NuRamp

University of Nebraska Institutional Review Board (IRB)	**FOR OFFICE USE ONLY** IRB #: 20221221984EP IRB Decision Date: 12/16/2022 Date Received: 11/14/2022 NuRamp Project ID: 22014 Form ID: UNL-00058672 Status: Approved by the IRB

The NU Human Research Protection Program policies and procedures along with guidance documents and templates are available for your reference and use during the completion of this application.

- Only projects that meet the definition of research AND human subjects
- If your project does not require IRB approval, you are not required to submit this application; however, please be aware, IRB approval may not be granted if the research has already started or been conducted and the determination of IRB applicability was made incorrectly by the investigator.
- If your project does require IRB approval, the decision charts may not be used for exemption determinations, expedited review, or continuing review. Certain state laws and institutional policies, not taken into account within the decision charts, may affect review categories and applicability. Exemption determinations are required to be made by designated Human Research Protection Program staff members and are required to be submitted for official review and certification by completion of this application.

Contact the IRB at for further guidance.

Any general comments regarding this form can be added to the "Comments" button at the top of this page.

Basic Project Information

1. Project Title:
If this project corresponds with a current grant, contract, and/or award, use the same proposal title to allow for efficient communication between all necessary UNL offices including Research Compliance Services, the IRB and the Office of Sponsored Programs.
Developing a Universal Screener for Youth in India

2. Principal Investigator is:
Graduate Student

Principal Investigator:

Om Joshi - om.joshi@huskers.unl.edu - 4024722223UNL

Principal Investigator's Department

Department of Educational Psychology UNL

3. Secondary Investigator is:
Faculty

Secondary Investigator:

Carrie Clark - caron.clark@unl.edu - 4024722223 UNL

Secondary Investigator's Department

Department of Educational Psychology UNL

Description of Multi-Institutional Study Coordination

4. Are external person(s) not affiliated as a faculty, staff or student with the University of Nebraska-Lincoln working on the project?
Yes

4.a. Please list all external persons working on the project along with their email address, role (e.g., research assistant, Co-Investigator, consultant, etc.), and institutional affiliation, if applicable.
Hardik Joshi, Ph.D., Co-investigator, Associate Professor, Gujarat University, India, hardikjjoshi@gmail.com
Dhvani Patel, Ph.D., Co-investigator, Director, Vadodara Psychological Club, dhvani.patel@gmail.com
Sumit Ghosal, M.A., Mental Health Consultant & Counselor at Charotar University of Science and Technology, sumitghosal.psy@gmail.com
Amogh Joshi, M.Phil., Technology Consultant, Graduate Student, Purdue University, joshi134@purdue.edu

5. Is this a multi-institutional study? (i.e., colleagues from other institutions are on the research team)
Yes

5.a. Will a NU-affiliated person be the Principal Investigator?
Yes

5.a.i. Describe each site's responsibilities during their involvement in the project including NU's. If applicable, please also describe how data/information will be shared or transferred among the collaborating site(s) and who is responsible for IRB review and approval.

The study will be conducted in two high school sites in India (site 1, and site 2). The sites will be responsible for scheduling students for computer-based assessments in their computer lab. The sites will avail a computer lab for data collection. Site-1 will allow time during 'zero' class periods during school hours.

The PI will be responsible for data collection and for obtaining informed consent from participants. The PI (Om Joshi) and secondary PI supervisor (Carrie Clark) will have access to both anonymized data and the master list, considering that if either of these investigators is unavailable due to situational reasons, the other investigator can act promptly to attend to the research and safety needs. Dr Hardik Joshi will be involved only in attending to administrative activities (e.g., collecting and delivering materials to/from the school office when the PI is not available). The only time identifiable information will be shared with Mr. Ghosal (mental health consultant) is when we find a student at higher risk and there is the potential for harm. In this case, we will reveal the particular students information to the school counselor and Mr. Ghosal to ensure proper steps are taken to safeguard the students. If, for any reason, Mr. Ghosal cannot attend to the need, the information will be shared with Dr. Patel (co-investigator) to avail of mental health services to students in need. For each individuals qualification related to their role, please refer to 7. c in this section.

The data will be transferred from the data collection site to the UNL server for analysis and storage. Specifically, we will set up a secured OneDrive folder accessible to both parties and managed by the IT team in CEHS. All data shared through this mechanism will be de-identified. The lead PI will be responsible for IRB review and approval.

