CENTER FOR DATA INSIGHTS AND INNOVATION
CALIFORNIA HEALTH & HUMAN SERVICES AGENCY

View xForm - Project Application v6

This form is for new projects that have not been previously approved by CPHS.

Data entry
- Submitted 01/10/2025 2:31 PM ET by Shannon Hill, MPH

New Submission Study Personnel

NEW CONTACT INSTRUCTIONS

February 2025 cycle.
_____HSC Project_____

A DSL from Northwestern University Feinberg School of Medicine is attached.
A LOS from DHCS is attached.
Minors are involved in this project.
The project is privately funded.

01/06/2025 • Sussan Atifeh • Internal

Summary:

Researchers from Northwestern University in Chicago submitted a new project application to CPHS to request approval for a project with human subjects' contacts.
The proposed project, titled "Implementation of Soluna Single-Session Components in California Schools," is a privately funded research initiative led by Northwestern University researchers. The study aims to evaluate the uptake, effectiveness, acceptability, and engagement of the Soluna digital mental health platform among youth aged 14 to 17 in California. Soluna, developed by Kooth, offers free self-help tools and peer support to young people in California, providing rapid access to mental health resources from any internet-connected device.

Key Points:
• Human Subjects Involvement: The study involves human subjects, specifically minors aged 14 to 17.
• Recruitment and Consent: Participants will be recruited through the Soluna digital platform. The study seeks a waiver for parental consent, allowing adolescents to self-consent after passing a capacity assessment.
• Data Collection: Participants will complete three online surveys over three months, assessing various mental health outcomes. Additionally, anonymous usage data from the Soluna app will be analyzed.

• Data Linkage: The project involves linking survey responses with de-identified usage data from the Soluna platform.
• State Department Data: A Letter of Support from the California Department of Health Care Services (DHCS) is attached. Researchers mentioned, "We will obtain their anonymous usage data for 8 weeks thru a one-time data pull. Kooth houses and manages the data they would be providing to us. These are not Medi-Cal data from DHCS. However, the data for Soluna users is specified to be owned in contract by DHCS."
• Risk Management: The study includes protocols to address potential risks, such as assessing and responding to indications of suicidal ideation among participants.
• Compensation: Participants will receive a $10 gift card for each completed survey, totaling up to $30.
• Consent Waiver: The study requests a waiver of only parental consent, citing the potential negative consequences of requiring parental permission for adolescents seeking mental health support.

01/07/2025 • Sussan Atifeh • Internal

If personnel are not found by their email address while trying to complete the following questions, you can add them in the system with the link below. Click on the "New Contact Form" and complete it. Within a few minutes of completing the form, you will receive an email notifying you of the availability of the new contact. You should then be able to add them in the subsequent questions.

User had the option to start a different form here.

PRINCIPAL INVESTIGATOR (PI)

Enter the Principal Investigator's email address.

Jessica Schleider, Ph.D.

Email: jessica.schleider@northwestern.edu **Business:** (312) 503-1725

Choose the institution with which the PI is affiliated (not the location at which the research is being conducted).

Northwestern University

Enter the city in which the PI's institution is located.

Chicago

Enter the state in which the PI's institution is located.

Start typing in the state name to select the name from the list.

Illinois

Attach a copy of the PI's Curriculum Vitae.

jessica_schleider_cv_nov_2024.pdf PI Curriculum Vitae

CO-PRINCIPAL INVESTIGATOR (CO-PI)

Enter the Co-PI's email address by clicking on the "Add Contact" button.

If there are multiple co-principal investigators, repeat this action for all Co-PIs. If there are no Co-PIs for this project, skip this question.

No answer provided.

ADMINISTRATIVE CONTACT

Enter the email address(es) for the administrative contact(s). If you are the administrative contact, enter your email address, and enter anyone else you want listed as an administrative contact.

Shannon Hill, MPH

Email: shannon.hill@northwestern.edu **Business:** (614) 329-8589

RESPONSIBLE OFFICIAL (RO)

Enter the RO's email address.

*The RO **cannot** be the same person as the PI or Co-PI. The RO must have supervisory authority, in the administrative structure of the institution, over the PI.*

Rinad Beidas, PhD

Email: rinad.beidas@northwestern.edu **Business:** (312) 503-1725

OTHER RESEARCH STAFF

Enter the email address for any other research staff by clicking the "Add Contact" button.

Repeat this action for all other research staff not previously provided on this screen that should receive notifications about this project. If there are no additional research staff, skip this question.

Andy Rapoport, MPH

Email: andy.rapoport@northwestern.edu **Business:** (847) 624-0336

Check for PI same as RO (internal only question) *(Internal)*

False

Project Information

SUBMITTER

Application completed by:

Shannon Hill, MPH

Email: shannon.hill@northwestern.edu **Business:** (614) 329-8589

PREVIOUSLY APPROVED EXEMPTION

Is there a previously-approved exemption from CPHS for this project?

No

PROJECT TITLE

Enter the project title (please capitalize each word in your title).

Implementation of Soluna Single-Session Components in California Schools

PROJECT SITE

Indicate the primary site at which the research will be conducted.

Northwestern University

STUDY PROCEDURES

Indicate the study procedures involved in this research. Check all that apply.

If you have requested any state data for conducting this study, please select "Data Registry" as well in this section and attach all lists of requested variables (using descriptive names) by attaching the formal data dictionaries in the "DATABASE DETAILS" section. In the attached list(s) you need to provide a brief explanation to justify requesting each variable and to show the use of the variables.

If you do not need access to any state data for conducting this study, you can disregard this comment. Thanks.

01/07/2025 • Sussan Atifeh • *Not* Internal

You mentioned in a new note in the "Procedures" section of this application, "the data for Soluna users is specified to be owned in contract by DHCS..." If DHCS owns the data, please select "Data Registry" at this stage. If the reviewers of your project make a different determination, you will be notified by them at a later stage. Thanks.

01/09/2025 • Sussan Atifeh • *Not* Internal

Recruitment-Participant
Surveys

TYPE OF RESEARCH REQUEST

Indicate which of the following applies to this research. Check all that apply.

*Death Data Only refers to health-related studies requesting existing mortality data from **within** the California Human Health Services Agency (CHHSA)*

*SB-13 (Information Practices Act) refers to health-related studies requesting existing data from **outside** the CHHSA (e.g. California Department of Corrections and Rehabilitation [CDCR], California Department of Education [CDE], etc.) **OR** studies requesting data **within** the CHHSA that are not state funded or involving state staff.*

Common Rule/Human Subjects refers to health-related studies that involve direct or indirect interaction with human subjects (e.g. recruitment, interviews, etc.)

*Common Rule Only refers to health-related studies requesting existing data from **within** the CHHSA (e.g. Office of Statewide Health Planning and Development [OSHPD], California Department of Public Health [CDPH], etc)*

Common rule/Human subjects

PROJECT TYPE DETAILS

Indicate which, if any, apply to this research. Check all that apply.

Question about the need to request a HIPAA waiver?

01/07/2025 • Sussan Atifeh • Internal

If the research does not involve any of following, choose "None of the above."

Minimal Risk
Consent form
Informed Consent Waiver

VULNERABLE POPULATIONS

Indicate which vulnerable populations, if any, will be involved with this research. Check all that apply.

If vulnerable populations are not part of the research, choose "Not applicable."
Note regarding minors: in the United States, a minor is under 18 years of age. If research is conducted outside the United States, a minor is under the age of majority in the countries where research is to be conducted.

Minors

Please click the link below to fill out the supplement involving children. After you've finished the form, you will need to save it locally and then attach in the space below.

