Pro2021001233 Consent Forms

Type	Last Update	Page Number
Parent Permission - ODU	Mod 11	2
Teen Assent - ODU	Mod 11	
Teen Consent - ODU	Mod 11	
Parent Permission - Rutgers	Mod 11	
Teen Assent - Rutgers	Mod 11	
Teen Consent - Rutgers	Mod 11	

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PARENTAL/LEGAL GUARDIAN PERMISSION TO PERMIT CHILD TO TAKE PART IN RESEARCH

TITLE OF RESEARCH: Sleep treatment for teens
Principal Investigators: Catherine Glenn, Ph.D., Old Dominion University; Evan Kleiman, Ph.D., Rutgers, the State University of New Jersey

RESEARCH SUMMARY: This parental/legal guardian permission form is part of an informed consent process for a research study, and it will provide information that will help you decide whether you want your child to take part in this research. It is your choice to allow your child to take part or not.

PURPOSE: The purpose of the research is to test the effectiveness of a digital sleep treatment for teens with suicidal thoughts and behaviors, who also have insomnia. If your child takes part in the research, they will be asked to: Phase 1 (one time): answer questions in an interview and complete surveys. Phase 2 (6-8 weeks): complete short (1-3 minute) surveys on their phone and wear a special watch (like a Fitbit) to measure their sleep. Your child will also have a random (2 in 3) chance of being offered to complete a digital (smartphone-based) sleep treatment during Phase 2 (treatment group). At the end of the 6-8 weeks, your child will be asked to complete an additional interview and survey. Phase 3 (one time): complete a final follow-up interview and survey one month after the end of Phase 2. If your child was not randomly assigned to receive the sleep treatment during Phase 2 (control group), they will be given access to the treatment at the end of Phase 3.

Their **time in the research will take:** Phase 1 (one time) will take 2 hours total; Phase 2 (6-8 weeks) will take less than 10 minutes per day for the daily surveys, and 1 hour for the assessment at the end of Phase 2. If your child is randomly assigned to complete the sleep treatment (treatment group), it will take them approximately 2 hours in total to complete (approximately 20 minutes/week for approximately 6 weeks); and Phase 3 (one time) will take 1 hour for the interview and survey at the end of the study.

RISKS/BENEFITS: Possible harms or burdens of taking part in the research may be feeling uncomfortable answering some questions (your child can skip any question they are uncomfortable with); breaking confidentiality with your child (and contacting you) if we are concerned for their safety, breaking confidentiality if we learn your child or another minor is being maltreated; and data breaches by unauthorized parties (we will take many steps to keep your child's data secure and confidential). Possible benefits of taking part may be therapeutic benefits, such as improved sleep and reduced mental health symptoms. Your child will be guaranteed to receive access to the sleep treatment, either immediately during Phase 2 of the study (for those in the treatment group), or at the end of Phase 3 of the study after 10 weeks (for those in the control group).

ALTERNATIVES: Your child's alternative to taking part in the research is not to take part in it.

The information in this parental/legal guardian permission form will provide more details about the research and what will be asked of your child if you permit them to take part in it. If you have any questions now or during the research, you should feel free to ask them and should expect to be given answers you completely understand. After all your questions have been answered and you wish your

child to take part in the research, you will be asked to sign this permission form. You are not giving up any of your child's legal rights by permitting them to take part in this research or by signing this parental/legal guardian permission form.

Who is conducting this research?
This is a study that has Principal Investigators at two different locations. Catherine Glenn, Ph.D., is Principal Investigator of the research study at Old Dominion University. Evan Kleiman, Ph.D., is the Principal Investigator of this research study at Rutgers. 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. Catherine Glenn may be reached at glennlab@odu.edu or 757-683-4249.

You will be given a copy of the signed parental/legal guardian permission form to keep.

Sponsor of the Research: This study is funded by the National Institute of Mental Health (NIMH).

Why is this research being done?
The purpose of this research study is to test how effective a smartphone-based sleep treatment, digital cognitive-behavioral therapy for insomnia (dCBT-I), is for teens with suicidal thoughts and behaviors who also have insomnia.

Who may take part in this research and who may not?
Adolescents, 14-18 years old, and one parent/guardian may take part in this study. This study focuses on teens who have recently received acute psychiatric care or hospitalization for suicidal thoughts and behaviors, and also have insomnia.

The inclusion criteria for adolescents are:
- Ages 14-18
- Recently hospitalized for suicidal thoughts and behaviors (i.e., discharged within the past 45 days)
- Clinically severe insomnia symptoms

The exclusion criteria for adolescents are:
- Prior experience with the sleep treatment used in this study (CBT-I)
- Bipolar disorder or substance use disorder
- Having a sibling who participated in the study
- Factors that prevent teens from being able to consent to participate in research or to complete the study (ex. severe mental difficulties that prevent understanding the study, inability to read or speak English)

This study requires that your child answer questions on their smartphone. If your child does not have a smartphone, we will loan your child a phone that can be used during the study.

Why has my child been asked to take part in this research?
Your child is being asked to take part in this study because they meet the criteria described in the prior section.

How long will the research take and how many participants will take part?
Approximately 120 adolescents and their parents/guardians will take part in this study across two sites: Old Dominion University, and Rutgers, the State University of New Jersey.

Your child's participation in the study will include three phases (described in the next section).

- Phase 1 (One time): Initial session (one time) will last approximately 2 hours total.
- Phase 2 (6-8 weeks): The active follow-up phase includes the following:
    - If your child is randomly assigned (2 in 3chance) to the treatment group, they will be asked to complete a sleep treatment consisting of six 20-minute sessions during Phase 2. If your child is randomly assigned (1 in 3 chance) to the control group, they will not complete the treatment at this time (but will be offered access at the end of the study).
    - All teens, regardless of whether they are in the treatment or control group, will complete daily surveys that last no more than 10 minutes per day, and wear a special watch (Fitbit-like device) that doesn't take any time (just needs to be worn during the study).
    - All teens, at the end of Phase 2, will complete a 1-hour assessment including an interview and survey.
- Phase 3 (One time): For all teens, a final assessment (interview and surveys) will occur one month after the end of Phase 2 and will take approximately 1 hour total. **If your child was not randomly assigned to receive the sleep treatment during Phase 2 (control group), they will be given access to the treatment at the end of Phase 3.**

Overall, your child's involvement in the study will last approximately 10-12 weeks (up to 12 weeks if your child is in the treatment group, and 10 weeks if your child is in the control group).

What will my child be asked to do if they take part in this research?
If you decide to allow your child to participate in this study, your child will be asked to do the following things:

Phase 1: Initial Session (one time). The first session will last approximately 2 hours total and will take place either: (1) during your child's hospitalization (on the unit); or (2) within 45 days after your child's discharge from the hospital (in our research lab or over the phone). This session can take place at one time (if in our lab or over the phone) or in a couple of separate sessions (on the hospital unit with your child and/or over the phone with you). During this session, your child will be asked a series of questions through interviews with the research team and in surveys they complete on their own. These questions will ask about your child's thoughts, feelings, behaviors (including their sleep, history of self-injury, suicidal thoughts and behaviors), and events that have happened to them. Your child will also have a random (2 in 3) chance of being offered to complete the sleep treatment during Phase 2 (treatment group). You and your child will receive an overview about the equipment needed for Phase 2 (smartphone-based app for surveys, a special watch, and the sleep treatment app for adolescents randomly assigned to the treatment group).

Phase 2: Active Follow-Up Phase (6-8 weeks).

- During this phase, your child will be asked to complete short surveys (1-3 minutes each) via smartphone several times during the day (your child will answer questions on their own phone). They won't be asked to complete surveys during school hours. Surveys will ask about their thoughts, feelings, behaviors (such as their sleep, self-injury, and suicidal thoughts and behaviors), and events that may have happened to them. The surveys will last for 6 weeks.
- In addition to answering survey questions on their phone, your child will be asked to wear a special watch to monitor their sleep and activity. Your child will be asked to wear the watch on their non-dominant (non-writing) wrist all the time, except for when they are showering or bathing. If removed, your child should put the watch back on as soon as possible. We will ask you or your child to return the watch to the research team when the study ends. Your child will be asked to wear the watch for 6 weeks.
- (*If your child is randomly assigned to complete the sleep treatment during Phase 2*) Your child will be asked to complete a phone-based sleep treatment that includes six 20-minute weekly sessions that need to be completed over 6 weeks (and no more than 8 weeks). (Note: Your

child will still have access to the sleep treatment after this time, but we will ask them to do their best to complete the sleep treatment within this time period).
    - Your child will also be asked to continue completing daily surveys and wearing the watch until they have finished the treatment or until 8 weeks has passed, whichever comes first.
- At the end of the active follow-up phase, your child will be asked to complete a 1-hour assessment including an interview (over the phone or in person) and survey. Questions will ask about their thoughts, feelings, behaviors (such as their sleep, self-injury, and suicidal thoughts and behaviors) and (if they completed the treatment during Phase 2) feedback on the treatment they completed.

Phase 3: 1-month Follow-up Phase (one time). One month after the end of Phase 2, your child will be asked to complete a final interview (over the phone or in person) and a survey, which will take 1 hour total. During this session, your child will be asked similar questions as other phases of the study – their thoughts, feelings, behaviors (including sleep, self-injury, suicidal thoughts and behaviors), and events that may have happened to them. We may also ask your child questions about what it was like to be in the study, which will help us with similar studies in the future.

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(Optional): Medical Record Follow-Up. With your permission, the research team may obtain information from your child's medical record about any additional admissions to psychiatric units or hospitals for one year after your child is enrolled in the study. This will help us know if your child has been to a hospital because of self-injury or suicide risk. This phase of the study does not require any interaction with you or your child. This part of the study is optional and will not impact your child's ability to participate in other parts of the study.

What are the risks of harm or discomforts my child might experience by taking part in this study?
Your child might find some of the questions asked in interviews and surveys to be upsetting or uncomfortable. It is important to know that previous studies have found that answering questions about self-injury and suicide does not increase risk for suicidal thoughts and behaviors. However, it is possible that your child may experience some distress during the study. If your child experiences distressing thoughts or feelings during or after the study, we strongly encourage you to let us know either when the study is in progress or after it has been completed (see contact information at the end of this form). Your child is encouraged to take breaks as needed if they become tired during the study, and they can skip any questions or tasks that they find uncomfortable.

Your child's safety is the top priority. If your child's answers to study questions indicate that your child may be at imminent risk for hurting themselves, the research team will contact them to ask additional questions and take appropriate steps to keep them safe (like contacting you, suggesting you go to the hospital, or call emergency services on your behalf). However, it is important for you to know that your child's answers are not monitored 24 hours a day, so your child's surveys should not be used as a way to get help in a crisis. We will provide resources to you and your child that can be used in a crisis situation (e.g., as a personalized safety plan).

If we learn during the study that your child or another child under 18 is being abused or neglected, we are ethically and legally obligated to file a report with the relevant local authorities (e.g., Department of Children and Families in NJ and Child Protective Services in VA). If they prefer not to disclose any information about child abuse, they can choose not to answer these kinds of questions during the study.

For the watch your child is being asked to wear, your child may experience mild redness or irritation on the wrist under the watch. This possible redness or irritation is temporary and not dangerous. If your

child experiences redness or irritation, they should remove the watch and clean it with mild soap and water before putting it back on. If redness or irritation persists after cleaning, your child should remove the device for the remainder of the study and inform the research team.

There is sometimes concern that sleep treatment, which includes sleep restriction (where people reduce their available time to sleep in order to improve their sleep quality), may be risky for youth with emotion regulation difficulties. To address this, sleep will not be restricted to less than 8 hours, making it safe for high-risk youth.

Although we take several steps to keep your child's study information secure and confidential, you should be aware that there is an extremely small possibility that your child's data could be viewed by unauthorized parties (such as computer hackers). However, your child's identifying information (such as your child's name) will not be stored with their survey data, so even hackers will not be able to link your child's data to their identity. (See section *How will information about my child be kept private or confidential?* for additional details.)

Are there any benefits to my child if they take part in this research?
The benefits of taking part in this research may be a therapeutic benefit by completing the sleep treatment, either in Phase 2 (treatment group) or at the end of Phase 3 (control group). Other potential benefits include learning more about your child's mental health and about mental health resources available to your family. However, it is possible that they may not receive any direct benefit from taking part in this research.

What are my child's alternatives if I do not want to take part in this research?
There are no alternative treatments available. Your alternative is not to allow your child to take part in this research.

