The Human Subjects Division (HSD) strives to ensure that people with disabilities have access to all services and content. **If you experience any accessibility-related issues with this form or any aspect of the application process, email hsdinfo@uw.edu for assistance.**

INSTRUCTIONS

- **This form is only for studies that will be reviewed by the UW IRB**. Before completing this form, check HSD's website to confirm that this should not be reviewed by an external (non-UW) IRB.
- **If you are requesting a determination** about whether the planned activity is human subjects research or qualifies for exempt status, you may skip all questions except those marked with **[DETERMINATION]** For example **1.1. [DETERMINATION]** must be answered. Do not upload consent materials for determinations in ***Zipline*** as HSD does not review or approve them.
- **Answer all questions**. If a question is not applicable to the research or if you believe you have already answered a question elsewhere in the application, state "NA" (and if applicable, refer to the question where you provided the information). If you do not answer a question, the IRB does not know whether the question was overlooked or whether it is not applicable. This may result in unnecessary "back and forth" for clarification. Use non-technical language as much as possible.
- For collaborative or multi-site research, describe only the UW activities unless you are requesting that the UW IRB provide the review and oversight for non-UW collaborators or co-investigators as well.
- You may reference other documents (such as a grant application) if they provide the requested information in non-technical language. Be sure to provide the document name, page(s), and specific sections, and upload it to ***Zipline***. Also, describe any changes that may have occurred since the document was written (for example, changes that you've made during or after the grant review process). In some cases, you may need to provide additional details in the answer space as well as referencing a document.
- **NOTE: Do not convert this Word document to PDF.** The ability to use "tracked changes" is required in order to modify your study and respond to screening requests

INDEX

1. OVERVIEW

Study Title: Evaluation of an Asynchronous Remote Communities Approach to Behavioral Activation for Depressed Adolescents

1.1. [DETERMINATION] **Home institution.** Identify the institution through which the lead researcher listed on the IRB application will conduct the research. Provide any helpful explanatory information.

In general, the home institution is the institution (1) that provides the researcher's paycheck and that considers them to be a paid employee, or (2) at which the researcher is a matriculated student. Scholars, faculty, fellows, and students who are visiting the UW and who are the lead researcher: identify your home institution and describe the purpose and duration of your UW visit, as well as the UW department/center with which you are affiliated while at the UW.

Note that many UW clinical faculty members are paid employees of non-UW institutions.

*The UW IRB provides IRB review and oversight for only those researchers who meet the criteria described in the **SOP Use of the UW IRB**.*

University of Washington

1.2. [DETERMINATION] **Consultation history**. Has there been any consultation with someone at HSD about this study?

It is not necessary to obtain advance consultation. However, if advance consultation was obtained, answering this question will help ensure that the IRB is aware of and considers the advice and guidance provided in that consultation.

☒ **No**

☐ **Yes →** Briefly describe the consultation: approximate date, with whom, and method (e.g., by email, phone call, in-person meeting).

Click or tap here to enter text.

1.3. [DETERMINATION] **Similar and/or related studies**. Are there any related IRB applications that provide context for the proposed activities?

Examples of studies for which there is likely to be a related IRB application: Using samples or data collected by another study; recruiting subjects from a registry established by a colleague's research activity; conducting Phase 2 of a multi-part project or conducting a continuation of another study; serving as the data coordinating center for a multi-site study that includes a UW site.

Providing this information (if relevant) may significantly improve the efficiency and consistency of the IRB's review.

☐ **No**

☒ **Yes →** Briefly describe the other studies or applications and how they relate to the proposed activities. If the other applications were reviewed by the UW IRB, please also provide: the UW IRB number, the study title, and the lead researcher's name.

Our team has IRB approval related to conducting a series of design, development and usability studies related to our digital mental health support tool for adolescent depression care, ActivaTeen (STUDY00002824; Designing for Adolescent Health). These studies have assisted us discovering target user needs, evaluation of proposed digital tool designs and user testing in mock scenarios with target users. The finalized ActivaTeen tool will be utilized in the present study as part of a pilot randomized clinical trial (RCT) to better understand feasibility, usability, acceptability, and engagement of the tool when used alongside behavioral activation (BA) for adolescent depression care. Both the usability and RCT lead researchers are Drs. Jenness and Kientz.

1.4. [DETERMINATION] **Externally-imposed urgency or time deadlines**. Are there any externally-imposed deadlines or urgency that affect the proposed activity?

HSD recognizes that everyone would like their IRB applications to be reviewed as quickly as possible. To ensure fairness, it is HSD policy to review applications in the order in which they are received. However, HSD will assign a higher priority to research with externally-imposed urgency that is beyond the control of the researcher. Researchers are encouraged to communicate as soon as possible with their HSD staff contact person when there is an urgent situation (in other words, before submitting the IRB application). Examples: a researcher plans to test an experimental vaccine that has just been developed for a newly emerging epidemic; a researcher has an unexpected opportunity to collect data from students when the end of the school year is only four weeks away.

HSD may ask for documentation of the externally-imposed urgency. A higher priority should not be requested to compensate for a researcher's failure to prepare an IRB application in a timely manner. Note that IRB review requires a certain minimum amount of time; without sufficient time, the IRB may not be able to review and approve an application by a deadline.

☒ **No**
☐ **Yes →** Briefly describe the urgency or deadline as well as the reason for it.

Click or tap here to enter text.

1.5. [DETERMINATION] **Objectives**. Using lay language, describe the purpose, specific aims, or objectives that will be met by this specific project. If hypotheses are being tested, describe them. You will be asked to describe the specific procedures in a later section.

If this application involves the use of a HUD "humanitarian" device: describe whether the use is for "on-label" clinical patient care, "off-label" clinical patient care, and/or research (collecting safety and/or effectiveness data).

The purpose of this project is to test the feasibility and acceptability a digital health intervention for both 1) clinicians delivering the intervention and 2) teenagers with depression (ages 13-19) receiving the intervention. The intervention is an add-on component to an established depression protocol called behavioral activation (BA). All patient participants will receive BA, either in-person or via telehealth. Half of the patients will be randomized to additionally receive the digital support tool, ActivaTeen, which is a type of asynchronous remote community (ARC). ActivaTeen is a digital support tool that is delivered on a platform (Microsoft Teams) that is HIPAA-compliant, accessible at all times, and allows patients to connect with other patient participants as well as with the clinicians who are delivering the intervention. Therefore, this study will compare clinical and implementation outcomes between the BA-Only and ActivaTeen+BA groups across the following specific aims:

1) Test the feasibility, usability, appropriateness, engagement, and acceptability of delivering ActivaTeen+BA compared to BA alone for clinicians
2) Test the feasibility, usability, appropriateness, engagement, and acceptability (i.e., implementation outcomes) of receiving ActivaTeen+BA compared to BA alone for patients
    a. Explore the effect of ActivaTeen+BA compared to BA alone on depression and anxiety as well as functional impairment (i.e., clinical outcomes)
    b. Explore the association of specific components of ActivaTeen with hypothesized treatment mechanisms including therapist alliance, timeliness of intervention, treatment efficiency, and social belongingness
    c. Explore race and ethnicity as moderators of implementation and clinical outcomes linked to ActivaTeen+BA

1.6. [DETERMINATION] **Study design**. Provide a one-sentence description of the general study design and/or type of methodology.

Your answer will help HSD in assigning applications to reviewers and in managing workload. Examples: a longitudinal observational study; a double-blind, placebo-controlled randomized study; ethnographic interviews; web scraping from a convenience sample of blogs; medical record review; coordinating center for a multi-site study.

This is a 2-arm pilot randomized controlled trial of the acceptability of a remote digital health intervention for teenagers (ActivaTeen), ages 13-19, with depression (n=70), in which the clinicians delivering the intervention (n=10) will also be enrolled in the research to provide feedback on the acceptability of using ActivaTeen to support care.

1.7. [DETERMINATION] **Intent**. Check all the descriptors that apply to your study. You must check at least one box.

This question is essential for ensuring that your application is correctly reviewed. Please read each option carefully.

Check all that apply	Descriptor
☐	Class project or other activity whose purpose is to provide an educational experience for the researcher (for example, to learn about the process or methods of doing research).
☐	Part of an institution, organization, or program's own internal operational monitoring.
☐	Improve the quality of service provided by a specific institution, organization, or program.
☒	Designed to expand the knowledge base of a scientific discipline or other scholarly field of study, and produce results that: • Are expected to apply to a larger population beyond the site of data collection or the specific subjects studied, or • Are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.
☐	Focus directly on the specific individuals about whom the information or biospecimens are collected through oral history, journalism, biography, or historical scholarship activities, to provide an accurate and evidence-based portrayal of the individuals.
☐	A quality improvement or program improvement activity conducted to improve the implementation (delivery or quality) of an accepted practice, or to collect data about the implementation of the practice for clinical, practical, or administrative purposes. This does not include the evaluation of the efficacy of different accepted practices, or a comparison of their efficacy.
☐	Public health surveillance activities conducted, requested, or authorized by a public health authority for the sole purpose of identifying or investigating potential public health signals or timely awareness and priority setting during a situation that threatens public health.
☒	Preliminary, exploratory or research development activities (such as pilot and feasibility studies, or reliability/validation testing of a questionnaire).
☐	Expanded access use of a drug or device not yet approved for this purpose.

Check all that apply	Descriptor
☐	Use of a Humanitarian Use Device.
☐	Other. Explain:

Click or tap here to enter text.

1.8. Background, experience, and preliminary work. Answer this question **only** if the proposed activity has one or more of the following characteristics. The purpose of this question is to provide the IRB with information that is relevant to its risk/benefit analysis.

- Involves more than minimal risk (physical or non-physical)
- Is a clinical trial, or
- Involves having the subjects use a drug, biological, botanical, nutritional supplement, or medical device.

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

1.8.a. Background. Provide the rationale and the scientific or scholarly background for the proposed activity, based on existing literature (or clinical knowledge). Describe the gaps in current knowledge that the project is intended to address.

This should be a plain language description. Do not provide scholarly citations. Limit your answer to less than one page or refer to an attached document with background information that is no more than three pages long.

About 3.1 million adolescents are diagnosed with depression (MDD) each year and adolescent-onset MDD is associated with chronic physical, mental, and psychosocial disability. However, over 60% of adolescents with MDD do not receive mental health care, and there is low treatment engagement among those who do. Further, as the world has rapidly embraced the use of digitally delivered evidence-based psychosocial interventions (EBPIs) due to the COVID-19 pandemic, this new intervention landscape provides an opportunity and need to improve digital tools to support mental health care. **This project addresses the need to develop innovative tools to improve access, engagement, and usability of current EBPIs.**

Given their ubiquitous access to and use of mobile technologies, adolescents may be better reached and engaged through technology platforms that leverage social media and mobile technology approaches. **Asynchronous Remote Communities (ARCs)** are a promising technology-based approach for engaging adolescents in mental health care that capitalizes on the reach and scalability of technology while also providing support, peer-to-peer social interactions, clinician-to-patient support and motivation to engage. ARCs use private online platforms (e.g., Slack, Microsoft Teams) to deliver and gather information from adolescents in a format that is lightweight, accessible, usable, and low burden.

The ARC designed by our team, called *ActivaTeen*, aims to support adolescents with MDD who are completing an EBPI known as behavioral activation (BA). The BA model proposes: 1) stressors lead to increased punishment and decreased reward in the environment, which triggers 2) negative emotions like sadness, irritability, or hopelessness and prompt 3) anhedonic symptoms like avoidant behaviors and

social withdrawal. Avoidant behaviors have negative consequences such as losing friendships, lowered grades, and conflicts that feed back into stress, negative emotions, and more avoidant behaviors, which perpetuates a "downward spiral" of depression. BA attempts to reverse this process through a number of behavioral strategies (e.g., mood-activity tracking, goal-setting, problem-solving barriers) with the ultimate goal of (1) increasing rewarding experiences to help improve mood and (2) decreasing avoidance of potentially rewarding activities, which may serve to reinforce MDD symptoms. Importantly, the BA approach is individually tailored to fit each individual's personal values and goals.

There are several core components of ARC-supported BA that may improve patient engagement and, ultimately, mental health and functional outcomes. ARC platforms allow for 1) *asynchronous therapist coaching* through direct messaging; 2) *between-session therapy homework and goal completion support* through interactive chatbots, reminders, and access to online worksheets; 3) *ecological momentary assessment (EMA) tracking* and visualizations of symptoms and behavior that can been viewed and shared by both patient and clinician; and 4) *scaffolded peer communities* that collectively respond to moderated engagement prompts to share homework goals and challenges, provide asynchronous peer coaching, and general peer support.

This research focuses on helping solve the significant gap between rates of adolescent depression and access to and engagement in high-quality EBPIs. ARC platforms capitalize on several key factors to close this gap, including 1) widespread use of scalable technology solutions by adolescents and 2) peer communities that provide social connection and engagement. Using ARC platforms as a delivery model for treatment is an innovative way to increase access to EBPIs through remote and asynchronously delivered content while simultaneously supporting synchronous therapy interactions through technology-based data collection, homework completion, and monitoring. ARC platforms provide an unparalleled opportunity for more precise characterization of symptoms and behavioral engagement via tools that support EMA. Inclusion of peer communities may boost treatment response via several proposed mechanisms including increased engagement with the EBPI content, increased social connection, and decreased stigma associated with mental health diagnoses. Improved engagement and effectiveness of EBPIs is essential for improving the significant morbidity and mortality associated with MDD, particularly in adolescents.

1.8.b. Experience and preliminary work. Briefly describe experience or preliminary work or data (if any) that you, your team, or your collaborators/co-investigators have that supports the feasibility and/or safety of this study.

It is not necessary to summarize all the discussion that has led to the development of the study protocol. The IRB is interested only in short summaries about experiences or preliminary work that suggest the study is feasible and that risks are reasonable relative to the benefits. Examples: Your team has already conducted a Phase 1 study of an experimental drug which supports the Phase 2 study being proposed in this application; your team has already done a small pilot study showing that the reading skills intervention described in this application is feasible in an after-school program with classroom aides; your team has experience with the type of surgery that is required to implant the study device; the study coordinator is experienced in working with subjects who have significant cognitive impairment.

In our NIMH R03-funded pilot work with a similarly-composed investigative team, we successfully built a preliminary prototype of the intervention being studied in this project. The prototype was considered to be acceptable, usable, and engaging to depressed adolescents and to mental health clinicians. This feedback was incorporated into the design and development of the full BA+ActivaTeen.

1.8.c. Subject matter expertise. Is the study a clinical trial and/or does the study involve use of a drug, biologic, botanical, nutritional supplement and/or is the study otherwise considered to be greater than minimal risk to subjects?

☒ **No** → Answering this question is optional.
☐ **Yes** → Provide the name, degree(s), and contact information (e.g., email, phone number) of someone with appropriate expertise in the subject matter described in the objectives and design of this study. The individual should be unaffiliated with the study and have no other apparent conflict of interest. The individual may be associated with the UW or external to the University. Ensure the individual is aware they may be contacted by HSD.

*Provision of this information is **required** for all clinical trials, for studies involving the use of a drug, biologic, botanical, nutritional supplement and for studies involving greater than minimal risk. For all other studies, the information is optional, though HSD reserves the right to request researcher assistance in providing a consultant if necessary to complete review of the study.*
For the consultant, the request involves a brief email or phone call with targeted questions that usually can be responded to in 30 minutes or less.

Click or tap here to enter text.

1.9. Supplements. Check all boxes that apply, to identify relevant SUPPLEMENTS that should be completed and uploaded to ***Zipline***.

This section is here instead of at the end of the form to reduce the risk of duplicating information in this IRB Protocol form that you will need to provide in these Supplements.

Check all that apply	Type of Research	Supplement Name and Link
☐	**Department of Defense** The research involves Department of Defense funding, facilities, data, or personnel.	SUPPLEMENT Department of Defense
☐	**Department of Energy** The research involves Department of Energy funding, facilities, data, or personnel.	SUPPLEMENT Department of Energy
☐	**Drug, biologic, botanical, supplement** Procedures involve the use of any drug, biologic, botanical or supplement, even if the item is not the focus of the proposed research.	SUPPLEMENT Drugs
☐	**Emergency exception to informed consent** Research that requires this special consent waiver for research involving more than minimal risk.	SUPPLEMENT Exception from Informed Consent for Emergency Research (EFIC)

Check all that apply	Type of Research	Supplement Name and Link
☐	**Genomic data sharing** Genomic data are being collected and will be deposited in an external database (such as the NIH dbGaP database) for sharing with other researchers, and the UW is being asked to provide the required certification or to ensure that the consent forms can be certified.	SUPPLEMENT Genomic Data Sharing
☐	**Medical device** Procedures involve the use of any medical device, even if the device is not the focus of the proposed research, except when the device is FDA-approved and is being used through a clinical facility in the manner for which it is approved.	SUPPLEMENT Devices
☒	**Multi-site or collaborative study** The UW IRB is being asked to review on behalf of one or more non-UW institutions in a multi-site or collaborative study.	SUPPLEMENT Multi-site or Collaborative Research
☐	**Non-UW Individual Investigators** The UW IRB is being asked to review on behalf of one or more non-UW individuals who are not affiliated with another organization for the purpose of the research.	SUPPLEMENT Non-UW Individual Investigators
☐	**Other REDCap Installation Attestation for Electronic Consent** The research will use a non-UW installation of REDCap for conducting and/or documenting informed consent.	SUPPLEMENT Other REDCap Installation
☐	None of the above.	

2. PARTICIPANTS

2.1. [DETERMINATION] **Participants**. Describe the general characteristics of the subject populations or groups, including age range, gender, health status, and any other relevant characteristics.

Clinician participants will be licensed mental health practitioners in the state of Washington or clinical psychology trainees supervised by a licensed mental health practitioner within the state of WA. In order to engage with the ARC platform, they must be proficient speaking English. To enroll in the study, clinician participants must complete BA certification with Drs. Jenness or McCauley.

Patient participants will be English-speaking teenagers (ages 13-19) who have a primary psychiatric diagnosis of current MDD. Patients will have been referred to Seattle Children's Hospital outpatient behavioral medicine clinic, and must have a PHQ-8 score of 8 or greater, indicating moderate or above depression. All patient participants will be screened for developmental disabilities and severe psychiatric comorbidities, for example active suicidality requiring a higher level of care or psychosis.

2.2. [DETERMINATION] **Inclusion and exclusion criteria.**

2.2.a. Inclusion criteria. Describe the specific criteria that will be used to decide who will be included in the research from among interested or potential subjects. Define any technical terms in lay language.