Project

6. Will the project involve an external performance site other than the University of Nebraska where data collection will occur?
Yes

6.a. Please list all other institutions or agencies:

Institution/Agency

1. Name of Institution/Agency:
Navrachna Vidyani Vidyalaya

2. Contact Information for the site:
Navrachana Vidyani Vidyalaya School
Address : Near Sama Sports Complex, Sama, Vadodara 390024 Gujarat (INDIA)
Tel. : 0265-2792285, 2780539
Email : vidyani@navrachana.edu.in
Website : www.vidyani.navrachana.in

3. Does the site have an IRB?
No

4. Has the site granted permission for the research to be conducted?
Yes

5. Is this site supported through a subaward?
No

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1. Name of Institution/Agency:
Vasu International School

2. Contact Information for the site:
Vasu International School
Address: Anandba Campus, Klarai Gam Road,
Sardar Patel Ring Road,
At & Po Valad, Dist. Gandhinagar,
Gujarat, India
Tel: 079-22808059
Email: vasuint.school@yahoo.in

3. Does the site have an IRB?
No

4. Has the site granted permission for the research to be conducted?
Yes

5. Is this site supported through a subaward?
No

7. Does this project involve any international sites where the PI will either conduct or supervise the study?
Yes

7.a. Name or describe the international location.
The study will be conducted in following high-schools in the state of Gujarat, India.

1. Navrachana Vidyani Vidyalaya School, near Sama Sports Complex, Sama, Vadodara 390024 Gujarat (INDIA)
2. Vasu International School, Anandba Campus, Klarai Gam Road, Sardar Patel Ring Road, At & Po

Valad, Dist. Gandhinagar, Gujarat, (INDIA)

7.b. Describe the study personnel's qualifications for conducting research at the international location.
The PI is a graduate student of Developmental and Learning Science at UNL. He is also a Nationally Certified School Psychologist (NCSP) and is credentialled in providing mental health services in India to school-going students. He will be supported by his advisor, Dr Clark, who will offer support and guidance regarding ethics, data analysis, and study planning.

Mr. Sumit Ghosal is a practicing Clinical Psychologist in India. He is employed as a university student mental health counselor at Charotar University of Science and Technology. He also provides counseling to school-going children as part of his private practice.

Dr. Hardik Joshi is a Computer Scientist and Associate Professor at Gujarat University.

Dr. Dhvani Patel is a Clinical Psychologist and Director of an organization with multiple licensed therapists.

7.c. Describe the procedures that have been considered and are in place, if applicable, to communicate with research participants throughout the research.
The consenting parents, school administrators, and school counselors, and assenting students will be provided with a hard copy of the consent form containing the PI's email address, PI's US and local (India) phone number, the secondary PI's (Carrie Clark) email address, and the Mental Health Consultant's (Mr. Ghosal) phone number. The PI will be the main point of contact for the participants and administrators.

7.d. Describe the procedures that have been considered and are in place to communicate with the UNL IRB throughout the research as needed.
The PI will communicate with UNL IRB personnel by email for most non-urgent businesses and a phone call if an urgent need arises.

The participants will be provided with UNL IRB's contact email address and phone number.

7.e. Describe the process that is in place for handling modifications to the research, including those that require submission via NUgrant and require approval by the IRB prior to implementation. Please consider not only communication with the IRB but also the study team.
The research team will first discuss any modification via email or a zoom meeting. Once the research team agrees, the request for modification/amendment will be sent to UNL IRB via NUgrant. The PI will be in regular contact with IRB personnel to ensure that required steps are followed prior to implementation of any study modifications.

7.f. Describe the process that is in place for handling research participant complaints, noncompliance, protocol deviations, protocol violations and unanticipated problems involving risk to subjects or others, including those that require submission via NUgrant through the reportable new information form. Please consider not only communication with the IRB but also the study team.
The research team will address participant complaints, noncompliance, protocol deviations,

protocol violations, and unanticipated problems involving risk to subjects or others by scheduling an urgent group meeting. The team will also determine necessary steps and act on them immediately to safeguard the participants and address the problem with noncompliance, protocol deviations, violation, or other unanticipated problem. Followed by the group meeting, the necessary paperwork will be submitted to UNL IRB via email or NUgrant. The PI will regularly contact IRB personnel to ensure that required steps are followed before implementation. In unanticipated urgent situations (e.g., imminent risk to participants or violations that pose a risk), the PI will contact the IRB immediately and the research will be suspended until it is deemed safe to continue.