Link to Children Supplemental Form

Checklist-For-Research-Involving-Children_revised-2-25-22 (5) 12.20.24.pdf	Children Supplemental Form

Deleted Attachments: 1 (Most Recent: Checklist-For-Research-Involving-Children_revised-2-25-22.pdf on 12/20/2024 10:36 AM ET)

FUNDING

Is this research funded?

Yes

Indicate the funding source for this project.
Privately funded

EXPEDITED REVIEW CONSIDERATION

Please check the criteria below that you think your project meets to qualify for an expedited review. If none of these expedited criteria are appropriate for your project, choose 'not applicable'; your protocol will be reviewed by the full committee. Note that CPHS will make the final determination of whether the project meets the criteria for expedited review.

Protected Health Information/Personally Identifiable Data (PHI/PID) is defined as information in any format that identifies the individual, including demographic information collected from an individual that can reasonably be used to identify the individual. Additionally, PHI is information created or received by a healthcare provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual, including any of the 18 HIPAA identifiers.

Note: Please be aware that individual participants may be identifiable by combining other items in the data even when none of the 18 HIPAA identifiers are present. Thus, a study may still contain PID even after removing or never acquiring the identifiers, and the investigator may still need to provide complete answers for the data security questions in the protocol.

***The Departments within the California Health and Human Services Agency (CHHSA) are: Aging, Alcohol and Drug Programs, Child Support Services, Community Services and Development, Developmental Services, Emergency Medical Services Authority, Health Care Services, Mental Health, Public Health, Rehabilitation, Social Services and Statewide Health Planning and Development.*

Not applicable

ANTICIPATED PROJECT START DATE

Projects cannot begin before they have been reviewed. The earliest possible start date is always the date of the next public meeting at which the project will be heard.

Projects cannot begin before they have been reviewed. The earliest possible start date is always the date of the next public meeting at which the project will be heard. Please select 2/7/25 or a date following this date within a few weeks. Thanks.

01/07/2025 • Sussan Atifeh • *Not* Internal • Resolved

For a list of public meeting dates, see the CPHS website

02/07/2025

ANTICIPATED PROJECT END DATE

12/31/2025

Project Details

PURPOSE

Include a brief statement, less than 500 words, describing the research project. Be sure to address the background for the project, including relevant literature, the major research questions to be addressed, and the expected end product (e.g., article, report or other publications). Include the location(s) where the project will take place. The summary should be understandable to the general public.

Soluna is a digital platform, made by Kooth for youth in the State of California, that provides users with rapid access to self-help tools and peer support from any internet-connected device. Kooth partners with the State of California to provide youth with access to the Soluna platform, allowing teens to access peer support and professional support at no cost to the user or caregiver. With the high prevalence of mental health difficulties for young people across the United States, and access to care for these difficulties presenting challenges, Soluna provides a unique and innovative method of providing immediate support for adolescents.

The purpose of this study is to provide Kooth a method of evaluating uptake, effectiveness, acceptability, and engagement of the Soluna platform among youth in California. As a result of this study, we will publish findings to peer-reviewed journals, and present study findings at conferences. The study will take place online via the Soluna app, and participants will respond to surveys using a unique Qualtrics link.

MAJOR RESEARCH QUESTION

What is the major research question to be addressed in this project?

The purpose of this study is to provide Kooth a method of evaluating uptake, effectiveness, acceptability, and engagement of the Soluna platform among youth in California.

STUDY PROCEDURES

Describe in detail all procedures for this research. Do not attach grant applications or similar documents. Information in this application must be sufficient to fully explain the procedures without such documents

Please describe in detail all procedures for this project. For example, you can start by providing a description of the data being used, such as electronic health records or administrative datasets, etc., and identify the "DATA SOURCE", noting whether it is publicly available, de-identified, or requires special access permissions and naming the data-providing state departments (if any). You can also clarify how subjects will be selected, including any specific criteria for inclusion or exclusion, and indicate if data from a state department will be used. Specify the total number of subjects, and detail the analysis plan justifying the use of requested variables.

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You have attached a support letter from DHCS. To determine whether CPHS has purview over this study, it is essential to clarify the nature of DHCS's involvement:
• Data Provision: If the study requires access to personally identifiable information held by DHCS, CPHS approval is necessary before such data can be released for research purposes.
• Engagement in Research: If DHCS employees or agents are engaged in the research by obtaining data about the subjects through intervention or interaction, or by obtaining informed consent from human subjects, CPHS oversight would be required.

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This study will enroll adolescents (age 14-17), and is inclusive of all sexual backgrounds and ethnicities. We aim to recruit 250-500 California Soluna users. The purpose of this study is to provide Kooth a method of evaluating uptake, effectiveness, acceptability, and engagement of the Soluna platform among youth in California.

All recruitment will happen through Soluna's digital platform. Within the Soluna platform, students will receive a message informing them of the opportunity to participate in a research study. Individuals who click on the link in the message will be taken to a web page on Qualtrics that will contain

information about the study (full flier) and a link to the baseline survey. The survey will ask participants to answer questions that will determine their eligibility for the study.

Enrollment criteria for this study are as follows:
• Between the ages of 14 and 17, inclusive
• Self-report proficiency in reading in English
• Have access to the internet through computer, phone, smartphone, etc.
• In California, where Soluna is available for youth
• Shares email address (for compensation), as well as phone number and parent/guardian phone number, which are to be used if responses indicate suicidal thoughts, or self-harm thoughts or behaviors
• Passes capacity to consent assessment (the answers with [correct] next to them are the accepted answers, and participants have two attempts, see Section 11 for more details):
? What will you be asked to do in this study?
• Complete six surveys over one year
• Complete three surveys over three months [correct]
• Complete three interviews over three months
• Complete two surveys over two years
? What is a potential risk of participating in this study?
• I might feel uncomfortable with some of the questions, but I must answer all of them
• You may learn something new
• Your confidentiality could be compromised [correct]
• The security of your information will be protected
? What happens if I no longer want to participate in the study?
• A secure website called Qualtrics will continue to obtain information from you
• It will be no issue if you wish to leave the research; we'll keep your information, but we won't if you tell us not to [correct]
• Your relationship with Northwestern University/Northwestern Memorial Healthcare will be changed
• We want to learn what teens think about using the Soluna app for mental health support

Participants are clearly informed that they can skip any questions they do not want to answer and that they can stop participating at any time. Participants who started the study and decide to opt-out may request their information be discarded from the study. Soluna will remain available to all user's who choose to not participate in the study at any time point.

All enrolled study activities will be conducted virtually via a secure data collection platform (Qualtrics). Participants will complete three surveys: one at study enrollment (baseline), one approximately one month after enrollment, and one approximately three months after study enrollment. Table 1 demonstrates which assessments will occur at which timepoints.

During the first survey (source: Qualtrics survey input), participants will enter their email address. The second and third surveys (source: Qualtrics survey input) will be sent to the participants via email. These surveys will include demographic questionnaires, measures of related proximal outcomes

(e.g., hopelessness, agency, functionality appreciation, body dissatisfaction), and information about treatment seeking. We anticipate that each survey will take approximately 20-30 minutes to complete.

Secondary data analysis will not involve human subject recruitment; it will involve existing anonymous data from users who provided consent to their information being used for research purposes. Anonymous usage data, who have provided consent for their information to be used for research purposes, is being provided by Kooth to the Northwestern researchers. A chart (attached below) is included outlining the variables collected from the Soluna app: Kooth Secondary Data Table.docx.

