

## CONSENT TO TAKE PART IN A RESEARCH STUDY

**Title of Study:** Supplementing brief psychotherapy with a mobile app (Project ACTIVATE)

**Principal Investigator:** Evan Kleiman, Ph.D.

**RESEARCH SUMMARY:** This consent form explains a research study to help you decide if you want to take part. Participation is completely voluntary.

**PURPOSE:** The study tests a smartphone app designed to support the skills you learn in therapy. If you join, you'll complete surveys today, then install the app after discharge and answer brief daily surveys for 4 weeks. The study lasts from now until 28 days after you leave the hospital, with an optional follow-up survey 3 months later. The first day takes about 35–60 minutes; other days take 15–25 minutes.

**RISKS/BENEFITS:** Some survey questions may cause discomfort. If you report being at immediate risk of self-harm, we may need to break confidentiality to ensure your safety. There are no direct benefits to you, but the study may help others in the future.

**ALTERNATIVES:** You may choose not to take part in this study.

The information in this consent form will provide more details about the research study and what will be asked of you if you choose to take part in it. If you have any questions now or during the study, if you choose to take part, you should feel free to ask them and should expect to be given answers you completely understand. After your questions have been answered and you wish to take part in the research study, you will be asked to sign this consent form. You are not giving up any of your legal rights by agreeing to take part in this research or by signing this consent form.

### Who is conducting this research?

Evan Kleiman, Ph.D. is the Principal Investigator of this research study. A Principal Investigator has the overall responsibility for the conduct of the research. However, there are often other individuals who are part of the research team.

Dr. Evan Kleiman may be reached at:  
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Piscataway, NJ 08854  
848-445-2345 | [kleimanlab@psych.rutgers.edu](mailto:kleimanlab@psych.rutgers.edu)

The Principal Investigator or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

**Sponsor of the Study:** This study is sponsored by the American Foundation for Suicide Prevention, in part.

### Why is this research being done?

After hospitalization, it can be hard to apply the skills you learned in therapy, which may reduce their effectiveness. This study tests a smartphone-based tool designed to help you practice those skills in daily life.

### The app may help in two ways:

1. It makes it easier to practice skills outside of therapy, even when you're not distressed, by giving you quick access to instructions.
2. If you're feeling distressed, the app provides immediate support by guiding you through the skills.

This study also aims to improve these exercises for future use.

### Who may take part in this study and who may not?

All patients receiving group therapy at Rutgers University Behavioral Health Care (UBHC) are eligible to take part in this study pending the presence of any factor that impairs an individual's ability to provide informed consent and comprehend and effectively participate in the study including: an inability to speak or write English fluently, the presence of gross cognitive impairment due to florid psychosis, intellectual disability, dementia, acute intoxication, or the presence of extremely agitated or violent behavior.

### Why have I been asked to take part in this study?

We invite you to take part in this research study because you are an adult patient who has been admitted to and received up to five sessions with a clinician that explained cognitive and behavioral therapeutic content at Rutgers University Behavioral Healthcare (UBHC).

### How long will the study take and how many subjects will take part?

This study will last from now until 28 days after you leave the hospital. As you will see below, study activities in the first day will require about 35 to 60 minutes. The remaining days should require about 15 to 25 minutes each day. We expect that 500 people will take part in this study. The entire study will last until 500 participants have completed the study.

### What will I be asked to do if I take part in this study?

The table below lists the main activities in the study, as well as how long each activity will take each day and over the course of the study. Below the table is more description of what we will ask you to do.

