HRP-591 - Protocol for
Human Subject Research

Protocol Title:

Provide the full title of the study as listed in item 1 on the "Basic Information" page in CATS IRB (http://irb.psu.edu).

Aevidum: Preliminary Evidence to Showcase a Student-Led Mental Health Program

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Version Date:

Provide a version date for this document. This date must be updated each time this document is submitted to the IRB office with revisions. DO NOT revise the version date in the footer of this document.

5.6.2022

Clinicaltrials.gov Registration #:

Provide the registration number for this study, if applicable. See "HRP-103- Investigator Manual", under "ClinicalTrials.gov" for more information.

NCT05018689

Important Instructions for Using This Protocol Template:

This template is provided to help investigators prepare a protocol that includes the necessary information needed by the IRB to determine whether a study meets all applicable criteria for approval.

1. **GENERAL INSTRUCTIONS:**
   - Prior to completing this protocol, ensure that you are using the most recent version by verifying the protocol template version date in the footer of this document with the current version provided in the CATS IRB Library.
   - Do not change the protocol template version date located in the footer of this document.
   - Some of the items may not be applicable to all types of research. If an item is not applicable, please indicate as such or skip question(s) if indicated in any of the instructional text.
   - **GRAY INSTRUCTIONAL BOXES:** Type your protocol responses below the gray instructional boxes of guidance language. If the section or item is not applicable, indicate not applicable.
     - **Do NOT delete the instructional boxes from the final version of the protocol.**
   - Add the completed protocol template to your study in CATS IRB (http://irb.psu.edu) on the "Basic Information" page.

2. **CATS IRB LIBRARY:**
   - Documents referenced in this protocol template (e.g. SOP's, Worksheets, Checklists, and Templates) can be accessed by clicking the Library link in CATS IRB (http://irb.psu.edu).

3. **PROTOCOL REVISIONS:**
   - When making revisions to this protocol as requested by the IRB, please follow the instructions outlined in the guides available in the Help Center in CATS IRB (http://irb.psu.edu) for using track changes.

- Update the Version Date on page 1 each time this document is submitted to the IRB office with revisions.

If you need help…

All locations:
Human Research Protection Program
Office for Research Protections
The 330 Building, Suite 205
University Park, PA 16802-7014
Phone: 814-865-1775
Fax: 814-863-8699
Email: irb-orp@psu.edu
https://www.research.psu.edu/irb

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1.0 Objectives

1.1 Study Objectives

Describe the purpose, specific aims or objectives. State the hypotheses to be tested.

The study purpose is to evaluate the effectiveness of the Aevidum curriculum (plus/minus club) to improve adolescent mental health knowledge, help-seeking intentions, and school culture. We will partner with 10 high schools for this study. Prior to the start of the 2021-2022 academic year, schools will be recruited and randomly assigned to implement the Aevidum curriculum (n=6) or the curriculum and club (n=6).

Curriculum: Aevidum has developed a 5-lesson 3-hour mental health curriculum that can be broken up and integrated into existing school health curricula. The study team in partnership with the Executive Director of Aevidum will collaborate with schools to implement the curriculum prior to February 2022 to their ninth grade students.

Curriculum + club. Schools assigned to the curriculum plus club will also start an Aevidum club at their school. Club basic processes and ideas for events are housed on the Aevidum website. Schools will select faculty and student leaders who will participate in a kickoff web-based training at the start of the academic year. The training is led by current Aevidum student leaders at schools with successful clubs. This is a standard orientation process that Aevidum has run for many years in-person, but has been adapted to a virtual format with the COVID-19 pandemic.

Aim 1: Assess Aevidum's curriculum in improving students' mental health knowledge and help-seeking intentions. Hypothesis: Exposure to Aevidum's five module mental health curriculum will result in significant improvements in knowledge and help seeking intentions between pre- and post-survey measures using the published University of Michigan Depression Center (UMDC) Peer-to-Peer Depression Awareness Assessment among the 6 schools assigned to curriculum only.

Aim 2: Assess the combination of Aevidum's curriculum AND club activities to improve student perceptions of school culture. Hypothesis: Exposure to both curriculum and club activities will have the added benefit of improving school environment/stigma and program visibility in addition to knowledge and help-seeking on the Peer-to-Peer Depression Awareness Assessment among the 6 schools assigned to curriculum + club.

Aim 3: Analyze Aevidum's impact on school mental health referrals and school climate indicators through faculty interviews. Hypothesis: School staff interviews will allow for a richer understanding of the challenges and successes with Aevidum curriculum and club activities that cannot be captured through student surveys, but will be crucial in planning for larger scale program evaluation.

Students from all 10 participating schools in grades 9-12th will be asked to complete a pre-post survey using the University of Michigan Depression Center (UMDC) Peer-to-Peer Depression Awareness Assessment to address aims 1 and 2. Separate interviews will be conducted via ZOOM with up to 5school staff member from each school (n=50) to supplement the UMDC survey results for more in-depth information on school climate and student mental health referrals.

1.2 Primary Study Endpoints

State the primary endpoints to be measured in the study.

Clinical trials typically have a primary objective or endpoint. Additional objectives and endpoints are secondary. The endpoints (or outcomes), determined for each study subject, are the quantitative measurements required by the objectives. Measuring the selected endpoints is the goal of a trial (examples: response rate and survival).

The primary endpoints are significant improvements in knowledge and help-seeking behaviors between pre- and post-survey measures using the UMDC Peer-to-Peer Depression Awareness Assessment.

1.3 Secondary Study Endpoints

State the secondary endpoints to be measured in the study.

The secondary endpoints will be 1) improvements in school climate and 2) a greater number of mental health referrals based on qualitative (interviews) with from school staff.

2.0 Background

2.1 Scientific Background and Gaps

Describe the scientific background and gaps in current knowledge.

For clinical research studies being conducted at Penn State Health/Penn State College of Medicine, and for other non-PSH locations as applicable, describe the treatment/procedure that is considered standard of care (i.e., indicate how patients would be treated in non-investigational setting); and if applicable, indicate if the study procedure is available to patient without taking part in the study.

It is important for schools to seek out opportunities to expand student's knowledge and awareness of mental health and suicide prevention, since suicide is the second leading cause of death for 10-24 year olds.[2] Schools can be an ideal setting to offer suicide prevention and mental health programming supplemental to state-mandated requirements (e.g., Act 71 mandated curriculum).[3] Prior research revealed that students are not more likely to commit suicide despite increased discussion on the topic, which actually has the potential to decrease distress in students who have suicidal ideation.[4] Most adolescents prefer to talk to peers about suicide and mental well-being, and student-led programming can help to open that conversation.[4] Though parents and other adults who work with youth encourage those at risk to report to trusted adults, a minority actually do. [5] Reasons for this include lack of knowledge, low self-efficacy, the belief that discussing suicide is taboo, and keeping a peer's wish for secrecy.[6] Programming – like Aevidum – can aid in increasing knowledge, awareness and help-seeking behaviors within schools.[7]

Since 1989, PA has conducted the biennial PA Youth Survey (PAYS) for youth in 6th, 8th, 10th and 12th grades to address relevant adolescent risk and protective factors. The 2017 PAYS survey found that 16.0% of PA students had seriously considered attempting suicide. [8] Additionally, female youth are over two times more likely to exhibit suicidal ideation and more likely to make suicidal attempts than male youth, but male youth are more likely to complete.[9-11] To address these concerns, schools are placing greater value on mental-health and suicide prevention programming.[12] There is an opportunity for schools to positive influence mental health behaviors, since students spend about half of their waking hours in a school setting. [13] In addition to PA Act 71 mandated curriculum, opportunities like Aevidum can aid schools by empowering students to support one another and expand their knowledge about mental health, stigma and help-seeking behaviors.[14]

2.2 Previous Data

Describe any relevant preliminary data.