We anticipate this data will come from 3500-4500 newly registered users of Soluna during the project period, who provided consent to their data being used for research purposes. We will obtain their anonymous usage data for 8 weeks thru a one-time data pull. Kooth houses and manages the data they would be providing to us. These are not Medi-Cal data from DHCS. However, the data for Soluna users is specified to be owned in contract by DHCS, and thus, we will also be applying to DRC for secure data usage.

This study does not require access to personally-identifiable information held by DHCS. Likewise, no DHCS employees or agents are engaged in the research by obtaining data about the subjects through intervention or interaction, or by obtaining informed consent from human subjects.

Please upload here any tables or charts related to your study procedures and any materials (such as surveys or interview questions) that will be presented to participants.

Assessment Timeline.docx	Other Documents
Follow-Up Messages (1).docx	Other Documents
Full flyer (first page of the Qualtrics survey_8.21.24 (1).docx	Other Documents
Kooth LOS NU.pdf	Other Documents
Kooth Secondary Data Table.docx	Other Documents
Mental Health Resources (2).pdf	Other Documents
Risk Message (1).docx	Other Documents
Riskflow_Kooth_10.25.24.docx	Other Documents
Teaser advertisement (Research card)_8.26.24.docx	Other Documents
UPDATED REMOTE MY COPING PLAN BLANK (Fillable) (1).pdf	Other Documents
Soluna Feedback and Assessment.pdf	Questionnaires

Soluna One Month Survey.pdf	Questionnaires
Soluna Three Month Survey.pdf	Questionnaires

RECORDING

Will audio or video recording occur?

No

DECEPTION

Will deception be used in this study?

No

CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY (CHHSA) DEPARTMENTS LIST

Indicate any of the following CHHSA department(s)' involvement in providing research staff, funding and/or patients from State mental hospitals for this project.

You selected DHCS in this section. Does DHCS provide research staff, funding and/or patients from State mental hospitals for this project? If yes, disregard this comment. If no, please select "Not Applicable."
Thanks.

01/07/2025 • Sussan Atifeh • *Not* Internal • Resolved

Not applicable

Study Population

POPULATION DESCRIPTION

Provide a full description of how human subjects will be involved in the research. Address characteristics of subjects such as: age; sex; ethnicity; and number of participants. Include requested participant number.

This study will enroll adolescents (age 14-17), and is inclusive of all sexual backgrounds and ethnicities. We aim to recruit 250-500 participants who have access to the Soluna digital platform, and for who we will obtain usage data from the Soluna app.

Secondary data analysis will not involve human subject recruitment; it will involve existing anonymous data from users who provided consent to their information being used for research purposes.

RATIONALE

What is the rationale for studying the requested group(s) of participants?

The purpose of this study is to provide Kooth a method of evaluating uptake, effectiveness, acceptability, and engagement of the Soluna platform among students in California. With the high prevalence of mental health difficulties for young people across the United States, and access to care for these difficulties presenting challenges, Soluna provides a unique and innovative method of providing immediate support for students. We anticipate this sample size will allow us to evaluate acceptability and effectiveness of the digital intervention provided through Soluna’s platform among students in California.

RECRUITMENT DETAILS

Describe how potential subjects will be identified for recruitment. Examples include: class rosters; group membership; individuals answering an advertisement; organization position titles (e.g., presidents, web designers, etc.). How will potential participants learn about the research and how will they be recruited (e.g., flyer, email, web posting, telephone, etc.)?

Important to remember: subjects cannot be contacted before IRB approval.

All recruitment will happen through Soluna's digital platform. Within the Soluna platform, students will receive a message informing them of the opportunity to participate in a research study. Individuals who click on the link in the message will be taken to a web page on Qualtrics that will contain information about the study (full flier) and a link to the baseline survey. The survey will ask participants to answer questions that will determine their eligibility for the study.

Attach copies of all recruitment materials.

Full flyer (first page of the Qualtrics survey_12.11.2024.docx	Recruitment Materials
Teaser advertisement (Research card)_12.11.24 (1).docx	Recruitment Materials

SCREENING

Will subjects be screened prior to entry into the research?

Yes

Please address the criteria for exclusion and inclusion in the research during the screening process. Provide reasons for not including women or minorities. Provide justification for including vulnerable populations such as children or prisoners. Please also provide a statement regarding what will happen to the information collected about the individual should they not enter into the study.
Enrollment criteria for this study are as follows:
• Between the ages of 14 and 17, inclusive
• Self-report proficiency in reading in English
• Have access to the internet through computer, phone, smartphone, etc.
• In California, where Soluna is available for youth
• Shares email address (for compensation), as well as phone number and parent/guardian phone number, which are to be used if responses indicate suicidal thoughts, or self-harm thoughts or behaviors
• Passes capacity to consent assessment (the answers with [correct] next to them are the accepted answers, and participants have two attempts, see Section 11 for more details):
? What will you be asked to do in this study?
• Complete six surveys over one year
• Complete three surveys over three months [correct]
• Complete three interviews over three months
• Complete two surveys over two years
? What is a potential risk of participating in this study?
• I might feel uncomfortable with some of the questions, but I must answer all of them
• You may learn something new
• Your confidentiality could be compromised [correct]
• The security of your information will be protected
? What happens if I no longer want to participate in the study?
• A secure website called Qualtrics will continue to obtain information from you
• It will be no issue if you wish to leave the research; we'll keep your information, but we won't if you tell us not to [correct]
• Your relationship with Northwestern University/Northwestern Memorial Healthcare will be changed
• We want to learn what teens think about using the Soluna app for mental health support

Participants are clearly informed that they can skip any questions they do not want to answer and that they can stop participating at any time. Participants who started the study and decide to opt-out may request their information be discarded from the study. Soluna will remain available to all user's who choose to not participate in the study at any time point.

COMPENSATION

Will subjects be compensated for participating in the study?

Yes

Compensation type
Gift card

Explain the amount and schedule of compensation that will be paid for participation in the study. Include provisions for prorating payment. The amount should not be coercive.
During this study, participants who choose to be in the study through the Soluna app will be eligible to receive a $10 gift card after completion of each of the three surveys (i.e., up to $30, across baseline, 1 month, & 3 month surveys). Eligibility is determined by in-app Soluna users who select to participate in our study by clicking the available research card that will re-direct them to the Qualtrics survey. All gift cards will be sent to the email address provided. Participants do not incur costs for participating in the study. This study will not involve more than minimal risk to participants; thus, additional compensations for research related injury does not apply to this project. Participants will be provided their gift cards within 10 business days of completing the survey.

STUDY DURATION

Estimate the probable duration of the entire study. This estimate should include the total time each subject is to be involved and the duration of each data collection about the subject.

E.G., This is a two-year study. Participants will be interviewed three times per year; each interview will last approximately two hours. Total approximate time commitment for participants is 12 hours.

All study activities will be conducted virtually via a secure data collection platform (Qualtrics). Participants will complete three surveys: one at study enrollment (baseline), one approximately one month after enrollment, and one approximately three months after study enrollment. Table 1 demonstrates which assessments will occur at which timepoints. At the end of the first survey, participants will enter their email address. The second and third surveys will be sent to the participants via email. These surveys will include demographic questionnaires, measures of related proximal outcomes (e.g., hopelessness, agency, functionality appreciation, body dissatisfaction), and information about treatment seeking. We anticipate that each survey will take approximately 20-30 minutes to complete.
We will keep our Qualtrics open to meet our quota, which means some participants who enroll in the study may begin at a later start date than the very first participant. For all interested participants to begin and complete the survey up to the three-month follow up point, we anticipate it requiring 6-months to for all participants to complete the study.