Timeline		Major activities (time to complete)
During your inpatient stay	Day 1 (today)	- Consenting (15 minutes) - Initial survey (20 minutes)
	Near discharge	- Training on apps (15 minutes) - Discharge survey
After you leave the hospital	After discharge	- Download smartphone app - Discharge survey if you have not yet completed it
	Every day for 28 days	- Daily tasks (15-25 minutes) - Complete one weekly smartphone survey (15 minutes)
	Three months after you leave the hospital	- Complete one follow-up survey

**If you decide to take part in this study, we will ask you to complete the following:**

1. **Initial Survey:** We will ask you to complete a series of self-report surveys, which will ask you questions about your demographic background and mental-health related factors. This will occur today and take approximately 20-30 minutes to complete.
2. **Smartphone App Training:** Either during the initial consent session or near discharge, the study research assistant will meet with you to show a demo of the MetricWire app on an iPad. This will and take approximately 15 minutes to complete.
3. **App Download and Discharge Survey:** After you are discharged from the hospital, the study research assistant with contact you to walk you through downloading and setting up the smartphone app. We will also ask you to complete a discharge survey that asks questions about your experiences in the study so far. This is expected to take approximately 15 minutes to complete.

The MetricWire app will send you brief, daily surveys throughout the day. The app requires minimal use of your cellular data and will use WiFi if you have a connection.

4. **Daily Smartphone Surveys:** We will ask you to complete 4 brief daily surveys through the MetricWire app on your phone for 28 days after you leave the hospital.

At least one of the surveys will be assessments that ask you about self-injurious thoughts and behaviors as well as related factors such as mood and sleep. Three surveys will be exercises to practice the skills you learned with the study therapist. The last survey will be a nightly survey that asks questions about your whole day.

In the MetricWire app, you also have the option of practicing the learned skills at any time through the skills practice survey. We ask that you use this survey if you feel distressed and want to practice a skill.

5. **Weekly and monthly survey:** Each week that you are in the study you will receive 1 weekly smartphone survey. This survey will also ask you questions about what you experienced in the prior week. It will take about 15 minutes to complete. We will send a similar survey three months after you leave the hospital.

**Other information:**

**Electronic Medical Record:** As a part of this study, we will collect information from your electronic medical record to test whether the information that you provide in your surveys can help us to predict how you do after leaving the hospital better than the information that the hospital has already collected from you. We will collect information from the first time you came to **UBHC** until 6 months after you finish the 28-day post-hospital period.

**Contacting you:** We may call, email, or text you throughout the study to check-in regarding study technology, engagement, and compliance. We may also contact you in the future to see if you are interested in participating in other studies that you may be eligible for. You may choose to opt out of this option at the bottom of this consent form.

**What are the risks of harm or discomforts I might experience if I take part in this study?**

There are some risks you might experience from being in this study.

**Feeling Upset (Psychological Distress):**

Some questions in the study are personal and may feel upsetting—for example, questions about suicide or self-harm. In rare cases, answering these questions repeatedly might increase those thoughts. You can skip any question you don't feel comfortable answering.

**Risk to Safety (Loss of Confidentiality):**

If we believe you—or someone else—is at serious risk of harm, we may take steps to help keep you safe. This might include sending emergency resources through the app, calling you to follow up, advising you to contact your clinician, or recommending you go to the ER or call 911. If you're in the hospital and we're concerned about your safety, we may notify the clinical staff. We'll keep you informed of any new information that may affect your safety or decision to stay in the study.

**Privacy Concerns (Loss of Privacy):**

There's a small chance someone might see you using the app or completing surveys and learn you're in the study. To reduce this risk, we encourage you to complete surveys in private. There's also a small risk of a data breach. We protect your information by using ID numbers (not your name) and storing all data on secure, encrypted servers. While we've taken strong steps to keep your data safe, no system is completely risk-free.

**IMPORTANT!**

We will ask questions about suicide on your smartphone, but it's important to know that we cannot see your responses in real time and cannot guarantee your safety during the study. If your answers suggest you're thinking about suicide, you may see an automatic pop-up encouraging you to seek help. These messages are not monitored live by our team.

If you feel very upset or have strong urges to harm yourself during the study, please contact your clinician, call 911, or go to the nearest emergency room.