8. The European Union's ('EU') General Data Protection Regulation ('GDPR'), regulates the processing by an individual, a company or an organization of personal data relating to individuals located (i.e., geographically and not to be confused with citizenship) in the EU. Will this project process/control any personal data, monitor the behavior of individuals, and/or offer good/services (paid or free) to or from someone who is located in an applicable country within the EU?
No

The GDPR applies to persons located in the following countries Iceland, Liechtenstein, Norway, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Ireland, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Spain, Slovakia, Slovenia, Sweden and the United Kingdom. To learn more about the EU GDPR, including possible additional consent requirements, please visit the IRB Guidance webpage and reference the topic titled, European Union General Data Protection Regulation (EU GDPR).

9. Does this project require review by Lincoln Public Schools (LPS)?
No

Note

Research can only begin at each performance site after the IRB receives and accepts the site's approval or agreement document.

10. Describe the location(s) where recruitment and participation will take place (e.g., UNL, UNMC, UNO, UNK, at home, in a community building, schools, hospitals, clinics, prisons, unions, online, etc.).
The recruitment will occur in selected high schools in Gujarat, India.

11. Describe the facilities available to conduct the research (e.g., there will be a quiet room in the school to conduct interviews, a private research space, a participant will use

their personal computer, etc).
The participants will use the institutions' computer labs. For guidance lessons, the school's auditorium will be used. Students will be encouraged to focus on their own surveys and to respect the privacy of others.

Funding

12. Funding source:
Present source

12.a. Funding source type:
Internal/Department Funds

12.b. Name or describe the funding sponsor. (e.g., NIH, NSF, USDA, name of company, name of non-profit, department funds, start-up funds, etc.) Along with the name, list the Office of Sponsored Programs NUgrant project ID number or the assigned WBS number, if available.
The part of this project is supported by the funds from a Bruning scholarship awarded to the PI. The Office of Sponsored Programs does not administer the Brunning Scholarships. The funds are deposited to the students account directly by the department.

12.c. Related OSP Projects

12.d. Will this project be funded through a subaward and not the primary award?
No

12.e. If this project is associated with a federal award, have you been contacted by a program officer with a specific timeline required for IRB review and approval?
No

Note

The protocol must be updated via a change request form when a new and/or additional funding source is received so the project can be reviewed based on the specific source's

policies and procedures.

Project Dates

Note

The dates identified below are intended to be estimates of when the project will start and end and not when the application process begins.

13. Project start date:
(Start date is dependent upon approval)
01/01/2023

14. Project end date:
12/31/2024

Clinical Trials

The conduct of a clinical trial per any of the definitions below, requires certain language specific to the description of a clinical trial to be included in the consent form(s). Template language for this requirement can be found on the IRB website under the heading *ClinicalTrials.gov (CT.gov) Template Language.*

15. Is this project a clinical investigation that is regulated by the Food and Drug Administration (FDA)?
No

16. Is this project a clinical trial that is funded or supported by a Federal Awarding Agency that follows the Common Rule at 45 CFR 46?
No

17. Is this project categorized as a clinical trial per the definitions provided by the National Institutes of Health (NIH)?
(Note: The NIH definition is only applicable if your funding source is from the NIH.)
No

18. Is this project categorized as a clinical trial per the definition provided by the International Committee of Medical Journal Editors (ICMJE) AND are you planning on submitting results of this project to journals that follow the ICMJE's recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals? A full list of journals that follow ICMJE recommendations is provided below. Please be aware some journals or sponsors may follow guidelines requiring ct.gov registration but are not listed. Please check with the specific journal or sponsor if you have questions regarding applicability of ct.gov registration.

Journals Following the ICMJE Recommendations
No

- Page 2 of the New Project Form is used to assign a preliminary review type (Exempt, Expedited or Full Board) upon submission to the IRB. Your selection of categories below will assist IRB staff in the assignment and initial review process. This assignment is only preliminary. IRB staff will also conduct an initial pre-review upon submission to confirm the most appropriate review type and applicable categories.