Clinicians:

Inclusion criteria:

1) Licensed mental health clinician in the state of Washington OR clinical psychology trainees supervised by a licensed mental health clinician within the state of WA
2) English-speaking
3) Completion of behavioral activation certification training

Patients:

***Inclusion criteria*:**

1) Aged 13-19
2) Referred for MDD treatment
3) Clinically assessed diagnosis of current MDD based on caregiver or patient report or a PHQ-8 total of 8 or greater (moderate MDD)
4) MDD clinically determined to be the primary diagnosis
5) English-speaking
6) Access to a smartphone device.

Caregivers:

***Inclusion criteria*:**

1) Primary caregiver of a patient who is enrolled in the study
2) English-speaking

2.2.b. Exclusion criteria. Describe the specific criteria that will be used to decide which of the subjects who meet the inclusion criteria listed above will be excluded from the research. Define any technical terms in lay language.

Clinicians:

***Exclusion criteria**:*

1) Failure to meet satisfactory BA fidelity for role play during certification training (i.e., completing <80% of required BA components on the BA fidelity checklist as measured by Drs. Jenness or McCauley);
2) Missing 3 consecutive supervision meetings once enrolled as a clinician participant

Patients:

Exclusion criteria:

1) Developmental disability (e.g., intellectual disability, autism spectrum disorder)
2) Severe psychiatric comorbidity (e.g., active suicidality requiring higher level of care; psychosis or substance use, bipolar, or conduct disorder)
3) Previously completed a full course of evidence based psychosocial intervention for depression

Caregivers:

***Exclusion criteria*:**

1) Unwilling or unable to complete study procedures

2.3. [DETERMINATION] **Prisoners**. IRB approval is required in order to include prisoners in research, even when prisoners are not an intended target population.

Is the research likely to have subjects who become prisoners while participating in the study?

For example, a longitudinal study of youth with drug problems is likely to have subjects who will be prisoners at some point during the study.

☒ **No**

☐ **Yes →** If a subject becomes a prisoner while participating in the study, will any study procedures and/or data collection related to the subject be continued while the subject is a prisoner?

☐ **No**

☐ **Yes →** Describe the procedures and/or data collection that will continue with prisoner subjects.

Click or tap here to enter text.

2.4. **[DETERMINATION]** Will the proposed research recruit or obtain data from individuals that are known to be prisoners?

For records reviews: if the records do not indicate prisoner status and prisoners are not a target population, select "No". Review the guidance on Prisoners for the definition of "prisoner", which is not necessarily tied to the type of facility in which a person is residing.

☒ **No**

☐ **Yes →** Answer the following questions (**2.4.a.** – **2.4.d.)**

2.4.a. Describe the type of prisoners, and their locations(s).

Click or tap here to enter text.

2.4.b. One concern about prisoner research is whether the effect of participation on prisoners' general living conditions, medical care, quality of food, amenities, and/or opportunity for earnings in prison will be so great that it will make it difficult for prisoners to adequately consider the research risks. How will the chances of this be reduced?

Click or tap here to enter text.

2.4.c. Describe what will be done to make sure that (a) recruitment and subject selection procedures will be fair to all eligible prisoners and (b) prison authorities or other prisoners will not be able to arbitrarily prevent or require particular prisoners from participating.

Click or tap here to enter text.

2.4.d. If the research is funded by one of these federal departments and agencies (Health & Human Services; Energy; Defense; Homeland Security; CIA; Social Security Administration), and/or will involve prisoners in federal facilities or in state/local facilities outside of Washington State: check the box below to provide assurance that study team members will (a) not encourage or facilitate the use of a prisoner's participation in the research to influence parole or pardon decisions, and (b) clearly inform each prisoner in advance (for example, in a consent form) that participation in the research will have no effect on his or her parole or pardon.

☐ **Confirmed**

2.5. [DETERMINATION] **Protected populations.** IRB approval is required for the use of the subject populations listed here. Check the boxes for any of these populations that will be purposefully included. (In other words, being a part of the populations is an inclusion criterion for the study.)

The WORKSHEETS describe the criteria for approval but do not need to be completed and should not be submitted.

Check all that apply	Population	Worksheet Name and Link
☐	Fetuses in utero	WORKSHEET Pregnant Women
☐	Neonates of uncertain viability	WORKSHEET Neonates
☐	Non-viable neonates	WORKSHEET Neonates
☐	Pregnant women	WORKSHEET Pregnant Women

2.5.a. If you check any of the boxes above, use this space to provide any information that may be relevant for the IRB to consider.

Click or tap here to enter text.

2.6. [DETERMINATION] **Native Americans or non-U.S. indigenous populations**. Will Native American or non-U.S. indigenous populations be actively recruited through a tribe, tribe-focused organization, or similar community-based organization?

Indigenous people are defined in international or national legislation as having a set of specific rights based on their historical ties to a particular territory and their cultural or historical distinctiveness from other populations that are often politically dominant.

Examples: a reservation school or health clinic; recruiting during a tribal community gathering.

☒ **No**

☐ **Yes →** Name the tribe, tribal-focused organization, or similar community-based organization. The UW IRB expects that tribal/indigenous approval will be obtained before beginning the research. This may or may not involve approval from a tribal IRB. The study team and any collaborators/investigators are also responsible for identifying any tribal laws that may affect the research.

Click or tap here to enter text.

2.7. [DETERMINATION] **UW Medicine and UW Dentistry residents and fellows.** Will the research involve UW Medicine or UW Dentistry residents or fellows as study subjects?

If it will → **(1)** Describe in the Recruiting section (4.1) and Risks section (10.1) how you will ensure that residents and fellows feel free to truly make a voluntary decision about participation (i.e., no negative consequences from supervisors for saying "no") and how you will ensure that any research data will not be used in the residents' and fellows' supervisor or program evaluation of them; **AND**

(2) You must inform the UW HR Labor Relations representative who negotiates with the resident's and fellows' union about the study before beginning it. This is currently Jennifer Mallahan mallaj@uw.edu .

2.8. [DETERMINATION] **Third party subjects.** Will the research collect private identifiable information about individuals *other than* the study subjects? Common examples include: collecting medical history information or contact information about family members, friends, co-workers.

"Identifiable" means any direct or indirect identifier that, alone or in combination, would allow you or another member of the research team to readily identify the person. For example, suppose that the research is about immigration history. If subjects are asked questions about their grandparents but are not asked for names or other information that would allow easy identification of the grandparents, then private identifiable information is not being collected about the grandparents and the grandparents are not subjects.

☐ **No**

☒ **Yes →** These individuals are considered human subjects in the study. Describe them and what data will be collected about them.

Caregivers of child patients will be recruited to be participants in the study. However, if a caregiver declines to participate but is willing to give permission for their child to participate, the caregiver will be a third-party subject. The contact information (phone number and email address) of the caregiver/legal guardian(s) of child patients enrolled in the study will be collected and stored with the identifiable child participant data. The first and last name of the legal guardian(s) and their relationship to the participant will be stored as well.

2.9. Number of subjects. Is it possible to predict or describe the maximum number of subjects (or subject units) needed to complete the study, for each subject group?

Subject units mean units within a group. For most research studies, a group will consist of individuals. However, the unit of interest in some research is not the individual. Examples:

- *Dyads such as caregiver-and-Alzheimer's patient, or parent and child*
- *Families*
- *Other units, such as student-parent-teacher*

Subject group means categories of subjects that are meaningful for the specific study. Some research has only one subject group – for example, all UW students taking Introductory Psychology. Some common ways in which subjects are grouped include:

- *By intervention – for example, an intervention group, and a control group.*
- *By subject population or setting – for example, urban versus rural families*
- *By age – for example, children who are 6, 10, or 14 years old.*

The IRB reviews the number of subjects in the context of risks and benefits. Unless otherwise specified if the IRB determines that the research involves no more than minimal risk: there are no restrictions on the total number of subjects that may be enrolled. If the research involves more than minimal risk: The number of enrolled subjects must be limited to the number described in this application. If it is necessary later to increase the number of subjects, submit a Modification. Exceeding the IRB-approved number (over-enrollment) will be considered non-compliance.

☐ **No →** Provide the rationale in the box below. Also, provide any other available information about the scope/size of the research. You do not need to complete the table.

Example: It may not be possible to predict the number of subjects who will complete an online survey advertised through Craigslist, but you can state that the survey will be posted for two weeks and the number who respond is the number who will be in the study.

Click or tap here to enter text.

☒ **Yes →** For each subject group, use the table below to provide the estimate of the maximum desired number of individuals (or other subject unit, such as families) who will complete the research.

Group name/description	Maximum desired number or individuals (or other subject unit) who will complete the research *Provide numbers for the site(s) reviewed by the UW IRB and for the study-wide total number; example: 20/100*
Patient BA+ActivaTeen group	40
Patient BA only group	40
Clinician group	10
Caregiver Group	80
Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.

3. NON-UW RESEARCH SETTINGS

Complete this section only if UW investigators and people named in the SUPPLEMENT Non-UW Individual Investigators will conduct research procedures outside of UW and Harborview

3.1. [DETERMINATION] **Research locations and rationale**. Identify the locations where the research will be conducted and include a description of the reason(s) for choosing the locations. If the research will be conducted internationally, be sure to list all the countries where the research will take place.

This is especially important when the research will occur in locations or with populations that may be vulnerable to exploitation. One of the three ethical principles the IRB must consider is Justice: ensuring that reasonable, non-exploitative, and well-considered procedures are administered fairly, with a fair distribution of costs and potential benefits.

Any recruitment and screening procedures that occur in-person are expected to take place at Seattle Children's Hospital (SCH). The clinicians in the study will be professional clinicians at SCH outpatient mental health clinics.

Seattle Children's Hospital Psychiatry and Behavioral Medicine Outpatient Clinic:
All in-person study procedures – which will entail the BA therapy sessions – will occur at SCH Psychiatry and Behavioral Medicine Outpatient Clinics. SCH Psychiatry and Behavioral Medicine is the premier children's mental health institute in a five-state region including Washington, Wyoming, Alaska, Montana, and Idaho (WWAMI). The main campus facility houses the child and adolescent outpatient and inpatient clinics, the psychiatry consultation and liaison service, child psychiatry administration offices, and the Pediatric Clinical Research Center.

SCH provides extensive support for clinical research, including outpatient space, free parking to patients, on-site and phone crisis support, research nursing services, laboratory and pharmacy services, and biostatistical consultation. BA psychotherapy is an evidence-based treatment used widely in the Mood and Anxiety Disorders Program (MAP) of Seattle Children's Hospital. The MAP clinic has a strong reputation for training advanced clinical psychology students across, externship, internship and post-doctoral training levels.

The clinician participants will have a clinical appointment at SCH, conducting mood disorder treatment as part of their normal course of work.

Clinicians may deliver BA treatment via SCH-provided telehealth software in accordance with their policies.

Recruitment flyers will be shared with adolescent outpatient primary care clinics and school-based mental health clinics in the community. However, no study-related procedures will occur at these locations.

3.2. [DETERMINATION] **Local context**. Culturally appropriate procedures and an understanding of local context are an important part of protecting subjects. Describe any site-specific cultural issues, customs, beliefs, or values that may affect the research, how it is conducted, or how consent is obtained or documented.

Examples: It would be culturally inappropriate in some international settings for a woman to be directly contacted by a male researcher; instead, the researcher may need to ask a male family member for permission before the woman can be approached. It may be appropriate to obtain permission from community leaders prior to obtaining consent from individual members of a group. In some distinct cultural groups, signing forms may not be the norm.

This federal site maintains an international list of human research standards and requirements: http://www.hhs.gov/ohrp/international/index.html

We plan to apply to conduct recruitment at Odessa Brown Children's Clinic (OBCC), a historic community pediatric clinic that offers care regardless of the patient's ability to pay for treatment. The OBCC has strong ties to the Black and immigrant communities of the greater Seattle area. Given the historical exploitation of communities of color and immigrant people in the United States, both within and beyond academic research, our research team will devote extra attention to examining our implicit biases, using cultural humility practices to communicate with OBCC staff and patients, and adapting our procedures to minimize burden on OBCC as much as possible.

3.3. [DETERMINATION] **Location-specific laws.** Describe any local laws that may affect the research (especially the research design and consent procedures). The most common examples are laws about:

- **Specimens** – for example, some countries will not allow biospecimens to be taken out of the country.
- **Age of consent** – laws about when an individual is considered old enough to be able to provide consent vary across states, and countries.
- **Legally authorized representative** – laws about who can serve as a legally authorized representative (and who has priority when more than one person is available) vary across states and countries.
- **Use of healthcare records** – many states have laws that are similar to the federal HIPAA law but that have additional requirements.

N/A

3.4. [DETERMINATION] **Location specific administrative or ethical requirements**. Describe local administrative or ethical requirements that affect the research.

Example: A school district may require researchers to obtain permission from the head district office as well as school principals before approaching teachers or students; a factory in China may allow researchers to interview factory workers but not allow the workers to be paid for their participation.

To engage in research recruitment at OBCC, a separate application is submitted and reviewed by staff and leadership at OBCC. We will only conduct recruitment at OBCC if our application is approved. For other primary

care recruitment or school-based recruitment, we will abide by any location-specific procedures related to recruiting for research.

3.5. [DETERMINATION] If the PI is a student: Does the research involve traveling outside of the U.S.?

☐ **No**

☐ **Yes →** Confirm by checking the box that (1) you will register with the UW Office of Global Affairs before traveling; (2) you will notify your advisor when the registration is complete; and (3) you will request a UW Travel Waiver if the research involves travel to the list of countries requiring a UW Travel Waiver.

☐ **Confirmed**

4. RECRUITING AND SCREENING PARTICIPANTS

4.1. [DETERMINATION] Recruiting and screening. Describe how subjects will be identified, recruited, and screened. Include information about: how, when, where, and in what setting. Identify who (by position or role, not name) will approach and recruit subjects, and who will screen them for eligibility.

Note: Per UW Medicine policy, the UW Medicine eCare/MyChart system may not be used for research recruitment purposes. Additionally, researchers may not use UW Medicine's Epic Care Everywhere data for research purposes unless the clinical data is necessary for patient/participant safety activities. This means Care Everywhere data cannot be used for recruitment, data abstraction, or any research activities other than those necessary for patient/participant safety.

Patient participants will be identified from patients referred to SCH to receive treatment for major depressive disorder at SCH Psychiatry and Behavioral Medicine Outpatient Clinics. Research staff will screen the SCH electronic health record of patients who have been referred and are scheduled for a diagnostic interview.

When research staff identify a patient as potentially eligible, based on age, reason for referral, and a lack of exclusion criteria, staff will alert the clinician assigned to conduct the patient's clinical diagnostic interview to mention the research study to adult patients or to the parent/caregiver of child patients. Clinicians will also be asked to share the study flyer. The clinician will ask the patient or parent/caregiver if the research staff can contact the adult patient or the parent/caregiver of child patients to discuss the study in more detail. If the parent agrees, the clinician will send a secure message through the electronic health record to study staff letting them know the parent can be contacted for recruitment.

Because the study intervention is a tool to support depression treatment, participants must begin the intervention as they are beginning their depression treatment. If a clinician forgets or otherwise fails to mention the study to a potentially eligible patient, the opportunity to enroll them may pass. Therefore, research staff will directly contact (cold contact) potentially eligible adult patients or parent/caregiver of child patients in the case the clinician does not mention the research during the intake visit.

Cold Contact

Research staff will send an email to the parent/caregiver of child patients or directly to adult patients. The email will not mention depression treatment. The project will be explained as a study at Seattle Children's related to mental health, and it will be described that they (or their child) were identified by a review of medical records. If no response is received within 3 business days, research staff will follow up with a phone call. If reached by phone, research staff will confirm the identity of the person before giving information about the study.

Adult patients

Research staff will give information over the phone about participation in the study. The patient will be informed of basic eligibility criteria, study procedures, and brief details about the ActivaTeen intervention. Research staff will elicit and answer any questions, and if the patient is interested, staff will obtain verbal consent to complete screening questions over the phone. The screening questions will include the PHQ-8 (Inclusion criterion 4) and questions about developmental disabilities and other psychiatric comorbidities (Exclusion criteria 1 & 2). All other inclusion and exclusion criteria will be verified by SCH clinical staff.

Child patients

Children will not be contacted directly about the research program. Instead, their parent or caregiver will be engaged by research staff for research purposes. Research staff will obtain permission from a parent or caregiver to complete some screening questions with the patient. Research staff will administer the PHQ-8 to the child patient directly, and will ask the parents about developmental disabilities and psychiatric comorbidities.

Word of Mouth

Patients or caregivers in the study are free to tell others who may be eligible about the study and to share the study flyer. Interested patients or parents may contact the study team to discuss and potentially enroll in the study. Patients who are not already receiving outpatient mental health treatment at SCH will have an SCH medical record created upon referral to SCH clinics. Once a teen is referred to treatment at SCH, the rest of the recruitment process will operate the same as for other candidate patients.

Recruitment of patient caregivers

The caregiver will be invited to join the research study to answer survey questions about the enrolled patient at regular intervals. The surveys will also collect some information about the caregivers (e.g. demographics, some health measures, environmental stressors). Because caregivers are included solely based on the participation of their child, a separate screening process is not needed.

Recruitment of clinicians

Potentially eligible clinicians will be approached by Dr. Jenness, Dr. McCauley, or other research staff (e.g. coordinator) either in-person at SCH or via email. They will be asked if they are interested in joining a research study that aims to improve the effectiveness of depression treatment for adolescents. The study rationale and procedures will be shared and clinician questions will be elicited and answered.

If a clinician is interested, they will complete a brief REDCap confirming their eligibility. If eligible, they will be emailed a copy of the consent form and asked to schedule an enrollment and onboarding session with either Dr Jenness or other research staff.

4.2. Recruitment materials.

4.2.a. What materials (if any) will be used to recruit and screen subjects?

Examples: talking points for phone or in-person conversations; video or audio presentations; websites; social media messages; written materials such as letters, flyers for posting, brochures, or printed advertisements; questionnaires filled out by potential subjects.

Study Flyer – *Seek general approval*
Recruitment Talking Points – *Upload Copy*
Screening Script – *Upload Copy*
Screening Questionnaire – *Upload Copy*
Cold Call Recruitment Email – *Upload Copy*
Cold Call Recruitment Flyer – *Upload Copy*

4.2.b. Upload descriptions of each type of material (or the materials themselves) to ***Zipline***. If letters or emails will be sent to any subjects, these should include a statement about how the subject's name and contact information were obtained. No sensitive information about the person (such as a diagnosis of a medical condition) should be included in the letter. The text of these letters and emails must be uploaded to ***Zipline*** (i.e., a description will not suffice).