During the 2015-2016 academic year, a group of researchers from the University of Michigan conducted a school-based study. They enrolled 10 schools in the school-based Peer-2-Peer Depression Awareness Program that aimed to decrease mental illness and promote well-being. Students were trained as peer leaders to design and implement a depression awareness campaign. That group of researchers found increased mental health awareness and literacy among students, and noted that the program may have improved detection of depression and decreased depressive episodes. We are planning to use the same pre-posttest questionnaire in this study to track changes in student's knowledge and help seeking intentions related to mental health following exposure to the Aevidum curriculum (plus/minus club), which is in widespread use in many Pennsylvania schools[1].

2.3 Study Rationale

Provide the scientific rationale for the research.

The proposed intervention targets high schools to improve adolescent knowledge and help seeking regarding mental health. Aevidum was established in 2009 as a student-led initiative to raise awareness and reduce the stigma surrounding mental illness. Their mental health curriculum and club activities are currently used in over 300 schools in PA and surrounding states. In comparison to current interventions, Aevidum is unique in that it provides students the opportunity to build a strong support system among peers. Aevidum's curriculum and club activities provide an opportunity for schools and students to engage with mental health and suicide prevention materials with a student-directed method. Youth voice is a powerful tool that schools and communities can utilize to make mental health and suicide prevention programming more impactful. Allowing youth the chance to lead and let their voices be heard can create greater buy-in for activities.[15] Attitudes, policies and structures change when students are engaged as partners in schools, which can lead to positive change in school culture.[16]

At present, there is not a strong evidence-base for the efficacy of student-led initiatives that aid in reaching mandated Act 71 curriculum standards for mental health and suicide prevention.[1,3] Aevidum lacks an evidence-base for its curriculum and club programming, which is freely available to schools. To continue offering free resources, while also maintaining and updating these resources to ensure they are innovative and best reflect student needs, Aevidum needs to establish an evidence-base to support future funding. This project plans to evaluate the effectiveness of these efforts in supporting adolescent mental health. Results will be used to inform school-based mental health programming and to establish an evidence-base for the Aevidum program, furthering mental health awareness and education, while also reducing mental health stigma.

3.0 Inclusion and Exclusion Criteria

Create a numbered list below in sections 3.1 and 3.2 of criteria subjects must meet to be eligible for study enrollment (e.g., age, gender, diagnosis, etc.).

Vulnerable Populations:

Indicate specifically whether you will include any of the following vulnerable populations in this research. You MAY NOT include members of these populations as subjects in your research unless you indicate this in your inclusion criteria because specific regulations apply to studies that involve vulnerable populations.

The checklists referenced below outline the determinations to be made by the IRB when reviewing research involving these populations. Review the checklists as these will help to inform your responses throughout the remainder of the protocol.

- **Children –**Review "HRP-416- Checklist - Children"

- **Pregnant Women** – Review "HRP-412- Checklist - Pregnant Women"
- **Cognitively Impaired Adults-** Review "HRP-417- Checklist - Cognitively Impaired Adults"
- **Prisoners-** Review "HRP-415- Checklist - Prisoners"
- **Neonates of uncertain viability or non-viable neonates-** Review "HRP-413- Checklist - Non-Viable Neonates" or "HRP-414- Checklist - Neonates of Uncertain Viability"

[Do not type here]

3.1 Inclusion Criteria

Create a numbered list of the inclusion criteria that define who will be included in your final study sample (e.g., age, gender, condition, etc.)

1. Students (grades 9-12) and staff from participating schools. For the first time during the 2021-2022 school year, all participating schools will be implementing the Aevidum curriculum, but only half of the participating schools will implement club activities in addition to the curriculum (n=5 schools will implement just the curriculum, and n=5 schools will implement the curriculum AND club activities.

School staff who participated in the Aevidum Training will be asked to complete a brief survey using our "Educator Training Feedback Survey" (included in supporting documents).

3.2 Exclusion Criteria

Create a numbered list of the exclusion criteria that define who will be excluded in your study.

Student Pre- and Post- Survey

1. Students not enrolled in one of the participating high schools (n=10)
2. Students not in grades 9-12
3. Students with disabilities that are deemed unable to participate by the school district
4. Non-English speaking students

School Staff Semi-structured Interviews

1. Individuals who are non-English speaking
2. Individuals who are <18 years old

3.3 Early Withdrawal of Subjects

3.3.1 Criteria for removal from study

Insert subject withdrawal criteria (e.g., safety reasons, failure of subject to adhere to protocol requirements, subject consent withdrawal, disease progression, etc.).

The intervention (Aevidum curriculum plus/minus club) will happen regardless of the research. These materials are already freely available and being utilized in schools across the Commonwealth. The research pieces are the student pre-post questionnaires and staff interviews to assess knowledge change, help-seeking and school culture/climate. student participants whose parents did not opt-them out may voluntarily withdraw from the study at any time by declining to have their child complete the pre and post survey.

School staff that participate in interviews at the end of the school year may also decline to answer any demographic questions or interview questions that they do not feel comfortable answering.

3.3.2 Follow-up for withdrawn subjects

Describe when and how to withdraw subjects from the study; the type and timing of the data to be collected for withdrawal of subjects; whether and how subjects are to be replaced; the follow-up for subjects withdrawn from investigational treatment.

NA

4.0 Recruitment Methods

- Upload recruitment materials for your study in CATS IRB (http://irb.psu.edu). **DO NOT** include the actual recruitment wording in this protocol.
- StudyFinder: If StudyFinder (http://studyfinder.psu.edu) is to be used for recruitment purposes, separate recruitment documents do not need to be uploaded in CATS IRB. The necessary information will be captured from the StudyFinder page in your CATS IRB study.
- Any eligibility screening questions (verbal/phone scripts, email, etc.) used when contacting potential participants must be uploaded to your study in CATS IRB (http://irb.psu.edu).

4.1 Identification of subjects

Describe the source of subjects and the methods that will be used to identify potential subjects (e.g., organizational listservs, established recruitment databases, subject pools, medical or school records, interactions during a clinic visit, etc.). If not recruiting subjects directly (e.g., database query for eligible records or samples) state what will be queried, how and by whom.

StudyFinder:

- If you intend to use StudyFinder (http://studyfinder.psu.edu) for recruitment purposes, include this method in this section.
- Information provided in this protocol needs to be consistent with information provided on the StudyFinder page in your CATS IRB study.