De-identified data collected from the Soluna app will occur in an 8-week window during the study period.

Risks and Benefits

RISK DESCRIPTION

Provide a description of possible risks to participants: physical, psychological, social, economic, loss of data security, and/or loss of confidentiality. Describe and justify whether the research is minimal risk or greater than minimal risk.

This study will involve no more than minimal risk. Participants may feel potential discomfort due to the length and content of the survey questionnaires. Participants may feel uncomfortable or sad when answering questions about their history of suicide or self-harming behaviors. Of note, however, research shows that assessing suicide risk does not increase implicit suicidality. In fact, there is evidence to suggest asking about suicide may have positive effects with respect to reducing distress, and in some cases reducing suicidal thoughts, among at-risk individuals. In light of this evidence, the likelihood of experiencing enduring emotional discomfort during the protocol is low. Moreover, participants are told in the consent form and reminded throughout the online survey that they can skip any questions they prefer not to answer as well as stop participating at any time.

Suicide risk is typically determined through a range of questions, and designations of "high" and "imminent" risk require answers to questions assessing current suicidal intent and/or self-reported ability to keep oneself safe, current suicidal thoughts/plans, and current access to methods (e.g., gun, pills). We are not asking questions that could indicate current level of risk for imminent suicidal thoughts or behaviors. Specifically, we will NOT ask about suicide ideation or suicide attempts in the past week, nor will we ask about suicide intent/ability to keep oneself safe.

There is a potential risk for coercion in any study that recruits from vulnerable populations (e.g., individuals under 18 years old). To mitigate this risk, participants will be provided with all of the information about the study that they need (within the consent form) to decide whether they wish to participate. As with most research, there is a risk of breach of confidentiality with identifiable data being collected.

Study personnel will employ multiple procedures to protect the privacy and to ensure the confidentiality of all data collected as part of this project. Data for this project will be stored as electronic data on a secure, internal network at NU (FSM Res Files) specific to the Lab for Scalable Mental Health. All survey data will be collected via Qualtrics, an encrypted and HIPAA-compliant platform. These data are only accessible to study personnel with IRB approval using unique, confidential usernames and passwords. Participant data will be de-identified, and data will be linked to a participant ID number. Only study personnel approved on this application will have access to the password-protected document linking participant IDs and identifying information. Participants' identities will remain private since the study takes place entirely online, no other direct participant identifiers besides email address will be collected, and participants will not interact with other participants or research personnel (unless the participant contacts the

research staff with questions).
Files stored on the server containing identifiable data are additionally protected via confidential passwords only known to research personnel and will be stored on a secure network at FSM Res Files. The identifying email addresses will only be stored with the data until data collection is complete and participants are compensated. Once compensation has been completed, all data will be de-identified. Participants' numeric codes linked to subject names are contained in a separate file with a separate access code.

Data Monitoring Plan to Ensure the Safety of Participants:
We are asking questions about suicidal ideation over the past month, in the form of the SIDAS scale (se section 8.0; SIDAS), as well as a question around self harm thoughts or behaviors in the last month (see section 8.0; Self-Harm Question), and a question about self harm thoughts in the last week (see section 8.0; YP-CORE). In the event a participant endorses a non-zero response to any item on the SIDAS scale, OR a "yes" answer to the self harm question, OR a non-zero answer to item 7 of the YP-CORE they will immediately be presented with the mental health resources again (see supplemental materials). They will have already provided both their phone number, and their parent or guardian's phone, alongside their email address (at each survey timepoint, all of which are required fields). They will receive a message explaining they will be contacted by a trained team member within 24 hours, who will conduct a risk assessment over the phone per the attached flowchart. There will be an automated message sent to those research team members alerting them of this need. The trained team members (Schleider & Cohen) have experience conducting risk assessments as part of research studies. If imminent risk is determined based on the assessment phone call, the youth's parent or guardian will be called, and 911 will be called. In situations per the attached flowchart where a Safety Plan is to be completed, "My Coping Plan" is a document previously used by the NU study team for risk response. It will here be used by the NU study team if risk arises; our team members will complete the document collaboratively with the participant.

Data files will be de-identified. Future use of the data includes research, publication, and archiving. Identifying information (i.e., email addresses) will be kept in a separate, password-protected file. The original identifiable data will remain on Qualtrics, through the NU Qualtrics license, for the next six years. Upon request from Page 20 of 20 HRP-583 / v05012023 other researchers, de-identified data files may be made available for secondary analysis. The proposed study does not involve any specimen banking.

Long-term Data and Specimen Storage and Sharing:
We will not be sharing identifiers and will not be collecting or sharing specimens.

Bender, T. W., Fitzpatrick, S., Hartmann, M.-A., Hames, J., Bodell, L., Selby, E. A., & Joiner, T. E., Jr. (2019). Does it hurt to ask? An analysis of iatrogenic risk during suicide risk assessment. Neurology, Psychiatry and Brain Research, 33, 73-81. https://doi.org/10.1016/j.npbr.2019.07.005

Gould, M. S., Marrocco, F. A., Kleinman, M., Thomas, J. G., Mostkoff, K.,

Cote, J., & Davies, M. (2005). Evaluating iatrogenic risk of youth suicide screening programs: a randomized controlled trial. JAMA, 293(13), 1635-1643. https://doi.org/10.1001/jama.293.13.1635

MEDICAL SERVICE RISKS

Describe how medical services will be provided if subjects suffer adverse mental or physical effects as result of research activity. If no services provided, state that clearly.

We are asking questions about suicidal ideation over the past month, in the form of the SIDAS scale, as well as a question around self harm thoughts or behaviors in the last month (Self-Harm Question), and a question about self harm thoughts in the last week (YP-CORE). In the event a participant endorses a non-zero response to any item on the SIDAS scale, OR a "yes" answer to the self harm question, OR a non-zero answer to item 7 of the YP-CORE they will immediately be presented with the mental health resources again (see supplemental materials). They will have already provided both their phone number, and their parent or guardian's phone, alongside their email address (at each survey timepoint, all of which are required fields). They will receive a message explaining they will be contacted by a trained team member within 24 hours, who will conduct a risk assessment over the phone per the attached flowchart. There will be an automated message sent to those research team members alerting them of this need. The trained team members (Schleider & Cohen) have experience conducting risk assessments as part of research studies. If imminent risk is determined based on the assessment phone call, the youth's parent or guardian will be called, and 911 will be called. In situations per the attached flowchart where a Safety Plan is to be completed, "My Coping Plan" is a document previously used by the NU study team for risk response. It will here be used by the NU study team if risk arises; our team members will complete the document collaboratively with the participant.

INTERNATIONAL RESEARCH

Will this research occur outside of the United States or U.S. territories?

Check with client to see if they consider territories to be outside the U.S. or not, as this can vary between institutions.

No

LESS RISKY METHODS

Describe any less risky methods and why they are not being used.

While we could choose to not include questions that involve suicidal ideation, however, we believe these questions are important to ask participants to understand the impacts and possible benefits of the interventions provided in the Soluna platform.

BENEFITS

Describe the benefits, if any, to the subjects or to society that will be realized as a result of this project. Discuss the benefits that may accrue directly to the subjects as well as to society. If there is no direct benefit anticipated for the subjects, state that clearly.

Participants may experience direct benefits associated with participatory research including learning something new, reducing symptoms of distress as a result of using the Soluna app, increasing perceived social support and outcome expectancies for mental health support, and enjoying the procedures (e.g., finding the survey or activities fun or engaging). During Trial 1, findings from the research collected from the Soluna app will result in increased acceptability of digital SSI's delivered through the Soluna platform and be considered helpful to the wellbeing and mental health of youth participants.

