

Will I be paid for taking part in this research?

Yes, you will receive a $50 USD Amazon Gift card via email. Incompletes will not be paid. Everyone who finishes the steps of the study will be emailed the Gift cards within 14 days of completion.

Conflict of Interest Disclosure

The PI and Research Coordinators of this study are employed by 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:

Your signature documents your consent to take part in this research.

I consent to being audio and video recorded as part of this research study. I further consent to further use and disclosure of my audio and video recordings as part of future research activities conducted by Kintsugi. By signing the ICF, you confirm that you meet all the inclusion criteria and no exclusion criteria. You confirm that you are over 22 years old, are able to read and understand English, have access to a device with a functioning microphone, will be videotaped and comply with study procedures, and reside within the state of California. You also confirm that you do not have any visual, motor, hearing impairment or medical condition that may prevent you from completing the online survey and/or clinician assessment or bias model performance including but not limited to neurodegenerative disorders, schizophrenia, voice and disorders. You also confirm that to the best of your knowledge, you have not participated in any Kintsugi-sponsored study previously.

I acknowledge and agree that this study is not intended for treatment purposes and no ongoing doctor-patient relationship is created based on my participation in the study. I agree to be in a private setting when I have the clinician assessment over teleconference. Any results or diagnoses that are shared with me are for my general information purposes and may not be accurate, complete, or otherwise represent my overall wellbeing. I further acknowledge and agree that, to the extent that I am in need of treatment or other services relating to my health, I am responsible for seeking such services from my health care provider. I will also contact my health care provider if I have any questions relating to my health. I shall not rely on my participation in this research to receive such services.

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

I understand and agree that you may use and disclose my personal and health information as described in this consent.

Signature of adult subject capable of consent.	Date.

Signature of person obtaining consent.	Date.

HIPAA Authorization Form

If you sign this document, you give permission to Kintsugi Mindful Wellness, Inc. ("Kintsugi") and the study researchers to use or disclose (release) your health information that identifies you for the research described below:

Kintsugi Voice Device API Pilot Study and other future research activities relating to Kintsugi products.

You agree that Kintsugi and the study researchers may share your health information with:

The vendors and providers assisting Kintsugi and the research team on the research for purposes such as review of psychiatrist interviews for variability, applicable institutional review board in case of an audit, and the U.S. Food and Drug Administration (FDA), the U.S. Department of Health and Human Services (HHS), or other applicable regulatory body in case of an audit or premarket submission.

Your health information may be further shared by the groups above. If shared by them, the information may no longer be covered by this authorization and may be further disclosed without your permission.

This authorization is voluntary and you do not have to sign this form. However, if you do not sign this form, you cannot participate in the research study.

Information collected includes but is not limited to:

- Voice sample provided as an audio recording
- Video recording of the psychiatrist interview
- Results of the surveys completed
- Medical history related to inclusion/exclusion criteria

You may change your mind and withdraw or take back your permission at any time by writing to: Do Hyung Kim at david@kintsugihello.com. When you withdraw your permission, your participation in the study will terminate and no new health information identifying you will be gathered after that date. All of your identifiable health information will be deleted after 7 years except to the extent Kintsugi already has taken action in reliance on your prior authorization or as otherwise required by law. This authorization shall remain in place unless earlier revoked as set forth herein.

HIPAA Authorization Signature:

Signature of adult subject capable of consent.	Date.
Signature of person obtaining consent.	Date.