- Before completing this page there are a few items you might find helpful to know:
  - More than one category in the review type of Exempt and Expedited can be selected. The higher review level (i.e., Expedited) will be the default if this occurs.
  - Question marks appear throughout this page to assist you in making an informed decision about the category selection. Each question mark contains category specific information, general information, and intended use.
  - Review at an IRB meeting is only required if a project will be reviewed under the Full Board review category. The IRB meets at least monthly throughout the year. Be aware of submission deadlines.
  - Exempt and Expedited projects are reviewed on an ongoing basis with no submission deadline requirements.
  - If there questions about any of the categories or review types, please contact the IRB at or or visit our website at https://research.unl.edu/researchcompliance/human-subjects-research/.

Full Board Category

Any categories selected at the proposal stage are only preliminary. The IRB Coordinator will confirm the appropriate review type and respective category upon initial review with final decision authority reserved by the IRB.

Is this project greater than minimal risk?
No

Will the project involve prisoners?
No

Exempt Category

Any categories selected at the proposal stage are only preliminary. The IRB Coordinator will confirm the appropriate review type and respective category upon initial review with final decision authority reserved by the IRB.

☐ **Exempt Category 1:** Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

☐ **Exempt Category 2:** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) **if at least one of the following criteria is met:**

- ☐ **(2a)** The information obtained is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the participants; or
- ☐ **(2b)** Any disclosure of the human participants' responses outside the research would not reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation; or
- ☐ **(2c)** The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

☐ **Exempt Category 3:** Research involving benign behavioral interventions in conjunction with the collection of information from an **adult (19 or older in the State of Nebraska)** subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and **at least one of the following criteria is met:**

- ☐ **(3a)** The information obtained is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained, directly or through identifiers linked to the subjects; or
- ☐ **(3b)** Any disclosure of the human participants' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, educational advancement, or reputation; or

☐ **(3c)** The information obtained is recorded by the investigator in such a manner that the identity of the human participants can readily be ascertained, directly or through identifiers linked to the participants, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

Regulatory Requirements for use of this category (3) and any of the criteria:
For the purposes of this category, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

☐ **Exempt Category 4:** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, **if at least one of the following criteria are met:**

☐ **(4a)** The identifiable private information or identifiable biospecimens are publicly available; or

☐ **(4b)** Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human participants cannot readily be ascertained directly or through identifiers linked to the participants, the investigator does not contact the participants, and the investigator will not re-identify participants; or

☐ **(4c)** The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under the Health Insurance Portability and Accountability Act (HIPAA) at 45 CFR parts 160 and 164, subparts A and E, for the purposes of health care options or research as those terms are defined at 45 CFR 164.501 or for public health activities and purposes as described under 45 CFR 164.512(b); or

☐ **(4d)** The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is nor will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems or records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

☐ **Exempt Category 5:** Research and demonstration projects which are conducted or supported by a Federal department or agency, or otherwise subject to approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for

obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

Regulatory Requirements for use of this category (5):
Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

☐ **Exempt Category 6:** Taste and food quality evaluation and consumer acceptance studies if wholesome foods without additives are consumed, or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration, or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Note
The following Exempt categories 7 & 8 would allow the storage, maintenance and/or use of identifiable private information and/or biospecimens if broad consent was used. The current categories are included in the application to gauge the interest of the UNL research community in implementing the use of broad consent under the Exempt categories.

At this time, it is the intention of the UNL IRB to potentially offer these Exemptions in the future as a way to reduce regulatory burden for investigators; however, there is also a considerable amount of work to be done to be able to ensure that the exemptions are implemented in a manner that meets all regulatory requirements, including the tracking of all non-consent for all projects using Exempt categories 7 & 8 at the institutional level. Although, the UNL IRB will not be approving the use of broad consent at this time under the Exempt categories, all previous regulatory requirements through traditional informed consent for non-exempt (i.e., Expedited or Full Board) storage, maintenance, and research use involving identifiable information and biospecimens are still available.

☐ **Exempt Category 7:** Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8).