JUSTIFICATION OF RISKS

Explain why study risks are reasonable in relation to the potential benefits to subjects and to society.

These findings as a result of including these assessments and questions in the survey may facilitate offering these services and digital health apps in schools to increase uptake of SSI's among youth.

Adminstrative Safeguards

PERSONALLY IDENTIFIABLE DATA (PID) INSTRUCTIONS

Protected Health Information/Personally Identifiable Data (PHI/PID) is defined as information in any format that identifies the individual, including demographic information collected from an individual that can reasonably be used to identify the individual. Additionally, PHI is information created or received by a healthcare provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual, including any of the 18 HIPAA identifiers.

Note: Please be aware that individual participants may be identifiable by combining other items in the data even when none of the 18 HIPAA identifiers are present. Thus, a study may still contain PID even after removing or never acquiring the identifiers, and the investigator may still need to provide complete answers for the data security questions in the protocol.

If the researcher demonstrates that he or she is unable to comply with any of the requirements below, he or she may request an exception from these requirements. The researcher should indicate any measures that will be taken to address this requirement. The exception request should be made in the text box of the corresponding requirement. An exception will only be granted if the researcher can demonstrate that adequate alternative measures have been taken to minimize risks so as to justify the exception.

HIPAA IDENTIFIERS

Please identify which HIPAA Identifiers you plan to request as part of your submission.

Telephone numbers
Email address

TRAINING PROCEDURES

Describe the procedures for training all research staff who have access to PID on privacy and security. Indicate if staff are required to sign a confidentiality statement related to general use, security, and privacy.

All research staff has completed CITI training required by the Northwestern University IRB.

STAFF VETTING PROCEDURES

Describe procedures, either background check or thorough reference check, for vetting staff who will have access to PID.

Study personnel will employ multiple procedures to protect the privacy and to ensure the confidentiality of all data collected as part of this project. Data for this project will be stored as electronic data on a secure, internal network at NU (FSM Res Files) specific to the Lab for Scalable Mental Health. All survey data will be collected via Qualtrics, an encrypted and HIPAA-compliant platform. These data are only accessible to study personnel with IRB approval using unique, confidential usernames and passwords. Participant data will be de-identified, and data will be linked to a participant ID number.

SUPPORT LETTER

Obtain and submit a department support/data release letter.

This is a statement from the state agency or department you are receiving data from. It must be on that agency's/department's letterhead and should include both

1) *that the release of the desired data is legal and*

2) *that the entity is willing to release the desired data to you, the researcher. If you are not receiving data, this letter should indicate that you are supported.*

***For VSAC requests, if you do not have a Departmental Letter of Support (LOS)/Data Release, you may upload a copy of the Data Request Form (application) from the department to secure a review for the upcoming cycle. The protocol will not be approved until the LOS is uploaded to the protocol.*

Please also review the CPHS Statement for Birth and Death Data.

DRC Letter of Support Schleider.pdf Department Letter of Support

PREVENTING RE-USE AND UNAUTHORIZED ACCESS

Explain how you will ensure that data will not be reused or provided to any unauthorized person or entity.

Unauthorized means that the person or entity does not have a need to access the data for purposes of the research project approved by CPHS.

Files stored on the server containing identifiable data are additionally protected via confidential passwords only known to research personnel and will be stored on a secure network at FSM Res Files. The identifying email addresses will only be stored with the data until data collection is complete and participants are compensated. Once compensation has been completed, all data will be de-identified. Participants' numeric codes linked to subject names are contained in a separate file with a separate access code.

CONFIDENTIALITY OF PUBLISHED DATA

Indicate whether information will be published that could possibly be used to identify an individual subject.

Data is de-identified and no identifying information will be published.

All data analyzed during this study will be published to disseminate our findings of the methods and results. Findings of the study will be presented to Kooth through status reports and slide decks. NU researchers will produce a final report and manuscript to be presented at conferences and to be published. The data published will not contain any identifying information connected to study participants. Results of the study will not be shared with participants.

DATA REQUEST JUSTIFICATION

Provide adequate justifications for the quantity of the data, the years and the variables being requested. Have you requested no more than the minimum necessary data to perform the research?

The original identifiable data will remain on Qualtrics, through the NU Qualtrics license, for the next six years. It allows for data to be collected and for analysis to be conducted.

Data provided directly from the Soluna app will be kept on the secure Northwestern University internal ResFiles for 6 years, which is the standard timeframe for NUIT.

LIMITATIONS TO DATA ACCESS

Indicate if access to data is limited only to those with a need to know for purposes of implementing or evaluating the research.

Only study personnel approved on this application will have access to the password-protected document linking participant IDs and identifying information. Participants' identities will remain private since the study takes place entirely online, no other direct participant identifiers besides email address will be collected, and participants will not interact with other participants or research personnel (unless the participant contacts the research staff with questions).

Files stored on the server containing identifiable data are additionally protected via confidential passwords only known to research personnel and will be stored on a secure network at FSM Res Files. The identifying email addresses will only be stored with the data until data collection is complete and participants are compensated. Once compensation has been completed, all data will be de-identified. Participants' numeric codes linked to subject names are contained in a separate file with a separate access code.

PROTECTION AGAINST SMALL CELL SIZES AND ASSOCIATED PROBLEMS

Describe appropriate and sufficient methods to protect the identity of individual subjects when small cells or small numbers and/or data linkage to another data set are involved in the research project.

Any descriptive statistics that involve cell sizes smaller than five participants, will not be presented as such, rather we will collate or combine categories so that any cell size is larger than five (ie. creating an "other" category).

LINKAGES

Will the data set be linked with any other data sets?

You mentioned, "Participant data will be de-identified, and data will be linked to a participant ID number." Please also explain briefly about the linkages that are planned to be implemented in this study.

01/07/2025 • Sussan Atifeh • *Not* Internal

No

DESTRUCTION OF PID VERIFICATION

Indicate that you will provide CPHS with a letter certifying that PID has been destroyed and/or returned to the data source once research is concluded.

Yes

DATA SECURITY LETTER

Upload a certification/statement from the Chief Information Officer, Privacy Officer, Security Officer or equivalent position of the researcher's institution that CPHS Data Security Standards are met.

- *Data security letters cannot be signed by the Principal Investigator or Responsible Official.*
- *The data security letter must be on your institution's letterhead.*
- *Example of data security letter*

schleider_jessica_STU00220789 - Signed.pdf Data Security Letter

Physical Safeguards

DATA PROTECTION

Indicate that research records and physical samples will be protected through the use of locked cabinets and locked rooms; PID in paper form will not be left unattended unless locked in a file cabinet, file room, desk, or office.

No

DATA DESTRUCTION

Will data/samples will be destroyed or returned as soon as it is no longer needed for the research project.

Yes

RETAINED DATA

Will the retained data/samples have personal identifiers or be de-identified?

data will be de-identified

Explain what identifiers will be removed and how.
Study personnel will employ multiple procedures to protect the privacy and to ensure the confidentiality of all data collected as part of this project. Data for this project will be stored as electronic data on a secure, internal network at NU (FSM Res Files) specific to the Lab for Scalable Mental Health. All survey data will be collected via Qualtrics, an encrypted and HIPAA-compliant platform. These data are only accessible to study personnel with IRB approval using unique, confidential usernames and passwords. Participant data will be de-identified, and data will be linked to a participant ID number. Only study personnel approved on this application will have access to the password-protected document linking participant IDs and identifying information. Participants' identities will remain private since the study takes place entirely online, no other direct participant identifiers besides email address will be collected, and phone numbers for themselves and their parents in case they indicate risk, and participants will not interact with other participants or research personnel (unless the participant contacts the research staff with questions).