How will I know if new information is learned that may affect whether I am willing to allow my child to stay in the research?
During the research, you will be updated about any new information that may affect whether you are willing to allow your child to continue taking part in the research. If new information is learned that may affect your child after the research or their follow-up is completed, you will be contacted.

Will I receive the results of the research?
In general, we will not give you any individual results from the study. If we find something of urgent medical importance to your child, we will inform you, although we expect that this will be a very rare occurrence.

You and your child will not receive results from your individual participation in the research study. It could take many years before we know the results of this research. However, when findings from the study become available, we will let you know by making research available on our lab website: https://sites.wp.odu.edu/yr2lab/research/sleepio-study/

Will there be any cost for my child to take part in this research?
There is no cost to your child to participate in this study.

Will my child be paid to take part in this research?
Your child will receive up to $170.00 for participating in all phases of the study. How much they will earn in each part of the study is provided below. Additionally, your child will receive free access to the sleep treatment (either during Phase 2 or at the end of Phase 3).

Activity	Rate	Frequency	Total

Phase 1: Initial Session	$15/hour	Once (2 hours)	$30
Phase 2: Active Follow-Up Phase			
Daily surveys during active follow-up	$10/weekly (for 65%+ survey completion)	6 weeks	$60
Weekly surveys during active follow-up	$5/weekly	6 weeks	$30
End of Phase 2 assessment	$20	Once	$20
Phase 3: 1-Month Follow-Up			
1-month follow-up assessment	$20	Once	$20
Returning Study Watch	$10	Once	$10
		TOTAL	**$170**

How will information about my child be kept private or confidential?
All efforts will be made to keep your child's personal information in the research record confidential, but total confidentiality cannot be guaranteed. We will take many steps to protect your child's identity, so no one knows your child participated in this study. For example, the information that may identify your child (names, dates of birth, phone numbers) will be kept separate from other information your child provides in this study. Your child's study information will be identified by a confidential ID number (e.g., #9999) that is only known to the research team. Your child's information will be kept in locked cabinets and password protected electronic files on secure networks. Only approved members of the research team will have access to your study information.

The research team may use or share your child's information collected or created for this research 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
- Our funding sponsor, the National Institute of Mental Health (NIMH)
- Non-ODU Investigators on the Study Team:
    - E.g. Evan Kleiman, Ph.D., Rutgers, the State University of New Jersey
- Our Data Safety Monitoring Board (DSMB)

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify your child in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your child's information from being used for other research if allowed by federal regulations.

Researchers may release information about your child 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. The Certificate of Confidentiality does not stop you from willingly releasing information about your child's involvement in this research. It also does not prevent you from having access to your child's information.

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

What will happen to my child's information collected for this research after the research is over?

After information that could identify your child has been removed, de-identified information collected for this research may be used for other research we conduct without obtaining additional parental/legal guardian permission from you.

What will happen if my child is injured during this research?
Participants in this research will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which are detailed in *"What are the risks of harm or discomforts I might experience if I take part in this study?"*. In addition, it is possible that during the course of this research, new adverse effects of CBT-I that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for participants who sustain personal injuries or illnesses as a direct consequence of participation in the research. The participant's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid, or TRICARE/CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University. However, by signing this form, you are not giving up any legal rights to seek further compensation.

What will happen if I do not wish my child to take part in the research or if I later decide that I do not wish my child to stay in the research?
It is your choice whether your child takes part in the research. You may choose to have your child take part, not to take part, or you may change your mind and withdraw your child from the research at any time. If you do not want your child to enter the research or decide to stop taking part, their relationship with the research staff will not change, and they may do so without penalty and without loss of benefits to which your child is otherwise entitled.

You may also withdraw your permission for the use of data already collected about your child, but you must do this in writing to Catherine Glenn, Ph.D. at Old Dominion University (glennlab@odu.edu). Any data that have already been sent to NIMH cannot be withdrawn because there will not be any identifiers with the data that indicate which data are yours.

Who can I call if I have questions?
If you have questions, concerns, problems, wish more information about your child taking part in the research, or if you feel your child may have suffered a research related injury, you can call the Principal Investigator at your site. If you are at the Old Dominion University Site, you should contact Catherine Glenn, Ph.D. at glennlab@odu.edu or 757-683-4249.

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research participant, you can contact the Rutgers IRB/Human Research Protection Program via phone at (973) 972-3608 or (732) 235-9806 OR
via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

PARENTAL/LEGAL GUARDIAN PERMISSION FOR CHILD

Parent or Legal Guardian
I have read this entire 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 or this study have been answered.

I am the [ ] parent or [ ] legal guardian of _____ (print name of child) and I agree for my child to take part in this research study.

Parent or Legal Guardian Name (Print):_____

Parent or Legal Guardian Signature:_____ Date:_____

(OPTIONAL) DIGITAL AGREEMENT FOR NDA DATA SUBMISSION

Additionally, your child will have the option to be a part of a larger data upload of de-identified data to the NIMH's data repository ("NDA") so that other researchers can use it. The NDA requires we create a non-identifiable ID called the GUID to link to your child's data. We will use your child's date of birth and place of birth on a secure computer program to generate this GUID, but your child's date of birth and place of birth will not be linked to their data. Your child can still participate in this research study even if you do not want their data to be added to the NDA, and you can decide to change that decision at any time. However, once their data is part of the NDA, the study researchers cannot take back the study data that was shared before they were notified that you or your child changed their mind. If you would like more information about the NDA, it is available at http://nda.nih.gov.

While the databases developed for future use and the NDA will be coded to protect your child's personal information, people may develop ways in the future that would allow someone to link your child's information back to them. It is also possible that there could be violations to the security of the computer systems. There also may be other privacy risks that we have not foreseen.

Do you agree to share your child's data with the NDA? ☐Yes ☐No
If you selected yes, please sign below

Subject Consent:

I agree to have my child's de-identified data submitted to the NIMH data repository (NDA).

Subject/Child's Name:_____

Parent/Guardian Name: _____

Parent/Guardian Signature:_____ Date:_____

(OPTIONAL) PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOUR CHILD FOR RESEARCH

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your child's medical record in this research. Their information will only be used as described here or as allowed or required by law. If you sign this parental/legal guardian permission form, you agree to let the investigators use your child's 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 child's information be used?
Your child is being invited to take part in this research which is described at the beginning of this form. The purpose of collecting and using their health information for this research is to help investigators answer the questions that are being asked in the research.

What information about my child will be used?

- All information in your child's medical record (relevant to their psychiatric treatment)

Who may use, share, or receive my child's information?
The research team may use or share your child's information collected or created for this research with the following people and institutions:

- Rutgers University Investigators involved in the research
- The Rutgers University Institutional Review Board
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- Our funding sponsor, the National Institute of Mental Health (NIMH)
- Non-ODU Investigators on the Study Team:
    - E.g. Evan Kleiman, Ph.D., Rutgers, the State University of New Jersey
- Our Data Safety Monitoring Board (DSMB)

Those persons or organizations that receive your child's 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 child's research record while the research is ongoing?
No. We are not able to share information in the research records with you until the research is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research.

Do I have to give my permission?
No. You do not have to permit use of your child's information. This part of the study is optional. (Saying no does not stop your child from getting medical care or other benefits they 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 child's information (and stop taking part in the research) at any time. If you take away permission, your child's information will no longer be used or shared in the research, 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 child's information in the research, you must write to the researcher at your site and tell them of your decision: at Old Dominion University, you should contact Catherine Glenn, Ph.D. (glennlab@odu.edu)

How long will my permission last?
There is no set date when your permission will end. Your health information may be studied for many years. Therefore, this permission will last indefinitely or until you request that you no longer want your or your child's data to be used.

Do you agree to share your child's health information? ☐Yes ☐No
If you selected yes, please sign below

Subject Consent:

I agree to let the investigators use my child's identifiable health information in the research.

Subject/Child's Name:_____

Parent/Guardian Name: _____

Parent/Guardian Signature:_____ Date:_____

CONSENT TO TAKE PART IN RESEARCH

Title of Research: Sleep treatment for teens
Principal Investigator: Evan Kleiman, Ph.D., Rutgers, the State University of New Jersey; Catherine Glenn, Ph.D., Old Dominion University

RESEARCH SUMMARY: This consent form is part of an informed consent process for a research study, and it will provide information that will help you decide whether you want to take part in this **research**. It is your choice whether to take part or not.

P**URPOSE**: The **purpose of the research** is to test the effectiveness of a digital sleep treatment for teens with suicidal thoughts and behaviors, who also have insomnia. If you take part in the research, you will be asked to If you take part in the research, you will be asked to: Phase 1 (one time): answer questions in an interview and complete surveys. Phase 2 (6-8 weeks): complete short (1-3 minute) surveys on your phone and wear a special watch (like a Fitbit) to measure your sleep. You will also have a random 2 in 3 chance of being offered to complete a digital (smartphone-based) sleep treatment during Phase 2 (treatment group). At the end of the 6-8 weeks, you will be asked to complete an additional interview and survey. Phase 3 (one time): complete a final follow-up interview and survey one month after the end of Phase 2. If you were not randomly assigned to receive the sleep treatment during Phase 2 (control group), you will be given access to the treatment at the end of Phase 3. Your time in the research will take: Phase 1 (one time) will take 2 hours total; Phase 2 (6-8 weeks) will take less than 10 minutes per day for the daily surveys, and 1 hour for the assessment at the end of Phase 2. If you are assigned to complete the sleep treatment (treatment group), it will take approximately 2 hours in total to complete (approximately 20 minutes/week for approximately 6 weeks); and Phase 3 (one time) will take 1 hour for the interview and survey at the end of the study.

RISKS/BENEFITS: Possible harms or burdens of taking part in the study may be feeling uncomfortable answering some questions (you can skip any question you are uncomfortable with); breaking your confidentiality (and contacting your parent/caregiver) if we are concerned for your safety, breaking confidentiality if we learn a child or another minor is being maltreated; and data breaches by unauthorized parties (we will take many steps to keep your data secure and confidential). Possible benefits of taking part may be therapeutic benefits, such as improved sleep and reduced mental health symptoms. You will be guaranteed to receive access to the sleep treatment, either immediately during Phase 2 of the study (for those in the treatment group), or at the end of Phase 3 of the study after 10 weeks (for those in the control group).

ALTERNATIVES: Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research and what will be asked of you if you choose to take part in it. If you have any questions now or during the research, 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, 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?

This is a study that has Principal Investigators at two different locations. Evan Kleiman, Ph.D., is the Principal Investigator of this research study at Rutgers. Catherine Glenn, Ph.D., is Principal Investigator of the research study at Old Dominion University. . 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 evan.kleiman@rutgers.edu or 848-445-2345.

You will be given a copy of the signed consent form to keep.

Sponsor of the Research: This study is funded by the National Institute of Mental Health (NIMH).

Why is this research being done?
The purpose of this research study is to test how effective a smartphone-based sleep treatment, digital cognitive-behavioral therapy for insomnia (dCBT-I), is for teens with suicidal thoughts and behaviors who also have insomnia.

Who may take part in this research and who may not?
Adolescents, 14-18 years old, and one parent/guardian may take part in this study. This study focuses on teens who have recently received acute psychiatric care or hospitalization for suicidal thoughts and behaviors, and also have insomnia.

The inclusion criteria for adolescents are:
- Ages 14-18
- Recently hospitalized for suicidal thoughts and behaviors (i.e., discharged within the past 45 days)
- Clinically severe insomnia symptoms

The exclusion criteria for adolescents are:
- Prior experience with the sleep treatment used in this study (CBT-I)
- Bipolar disorder or substance use disorder
- Having a sibling who participated in the study
- Factors that prevent teens from being able to consent to participate in research or to complete the study (ex. severe mental difficulties that prevent understanding the study, inability to read or speak English)

This study requires that you answer questions on your smartphone. If you do not have a smartphone, we will loan you a phone that can be used during the study.

Why have I been asked to take part in this research?
You are being asked to take part in this study because you meet the criteria described in the prior section.

How long will the research take and how many participants will take part?
Approximately 120 adolescents and their parents/guardians will take part in this study across two sites: Old Dominion University, and Rutgers, the State University of New Jersey.