☐ **Exempt Category 8:** Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if all of the following criteria are met:

☐ **(8a)** Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR 46.111(a)(8); and the reviewer conducts a limited IRB review and makes the determination in accordance with 45 CFR 46.111(a)(7); and the reviewer makes the determination that the research

to be conducted is within the scope of broad consent; the return of individual research results to subjects is not part of the study plan (this provision does not prevent an investigator from abiding by any legal requirements to return individual research results); and documentation of informed consent was obtained in accordance with 45 CFR 46.117.

☐ **(8b)** Waiver of documentation of consent was obtained in accordance with 45 CFR 46.117.

Expedited Category

Any categories selected at the proposal stage are only preliminary. The IRB Coordinator will confirm the appropriate review type and respective category upon initial review with final decision authority reserved by the IRB.

☐ **Expedited Category 1:** Clinical studies of drugs and medical devices only when one of the two conditions is met:

☐ Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required.

☐ Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

☐ **Expedited Category 2:** Collection of blood sample by finger stick, heel stick, ear stick, or venipuncture as follows:

☐ From healthy, non-pregnant adults who weigh at least 110 pounds. In studies in which more than 400 ml of blood is to be drawn within an 8 week period, the participant must have a baseline hemoglobin level of 12.0 grams. After 250 ml of blood has been drawn, the hemoglobin level must be retested; anyone whose hemoglobin has fallen below 11.0 grams must be withdrawn from the study; or

☐ From other adults and children, considering the age, weight, and health of the participants, the collection procedure, the amount of blood to be collected and the frequency with which it will be collected. For these participants, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times (or research sessions) per week.

☐ **Expedited Category 3:** Prospective collection of biological specimens for research purposes by non-invasive means.

☐ **Expedited Category 4:** Collection of data through non-invasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice (excluding procedures involving x-rays or microwaves). Where medical devices are employed, they must be cleared or approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

☐ **Expedited Category 5:** Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

☐ **Expedited Category 6:** Collection of data from voice, video, digital, or image recordings made for research purposes.

☒ **Expedited Category 7:** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Description of Participants

* 1. Estimate the number of participants per category via the table provided:

	Male	Female	Unspecified	Totals
Adults				
	0			
Children				

1000

1000

100

2100

Totals

1000

1000

100

2100

* 2. Please indicate all special groups who will be **purposefully** recruited for the project. Please check all that apply.

- ☒ Adults, non students
- ☐ Employees
- ☐ NU Students
- ☐ Persons currently serving in the military
- ☒ Students attending external institutions (i.e., not NU)
- ☐ Veterans

- ☒ Children (under age 19)
- ☐ Persons with language impairment(s)
- ☐ Persons who are institutionalized
- ☐ Persons with mental disabilities
- ☐ Prisoners
- ☐ Persons with physical disabilities
- ☐ Pregnant women/fetuses/neonates
- ☐ Persons with psychological impairment
- ☐ Persons who are experiencing restricted or inequitable civil rights (including parolees and LGBT people in certain states)
- ☐ Persons who are decisionally-impaired
- ☐ Persons with HIV/AIDS
- ☐ Persons with neurological impairment
- ☐ Adults and/or children with legal representatives
- ☐ Wards of the state
- ☐ Other

Inclusion Criteria

3. Will both male and female participants be recruited?
Yes

4. Will participation be limited to certain racial or ethnic groups?
No

5. Describe the inclusion criteria that will be followed to select the participants to be enrolled in the research, including the lower and upper age range of participants. If the project will include various stages of recruitment, please describe the selection or inclusion criteria for each phase.

Students from age 13 to 18 years attending the participating high schools will be recruited as a part of the study.
Parents of the participating students will be included.

Note

Nebraska age of majority is 19 years of age, with exceptions. If any participants below the age of 19 years will be included in the research, additional requirements may be necessary based on the inclusion of minors, the research review level and the category in which the project will be reviewed under.

6. Describe the process that will be followed to screen and determine the participant's eligibility. For example, eligibility determinations could be completed through a participant self-determination process, screening questions included in a survey, pre-screening interview questions, or through access of private information or biospecimens.
Anyone attending participating high schools and between 13 to 18 years will be eligible.
Parents or legal guardians of the participating students will be eligible.