DESTRUCTION METHODS

Describe how you will ensure the PID in paper form is disposed of through confidential means, such as cross cut shredding or pulverizing.

There will be no PID in paper form.

FAXING

Describe how you will ensure that faxes with PID are not left unattended and fax machines are in secure areas.

There will be no faxes containing PID.

MAILING

Indicate whether mailings of PID are sealed and secured from inappropriate viewing; and whether mailings of 500 or more individually identifiable records of PID in a single package, and all mailings of PID to vendors/contractors/co-researchers, are sent using a tracked mailing method, which includes verification of delivery and receipt, such as UPS, U.S. Express Mail, or Federal Express, or by bonded courier.

No PID will be mailed.

ELECTRONIC STORAGE

State whether PID in paper or electronic form, e.g., stored on laptop computers and portable electronic storage media (e.g., USB drives and CDs), will ever be left unattended in cars or other unsecured locations.

There will be no PID in paper or electronic form that will ever be left unattended in cars or other unsecured locations.

PHYSICAL STORAGE

Describe whether facilities, which store PID in paper or electronic form, have controlled access procedures, and 24 hour guard or monitored alarm service.

Northwestern University has approved the use of Qualtrics, having conducted its own vetting process. Data stored on the secured network file at Northwestern University requires additional approval and Northwestern credentials to access. Files specific to this research will only be accessible to research staff given access to the network drive as provided by Northwestern IT.

SERVER SECURITY

Provide a description of whether all servers containing unencrypted PID are housed in a secure room with controlled access procedures.

Northwestern University has approved the use of Qualtrics, having conducted its own vetting process.

STORING IDENTIFIERS

Indicate whether identifiers will be stored separately from analysis data.

Data files will be de-identified. Future use of the data includes research, publication, and archiving. Identifying information (i.e., email addresses) will be kept in a separate, password-protected file. The original identifiable data will remain on Qualtrics, through the NU Qualtrics license, for the next six years. Upon request from Page 20 of 20 HRP-583 / v05012023 other researchers, de-identified data files may be made available for secondary analysis. The proposed study does not involve any specimen banking.

DISK STORAGE

State whether all disks with PID will be destroyed.

There are no disks containing PID that will be generated.

Electronic Safeguard

COMPUTER ACCESS OVERVIEW

State whether all computer access will be protected through the use of encryption, passwords, and other protections.

Files stored on the server containing identifiable data are additionally protected via confidential passwords only known to research personnel and will be stored on a secure network at FSM Res Files. The identifying email addresses will only be stored with the data until data collection is complete and participants are compensated. Once compensation has been completed, all data will be de-identified. Participants' numeric codes linked to subject names are contained in a separate file with a separate access code. All devices used by the study team are managed by Northwestern IT, and require individual passwords to access.

FIPS 140-2 COMPLIANCE: WORKSTATIONS

Indicate whether all workstations that contain PID have full disc encryption that uses FIPS 140-2 compliant software. If not, explain why not and what encryption will be used.

Yes. Bitlocker is active and by default by NU FSM IT

FIPS 140-2 COMPLIANCE: LAPTOPS

Indicate if all laptops that contain PID have full disc encryption that uses FIPS 140-2 compliant software. If not, explain why not and what encryption will be used.

Yes, configured upon deployment by FSM IT

FIPS 140-2 COMPLIANCE: REMOVABLE MEDIA DEVICES

Indicate if PID on removable media devices (e.g. USB thumb drives, CD/DVD, smartphones, backup recordings) are encrypted with software that is FIPS 140-2 compliant.

Yes, but our team will not be using removeable devices for data usage anyways.

SECURITY PATCHES

Indicate if all workstations, laptops and other systems that process and/or store PID have security patches applied in a reasonable time frame.

Yes. Patches are released on a regular basis for all operating systems and are automated by NU FSM IT.

PASSWORD CONTROLS

Indicate if sufficiently strong password controls are in place to protect PID stored on workstations, laptops, servers, and removable media.

Yes. All NU NetID's are within HIPPA protections.

ELECTRONIC SECURITY CONTROLS

Indicate if sufficient system security controls are in place for automatic screen timeout, automated audit trails, intrusion detection, anti-virus, and periodic system security/log reviews.

Yes, all are configured by default on deployment of FSM IT managed devices.

FIPS 140-2 COMPLIANCE: ELECTRONIC TRANSMISSION

Explain whether all transmissions of electronic PID outside the secure internal network (e.g., emails, website access, and file transfer) are encrypted using software which is compliant with FIPS 140-2.

We don't encrypt by default, but can be managed by FSM IT and is encrypted for services SFTP and Globis. We will not be sending data out to anyone.

INTERNET ACCESSIBILITY

Note if PID in an electronic form will be accessible to the internet.

Our laptops when connected to some university networks are publicly addressable to the internet. We will not be storing any data on our local machines, only on encrypted services managed by FSM IT like OneDrive and ResFiles.

DISPOSING OF PID

When disposing of electronic PID, indicate whether sufficiently secure wiping, degaussing, or physical destruction will be used.

Yes, FSM IT has a formal process to wipe or destruct decommissioned devices.

Conflict of Interest Information

CONFLICT OF INTEREST (COI) INSTRUCTIONS

A COI is defined as any financial or other relationships of the researcher(s) or the institution that could be perceived as affecting the objective conduct of the research, including the interpretation and publication of the findings. Researchers must disclose any COI, including perceived COI.

Financial relationships to be disclosed include but are not limited to the following:

- **Present or anticipated ownership of stock, stock options, or other financial obligations of the source of funding.**
- **Receipt or expectation of payment of any sort in connection with papers, symposia, consulting, editing, etc. from the source of funding.**
- **The sale or licensing or anticipated sale or licensing of medical or other products or intellectual property, such as patents, copyrights, or trade secrets to the source of funding or other entities.**
- **Any past, present or anticipated receipt of money or other valuable consideration from the source of research funding by the researcher(s), the family of the researcher(s), the research institution, or by an institution in which the researcher(s) or the family of the researcher(s) has an interest as owner, creditor, or officer.**

DISCLOSURES

Does any member of the study team, members' spouses, or members' dependent children have any significant financial interests related to the work to be conducted as part of the above-referenced project?

No

Informed Consent Procedures

INFORMED CONSENT PROCEDURES

Provide a description of procedures to be used in obtaining and documenting informed consent from participants.

See instructions and examples on CPHS website.

We will only be collecting participant consent for this study. We assess capacity to provide informed consent. Our request for parental consent waiver is included in the next page.

One of our inclusion criteria for the study is:

• Passes capacity to consent assessment (the answers with [correct] next to them are the accepted answers, and participants have two attempts, see Section 11 for more details):
? What will you be asked to do in this study?
• Complete six surveys over one year
• Complete three surveys over three months [correct]
• Complete three interviews over three months
• Complete two surveys over two years
? What is a potential risk of participating in this study?
• I might feel uncomfortable with some of the questions, but I must answer all of them
• You may learn something new
• Your confidentiality could be compromised [correct]
• The security of your information will be protected
? What happens if I no longer want to participate in the study?
• A secure website called Qualtrics will continue to obtain information from you
• It will be no issue if you wish to leave the research; we'll keep your information, but we won't if you tell us not to [correct]
• Your relationship with Northwestern University/Northwestern Memorial Healthcare will be changed
• We want to learn what teens think about using the Soluna app for mental health support

Consent will be completed online. All participants who screen eligible will be automatically routed to the consent form within the same Qualtrics survey. After reviewing the consent form summarizing key information, participants will complete a capacity to consent assessment based on the UCSD Task Force on Decisional Capacity recommendations (UCSD Task Force on Decisional Capacity, 2003). Participants who do not answer the questions correctly will be given another opportunity to answer the capacity to consent questions, but a second failure to answer the questions correctly will deem the participant ineligible for the study, and they will be directed to mental health resources on Qualtrics immediately, which we have included as a separate document for review. To the best of our ability, we have made the questions simple so that anyone who can read at a 6th grade level in English and has read the consent form can answer the questions correctly. Participants can download a copy of the consent form and the supplementary summary for their reference.

