



INDIANA UNIVERSITY



Syrenity

## SYRA HEALTH INFORMED CONSENT STATEMENT FOR RESEARCH

### Mental Health-App for Improving Depression

**You are being asked to participate in a research study.** Scientists do research to answer important questions that might help change or improve the way we do things in the future. This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study. The purpose of this study is to study how useful our mental health app (“Syrenity”) is for helping you with your mood. Risks of participating in this study include: feeling uncomfortable answering questions related to your mental health or a potential loss of confidentiality. It is possible that if you are assigned to the condition that receives the Syrenity app that it could improve your mood and functioning. If you participate in this study we will ask you to complete surveys after you consent, for us to know you better. After, we will send you weekly surveys (~5 minutes), a 10-15 minute survey at the end of the study, and 10-15 minute survey six weeks after that. You will be compensated for completing the survey today (\$25 Amazon gift card), at the end of the study (\$25 Amazon gift card), and if you complete at least 3 out of the 5 weekly surveys (\$10 Amazon gift card). The follow-up survey six weeks after that is unpaid.

**Number of participants.** We will recruit 300 participants, half of whom will be assigned to the Syrenity app condition, and half who will receive access to the Syrenity app six weeks after entering the study.

**To be eligible for this study.** You must be at least 18 years of age, use an iPhone or Android phone, and be fluent in English.

**All research is voluntary.** You can choose not to take part in this study. If you decide to participate, you can change your mind later and leave the study at any time. You will not be penalized or lose any benefits if you decide not to participate or choose to leave the study later.

**The purpose of this study** is to test the usefulness and acceptability of the Syrenity app. If you participate, you will be randomized, like flipping a coin, to either receive the Syrenity app right away or in 6 weeks.

[Insert Protocol-specific version number]

We are asking you if you want to be in this study because you clicked on the link advertised on social media or found out about the study elsewhere. The study is being conducted by SYRA Health. This is an online study and is not being conducted in a place of medical or psychological treatment.

**If you agree to be in the study, you will do the following things.**

First you will complete some questionnaires, which will ask about things like demographic information (e.g., age), mental health, and your overall well-being. The survey should take around 15 minutes to complete. You will be notified at the end of the survey of your eligibility. If you are eligible, you will provide your contact information including phone number and email address.

After completing the baseline survey, if you qualify you will either be given access to the Syrenity app right away, or be told that you will receive access in 6 weeks. The app will consist of a series of interactive interventions and education content that teach you about health and well-being. **You must have an iPhone or Android to use the app.**

Depending on which condition you are placed in, you will either be given access to the Syrenity App right away or be given access to it in 6 weeks.

**Syrenity App Condition:** The Syrenity App is a mental health app that has been designed to help improve mental health and well-being. The content on the app was created using cognitive-behavioral therapy principles. It uses both active and passive interventions. Active interventions are interventions where the user engages with the app in a back and forth dialogue (e.g., a conversation about restructuring unhelpful thoughts). Passive interventions meanwhile consist of text or videos that the user can read or watch and do not require dialogue with the app.

You will be asked to complete a survey today that will take around 15 minutes to complete. You will be given access to the Syrenity App to download it onto your cell-phone. You will be sent a brief weekly survey each week (a total of five). After six weeks we will ask you to complete a survey similar to the one that you complete today that will take around 10-15 minutes. Finally, after 12 weeks we will ask you to complete a follow-up survey that will take 10-15 minutes. We will provide you with your scores on some psychological symptom measures which may impact your decision to stay in the study or not.

When	What do I have to do?	How much will I be paid?
Today	Complete 15 minute survey + download Syrenity App	\$25
In one week	Complete 2-5 minute survey	*
In two weeks	Complete 2-5 minute survey	*
In three weeks	Complete 2-5 minute survey	*
In four weeks	Complete 2-5 minute survey	*
In five weeks	Complete 2-5 minute survey	*

In six weeks	Complete 10-15 minute survey	\$25
In twelve weeks	Complete 10-15 minute survey	Unpaid

\*if you complete at least 3 out of the 5 week one through week five surveys you will receive a \$10 bonus

**Waitlist Condition:** You will be asked to complete a survey today that will take around 15 minutes to complete. You will be sent a brief weekly survey each week (a total of five). After six weeks we will ask you to complete a survey similar to the one that you complete today that will take around 10-15 minutes. Finally, after 12 weeks we will ask you to complete a follow-up survey that will take 10-15 minutes. At the end of the study, you will be given access to the Syrenity App to download it onto your cell-phone if you would like.