Your participation in the study will include three phases (described in the next section).
- Phase 1 (One time): Initial session (one time) will last approximately 2 hours total.
- Phase 2 (6-8 weeks): The active follow-up phase includes the following:
  If you are randomly assigned (2 in 3 chance) to the treatment group, you will be asked to complete a sleep treatment consisting of six 20-minute sessions during Phase 2. If you are

randomly assigned (1 in 3 chance) to the control group, you will not complete the treatment at this time (but will be offered access at the end of the study).
All teens, regardless of whether they are in the treatment or control group, will complete daily surveys that last no more than 10 minutes per day, and wear a special watch (Fitbit-like device) that doesn't take any time (just needs to be worn during the study).
All teens, at the end of Phase 2, will complete a 1-hour assessment including an interview and survey.

- Phase 3 (One time): For all teens, a final assessment (interview and surveys) will occur one month after the end of Phase 2 and will take approximately 1 hour total.
  If you were not randomly assigned to receive the sleep treatment during Phase 2 (control group), you will be given access to the treatment at the end of Phase 3.

Overall, your involvement in the study will last approximately 10-12 weeks (up to 12 weeks if you are in the treatment group, and 10 weeks if you are in the control group).

What will I be asked to do if I take part in this research?
If you decide to participate in this study, you will be asked to do the following things:

Phase 1: Initial Session (one time). The first session will last approximately 2 hours total and will take place either: (1) during your hospitalization (on the unit); or (2) within 45 days after your discharge from the hospital (in our research lab or over the phone). This session can take place at one time (if in our lab or over the phone) or in a couple of separate sessions (on the hospital unit and/or over the phone with you). During this session, you will be asked a series of questions through interviews with the research team and in surveys you complete on your own. These questions will ask about your thoughts, feelings, behaviors (including your sleep, history of self-injury, suicidal thoughts and behaviors), and events that have happened to you. You will also have a random (2 in 3) chance of being offered to complete the sleep treatment during Phase 2 (treatment group). You will receive an overview about the equipment needed for Phase 2 (smartphone-based app for surveys, a special watch, and the sleep treatment app for adolescents randomly assigned to the treatment group).

Phase 2: Active Follow-Up Phase (6-8 weeks).

- During this phase, you will be asked to complete short surveys (1-3 minutes each) via smartphone several times during the day. You won't be asked to complete surveys during school hours. Surveys will ask about your thoughts, feelings, behaviors (such as your sleep, self-injury, and suicidal thoughts and behaviors), and events that may have happened to you. The surveys will last for 6 weeks.
- In addition to answering survey questions on your phone, you will be asked to wear a special watch to monitor your sleep and activity. You will be asked to wear the watch on your non-dominant (non-writing) wrist all the time, except for when you are showering or bathing. If removed, you should put the watch back on as soon as possible. We will ask you or your parent/caregiver to return the watch to the research team when the study ends. You will be asked to wear the watch for 6 weeks.
- (*If you are randomly assigned to complete the sleep treatment during Phase 2*) You will be asked to complete a phone-based sleep treatment that includes six 20-minute weekly sessions that need to be completed over 6 weeks (and no more than 8 weeks). (Note: You will still have access to the sleep treatment after this time, but we will ask you to do your best to complete the sleep treatment within this time period).
  - You will also be asked to continue completing daily surveys and wearing the watch until you have finished the treatment or until 8 weeks has passed, whichever comes first.
  -
- At the end of the active follow-up phase, you will be asked to complete a 1-hour assessment including an interview (over the phone or in person) and survey. Questions will ask about your

thoughts, feelings, behaviors (such as your sleep, self-injury, and suicidal thoughts and behaviors) and (if you completed the treatment during Phase 2) feedback on the treatment you completed.

Phase 3: 1-month Follow-up Phase (one time). One month after the end of Phase 2, you will be asked to complete a final interview (over the phone or in person) and a survey, which will take 1 hour total. During this session, you will be asked similar questions as other phases of the study – your thoughts, feelings, behaviors (including sleep, self-injury, suicidal thoughts and behaviors), and events that may have happened to you. We may also ask you questions about what it was like to be in the study, which will help us with similar studies in the future.

(Optional): Medical Record Follow-Up. With your permission, the research team may obtain information from your medical record about any additional admissions to psychiatric units or hospitals for one year after you are enrolled in the study. This will help us know if you have been to a hospital because of self-injury or suicide risk. This phase of the study does not require any interaction with you. This part of the study is optional and will not impact your ability to participate in other parts of the study.

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

You might find some of the questions asked in interviews and surveys to be upsetting or uncomfortable. It is important to know that previous studies have found that answering questions about self-injury and suicide does not increase risk for suicidal thoughts and behaviors. However, it is possible that you may experience some distress during the study. If you experience distressing thoughts or feelings during or after the study, we strongly encourage you to let us know either when the study is in progress or after it has been completed (see contact information at the end of this form). You are encouraged to take breaks as needed if you become tired during the study, and you can skip any questions or tasks that you find uncomfortable.

Your safety is the top priority. If your answers to study questions indicate that you may be at imminent risk for hurting yourself, the research team will contact you to ask additional questions and take appropriate steps to keep you safe (like contacting your parent/caregiver, suggesting you go to the hospital, or call emergency services on your behalf). However, it is important for you to know that your answers are not monitored 24 hours a day, so your surveys should not be used as a way to get help in a crisis. We will provide resources to you that can be used in a crisis situation (e.g., as a personalized safety plan).

If we learn during the study that a child under 18 is being abused or neglected, we are ethically and legally obligated to file a report with the relevant local authorities (e.g., Department of Children and Families in NJ and Child Protective Services in VA). If you prefer not to disclose any information about child abuse, you can choose not to answer these kinds of questions during the study.

For the watch you are being asked to wear, you may experience mild redness or irritation on your wrist under the watch. This possible redness or irritation is temporary and not dangerous. If you experience redness or irritation, you should remove the watch and clean it with mild soap and water before putting it back on. If redness or irritation persists after cleaning, you should remove the device for the remainder of the study and inform the research team.

There is sometimes concern that sleep treatment, which includes sleep restriction (where people reduce their available time to sleep in order to improve their sleep quality), may be risky for youth with emotion regulation difficulties. To address this, sleep will not be restricted to less than 8 hours, making it safe for high-risk youth.

Although we take several steps to keep your study information secure and confidential, you should be aware that there is an extremely small possibility that your data could be viewed by unauthorized parties (such as computer hackers). However, your identifying information (such as your name) will not be stored with your survey data, so even hackers will not be able to link your data to your identity. (See section *How will information about me be kept private or confidential?* for additional details.)

Are there any benefits to me if I choose to take part in this research?
The benefits of taking part in this research may be a therapeutic benefit by completing the sleep treatment, either in Phase 2 (treatment group) or at the end of Phase 3 (control group). Other potential benefits include learning more about your mental health and about mental health resources available to your family. However, it is possible that you may not receive any direct benefit from taking part in this research.

What are my alternatives if I do not want to take part in this research?
There are no alternative treatments available. Your alternative is not to take part in this research.

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

Will I receive the results of the research?
In general, we will not give you any individual results from the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

You will not receive results from your individual participation in the research study. It could take many years before we know the results of this research. However, when findings from the study become available, we will let you know by making research available on our lab website: https://kleimanlab.org/sleepio-study/

Will there be any cost to me to take part in this study?
There are no costs to you for participating in this research.

Will I be paid to take part in this study?
You will receive up to $170.00 for participating in all phases of the study. How much you will earn in each part of the study is provided below. Additionally, you will receive free access to the sleep treatment (either during Phase 2 or at the end of Phase 3).

Activity	Rate	Frequency	Total
Phase 1: Initial Session	$15/hour	Once (2 hours)	$30
Phase 2: Active Follow-Up Phase			
Daily surveys during active follow-up	$10/weekly (for 65%+ survey completion)	6 weeks	$60
Weekly surveys during active follow-up	$5/weekly	6 weeks	$30
End of Phase 2 assessment	$20	Once	$20
Phase 3: 1-Month Follow-Up			
1-month follow-up assessment	$20	Once	$20

Returning Study Watch	$10	Once	$10
		TOTAL	**$170**

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. We will take many steps to protect your identity, so no one knows you participated in this study. For example, the information that may identify you (names, dates of birth, phone numbers) will be kept separate from other information you provide in this study. Your study information will be identified by a confidential ID number (e.g., #9999) that is only known to the research team. Your information will be kept in locked cabinets and password protected electronic files on secure networks. Only approved members of the research team will have access to your study information.

The research team may use or share your information collected or created for this research 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
- Our funding sponsor, the National Institute of Mental Health (NIMH)
- Non-ODU Investigators on the Study Team:
    - E.g. Evan Kleiman, Ph.D., Rutgers, the State University of New Jersey
- Our Data Safety Monitoring Board (DSMB)

A description of this clinical trial will be available on 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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

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. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

What will happen to my information collected for this research after the research 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.

What will happen if I am injured during this research?
Participants in this research will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which are detailed in "*What are the risks of harm or discomforts I might experience if I take part in this research?".* In addition, it is possible that during the course of this research, new adverse effects of CBT-I that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for participants who sustain personal injuries or illnesses as a direct consequence of participation in the research. The participant's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid, or TRICARE/CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University. However, by signing this form, you are not giving up any legal rights to seek further compensation.

What will happen if I do not wish to take part in the research or if I later decide not to stay in the research?
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 research at any time. If you do not want to enter the research or decide to stop taking part, your relationship with the research 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**:** Evan Kleiman, Ph.D. at Rutgers, the State University of New Jersey (evan.kleiman@rutgers.edu). Any data that have already been sent to NIMH cannot be withdrawn because there will not be any identifiers with the data that indicate which data are yours.

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 at your site. If you are at the Rutgers University Site, you should contact Evan Kleiman, Ph.D. at evan.kleiman@rutgers.edu or 848-445-2345.

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research participant, you can contact the Rutgers IRB/Human Research Protection Program via phone at (973) 972-3608 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

AGREEMENT TO TAKE PART IN RESEARCH

Participant 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 research have been answered. I agree to take part in this research.

Participant Name (Print):_____

Participate Signature:_____ Date:_____

(OPTIONAL) DIGITAL AGREEMENT FOR NDA DATA SUBMISSION

Additionally, you have the option to be a part of a larger data upload of de-identified data to the NIMH's data repository ("NDA") so that other researchers can use it. "De-identified" means that people will not be able to see your name or any personal information that would connect you to the data; they will only see the data by itself. The NDA requires we create a non-identifiable ID called the GUID to link to your data instead of your name. We will use your date of birth and place of birth on a secure computer program to generate this GUID, but your date of birth and place of birth will not be linked to your data. You can still participate in this research study even if you do not want your data to be added to the NDA, and you can decide to change that decision at any time. However, once your data is part of the NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about the NDA, it is available at http://nda.nih.gov.

While the databases developed for future use and for the NDA will be coded to protect your personal information (see above), people may develop ways in the future that would allow someone to link your information back to them. It is also possible that there could be violations to the security of the computer systems. There also may be other privacy risks that we have not foreseen.

Do you agree to share your data with the NDA? ☐Yes ☐No
If you selected yes, please sign below

Participant Consent:

I agree to submit de-identified data to the NIMH data repository (NDA).

Participant Name:_____

Participant Signature:_____ Date:_____

(OPTIONAL) PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR RESEARCH

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 invited to take part in this research which is described at the beginning of this form. The purpose of collecting and using your health information for this research 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 research with the following people and institutions:

- Rutgers University Investigators Involved in the Research
- The Rutgers University Institutional Review Board
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- Our funding sponsor, the National Institute of Mental Health (NIMH)
- Non-Rutgers Investigators on the Study Team:
    - E.g. Catherine Glenn, Ph.D., Old Dominion University
- Our Data Safety Monitoring Board (DSMB)

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 research is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research.

Do I have to give my permission?
No. You do not have to permit use of your information. This part of the study is optional. (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 stop taking part in the research) at any time. If you take away permission, your information will no longer be used or shared in the research, 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 at your site and tell them of your decision: at Rutgers, the State University of New Jersey, you should contact Evan Kleiman Ph.D. (evan.kleiman@rutgers.edu)

How long will my permission last?
There is no set date when your permission will end. Your health information may be studied for many years.

Do you agree to share your health information? ☐Yes ☐No
If you selected yes, please sign below

Subject Consent:

I agree to let the investigators use my identifiable health information in the research.