For Penn State Health submissions using Enterprise Information Management (EIM) for recruitment, and for non-Hershey locations as applicable, attach your EIM Design Specification form on in CATS IRB (http://irb.psu.edu). See "HRP-103- Investigator Manual, What is appropriate for study recruitment?" for additional information. **DO NOT** include the actual recruitment material or wording in this protocol.

In partnership with Ms. Francesca Pileggi, the Executive Director of Aevidum, our PRO Wellness team will recruit 10 public high schools, with an interest in implementing Aevidum. Schools will be randomly assigned to either the Aevidum curriculum (n=5) *or* Aevidum curriculum plus club (n=5). We will randomize schools to 1 of the 2 arms using covariate-constrained randomization to ensure balance across study arms with respect to the following variables: location (urban vs rural), % economically disadvantaged, student demographics (e.g. race/ethnicity). These data are readily available from https://www.paschoolperformance.org/. Schools will be enrolled in advance of the 2021-2022 academic year, and we will specifically target schools representing both rural and urban locales, a range of socioeconomic status (SES), and diverse student populations. Educators who participated in the Aevidum Curriculum Training will be asked to complete a brief survey on the training.

4.2 Recruitment process

Describe how potential subjects first learn about this research opportunity or indicate as not applicable if subjects will not be prospectively recruited to participant in the research. Subject recruitment can involve various methods (e.g., approaching potential subjects in person, contacting potential subjects via email, letters, telephone, ResearchMatch, or advertising to a general public via flyers, websites,

StudyFinder, newspaper, television, and radio etc.). **DO NOT** include the actual recruitment material or wording in this protocol.

4.2.1 How potential subjects will be recruited.

Schools will be recruited via email communication (See attached School Recruitment Email and Aevidum One Pager) in partnership with the Executive Director of Aevidum, Francesca Pileggi. We anticipate beginning recruitment efforts by reaching out to schools who have already expressed interest in Aevidum and/or schools that PRO Wellness and Aevidum already have a connection with. Schools currently utilize the Aevidum curriculum and run club activities independent of the proposed research work (student pre-post surveys and staff interviews). Educators who completed the Aevidum Training will be contacted to complete the "Educator Training Feedback Survey".

Student Pre- and Post- Survey
Given the low-risk of the pre- and post-survey, all students who are enrolled at participating schools will be provided a link to REDCAp to complete the pre-survey. To link pre- and post- surveys, students will provide their email address at the time of the pre-survey. Post-surveys will be sent via REDCap directly to that email provided during the pre-survey. Once post-surveys are completed, email addresses will be unlinked from survey responses.

4.2.2 Where potential subjects will be recruited.

Student Pre- and Post- Survey
All students in grades 9-12 will be invited to participate in the survey (with the exception of ineligible students) by the school.

School Staff Semi-structured Interviews
Faculty advisors and staff members will be identified with the assistance of the original school contact.

4.2.3 When potential subjects will be recruited.

Schools will be recruited ahead of the commencement of the 2021/2022 school year.

4.2.4 Describe the eligibility screening process and indicate whether the screening process will occur before or after obtaining informed consent. Screening begins when the investigator obtains information about or from a prospective participant in order to determine their eligibility. In some studies, these procedures may not take place unless HIPAA Authorization is obtained OR a waiver of HIPAA Authorization when applicable for the screening procedures is approved by the IRB.

[*For FDA regulated studies, consent for any screening activities would need to be obtained prior to screening unless specifically waived by the IRB.]*

Schools will provide the REDCap link to all eligible students during the school day to complete the pre-survey. Students will be asked to provide their email address at this time so they can complete the post-survey following curriculum completion. Once students complete the post-survey, email addresses will be unlinked from survey responses.

5.0 Consent Process and Documentation

Refer to the following materials:

- The "HRP-090- SOP - Informed Consent Process for Research" outlines the process for obtaining informed consent.

- The "HRP-091– SOP - Written Documentation of Consent" describes how the consent process will be documented.
- The "HRP-314- Worksheet - Criteria for Approval" section 7 lists the required elements of consent.
- The "HRP-312- Worksheet - Exemption Determination" includes information on requirements for the consent process for exempt research. In addition, the CATS IRB Library contains consent guidance and templates for exempt research.
- The CATS IRB library contains various consent templates for expedited or full review research that are designed to include the required information.
- Add the consent document(s) to your study in CATS IRB (http://irb.psu.edu). Links to Penn State's consent templates are available in the same location where they are uploaded. **DO NOT** include the actual consent wording in this protocol.

[Do not type here]

5.1 Consent Process:

Check all applicable boxes below:

☐ **Informed consent will be sought and documented with a written consent form *[Complete Sections 5.2 and 5.6]***

☒ **Implied or verbal consent will be obtained – subjects will not sign a consent form (waiver of written documentation of consent) *[Complete Sections 5.2, 5.3 and 5.6]***

☐ **Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception). *[Complete section 5.2, 5.4 and 5.6]***

☐ **Informed consent will not be obtained – request to completely waive the informed consent requirement. *[Complete Section 5.5]***

The following checkbox is for all locations EXCEPT Penn State Health and College of Medicine:

☐ **Exempt Research at all Locations Except Penn State Health and the College of Medicine: If you believe that the research activities outlined meet one or more of the criteria outlined in "HRP-312- Worksheet- Exemption Determination." Please verify by checking this box that if conducting an exempt research study, the consent process will disclose the following (all of which are included in "HRP-590- Consent Guidance for Exempt Research"):**

Penn State affiliation; name and contact information for the researcher and advisor (if the researcher is a student); the activities involve research; the procedures to be performed; participation is voluntary; that there are adequate provisions to maintain the privacy interests of subjects and the confidentiality of the data; and subjects may choose not to answer specific questions.

If the research includes the use of student educational records include the following language in this section (otherwise delete): The parent or eligible student will provide a signed and dated written consent that discloses: the records that may be disclosed; the purpose of the disclosure; the party or class of parties to whom the disclosure may be made; if a parent or adult student requests, the school will provide him or her with a copy of the records disclosed; if the parent of a student who is not an adult so requests, the school will provide the student with a copy of the records disclosed.

Note: If this box has been checked, skip the remainder of section 5 and proceed to section 6 of this protocol. If the investigator's assessment is inaccurate, an IRB Analyst will request revision to the

protocol and that an informed consent form be submitted for review and approval. Except for exemptions where Limited IRB Review (see "HRP-312- Worksheet- Exemption Determination") is required or where otherwise requested by the IRB, informed consent forms for research activities determined to be exempt without Limited IRB Review are generally not required to be submitted for review and approval by the University Park IRB.

5.2 Obtaining Informed Consent

5.2.1 Timing and Location of Consent

Describe where and when the consent process will take place.