HSD encourages researchers to consider uploading descriptions of most recruitment and screening materials instead of the materials themselves. The goal is to provide the researchers with the flexibility to change some information on the materials without submitting a Modification for IRB approval of the changes. Examples:

- *Provide a list of talking points that will be used for phone or in-person conversations instead of a script.*
- *For the description of a flyer, include the information that it will provide the study phone number and the name of a study contact person (without providing the actual phone number or name). This means that a Modification would not be necessary if/when the study phone number or contact person changes. Also, instead of listing the inclusion/exclusion criteria, the description below might state that the flyer will list one or a few of the major inclusion/exclusion criteria.*
- *For the description of a video or a website, include a description of the possible visual elements and a list of the content (e.g., study phone number; study contact person; top three inclusion/exclusion criteria; payment of $50; study name; UW researcher).*

4.3. [DETERMINATION] **Relationship with participant population**. Do any members of the study team have an existing relationship with the study population(s)?

Example: a study team member may have a dual role with the study population such as being their clinical care provider, teacher, laboratory directory or tribal leader in addition to recruiting them for their research.

☐ **No**
☒ **Yes →** Describe the nature of the relationship.

Some members of the investigative team (Drs. Jenness and McCauley) will be colleagues of the clinician participants at SCH. Clinicians will be assured they are not required to participate in the study, and that their professional and training opportunities will not be affected by choosing to participate or declining participation.

The clinician participants will be involved in the clinical treatment of the patient participants. If a patient participant decides to withdraw, or a candidate patient decides not to enroll, they will continue care with SCH, but not in the context of the research project. Generally, clinician participants will not be involved in recruitment other than helping to connect patients with research staff, and ensuring that patients and patient families understand that they are not obligated to participate and that their care will not be affected by declining to participate.

A member of the study team who is based at Seattle Children's Hospital and may conduct screening and/or consent procedures may also be a clinician participant in the study.

4.4. Payment to participants. The IRB must evaluate subject payment for the possibility that it will unduly influence subjects to participate. Refer to the guidance on Subject Payment when designing subject payment plans. Provide the following information about your plans for paying research subjects in the text box below or note that the information can be found in the consent form.

- The total amount/value of the payment
- Schedule/timing of the payment [i.e., when will subjects receive the payment(s)]

- Purpose of the payment [e.g., reimbursement, compensation, incentive]
- Whether payment will be "pro-rated" so that participants who are unable to complete the research may still receive some part of the payment

The IRB expects the consent process or study information provided to the subjects to include all of the above-listed information about payment, including the number and amount of payments, and especially when subjects can expect to receive payment. One of the most frequent complaints received by HSD is from subjects who expected to receive cash or a check on the day that they completed a study and who were angry or disappointed when payment took 6-8 weeks to reach them.

Researchers should review current UW Financial Management requirements about when Social Security Numbers must be collected, and when research payment must be reported to the UW Tax Office and the IRS: https://finance.uw.edu/ps/how-pay/research-subjects.

If your study involves the use of Amazon's Mechanical Turk (MTurk), you must comply with the UW Procurement Services policy that no UW employee, family member, or student directly involved in the research will participate as a subject. The policy requires adding a qualifying question that asks whether the subject is a UW employee or family member, or UW student who is directly involved in the research. If they answer yes, they must be disqualified from MTurk activities.

Patient participants will be reimbursed with $40 electronic gift cards for each online assessment visit (Baseline, Week 12, Week 24) and $15 for completing the mid-treatment online surveys (Weeks 4 and 8). Patients will also receive up to $60 for completion of the EMA surveys (up to $5/week for 12 weeks). This sums to a total possible reimbursement of $210 ($120 total for 3 longer visits, $30 total for two survey visits, $60 for mood-activity reports).

Caregivers will be reimbursed $20 for the Baseline study visit and Month 3 study visit (up to $40 total).

Clinician participants will not be reimbursed for their time spent on the study.

4.5. [DETERMINATION] **Non-monetary compensation**. Describe any non-monetary compensation that will be provided. Example; extra credit for students; a toy for a child.

N/A

4.5.a. If class credit will be offered to students, there must be an alternate way for the students to earn the extra credit without participating in the research. If you will offer class credit, describe the alternative non-research method by which students can earn that same course credit, including who will provide the alternative (e.g., a student subject pool; the course instructor).

Click or tap here to enter text.

4.6. [DETERMINATION] **Will data or specimens be accessed or obtained for recruiting and screening procedures prior to enrollment?**

Examples: names and contact information; the information gathered from records that were screened; results of screening questionnaires or screening blood tests; Protected Health Information (PHI) from screening medical records to identify possible subjects.

☐ **No →** Skip the rest of this section; go to question **5.1.**

☒ **Yes →** Describe the data and/or specimens (including PHI) and whether it will be retained as part of the study data.

Research staff will access patient PHI and family contact information for patients referred for MDD treatment in the SCH system who are awaiting a diagnostic intake clinic visit. The PHI will be accessed through the SCH electronic health record (EHR) system to determine if a patient is potentially eligible. Health information including previous diagnoses and both outpatient/inpatient encounters will be accessed and viewed directly in the SCH EHR system by research staff to aid this determination.

Via the SCH electronic health record system, research staff will transmit the names of potentially eligible patients to the clinician assigned to conduct each patient's diagnostic intake visit in the clinic prior to the intake appointment, to ask the clinician to mention the research study to the patient, share the flyer, and ask if the patient/caregiver wants to hear more about it. Research staff will obtain the first name and medical record number of screened patients, in order to confirm they do not send a message for the same patient twice and to track whether the clinician mentioned the study to the patient. This database will serve as a method to count the number of potentially eligible patients who did not enroll, which is crucial information for understanding the feasibility of a study. The identifiable data will be stored in a HIPAA-compliant REDCap database separate from all other study data, and this database will be deleted at the end of the study after relevant statistics from the database have been tabulated (e.g. counting the number of patients screened). The PHI of enrolled participants will be obtained and stored in a separate manner.

If a clinician does not mention the study to a patient that had been identified by research staff (thus giving no opportunity for verbal consent to be contacted for research), research staff will reach out to the patient's family or to the patient directly if they are an adult teen. For this, research staff will access contact information via the SCH electronic health record system.

Clinicians will indicate to research staff via electronic health record message that a patient or patient parent has agreed to be contacted about the research. Research staff will obtain name and contact information for candidate patients or patient parents who have verbally consented to their information being shared. Research staff will describe study details and seek permission from the family (or verbal consent for adult patients) to complete screening with the candidate patient. During screening, additional data will be obtained as part of screening responses. These data will be retained as part of study data to evaluate the effectiveness of recruitment and screening procedures and to characterize people who are ineligible for the study. All candidate patients will be assigned a screening ID and their screening data will be stored separately from identifiable information.

4.7. Consent for recruiting and screening. Will consent be obtained for any of the recruiting and screening procedures? (Section 8: Consent of Adults asks about consent for the main study procedures).

"Consent" includes: consent from individuals for their own participation; parental permission; assent from children; consent from a legally authorized representative for adult individuals who are unable to provide consent.

Examples:

- *For a study in which names and contact information will be obtained from a registry: the registry should have consent from the registry participants to release their names and contact information to researchers.*
- *For a study in which possible subjects are identified by screening records: there will be no consent process.*
- *For a study in which individuals respond to an announcement and call into a study phone line: the study team person talking to the individual may obtain non-written consent to ask eligibility questions over the phone.*

☐ **No →** Skip the rest of this section; go to question **5.1.**
☒ **Yes →** Describe the consent process.

Patient/Caregiver Recruitment
There will be no consent process for research staff viewing EHR for adolescent patients referred to outpatient mood disorder treatment at SCH and obtaining first name and MRN to avoid repeat contact of a patient.

Verbal consent will generally be obtained for research staff to contact potentially eligible patients, or their parent if a child patient, after the patient completes their diagnostic interview. However, if the clinician who conducts the interview does not mention the study to the potentially eligible patient (due to time constraints, forgetting, etc), research staff will contact the patient or their parent without a consent process (i.e. cold contact).

Research staff will obtain parent/guardian permission to complete screening procedures with a potentially eligible child patient. Research staff will obtain verbal assent from candidate child patients to complete screening. Verbal consent will be obtained directly from adult patients.

Clinician Recruitment
When a clinician follows the link to the brief REDCap screening survey, the initial page(s) will have information about the study and what will be done with their screening data. They will be asked with a multiple choice (Yes/No) if they agree to complete screening and they can only proceed with the screening survey if they select "Yes" they agree.

4.7.a. Documentation of consent. Will a written or verifiable electronic signature from the subject on a consent form be used to document consent for the recruiting and screening procedures?

☒ **No →** Describe the information that will be provided during the consent process and for which procedures.

Patient Screening
The clinician completing the diagnostic interview will inform a parent/guardian of a child patient (or an adult patient directly) that their child (or the adult patient) may be eligible for a research study aimed at improving engagement in depression treatment. They will be told that participating in the research study is entirely voluntary and they can decline the research study at any point without affecting treatment in the clinic.

Prior to completing screening questions, research staff will reiterate 1) research is voluntary; 2) they or the child may choose to stop at any point with no penalty to them or impact on their treatment; 3) their screening data will be retained as part of the study data whether or not they are eligible.

Staff will then ask for permission from the parent to complete screening questions and assent from the child, or for adult patients, research staff will ask the adult patient for consent.

Clinician Screening
Prior to completing the brief screening survey, potentially eligible clinicians will be presented with information about the study and how their screening data will be stored. The information presented will emphasize that participating in the research is voluntary and will not affect their professional role at SCH. They will have been sent the study consent form to review details of the study prior to screening.

☐ **Yes, written →** If yes and a written signature will be used to document consent:

- Upload the consent form to ***Zipline***.

☐ **Yes, electronic →** If yes and an electronic signature will be used to document consent:

- Upload the consent form to ***Zipline***.
- **If the eSignature process or method for recruiting and screening is different than for the main study procedures**, use the questions about electronic consent in Sections 8.3. and 8.4. to differentiate between recruiting/screening and main study electronic consent. **If electronic consent will be used for recruiting/screening but not main study consent**, use 8.3. and 8.4. to describe e-consent and note that it is only for recruiting/screening.

5. PROCEDURES

5.1. [DETERMINATION] **Study procedures**. Using lay language, provide a complete description of the study procedures, including the sequence, intervention, or manipulation (if any), drug dosing information (if any), blood volumes and frequency of draws (if any), use of records, time required, and setting/location. If it is available: Upload a study flow sheet or table to ***Zipline***.

For studies comparing standards of care: It is important to accurately identify the research procedures. Review the section titled, "When to describe risks for studies evaluating medically recognized standards of care" in the Identifying and Describing Reasonably Foreseeable Risks in Research guidance and the draft guidance from the federal Office of Human Research Protections, "Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care"; October 20, 2014.

Information about pediatric blood volume and frequency of draws that would qualify for expedited review can be found in this **reference table** *on the Seattle Children's IRB website.*

Study Procedures & Assessments – Patient & Caregiver Participants

All enrolled patient participants will complete a total of 5 study visits, each of which will involve filling out a series of self-report surveys (see Schedule of Evaluations below and the table in Section 5.4). Study visits will occur remotely, with the patient (and their caregiver for teen patients) joining Zoom videoconference with research staff while completing surveys. Self-report surveys will include assessment of mood symptoms, functional impairment, loneliness, therapeutic alliance, and other psychological constructs. Surveys will also assess intervention engagement mechanisms and the acceptability of both intervention arms. For all patient participants, some visits will also include a semi-structured interview with research staff interview assessing the presence of depression. Lastly, patient participants will complete a weekly assessment of depression and anxiety symptoms at each BA treatment session.

Along with the patient, the parent/caregiver of teen participants will also be asked to fill out surveys at Visits 1, 4, and 5 assessing the mood and behavior of the patient participant as well as surveys about their family environment (e.g., family make-up), demographics, family history of mental health diagnoses, and self-reported symptoms of depression at the baseline Visit 1 only (see Section 5.4 "Source" column within table).

After completing informed consent, participants will be scheduled for a time to conduct the first study visit. These procedures can occur immediately after informed consent or at a different time depending on the participant's schedule. Once they are logged into Zoom videoconferencing, research staff will conduct a brief interview to assess the presence of depression. Then patient participants will access the surveys via REDCap link sent to their parent's email or to their personal email if they are an adult and prefer the link to be sent to them directly. Research staff

will be available on the Zoom call to answer any questions about the survey. The teenage patient will complete the self-report surveys that apply to them, and the caregiver will then complete surveys assessing the patient (e.g. the frequency of depression symptoms the child is displaying), the patient's family and themselves.

After completing all surveys for the baseline (Day 1), participants will be randomized to BA only or BA+ActivaTeen app. Regardless of group, participants will be able to ask questions about the upcoming BA treatment. Participants in the treatment group (BA+ActivaTeen) will be given an onboarding for using the ActivaTeen app, and credentials will be shared with the participant (and/or parent if the participant is a child) to log into the app.

All participants will be asked to attend weekly BA sessions, which is part of routine care at SCH outpatient mental health clinics. BA sessions will be recorded for the purposes of clinical supervision and assessing treatment fidelity.

During the post-treatment study visit (Week 12) in addition to surveys, teen patiecontacnts will be asked to complete a semi-structured qualitative interview to give detailed feedback on the acceptability, usability, and cultural fit of the treatment they received as part of the study (either BA only or BA+ActivaTeen). These interviews will occur over Zoom and will be recorded to the HIPAA-compliant Zoom cloud. Recordings will be transcribed for analysis and all identifying information will be removed. The original, unedited transcript and recording will be retained as part of study data.

	Pre-consent	Visit 1 Day 1 (Week 1)	Visit 2 Day 28 (Week 4)	Visit 3 Day 56 (Week 8)	Visit 4 Day 84 (Week 12)	Visit 5 Day 168 (Week 24)	Daily	Weekly (Weeks 1 -12)	Unscheduled Visit
Procedures									
Screening & Recruitment	X								
Informed Consent		X							
Randomization		X							
Intervention Initiation		X							
Adverse Events Reporting			X	X	X	X			X
Baseline Only Data									
Demographics		XX*							
Family & Medical History		XX							
Technology Comfort		X							
Neighborhood		XX*							
Outcome Evaluation									
Depression Symptoms		**XX^**	X	X	**X**	**X**		X	
Anxiety Symptoms		**X**	X	X	**X**	**X**		X	
Functional Impairment		**X**			**X**	**X**			
Loneliness		X	X	X	X	X			
Therapeutic Alliance			X	X	X				
Depressive Disorder		X			X	X			
Conduct		**X**			**X**	**X**			
Treatment Satisfaction					X				
Treatment Engagement								X	

Qualitative Interview						X			
Acceptability/Usability			X	X	X				
Mood & Activity Log							X		
ActivaTeen Only									
Group Cohesiveness			X	X	X				
ActivaTeen Engagement			X	X	X		X		

* Measures marked with a double X ("XX") are completed by both the teen and teen's caregiver. The caregiver questions will ask about the caregiver (e.g. the caregiver's demographics).
^ Measures marked with **Bold X** are also completed by patient's caregiver in reference to the patient (e.g. rating the patient's level of depression).

Study Treatment and Comparison Groups

Patient participants randomized to the intervention will receive behavioral activation (BA) therapy plus access to the ActivaTeen app, while those randomized to the control group will receive BA alone. The control group will complete daily mood logging (see "Mood and Activity Tracking" section below) to serve as a comparison to the ActivaTeen group.

Behavioral Activation Treatment

Behavioral activation therapy involves weekly sessions with a trained therapist for 12 weeks. The sessions are completed either in-person or via telehealth. The treatment focuses on behavioral manifestations of depression such as isolating, and how these behaviors are interconnected with low mood and depressive emotions. BA helps patients find ways to engage in behaviors that are meaningful to them based on their values, priorities, and goals, with the aim of creating positive loops between doing meaningful activities and improved mood. The therapist provides structure and problem-solving for activating these behaviors and keeping track of changes over time. The treatment sessions will be audio recorded for use in treatment supervision sessions.

The standard of care at SCH adolescent outpatient mood clinics is group BA therapy with the option to follow up with individualized therapy after finishing group. Participants in this study will be routed to individualized care upon enrollment.

ActivaTeen App

The ActivaTeen app is built on Seattle Children's Hospital's HIPAA-compliant instance of Microsoft Teams. Participants in the treatment group can access the app at any time via desktop or mobile, where they can find features designed to enhance their receipt of BA therapy. These features include: weekly BA skills and homework completion support, in-app messaging with their BA therapist, mood and activity tracking and data visualizations, chatbot check-ins on progress and guided problem-solving around barriers, and moderated peer support using the ActivaTeen app. The app will have a moderator, who is part of the study team, to manage peer-to-peer interactions within ActivaTeen. The components of ActivaTeen are described in more detail below:

BA Skills and Homework Support

Participants in the ActivaTeen+BA group will have access to homework assignments and reminders as part of the app. There are several built in, guided homework tools such as tracking situations, moods, and behaviors related to positive and negative moods in the week (i.e, Upward/Downward Mood Spirals), choosing, setting, and following through on therapy goals (i.e., SMART Goal Planning), and problem-solving barriers to goal completion (i.e., Overcoming Internal/External Barriers). There is also a "custom homework" option where clinicians can attach editable homework documents for the patient to complete. The patient will only have access to assigned homework by the clinician with the exception of SMART Goal Planning and Overcoming Internal/External Barriers, which can be initiated by the patient as needed.

Communication with Clinicians
Patients can send direct messages to their therapist via the app to ask questions about the weekly exercises or about other aspects of therapy.

Mood and Activity Tracking
Participants will receive 5 random text message notifications each day asking them to log their current mood and what activity they are engaging in. There will also be an open text field for patients to provide more context about their mood/activities. These notifications will also be sent to control participants in order to compare mood ratings over time.

Chatbot Coaching
Participants can access an automated chatbot that offers BA coaching related to Overcoming Internal/External Barriers. This is only initiated after a patient has set a SMART Goal and is meant to provide a check-in on progress and assist in problem-solving barriers to goal completion.

Peer Support
Participants can interact with other study participants who are currently in the intervention via a moderated group Team "channel" (i.e., a private group set up by the moderator that includes 3-10 teens) in the ActivaTeen Teams tenant. The moderator will send weekly posts that ask teen participants to reflect on BA skill successes and challenges as well as provide support to one another. They will be able to request via the platform moderator (see below) to create a direct chat with another participant if desired. The second participant must consent to the request for the moderator to create the chat. The moderator will be able to review and monitor all direct chats and chats occurring on the peer channel.