Participant Name: _____

Participant Signature:_____ Date:_____

OLD DOMINION UNIVERSITY
Department of Psychology
250 Mills Godwin Building
Norfolk, VA 23529-0267
Phone 757-683-4439 • Fax 757-683-5087

RUTGERS
Department of Psychology
School of Arts and Sciences
Rutgers, The State University of New Jersey
53 Avenue E, Room 627
Piscataway, NJ 08854

ASSENT TO TAKE PART IN RESEARCH

TITLE OF RESEARCH: Sleep treatment for teens
Principal Investigator: Evan Kleiman, Ph.D., Rutgers, the State University of New Jersey; Catherine Glenn, Ph.D., Old Dominion University

Who are you and why are you meeting with me?
I am a researcher and I work at Rutgers, the State University of New Jersey, School of Arts and Sciences in the Department of Psychology. I would like to tell you about a research study that involves people like yourself and see if you would like to take part in it. Please ask me, other research staff, or your parent/guardian to explain any words you don't understand about the research.

What is this research about?
The purpose of this research study is to test how effective a sleep treatment, available on your phone, called digital cognitive-behavioral therapy for insomnia (dCBT-I), is for teens who have recently been in the hospital for suicidal thoughts or behaviors, and also have insomnia.

Why have I been asked to take part in this research?
You are being asked to take part in this study because you are 14-18 years-old, were recently in the hospital for suicide risk, and have problems with insomnia.

Who can be in this research? And who may not? How long will the research take?
Adolescents, 14-18 years old, and one parent/guardian may take part in this study. This study focuses on teens who have recently received acute psychiatric care or hospitalization for suicidal thoughts and behaviors, and also have insomnia.

Who can be in this study?
- Ages 14-18
- Recently hospitalized for suicidal thoughts and behaviors (i.e., discharged within the past 45 days)
- Clinically severe insomnia symptoms

Who may not be in this study?
- Prior experience with the sleep treatment used in this study (CBT-I)
- Bipolar disorder or substance use disorder
- Having a sibling who participated in the study
- Factors that prevent teens from being able to consent to participate in research or to complete the study (ex. severe mental difficulties that prevent understanding the study, inability to read or speak English)

This study requires that you answer questions on your smartphone. If you do not have a smartphone, we will loan you a phone that can be used during the study.

How long will the study last?
Your participation in the study will include three phases (described in the next section).

- Phase 1 (One time): Initial session (one time) will last approximately 2 hours total.
- Phase 2 (6-8 weeks): The active follow-up phase includes the following:
    - If you are randomly assigned (2 in 3 chance) to the treatment group, you will be asked to complete a sleep treatment consisting of six 20-minute sessions during Phase 2. If you are randomly assigned (1 in 3 chance) to the control group, you will not complete the treatment at this time (but will be offered access at the end of the study).
    - All teens, regardless of whether they are in the treatment or control group, will complete daily surveys that last no more than 10 minutes per day, and wear a special watch (Fitbit-like device) that doesn't take any time (just needs to be worn during the study).
    - All teens, at the end of Phase 2, will complete a 1-hour assessment including an interview and survey.
- Phase 3 (One time): For all teens, a final assessment (interview and surveys) will occur one month after the end of Phase 2 and will take approximately 1 hour total.
  If you were not randomly assigned to receive the sleep treatment during Phase 2 (control group), you will be given access to the treatment at the end of Phase 3.

Overall, your involvement in the study will last approximately 10-12 weeks (up to 12 weeks if you are in the treatment group, and 10 weeks if you are in the control group).

What will happen to me if I take part in this research?
If you decide to participate in this study, you will be asked to do the following things:

Phase 1: Initial Session (one time). The first session will last approximately 2 hours total and will take place either: (1) during your hospitalization (on the unit); or (2) within 45 days after your discharge from the hospital (in our research lab or over the phone). This session can take place at one time (if in our lab or over the phone) or in a couple of separate sessions (on the hospital unit and/or over the phone with you). During this session, you will be asked a series of questions through interviews with the research team and in surveys you complete on your own. These questions will ask about your thoughts, feelings, behaviors (including your sleep, history of self-injury, suicidal thoughts and behaviors), and events that have happened to you. You will also have a random (2 in 3) chance of being offered to complete the sleep treatment during Phase 2 (treatment group). You will receive an overview about the equipment needed for Phase 2 (smartphone-based app for surveys, a special watch, and the sleep treatment app for adolescents randomly assigned to the treatment group).

Phase 2: Active Follow-Up Phase (6-8 weeks).

- During this phase, you will be asked to complete short surveys (1-3 minutes each) via smartphone several times during the day. You won't be asked to complete surveys during school hours. Surveys will ask about your thoughts, feelings, behaviors (such as your sleep, self-injury, and suicidal thoughts and behaviors), and events that may have happened to you. The surveys will last for 6 weeks.

- In addition to answering survey questions on your phone, you will be asked to wear a special watch to monitor your sleep and activity. You will be asked to wear the watch on your non-dominant (non-writing) wrist all the time, except for when you are showering or bathing. If removed, you should put the watch back on as soon as possible. We will ask you or your parent/guardian to return the watch to the research team when the study ends. You will be asked to wear the watch for 6 weeks.
- (If you are randomly assigned to complete the sleep treatment during Phase 2) You will be asked to complete a phone-based sleep treatment that includes six 20-minute weekly sessions that need to be completed over 6 weeks (and no more than 8 weeks). (Note: You will still have access to the sleep treatment after this time, but we will ask you to do your best to complete the sleep treatment within this time period).
    - You will also be asked to continue completing daily surveys and wearing the watch until you have finished the treatment or until 8 weeks has passed, whichever comes first.
- At the end of the active follow-up phase, you will be asked to complete a 1-hour assessment including an interview (over the phone or in person) and survey. Questions will ask about your thoughts, feelings, behaviors (such as your sleep, self-injury, and suicidal thoughts and behaviors) and (if you completed the treatment during Phase 2) feedback on the treatment you completed.

Phase 3: 1-month Follow-up Phase (one time). One month after the end of Phase 2, you will be asked to complete a final interview (over the phone or in person) and a survey, which will take 1 hour total. During this session, you will be asked similar questions as other phases of the study – your thoughts, feelings, behaviors (including sleep, self-injury, suicidal thoughts and behaviors), and events that may have happened to you. We may also ask you questions about what it was like to be in the study, which will help us with similar studies in the future.

(Optional): Medical Record Follow-Up. With your parent/guardian's permission, the research team may obtain information from your medical record about any additional admissions to psychiatric units or hospitals for one year after you are enrolled in the study. This will help us know if you have been to a hospital because of self-injury or suicide risk. This phase of the study does not require any interaction with you. This part of the study is optional and will not impact your ability to participate in other parts of the study.

Can something bad happen to me or will I feel uncomfortable if I take part in this research?

Sometimes things happen to people in research studies that may hurt them or make them feel bad. These are called risks. The risks of this research are that you might find some of the questions asked in interviews and surveys to be upsetting or uncomfortable. It is important to know that previous studies have found that answering questions about self-injury and suicide does not increase risk for suicidal thoughts and behaviors. However, it is possible that you may experience some distress during the study. If you experience distressing thoughts or feelings during or after the study, we strongly encourage you to let us know either when the study is in progress or after it has been completed (see contact information at the end of this form). You are encouraged to take breaks as needed if you become tired during the study, and you can skip any questions or tasks that you find uncomfortable.

Your safety is the top priority. If your answers to study questions indicate that you may be at imminent risk for hurting yourself, the research team will contact you to ask additional questions and take appropriate steps to keep you safe (like contacting your parent/guardian, suggesting you go to the hospital, or call emergency services on your behalf). However, it is important for you to know that your answers are not monitored 24 hours a day, so your surveys should not be used as a way to get help in a crisis. We will provide resources to you that can be used in a crisis situation (e.g., as a personalized safety plan).

If we learn during the study that a child under 18 is being abused or neglected, we are ethically and legally obligated to file a report with the relevant local authorities (e.g., Department of Children and Families in NJ and Child Protective Services in VA). If you prefer not to disclose any information about child abuse, you can choose not to answer these kinds of questions during the study.

For the watch you are being asked to wear, you may experience mild redness or irritation on your wrist under the watch. This possible redness or irritation is temporary and not dangerous. If you experience redness or irritation, you should remove the watch and clean it with mild soap and water before putting it back on. If redness or irritation persists after cleaning, you should remove the device for the remainder of the study and inform the research team.

There is sometimes concern that sleep treatment, which includes sleep restriction (where people reduce their available time to sleep in order to improve their sleep quality), may be risky for youth with emotion regulation difficulties. To address this, sleep will not be restricted to less than 8 hours, making it safe for high-risk youth.

Although we take several steps to keep your study information secure and confidential, you should be aware that there is an extremely small possibility that your data could be viewed by unauthorized parties (such as computer hackers). However, your identifying information (such as your name) will not be stored with your survey data, so even hackers will not be able to link your data to your identity. (See section “Will others know what I say and do in the research?” for additional details.)

Can something good happen to me if I take part in the research?
The benefits of taking part in this research may be a therapeutic benefit by completing the sleep treatment, either in Phase 2 (treatment group) or at the end of Phase 3 (control group). Other potential benefits include learning more about your mental health and about mental health resources available to your family. However, it is possible that you may not receive any direct benefit from taking part in this research.

Will others know what I say and do in the research?
The information collected about you during this study will be kept safely secured and only accessible by the research team. Nobody will know who you are except the people doing the research. We will take many steps to protect your identity, so no one can know that you participated in this study. For example, the information that may identify you (your name, date of birth, phone number) will be kept separate from other information you provide in this study. Your study information will be identified by a confidential ID number (such as #9999) that is only known to the research team. Your information will be kept in locked cabinets and password

protected electronic files on secure networks. To help us further protect your privacy, we have obtained a Certificate of Confidentiality. This Certificate means the research team cannot be made to give out information that may identify you to people who are not part of the research team. The Certificate does not stop you or a member of your family from giving out information about yourself or your involvement in this research. If we write an article about what we learn from the study, we will not use your name.

Will I be given anything to take part in this research?
You will receive up to $170.00 for participating in all phases of the study. How much you will earn in each part of the study is provided below. Additionally, you will receive free access to the sleep treatment (either during Phase 2 or at the end of Phase 3).

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Phase 1: Initial Session	$15/hour	Once (2 hours)	$30
Phase 2: Active Follow-Up Phase			
Daily surveys during active follow-up	$10/weekly (for 65%+ survey completion)	6 weeks	$60
Weekly surveys during active follow-up	$5/weekly	6 weeks	$30
End of Phase 2 assessment	$20	Once	$20
Phase 3: 1-Month Follow-Up			
1-month follow-up assessment	$20	Once	$20
Returning Study Watch	$10	Once	$10
		TOTAL	**$170**

What if I do not want to take part in this research?
You don't have to take part in this research if you don't want to. No one will get angry or upset if you do not want to be in the research. Just tell us. And remember, you can change your mind later if you decide you don't want to be in the research anymore.

What if I have questions?
You can ask questions at any time. You can ask now. You can ask later. You can talk to the researcher, or you can talk to someone else at any time during the research. If you have questions, concerns, or want more information about the research you can call the researcher at your study site. If you are at the Rutgers Site, you should contact Evan Kleiman, Ph.D. at evan.kleiman@rutgers.edu or 848-445-2345.

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research participant, you can contact the Rutgers IRB/Human Research Protection Program via phone at (973) 972-3608 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

What are my rights if I decide to take part in this research?

You may ask questions about any part of the research at any time. Do not sign this form unless you have had a chance to ask questions and have been given answers to all your questions and agree to take part in the research.

If you say yes, your parent(s) or guardian will also be asked if it is ok for you to take part in this research. You will be given a copy of this form to keep.

ASSENT TO TAKE PART IN THIS RESEARCH

Participant's Signature:

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

Participant Name (Print): _____

Participant Signature:_____Date: _____

(OPTIONAL) DIGITAL AGREEMENT FOR NDA DATA SUBMISSION

You have the option to be a part of a larger data upload of de-identified data to the NIMH's data repository ("NDA") so that other researchers can use it. "De-identified" means that people will not be able to see your name or any personal information that would connect you to the data; they will only see the data by itself. The NDA requires we create a non-identifiable ID called the GUID to link to your data instead of your name. We will use your date of birth and place of birth on a secure computer program to generate this GUID, but your date of birth and place of birth will not be linked to your data. You can still participate in this research study even if you do not want your data to be added to NDA, and you can decide to change that decision at any time. However, once your data is part of NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, it is available at http://nda.nih.gov.

Do you agree to share your data with the NDA? ☐Yes ☐No

If you selected yes, please sign below

Participant Consent:

I agree to submit de-identified data to the NIMH data repository (NDA).