Student Pre- and Post- Survey
All eligible students will be provided a link to participate in the REDCap survey. This link will be provided directly by the school using a method that works best for them. The study team will suggest that schools either 1) Send an email to the student's school email addresses with the link (see attached "Student Pre Survey Email Invitation") or 2) Instruct their teachers to write the link on their whiteboards for students to enter directly into their school computer's web browser. Subjects who follow the link will review the study information and provide their email address if they wish to participate in the post-survey. The consent process will take place prior to completing the demographics and survey, as participants will be provided the Summary Explanation of Research and be notified that their completion of the demographic questionnaire implies their voluntary consent to participate in the research.

School Staff Semi-structured Interviews
Faculty advisors and identified staff members will receive an email invitation (See attached "School Staff Email Interview Invitation") with a link to REDCap to participate in the interviews. The consent process will take place prior to completing the demographic survey, as participants will be provided the Summary Explanation of Research and be notified that their completion of the demographic questionnaire implies their voluntary consent to participate in the research. At the beginning of each Zoom interview, participants will be asked if they have questions regarding the research. Semi-structured interviews will be conducted with a minimum of two school staff members (maximum of 5). Interviews will be conducted individually or with up to two staff members at the same time.

5.2.2 Coercion or Undue Influence during Consent

Describe the steps that will be taken to minimize the possibility of coercion or undue influence in the consent process.

Participants will be reminded (written) that their participation is voluntary and they can decline to answer any questions they do not want to answer.

5.3 Waiver of Written Documentation of Consent

Review "HRP – 411 – Checklist – Waiver of Written Documentation of Consent."

5.3.1 Indicate which of the following conditions applies to this research:

☒ The research presents no more that minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

OR

☐ The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject

will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern. (*Note: This condition is not applicable for FDA-regulated research. If this category is chosen, include copies of a consent form and /or parental permission form for participants who want written documentation linking them to the research.)*

OR

☐ If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained. (*Note: This condition is not applicable for FDA-regulated research.)*

Describe the alternative mechanism for documenting that informed consent was obtained:

[Type protocol text here]

5.3.2 Indicate what materials, if any, will be used to inform potential subjects about the research (e.g., a letter accompanying a questionnaire, verbal script, implied consent form, or summary explanation of the research)

This research presents no more than minimal risk of harm to subjects. Therefore, we will use implied consent. All participants will receive a Summary Explanation of Research prior to participating in the pre- and post- surveys as well as the interviews.

5.4 Informed consent will be sought but some of the elements of informed consent will be omitted or altered (e.g., deception).

Review "HRP-410-Checklist -Waiver or Alteration of Consent Process" to ensure that you have provided sufficient information.

5.4.1 Indicate the elements of informed consent to be omitted or altered

NA

5.4.2 Indicate why the research could not practicably be carried out without the omission or alteration of consent elements

NA

5.4.3 Describe why the research involves no more than minimal risk to subjects.

NA

5.4.4 Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.

NA

5.4.5 If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not be practicably be carried out without using such information or biospecimens in an identifiable format.

NA

5.4.6 Debriefing

Explain whether and how subjects will be debriefed after participation in the study. If subjects will not be debriefed, provide a justification for not doing so. Add any debriefing materials to the study in CATS IRB.

NA

5.5 Informed consent will not be obtained – request to completely waive the informed consent requirement

Review "HRP-410-Checklist -Waiver or Alteration of Consent Process" to ensure that you have provided sufficient information.

5.5.1 Indicate why the research could not practicably be carried out without the waiver of consent

NA

5.5.2 Describe why the research involves no more than minimal risk to subjects.

NA

5.5.3 Describe why the alteration/omission will not adversely affect the rights and welfare of subjects.

NA

5.5.4 If the research involves using identifiable private information or identifiable biospecimens, describe why the research could not be practicably be carried out without using such information or biospecimens in an identifiable format.

NA

5.5.5 Additional pertinent information after participation

Explain if subjects will be provided with additional pertinent information after participation. If not applicable, indicate "not applicable."

NA

5.6 Consent – Other Considerations

5.6.1 Non-English-Speaking Subjects

Indicate what language(s) other than English are understood by prospective subjects or representatives.

If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.

Indicate whether the consent process will be documented in writing with the long form of the consent documentation or with the short form of the consent documentation. Review "HRP-091 –SOP- Written Documentation of Consent" and "HRP-103 -Investigator Manual" to ensure that you have provided sufficient information.

NA

5.6.2 Cognitively Impaired Adults

Refer "HRP-417 -CHECKLIST- Cognitively Impaired Adults" for information about research involving cognitively impaired adults as subjects.

5.6.2.1 Capability of Providing Consent

Describe the process to determine whether an individual is capable of consent.

NA

5.6.2.2 Adults Unable to Consent

Describe whether and how informed consent will be obtained from the legally authorized representative. Describe who will be allowed to provide informed consent. Describe the process used to determine these individual's authority to consent to research.

For research conducted in the state of Pennsylvania, review "HRP-013 -SOP- Legally Authorized Representatives, Children and Guardians" to be aware of which individuals in the state of Pennsylvania meet the definition of "legally authorized representative."

For research conducted outside of the state of Pennsylvania, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "children" in "HRP-013 - SOP- Legally Authorized Representatives, Children, and Guardians."

NA

5.6.2.3 Assent of Adults Unable to Consent

Describe the process for assent of the subjects. Indicate 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.

If assent will not be obtained from some or all subjects, provide an explanation of why not.

Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.

NA

5.6.3 Subjects who are not yet adults (infants, children, teenagers)

5.6.3.1 Parental Permission

Describe whether and how parental permission will be obtained. If permission will be obtained from individuals other than parents, describe who will be allowed to provide permission. Describe the process used to determine these individual's authority to consent to each child's general medical care.

For research conducted in the state of Pennsylvania, review "HRP-013-SOP- Legally Authorized Representatives, Children and Guardians" to be aware of which individuals in the state of Pennsylvania meet the definition of "children."

For research conducted outside of the state of Pennsylvania, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along with the definition of "children" in "HRP-013-SOP- Legally Authorized Representatives, Children, and Guardians."

We are requesting a waiver of informed consent since this research presents no more than minimal risk of harm to subjects (i.e. students) and regardless of study activities schools could introduce Aevidum program activities. Instead, parents will be provided an opt-out letter at the beginning of the school year, detailing the Aevidum curriculum (for 9th grade students) and pre/post surveys (for all 9th-12th grade students). Parents will have the opportunity to opt their child out from completing both the pre and post surveys.

5.6.3.2 Assent of subjects who are not yet adults

Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. When assent of children is obtained describe whether and how it will be documented.

This research presents no more than minimal risk of harm to subjects. Therefore, we will use implied assent/consent. All students will receive the Summary

Explanation of Research prior to participating in the pre- and post- surveys. The University of Michigan Depression Center (UMDC) Peer-to-Peer Depression Awareness Assessment is included in the attachment. Schools will be provided a copy of the assessment during recruitment. The UDMC tool focuses on depression knowledge and help-seeking intentions based on information learned in the Aevidum curriculum as well as culture/climate changes and visibility noted with club activities, but does not ask students to share any personal information.