ActivaTeen Moderator
A study staff member will have access to the ActivaTeen platform being used by patient and clinician participants in order to serve in a moderator role. The moderator will monitor the main ActivaTeen peer channel once per business day to monitor activity. Teen participants will be given a "Group Guidelines" document (see attachment) that is based on previous teen ARCs conducted by the present research team. If a moderator observes unallowed activity or behavior from a teen, they will follow the protocol outlined in the Group Guidelines document. Teen participants can contact the moderator if needed with concerns about the behavior or language of other teens. The moderator will also review all peer-to-peer direct chats on a daily basis. See risk/benefit assessment for mitigation procedures if unwanted interaction between peers occurs.

Study Procedures & Assessments – Clinician Participants

Newly-enrolled clinicians will complete a battery of surveys assessing demographics and comfort with technology. Clinicians will also complete certification in BA training and will be trained in how to use the ActivaTeen platform. All clinicians will be onboarded to ActivaTeen, as they will treat participants in both intervention groups.

Group BA is the standard of care at the SCH Outpatient Psychiatry Clinic and individual BA is commonly offered, so therapy sessions and session preparations not related to study participation will be billed to insurance/workplace and not to the study. Clinicians seeing BA+ActivaTeen patients will be asked to review EMA survey completion during sessions and respond to patient questions on the app during their normal business hours. Beyond this, they will be encouraged to use the platform as desired and clinically indicated. They will not be asked to monitor for crisis or safety concerns as a moderator will be assigned per ActivaTeen group. Twice per month clinical supervision meetings will be required as part of study participation to ensure treatment fidelity.

Clinician participants will keep a time diary of time spent working on the ActivaTeen platform (sent 2x/week). They will also be asked to self-report on session fidelity and patient engagement per treatment session. They will be asked to remain in the study for the duration of the treatment phase of the clinical trial. They will be asked to

complete a semi-structured interview to share opinions and feedback on the acceptability and feasibility of the ActivaTeen app at two time points- once after approximately 3-months of study participation and once when a clinician terminates their study participation. These interviews will occur over Zoom and will be recorded to the HIPAA-compliant Zoom cloud. Recordings will be transcribed for analysis and all identifying information will be removed. The original, unedited transcript and recording will be retained as part of study data.

	Pre-consent	Visit 1 Day 1	Weekly (Patient's Weeks 1 -12)	Visit 2 Day 90	Visit 3 Day 545	Unscheduled Visit
Procedures						
Screening & Recruitment	X					
Informed Consent		X				
Adverse Events Reporting						X
Baseline Only Data						
Demographics		X				
Technology Comfort		X				
Outcome Evaluation						
Therapeutic Alliance			X			
Treatment Engagement			X			
Treatment Fidelity			X			
Qualitative Interview				X	X	
Acceptability/Usability				X	X	
Therapist Time Diary			X			
Intervention Engagement			X			

5.2. [DETERMINATION] **Recordings**. Does the research involve creating audio or video recordings?

☐ **No →** Go to question **5.3.**

☒ **Yes →** Verify that you have described what will be recorded in the answer to question **5.1.**, and answer question the question below**.**

5.2.a. Before recording, will consent for being recorded be obtained from subjects and any other individuals who may be recorded?

☐ **No →** Email hsdinfo@uw.edu before submitting this application in ***Zipline***. In the email, include a brief description of the research and a note that individuals will be recorded without their advance consent.

☒ **Yes**

5.3. [DETERMINATION] **MRI scans**. Will any subjects have a Magnetic Resonance Imaging (MRI) scan as part of the study procedures?

This means scans that are performed solely for research purposes or clinical scans that are modified for research purposes (for example, using a gadolinium-based contrast agent when it is not required for clinical reasons).

☒ **No →** Go to question **5.4.**

☐ **Yes →** Answer questions **5.3.a** through **5.3.c.**

5.3.a. Describe the MRI scan(s). Specifically:

- What is the purpose of the scan(s)? *Examples: obtain research data; safety assessment associated with a research procedure.*
- Which subjects will receive an MRI scan?
- Describe the minimum and maximum number of scans per subject, and over what time period the scans will occur. *For example: all subjects will undergo two MRI scans, six months apart.*

Click or tap here to enter text.

5.3.b. MRI facility. At which facility(ies) will the MRI scans occur? Check all that apply.

☐ UWMC Radiology/Imaging Services (the UWMC clinical facility)
☐ DISC Diagnostic Imaging Sciences Center (UWMC research facility)
☐ CHN Center for Human Neuroscience MRI Center (Arts & Sciences research facility)
☐ BMIC Biomolecular Imaging Center (South Lake Union research facility)
☐ Harborview Radiology/Imaging Services (the Harborview clinical facility)
☐ Northwest Diagnostic Imaging
☐ Other: identify in the text box below:

Click or tap here to enter text.

5.3.c. Personnel. For MRI scans that will be conducted at the DISC, CHN or BMIC research facilities: Indicate who will be responsible for operating the MRI scanner by checking all that apply.

☐ MRI technician who is formally qualified
☐ Researcher who has completed scanner operator training provided by a qualified MRI operator

5.4. [DETERMINATION] **Data variables**. Describe the specific data that will be obtained (including a description of the most sensitive items). Alternatively, a list of the data variables may be uploaded to ***Zipline***.

Measure	Type of measure	Instrument	Source
Sample Characteristics			
Demographics	Descriptive	Questionnaire	Patient, Clinician
Medical History and Comorbidities	Descriptive	Electronic Health Record, DSM-5 Cross-Cutting Symptoms Measure Survey	Case Report Form, Patient, Caregiver
Neighborhood	Descriptive	MESA Neighborhood Questionnaire	Patient, Caregiver
Intervention Acceptability	Primary outcome	System Usability Scale	Patient, Clinician
		User Burden Scale	Patient, Clinician
		AIAFIM	Patient, Clinician
		CSQ-18	Patient, Clinician
Trial Design Feasibility	Secondary outcome	Recruitment/Enrollment rate, Loss to Follow Up rate	Case Report Form
Treatment Engagement	Secondary outcome	BA Session Attendance, Homework Completion, Skill Use	Case Report Form
Intervention Engagement	Secondary outcome	Time on platform, messaging rates, latency to respond to prompts	Case Report Form
Intervention Safety	Secondary outcome	Adverse Events Interview	Patient, Caregiver, Clinician
Suicidality	Secondary outcome	SMFQ-4	Case Report Form
Depression	Secondary outcome	PHQ-9, BDI (caregiver only)	Patient, Caregiver
Anxiety	Secondary outcome	GAD-7	Patient, Caregiver
Functional Impairment	Secondary outcome	WFIRS	Patient, Caregiver
Loneliness	Secondary outcome	NIH Loneliness Survey	Patient
Therapeutic Alliance	Secondary outcome	WAI-SR	Patient
Depressive Disorder	Secondary outcome	CDRS-R	Patient
Conduct	Secondary outcome	Strengths and Difficulties Questionnaire	Patient, Caregiver
Technology Comfort	Secondary outcome	FACETS	Patient
Online intervention attitudes	Exploratory	ETAP 16	Patient
Client-centeredness of treatment	Exploratory	GYV-20	Patient
Baseline Anxiety	Descriptive	RCADS-25	Caregiver

5.5. [DETERMINATION] **Data sources**. For all types of data that will be accessed or collected for this research: Identify whether the data are being obtained from the subjects (or subjects' specimens) or whether they are being obtained from some other source (and identify the source).

If you have already provided this information in Question 5.1, you do not need to repeat the information here.

See Section 5.4

5.6. [DETERMINATION] **Identifiability of data and specimens.** Answer these questions carefully and completely. This will allow HSD to accurately determine the type of review that is required and the relevant compliance requirements. Review the following definitions before answering the questions:

Access *means to view or perceive data, but not to possess or record it. Consider, in contrast, the definition of "obtain".*
Identifiable *means that the identity of an individual is or may be readily (1) ascertained by the researcher or any other member of the study team from specific data variables or from a combination of data variables, or (2) associated with the information.*
Direct identifiers *are direct links between a subject and data/specimens. Examples include (but are not limited to): name, date of birth, medical record number, email or IP address, pathology or surgery accession number, student number, or a collection of data that is (when taken together) identifiable.*
Indirect identifiers *are information that links between direct identifiers and data/specimens. Examples: a subject code or pseudonym.*
Key *refers to a single place where direct identifiers and indirect identifiers are linked together so that, for example, coded data can be identified as relating to a specific person. Example: a master list that contains the data code and the identifiers linked to the codes.*
Obtain *means to possess or record in any fashion (writing, electronic document, video, email, voice recording, etc.) for research purposes and to retain for any length of time. This is different from accessing, which means to view or perceive data.*

5.6.a. Will you or any members of you team have access to any direct or indirect identifiers?

☒ **Yes →** Describe which identifiers and for which data/specimens.

Direct identifiers of participants (both clinicians and patients) will be stored in a REDCap database that can be accessed by study team members. These include: name, date of birth, phone number, MRN, email, and mailing address. All direct identifiers will be stored together and with a study ID linking each individual to their study data that is stored in a separate REDCap database. Direct identifiers of third-party subjects (name and contact information of parent/guardian of child participants) will also be stored in the database of identifiable data and will be stored with the associated child's identifiable information.

☐ **No →** Select the reason(s) why you (and all members of your team) will not have access to direct or indirect identifiers.

☐ There will be no identifiers
☐ Identifiers or the key have been (or will have been) destroyed before access.
☐ There is an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to study team members under any circumstances.

This agreement should be available upon request from the IRB. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

☐ There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.
☐ There are other legal requirements prohibiting the release of the identifiers or key. Describe them below.

Click or tap here to enter text.

5.6.b. Will you or any study team members obtain any direct or indirect identifiers?

☒ **Yes →** Describe which identifiers and for which data/specimens.

Yes, the accessible identifiers described in part 5.6.a will be obtained and stored as part of the study records.

☐ **No →** Select the reason(s) why you (and all members of your team) will not obtain direct or indirect identifiers.

☐ There will be no identifiers.
☐ Identifiers or the key have been (or will have been) destroyed before access.
☐ There will be an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key under any circumstances.

This agreement should be available upon request from the IRB. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

☐ There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.
☐ There are other legal requirements prohibiting the release of the identifiers or key. Describe them below.

Click or tap here to enter text.

5.6.c. If any identifiers will be obtained, indicate how the identifiers will be stored (and for which data). NOT: Do not describe the data security plan here, that information is requested in question **9.6.**

☐ Identifiers will be stored with the data. Describe the data to which this applies:

Click or tap here to enter text.

☒ Identifiers and study data will be stored separately but a link will be maintained between the identifiers and the study data (for example, through the use of a code). Describe the data to which this applies:

All identifiable data will be stored in a separate REDCap database from study data (e.g. treatment history, self-report survey responses). The identifiable database will include a study ID that can be used to link the study data to the identifiable data.

☐ Identifiers and study data will be stored separately, with no link between the identifiers and the study data. Describe the data to which this applies:

Click or tap here to enter text.

5.6.d. Research collaboration. Will individuals who provide coded information or specimens for the research also collaborate on other activities for this research? If yes, identify the activities and provide the name of the collaborator's institution/organization.

Examples include but are not limited to: (1) study, interpretation, or analysis of the data that results from the coded information or specimens; and (2) authorship on presentations or manuscripts related to this work.

N/A

5.7. [DETERMINATION] **Protected Health Information (PHI).** Will participants' identifiable PHI be accessed, obtained, used, or disclosed for any reason (for example, to identify or screen potential subjects, to obtain study data or specimens, for study follow-up) that does not involve the creation or obtaining of a Limited Data Set?

PHI is individually identifiable healthcare record information or clinical specimens from an organization considered a "covered entity" by federal HIPAA regulations, in any form or media, whether electronic, paper, or oral. ***You must answer yes to this question if the research involves identifiable health care records (e.g., medical, dental, pharmacy, nursing, billing, etc.), identifiable healthcare information from a clinical department repository, or observations or recordings of clinical interactions.***

For information about what constitutes the UW Covered Entity, review UW Medicine Compliance Patient Information Privacy Policy 101 and diagram of the healthcare components.

☐ **No →** Skip the rest of this question; go to question **5.8**.
☒ **Yes →** Answer all of the questions below (**5.7.a.** through **5.7.f.**)

5.7.a. Describe the PHI and the reason for using it. *Be specific. For example, will any "free text" fields (such as physician notes) be accessed, obtained, or used?*

Screening
Patient medical records will be accessed during screening in order to identify potentially eligible patients from SCH outpatient mental health clinics. The following will be reviewed for each patient to assess potential eligibility:

- Patient Information
  - Confirm age and primary language of English
- Active problem list
  - Screen for exclusions such as intellectual disability, developmental disorder, psychosis, substance use
- Intake visit conducted during initial visit with SCH outpatient mental health
  - Confirm primary psychiatric diagnosis of major depressive disorder
  - Screen for exclusions such as intellectual disability, developmental disorder, psychosis, substance use

Research staff will obtain contact information for potentially eligible patients to be used in recruitment and screening.

Study Data Collection

Once a patient is enrolled and a HIPAA authorization has been obtained, research staff will access and obtain patient PHI.

The eligibility data described in the list above will be obtained as part of study data.

Research staff will obtain the following from the patient medical record:

- Behavioral treatment records at the SCH outpatient clinic including the pre-consent intake visit
- Current and past history of mental health diagnoses
- Current physical health diagnosis
- Mental health symptom surveys or interviews completed during treatment
- Current medications

Treatment records generated before or during the patient's participation in the study will be eligible to be obtained.

5.7.b. Is any of the PHI located in Washington State?

☐ **No**
☒ **Yes**

5.7.c. Describe the pathway of how the PHI will be accessed or obtained, starting with the source/location and then describing the system/path/mechanism by which it will be identified, accessed, and copied for the research. *Be specific. For example: directly view records; search through a department's clinical database; submit a request to Leaf.*

Screening
Records will be directly viewed by research staff. First name and MRN will be obtained for all those screened via medical record to avoid repeat contacts. When study recruitment is complete, identifiable data will be deleted for anyone who is not screened or enrolled in the study. Aggregate statistics (e.g. number of records screened, outcomes) will be calculated and retained with study data. During recruitment, contact information will be accessed in order to initiate cold contact.

Study Data Collection
Research staff will access the SCH medical record system remotely, in line with SCH policy, or via an SCH desktop computer. Information from the EHR will be recorded to an electronic case report form (CRF) that is stored in REDCap.

5.7.d. For which PHI will subjects provide HIPAA authorization before the PHI is accessed, obtained and/or used?

Enrolled participants will provide HIPAA Authorization for all access and obtaining of PHI completed by the research team during their study involvement.

Confirm by checking the box that UW Medicine HIPAA Authorization form maintained on the HSD website will be used to access obtain, use, or disclose any UW Medicine PHI.

☐ **Confirmed**

5.7.e. Will you obtain any HIPAA authorizations electronically (i.e., e-signature)?

☐ **No**
☒ **Yes →** Confirm by checking the box that you have read and understand the *Electronic Documentation of Consent* section of the worksheet on Consent Requirements and Waivers the guidance on Documentation of Consent for information regarding the use of electronic signatures and HIPAA authorizations.

☒ **Confirmed**

5.7.f. For which PHI will HIPAA authorization NOT be obtained from the subjects?

HIPAA Authorization will not be obtained for screening patient records research staff or obtaining name and MRN for those whose medical records have been screened. The contact information obtained by the research team will be deleted for those who do not eventually screen or consent for the study. The PHI will be the minimum amount needed for the research team to make contact with potential participants.

Provide the following assurances by checking the boxes.

☒ The minimum necessary amount of PHI to accomplish the purposes described in this application will be accessed, obtained and/or used.
☒ The PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.
☒ The HIPAA "accounting for disclosures" requirement will be fulfilled, if applicable. Review UW Medicine Compliance Policy #104.
☒ There will be reasonable safeguards to protect against identifying, directly or indirectly, any patient in any report of the research.

5.8. [DETERMINATION] **Genomic data sharing**. Will the research obtain or generate genomic data?

☒ **No**
☐ **Yes →** Answer the question below.

5.8.a. Will genomic data from this research be sent to a national database (for example, NIH's dbGaP database)?

☐ **No**
☐ **Yes →** Complete the supplement for Genomic Data Sharing and upload it to ***Zipline***.

5.9. Whole genome sequencing. For research involving biospecimens: Will the research include whole genome sequencing?

Whole genome sequencing is sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.

☒ **No**
☐ **Yes**

5.10. [DETERMINATION] **Cannabis (marijuana), hemp, and related compounds**. These questions are about: cannabis (any part of the plant in any form), hemp, cannabidiol (CBD), delta-8-THC, any product derived from cannabis or hemp, and related synthesized compounds. All UW research must comply with federal laws about cannabis because of conditions associated with the federal money that UW receives. Answer the questions below so that HSD can determine whether the federal laws apply to your specific situation. Review the UW Guidance on Research Involving Marijuana for additional information.

5.10.a. Does your research involve any of the following? Check all that apply.

☐ Study staff will obtain or handle any of the above items
☐ Study will provide money to the participants to obtain any of the above items
☐ Study participants will use or consume any of the above items on campus or in any UW-owned or leased facility
☒ None of the above

5.10.b. If you checked any box except "None of the above", provide the following information about each cannabis and related item your research will involve: Name of the item, how you will obtain it, the source, and whether it contains ≥0.3% THC (tetrahydrocannabinol).

Click or tap here to enter text.

5.11. [DETERMINATION] **Possible secondary use or sharing of information, specimens, or subject contact information.** Please consider the broadest possible future plans and whether consent will be obtained now from the subjects for future sharing or research uses (which it may not be possible to describe in detail at this time).

Many federal grants and contracts now require data or specimen sharing as a condition of funding, and many journals require data sharing as a condition of publication. "Sharing" may include (for example): analyzing data using machine learning models; informal arrangements to share banked data/specimens with other investigators; establishing a repository that will formally share with other researchers through written agreements; or sending data/specimens to a third-party repository/archive/entity such as the Social Science Open Access Repository (SSOAR), or the UCLA Ethnomusicology Archive.

5.11.a Is this research funded by an NIH funding application submitted on or after January 25, 2023.

☒ **No →** Continue to next question.
☐ **Yes →** NIH Data Management and Sharing Policy applies to this research. Complete the rest of this section accordingly. If the policy applies and data will not be shared, provide the justification in response to **5.11.d** and write **NA** in response to the other questions.

5.11.b. Does this research involve analyzing UW patient health information using machine learning outside of UW IT systems (e.g., ChatGPT or other external language models)?

☒ **No →** Continue to next question.
☐ **Yes →** A security review of the research is required by UW Medicine. Please check the box to confirm that this review has been completed and upload a copy of the approval letter to *Zipline.*

Note: Your IRB application cannot be approved without documentation that the security review has been completed. For more information about the security review, contact Sally Beahan, Senior Director, UW Medicine Enterprise Records & Health Information at sbeahan@uw.edu .