Participant Name:

Participant Signature:

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PARENTAL/LEGAL GUARDIAN PERMISSION TO PERMIT CHILD TO TAKE PART IN RESEARCH

TITLE OF RESEARCH: Sleep treatment for teens
Principal Investigators: Evan Kleiman, Ph.D., Rutgers, the State University of New Jersey; Catherine Glenn, Ph.D., Old Dominion University

RESEARCH SUMMARY: This parental/legal guardian permission form is part of an informed consent process for a research study, and it will provide information that will help you decide whether you want your child to take part in this research. It is your choice to allow your child to take part or not.

PURPOSE: The purpose of the research is to test the effectiveness of a digital sleep treatment for teens with suicidal thoughts and behaviors, who also have insomnia. If your child takes part in the research, they will be asked to: Phase 1 (one time): answer questions in an interview and complete surveys. Phase 2 (6-8 weeks): complete short (1-3 minute) surveys on their phone and wear a special watch (like a Fitbit) to measure their sleep. Your child will also have a random 2 in 3 chance of being offered to complete a digital (smartphone-based) sleep treatment during Phase 2 (treatment group). At the end of the 6-8 weeks, your child will be asked to complete an additional interview and survey. Phase 3 (one time): complete a final follow-up interview and survey one month after the end of Phase 2. If your child was not randomly assigned to receive the sleep treatment during Phase 2 (control group), they will be given access to the treatment at the end of Phase 3.

Their **time in the research will take:** Phase 1 (one time) will take 2 hours total; Phase 2 (6-8 weeks) will take less than 10 minutes per day for the daily surveys, and 1 hour for the assessment at the end of Phase 2. If your child is randomly assigned to complete the sleep treatment (treatment group), it will take them approximately 2 hours in total to complete (approximately 20 minutes/week for approximately 6 weeks); and Phase 3 (one time) will take 1 hour for the interview and survey at the end of the study.

RISKS/BENEFITS: Possible harms or burdens of taking part in the research may be feeling uncomfortable answering some questions (your child can skip any question they are uncomfortable with); breaking confidentiality with your child (and contacting you) if we are concerned for their safety, breaking confidentiality if we learn your child or another minor is being maltreated; and data breaches by unauthorized parties (we will take many steps to keep your child's data secure and confidential).

Possible benefits of taking part may be therapeutic benefits, such as improved sleep and reduced mental health symptoms. Your child will be guaranteed to receive access to the sleep treatment, either immediately during Phase 2 of the study (for those in the treatment group), or at the end of Phase 3 of the study after 10 weeks (for those in the control group).

ALTERNATIVES: Your child's alternative to taking part in the research is not to take part in it.

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

Who is conducting this research?
This is a study that has Principal Investigators at two different locations. Evan Kleiman, Ph.D., is the Principal Investigator of this research study at Rutgers. Catherine Glenn, Ph.D., is Principal Investigator of the research study at Old Dominion University. 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 evan.kleiman@rutgers.edu or 848-445-2345.

You will be given a copy of the signed parental/legal guardian permission form to keep.

Sponsor of the Research: This study is funded by the National Institute of Mental Health (NIMH).

Why is this research being done?
The purpose of this research study is to test how effective a smartphone-based sleep treatment, digital cognitive-behavioral therapy for insomnia (dCBT-I), is for teens with suicidal thoughts and behaviors who also have insomnia.

Who may take part in this research and who may not?
Adolescents, 14-18 years old, and one parent/guardian may take part in this study. This study focuses on teens who have recently received acute psychiatric care or hospitalization for suicidal thoughts and behaviors, and also have insomnia.

The inclusion criteria for adolescents are:
- Ages 14-18
- Recently hospitalized for suicidal thoughts and behaviors (i.e., discharged within the past 45 days)
- Clinically severe insomnia symptoms

The exclusion criteria for adolescents are:
- Prior experience with the sleep treatment used in this study (CBT-I)
- Bipolar disorder or substance use disorder
- Having a sibling who participated in the study
- Factors that prevent teens from being able to consent to participate in research or to complete the study (ex. severe mental difficulties that prevent understanding the study, inability to read or speak English)

This study requires that your child answer questions on their smartphone. If your child does not have a smartphone, we will loan your child a phone that can be used during the study.

Why has my child been asked to take part in this research?
Your child is being asked to take part in this study because they meet the criteria described in the prior section.

How long will the research take and how many participants will take part?
Approximately 120 adolescents and their parents/guardians will take part in this study across two sites: Old Dominion University, and Rutgers, the State University of New Jersey.

Your child's participation in the study will include three phases (described in the next section).

- Phase 1 (One time): Initial session (one time) will last approximately 2 hours total.
- Phase 2 (6-8 weeks): The active follow-up phase includes the following:
    - If your child is randomly assigned (2 in 3 chance) to the treatment group, they will be asked to complete a sleep treatment consisting of six 20-minute sessions during Phase 2. If your child is randomly assigned (1 in 3 chance) to the control group, they will not complete the treatment at this time (but will be offered access at the end of the study).
    - All teens, regardless of whether they are in the treatment or control group, will complete daily surveys that last no more than 10 minutes per day, and wear a special watch (Fitbit-like device) that doesn't take any time (just needs to be worn during the study).
    - All teens, at the end of Phase 2, will complete a 1-hour assessment including an interview and survey.
- Phase 3 (One time): For all teens, a final assessment (interview and surveys) will occur one month after the end of Phase 2 and will take approximately 1 hour total. **If your child was not randomly assigned to receive the sleep treatment during Phase 2 (control group), they will be given access to the treatment at the end of Phase 3.**

Overall, your child's involvement in the study will last approximately 10-12 weeks (up to 12 weeks if your child is in the treatment group, and 10 weeks if your child is in the control group).

What will my child be asked to do if they take part in this research?
If you decide to allow your child to participate in this study, your child will be asked to do the following things:

Phase 1: Initial Session (one time). The first session will last approximately 2 hours total and will take place either: (1) during your child's hospitalization (on the unit); or (2) within 45 days after your child's discharge from the hospital (in our research lab or over the phone). This session can take place at one time (if in our lab or over the phone) or in a couple of separate sessions (on the hospital unit with your child and/or over the phone with you). During this session, your child will be asked a series of questions through interviews with the research team and in surveys they complete on their own. These questions will ask about your child's thoughts, feelings, behaviors (including their sleep, history of self-injury, suicidal thoughts and behaviors), and events that have happened to them. Your child will also have a random (2 in 3) chance of being offered to complete the sleep treatment during Phase 2 (treatment group). You and your child will receive an overview about the equipment needed for Phase 2 (smartphone-based app for surveys, a special watch, and the sleep treatment app for adolescents randomly assigned to the treatment group).

Phase 2: Active Follow-Up Phase (6-8 weeks).

- During this phase, your child will be asked to complete short surveys (1-3 minutes each) via smartphone several times during the day (your child will answer questions on their own phone). They won't be asked to complete surveys during school hours. Surveys will ask about their

thoughts, feelings, behaviors (such as their sleep, self-injury, and suicidal thoughts and behaviors), and events that may have happened to them. The surveys will last for 6 weeks.

- In addition to answering survey questions on their phone, your child will be asked to wear a special watch to monitor their sleep and activity. Your child will be asked to wear the watch on their non-dominant (non-writing) wrist all the time, except for when they are showering or bathing. If removed, your child should put the watch back on as soon as possible. We will ask you or your child to return the watch to the research team when the study ends. Your child will be asked to wear the watch for 6 weeks.
- (*If your child is randomly assigned to complete the sleep treatment during Phase 2*) Your child will be asked to complete a phone-based sleep treatment that includes six 20-minute weekly sessions that need to be completed over 6 weeks (and no more than 8 weeks). (Note: Your child will still have access to the sleep treatment after this time, but we will ask them to do their best to complete the sleep treatment within this time period).
    - Your child will also be asked to continue completing daily surveys and wearing the watch until they have finished the treatment or until 8 weeks has passed, whichever comes first.
- At the end of the active follow-up phase, your child will be asked to complete a 1-hour assessment including an interview (over the phone or in person) and survey. Questions will ask about their thoughts, feelings, behaviors (such as their sleep, self-injury, and suicidal thoughts and behaviors) and (if they completed the treatment during Phase 2) feedback on the treatment they completed.

Phase 3: 1-month Follow-up Phase (one time). One month after the end of Phase 2, your child will be asked to complete a final interview (over the phone or in person) and a survey, which will take 1 hour total. During this session, your child will be asked similar questions as other phases of the study – their thoughts, feelings, behaviors (including sleep, self-injury, suicidal thoughts and behaviors), and events that may have happened to them. We may also ask your child questions about what it was like to be in the study, which will help us with similar studies in the future.

(Optional): Medical Record Follow-Up. With your permission, the research team may obtain information from your child's medical record about any additional admissions to psychiatric units or hospitals for one year after your child is enrolled in the study. This will help us know if your child has been to a hospital because of self-injury or suicide risk. This phase of the study does not require any interaction with you or your child. This part of the study is optional and will not impact your child's ability to participate in other parts of the study.

What are the risks of harm or discomforts my child might experience by taking part in this study?
Your child might find some of the questions asked in interviews and surveys to be upsetting or uncomfortable. It is important to know that previous studies have found that answering questions about self-injury and suicide does not increase risk for suicidal thoughts and behaviors. However, it is possible that your child may experience some distress during the study. If your child experiences distressing thoughts or feelings during or after the study, we strongly encourage you to let us know either when the study is in progress or after it has been completed (see contact information at the end of this form). Your child is encouraged to take breaks as needed if they become tired during the study, and they can skip any questions or tasks that they find uncomfortable.

Your child's safety is the top priority. If your child's answers to study questions indicate that your child may be at imminent risk for hurting themselves, the research team will contact them to ask additional questions and take appropriate steps to keep them safe (like contacting you, suggesting you go to the hospital, or call emergency services on your behalf). However, it is important for you to know that your child's answers are not monitored 24 hours a day, so your child's surveys should not be used as a way

to get help in a crisis. We will provide resources to you and your child that can be used in a crisis situation (e.g., as a personalized safety plan).

If we learn during the study that your child or another child under 18 is being abused or neglected, we are ethically and legally obligated to file a report with the relevant local authorities (e.g., Department of Children and Families in NJ and Child Protective Services in VA). If they prefer not to disclose any information about child abuse, they can choose not to answer these kinds of questions during the study.

For the watch your child is being asked to wear, your child may experience mild redness or irritation on the wrist under the watch. This possible redness or irritation is temporary and not dangerous. If your child experiences redness or irritation, they should remove the watch and clean it with mild soap and water before putting it back on. If redness or irritation persists after cleaning, your child should remove the device for the remainder of the study and inform the research team.

There is sometimes concern that sleep treatment, which includes sleep restriction (where people reduce their available time to sleep in order to improve their sleep quality), may be risky for youth with emotion regulation difficulties. To address this, sleep will not be restricted to less than 8 hours, making it safe for high-risk youth.

Although we take several steps to keep your child's study information secure and confidential, you should be aware that there is an extremely small possibility that your child's data could be viewed by unauthorized parties (such as computer hackers). However, your child's identifying information (such as your child's name) will not be stored with their survey data, so even hackers will not be able to link your child's data to their identity. (See section *How will information about my child be kept private or confidential?* for additional details.)

Are there any benefits to my child if they take part in this research?
The benefits of taking part in this research may be a therapeutic benefit by completing the sleep treatment, either in Phase 2 (treatment group) or at the end of Phase 3 (control group). Other potential benefits include learning more about your child's mental health and about mental health resources available to your family. However, it is possible that they may not receive any direct benefit from taking part in this research.

What are my child's alternatives if I do not want to take part in this research?
There are no alternative treatments available. Your alternative is not to allow your child to take part in this research.

How will I know if new information is learned that may affect whether I am willing to allow my child to stay in the research?
During the research, you will be updated about any new information that may affect whether you are willing to allow your child to continue taking part in the research. If new information is learned that may affect your child after the research or their follow-up is completed, you will be contacted.

Will I receive the results of the research?
In general, we will not give you any individual results from the study. If we find something of urgent medical importance to your child, we will inform you, although we expect that this will be a very rare occurrence.

You and your child will not receive results from your individual participation in the research study. It could take many years before we know the results of this research. However, when findings from the study become available, we will let you know by making research available on our lab website: https://kleimanlab.org/sleepio-study/

Will there be any cost for my child to take part in this research?
There is no cost to your child to participate in this study.

Will my child be paid to take part in this research?
Your child will receive up to $170.00 for participating in all phases of the study. How much they will earn in each part of the study is provided below. Additionally, your child will receive free access to the sleep treatment (either during Phase 2 or at the end of Phase 3).