7. Describe your access to the population that will allow recruitment of the necessary number of participants. For example, if you are an employee of an organization that will allow for the research to occur, are the instructor of the classroom in which the research will take place, or you have a professional/personal relationship with someone in the targeted population, etc., describe that in your response.
The PI visited schools in India during the summer of 2022 to learn about their interest in participating in a School Well-being And Youth Mental-health (SWAYM) study. (Please see SWAYM_description in section 9). The school administrators have provided initial permission to participate in the study. The PI will contact the schools upon IRB approval to implement the study. The PI is piloting universal mental health screening development for schools in India. The screening is free/non-commercial. Students may be asked to participate in screening by the school; we will only use the data for the students whose parents provide written consent and for students who assent.

8. Describe the process that will be followed, facilities available, or locations that will be used during the conduct of research to protect the privacy of participants, if applicable. In this question, privacy refers to procedures such as how a participant will complete a sensitive research questionnaire in private without having the possibility of someone reading their responses over their shoulder or possibly having someone overhear responses during an interview.
The student participants will be invited to the computer lab as a part of the computer class. A small group of students will also be selected, based on their responses to the CPFQ and QUEST surveys, to complete phase 2, which includes some follow-up classes with the PI and EMA and heart rate variability metrics (see Section 5 for further details about how this sample will be selected).

We will take careful steps to safeguard the privacy of all students. First, the computer lab monitors are reasonably spaced from each other, where it is not easy to read from another screen from an angle. Second, we have randomized the question blocks so students may get different sets of questions simultaneously, reducing the chances of two neighboring students' knowledge of each others questions. Finally, the PI/coinvestigator and the lab instructors will be invigilating the data collection 100% of the time to ensure that students focus only on their screens and not looking at each others computers. If a student tries to see another students screen, the lab instructor and/or

PI/co-investigator will approach the student and redirect them to their computer screen.

The guidance lesson provided to the stratified sample will happen during the zero class period, where all students participate in some activity such as Debate club or cleanliness drive. Therefore, a small group of students interacting with the PI would not automatically identify them as research participants. Furthermore, the guidance lesson will occur in the school auditorium, where no other students will be allowed to enter.

All students will be asked to fill out the student assent form. However, we will only keep the data for the students whose parents have signed the consent form. This way, the privacy of the students with parental consent will be protected from administrators and teachers. Students' survey responses that do not contain parental consent will be discarded for the purposes of this research.

Exclusion Criteria

9. If not already described above, will any groups or categories of participants be excluded from the project?
No

10. Specifically, will females of child-bearing potential or pregnant females be excluded?
No

11. Will subjects be vulnerable to coercion or undue influence? This question must be answered as yes, if a member of the research team or an immediate family member are in or perceived to be in a position of authority over potential participants. For example, this may be a boss/director of an organization, or the instructor of classroom in which research takes place.
Yes

11.a. Describe the additional safeguards that will be followed to protect their rights and welfare.
To avoid undue influence of school administration, teachers, and peer group participation, we will take the following steps,
a. While orienting parents and students about the study, the PI will reinforce the message that participation in the research study is voluntary and confidential. Reasonable steps will be taken to keep the participating students identities confidential from the teachers, school administrators, and other students. Their decision to participate will not impact their relationship with their school teachers. We have made this clear in the consent and assent forms.
b. The consent and assent will be collected in a sealed envelope, and only the PI will open the sealed consent form.
c. Every student is participating in the survey activity regardless of parental consent and student assent, which further reduces the chances of a participating student being identified by anyone in school.

Research Methodology and Data Sources

1. Will the project involve audio recording?
No

2. Will information be obtained from study participant(s) utilizing web, mobile or online data transmission procedures? For example, this question would be answered "yes" if the project involves the use of Qualtrics as an online survey provider or a mobile application.
Yes

2.a. What web, mobile, or online program will be used? Will the data be sent to a secure server? Will the data be encrypted while in transit? Will IP addresses be collected by the online program? If IP addresses will be collected by the program, will they be stored in the research records external to the web, mobile or online program? If so, what is the purpose of storage and use as it relates to the purpose of the research? If applicable, will a third-party or external organization also have access to the data?
The Qualtrics web platform will be used to collect the survey data and the PsyToolkit application will be used to collect the task-based data. PsyToolkit is a web-based research platform that requires a secure HTTPS connection and is encrypted using secure cyphers.