When	What do I have to do?	How much will I be paid?
Today	Complete 15 minute survey	\$25
In one week	Complete 2-5 minute survey	*
In two weeks	Complete 2-5 minute survey	*
In three weeks	Complete 2-5 minute survey	*
In four weeks	Complete 2-5 minute survey	*
In five weeks	Complete 2-5 minute survey	*
In six weeks	Complete 10-15 minute survey	\$25
In twelve weeks	Complete 10-15 minute survey	Unpaid

\*if you complete at least 3 out of the 5 week one through week five surveys you will receive a \$10 bonus

**Before agreeing to participate, please consider the risks and potential benefits of taking part in this study.**

There is a risk of possible loss of confidentiality. All research interactions will occur on secure platforms (e.g., Syrenity App, REDCap), and your data will be kept in a secure location. Nonetheless, we cannot guarantee that your confidentiality is 100% secure, for example, if you complete measure or use the Syrenity App in front of other people. In order to prevent your information from no longer being confidential the research team has made sure that your answers are stored within a protected database. Only the research team will have access to your information during the time of the study. We do not believe that there will be any issues of confidentiality but please be aware that a breach of confidentiality could place you at additional risk. This study will ask questions about your mental health. Any breach of confidentiality could result in damage to your reputation, negative stigma or your ability to be employed.

You could experience some discomfort in answering the survey questions. If at any time you feel uncomfortable with one of the survey questions or if you feel uncomfortable answering any section of the survey you are allowed to skip that question. You are also allowed to decide if you would like to complete the research study or withdraw. Please contact anyone on the research team **such as** the PI [lolorenz@indiana.edu](mailto:lolorenz@indiana.edu). ***If you need emotional or psychological support the researcher will provide written information for mental health services/treatment.***

We do not anticipate any additional risks, but there is always the possibility of unforeseeable risks that we have not identified. No compensation will be provided for injuries.

We may terminate your participation from this study under certain circumstances. For example, if we are concerned about your safety.

In the event that your symptoms worsen or you feel the need to seek outside help, participating in this study will not prohibit you from seeking other treatment (e.g., individual therapy or medication). We do not anticipate that withdrawing from this study will put you in any additional mental health risk.

It's possible you may experience personal benefits from taking part in this study. The Syrenity App may teach you new skills. Additionally, there is a chance that you may experience a reduction in your anxiety, stress, or depression symptoms.

**You will be paid for participating in this study.** You will receive \$25 for the baseline assessment, \$25 for the assessment at the end of the study (after week 6), and \$10 if you complete at least 3 out of the 5 weekly 2-5 minute surveys, totaling \$60 if you complete the entire study. Payment will be provided in the form of **Amazon gift cards** and will be provided directly after completing each respective assessment. **There is no cost to participate in the study. We will not pay participants if they are deemed to be fraudulent responders as indicated by unduly fast responding, inconsistent responses, duplicate contact information, or other anomalous behavior (e.g., completing the survey when we are not recruiting).**

**We will protect your information** and make every effort to keep your personal information confidential, but we cannot guarantee absolute confidentiality. No information which could identify you will be shared in publications about this study.

Your personal information may be shared outside the research study if required by law. We also may need to share your research records with other groups (e.g., the IRB) for quality assurance or data analysis, including state or federal agencies who may need to access the research records (as allowed by law). Identifiable information will be retained for three years.

Information collected in this study may be used for other research studies or shared with other researchers for future research. If this happens, information that could identify you, such as your name and other identifiers, will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent, however, you may withdraw your consent (see below).

**If you have questions about the study or encounter a problem with the research,** contact the researcher, Lorenzo Lorenzo-Luaces at 812-856-0866.

For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact Pearl IRB at 317-899-9341.

#### **Pearl IRB**

Hours: Monday through Friday: 9-5 EST/EDT

29 East McCarty Street Suite 100 Indianapolis, IN 46225 support@pearlirb.com 317-899-9341 (main)  
317-602-6554 (fax) <https://www.pearlirb.com/>

**If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future.** If you decide to withdraw, you can inform the PI, Lorenzo Lorenzo-Luaces at 812-856-0866, and we will help you exit the study.

Please note that this App is not intended to be used in place of medical or psychological treatment or diagnosis.

**If you are interested in treatment below are some resources that you may use to find a treatment:**

#### **Resources for finding treatments:**

U.S. Department of Health & Human Services: <https://www.findtreatment.gov>

Mental Health America: <https://mhanational.org/get-help>

National Alliance on Mental Illness: <https://www.nami.org/findsupport>

Call: 211

988 Suicide and Crisis Lifeline: Call 988

#### **PARTICIPANT'S CONSENT**

In consideration of all of the above, I agree to participate in this research study. I will be given a copy of this informed consent document to keep for my records.

**Select "I consent" or "I do not consent or I am not eligible"**