6.0 HIPAA Research Authorization and/or Waiver or Alteration of Authorization

This section is about the access, use or disclosure of Protected Health Information (PHI). PHI is individually identifiable health information (i.e., health information containing one or more 18 identifiers) that is transmitted or maintained in any form or medium by a Covered Entity or its Business Associate. A Covered Entity is a health plan, a health care clearinghouse or health care provider who transmits health information in electronic form. See "HRP-103 -Investigator Manual" for a list of the 18 identifiers.

If requesting a waiver/alteration of HIPAA authorization, complete sections 6.2 and 6.3 in addition to section 6.1. The Privacy Rule permits waivers (or alterations) of authorization if the research meets certain conditions. Include only information that will be accessed with the waiver/alteration.

[Do not type here]

6.1 Authorization and/or Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

Check all that apply:

☒ **Not applicable, no identifiable protected health information (PHI) is accessed, used or disclosed in this study.** *[Mark all parts of sections 6.2 and 6.3 as not applicable]*

☐ **Authorization will be obtained and documented as part of the consent process.** *[If this is the only box checked, mark sections 6.2 and 6.3 as not applicable]*

☐ **Partial waiver is requested for recruitment purposes only (Check this box if patients' medical records will be accessed to determine eligibility before consent/authorization has been obtained).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Full waiver is requested for entire research study (e.g., medical record review studies).** *[Complete all parts of sections 6.2 and 6.3]*

☐ **Alteration is requested to waive requirement for written documentation of authorization (verbal authorization will be obtained).** *[Complete all parts of sections 6.2 and 6.3]*

6.2 Waiver or Alteration of Authorization for the Uses and Disclosures of PHI

6.2.1 Access, use or disclosure of PHI representing no more than a minimal risk to the privacy of the individual

6.2.1.1 Plan to protect PHI from improper use or disclosure

Include the following statement as written – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a waiver of authorization. **If the section is <u>not</u> applicable, <u>remove</u> the statement and <u>indicate as not applicable</u>.**

Not applicable.

6.2.1.2 Plan to destroy identifiers or a justification for retaining identifiers

Describe the plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research. Include when and how identifiers will be destroyed. If identifiers will be retained, provide the legal, health or research justification for retaining the identifiers.

NA

6.2.2 Explanation for why the research could not practicably be conducted without access to and use of PHI

Provide an explanation for why the research could not practicably be conducted without access to and use of PHI.

NA

6.2.3 Explanation for why the research could not practicably be conducted without the waiver or alteration of authorization

Provide an explanation for why the research could not practicably be conducted without the waiver or alternation of authorization.

NA

6.3 Waiver or alteration of authorization statements of agreement

By submitting this study for review with a waiver of authorization, you agree to the following statement – DO NOT ALTER OR DELETE unless this section is not applicable because the research does not involve a waiver or alteration of authorization. **If the section is <u>not</u> applicable, <u>remove</u> the statement and <u>indicate as not applicable.</u>**

Not applicable.

7.0 Study Design and Procedures

Data collection materials that will be seen or used by subjects in your study must be uploaded to CATS IRB (http://irb.psu.edu). **DO NOT** include any actual data collection materials in this protocol (e.g., actual survey or interview questions)

[Do not type here]

7.1 Study Design

Describe and explain the study design.

This study design is a cluster randomized trial. Schools will be randomized to implement either the Aevidum curriculum alone (n=5) or Avedium curriculum plus club activities (n=5). Students in grades 9-12 at each school whose parents did not opt them out will be asked to complete pre- and post-surveys. School staff who participated in the Aevidum curriculum training will be asked to complete the "Educator Training Feedback Survey".

7.2 Study Procedures

Provide a step by step description of all research procedures being conducted (broken down by visit, if applicable) including such information as below (where and when applicable); describe the following:

- HOW: (e.g., data collection via interviews, focus groups, forms such as surveys and questionnaires, medical/school records, audio/video/digital recordings, photographs, EKG procedures, MRI, mobile devices such as electronic tablets/cell phones, observations, collection of specimens, experimental drug/device testing, manipulation of behavior/use of deception, computer games, etc.)
- WHERE: (e.g., classrooms, labs, internet/online, places of business, medical settings, public spaces, etc.)

Partnering with 10 high schools to evaluate the effectiveness of the Aevidum curriculum (plus/minus club) to improve adolescent mental health knowledge, help-seeking intentions, and school culture. Prior to the start of the 2021-2022 academic year, schools will be recruited and randomly assigned to implement the Aevidum curriculum (n=5) *or* the curriculum and club (n=5). Regardless of the research, the schools have the autonomy to introduce the intervention(s) (Aevidum curriculum plus/minus club) on their own. The Aevidum curriculum will be delivered to only 9th grade students in their health classes.

Student Pre- and Post- Survey

To measure aims 1 and 2, pre- and post-surveys (see attached, using the University of Michigan Depression Center (UMDC) Peer-to-Peer Depression Awareness Assessment) will be completed by students in grades 9th – 12th at all 10 participating schools. All eligible students whose parents did not opt them out from pre-post survey completion will be provided a link to participate in the REDCap survey. This link will be provided directly by the school. Subjects will be provided a link to review the study information and provide their email address if they wish to participate in the post-survey. The consent process will take place prior to completing the demographic and survey, as participants will be provided the Summary Explanation of Research and be notified that their completion of the demographic questionnaire implies their voluntary consent to participate in the research.

School Staff Semi-structured Interviews

Zoom interviews (maximum of 50) will be conducted with two school staff members from each school to measure Aevidum's impact on school mental health referrals and school climate indicators. School staff members will be identified by the school contact and invited to participate. Participants will be instructed to turn off their camera and the interview will be recorded (only voices) via PSH HIPAA Compliant Zoom. Interviews will begin with introductions and information on the project. Participants will have the opportunity to ask questions about the study. See School Staff Demographics and Interview Guide to view open-ended questions to address study aims.

Analysis of Zoom Interview Data:

Rev.com, a professional service will be used by the research team to transcribe the audio recordings. Transcripts will be uploaded into a qualitative software system (Nvivo 12 plus). 20% of the transcripts will be coded independently using a codebook developed by the research team by two team members until an acceptable inter-rater reliability score is achieved. Once the coding process is complete, the team will meet to identify themes.

Additionally, we will recruit school staff members who participated in the Aevidum curriculum training to complete the "Educator Training Feedback Survey". We are not collecting any PHI, nor will names of the school staff participants be disclosed in the use of manuscripts/ written publications.

7.2.1 Visit 1 or Day 1 or Pre-test, etc.

Provide a description of what procedures will be performed on visit 1 or day 1 or pre-test in order of how these will be done. If your study only involves one session or visit, use this section only and indicate 7.2.2 as not applicable.

Student Pre- and Post- Survey
The pre-survey will be completed by students in grades 9^{th} – 12^{th} at all 10 participating schools at the beginning of the school year (September-October 2021). All eligible students will be provided a link to participate in the REDCap survey. This link will be provided directly by the school. Subjects will be provided a link to review the study information and provide their email address if they wish to participate in the post-survey. The consent process will take place prior to completing the demographic and survey, as participants will be provided the Summary Explanation of Research and be notified that their completion of the demographic questionnaire implies their voluntary consent to participate in the research. Demographics will include sex, age (in years), race/ethnicity and grade. Once students complete the post-survey, their email addresses will be unlinked from their survey responses.