☐ **Confirmed**

Answer all of the questions below. If sharing is unlikely or if the only sharing will be through the NIH Genomic Data Sharing per question **5.8**., write **NA** in remaining response boxes.

5.11.c. Describe what will be stored for future use, including whether any direct or indirect (e.g., subject codes) identifiers will be stored.

We will store all study data with indirect identifiers for future use. Direct identifiers will be retained in accordance with federal regulations but will not be eligible for sharing.

5.11.d. Describe what will be shared with other researchers or with a repository/database/registry/machine learning platform, including whether direct identifiers will be shared and (for specimens) what data will be released with the specimens. If shared through a repository, specify if it is unrestricted access (i.e., publicly accessible).

A de-identified dataset will be available for sharing in some circumstances (see 5.11.d). No direct identifiers will be shared with outside researchers.

5.11.e. Who will oversee and/or manage the sharing?

The principal investigator, Dr. Jessica Jenness

5.11.f. Describe the possible future uses, and any limitations or restrictions on future uses or users.

Examples of limitations:

- *Consent prohibits or limits the scope of sharing and use (e.g., consent states that data will be used only for cardiovascular research)*
- *Privacy or safety or research participants would be compromised (e.g., there is risk of reidentification and/or harm)*
- *Explicit federal, state, or local, or Tribal law, regulation, or policy prohibits disclosure*
- *Restrictions imposed by existing or anticipated agreements (e.g., with third party funders, partners, with repositories, medical centers providing health information under a data use agreement)*

De-identified data will be eligible to be shared:

- For any purpose related to fulfilling grant requirements and obligations
- To meet requirements for scientific publication
- With all co-investigators for secondary analysis
- With other academic research teams or researchers, given written permission by this study's principal investigator (Dr. Jenness)
- With other projects for which Dr. Jenness is a PI or co-I
- With University of Washington students under the guidance of Dr. Jenness for the purpose of teaching or publication

Identified data will not be shared beyond the study research team.

5.11.g. **Consent.** Will consent be obtained now from subjects for the secondary use, banking, and/or future sharing?

☐ **No**
☒ **Yes →** Be sure to include the information about this consent process in the consent form (if there is one) and in the answers to the consent question in Section 8.

5.11.h. **Withdrawal.** Will subjects be able to withdraw their data/specimens from secondary use, banking or sharing?

☒ **No**
☐ **Yes →** Describe how, and whether there are any limitations on withdrawal.

Example: data can be withdrawn from the repository but cannot be retrieved after they are released.

Click or tap here to enter text.

5.11.i. Agreements for sharing or release. Confirm by checking the box that the sharing or release will comply with UW (and, if applicable, UW Medicine) policies that require a formal agreement with the recipient for release of data or specimens to individuals or entities other than federal databases.

Data Use Agreements or Gatekeeping forms are used for data; Material Transfer Agreements are used for specimens (or specimens plus data). Do not attach any template agreement forms; the IRB neither reviews nor approves them.

☒ **Confirmed**

5.12. Communication with subjects during the study. Describe the types of communication (if any) the research team will have with already-enrolled subjects during the study. Provide a description instead of the actual materials themselves.

Examples: email, texts, phone, or letter reminders about appointments or about returning study materials such as a questionnaire; requests to confirm contact information.

Enrolled participants or their parent/legal guardian(s) may receive phone call, email, and/or text reminders of study and treatment appointments and completion of online data collection (e.g., mood-activity ecological momentary assessment measures).

5.13. **Future contact with subjects**. Is there a plan to retain any contact information for subjects so that they can be contacted in the future?

☐ **No**
☒ **Yes →** Describe the purpose of the future contact, and whether use of the contact information will be limited to the study team; if not, describe who else could be provided with the contact information. Describe the criteria for approving requests for information.

Examples: inform subjects about other studies; ask subjects for additional information or medical record access that is not currently part of the study proposed in this application; obtain another sample.

Participants will be asked if they would like to be re-contacted in the future about other research projects that they might be eligible for. Contact information will be used by the study team or by future study teams led by the PI, Dr. Jenness. Only projects under Dr. Jenness's purview as Principal Investigator or Co-Investigator will be allowed to access contact information for future contact

5.14. Alternatives to participation. Are there any alternative procedures or treatments that might be advantageous to the subjects?

If there are no alternative procedures or treatments, select "No". Examples of advantageous alternatives: earning extra class credit in some time-equivalent way other than research participation; obtaining supportive care or a standard clinical treatment from a health care provider instead of participating in research with an experimental drug.

☐ **No**
☒ **Yes →** Describe the alternatives.

Patients who decline to participate or who withdraw participation will be able to continue clinical mental health care at SCH. If they have begun BA treatment as part of the study, they will be able to continue this treatment if desired.

5.15. Upload to *Zipline* all data collection forms (if any) that will be directly used by or with the subjects, and any scripts/talking points that will be used to collect the data. Do not include data collection forms that will be used to abstract data from other sources (such as medical or academic records), or video recordings.

- ***Examples****: survey, questionnaires, subject logs or diaries, focus group questions.*
- ***NOTE****: Sometimes the IRB can approve the general content of surveys and other data collection instruments rather than the specific form itself. This prevents the need to submit a modification request for future minor changes that do not add new topics or increase the sensitivity of the questions. To request this general approval, use the text box below to identify the questionnaires/surveys/ etc. for which you are seeking this more general approval. Then briefly describe the scope of the topics that will be covered and the most personal and sensitive questions. The HSD staff person who screens this application will let you know whether this is sufficient or whether you will need to provide more information.*
- ***For materials that cannot be uploaded****: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*
- ***For data that will be gathered in an evolving way****: This refers to data collection/questions that are not pre-determined but rather are shaped during interactions with participants in response to observations and responses made during those interactions. If this applies to the proposed research, provide a description of the process by which the data collection/questions will be established during the interactions with subjects, how the data collection/questions will be documented, the topics likely to be addressed, the most sensitive type of information likely to be gathered, and the limitations (if any) on topics that will be raised or pursued.*

Use this text box (if desired) to provide:

- Short written descriptions of materials that cannot be uploaded, such as URLs
- A description of the process that will be used for data that will be gathered in an evolving way.
- The general content of questionnaires, surveys and similar instruments for which general approval is being sought. (Review the **NOTE** bullet point in the instructions above.)

Click or tap here to enter text.

6. CHILDREN (MINORS) AND PARENTAL PERMISSION

6.1. [DETERMINATION] **Involvement of minors**. Does the research include minors (children)?

Minor or child means someone who has not yet attained the legal age for consent for the research procedures, as described in the applicable laws of the jurisdiction in which the research will be conducted. This may or may not be the same as the definition used by funding agencies such as the National Institutes of Health.

- In Washington State the generic age of consent is 18, meaning that anyone under the age of 18 is considered a child.
- There are some procedures for which the age of consent is much lower in Washington State.
- The generic age of consent may be different in other states, and in other countries.

☐ **No** → Go to Section 8.

☒ **Yes** → Provide the age range of the minor subjects for this study and the legal age for consent in the study population(s). If there is more than one answer, explain.

Participants are aged 13-18; legal age of consent is age 18.

☐ **Don't know** → This means is it not possible to know the age of the subjects. For example, this may be true for some research involving social media, the Internet, or a dataset that is obtained from another researcher or from a government agency. Go to Section 8.

6.2. Parental permission. Parental permission means actively obtaining the permission of the parents. This is not the same as "passive" or "opt out" permission where it is assumed that parents are allowing their children to participate because they have been provided with information about the research and have not objected or returned a form indicating they don't want their children to participate.

6.2.a. Will parental permission be obtained for:

☒ All of the research procedures → Go to question **6.2.b**.

☐ None of the research procedures → Use the table below to provide justification and skip question **6.2.b.**

☐ Some of the research procedures → Use the table below to identify the procedures for which parental permission will not be obtained.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO parental permission[2]	Reason why parental permission will not be obtained	Will parents be informed about the research?[3]	
			YES	NO
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐	☐
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐	☐
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐	☐

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO parental permission[2]	Reason why parental permission will not be obtained	Will parents be informed about the research?[3] YES	NO
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐	☐
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐	☐

Table footnotes

1. *If the answer is the same for all children groups or all procedures: collapse the answer across the groups and/or procedures.*
2. *If identifiable information or biospecimens will be obtained without parent permission, any waiver granted by the IRB does not override parents' refusal to provide broad consent (for example, through the Northwest Biotrust).*
3. *Will parents be informed about the research beforehand even though active permission is not being obtained?*

6.2.b. Indicate the plan for obtaining parental permission. One or both boxes must be checked.

☐ Both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
☒ One parent, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

This is all that is required for minimal risk research.

If both are checked explain:

Click or tap here to enter text.

6.3. Children who are wards. Will any of the children be wards of the State or any other agency, institution, or entity?

☒ **No**
☐ **Yes →** An advocate may need to be appointed for each child who is a ward. The advocate must be in addition to any other individual acting on behalf of the child as guardian or in loco parentis. The same individual can serve as advocate for all children who are wards.
Describe who will be the advocate(s). The description must address the following points:

- Background and experience
- Willingness to act in the best interests of the child for the duration of the research
- Independence of the research, research team, and any guardian organization

Click or tap here to enter text.

6.4. UW Office of the Youth Protection Coordinator. If the project involves interaction (in-person or remotely) with individuals under the age of 18, researchers must comply with UW Administrative Policy Statement 10.13 and the requirements listed at this website. This includes activities that are deemed to be Not Research or Exempt. It does not apply to third-party led research (i.e., research conducted by a non-UW PI). Information and FAQs for researchers are available.

This point is advisory only; there is no need to provide a response.

7. ASSENT OF CHILDREN (MINORS)

Go to Section 8 if your research does not involve children (minors).

When designing assent processes and forms, researchers should first review the guidance on *Protected and Vulnerable Populations* and tipsheet on *Assent and Legally Authorized Representative*.

7.1. Assent of children (minors). Though children do not have the legal capacity to "consent" to participate in research, they should be involved in the process if they are able to "assent" by having a study explained to them and/or by reading a simple form about the study, and then verbally expressing whether they want to participate. They may also provide a written assent if they are older. Review the guidance on *Protected and Vulnerable Populations* and the worksheet on **Children** for circumstances in which a child's assent may be unnecessary or inappropriate.

7.1.a. Will assent be obtained for:

☒ All research procedures and child groups → Go to question **7.2**.

☐ None of the research procedures and child groups → Use the table below to provide justification, then skip to question **7.6.**

☐ Some of your research procedures and child groups → Use the table below to identify the procedures for which assent will not be obtained.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will not be obtained	Reason why assent will not be obtained
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.

Table footnotes

1. *If the answer is the same for all children groups or all procedures, collapse your answer across the groups and/or procedures.*

7.2. Assent process. Describe how assent will be obtained, for each child group. If the research involves children of different ages, answer separately for each group. If the children are non-English speakers, include a description of how their comprehension of the information will be evaluated.

All children will be English speaking adolescents. Assent will be obtained by either the PI or RA (referred to as the interviewer) via a HIPAA compliant video conference platform (e.g., Zoom). Once the participant and their parent/guardian have entered the video conference, assent will be reviewed and signed via REDCap by sending the family the REDCap link and screen sharing while we review

assent/consent. The assent is written in age-appropriate language (see attached forms). The interviewer will then go through each point of the informed consent/assent allowing the participant and their parent/guardian to ask any questions they have before the interviewer goes on to the next section. Once the interviewer has thoroughly gone over the consent/assent/authorization form with the subject and their guardian, the interviewer will then follow up by asking "Do you have any questions about the study or is anything unclear to you?" The interviewer will ensure that the participant is given sufficient time to review the consent and assent forms. Only after the participant and their parent/guardian have thoroughly read the forms and the interviewer has answered all questions will the interviewer offer to let the participant and their parent to electronically sign the forms on REDCap. The interviewer will then provide an electronic signature on the form as the "witness."

At all stages of the study, participants and parents will be informed that refusal to participate will not affect their ability to receive care at the University of Washington or Seattle Children's Hospital clinics and that they are free to withdraw at any time. Parents will also be informed about federal and state laws mandating reporting (e.g., child, elder abuse; risk of harm to self or others) . In cases where mandated reporting is required, the family will be told prior to our contacting any state agency (see **10.1 Anticipation of Risks**).

7.3. Dissent or resistance. Describe how a child's objection or resistance to participation (including non-verbal indications) will be identified during the research, and what the response will be.

Examples of verbal dissent include the youth participant clearly stating they do not wish to participate, asking their parent why they are being asked to participate or if they "need" to participate, or asking whether they can have more time to think about participating. Possible examples of non-verbal dissent include not reading the assent, shrugging, sighing, or not making eye contact when asked if they have questions, when asked if they would like to participate after reviewing the assent, or during any other point in the consent/assent process. If the youth participant either verbally or non-verbally indicates dissent or resistance to participate in the study, the interviewer will again review that participation is completely voluntary and dependent upon both the youth and parent agreeing to participate. The interviewer will offer to provide the youth and parent with more information, answer any remaining questions, and provide a private space to the youth/parent to discuss participation. If there is still concern with whether the youth objects to participation, the interviewer will offer to cancel the visit to give the youth and their parent more time to think about whether they would like to participate. The interviewer will offer to either re-contact the family after an agreed upon amount of time has passed or to wait for the family to contact the study coordinator, depending on family preference.

7.4. E-consent. Will any electronic processes (email, websites, electronic signatures, etc.) be used to present assent information to subjects/and or to obtain documentation (signatures) of assent? If yes, describe how this will be done.

Consent/assent will be reviewed and signed via REDCap by sending the family the REDCap link and screen sharing while we review assent/consent.

7.5. Documentation of assent. Which of the following statements describes whether documentation of assent will be obtained?

☐ None of the research procedures and child groups → Use the table below to provide justification, then go to question **7.5.b.**

☒ All of the research procedures and child groups → Go to question **7.5.a**., do not complete the table.
☐ Some of the research procedures and/or child groups → Complete the table below and then go to question **7.5.a.**

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be documented
Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.
Click or tap here to enter text.	Click or tap here to enter text.

Table footnotes

1. *If the answer is the same for all children groups or all procedures, collapse your answer across the groups and/or procedures.*

7.5.a. Describe how assent will be documented. If the children are functionally illiterate or are not fluent in English, include a description of the documentation process for them.

Assent will be documented and stored electronically on REDCap. Non-English speaking or illiterate youth will not be eligible to participate in this study.

7.5.b. Upload all assent materials (talking points, videos, forms, etc.) to ***Zipline***. Assent materials are not required to provide all of the standard elements of adult consent; the information should be appropriate to the age, population, and research procedures. The documents should be in Word, if possible.

7.6. Children who reach the legal age of consent during participation in longitudinal research.

When children are enrolled at a young age and continue for many years, it is best practice to re-obtain assent (or to obtain it for the first time, if it was not obtained at the beginning of their participation).

When children reach the legal age of consent, informed consent must be obtained from the now-adult subject for (1) any ongoing interactions or interventions with the subjects, or (2) the continued analysis of specimens or data for which the subject's identify is readily identifiable to the researcher, unless the IRB waives this requirement.

7.6.a. Describe the plans (if any) to re-obtain assent from children.

The study length is 24 weeks, so re-assent will not be necessary.

7.6.b. Describe the plans (if any) to obtain consent for children who reach the legal age of consent.

- If adult consent will be obtained from them, describe what will happen regarding now-adult subjects who cannot be contacted.
- If consent will not be obtained or will not be possible, explain why.

If a youth turns 18 during the study, we will obtain consent as an adult from the youth at that time. In order to continue to send mood-activity report promts to their smartphones on a daily basis, we will

consent them over the phone for EMA notifications as soon as possible once they turn 18. We will then obtain written consent for all study procedures when the youth comes in for the next face to face session. See "Consent Forms and Recruitment Materials" for the Youth Consent Form.

7.7. Other regulatory requirements. (This is for information only; no answer or response is required.) Researchers are responsible for determining whether their research conducted in schools, with student records, or over the Internet comply with permission, consent, and inspection requirements of the following federal regulations:

- PPRA – Protection of Pupil Rights Amendment
- FERPA – Family Education Rights and Privacy Act
- COPPA – Children's Online Privacy Protection Act

8 CONSENT OF ADULTS

We provide researchers with many resources for designing the consent process and form(s).

- The general Consent guidance provides a broad overview of all consent-related topics. Researchers are strongly encouraged to review HSD's Consent Overview and the section on Key Information before designing consent process/form.
- The guidance on Designing the Consent Process lists the general requirements for consent, required elements of consent, and the criteria for waivers of consent and documentation of consent. This guidance can be used with, or independent of, our Consent Templates.
- Information about parental permission can be found in the guidance on *Protected and Vulnerable Populations.*

Review the following definitions before answering the questions in this section.

Consent is the process of informing potential subjects about the research and asking them whether they want to participate. It does not necessarily include the signing of a consent form.

Parental permission is the parent's active permission for the child to participate in the research. Parental permission is subject to the same requirements as consent, including written documentation of permission and required elements.

Consent form is a document that provides details about the research so that subjects can make an informed decision about whether they want to participate.

General requirements for consent are the qualities of the consent process as a whole and can be found in the guidance on Designing the Consent Process.

Elements of consent are specific information that is required to be provided to subjects and can be found in the guidance on Designing the Consent Process.

Consent documentation refers to how a subject's decision to participate in the research is documented. This is usually obtained by having the subject sign a consent form.

Short form consent is an alternative way of obtaining written documentation of consent for the unanticipated enrollment of individuals with low literacy or whose language is one for which translated consent forms are not available.

Waiver of consent means there is IRB approval for not obtaining consent or for not including some of the elements of consent in the consent process. **Note** if you plan to obtain identifiable information or identifiable biospecimens without consent, any waiver granted by the IRB does not override a subject's refusal to provide broad consent (for example, the Northwest Biotrust).

Waiver of documentation of consent means that there is IRB approval for not obtaining written documentation of consent.

8.1. Groups. Identify the groups to which the answers in this section apply:

☒ **Adult** subjects
☒ **Parents** who are providing permission for their children to participate in research

→ *If you selected **PARENTS**, the word "consent" below should also be interpreted as applying to parental permission and "subjects" should also be interpreted as applying to the parents.*

8.2. The consent process and characteristics. This series of questions is about whether consent will be obtained for all procedures except recruiting and screening, and, if yes, how.

The issue of consent for recruiting and screening activities is address in question 4.7. You do not need to repeat your answer to question 4.7.

8.2.a. Are there any procedures for which consent will not be obtained?

☒ **No**
☐ **Yes** → Use the table below to identify the procedures for which consent will not be obtained. "All" is an acceptable answer for some studies.

Be sure to consider all research procedures and plans, including future contact, and sharing/banking of data and specimens for future work.