Activity	Rate	Frequency	Total
Phase 1: Initial Session	$15/hour	Once (2 hours)	$30
Phase 2: Active Follow-Up Phase			
Daily surveys during active follow-up	$10/weekly (for 65%+ survey completion)	6 weeks	$60
Weekly surveys during active follow-up	$5/weekly	6 weeks	$30
End of Phase 2 assessment	$20	Once	$20
Phase 3: 1-Month Follow-Up			
1-month follow-up assessment	$20	Once	$20
Returning Study Watch	$10	Once	$10
		TOTAL	**$170**

How will information about my child be kept private or confidential?
All efforts will be made to keep your child's personal information in the research record confidential, but total confidentiality cannot be guaranteed. We will take many steps to protect your child's identity, so no one knows your child participated in this study. For example, the information that may identify your child (names, dates of birth, phone numbers) will be kept separate from other information your child provides in this study. Your child's study information will be identified by a confidential ID number (e.g., #9999) that is only known to the research team. Your child's information will be kept in locked cabinets and password protected electronic files on secure networks. Only approved members of the research team will have access to your study information.

The research team may use or share your child's information collected or created for this research 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
- Our funding sponsor, the National Institute of Mental Health (NIMH)
- Non-Rutgers Investigators on the Study Team:
    - E.g. Catherine Glenn, Ph.D., Old Dominion University
- Our Data Safety Monitoring Board (DSMB)

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify your child in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug

Administration (FDA). The Certificate also DOES NOT prevent your child's information from being used for other research if allowed by federal regulations.

Researchers may release information about your child 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. The Certificate of Confidentiality does not stop you from willingly releasing information about your child's involvement in this research. It also does not prevent you from having access to your child's information.

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

What will happen to my child's information collected for this research after the research is over?

After information that could identify your child has been removed, de-identified information collected for this research may be used for other research we conduct without obtaining additional parental/legal guardian permission from you.

What will happen if my child is injured during this research?
Participants in this research will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which are detailed in *"What are the risks of harm or discomforts I might experience if I take part in this study?"*. In addition, it is possible that during the course of this research, new adverse effects of CBT-I that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for participants who sustain personal injuries or illnesses as a direct consequence of participation in the research. The participant's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid, or TRICARE/CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University. However, by signing this form, you are not giving up any legal rights to seek further compensation.

What will happen if I do not wish my child to take part in the research or if I later decide that I do not wish my child to stay in the research?
It is your choice whether your child takes part in the research. You may choose to have your child take part, not to take part, or you may change your mind and withdraw your child from the research at any time. If you do not want your child to enter the research or decide to stop taking part, their relationship with the research staff will not change, and they may do so without penalty and without loss of benefits to which your child is otherwise entitled.

You may also withdraw your permission for the use of data already collected about your child, but you must do this in writing to Evan Kleiman, Ph.D. at Rutgers, at the State University of New Jersey (evan.kleiman@rutgers.edu). Any data that have already been sent to NIMH cannot be withdrawn because there will not be any identifiers with the data that indicate which data are yours.

Who can I call if I have questions?
If you have questions, concerns, problems, wish more information about your child taking part in the research, or if you feel your child may have suffered a research related injury, you can call the Principal Investigator at your site. If you are at the Rutgers University Site, you should contact Evan Kleiman, Ph.D. at evan.kleiman@rutgers.edu or 848-445-3245.

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research participant, you can contact the Rutgers IRB/Human Research Protection Program via phone at (973) 972-3608 or (732) 235-9806 OR
via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

PARENTAL/LEGAL GUARDIAN PERMISSION FOR CHILD

Parent or Legal Guardian
I have read this entire 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 or this study have been answered.

I am the [ ] parent or [ ] legal guardian of _____ (print name of child) and I agree for my child to take part in this research study.

Parent or Legal Guardian Name (Print):_____

Parent or Legal Guardian Signature:_____ Date:_____

(OPTIONAL) DIGITAL AGREEMENT FOR NDA DATA SUBMISSION

Additionally, your child will have the option to be a part of a larger data upload of de-identified data to the NIMH's data repository ("NDA") so that other researchers can use it. The NDA requires we create a non-identifiable ID called the GUID to link to your child's data. We will use your child's date of birth and place of birth on a secure computer program to generate this GUID, but your child's date of birth and place of birth will not be linked to their data. Your child can still participate in this research study even if you do not want their data to be added to the NDA, and you can decide to change that decision at any time. However, once their data is part of the NDA, the study researchers cannot take back the study data that was shared before they were notified that you or your child changed their mind. If you would like more information about the NDA, it is available at http://nda.nih.gov.

While the databases developed for future use and the NDA will be coded to protect your child's personal information, people may develop ways in the future that would allow someone to link your child's information back to them. It is also possible that there could be violations to the security of the computer systems. There also may be other privacy risks that we have not foreseen.

Do you agree to share your child's data with the NDA? ☐Yes ☐No
If you selected yes, please sign below

Subject Consent:

I agree to have my child's de-identified data submitted to the NIMH data repository (NDA).

Subject/Child's Name:_____

Parent/Guardian Name: _____

Parent/Guardian Signature:_____ Date:_____

(OPTIONAL) PERMISSION (Authorization) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOUR CHILD FOR RESEARCH

The next few paragraphs tell you about how investigators want to use and share identifiable health information from your child's medical record in this research. Their information will only be used as described here or as allowed or required by law. If you sign this parental/legal guardian permission form, you agree to let the investigators use your child's 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 child's information be used?
Your child is being invited to take part in this research which is described at the beginning of this form. The purpose of collecting and using their health information for this research is to help investigators answer the questions that are being asked in the research.

What information about my child will be used?

- All information in your child's medical record (relevant to their psychiatric treatment)

Who may use, share, or receive my child's information?
The research team may use or share your child's information collected or created for this research with the following people and institutions:

- Rutgers University Investigators involved in the research
- The Rutgers University Institutional Review Board
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- Our funding sponsor, the National Institute of Mental Health (NIMH)
- Non-Rutgers Investigators on the Study Team:
    - E.g. Catherine Glenn, Ph.D., Old Dominion University
- Our Data Safety Monitoring Board (DSMB)

Those persons or organizations that receive your child's 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 child's research record while the research is ongoing?
No. We are not able to share information in the research records with you until the research is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research.

Do I have to give my permission?
No. You do not have to permit use of your child's information. This part of the study is optional. (Saying no does not stop your child from getting medical care or other benefits they 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 child's information (and stop taking part in the research) at any time. If you take away permission, your child's information will no longer be used or shared in the research, 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 child's information in the research, you must write to the researcher at your site and tell them of your decision: at Rutgers, you should contact Evan Kleiman, Ph.D. (evan.kleiman@rutgers.edu)

How long will my permission last?
There is no set date when your permission will end. Your health information may be studied for many years. Therefore, this permission will last indefinitely or until you request that you no longer want your or your child's data to be used.

Do you agree to share your child's health information? ☐Yes ☐No
If you selected yes, please sign below

Subject Consent:

I agree to let the investigators use my child's identifiable health information in the research.

Subject/Child's Name:_____

Parent/Guardian Name: _____

Parent/Guardian Signature:_____ Date:_____

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CONSENT TO TAKE PART IN RESEARCH

Title of Research: Sleep treatment for teens
Principal Investigator: Catherine Glenn, Ph.D., Old Dominion University; Evan Kleiman, Ph.D., Rutgers, the State University of New Jersey

RESEARCH SUMMARY: This consent form is part of an informed consent process for a research study, and it will provide information that will help you decide whether you want to take part in this **research**. It is your choice whether to take part or not.

P**URPOSE**: The **purpose of the research** is to test the effectiveness of a digital sleep treatment for teens with suicidal thoughts and behaviors, who also have insomnia. If you take part in the research, you will be asked to If you take part in the research, you will be asked to: Phase 1 (one time): answer questions in an interview and complete surveys. Phase 2 (6-8 weeks): complete short (1-3 minute) surveys on your phone and wear a special watch (like a Fitbit) to measure your sleep. You will also have a random 2 in 3 chance of being offered to complete a digital (smartphone-based) sleep treatment during Phase 2 (treatment group). At the end of the 6-8 weeks, you will be asked to complete an additional interview and survey. Phase 3 (one time): complete a final follow-up interview and survey one month after the end of Phase 2. If you were not randomly assigned to receive the sleep treatment during Phase 2 (control group), you will be given access to the treatment at the end of Phase 3. Your time in the research will take: Phase 1 (one time) will take 2 hours total; Phase 2 (6-8 weeks) will take less than 10 minutes per day for the daily surveys, and 1 hour for the assessment at the end of Phase 2. If you are assigned to complete the sleep treatment (treatment group), it will take approximately 2 hours in total to complete (approximately 20 minutes/week for approximately 6 weeks); and Phase 3 (one time) will take 1 hour for the interview and survey at the end of the study.

RISKS/BENEFITS: Possible harms or burdens of taking part in the study may be feeling uncomfortable answering some questions (you can skip any question you are uncomfortable with); breaking your confidentiality (and contacting your parent/caregiver) if we are concerned for your safety, breaking confidentiality if we learn a child or another minor is being maltreated; and data breaches by unauthorized parties (we will take many steps to keep your data secure and confidential). Possible benefits of taking part may be therapeutic benefits, such as improved sleep and reduced mental health symptoms. You will be guaranteed to receive access to the sleep treatment, either immediately during Phase 2 of the study (for those in the treatment group), or at the end of Phase 3 of the study after 10 weeks (for those in the control group).

ALTERNATIVES: Your alternative to taking part in the research study is not to take part in it.

The information in this consent form will provide more details about the research and what will be asked of you if you choose to take part in it. If you have any questions now or during the research, 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, 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?

This is a study that has Principal Investigators at two different locations. Catherine Glenn, Ph.D., is Principal Investigator of the research study at Old Dominion University. Evan Kleiman, Ph.D., is the Principal Investigator of this research study at Rutgers. 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. Catherine Glenn may be reached at glennlab@odu.edu or 757-683-4249.

You will be given a copy of the signed consent form to keep.

Sponsor of the Research: This study is funded by the National Institute of Mental Health (NIMH).

Why is this research being done?
The purpose of this research study is to test how effective a smartphone-based sleep treatment, digital cognitive-behavioral therapy for insomnia (dCBT-I), is for teens with suicidal thoughts and behaviors who also have insomnia.

Who may take part in this research and who may not?
Adolescents, 14-18 years old, and one parent/guardian may take part in this study. This study focuses on teens who have recently received acute psychiatric care or hospitalization for suicidal thoughts and behaviors, and also have insomnia.

The inclusion criteria for adolescents are:
- Ages 14-18
- Recently hospitalized for suicidal thoughts and behaviors (i.e., discharged within the past 45 days)
- Clinically severe insomnia symptoms

The exclusion criteria for adolescents are:
- Prior experience with the sleep treatment used in this study (CBT-I)
- Bipolar disorder or substance use disorder
- Having a sibling who participated in the study
- Factors that prevent teens from being able to consent to participate in research or to complete the study (ex. severe mental difficulties that prevent understanding the study, inability to read or speak English)

This study requires that you answer questions on your smartphone. If you do not have a smartphone, we will loan you a phone that can be used during the study.

Why have I been asked to take part in this research?
You are being asked to take part in this study because you meet the criteria described in the prior section.

How long will the research take and how many participants will take part?
Approximately 120 adolescents and their parents/guardians will take part in this study across two sites: Old Dominion University, and Rutgers, the State University of New Jersey.

Your participation in the study will include three phases (described in the next section).
- Phase 1 (One time): Initial session (one time) will last approximately 2 hours total.
- Phase 2 (6-8 weeks): The active follow-up phase includes the following:
  If you are randomly assigned (2 in 3 chance) to the treatment group, you will be asked to complete a sleep treatment consisting of six 20-minute sessions during Phase 2. If you are

randomly assigned (1 in 3 chance) to the control group, you will not complete the treatment at this time (but will be offered access at the end of the study).
All teens, regardless of whether they are in the treatment or control group, will complete daily surveys that last no more than 10 minutes per day, and wear a special watch (Fitbit-like device) that doesn't take any time (just needs to be worn during the study).
All teens, at the end of Phase 2, will complete a 1-hour assessment including an interview and survey.

- Phase 3 (One time): For all teens, a final assessment (interview and surveys) will occur one month after the end of Phase 2 and will take approximately 1 hour total.
  If you were not randomly assigned to receive the sleep treatment during Phase 2 (control group), you will be given access to the treatment at the end of Phase 3.