Participants who pass the capacity to consent assessment will be presented with the option to select "I agree to participate in the study", "I do not agree to participate in the study," or "I am not sure I want to participate at this time." If participants decide not to participate, they will be directed to other mental health resources. If they select "I agree," they will be asked to provide an electronic signature (which will serve as consent documentation) and then can continue to the baseline questionnaires within the same Qualtrics survey. If they select, "I am not sure," they will be encouraged to contact the research team with questions and advised not to participate if they remain hesitant. For one week, these participants will be permitted to return to the consent form where they left off, provide their electronic signature, and continue with the rest of the study, if they choose to do so. E-mail addresses for the PI and the Northwestern University IRB are listed in the consent form in case a participant has a question or would like to discuss the study.

CONSENT FORMS

Attach copies of consent forms and any other documents or oral scripts used to inform potential research subjects about the study. See examples of consent and assent forms on the CPHS website.

Be sure to include a concise explanation of key information for participants at the beginning of your consent form, as shown in the examples on the website. Also attach the Participant's Bill of Rights (download the revised version from the same CPHS website). CPHS may approve the use of a consent procedure which does not include, or which alters, some or all of the elements of informed consent. If a waiver or alteration of informed consent is being requested, attach a document that explains how all of the criteria below will be satisfied.

CA IRB Youth Consent Form 12.20.24.docx Consent Form

Deleted Attachments: 2 (Most Recent: CA Soluna Consent Form 12.17.2024.pdf on 12/20/2024 10:28 AM ET)

Informed Consent Waiver

INFORMED CONSENT WAIVER

Are you requesting a waiver or alteration of informed consent?

Yes

Provide a rationale as to why the research could not practicably be conducted without the waiver or alteration.
We are requesting a waiver for parental consent for these adolescent participants. This study meets the criteria for such a waiver as outlined below under Section 8 of the HRP-416 checklist:

• The research is not FDA-regulated.
• Research does not involve non-viable neonates.
• The research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects.

a. Attempting to obtain parent or guardian consent could result in serious negative consequences for the participant. For example, if parents are unaware of an adolescent's need for mental health support, requiring parental consent to take part in the study may cause the adolescent significant psychological and interpersonal distress. In fact, some parents may not want their teens to access mental health support due to cultural or internalized stigma.
b. A large majority of youth experiencing mental health concerns fail to access mental health services of any kind. A significant contributor to this lack of access to support is adolescents' motivations not to share about their mental health problems with their parents (Cavazos-Rehg et al., 2020). Waiving parental consent for this study will reduce critical barriers to obtaining a potentially helpful support for adolescents who are otherwise likely to go without support entirely.
c. The current study will be conducted online and obtaining parental consent online is both impractical and logistically difficult to ensure. On an online platform, it is impossible to determine whether a given message is sent from the parent, a child pretending to be a parent, or another adult who is not the child's legal guardian.
d. The State of California partnered with Kooth allow youth to receive the Soluna platform and services independently and as they perceive need. To conduct a representative evaluation, it is necessary to follow similar recruitment and consent procedures.

• An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted.

e. The consent process will involve developmentally-appropriate consent materials, including a capacity to consent assessment. These procedures will ensure that participants are fully informed about the study goals, procedure, risks, benefits, and data protection.
f. All participants will be provided with mental health resources through the

Soluna platform

• The waiver is not inconsistent with Federal, State, or local law.

g. Mature minor laws across the country permit youth as young as 12 to self-consent to mental healthcare. These laws recognize that requiring parental/guardian permission for mental health concerns that are sensitive or potentially stigmatizing may inhibit adolescents' willingness to seek care for these concerns. For an overview of minor consent laws, see Sharko et al., 2022.

Sharko, M., Jameson, R., Ancker, J. S., Krams, L., Webber, E. C., & Rosenbloom, S. T. (2022). State-by-State Variability in Adolescent Privacy Laws. Pediatrics, 149(6), e2021053458. https://doi.org/10.1542/peds.2021-053458

Provide a detailed account of the plans and measures that will be in place to protect the rights and welfare of the subjects.
As we have outlined in previous sections of this proposal, we are asking questions that may indicate suicidality, and have included the necessary protocols and procedures our lab will take if any participant were to answer certain questions to trigger a response email from our team. We've included that same language below:

Suicide risk is typically determined through a range of questions, and designations of "high" and "imminent" risk require answers to questions assessing current suicidal intent and/or self-reported ability to keep oneself safe, current suicidal thoughts/plans, and current access to methods (e.g., gun, pills). We are not asking questions that could indicate current level of risk for imminent suicidal thoughts or behaviors. Specifically, we will NOT ask about suicide ideation or suicide attempts in the past week, nor will we ask about suicide intent/ability to keep oneself safe.

There is a potential risk for coercion in any study that recruits from vulnerable populations (e.g., individuals under 18 years old). To mitigate this risk, participants will be provided with all of the information about the study that they need (within the consent form) to decide whether they wish to participate. As with most research, there is a risk of breach of confidentiality with identifiable data being collected. Possible solutions to these concerns are discussed below.

Bender, T. W., Fitzpatrick, S., Hartmann, M.-A., Hames, J., Bodell, L., Selby, E. A., & Joiner, T. E., Jr. (2019). Does it hurt to ask? An analysis of iatrogenic risk during suicide risk assessment. Neurology, Psychiatry and Brain Research, 33, 73–81. https://doi.org/10.1016/j.npbr.2019.07.005

Gould, M. S., Marrocco, F. A., Kleinman, M., Thomas, J. G., Mostkoff, K., Cote, J., & Davies, M. (2005). Evaluating iatrogenic risk of youth suicide screening programs: a randomized controlled trial. JAMA, 293(13), 1635–1643. https://doi.org/10.1001/jama.293.13.1635

HIPAA Determination

HIPAA INSTRUCTIONS

To determine if this project is covered by HIPAA, answer the following questions.

COVERED ENTITY

Will health information be obtained from a covered entity, known as a clearinghouse, such as Blue Cross, that processes or facilitates processing health data from another entity, including but not limited to state databases?

No

HEALTHCARE PROVISIONS

Will the study involve the provision of healthcare by a covered entity, such as the UCD Medical Center?

No

OTHER HIPAA CRITERIA

Will the study involve other HIPAA criteria not listed above?

No

Cover Letter and PI Signature for PI Submission

BUDGET

Does this project have a budget?

Yes

Attach a copy of your project budget here

NU Kooth Budget.xlsx Project Budget

COVER LETTER

Attach a copy of your project cover letter.

Dear Researchers: Before resubmitting this application, please check all pages (scroll down to see the entire page) and ensure you have addressed all comments. Some new comments were added after the application was sent to Data Entry stage. Thanks.

01/09/2025 • Sussan Atifeh • *Not* Internal • Resolved

Cover letter must have the requesting institution's letterhead.