Group[1]	Describe the procedures of data/specimen collection (if any) for which there will be NO consent process	Reason why consent will not be obtained	Will subjects be provided with info about the research after they finish? (Check Yes or No)	
			YES	NO
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐	☐
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐	☐

Group[1]	Describe the procedures of data/specimen collection (if any) for which there will be NO consent process	Reason why consent will not be obtained	Will subjects be provided with info about the research after they finish? (Check Yes or No)	
			YES	NO
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐	☐
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐	☐
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐	☐
Click or tap here to enter text.	Click or tap here to enter text.	Click or tap here to enter text.	☐	☐

Table footnotes

1. If the answer is the same for all groups, collapse your answer across the groups and/or procedures.

8.2.b. Describe the consent process, if consent will be obtained for any or all procedures, for any or all groups. Address groups and procedures separately if the consent processes are different.

Be sure to include:

- *The location/setting where consent will be obtained*
- *Who will obtain consent (refer to positions, roles, or titles, not names)*
- *How subjects will be provided sufficient opportunity to discuss the study with the research team and consider participation.*

Similar to the assent process, informed consent will be obtained by either the PI or RA (referred to as the interviewer) via a HIPAA compliant video conference platform (e.g., Zoom). Once the participant and their parent/guardian have entered the video conference consent will be reviewed and signed via REDCap by sending the family the REDCap link and screen sharing while we review consent. The consent is written in age-appropriate language (see attached forms). The interviewer will then go through each point of the informed consent allowing the participant and their parent/guardian to ask any questions they have before the interviewer goes on to the next section. Once the interviewer has thoroughly gone over the consent form with the subject and their guardian, the interviewer will then follow up by asking "Do you have any questions about the study or is anything unclear to you?" The interviewer will ensure that the participant is given sufficient time to review the consent forms. Only after the participant and their parent/guardian have thoroughly read the forms and the interviewer has answered all questions will the interviewer offer to let the participant and their parent to electronically sign the forms on REDCap. The interviewer will then provide an electronic signature on the form as the "witness."

At all stages of the study, participants and parents will be informed that refusal to participate will not affect their ability to receive care at the University of Washington or Seattle Children's Hospital clinics and that they are free to withdraw at any time. Parents will also be informed about federal and state laws for mandated reporting , verbally and in writing. In cases where a report of child abuse is indicated, the family will be told prior to our contacting any state agency (see **10.1 Anticipation of Risks**).

Clinician Participants
After filling out a brief survey to confirm eligibility, clinician participants will be sent the link to the electronic consent. The research coordinator will reach out and ask to schedule a brief call to discuss the consent form and study procedures, and to answer any questions. During the call the clinician will complete the electronic consent.

8.2.c. Comprehension. Describe the methods that will be used to ensure or test the subjects' understanding of the information during the consent process.

Parents and youth will be given an opportunity to ask questions and will be prompted with questions throughout the reading of the consent/assent process.

8.2.d. Influence. Does the research involve any subject groups that might find it difficult to say "no" to participation because of the setting or their relationship with someone on the study team, even if they aren't pressured to participate?

Examples: Student participants being recruited into their teacher's research; patients being recruited into their healthcare provider's research; study team members who are participants; outpatients recruited from an outpatient surgery waiting room just prior to their surgery.

☐ **No**

☒ **Yes** → Describe what will be done to reduce any effect of the setting or relationship on the participation decision.

Examples: a study coordinator will obtain consent instead of the subject's physician; the researcher will not know which subjects agreed to participate; subjects will have two days to decide after hearing about the study.

Patient participants and parents may be concerned that not participating in the study will affect their treatment, especially if the clinician providing treatment is already in the study. They will be assured that they are free to choose not to participate. Research staff not involved in the care of the patient will conduct consent procedures and study visits.

Clinician participants may feel pressure to participate if they are a colleague of Drs. Jenness or McCauley and/or if they are professionally supervised by them. Potential clinician participants will be assured that their participation will have no bearing on their professional relationship with Drs. Jenness or McCauley.

8.2.e. Information provided is tailored to the needs of the subject population. Describe the basis for concluding that the information that will be provided to subjects (via written or oral methods) is what a *reasonable member* of the *subject population(s)* would want to know. If the research consent materials contain a key information section, also describe the basis for concluding that the information present in that section is that which is *most likely* to assist the selected subject population with making a decision. Review the guidance on Key Information and examples of Key Information.

For example: Consultation with publications about research subjects' preferences, disease-focused nonprofit groups, patient interest groups, or other researchers/study staff with experience with the specific population. It may also involve directly consulting selected members of the study population.

We have developed the consent forms based on the prior experience of our researchers in working with populations of parents and their children as well as mental health clinicians. Dr. Jenness has experiences with clinical trials, parents, clinicians and youth.

8.2.f. Ongoing process, new information, and reconsent.

For research that involves multiple or continued interaction with subjects over time, describe the opportunities (if any) that will be given to subjects to ask questions or to change their minds about participating.

Throughout the course of the study, subjects may need to be notified about new information. This might take the form of a verbal or written communication or may require subjects to provide reconsent. When a modification is submitted in which subjects need to be informed about new information, describe the method and process the research team will use to provide this information.

Review the tipsheet on Reconsent and Ongoing Subject Communication and guidance on Reconsent and Ongoing Subject Communication for details.

When scheduling follow-up visits and phone calls we will instruct research assistants to phrase scheduling requests in a way that indicates the participant has a chance to change their mind about participation (i.e., "Are you still interested in scheduling this follow-up visit/phone call?"

8.3. **Electronic presentation of consent information**. Will any part of the consent-related information be provided electronically for some, or all of the subjects?

This refers to the use of electronic systems and processes instead of (or in addition to) a paper consent form. For example, an emailed consent form, a passive or an interactive website, graphics, audio, video podcasts. Review the guidance on Electronic Consent and Documentation of Consent for information about electronic consent requirements at UW.

☐ **No →** Skip to question **8.4.**

☒ **Yes →** Answer questions **8.3.a.** through **8.3.e.**

8.3.a. Describe the electronic consent methodology and the information that will be provided.

All information materials must be made available to the IRB. Website content should be provided as a Word document. It is considered best practice to give subjects information about multi-page/multi-screen information that will help them assess how long it will take them to complete the process. For example, telling them that it will take about 15 minutes, or that it involves reading six screens or pages.

Once the participant and their parent/guardian have joined the HIPAA compliant video conference platform (e.g., Zoom) they will be presented with a copy of the informed consent (parent/guardian) signed via REDCap. If the consent process is conducted over Zoom, the family will be sent the REDCap link and the consent will be reviewed with the parent/guardian through screen sharing. The consent is written in age-appropriate language (see attached forms). The interviewer will then go through each point of the informed consent allowing the participant and their parent/guardian to ask any questions they have before the interviewer goes on to the next section. Once the interviewer has thoroughly gone over the consent/assent/authorization form with the subject and their guardian, the interviewer will then follow up by asking "Do you have any questions about the study or is anything unclear to you?" The interviewer will ensure that the participant's parent/guardian is given sufficient time to review the consent forms. Only after the participant and their parent/guardian have thoroughly read the forms and the interviewer

has answered all questions will the interviewer offer to let the participant and their parent to electronically sign the forms on REDCap. The interviewer will then provide an electronic signature on the form as the "witness."

8.3.b. Describe how the information can be navigated (if relevant).

For example, will the subject be able to proceed forward or backward within the system, or to stop and continue at a later time?

On the RedCap online consent form, participants will be able to navigate forwards and backwards during their review.

8.3.c. In a standard paper-based consent process, the subjects generally have the opportunity to go through the consent form with study staff and/or to ask study staff about any question they may have after reading the consent form. Describe what will be done, if anything, to facilitate the subject's comprehension and opportunity to ask questions when consent information is presented electronically. Include a description of any provisions to help ensure privacy and confidentiality during this process.

Examples: hyperlinks, help text, telephone calls, text messages or other type of electronic messaging, video conference, live chat with remotely located study team members.

Once the interviewer has thoroughly gone over the consent/assent/authorization form with the subject and their guardian, the interviewer will then follow up by asking "Do you have any questions about the study or is anything unclear to you?" The interviewer will ensure that the participant is given sufficient time to review the consent and assent forms. Participants and their parent(s)/guardian(s) will be able to ask questions as needed on the Zoom conference if meeting virtually. Questions can be asked/answered verbally or through the chat feature on Zoom.

8.3.d. What will happen if there are individuals who wish to participate but who do not have access to the consent methodology being used, or who do not wish to use it? Are there alternative ways in which they can obtain the information, or will there be some assistance available? If this is a clinical trial, these individuals cannot be excluded from the research unless there is a compelling rationale.

For example, consider individuals who lack familiarity with electronic systems, have poor eyesight or impaired motor skills, or who do not have easy email or internet access.

Paper/PDF consent forms will be available for participant/parent/guardian review if requested. Text size of documents can be adjusted via print or electronically.

8.3.e. How will the research team ensure continued accessibility of consent materials and information during the study?

Participants and parents will be given a copy of the consent form to retain for their review as needed. They will be advised they can ask the research staff questions about their consent at any time.

During research meetings, we will review the consent process and any questions or concerns that are coming up regarding understanding of the materials. We will update and consult with the IRB if needed.

8.3.f. How will additional information be provided to subjects during the research, including any significant new findings (such as new risk information). If this is not an issue, explain why.

Adult participants or a parent of each child participant will be informed promptly about any unanticipated serious adverse event that the independent study monitor determines is definitely related to the study intervention.

Otherwise, since this is a user centered design study seeking feedback regarding a digital support tool added onto a standard of care treatment, we do not anticipate new findings or new risk information from this work. In addition, as a pilot study, we would not be able to determine if any findings would be significant enough to share with participants.

8.4. Written documentation of consent. Which of the statements below describe whether documentation of consent will be obtained? NOTE: This question does not apply to screening and recruiting procedures which have already been addressed in question **4.7**.

Documentation of consent that is obtained electronically is not considered written consent unless it is obtained by a method that allows verification of the individual's signature. In other words, saying "yes" by email is rarely considered to be written documentation of consent.

8.4.a. Is written documentation being obtained for:

☐ **None** of the research procedures → Use the following table to provide justification then go to question **8.5.**

☐ **All** of the research procedures → Do not complete the following table, go to question **8.4.b.**

☒ **Some** of the research procedures → Use the following table to identify the procedures for which written documentation of consent will not be obtained from adult subjects.

Adult subject group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO documentation of consent	Will they be provided with a written statement describing the research (optional)? (Check Yes or No) YES	NO
Youth who turn 18 during study	As noted previously, if a youth turns 18 during the study, we will obtain consent as an adult from the youth at that time. In order to continue to send mood-activity report promts to their smartphone, we will obtain verbal consent over the phone for monitoring their smartphones as soon as possible once they turn 18. We will then obtain written consent for all study procedures when the youth comes in for the next face to face session, so will eventually be provided with a written statement of the research. See "Consent Forms and Recruitment Materials" for the Youth Consent Form.	☒	☐

Adult subject group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO documentation of consent	Will they be provided with a written statement describing the research (optional)? (Check Yes or No)	
		YES	NO
Click or tap here to enter text.	Click or tap here to enter text.	☐	☐
Click or tap here to enter text.	Click or tap here to enter text.	☐	☐
Click or tap here to enter text.	Click or tap here to enter text.	☐	☐
Click or tap here to enter text.	Click or tap here to enter text.	☐	☐

Table footnotes

1. If the answer is the same for all adult groups or all procedures, collapse the answer across the groups and/or procedures.

8.4.b. Electronic consent signature. For studies in which documentation of consent will be obtained, will subjects use an electronic method to provide their consent signature?

- Review the guidance on *Documentation of Consent* and *UW E-Signature Tools* *for information about options (including **REDCap** e-signature and the **DocuSign** system) and any associated requirements.*
- *FDA-regulated studies must use a system that complies with the FDA's "Part 11" requirements about electronic systems and records. Note that the UW-IT supported DocuSign e-signature system does not meet this requirement.*
- *Having subjects check a box at the beginning of an emailed or web-based questionnaire is not considered legally effective documentation of consent.*

☐ **No**

☒ **Yes** → Indicate which methodology will be used

☒ **UW ITHS REDCap** (excludes REDCap Mobile application, which is a separate software application for use with a mobile device for consent when internet service is absent or unreliable)

☐ **Other REDCap installation** → Please name the institutional version you will be using (e.g., Vanderbilt, Univ. of Cincinnati) in the following field and provide a completed supplement **Other REDCap Installation** with your submission.

Click or tap here to enter text.

☐ **UW DocuSign**

☐ **Other** → Please describe in the following field and provide a signed **Other E-signature Attestation Letter** with your submission.

Click or tap here to enter text.

8.4.b.1. Is this method legally valid in the jurisdiction where the research will occur?

NOTE: UW ITHS REDCap (excludes REDCap Mobile application) and UW DocuSign have been vetted for compliance with Washington State and federal laws regarding electronic signatures.

☐ **No**

☐ **Yes →** What is the source of information about legal validity?

Click or tap here to enter text.

8.4.b.2. Will verification of the subject's identity be obtained if the signature is not personally witnessed by a member of the study team? Note that this is required for FDA-regulated studies.

Review the guidance Documentation of Consent for information and examples

☐ **No →** Provide the rationale for why this is not required or necessary to protect subjects or the integrity of the research. Also, what would be the risks to the actual subject if somebody other than the intended signatory provides the consent signature?

Click or tap here to enter text.

☐ **Yes →** Describe how subject identity will be verified, providing a non-technical description that the reviewer will understand.

Click or tap here to enter text.

8.4.b.3. How will the requirement be met to provide a copy of the consent information (consent form) to individuals who provide an e-signature?

The copy can be paper or electronic and may be provided on an electronic storage device or via email. If the electronic consent information uses hyperlinks or other websites or podcasts to convey information specifically related to the research, the information in these hyperlinks should be included in the copy provided to the subjects and the website must be maintained for the duration of the entire study.

Click or tap here to enter text.

8.4.c. Barriers to written documentation of consent. There are many possible barriers to obtaining written documentation of consent. Consider, for example, individuals who are functionally illiterate; do not read English well; or have sensory or motor impairments that may impede the ability to read and sign a consent form.

8.4.c.1. Describe the plans (if any) for obtaining written documentation of consent from potential subjects who may have difficulty with the standard documentation process (that is, reading and signing a consent form).

Examples of solutions: Translated consent forms; use of the Short Form consent process; reading the form to the person before they sign it; excluding individuals who cannot read and understand the consent form.

Our inclusion criteria include English-speaking youth and parents and exclusions criteria include IQ<80 and or the presence of a developmental disability that would preclude understanding of our protocol and treatment, as it would not be clinically appropriate to enroll a youth in an intervention that they are unable to understand. Therefore, we do not anticipate difficulty with the standard documentation process.

8.5. Non-English-speaking or-reading adult subjects. Will the research enroll adult subjects who do not speak English or who lack fluency or literacy in English?

☒ **No**

☐ **Yes →** Describe the process that will be used to ensure that the oral and written information provided to them during the consent process and throughout the study will be in a language readily understandable to them and (for written materials such as consent forms or questionnaires) at an appropriate reading/comprehension level.

Click or tap here to enter text.

8.5.a. Interpretation. Describe how interpretation will be provided, and when. Also, describe the qualifications of the interpreter(s) - for example, background, experience, language proficiency in English and in the other language, certification, other credentials, familiarity with the research related vocabulary in English and the target language.

Click or tap here to enter text.

8.5.b. Translations. Describe how translations will be obtained for all study materials (not just consent forms). Also, describe the method for ensuring that the translations meet the UW IRB's requirement that translated documents will be linguistically accurate, at an appropriate reading level for the participant population, and culturally sensitive for the local in which they will be used.

☐ Check this box to confirm that before using them with subjects, you will upload in *Zipline* all translated consent materials that will be provided to subjects in written or electronic form (per **HSD policy**).

If the IRB determines that your study is greater than minimal risk, or otherwise determines it is required, you will need to work with your translator to provide a Translation Attestation. If the attestation is required, you will be informed by the IRB during the course of the review.

Click or tap here to enter text.

8.6. [DETERMINATION] **Deception**. Will information be deliberately withheld, or will false information be provided, to any of the subjects?

NOTE: "Blinding" subjects to their study group/condition/arm is not considered to be deception, but not telling them ahead of time that they will be subjects to an intervention or about the purpose of the procedure(s) is deception.

☒ **No**
☐ **Yes →** Describe what information and why.

Example: it may be necessary to deceive subjects about the purpose of the study (describe why).

Click or tap here to enter text.

8.6.a. Will subjects be informed beforehand that they will be unaware of or misled regarding the nature or purposes of the research? (Note: this is not necessarily required.)

☐ **No**
☐ **Yes**

8.6.b. Will subjects be debriefed later? (Note: this is not necessarily required.)

☐ **No →** Provide your reasoning for not debriefing subjects.

Click or tap here to enter text.

☐ **Yes →** Describe how and when this will occur. Upload any debriefing materials, including talking points or a script, to ***Zipline***.

Click or tap here to enter text.

8.7. [DETERMINATION] **Cognitively impaired adults, and other adults unable to consent**. Will such individuals be included in the research?

Examples: individuals with Traumatic Brain Injury (TBI) or dementia; individuals who are unconscious, or who are significantly intoxicated.

☒ **No →** Go to question **8.8.**
☐ **Yes →** Answer the following question.

8.7.a. Rationale. Provide the rationale for including this population.

Click or tap here to enter text.

8.7.b. Capacity for consent/decision making capacity. Describe the process that will be used to determine whether a cognitively impaired individual is capable of consent decision making with respect to the research protocol and setting.

Click or tap here to enter text.

8.7.b.1. If there will be repeated interactions with the impaired subjects over a time period when cognitive capacity could increase of diminish, also describe how (if at all) decision-making capacity will be re-assessed and (if appropriate) consent obtained during that time.

Click or tap here to enter text.

8.7.c. Permission (surrogate consent). If the research will include adults who cannot consent for themselves, describe the process for obtaining permission ("surrogate-consent") from a legally authorized representative (LAR).

For research conducted in Washington State, review the guidance on Diminished and Fluctuating Consent Capacity and Use of a Legally Authorized Representative (LAR) to learn which individuals meet the state definition of "legally authorized representative".

Click or tap here to enter text.

8.7.d. Assent. Describe whether assent will be required of all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not (and why not). Describe any process that will be used to obtain and document assent from the subjects.

Click or tap here to enter text.

8.7.e. Dissent or resistance. Describe how a subject's objection or resistance to participation (including non-verbal) during the research will be identified, and what will occur in response.

Click or tap here to enter text.