A member of our research team will check study data each day. If we notice something concerning, we may try to contact you by phone, text, or email to check in and possibly do a brief safety assessment. If we can't reach you, we may call one of two emergency contacts you provide (such as a family member or your mental health provider). We will only reach out to them if we've tried multiple times to reach you directly or if we're seriously concerned about your safety.

Because we don't monitor responses in real time, please don't rely on the app or research team for immediate help. It's your responsibility to reach out for support if you are in danger. Use 911, go to the emergency room, or contact your clinician if you are at risk.

**Are there any benefits to me if I choose to take part in this study?**

There are no direct benefits to you from your participation in this research. We cannot promise any benefits to others from your participation in this research. However, we expect the knowledge gained from this research will help other people in the future. Your participation will result in greater

knowledge about the factors that contribute to effective use of therapy skills post discharge from hospitalization. This understanding will be important in helping individuals who have been recently hospitalized.

**What are my alternatives if I do not want to take part in this study?**

There are no alternative treatments available. Your alternative is not to take part in this study.

**How will I know if new information is learned that may affect whether I am willing to stay in the study?**

During the study, you will be updated about any new information that may affect whether you are willing to continue taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

**Will there be any cost to me to take Part in this study?**

Taking part in this study may lead to added costs to you. If we text or call you, standard text messaging and call fees apply. You may inform us that you would like to opt out of text messages at any time throughout the study.

**Will I be paid to take part in this study?**

If you agree to take part in this research study, we will pay you up to \$120 for your time and effort. A summary of the payment schedule is in the table below.

ITEM	Compensation (per item)	Frequency	Total
Completing each daily assessment/ exercise	\$0.50	5x/day	\$70
Completing baseline survey	\$10.00	1x/study	\$10
Completing discharge survey	\$5.00	1x/study	\$5
Completing optional weekly surveys	\$5.00	3x/study	\$15
Completing optional 4 <sup>th</sup> week and 3 month survey	\$10	2x/study	\$20
		SUBTOTAL	\$120

You can choose to be compensated through a gift card (e.g., Amazon.com). You will be compensated at the following points: (1) When you leave the hospital and (2) upon completion of weekly surveys, (3) after the conclusion of the study

**How will information about me be kept private or confidential?**

We will do everything we can to keep your personal information private, but we cannot promise complete confidentiality.

Here are the steps we're taking to protect your privacy:

1. We will store your name and other identifying details separately from your survey responses so no one outside the research team can connect them to you.
2. The apps we use will store your data in a secure, encrypted way. Your data will go from your device over Wi-Fi to a secure cloud, and then to our protected study server.
3. Any data we use from your medical record will be linked to your other data using a code number—not your name.
4. Your personal information will **not** be shared with anyone except:
  - Members of the research team
  - Members of the ethics board that oversees the research
  - Public health and safety authorities (for example, if we learn that you or someone you know may be at risk of harm)
  - Any people that you identify that we can contact to help us find you if we are unable to reach you directly. We will ask you to give us the contact information (e.g., phone number, email address) for at least one emergency contact that we can reach out to if we need to get ahold of you but cannot. If we do reach out to your emergency contact, we will only tell them that we are trying to get ahold of you. We will not tell them about the study you are in.

If you provide someone else's personal information (for example, an emergency contact) you should make them aware that you have provided the information to us. We will only use such personal information in accordance with this informed consent form and applicable law.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent. The results of this research study may be published in a medical book or journal or used to teach others. However, your name or other identifying information will not be used for these purposes without your specific permission.

The research team may use or share your information collected or created for this study with the following people and institutions:

- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services

A description of this research study will be available on [ClinicalTrials.gov](https://clinicaltrials.gov), as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research.

What will happen to my information—data, recordings and/or images—collected for this research after the study is over?

- After information that could identify you has been removed, de-identified information collected for this research may be used for other research we conduct without obtaining additional informed consent from you.
- We will share your **coded** data (coded with a study identification number and without personal identifiers) with research teams that our study collaborates with.
- If we remove your name and other identifying information from the data or samples collected in this study, they may be used in future research or shared with other researchers without asking you again. The results of this study may be published or used for teaching, but your name or any identifying details will not be included unless you give permission.