CA IRB_NU LOS.docx Cover Letter

In order for the PI to review and sign this form, you will need to click "Next" and on the next page, click "Submit." At that point the PI will receive notification that will need to review the application and if they request changes, they will return the form to you and you will receive an email notification.

PI Signature for Coordinator Submission (Initial) - Submitted 01/10/2025 2:58 PM ET by Jessica Schleider, Ph.D.

PI Review

Please click "Next" and "Submit" in order to submit this application, regardless of whether or not it is ready for review. If you indicated it is ready for review, it will go to the Responsible Official for review and signature, and if not, it will be returned to the individual who completed the form for changes.

Is this application ready to be reviewed by the IRB? If not, choose no to have the application sent back to the coordinator for revisions.

Yes

To sign this form, enter your IRBManager password. By signing this form, you are indicating that the information within this application is accurate and reflects the proposed research and that you attest to the conflict of interest disclosures for all study team members.

Signed Friday, January 10, 2025 2:58:50 PM ET by Jessica Schleider, Ph.D.

Responsible Official Signature
- Submitted 01/06/2025 6:08 PM ET by Rinad Beidas, PhD

Responsible Official Signature

After reviewing this application, is it ready for submission to the CPHS IRB?

Yes, ready for submission to IRB.

Enter your password to sign this protocol. By signing this protocol, you are attesting that the information within is accurate and reflects the details of the proposed research project.

Signed Monday, January 6, 2025 6:08:40 PM ET by Rinad Beidas, PhD

After choosing whether or not the submission is ready for CPHS IRB review, please click "next" and "submit" (on the next screen) to move the form forward to the CPHS IRB or back to the Researcher.

Notify IRB for Pre-Screening
- Submitted 01/14/2025 1:39 PM ET by Sussan Atifeh

Internal IRB Screening

CPHS Office: The questions on this page will appear every time the project is resubmitted to the CPHS IRB (even after review). Once the project has been reviewed by a committee member, unless researcher has changed questions on the form that impact the level of review, you do not need to update the questions here. If the changes made are not clear and require additional clarification change the 'ready for review' to 'no' and require changes. When you change the answer back to yes, it will remember your previous answers.

Is this study ready to be reviewed by the CPHS panel?

Yes

Choose the IRB committee to review this study (this defaults to CPHS)

CPHS

Level of Review Determination (once the level of review is assigned for this project, do not change this answer unless the reviewer/committee has decided that the study requires a different level of review)

Full Board Minimal Risk

Please provide a rationale for your level of review preliminary determination

Researchers from Northwestern University have submitted this project which is aimed to evaluate the uptake, effectiveness, acceptability, and engagement of the Soluna digital mental health platform among youth aged 14 to 17 in California. Soluna, developed by Kooth, offers free self-help tools and peer support to young people in California, providing rapid access to mental health resources from any internet-connected device.

Key Points:
• Human Subjects Involvement: The study involves human subjects, specifically minors aged 14 to 17.
• Recruitment and Consent: Participants will be recruited through the Soluna digital platform. The study seeks a waiver for parental consent, allowing adolescents to self-consent after passing a capacity assessment.
• Data Collection: Participants will complete three online surveys over three months, assessing various mental health outcomes. Additionally, anonymous usage data from the Soluna app will be analyzed.
• Data Linkage: The project involves linking survey responses with de-identified usage data from the Soluna platform.
• State Department Data: A Letter of Support from the California Department of Health Care Services (DHCS) is attached to the application. We asked for more clarifications regarding this support letter since they had not referred to DHCS in any other sections of the application and they mentioned, "We anticipate this data will come from 3500-4500 newly registered users of Soluna during the project period, who provided consent to their data being used for research purposes. We will obtain their anonymous usage data for 8 weeks thru a one-time data pull. Kooth houses and manages the data they would be providing to us. These are not Medi-Cal data from DHCS. However, the data for Soluna users is specified to be owned in contract by DHCS, and thus, we will also be applying to DRC for secure data usage."
• Risk Management: The study includes protocols to address potential risks, such as assessing and responding to indications of suicidal ideation among participants.
• Compensation: Participants will receive a $10 gift card for each completed survey, totaling up to $30.
• Consent Waiver: The study requests a waiver of only parental consent, citing the potential negative consequences of requiring parental permission for adolescents seeking mental health support.

Funding:
This project is Privately funded.

Choose the CPHS Chair
Catherine Hess, PhD

Select the vice chair of the committee

Larry Dickey, MD, MPH, MSW

Assign to Cycle

February

Assign to cycle year
2025

Load into IRBManager (Initial Submission)
- Submitted 01/14/2025 1:39 PM ET by The System

Chair Review and Full Board Set-Up
- Submitted 01/14/2025 3:26 PM ET by Sussan Atifeh

Full Board Set Up

Project number

2025-011

The office will complete the questions on this page and submit the form after the teleconference with the chairs regarding this project is completed.

Confirmation of level of review

Full Board Minimal Risk

Provide the rationale for the level of review determination
Researchers from Northwestern University in Chicago submitted a new project application to CPHS to request approval for a project with human subjects' contacts.
The proposed project, titled "Implementation of Soluna Single-Session Components in California Schools," is a privately funded research initiative led by Northwestern University researchers. The study aims to evaluate the uptake, effectiveness, acceptability, and engagement of the Soluna digital mental health platform among youth aged 14 to 17 in California. Soluna, developed by Kooth, offers free self-help tools and peer support to young people in California, providing rapid access to mental health resources from any internet-connected device.

Key Points:
• Human Subjects Involvement: The study involves human subjects, specifically minors aged 14 to 17.
• Recruitment and Consent: Participants will be recruited through the Soluna digital platform. The study seeks a waiver for parental consent, allowing adolescents to self-consent after passing a capacity assessment.
• Data Collection: Participants will complete three online surveys over three months, assessing various mental health outcomes. Additionally, anonymous usage data from the Soluna app will be analyzed.
• Data Linkage: The project involves linking survey responses with de-identified usage data from the Soluna platform.
• State Department Data: A Letter of Support from the California Department of Health Care Services (DHCS) is attached. Researchers mentioned, "We will obtain their anonymous usage data for 8 weeks thru a one-time data pull. Kooth houses and manages the data they would be providing to us. These are not Medi-Cal data from DHCS. However, the data for Soluna users is specified to be owned in contract by DHCS."
• Risk Management: The study includes protocols to address potential risks, such as assessing and responding to indications of suicidal ideation among participants.
• Compensation: Participants will receive a $10 gift card for each completed survey, totaling up to $30.
• Consent Waiver: The study requests a waiver of only parental consent, citing the potential negative consequences of requiring parental permission for adolescents seeking mental health support.

Assign SME to study

Maria Ventura, PhD

Enter the meeting date for this project

02/07/2025

SME Review

SME review

After reviewing the application, complete the question(s) below. If you wish to make comments on the application for the researcher, use the 'add note' feature on each question (be certain to unmark the internal only box and do not mark changes required). To navigate the application, you can either use the 'previous' button at the bottom of the page or from the drop down at the top of this page choose 'view previous stages'. Once you have completed the questions that appear on this page (different questions will appear depending on your answer to the first question), you will need to click 'next' (from either the top of the bottom of the screen) and then click 'submit'.

If you are requiring revisions before the full committee review, the form will be returned to the researcher for revisions and returned to you upon re-submission.

Does the researcher need to provide additional information/revisions before the committee meeting? If there is insufficient time for the researcher to make changes prior to the committee meeting, choose 'no' in order to route the form correctly.

No answer provided.

In order to either return this application to the researcher or to move forward for the full meeting review, click 'next' and 'submit' on the next screen.