8.8. Research use of human fetal tissue obtained from elective abortion. Federal and UW Policy specify some requirements for the consent process. If you are conducting this type of research, check the boxes to confirm these requirements will be followed.

☐ Informed consent for the donation of fetal tissue for research use will be obtained by someone other than the person who obtained the informed consent for abortion.
☐ Informed consent for the donation of fetal tissue for research use will be obtained after the informed consent for abortion.
☐ Participation in the research will not affect the method of abortion.
☐ No enticements, benefits or financial incentives will be used at any level of the process to incentivize abortion or the donation of human fetal tissue.
☐ The informed consent form for the donation of fetal tissue for use in research will be signed by both the woman and the person who obtains the informed consent.

8.9. Consent-related materials. Upload to ***Zipline*** all consent scripts/talking points, consent forms, debriefing statements, Information Statements, Short Form consent forms, parental permission forms, and any other consent related materials that will be used. Materials that will be used by a specific site should be uploaded to that site's Local Site Documents page.

- *Translations must be submitted and approved before they can be used. However, we strongly encourage you to wait to provide them until the IRB has approved the English versions.*
- *Combination forms: it may be appropriate to combine parental permission with consent if parents are subjects as well as providing permission for the participation of their children. Similarly, a consent form may be appropriately considered an assent form for older children.*
- *For materials that cannot be uploaded: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participants. URLs (website addresses) may also be provided, or written descriptions of websites. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered text; licensed and restricted standardized tests.*

9. PRIVACY AND CONFIDENTIALITY

9.1. [DETERMINATION] **Privacy protections.** Describe the steps that will be taken, if any, to address possible privacy concerns of subjects and potential subjects.

Privacy refers to the sense of being in control of access that others have to ourselves. This can be an issue with respect to recruiting, consenting, sensitivity of the data being collected, and the method of data collection.
Examples:

- *Many subjects will feel a violation of privacy if they receive a letter asking them to participate in a study because they have ____ medical condition, when their name, contact information, and medical condition were drawn from medical records without their consent. Example: the IRB expects that "cold contact" recruitment letters will inform the subject about how their information was obtained.*
- *Recruiting subjects immediately prior to a sensitive or invasive procedure (e.g., in an outpatient surgery waiting room) will feel like an invasion of privacy to some individuals.*
- *Asking subjects about sensitive topics (e.g., details about sexual behavior) may feel like an invasion of privacy to some individuals.*

All online telecommunication platforms will be HIPAA compliant and administered through UW/Seattle Children's Hospital supported accounts. To ensure privacy and confidentiality, we will do and inform subjects of the following:

- All consent/assent forms will be signed electronically via REDCap. If the parent/child requests a paper copy to sign, they will be placed into a manila envelope and kept with the interviewer. The forms will be placed in a locked file cabinet, in a locked room at Dr. Jenness' Lab after the session is complete.
- All data will be identified only with a subject number, including interviews and questionnaires .
- Any data linking identifiers with a subject number will be kept in REDCap in a separate project from study data.
- We will ask youth and parents for their permission to record treatment sessions to ensure therapist fidelity to the treatment protocol. To ensure privacy, we will utilize digital recording devices that will allow us to immediately upload digital recordings to our secure, password protected server. All recordings will be labeled by subject ID and recordings will be erased from

the recorder immediately after uploading to the server. Recordings will be kept on the server for at least 3 years after study end.

- Because all patient participants will receive treatment from SCH, we will need to open a medical record at SCH where we will keep very general notes regarding the youth's participation in treatment (i.e., we would include the teaching content of the session, but not specific quotes from the patient). These notes will be in line with standard clinical notes recorded during BA sessions.
- All teens in the study will use the ActivaTeen app. The control group will log their mood, while the treatment group will have full access. Teens will be informed that the data shared through the platform may be vulnerable to being hacked or leaked. ActivaTeen is hosted on an instance of Microsoft Teams operated by Seattle Children's Hospital. It has been developed to be secure and HIPAA compliant.

9.2. [DETERMINATION] **Identification of individuals in publications and presentations.** Will potentially identifiable information about subjects be used in publications and presentations, or is it possible that individual identities could be inferred from what is planned to be published or presented?

☒ **No**
☐ **Yes →** Will subject consent be obtained for this use?

☐ **Yes**
☐ **No →** Describe the steps that will be taken to protect subjects (or small groups of subjects) from being identifiable.

Click or tap here to enter text.

9.3. [DETERMINATION] **State mandatory reporting**. Each state has reporting laws that require some types of individuals to report some kinds of abuse, and medical conditions that are under public health surveillance. These include:

- Child abuse
- Abuse, abandonment, neglect, or financial exploitation of a vulnerable adult
- Sexual assault
- Serious physical assault
- Medical conditions subject to mandatory reporting (notification) for public health surveillance

Are you or a member of the research team likely to learn of any of the above events or circumstances while conducting the research **AND** feel obligated to report it to state authorities?

☐ **No**
☒ **Yes →** The UW IRB expects subjects to be informed of this possibility in the consent form or during the consent process, unless you provide a rationale for not doing so:

Click or tap here to enter text.

9.4. [DETERMINATION] **Records retention requirements.** Check the box below to indicate assurance that any identifiers (or links between identifiers and data/specimens) and data that are part of the research records will not be destroyed until after the end of the applicable records retention requirements (e.g., Washington State; funding agency or sponsor; Food and Drug Administration). If it is important to say something about destruction of

identifiers (or links to identifiers) in the consent form, state that identifying information will be destroyed at the end of the study or after the records retention period required by state and/or federal law.

Review the "Research Data" and "Personal Identifiers" sections of the following website for UW Records management for the Washington State research records retention schedules that apply in general to the UW (not involving UW Medicine data): ***http://f2.washington.edu/fm/recmgt/gs/research?title=R; https://finance.uw.edu/recmgt/gs/research?title=P.***

Review the "Research Records and Data" information in Section 8 of this document for the retention schedules for UW Medicine Records: ***https://www.uwmedicine.org/recordsmanagementuwm-records-retention-schedule.pdf***

☒ **Confirm**

9.5. **[DETERMINATION]** **Certificates of Confidentiality.** Will a federal Certificate of Confidentiality be obtained for the research data? *NOTE: Answer "No" if the study is funded by NIH or the CDC, because most NIH-funded and CDC-funded studies automatically have a Certificate.*

☒ **No**
☐ **Yes**

9.6. **[DETERMINATION]** **Data and specimen security protections**. Identify the data classifications and the security protections that will be provided for all sites where data will be collected, transmitted, or stored, referring to the guidance on Data and Security Protections for the minimum requirements for each data classification level. ***It is not possible to answer this question without reading this document. Data security protections should not conflict with records retention requirements.***

9.6.a. Choose the level(s) of protections that will be applied to the data and specimens. If more than one level will be used, use the text box to describe which level will apply to which data and which specimens and at which sites.

☐ **Level 1:** Very low risk of harm if disclosed
☐ **Level 2:** Some risk of minor harm if disclosed
☒ **Level 3:** Could cause risk of material harm if disclosed
☐ **Level 4:** Would likely cause serious harm to individuals if disclosed
☐ **Level 5:** Extremely sensitive; could cause severe harm to individuals if disclosed

Click or tap here to enter text.

9.6.b. Use this space to provide additional information, details, or to describe protections that do not fit into one of the levels. **HSD allows researchers to request exceptions to data security requirements, if the exception is necessary and does not significantly increase risk to participants**. If there are any protections within the level listed in 9.6.a which will not be followed, list those here, including identifying the sites where this exception will apply. For example, if you intend to store subject identifiers with study data (not permitted under requirement U9 for Risk Levels 3-5), then indicate this in the box below (e.g., "We will not adhere to requirement U9 for screening data").

Click or tap here to enter text.

10. RISK / BENEFIT ASSESSMENT

10.1. [DETERMINATION] **Anticipated risks.** Describe the anticipated risks of harm, discomforts, and hazards to the subjects and others of the research procedures.

For each harm, discomfort, or hazard:

- Describe the magnitude, probability, duration, and/or reversibility of the harm, discomfort, or hazard, AND
- Describe how the risks will be reduced or managed. Do not describe data security protections here, these are already described in question **9.6**.

- *Consider possible physical, psychological, social, legal, and economic harms, including possible negative effects on financial standing, employability, insurability, educational advancement, or reputation. For example, a breach of confidentiality might have these effects.*
- *Examples of "others": embryo, fetus, or nursing child; family members; a specific group.*
- *Ensure applicable risk information from any Investigator Brochures, Drug Package Inserts, and/or Device Manuals is included in your description.*
- *Do not include the risks of non-research procedures that are already being performed.*
- *If the study design specifies that subjects will be assigned to a specific condition or intervention, then the condition or intervention is a research procedure - even if it is a standard of care.*
- *Examples of mitigation strategies: inclusion/exclusion criteria; taking blood samples to monitor something that indicates drug toxicity.*
- *Review the guidance on Identifying and Describing Reasonably Foreseeable Risks in Research for information about which risks should be described in the consent process/form.*
- *As with all questions on this application, you may refer to uploaded documents.*

Risks to Patient Participants

Interviews and Questionnaires. There is a moderate likelihood that patient participants will experience psychological distress, fatigue, or a time burden during completion of the study interviews. Patient participants will be asked about psychiatric symptoms that may be distressing. Participant psychological distress during completion of the study interview is likely to be mild to moderate in severity. All questions included in study interviews have been used extensively in prior intervention and depression research, and alternative procedures for obtaining information on these constructs, which are of central importance to study hypotheses, are unavailable. Participants will be reminded that all information they provide is voluntary and they are able to skip questions they may feel uncomfortable answering.

Psychological distress will be addressed during the interview using standard interviewing and debriefing strategies. Interviewers will be trained to take a nonjudgmental matter-of-fact stance in their interactions with participants designed to reduce any embarrassment associated with questions or answers. Normalization phrases will be used throughout the interview to reduce discomfort or embarrassment (e.g., "Lots of people feel…How about you? Have you ever felt this way?). Positive filler questions will be interspersed throughout the interview to give participants an opportunity to discuss pleasant topics. Research staff will be trained to identify participant distress through behavioral observation (i.e., tearful, sudden lack of responding to questions) and monitoring answers to specific questions (i.e., reporting suicidal ideation) and will inform Dr. Jenness immediately if this occurs during the in-person visits or follow-up calls. Dr. Jenness will conduct an additional assessment prior to the end of the assessment for all participants reported to have displayed significant distress in response. Dr. Jenness will ask explicit questions about distress caused by the interview and evaluate the extent to which participants continue to experience distress. Any participant continuing to display distress by the assessment's end will be contacted again by a research staff member within 48 hours of the visit to re-assess psychological distress and discuss whether study participation is appropriate and/or a mental health referral is needed at this time.

Patient Clinical Deterioration. Even with evidence-based treatment, continued depression or worsening of depressive symptoms is always a possibility, even for those treated with medication and/or psychotherapy. Patient participants will receive access to BA intervention within 3 weeks of the Baseline visit, and their psychiatric symptoms will be monitored on a weekly basis while enrolled in treatment to monitor for latent (e.g., bipolar disorder) or worsening (e.g., increase in depression symptoms) psychiatric conditions. By study completion, all participants deemed appropriate for inclusion will have received treatment with high-quality BA, one of the evidence-based treatments for adolescent depression. Patient participants will, at a minimum, receive weekly monitoring of psychiatric symptoms and suicidality that are reviewed by their clinician who will meet weekly with MPI Dr. Jenness for supervision, and the study will follow standard safety procedures to ensure that all adolescents are receiving optimal care throughout the study.

The risk of worsening of psychiatric illness will be addressed by 1) by providing psychoeducation about depression and developing a safety and crisis prevention/distress management plan with all study participants who endorse current suicidal ideation/plan throughout the study and 2) monitoring symptoms of depression closely during weekly assessments that occur as part of BA treatment.

If a participant deteriorates clinically defined as an increase in PHQ-9 >4 above their baseline PHQ-9 score (i.e., ~1 standard deviation increase), and/or becomes suicidal, we will review the case in the research team's weekly clinical supervision meetings to outline strategies needed to address participant treatment issues and conduct an additional session that week if indicated. Additionally, if the increase in PHQ-9 persists over three weeks of treatment, the research team will consult with the Independent Study Monitor, Cari McCarty, PhD, (approved by NIMH) in order to determine whether the participant can still be safely managed in the study and what course of action is recommended, which could include continuing in treatment with increased frequency of sessions, change in treatment intensity (e.g., inpatient hospitalization), or referral for a different treatment modality (e.g., family therapy, antidepressant medication). Dr. McCarty is not affiliated with the study and has no conflict of interest with the project or its principal investigators. If Dr. McCarty recommends either increased intensity or a different treatment modality and the family and participant agree, we will provide close case management to find an appropriate provider (i.e., location that is convenient for the family, appropriate specialization, accepts the family's insurance plan, and who does not have an extensive waiting list) across UW, SCH, and other community clinics or private practice practitioners. If feasible, even if treatment is modified, participants will be asked to complete remaining research assessments, which are voluntary and can be declined.

Some youth will encounter crises. Most crisis management involves a combination of case management and creative problem solving, which can be accomplished within the framework of the existing treatment with the youth's treating clinician. If participants miss appointments or self-report by mobile phone, the PI or study staff will contact the participant and family, and if that is unsuccessful, we will have obtained parent and participant permission to activate the emergency contacts obtained at the initial assessment in order to re-engage with the family.

Safety and Reporting.

Suicidality**.** Patients with current suicidal ideation or past suicide attempts are eligible for the study (unless required level of care is more intense than outpatient treatment), as ongoing suicidal ideation and behaviors are frequently seen in depressed youth. Therefore, ongoing suicidal ideation or worsening of suicidal ideation and behavior may occur. Dr. Jenness and research therapists are clinically experienced in working with suicidal individuals and minimizing the risk of suicidality.

Adolescent patient participants and families will be educated about suicidal thinking and behaviors prior to initiating treatment as well as undergo safety and crisis prevention/distress management planning if suicidality is indicated which will be updated throughout treatment as well as throughout study visits. All participants will be given county and teen specific 24-hour crisis line information if they experience any worsening or emergence of suicidal ideation. Information on local and national crisis resources is also included as part of the ActivaTeen dashboard (accessible to ActivaTeen enrolled participants) and embedded within the mood-activity EMA logs (accessible to all participants). As part of the safety and crisis prevention plans, families will be coached to take their teen to their local emergency room if they are concerned for their child's safety or can contact their treating BA clinician for non-emergent concerns.

Adolescents will complete weekly self-report measures of depression as part of their clinical care that includes a question about suicidal ideation. If this question is endorsed by a participant, the therapist will conduct a suicide risk assessment as part of their clinical session with the adolescent. Adolescents who are at risk of suicide attempts may need to be psychiatrically hospitalized. We follow the procedures of the AACAP Practice Parameters on Suicidal Behavior. These parameters indicate that subjects should be referred for hospitalization if their condition is unstable—as manifested by, suicidal ideation with inability to contract for safety, psychosis, current intoxication, mania, rapid cycling, or mixed state. Social factors that may cause the clinician to consider hospitalization include lack of sufficient environmental support and structure to guarantee the child's safety.

Mandated Reporting. There is the possibility that adolescents will disclose information that we may be required to report to the appropriate state or local government agency, such as homicidal intent or current or past maltreatment of youth or elders. In the case of maltreatment, this has potential legal risks to the abuse perpetrator, which could be the parent or legal guardian. If a participant discloses that they are being abused or neglected, we will be legally obligated to report that information to the Department of Children, Youth, & Families (DCYF) in the state of Washington. The provision of such a report may result in DCYF initiating an investigation into potential maltreatment of the patient participant or other abused individual. Legal charges and change of custody may occur in serious instances of abuse or neglect. In such a case, reporting this information to DCYF is most likely in the best interest of the child. We will refrain from informing the parent or guardian that we have made a report when we believe the child's safety may be jeopardized by sharing that information or when we believe the child is in imminent danger. The exact scenarios that may arise are difficult to predict. Oftentimes, informing the parent or guardian is an effective step to protecting the child, as the parent can limit contact with the suspected party. Generally, we will refrain from informing the parent or guardian if any of the following are true:

- We have reasonable suspicion the parent or guardian is directly causing the abuse or neglect or is aware of it and is not acting to stop it
- We have reasonable suspicion the parent or guardian may retaliate against the child if they know we have made a report or will allow someone else to retaliate against the child

Reasonable suspicion will rely on the report of the teen (for example, if the teen reports abuse and states they believe their parent will retaliate if their parent knows abuse has been reported to authorities), and if that is absent, the judgment of the PIs based on qualitative interactions (or reports of interactions from staff) with the teen and parent/guardian.

While there is some degree of risk in the potential reporting of abuse or neglect to DCYF, if an adolescent participant is being maltreated, disclosure to DCYF is required by law, and it is in the best interest of the participant that the legal authorities are made aware of the situation. Drs. Jenness and McCauley are both licensed clinical psychologists and have extensive experience working with children and adolescents who have been maltreated, in research and clinical contexts. Dr. Jenness has previously had to file numerous reports

about potential child abuse or neglect to child protection agencies and is familiar with the procedures involved in doing so. Drs. Jenness and McCauley will ensure that the state of Washington guidelines regarding the reporting of abuse or neglect of a minor are upheld. Any referral to DCYF will be made by a licensed clinical psychologist and supervised by Dr. Jenness who has extensive experience assessing and treating children who have been maltreated in both research and clinical contexts.

Digital Support Tool. The ActivaTeen platform has undergone user testing to identify software bugs and technical challenges experienced by teen patients, and this study will represent the first full evaluation of the platform. As such, the risk profile of the ActivaTeen platform is not fully known. Based on both user testing results and the design and clinical experience of the investigative team we expect the following risks could be possible:

- EMA bothersome/burdensome (moderate probability, low severity, short duration, high reversibility)
    - Note: this also applies to the control group who will do EMA but not the other components of ActivaTeen
- Peer-to-peer bullying, harassment, unwanted contact via the platform (low probability, moderate severity, short duration, moderate reversibility) – similar to in group therapy, moderator role will mitigate this concern
- Emotional distress such as frustration or sadness (moderate probability, low severity, short duration, high reversibility)
    - Associated with completing homework tasks within app
    - If encountering software bugs/glitches that affect usability of the platform
    - A breach in confidentiality of ActivaTeen platform data is unlikely. Data security is described in 9.1.

Risks to Clinician Participants
Interviews and Questionnaires. Clinician participants may experience fatigue or time burden associated with completing study assessments. We expect this to be moderate probability with mild severity, short duration, and high reversibility. Participants will be reminded they can skip questions if needed. Drs. Jenness and McCauley will utilize intervention supervision sessions with clinician participants who are fatigued or time burdened from study assessments to problem-solve.