Overall, your involvement in the study will last approximately 10-12 weeks (up to 12 weeks if you are in the treatment group, and 10 weeks if you are in the control group).

What will I be asked to do if I take part in this research?
If you decide to participate in this study, you will be asked to do the following things:

Phase 1: Initial Session (one time). The first session will last approximately 2 hours total and will take place either: (1) during your hospitalization (on the unit); or (2) within 45 days after your discharge from the hospital (in our research lab or over the phone). This session can take place at one time (if in our lab or over the phone) or in a couple of separate sessions (on the hospital unit and/or over the phone with you). During this session, you will be asked a series of questions through interviews with the research team and in surveys you complete on your own. These questions will ask about your thoughts, feelings, behaviors (including your sleep, history of self-injury, suicidal thoughts and behaviors), and events that have happened to you. You will also have a random (2 in 3) chance of being offered to complete the sleep treatment during Phase 2 (treatment group). You will receive an overview about the equipment needed for Phase 2 (smartphone-based app for surveys, a special watch, and the sleep treatment app for adolescents randomly assigned to the treatment group).

Phase 2: Active Follow-Up Phase (6-8 weeks).

- During this phase, you will be asked to complete short surveys (1-3 minutes each) via smartphone several times during the day. You won't be asked to complete surveys during school hours. Surveys will ask about your thoughts, feelings, behaviors (such as your sleep, self-injury, and suicidal thoughts and behaviors), and events that may have happened to you. The surveys will last for 6 weeks.
- In addition to answering survey questions on your phone, you will be asked to wear a special watch to monitor your sleep and activity. You will be asked to wear the watch on your non-dominant (non-writing) wrist all the time, except for when you are showering or bathing. If removed, you should put the watch back on as soon as possible. We will ask you or your parent/caregiver to return the watch to the research team when the study ends. You will be asked to wear the watch for 6 weeks.
- (*If you are randomly assigned to complete the sleep treatment during Phase 2*) You will be asked to complete a phone-based sleep treatment that includes six 20-minute weekly sessions that need to be completed over 6 weeks (and no more than 8 weeks). (Note: You will still have access to the sleep treatment after this time, but we will ask you to do your best to complete the sleep treatment within this time period).
  - You will also be asked to continue completing daily surveys and wearing the watch until you have finished the treatment or until 8 weeks has passed, whichever comes first.
- At the end of the active follow-up phase, you will be asked to complete a 1-hour assessment including an interview (over the phone or in person) and survey. Questions will ask about your thoughts, feelings, behaviors (such as your sleep, self-injury, and suicidal thoughts and

behaviors) and (if you completed the treatment during Phase 2) feedback on the treatment you completed.

Phase 3: 1-month Follow-up Phase (one time). One month after the end of Phase 2, you will be asked to complete a final interview (over the phone or in person) and a survey, which will take 1 hour total. During this session, you will be asked similar questions as other phases of the study – your thoughts, feelings, behaviors (including sleep, self-injury, suicidal thoughts and behaviors), and events that may have happened to you. We may also ask you questions about what it was like to be in the study, which will help us with similar studies in the future.

(Optional): Medical Record Follow-Up. With your permission, the research team may obtain information from your medical record about any additional admissions to psychiatric units or hospitals for one year after you are enrolled in the study. This will help us know if you have been to a hospital because of self-injury or suicide risk. This phase of the study does not require any interaction with you. This part of the study is optional and will not impact your ability to participate in other parts of the study.

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

You might find some of the questions asked in interviews and surveys to be upsetting or uncomfortable. It is important to know that previous studies have found that answering questions about self-injury and suicide does not increase risk for suicidal thoughts and behaviors. However, it is possible that you may experience some distress during the study. If you experience distressing thoughts or feelings during or after the study, we strongly encourage you to let us know either when the study is in progress or after it has been completed (see contact information at the end of this form). You are encouraged to take breaks as needed if you become tired during the study, and you can skip any questions or tasks that you find uncomfortable.

Your safety is the top priority. If your answers to study questions indicate that you may be at imminent risk for hurting yourself, the research team will contact you to ask additional questions and take appropriate steps to keep you safe (like contacting your parent/caregiver, suggesting you go to the hospital, or call emergency services on your behalf). However, it is important for you to know that your answers are not monitored 24 hours a day, so your surveys should not be used as a way to get help in a crisis. We will provide resources to you that can be used in a crisis situation (e.g., as a personalized safety plan).

If we learn during the study that a child under 18 is being abused or neglected, we are ethically and legally obligated to file a report with the relevant local authorities (e.g., Department of Children and Families in NJ and Child Protective Services in VA). If you prefer not to disclose any information about child abuse, you can choose not to answer these kinds of questions during the study.

For the watch you are being asked to wear, you may experience mild redness or irritation on your wrist under the watch. This possible redness or irritation is temporary and not dangerous. If you experience redness or irritation, you should remove the watch and clean it with mild soap and water before putting it back on. If redness or irritation persists after cleaning, you should remove the device for the remainder of the study and inform the research team.

There is sometimes concern that sleep treatment, which includes sleep restriction (where people reduce their available time to sleep in order to improve their sleep quality), may be risky for youth with emotion regulation difficulties. To address this, sleep will not be restricted to less than 8 hours, making it safe for high-risk youth.

Although we take several steps to keep your study information secure and confidential, you should be aware that there is an extremely small possibility that your data could be viewed by unauthorized parties (such as computer hackers). However, your identifying information (such as your name) will not be stored with your survey data, so even hackers will not be able to link your data to your identity. (See section *How will information about me be kept private or confidential?* for additional details.)

Are there any benefits to me if I choose to take part in this research?
The benefits of taking part in this research may be a therapeutic benefit by completing the sleep treatment, either in Phase 2 (treatment group) or at the end of Phase 3 (control group). Other potential benefits include learning more about your mental health and about mental health resources available to your family. However, it is possible that you may not receive any direct benefit from taking part in this research.

What are my alternatives if I do not want to take part in this research?
There are no alternative treatments available. Your alternative is not to take part in this research.

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

Will I receive the results of the research?
In general, we will not give you any individual results from the study. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

You will not receive results from your individual participation in the research study. It could take many years before we know the results of this research. However, when findings from the study become available, we will let you know by making research available on our lab website: https://sites.wp.odu.edu/yr2lab/research/sleepio-study/

Will there be any cost to me to take part in this study?
There are no costs to you for participating in this research.

Will I be paid to take part in this study?
You will receive up to $170.00 for participating in all phases of the study. How much you will earn in each part of the study is provided below. Additionally, you will receive free access to the sleep treatment (either during Phase 2 or at the end of Phase 3).

Activity	Rate	Frequency	Total
Phase 1: Initial Session	$15/hour	Once (2 hours)	$30
Phase 2: Active Follow-Up Phase			
Daily surveys during active follow-up	$10/weekly (for 65%+ survey completion)	6 weeks	$60
Weekly surveys during active follow-up	$5/weekly	6 weeks	$30
End of Phase 2 assessment	$20	Once	$20
Phase 3: 1-Month Follow-Up			
1-month follow-up assessment	$20	Once	$20
Returning Study Watch	$10	Once	$10
		TOTAL	**$170**

How will information about me be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. We will take many steps to protect your identity, so no one knows you participated in this study. For example, the information that may identify you (names, dates of birth, phone numbers) will be kept separate from other information you provide in this study. Your study information will be identified by a confidential ID number (e.g., #9999) that is only known to the research team. Your information will be kept in locked cabinets and password protected electronic files on secure networks. Only approved members of the research team will have access to your study information.

The research team may use or share your information collected or created for this research 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
- Our funding sponsor, the National Institute of Mental Health (NIMH)
- Non-ODU Investigators on the Study Team:
    - E.g. Evan Kleiman, Ph.D., Rutgers, the State University of New Jersey
- Our Data Safety Monitoring Board (DSMB)

A description of this clinical trial will be available on 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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

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. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

What will happen to my information collected for this research after the research 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.

What will happen if I am injured during this research?
Participants in this research will be exposed to certain risks of personal injury in addition to those associated with standard forms of treatment, which are detailed in "*What are the risks of harm or*

discomforts I might experience if I take part in this research?". In addition, it is possible that during the course of this research, new adverse effects of CBT-I that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for participants who sustain personal injuries or illnesses as a direct consequence of participation in the research. The participant's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid, or TRICARE/CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University. However, by signing this form, you are not giving up any legal rights to seek further compensation.

What will happen if I do not wish to take part in the research or if I later decide not to stay in the research?
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 research at any time. If you do not want to enter the research or decide to stop taking part, your relationship with the research 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 Catherine Glenn, Ph.D. at Old Dominion University (glennlab@odu.edu). Any data that have already been sent to NIMH cannot be withdrawn because there will not be any identifiers with the data that indicate which data are yours.

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 at your site. If you are at the Old Dominion University Site, you should contact Catherine Glenn, Ph.D. at glennlab@odu.edu or 757-683-4249.

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research participant, you can contact the Rutgers IRB/Human Research Protection Program via phone at (973) 972-3608 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

AGREEMENT TO TAKE PART IN RESEARCH

Participant 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 research have been answered. I agree to take part in this research.

Participant Name (Print):_____

Participate Signature:_____ Date:_____

(OPTIONAL) DIGITAL AGREEMENT FOR NDA DATA SUBMISSION

Additionally, you have the option to be a part of a larger data upload of de-identified data to the NIMH's data repository ("NDA") so that other researchers can use it. "De-identified" means that people will not be able to see your name or any personal information that would connect you to the data; they will only see the data by itself. The NDA requires we create a non-identifiable ID called the GUID to link to your data instead of your name. We will use your date of birth and place of birth on a secure computer program to generate this GUID, but your date of birth and place of birth will not be linked to your data. You can still participate in this research study even if you do not want your data to be added to the NDA, and you can decide to change that decision at any time. However, once your data is part of the NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about the NDA, it is available at http://nda.nih.gov.

While the databases developed for future use and for the NDA will be coded to protect your personal information (see above), people may develop ways in the future that would allow someone to link your information back to them. It is also possible that there could be violations to the security of the computer systems. There also may be other privacy risks that we have not foreseen.

Do you agree to share your data with the NDA? ☐Yes ☐No
If you selected yes, please sign below

Participant Consent:

I agree to submit de-identified data to the NIMH data repository (NDA).

Participant Name:_____

Participant Signature:_____ Date:_____

(OPTIONAL) PERMISSION (AUTHORIZATION) TO USE OR SHARE HEALTH INFORMATION THAT IDENTIFIES YOU FOR RESEARCH

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 invited to take part in this research which is described at the beginning of this form. The purpose of collecting and using your health information for this research 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 research with the following people and institutions:

- Rutgers University Investigators Involved in the Research
- The Rutgers University Institutional Review Board
- The Office for Human Research Protections in the U.S. Dept. of Health and Human Services
- Our funding sponsor, the National Institute of Mental Health (NIMH)
- Non-ODU Investigators on the Study Team:
    - E.g. Evan Kleiman, Ph.D., Rutgers, the State University of New Jersey
- Our Data Safety Monitoring Board (DSMB)

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 research is over. To ask for this information, please contact the Principal Investigator, the person in charge of this research.

Do I have to give my permission?
No. You do not have to permit use of your information. This part of the study is optional. (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 stop taking part in the research) at any time. If you take away permission, your information will no longer be used or shared in the research, 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 at your site and tell them of your decision: at Old Dominion University, you should contact Catherine Glenn, Ph.D. (glennlab@odu.edu)

How long will my permission last?
There is no set date when your permission will end. Your health information may be studied for many years.

Do you agree to share your health information? ☐Yes ☐No
If you selected yes, please sign below

Subject Consent:

I agree to let the investigators use my identifiable health information in the research.

Participant Name: _____

Participant Signature:_____ Date:_____

OLD DOMINION UNIVERSITY
Department of Psychology
250 Mills Godwin Building
Norfolk, VA 23529-0267
Phone 757-683-4439 • Fax 757-683-5087

RUTGERS
Department of Psychology
School of Arts and Sciences
Rutgers, The State University of New Jersey
53 Avenue E, Room 627
Piscataway, NJ 08854

ASSENT TO TAKE PART IN RESEARCH

TITLE OF RESEARCH: Sleep treatment for teens
Principal Investigator: Catherine Glenn, Ph.D., Old Dominion University; Evan Kleiman, Ph.D., Rutgers, the State University of New Jersey

Who are you and why are you meeting with me?
I am a researcher and I work at Old Dominion University in the Department of Psychology. I would like to tell you about a research study that involves people like yourself and see if you would like to take part in it. Please ask me, other research staff, or your parent/guardian to explain any words you don't understand about the research.