School Staff Semi-structured Interviews
Semi-structured interviews will also be conducted with up to 5 school staff members at the end of the school year. The main point of contact at the school will identify interested subjects who will be provided a link to review the Summary Explanation of Research, determine eligibility and indicate assent by completion of the demographic survey. Eligible school staff will be contacted by the study team to schedule their interview based on their availability. Up to two participants may be interviewed at the same time. Prior to the Zoom interviews participants will be reminded that their completion in the interview implies their voluntary consent to participate in the research.

7.2.2 Visit 2 or Day 2 or Post-test, etc. (If applicable)

Provide a description of what procedures will be performed on visit 2 or day 2 or post-test in order of how these will be done. If your study involves more than two sessions or visits replicate this section for each additional session or visit (e.g., 7.2.3, 7.2.4, etc.).

At the end of the school year (April-May 2022), students who participated in the pre-survey will receive the post-survey via REDCap invitation to the email provided during the pre-survey.

7.3 Duration of Participation

Describe how long subjects will be involved in this research study. Include the number of sessions and the duration of each session - consider the total number of minutes, hours, days, months, years, etc.

Schools will be enrolled in the study for the 2021/2022 school year. The duration of the pre- and post-surveys is approximately 10-15 minutes. The duration of the semi-structured interviews will be approximately 15-20 minutes if being interviewed individually or 25-35 minutes in length if two individuals are being interviewed at the same time.

The school staff members who complete the "Educator Training Feedback Survey" is limited to the 5 minutes it takes for them to complete it.

8.0 Number of Subjects and Statistical Plan

8.1 Number of Subjects

Indicate the maximum number of subjects to be accrued/enrolled. Distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures if applicable (i.e., numbers of subjects excluding screen failures.)

A total of 10 high schools will be enrolled in the study, representing nearly 1,000 students.

School Staff Semi-structured Interviews
Up to 50 (35 faculty/staff members from each of the 10 high schools).

8.2 Sample size determination

If applicable, provide a justification of the sample size outlined in section 8.1 to include reflections on, or calculations of, the power of the study.

Student Pre- and Post- Survey
The sample size was chosen primarily based on feasibility of enrolling schools, implementing the Aevidum curriculum at all schools, and setting up school-specific processes for collecting data at each school. A total of 10 schools was deemed feasible.

When determining the number of schools to enroll, the study team took the following into consideration: 1) Retention and changes in school administration and their priorities, which impacted the ability of schools to participate as planned in the context of PRO Wellness's SHIELD study. 2) the number of schools which could implement Aevidum 3) Results of a previous school-based study conducted by Parikh et al. (2018) that used the UMDC survey instrument. The Parikh study included ten high schools and found a number of significant differences over time. We anticipate the same potential for this work that will include more schools and students. We have added two additional schools in this proposal and will plan to keep a "waitlist" of schools interested in participation, as schools will continue to utilize the curriculum and club independently of the proposed study. This will allow us to replace a school that ultimately decides not to participate.

School Staff Semi-structured Interviews
N/A

8.3 Statistical methods

Describe the statistical methods (or non-statistical methods of analysis) that will be employed.

Student Pre- and Post- Survey
In primary statistical analysis, schools implementing only the curriculum (Aim 1) and schools implementing the curriculum and club activities (Aim 2) will be analyzed separately, using the same methods. Descriptive statistics will be calculated and survey items will be presented graphically over time. Mixed effects linear and logistic regression models appropriate for longitudinal (repeated measures) data will be used to analyze all survey items collected at each time point. The models will contain a fixed effect for time (pre vs. post) and random effects for school and student. The parameter for time is the primary parameter of interest in the model, as it indicates the change over time with intervention implementation. Parameter estimates and standard errors from the models will be reported along with corresponding 95% confidence intervals and p-values.

In secondary statistical analysis, we will compare the curriculum-only schools to the curriculum plus club activities schools directly.

Specifically: 1) Compare students from schools in Aim 1 (curriculum only) to those in Aim 2 (curriculum plus club) regarding changes in knowledge, help-seeking behavior, school environment/stigma and program visibility.
2) Compare the impact on 9th graders in curriculum schools versus 9th graders in curriculum plus club schools.

The same mixed effects regression models will be used for each survey item, except that the model will also include fixed effects for group (curriculum-only vs. curriculum plus club activities) and a group by time interaction effect. A positive interaction effect indicates that schools which implemented curriculum and club activities had larger changes over time than curriculum alone.

School Staff Semi-structured Interviews
Interviews will be analyzed to determine themes and Aevidum curriculum/club impact (Aim 3). Guided by Dr. Stuckey's qualitative analysis expertise, thematic categories will be developed by reading and coding themes from the interview transcripts. Themes will be compared and contrasted to illustrate impacts of Aevidum on the selected high schools.

9.0 Data and Safety Monitoring Plan

This section is required when research involves more than Minimal Risk to subjects as defined in "HRP-001 SOP- Definitions."

Minimal Risk is defined as the probability and magnitude of harm or discomfort anticipated in the research that are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For research involving prisoners, Minimal Risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

Please complete the sections below if the research involves more than minimal risk to subjects, otherwise indicate each section as not applicable.

[Do not type here]

9.1 Periodic evaluation of data

Describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.

Not applicable: This study does not involve more than minimal risk to subjects, and the magnitude of harm/discomfort is not greater than that ordinarily encountered in daily life.

9.2 Data that are reviewed

Describe the data that are reviewed, including safety data, untoward events, and efficacy data.

NA

9.3 Method of collection of safety information

Describe the method by which the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls and with subjects).

NA

9.4 Frequency of data collection

Describe the frequency of data collection, including when safety data collection starts.

NA

9.5 Individuals reviewing the data

Identify the individuals who will review the data. The plan might include establishing a data and safety monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.

NA

9.6 Frequency of review of cumulative data

Describe the frequency or periodicity of review of cumulative data.

NA

9.7 Statistical tests

Describe the statistical tests for analyzing the safety data to determine whether harms are occurring.

NA

9.8 Suspension of research

Describe any conditions that trigger an immediate suspension of research.

NA

10.0 Risks

List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the IRB's consideration, a description of the probability, magnitude, duration and reversibility of the risks. Consider all types of risk including physical, psychological, social, legal, and economic risks. Note: Loss of confidentiality is a potential risk when conducting human subject research.

- If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.
- If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.
- If applicable, describe risks to others who are not subjects.

Risks involved in participating in this study are low. The questions asked in the surveys and interview are not sensitive in nature. Loss of confidentiality is a potential risk.

11.0 Potential Benefits to Subjects and Others

11.1 Potential Benefits to Subjects

Describe the potential benefits that individual subjects may experience from taking part in the research. If there is no direct benefit to subjects, indicate as such. Compensation is not considered a benefit. Compensation should be addressed in section 13.0.