What will happen if I do not wish to take part in the study or if I later decide not to stay in the study?

It is your choice whether to take part in the research. You may choose to take part, not to take part or you may change your mind and withdraw from the study at any time. If you do not want to enter the study or decide to stop taking part, your relationship with the study staff will not change, and you may do so without penalty and without loss of benefits to which you are otherwise entitled.

You may also withdraw your consent for the use of data already collected about you, but you must do this in writing to Dr. Evan Kleiman at Tillett Hall, 53 Avenue E, Piscataway, NJ 08854.

You can leave the research at any time, and it will not be held against you. If you do decide to leave (withdraw from) the study, you do not have to leave the entire study. If you decide to withdraw, we will ask you some questions about why you want to withdraw (which will help us in the future) and will give you some options to stop parts of the study, but not the entire study. For example, you may be able to stop the assessments, but continue doing surveys and exercises.

Who can I contact if I have questions?

If you have questions, concerns or complaints about the research, wish more information or if you feel you may have suffered a research related injury, you can contact the Principal Investigator: Dr. Evan Kleiman at [kleimanlab@rutgers.edu](mailto:kleimanlab@rutgers.edu)

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research subject, you can contact the Rutgers IRB or the Rutgers Human Subjects Protection Program via phone at (973) 972-3608 or (732) 235-2866 or (732) 235-9806

OR via email [irboffice@research.rutgers.edu](mailto:irboffice@research.rutgers.edu), or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

## PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR A RESEARCH STUDY

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your medical record in this research. Your information will only be used as described here or as allowed or required by law. If you sign this consent form, you agree to let the investigators use your identifiable health information in the research and share it with others as described below. Ask questions if there is something you do not understand.

### What Is The Purpose Of The Research And How Will My Information Be Used?

You are being invited to take part in this research study which is described at the beginning of this form. The purpose of collecting and using your health information for this study is to help investigators answer the questions that are being asked in the research.

### What Information About Me Will Be Used?

All information in your medical record (relevant to your psychiatric treatment)

### Who May Use, Share or Receive My Information?

The research team may use or share your information collected or created for this study with the following people and institutions:

- Rutgers University Investigators Involved in the Study
- The Rutgers University Institutional Review Board and Compliance Boards
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- Hospital Personnel as Necessary For Clinical Care
  - Rutgers University Behavioral Healthcare (UBHC)

Those persons or organizations that receive your information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, if permitted by the laws governing them.

### Will I Be Able To Review My Research Record While The Research Is Ongoing?

No. We are not able to share information in the research records with you until the study is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research study.

**Do I Have To Give My Permission?**

No. You do not have to permit use of your information. But, if you do not give permission, you cannot take part in this study. (Saying no does not stop you from getting medical care or other benefits you are eligible for outside of this study.)

**If I Say Yes Now, Can I Change My Mind And Take Away My Permission Later?**

Yes. You may change your mind and not allow the continued use of your information (and to stop taking part in the study) at any time. If you take away permission, your information will no longer be used or shared in the study, but we will not be able to take back information that has already been used or shared with others. If you say yes now but change your mind later for use of your information in the research, you must write to the researcher and tell them of your decision: Dr. Evan Kleiman at Tillett Hall, 53 Avenue E, Piscataway, NJ 08854.

**How Long Will My Permission Last?**

Your permission for the use and sharing of your health information will last until the end of the monitoring period, which is 6 months after your discharge from UBHC.

**AGREEMENT TO TAKE PART IN RESEARCH**

Subject Consent:

I have read this entire consent form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form and this study have been answered. I agree to take part in this study.

Subject Name (Print): \_\_\_\_\_

Subject Signature: \_\_\_\_\_ Date: \_\_\_\_\_