What is this research about?
The purpose of this research study is to test how effective a sleep treatment, available on your phone, called digital cognitive-behavioral therapy for insomnia (dCBT-I), is for teens who have recently been in the hospital for suicidal thoughts or behaviors, and also have insomnia.

Why have I been asked to take part in this research?
You are being asked to take part in this study because you are 14-18 years-old, were recently in the hospital for suicide risk, and have problems with insomnia.

Who can be in this research? And who may not? How long will the research take?
Adolescents, 14-18 years old, and one parent/guardian may take part in this study. This study focuses on teens who have recently received acute psychiatric care or hospitalization for suicidal thoughts and behaviors, and also have insomnia.

Who can be in this study?
- Ages 14-18
- Recently hospitalized for suicidal thoughts and behaviors (i.e., discharged within the past 45 days)
- Clinically severe insomnia symptoms

Who may not be in this study?
- Prior experience with the sleep treatment used in this study (CBT-I)
- Bipolar disorder or substance use disorder
- Having a sibling who participated in the study
- Factors that prevent teens from being able to consent to participate in research or to complete the study (ex. severe mental difficulties that prevent understanding the study, inability to read or speak English)

This study requires that you answer questions on your smartphone. If you do not have a smartphone, we will loan you a phone that can be used during the study

How long will the study last?
Your participation in the study will include three phases (described in the next section).
- Phase 1 (One time): Initial session (one time) will last approximately 2 hours total.

- Phase 2 (6-8 weeks): The active follow-up phase includes the following:
    - If you are randomly assigned (2 in 3 chance) to the treatment group, you will be asked to complete a sleep treatment consisting of six 20-minute sessions during Phase 2. If you are randomly assigned (1 in 3 chance) to the control group, you will not complete the treatment at this time (but will be offered access at the end of the study).
    - All teens, regardless of whether they are in the treatment or control group, will complete daily surveys that last no more than 10 minutes per day, and wear a special watch (Fitbit-like device) that doesn't take any time (just needs to be worn during the study).
    - All teens, at the end of Phase 2, will complete a 1-hour assessment including an interview and survey.
- Phase 3 (One time): For all teens, a final assessment (interview and surveys) will occur one month after the end of Phase 2 and will take approximately 1 hour total.
  If you were not randomly assigned to receive the sleep treatment during Phase 2 (control group), you will be given access to the treatment at the end of Phase 3.

Overall, your involvement in the study will last approximately 10-12 weeks (up to 12 weeks if you are in the treatment group, and 10 weeks if you are in the control group).

What will happen to me if I take part in this research?
If you decide to participate in this study, you will be asked to do the following things:

Phase 1: Initial Session (one time). The first session will last approximately 2 hours total and will take place either: (1) during your hospitalization (on the unit); or (2) within 45 days after your discharge from the hospital (in our research lab or over the phone). This session can take place at one time (if in our lab or over the phone) or in a couple of separate sessions (on the hospital unit and/or over the phone with you). During this session, you will be asked a series of questions through interviews with the research team and in surveys you complete on your own. These questions will ask about your thoughts, feelings, behaviors (including your sleep, history of self-injury, suicidal thoughts and behaviors), and events that have happened to you. You will also have a random (2 in 3) chance of being offered to complete the sleep treatment during Phase 2 (treatment group). You will receive an overview about the equipment needed for Phase 2 (smartphone-based app for surveys, a special watch, and the sleep treatment app for adolescents randomly assigned to the treatment group).

Phase 2: Active Follow-Up Phase (6-8 weeks).

- During this phase, you will be asked to complete short surveys (1-3 minutes each) via smartphone several times during the day. You won't be asked to complete surveys during school hours. Surveys will ask about your thoughts, feelings, behaviors (such as your sleep, self-injury, and suicidal thoughts and behaviors), and events that may have happened to you. The surveys will last for 6 weeks.
- In addition to answering survey questions on your phone, you will be asked to wear a special watch to monitor your sleep and activity. You will be asked to wear the watch on your non-dominant (non-writing) wrist all the time, except for when you are showering or bathing. If removed, you should put the watch back on as soon as possible. We will ask

you or your parent/guardian to return the watch to the research team when the study ends. You will be asked to wear the watch for 6 weeks.

- (If you are randomly assigned to complete the sleep treatment during Phase 2) You will be asked to complete a phone-based sleep treatment that includes six 20-minute weekly sessions that need to be completed over 6 weeks (and no more than 8 weeks). (Note: You will still have access to the sleep treatment after this time, but we will ask you to do your best to complete the sleep treatment within this time period).
    - You will also be asked to continue completing daily surveys and wearing the watch until you have finished the treatment or until 8 weeks has passed, whichever comes first.
- At the end of the active follow-up phase, you will be asked to complete a 1-hour assessment including an interview (over the phone or in person) and survey. Questions will ask about your thoughts, feelings, behaviors (such as your sleep, self-injury, and suicidal thoughts and behaviors) and (if you completed the treatment during Phase 2) feedback on the treatment you completed.

Phase 3: 1-month Follow-up Phase (one time). One month after the end of Phase 2, you will be asked to complete a final interview (over the phone or in person) and a survey, which will take 1 hour total. During this session, you will be asked similar questions as other phases of the study – your thoughts, feelings, behaviors (including sleep, self-injury, suicidal thoughts and behaviors), and events that may have happened to you. We may also ask you questions about what it was like to be in the study, which will help us with similar studies in the future.

(Optional): Medical Record Follow-Up. With your parent/guardian's permission, the research team may obtain information from your medical record about any additional admissions to psychiatric units or hospitals for one year after you are enrolled in the study. This will help us know if you have been to a hospital because of self-injury or suicide risk. This phase of the study does not require any interaction with you. This part of the study is optional and will not impact your ability to participate in other parts of the study.

Can something bad happen to me or will I feel uncomfortable if I take part in this research?

Sometimes things happen to people in research studies that may hurt them or make them feel bad. These are called risks. The risks of this research are that you might find some of the questions asked in interviews and surveys to be upsetting or uncomfortable. It is important to know that previous studies have found that answering questions about self-injury and suicide does not increase risk for suicidal thoughts and behaviors. However, it is possible that you may experience some distress during the study. If you experience distressing thoughts or feelings during or after the study, we strongly encourage you to let us know either when the study is in progress or after it has been completed (see contact information at the end of this form). You are encouraged to take breaks as needed if you become tired during the study, and you can skip any questions or tasks that you find uncomfortable.

Your safety is the top priority. If your answers to study questions indicate that you may be at imminent risk for hurting yourself, the research team will contact you to ask additional questions and take appropriate steps to keep you safe (like contacting your parent/guardian, suggesting you go to the hospital, or call emergency services on your behalf). However, it is

important for you to know that your answers are not monitored 24 hours a day, so your surveys should not be used as a way to get help in a crisis. We will provide resources to you that can be used in a crisis situation (e.g., as a personalized safety plan).

If we learn during the study that a child under 18 is being abused or neglected, we are ethically and legally obligated to file a report with the relevant local authorities (e.g., Department of Children and Families in NJ and Child Protective Services in VA). If you prefer not to disclose any information about child abuse, you can choose not to answer these kinds of questions during the study.

For the watch you are being asked to wear, you may experience mild redness or irritation on your wrist under the watch. This possible redness or irritation is temporary and not dangerous. If you experience redness or irritation, you should remove the watch and clean it with mild soap and water before putting it back on. If redness or irritation persists after cleaning, you should remove the device for the remainder of the study and inform the research team.

There is sometimes concern that sleep treatment, which includes sleep restriction (where people reduce their available time to sleep in order to improve their sleep quality), may be risky for youth with emotion regulation difficulties. To address this, sleep will not be restricted to less than 8 hours, making it safe for high-risk youth.

Although we take several steps to keep your study information secure and confidential, you should be aware that there is an extremely small possibility that your data could be viewed by unauthorized parties (such as computer hackers). However, your identifying information (such as your name) will not be stored with your survey data, so even hackers will not be able to link your data to your identity. (See section “Will others know what I say and do in the research?” for additional details.)

Can something good happen to me if I take part in the research?
The benefits of taking part in this research may be a therapeutic benefit by completing the sleep treatment, either in Phase 2 (treatment group) or at the end of Phase 3 (control group). Other potential benefits include learning more about your mental health and about mental health resources available to your family. However, it is possible that you may not receive any direct benefit from taking part in this research.

Will others know what I say and do in the research?
The information collected about you during this study will be kept safely secured and only accessible by the research team. Nobody will know who you are except the people doing the research. We will take many steps to protect your identity, so no one can know that you participated in this study. For example, the information that may identify you (your name, date of birth, phone number) will be kept separate from other information you provide in this study. Your study information will be identified by a confidential ID number (such as #9999) that is only known to the research team. Your information will be kept in locked cabinets and password protected electronic files on secure networks. To help us further protect your privacy, we have obtained a Certificate of Confidentiality. This Certificate means the research team cannot be made to give out information that may identify you to people who are not part of the research

team. The Certificate does not stop you or a member of your family from giving out information about yourself or your involvement in this research. If we write an article about what we learn from the study, we will not use your name.

Will I be given anything to take part in this research?
You will receive up to $170.00 for participating in all phases of the study. How much you will earn in each part of the study is provided below. Additionally, you will receive free access to the sleep treatment (either during Phase 2 or at the end of Phase 3).

Activity	Rate	Frequency	Total
Phase 1: Initial Session	$15/hour	Once (2 hours)	$30
Phase 2: Active Follow-Up Phase			
Daily surveys during active follow-up	$10/weekly (for 65%+ survey completion)	6 weeks	$60
Weekly surveys during active follow-up	$5/weekly	6 weeks	$30
End of Phase 2 assessment	$20	Once	$20
Phase 3: 1-Month Follow-Up			
1-month follow-up assessment	$20	Once	$20
Returning Study Watch	$10	Once	$10
		TOTAL	**$170**

What if I do not want to take part in this research?
You don't have to take part in this research if you don't want to. No one will get angry or upset if you do not want to be in the research. Just tell us. And remember, you can change your mind later if you decide you don't want to be in the research anymore.

What if I have questions?
You can ask questions at any time. You can ask now. You can ask later. You can talk to the researcher, or you can talk to someone else at any time during the research. If you have questions, concerns, or want more information about the research you can call the researcher at your study site. If you are at the Old Dominion University Site, you should contact Catherine Glenn, Ph.D. at glennlab@odu.edu or 757-683-4249.

If you have questions, concerns, problems, information or input about the research or would like to know your rights as a research participant, you can contact the Rutgers IRB/Human Research Protection Program via phone at (973) 972-3608 or (732) 235-9806 OR via email irboffice@research.rutgers.edu, or you can write us at 335 George Street, Liberty Plaza Suite 3200, New Brunswick, NJ 08901.

What are my rights if I decide to take part in this research?
You may ask questions about any part of the research at any time. Do not sign this form unless you have had a chance to ask questions and have been given answers to all your questions and agree to take part in the research.

If you say yes, your parent(s) or guardian will also be asked if it is ok for you to take part in this research. You will be given a copy of this form to keep.

ASSENT TO TAKE PART IN THIS RESEARCH

Participant's Signature:

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

Participant Name (Print): _____

Participant Signature:_____Date: _____

(OPTIONAL) DIGITAL AGREEMENT FOR NDA DATA SUBMISSION

You have the option to be a part of a larger data upload of de-identified data to the NIMH's data repository ("NDA") so that other researchers can use it. "De-identified" means that people will not be able to see your name or any personal information that would connect you to the data; they will only see the data by itself. The NDA requires we create a non-identifiable ID called the GUID to link to your data instead of your name. We will use your date of birth and place of birth on a secure computer program to generate this GUID, but your date of birth and place of birth will not be linked to your data. You can still participate in this research study even if you do not want your data to be added to NDA, and you can decide to change that decision at any time. However, once your data is part of NDA, the study researchers cannot take back the study data that was shared before they were notified that you changed your mind. If you would like more information about NDA, it is available at http://nda.nih.gov.

Do you agree to share your data with the NDA? ☐Yes ☐No
If you selected yes, please sign below

Participant Consent:

I agree to submit de-identified data to the NIMH data repository (NDA).

Participant Name:_____

Participant Signature:_____ Date:_____