Potential benefits to individual 9th grade students who receive the Aevidum curriculum include increased knowledge about mental health and help-seeking behaviors.

11.2 Potential Benefits to Others

Include benefits to society or others.

There is a potential benefit for the school to improve referrals for student mental health as well as the climate within the school building. Additionally, a potential benefit exists for the Aevidum initiative to establish an evidence-base.

12.0 Sharing Results with Subjects

Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how information will be shared.

Study results will not be shared with individual students who complete the pre-post surveys (University of Michigan Depression Center (UMDC) Peer-to-Peer Depression Awareness Assessment) or with faculty/school staff members who participate in the semi-structured Zoom interviews.

13.0 Subject Payment and/or Travel Reimbursements

Describe the amount, type (cash, check, gift card, other) and timing of any subject payment or travel reimbursement. If there is **no** subject payment or travel reimbursement, indicate as not applicable.

Extra or Course Credit: Describe the amount of credit **and** the available alternatives. Alternatives should be equal in time and effort to the amount of course or extra credit offered. It is not acceptable to indicate that the amount of credit is to be determined or at the discretion of the instructor of the course.

Approved Subject Pool: Indicate which approved subject pool will be used; include in response below that course credit will be given and alternatives will be offered as per the approved subject pool procedures.

Schools

The 5 of the 10 schools that are randomly assigned to implement 2 Aevidum club activities will receive a $1,000 stipend to support club activities during the 21-22 academic school year. The remaining 5 schools who are randomly assigned to implement just the Aevidum curriculum will receive a $1,000 stipend for club activities at the end of the 2021-2022 school year after completion of the research.

An incentive will be offered to schools who have post-survey completion rates of 60%. Schools who hit this goal will be sent an additional $100 stipend to put towards their Aevidum club.

Student Pre- and Post- Survey

All students who complete the pre and post surveys (University of Michigan Depression Center (UMDC) Peer-to-Peer Depression Awareness Assessment) will have the chance to be entered into a drawing to receive an Amazon electronic gift card. Among these, eight students (four after pre-test and four after post-test) from each of the 10 participating high schools (total 96 students) will be chosen as winners. After completion of the pre-survey, four students will be randomly chosen to win a $20 gift card from each school. After completion of the post-survey, four students will be randomly chosen to win a $30 gift card from each school. Participants will receive the gift card via email within 2 weeks of closing either the pre or post survey respectively.

School Staff Semi-structured Interviews
Faculty advisors/school staff who participate in the semi-structured interviews will be compensated with a $25 electronic gift card for their time. Participants will receive the electronic gift card via email within 2 weeks of participating in the interview.

School Staff Educator Training Feedback Survey
School staff who participated in the educator training at the beginning of the school year will have their provided email address entered into a raffle for the chance to win a $10 Amazon electronic gift card. 10 winners will be selected and they will receive the gift card via email within 3 weeks of completing the survey.

14.0 Economic Burden to Subjects

14.1 Costs

Describe any costs that subjects may be responsible for because of participation in the research.

There are no financial costs associated with participating in this research.

14.2 Compensation for research-related injury

If the research involves more than Minimal Risk to subjects, describe the available compensation in the event of research related injury.

If there is no sponsor agreement that addresses compensation for medical care for research subjects with a research-related injury, include the following text as written - DO NOT ALTER OR DELETE:
It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Costs for the treatment of research-related injuries will be charged to subjects or their insurance carriers.

For sponsored research studies with a research agreement with the sponsor that addresses compensation for medical care for research-related injuries, include the following text as written - DO NOT ALTER OR DELETE:
It is the policy of the institution to provide neither financial compensation nor free medical treatment for research-related injury. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. Such charges may be paid by the study sponsor as outlined in the research agreement and explained in the consent form.

N/A

15.0 Resources Available

15.1 Facilities and locations

Identify and describe the facilities, sites and locations where recruitment and study procedures will be performed.

If research will be conducted outside the United States, describe site-specific regulations or customs affecting the research, and describe the process for obtaining local ethical review. Also, describe the principal investigator's experience conducting research at these locations and familiarity with local culture.

Pre- and post- surveys will be completed during the school day. Zoom interviews with school staff will take place at a pre-determined time with the interviewer and study participant and will occur using the PSH HIPAA Compliant Zoom platforms (audio recorded only, no video).

15.2 Feasibility of recruiting the required number of subjects

Indicate the number of potential subjects to which the study team has access. Indicate the percentage of those potential subjects needed for recruitment.

The study team does not anticipate difficulty recruiting all 10 high schools for the 2021-2022 academic year. Several schools have already expressed interest in implementing Aevidum. Additional schools will be recruited through current and past relationships with schools that both the study team and Aevidum's Executive Director has with schools. Both have extensive experience in school recruitment.

15.3 PI Time devoted to conducting the research

Describe how the PI will ensure that a sufficient amount of time will be devoted to conducting and completing the research. Please consider outside responsibilities as well as other on-going research for which the PI is responsible.

Dr. Sekhar will monitor the progress of participant recruitment and hold bi-weekly meetings with research staff.

15.4 Availability of medical or psychological resources

Describe the availability of medical or psychological resources that subjects might need as a result of their participation in the study, if applicable.

Given that the study procedures are minimal risk, it is not anticipated that medical or psychological resources will be needed. However, schools in PA are required to have a protocol and follow a plan to address any student who displays signs/symptoms of depression and expresses suicidal ideation.

15.5 Process for informing Study Team

Describe the training plans to ensure members of the research team are informed about the protocol and their duties, if applicable.

The investigators and study team members have completed the required Collaborative IRB Training Initiative (CITI) in the protection of human research subjects. The study team will maintain confidentiality, and ensure data is secured and handled properly.

16.0 Other Approvals

16.1 Other Approvals from External Entities

Describe any approvals that will be obtained prior to commencing the research (e.g., from engaged cooperating institutions IRBs who are also reviewing the research and other required review committees, community leaders, schools, research locations where research is to be conducted by the Penn State investigator, funding agencies, etc.).

Approval will be obtained from all participating schools. A district staff member will be requested to sign HRP-504, which will be kept on file by the study team.

16.2 Internal PSU Committee Approvals

Check all that apply:

☐ Anatomic Pathology – **Penn State** Health **only** – Research involves the collection of tissues or use of pathologic specimens. Upload a copy of "HRP-902 - Human Tissue For Research Form" in CATS IRB.

☐ Animal Care and Use – **All campuses** – Human research involves animals and humans or the use of human tissues in animals

☐ Biosafety – **All campuses** – Research involves biohazardous materials (human biological specimens in a PSU research lab, biological toxins, carcinogens, infectious agents, recombinant viruses or DNA or gene therapy).

☐ Clinical Laboratories – **Penn State Health only** – Collection, processing and/or storage of extra tubes of body fluid specimens for research purposes by the Clinical Laboratories; and/or use of body fluids that had been collected for clinical purposes but are no longer needed for clinical use. Upload a copy of "HRP-901 - Human Body Fluids for Research Form" in CATS IRB.