Using ActivaTeen. As stated above, the risk profile of ActivaTeen platform has not been fully established, but user testing and previous work by the investigative team suggest minimal and mild risks associated with administering the study intervention for clinicians.

- Time burden
- Psychological distress
    - Responding to patient messages and concerns
    - Distress related to encountering bugs or glitches
    - Breach in confidentiality

10.2. [DETERMINATION] **Reproductive risks**. Are there any risks of the study procedures to subjects or partner of subjects related to pregnancy, fertility, lactation or effects on a fetus or neonate?

Examples: direct teratogenic effects; possible germline effects; effects on fertility; effects on a woman's ability to continue a pregnancy; effects on future pregnancies.

☒ **No** → Go to question **10.3**.

☐ **Yes →** Answer the following questions:

10.2.a. Risks. Describe the magnitude, probability, duration and/or reversibility of the risks.

Click or tap here to enter text.

10.2.b. Steps to minimize risk. Describe the specific steps that will be taken to minimize the magnitude, probability or duration of these risks.

Examples: inform the subjects about the risks and how to minimize them; require a pregnancy test before and during the study; require subjects to use contraception; advise subjects about banking of sperm and ova.

If the use of contraception will be required, describe the allowable methods and the time period when contraception must be used.

Click or tap here to enter text.

10.2.c. Pregnancy. Describe what will be done if a subject (or a subject's partner) becomes pregnant.

For example; will subjects be required to immediately notify study staff, so that the study procedures can be discontinued or modified, or for a discussion of risks, and/or referrals or counseling?

Click or tap here to enter text.

10.3. [DETERMINATION] **MRI risk management**. A rare but serious adverse reaction called nephrogenic systemic fibrosis (NSF) has been observed in individuals with kidney disease who received gadolinium-based contrast agents (GBCAs) for the scans. Also, a few healthy individuals have a severe allergic reaction to GBCAs.

10.3.a. Use of gadolinium. Will any of the MRI scans involve the use of a gadolinium-based contrast agent (GBCA)?

☒ **No**

☐ **Yes →** Which agents will be used? *Check all that apply.*

Check all that apply	Brand Name	Generic Name	Chemical Structure
☐	Dotarem	Gadoterate meglumine	Macrocylic
☐	Eovist / Primovist	Gadoxetate disodium	Linear
☐	Gadavist	Gadobutro	Macrocyclic
☐	Magnevist	Gadpentetate dimeglumine	Linear
☐	MultiHance	Gadobenate dimeglumine	Linear
☐	Omniscan	Gadodiamide	Linear
☐	OptiMARK	Gadoversetamide	Linear
☐	ProHance	Gadoteridol	Macrocyclic
☐	Other, provide name:		
	Click or tap here to enter text.		

10.3.a.1. The FDA has concluded that gadolinium is retained in the body and brain for a significantly longer time than previously recognized, especially for linear GBCAs. The health-related risks of this longer retention are not yet clearly established. However, the UW IRB expects

researchers to provide a compelling justification for using a linear GBCA instead of a macrocyclic GBCA, to manage the risks associated with GBCAs.

Describe why it is important to use a GBCA with the MRI scan(s). Describe the dose that will be used and (if it is more than the standard clinical dose recommended by the manufacturer) why it is necessary to use a higher dose. If a linear GBCA will be used, explain why a macrocyclic GBCA cannot be used.

Click or tap here to enter text.

10.3.a.2. Information for subjects. Confirm by checking this box that subjects will be provided with the FDA-approved Patient Medication Guide for the GBCA being used in the research or that the same information will be inserted into the consent form.

☐ **Confirmed**

10.3.b. Who will (1) calculate the dose of GBCA; (2) prepare it for injection; (3) insert and remove the IV catheter; (4) administer the GBCA; and (5) monitor for any adverse effects of the GCBA? Also, what are the qualifications and training of these individual(s)?

Click or tap here to enter text.

10.3.c. Describe how the renal function of subjects will be assessed prior to MRI scans and how that information will be used to exclude subjects at risk for NSF.

Click or tap here to enter text.

10.3.d. Describe the protocol for handling a severe allergic reaction to the GBCA or any other medical event/emergency during the MRI scan, including who will be responsible for which actions.

Click or tap here to enter text.

10.4. [DETERMINATION] **Unforeseeable risks**. Are there any research procedures that may have risks that are currently unforeseeable?

Example: using a drug that hasn't been used before in this subject population.

☒ **No**
☐ **Yes →** Identify the procedures.

Click or tap here to enter text.

10.5. Subjects who will be under regional or general anesthesia. Will any research procedures occur while patients are under general or regional anesthesia, or during the 3 hours preceding general or regional anesthesia (supplied for non-research reasons)?

☒ **No**
☐ **Yes →** Check all the boxes that apply.
☐ Administration of any drug for research purposes

☐ Inserting an intra-venous (central or peripheral) or intra-arterial line for research purposes
☐ Obtaining samples of blood, urine, bone marrow or cerebrospinal fluid for research purposes
☐ Obtaining a research sample from tissue or organs that would not otherwise be removed during surgery.
☐ Administration of a radio-isotope for research purposes**
☐ Implantation of an experimental device
☐ Other manipulations or procedures performed solely for research purposes (e.g., experimental liver dialysis, experimental brain stimulation)

If any of the boxes are checked:

Provide the name and institutional affiliation of a physician anesthesiologist who is a member of the research team or who will serve as a safety consultant about the interactions between the research procedures and the general or regional anesthesia of the subject-patients. If the procedures will be performed at a UW Medicine facility or affiliate, the anesthesiologist must be a UW faculty member, and the Vice Chair of Clinical Research in the UW Department of Anesthesiology and Pain Medicine must be consulted in advance for feasibility, safety and billing.

Click or tap here to enter text.

*** If the box about radio-isotopes is checked, the study team is responsible for informing in advance all appropriate clinical personnel (e.g., nurses, technicians, anesthesiologists, surgeons) about the administration and use of the radio-isotope, to ensure that any personal safety issues (e.g., pregnancy) can be appropriately addressed. This is a condition of IRB approval.*

10.6. Data and Safety Monitoring. A Data and Safety Monitoring Plan (DSMP) is required for clinical trials (as defined by NIH). If required for this research, or if there is a DSMP for the research regardless of whether it is required, upload the DSMP to ***Zipline***. If it is embedded in another document being uploading (for example, a Study Protocol) use the text box below to name the document that has the DSMP. Alternatively, provide a description of the DSMP in the text box below. For guidance on developing a DSMP, review the ITHS webpage on Data and Safety Monitoring Plans.

We have uploaded our DSMP ("R34_Jenness_Data and Safety Monitoring Plan_ISMUpdate-11-2023.pdf").

10.7. Un-blinding. If this is a double-blinded or single-blinded study in which the participant and/or relevant study team members do not know the group to which the participant is assigned, describe the circumstances under which un-blinding would be necessary, and to whom the un-blinded information would be provided.

N/A

10.8. Withdrawal of participants. If applicable, describe the anticipated circumstances under which participants will be withdrawn from the research without their consent. Also, describe any procedures for orderly withdrawal of a participant, regardless of the reason, including whether it will involve partial withdrawal from procedures and any intervention but continued data collection or long-term follow-up.

Participants are free to withdraw from the study at any time. If a participant chooses to withdraw from BA treatment or research assessments, they will be asked to return for a final assessment and exit interview. If clinically appropriate, participants will be given recommendations for treatment, and will be asked if they may be contacted in the future to determine how the adolescent is doing. Patient participants and their families are told that access to future services in our program is not affected by their participation status. Similarly, clinician

participants are told that their withdrawal will not impact relationships with study team members, UW, or SCH or their employment with SCH. Patient participants who miss 3 consecutive treatment sessions, develop exclusionary criteria (e.g., psychosis, mania, substance abuse, pregnancy) or require a higher level of care will continue to be followed for clinical assessment pursuant to an intent to treat approach. If the participant withdraws or is removed due to needing different or a higher level of care, they will be offered close case management assistance to match them with a provider that is convenient for the family, with appropriate specialization, who accepts the family's insurance plan, and who does not have an extensive waiting list.

10.9. [DETERMINATION] **Anticipated direct benefits to participants**. If there are any direct research-related benefits that some or all individual participants are likely to experience from taking part in the research, describe them below:

Do not include benefits to society or others, and do not include subject payment (if any). Examples: medical benefits such as laboratory tests (if subjects receive the results); psychological resources made available to participants; training or education that is provided.

Generally we do not expect direct benefits to patient participants. We expect participants in the study will, on average, benefit from receiving high-quality, supervised BA care for depression; however this care will be available to similar patients who are not in the study. All patient participants will receive an intensive clinical evaluation that may provide more detail than what would be ordinarily available in the community.

If participants are still depressed after treatment, they will be offered close case management assistance to match them with a provider that is convenient for the family, with appropriate specialization, who accepts the family's insurance plan, and who does not have an extensive waiting list.

We do not expect direct benefit to the clinician participants.

10.10. [DETERMINATION] **Return of individual research results.**

In this section, provide your plans for the return of individual results. An "individual research result" is any information collected, generated or discovered in the course of a research study that is linked to the identity of a research participant. These may be results from screening procedures, results that are actively sought for purposes of the study, results that are discovered unintentionally, or after analysis of the collected data and/or results has been completed.

Review the guidance on Return of Individual Results for information about results that should and should not be returned, validity of results, the Clinical Laboratory Improvement Amendment (CLIA), consent requirements and communicating results.

10.10.a. Is it anticipated that the research will produce any individual research results that are clinically actionable?

"Clinically actionable" means that there are established therapeutic or preventive interventions or other available actions that have the potential to change the clinical course of the disease/condition or lead to an improved health outcome.

In general, every effort should be made to offer results that are clinically actionable, valid and pose life-threatening or severe health consequences if not treated or addressed quickly. Other clinically actionable results should be offered if this can be accomplished without compromising the research.

☒ **No**

☐ **Yes →** Answer the following questions (**10.10.a.1** through **10.10.a.3.**)

10.10.a.1. Describe the clinically actionable results that are anticipated and explain which results, if any, could be urgent (i.e., because they pose life-threatening or severe health consequences if not treated or addressed quickly).

Examples of urgent results include very high calcium levels, highly elevated liver function test results, positive results for reportable STDs.

10.10.a.2. Explain which of these results will be offered to subjects.

Click or tap here to enter text.

10.10.a.3. Explain which results will <u>not</u> be offered to subjects and provide the rationale for not offering these results.

Reasons not to offer the results might include:

- *There are serious questions regarding validity or reliability*
- *Returning the results has the potential to cause bias*
- *There are insufficient resources to communicate the results effectively and appropriately*
- *Knowledge of the result could cause psychosocial harm to subjects*

Click or tap here to enter text.

10.10.b. Is there a plan for offering subjects any results that are <u>not</u> clinically actionable?

Examples: non-actionable genetic results, clinical tests in the normal range, experimental and/or uncertain results.

☒ **No**

☐ **Yes →** Explain which results will be offered to subjects and provide the rationale for offering these results.

10.10.c. Describe the validity and reliability of any results that will be offered to subjects.

The IRB will consider evidence of validity such as studies demonstrating diagnostic, prognostic, or predictive value, use of confirmatory testing, and quality management systems.

N/A

10.10.d. Describe the process for communicating results to subjects and facilitating understanding of the results. In the description, include who will approach the participant with regard to the offer of results, who will communicate the result (if different), the circumstances, timing, and communication methods that will be used.

N/A

10.10.e. Describe any plans to share results with family members (e.g., in the event a subject becomes incapacitated or deceased).

N/A

10.10.f. Check the box to indicate that any plans for return of individual research results have been described in the consent document. If there are no plans to provide results to participants, this should be stated in the consent form.

Review the guidance on Return of Individual Results for information about consent requirements.

☐ **Confirmed**

10.11. Commercial products or patents. Is it possible that a commercial product or patent could result from this study?

☐ **No**

☒ **Yes →** Describe whether subjects might receive any remuneration/compensation and, if yes, how the amount will be determined.

Participants will be reimbursed for time spent completing the study. There is no current plan for any participant renumeration/compensation in the event of a commercial product or patent resulting from the research.

11. ECONOMIC BURDEN TO PARTICIPANTS

11.1. Financial responsibility for research-related injuries. Answer this question only if the lead researcher is not a UW student, staff member, or faculty member whose primary paid appointment is at the UW.

For each institution involved in conducting the research: Describe who will be financially responsible for research-related injuries experienced by subjects, and any limitations. Describe the process (if any) by which participants may obtain treatment/compensation.

Click or tap here to enter text.

11.2. Costs to subjects. Will there be any research-related costs for which subjects and/or their health insurance may be responsible (examples might include: CT scan required for research eligibility screening; co-pays; surgical costs when a subject is randomized to a specific procedure; cost of a device; travel and parking expenses that will not be reimbursed)?

☒ **No**

☐ **Yes →** Provide a description of the costs that may be incurred.

Click or tap here to enter text.

12. RESOURCES

12.1. [DETERMINATION] **Faculty Advisor**. (For researchers who are students or residents.) Provide the following information about the faculty advisor.

- Advisor's name

- Your relationship with your advisor (for example: graduate advisor; course instructor)
- Your plans for communication/consultation with your advisor about progress, problems, and changes.

Click or tap here to enter text.

12.2. UW Principal Investigator Qualifications. Upload a current or recent Curriculum Vitae (CV), Biosketch (as provided to federal funding agencies), or similar document to the Local Site Documents page in ***Zipline***. The purpose of this is to address the PI's qualifications to conduct the proposed research (education, experience, training, certifications, etc.).

For help with creating a CV, review http://adai.uw.edu/grants/nsf_biosketch_template.pdf and https://intranet.medicine.uw.edu/academic-hr/curriculum-vitae-cv

☒ **The CV will be uploaded.**

12.3. UW Study team qualifications. Describe the qualifications and/or training for each UW study team member to fulfill their role on the study and perform study procedures. (You may be asked about non-UW study team members during the review; they should not be described here.) You may list these individuals by name, however if you list an individual by name, you will need to modify this application if that individual is replaced. Alternatively, you can describe study roles and the qualifications and training the PI or study leadership will require for any individual who might fill that role. The IRB will use this information to assess whether risks to subjects are minimized because study activities are being conducted by properly qualified and trained individuals.

Describe: The role (or name of person), the study activities they will perform, and the qualifications or training that are relevant to performing those study activities.

Examples:
Research Study Coordinator: Obtain consent, administer surveys, blood draw. Will have previous experience coordinating clinical research and be a certified phlebotomist in WA.

Undergraduate Research Assistant: Obtain consent, perform all study procedures. Will have had coursework in research methods, complete an orientation to human subjects protections given by the department, and will receive training from the PI or the graduate student project lead on obtaining consent and debriefing subjects.

Acupuncturist: Perform acupuncture procedures and administer surveys. Must be licensed with WA State DoH and complete training in administering research surveys given by the project director, an experienced survey researcher.

Co-Investigator: Supervise MRI and CT scan procedures and data interpretation, obtain consent. MD, specialty in interventional radiology and body imaging. 5-years clinical research experience.

Key Personnel

Jessica Jenness, PhD, PD/PI: Dr. Jenness serves as the PI and will take the primary lead on all aspects of the research including data collection and management, supervising study staff and the postdoctoral fellow, and coordinating with Dr. McCauley at our partner site, Seattle Children's Hospital (SCH). She will also oversee research therapist participant recruitment, training and management, and adolescent patient participant recruitment and retention. As a licensed clinical psychologist, Dr. Jenness will be responsible for supervising assessment and reporting related to the safety of patient participants (e.g., reports of suicidality or maltreatment). Dr. Jenness will also assist in data analysis, manuscript publication, and preparing future grants that stem from this pilot work.

Julie Kientz, PhD, PD/PI: will serve as MPI and will serve in a supervisory role to monitor all aspects of the research including having ultimate responsibility for data collection and management and coordinating with data analysts for analyses. Dr. Kientz will assist in data analysis, manuscript publication, and preparing future grants that result from this pilot work.

Elin A. Björling, PhD, Co-Investigator: will be responsible for direct implementation of study goals including data collection and management, supervising research staff, coordinating with the SCH IT Team regarding implementation of design specifications, and assisting with data analysis and manuscript publications.

Sean Munson, PhD, Co-Investigator: will be responsible for providing weekly consultation on the design and build of the ARC platform, with greater time spent on usability testing and a reduced role in consultation across once the platform has been implemented in the RCT.

Other Personnel

Data Scientists (MS or PhD) will have expertise in quantitative analyses, especially comparative effectiveness trials, psychometric evaluation, structural equation modeling, and multivariate modeling. They will conduct quantitative analyses and prepare dissemination materials.

Research Coordinator (BA/BS or higher): will be trained by the MPIs and Co-Is and responsible for participant recruitment, telephone screening procedures, informed consent process, conducting study visits, data management, moderating the ARC platform, and creating and managing our participant database.

***Research Assistants (BA/BS or higher)*:** will be trained by the MPIs, Co-Is, and/or project coordinator and responsible for assisting the research team with participant recruitment, telephone screening procedures, informed consent process, conducting study visits, data management, moderating the ARC platform, and data entry.

12.4. Study team training and communication. Describe how it will be ensured that each study team member is adequately trained and informed about the research procedures and requirements (including any changes) as well as their research-related duties and functions.

☐ There is no study team

All team members that will interact with study participants will complete a Collaborative Institutional Training Initiative (CITI) training in Good Clinical Practice. Those who access study databases will be complete courses in HIPAA compliance. Our team will develop SOPs (standard operating procedures) based on the approved study protocol. New team members will utilize the SOPs to learn study procedures.

13. OTHER APPROVALS, PERMISSIONS, AND REGULATORY ISSUES

13.1. [DETERMINATION] **Approvals and permissions**. Identify any other approvals or permissions that will be obtained. For example: from a school, external site/organization, funding agency, employee union, UW Medicine clinical unit.

Do not attach the approvals and permissions unless requested by the IRB.

N/A

13.2. Financial Conflict of Interest. Does any UW member of the team have ownership or other Significant Financial Interest (SFI) with this research as defined by UW policy GIM 10?

☒ **No**

☐ **Yes →** Has the Office of Research made a determination regarding this SFI as it pertains to the proposed research?

☐ **No →** Contact the Office of Research (206.616.0804, research@uw.edu) for guidance on how to obtain the determination.

☐ **Yes →** Upload the Conflict Management Plan for every UW team member who has a FCOI with respect to the research, to ***Zipline***. If it is not yet available, use the text box to describe whether the Significant Financial Interest has been disclosed already to the UW Office of Research and include the FIDS Disclosure ID if available.

Click or tap here to enter text.