Participants will log into the computer systems provided on the research site using the credentials provided by their institution and access the Qualtrics Survey using a web browser. Participants will be provided with a unique numeric ID that they will use in the Qualtrics survey and the PsyToolkit tasks so that their names are not included on the data. The students will use the same ID for Phase 2 EMA surveys if selected. Apart from the inventories mentioned (see attached list of inventories), Qualtrics also collects web-analytics data (e.g., IP address, approximate location). We will force Qualtrics to remove IP addresses. Qualtrics encrypts the data while in transit and stores the data on secure cloud storage. Research records will not be stored external to Qualtrics and can only be accessed by a secured authentication through UNL access to the Qualtrics web platform.

Parents will use Qualtrics to fill out parental questionnaires. Parents will be provided with a unique numeric ID that they will have to enter while taking the Qualtrics survey.

Only the PI (Om Joshi) and supervisory Secondary PI (Dr. Carrie Clark) will have access to data. Only the PI will have access to the master list with linked participant's name and their numeric code. In other words, no third-party or external organization will have access to the named or identifiable data.

2.b. Based on the nature of web-based studies and global accessibility, participants from an EU GDPR regulated country could be incidentally included and the GDPR may be applicable if the project processes/controls any personal data, monitors the behavior of individuals, and/or offers good/services (paid or free) to or from someone who is located in an applicable country within the EU. Will participants from a regulated country be targeted for inclusion or will responses be restricted to those only in the United States and those in non-regulated countries?
Restricted to US and non-regulated countries only

Note
The GDPR applies to persons located in the following countries Iceland, Liechtenstein, Norway, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Italy, Ireland, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Spain, Slovakia, Slovenia, Sweden and the United Kingdom. To learn more about the EU GDPR, including possible additional consent requirements, please visit the IRB Guidance webpage and reference the topic titled, European Union General Data Protection Regulation (EU GDPR).

According to the European Commission, personal data is any information that relates to an identified or identifiable living individual. Different pieces of information, which collected together can lead to the identification of a particular person, also constitute personal data.

Personal data that has been de-identified, encrypted or pseudonymised but can be used to re-identify a person remains personal data and falls within the scope of the GDPR.

Personal data that has been rendered anonymous in such a way that the individual is not or no longer identifiable is no longer considered personal data. For data to be truly anonymised, the anonymisation must be irreversible.

The GDPR protects personal data regardless of the technology used for processing that data – it's technology neutral and applies to both automated and manual processing, provided the data is organized in accordance with pre-defined criteria (for example alphabetical order). It also doesn't matter how the data is stored – in an IT system, through video surveillance, or on paper; in all cases, personal data is subject to the protection requirements set out in the GDPR.

Examples of personal data:

- a name and surname;
- a home address;
- an email address such as name.surname@company.com;
- an identification card number;
- location data (for example the location data function on a mobile phone);
- an Internet Protocol (IP) address;
- a cookie ID;
- the advertising identifier of your phone;
- data held by a hospital or doctor, which could be a symbol that uniquely identifies a person.

Examples of data not considered personal data:

- a company registration number;
- an email address such as info@company.com;
- anonymous data.

To learn more about the EU GDPR, including possible additional consent requirements, please visit the IRB Guidance webpage and reference the topic titled, European Union General Data Protection Regulation (EU GDPR).

2.b.i. Describe how the project will restrict responses from those in an applicable EU

GDPR country if you are collecting personal data?
The study will only be available to students in the Indian high schools we are partnering with and will not be accessible outside of this context.

3. Will the project obtain, use, study, or analyze Protected Health Information (PHI) (i.e., information obtained from or provided to a covered entity or business associate such as a doctor's office, hospital, nursing home, insurance company, etc.)? If this project uses PHI, training is required to be completed by PIs, Supervising Investigators and participating personnel who conduct research applicable to the Health Insurance Portability and Accountability Act (HIPAA). *Information Privacy and Security – Information for Researchers: Basic Course* is completed through the Collaborative Institutional Training Initiative (CITI).

Note

Self-reported health information provided directly to the investigator is not covered by the Privacy Rule if that investigator is not part of the workforce of a covered entity.

No

4. Will the project ask questions about illegal drug use or criminal activity that could place participants at risk for legal action?
No

5. Does a Certificate of Confidentiality apply to this project?

Note

Certificates of Confidentiality are obtained from federal agencies, such as the National Institutes of Health or the Department of Justice.
Learn more about Certificates of Confidentiality on the UNL IRB webpage. If a project involves a Certificate of Confidentiality, specific information must be present in the consent form informing participants of the certificate. See the IRB website for more information.