☐ Clinical Research Center (CRC) Advisory Committee – **All campuses** – Research involves the use of CRC services in any way.

☐ Conflict of Interest Review – **All campuses** – Research has one or more of study team members indicated as having a financial interest.

☐ Radiation Safety – **Penn State Health only** – Research involves research-related radiation procedures. All research involving radiation procedures (standard of care and/or research-related) must upload a copy of "HRP-903 - Radiation Review Form" in CATS IRB.

☐ IND/IDE Audit – **All campuses** – Research in which the PSU researcher holds the IND or IDE or intends to hold the IND or IDE.

☐ Scientific Review – **Penn State Health only** – All investigator-written research studies requiring review by the convened IRB must provide documentation of scientific review with the IRB submission. The scientific review requirement may be fulfilled by one of the following: (1) external peer-review process; (2) department/institute scientific review committee; or (3) scientific review by the Clinical Research Center Advisory committee. NOTE: Review by the Penn State Health Cancer Institute (PSCI) Protocol Review Committee or the PSCI Disease Team is required if the study

involves cancer prevention studies or cancer patients, records and/or tissues. For more information about this requirement see the IRB website.

☐ St. Joseph Administrative Review – **Penn State Health only** – Penn State Health Research that will be conducted at St. Joseph Medical Center or St. Joseph Community Medical Groups.

17.0 Multi-Site Study

If this is a multi-site study (i.e., a study in which two or more institutions coordinate, with each institution completing all research activities outlined in a specific protocol) and the Penn State PI is the lead investigator, describe the processes to ensure communication among sites in the sections below.

[Do not type here]

17.1 Other sites

List the name and location of all other participating sites. Provide the name, qualifications and contact information for the principal investigator at each site and indicate which IRB will be reviewing the study at each site.

NA

17.2 Communication Plans

Describe the plan for regular communication between the overall study director and the other sites to ensure that all sites have the most current version of the protocol, consent document, etc. Describe the process to ensure all modifications have been communicated to sites. Describe the process to ensure that all required approvals have been obtained at each site (including approval by the site's IRB of record). Describe the process for communication of problems with the research, interim results and closure of the study.

NA

17.3 Data Submission and Security Plan

Describe the process and schedule for data submission and provide the data security plan for data collected from other sites. Describe the process to ensure all engaged participating sites will safeguard data as required by local information security policies.

NA

17.4 Subject Enrollment

Describe the procedures for coordination of subject enrollment and randomization for the overall project.

NA

17.5 Reporting of Adverse Events and New Information

Describe how adverse events and other information will be reported from the clinical sites to the overall study director. Provide the timeframe for this reporting.

NA

17.6 Audit and Monitoring Plans

Describe the process to ensure all local site investigators conduct the study appropriately. Describe any on-site auditing and monitoring plans for the study.

NA

18.0 Adverse Event Reporting

18.1 Reporting Adverse Reactions and Unanticipated Problems to the Responsible IRB

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

In accordance with applicable policies of The Pennsylvania State University Institutional Review Board (IRB), the investigator will report, to the IRB, any observed or reported harm (adverse event) experienced by a subject or other individual, which in the opinion of the investigator is determined to be (1) unexpected; and (2) probably related to the research procedures. Harms (adverse events) will be submitted to the IRB in accordance with the IRB policies and procedures.

19.0 Study Monitoring, Auditing and Inspecting

19.1 Auditing and Inspecting

By submitting this study for review, you agree to the following statement – DO NOT ALTER OR DELETE:

The investigator will permit study-related monitoring, audits, and inspections by the Penn State quality assurance program office(s), IRB, the sponsor, and government regulatory bodies, of all study related documents (e.g., source documents, regulatory documents, data collection instruments, study data etc.). The investigator will ensure the capability for inspections of applicable study-related facilities (e.g., pharmacy, diagnostic laboratory, etc.).

20.0 Future Undetermined Research: Data and Specimen Banking

If this study is collecting **identifiable** data and/or specimens that will be banked for future **undetermined research**, please describe this process in the sections below. This information should not conflict with information provided in section 22 regarding whether or not data and/or specimens will be associated with identifiers (directly or indirectly). If **NOT applicable**, indicate as such below in all sections.

[Do not type here]

20.1 Data and/or specimens being stored

Identify what data and/or specimens will be stored and the data associated with each specimen.

NA

20.2 Location of storage

Identify the location where the data and/or specimens will be stored.

NA

20.3 Duration of storage

Identify how long the data and/or specimens will be stored. If data and/or specimens will be stored indefinitely, indicate as such.

NA

20.4 Access to data and/or specimens

Identify who will have access to the data and/or specimens.

NA

20.5 Procedures to release data or specimens

Describe the procedures to release the data and/or specimens, including: the process to request a release, approvals required for release, who can obtain data and/or specimens, and the data to be provided with the specimens.

NA

20.6 Process for returning results

Describe the process for returning results about the use of the data and/or specimens.

NA

21.0 References

List relevant references in the literature which highlight methods, controversies, and study outcomes.

1) Parikh S, Taubman D, Antoun C, et al. The Michigan Peer-to-Peer Depression Awareness Program : School-Based Prevention to Address Depression Among Teens. *Psychiatr Serv*. 2018;69(4):487-491. doi:10.1176/appi.ps.201700101
2) Salerno JP. Effectiveness of universal school-based mental health awareness programs among youth in the US: a systematic review. *J Sch Health*. 2016;86(12):922-931. doi:10.1111/josh.12461.
3) Pennsylvania Department of Education. *Act 71: Section 1526 of School Code, 24 PS § 15-1526*. United States of America; 2014.
4) Dunham K. Young Adults' Support Strategies when Peers Disclose Suicidal Intent. *Suicide Life-Threatening Behav*. 2004;34(1):56-65. doi:10.1521/suli.34.1.56.27773
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22.0 Confidentiality, Privacy and Data Management

IMPORTANT: The following section is required for all locations EXCEPT Penn State Health and the College of Medicine. Penn State Health and College of Medicine should skip this section and complete "HRP-598 Research Data Plan Review Form." In order to avoid redundancy, for this section state "See the Research Data Plan Review Form" if you are conducting Penn State Health research. Delete all other sub-sections of section 22.

For research being conducted at Penn State Health or by Penn State Health researchers only: The research data security and integrity plan is submitted using "HRP-598 – Research Data Plan Review Form."

Refer to Penn State College of Medicine IRB's "Standard Operating Procedure Addendum: Security and Integrity of Human Research Data," which is available on the IRB's website. In order to avoid redundancy, for this section state "See the Research Data Plan Review Form" if you are conducting Penn State Health research. Delete all sub-sections of section 22.

For all other research: complete the following section. Please refer to PSU Policy AD95 for information regarding information classification and security standards and requirements. It is recommended that you work with local IT staff when planning to store, process, or access data electronically to ensure that your plan can be carried out locally and meets applicable requirements. If you have questions about Penn State's Policy AD95 or standards or need a consultation regarding data security, please contact security@psu.edu.

See the Research Data Plan Review Form