No

6. Will the project involve photography?
No

7. Will the project involve videography?
No

8. Will the project use, or analyze archival or secondary data?
No

9. Will the project collect, use, study, analyze, or generate bio-specimens such as cells, tissues, saliva, blood, serum, human excreta, tissue, hair, teeth, etc.?
No

10. Will this project store, maintain, use or generate identifiable private biospecimens or information, including participant contact information, for the purposes of future use by the study team or others outside of the study team? Typically information or biospecimens for future use are stored in a biorepository, data repository or registry.

Note

Biospecimens or information are considered identifiable if identifier(s) are readily accessible to at least one member of the study team, including a master list linking names and codes.

No

11. Does this project utilize human embryonic stem cells (hESC) and/or their derivatives?
No

12. Does this project utilize human fetal cells, fetal tissue (hFT) and/or their derivatives?
No

13. Does this project involve the use of ionizing radiation or ionizing radiation-emitting device(s) that is not part of a clinical patient's standard of care?

Note

A magnetic-resonance imaging (MRI) machine does not emit ionizing radiation.

No

14. Will the project ask participants to perform physical tasks (e.g. climbing a ladder, doing a push-up, contracting a muscle, running on a treadmill, etc.)?

No

15. Does this project involve a medical device and it is the object of the investigation?

Note

Even some smartphone applications could be regulated by the FDA if they meet the definition of a medical device. Always consult with your IRB coordinator if you are unsure how to answer this question. Be aware, all projects regulated by the FDA are referred to the UNMC IRB for review under the FDA regulations.

No

16. Does this project involve a FDA-approved and marketed device and it is NOT the object of the investigation?
No

Purpose, Methods & Procedures

1. Indicate the project's design by checking the appropriate box(es):
☐ Action research

☐ Case-control

☐ Class Project

☐ Cohort

☒ Correlational

☐ Cross-sectional

☐ Ethnography

☒ Exploratory

☐ Evaluation

☐ Intervention

☒ Longitudinal

☒ Pilot

☐ Randomized

☐ Other

2. What is the significance/purpose of the project? (Provide a brief description in lay terms including a brief literature justification and objectives/aims of the research.)
India is a developing country with the largest youth population globally, totaling approximately 356 million 10-24 year-olds (UN report, 2014). As one of the fastest-growing countries, India experiences frequent lifestyle changes. As a result of these changes, mental health challenges have increased considerably (Shastri, 2008). Although India is becoming better equipped to offer mental health services, the unregulated provision of these services has also increased (Yadav, 2017). Based on a 2001 World Health Organization report, Shastri (2008) determined that around 66 million Indian children suffer from mental and behavioral disorders. The most commonly reported childhood psychiatric disorder in India is anxiety disorder (5%), followed by mood disorder (3%), hyperactivity (12%), autism, and schizophrenia (1%) (Srinath et al., 2005). Despite having the world's largest youth population and a high need for mental health services, quality improvement measures for mental health counseling are non-existent in India. The picture of mental health problems in school-going children is disappointing, and no school-based systematic universal screening approach has been utilized yet in India.

In the United States, universal screening has effectively identified at-risk students and provided them with early intervention to mitigate challenges. Such efforts have resulted in better academic, behavioral, and social-emotional outcomes (Huang et al., 2019; Kligus et al., 2016). Most universal mental health screeners are targeted to assess mental health problems that may not give an individual a complete picture. Assessing well-being, protective, and cognitive functional factors may give the schools a complete picture of strengths and weaknesses (Suldo & Shaffer, 2008). Schools can utilize such information to further their organizational culture and instructional approach. Most universal screeners are implemented once a year, mainly at the beginning of the year. However, the level of distress in school-going children may be higher in the later part of the year. Especially in India, students reported that exams and failure to get good grades are significantly stressful (Mathew et al., 2015). A good screener should be able to measure distress over a period of time and offer the ability to monitor at-risk students. Therefore, the feasibility of a screener is critical. A screener that can be answered in less than five minutes using a personal device such as a cell phone makes the most plausible case of being successful.

Furthermore, most screeners are based on self-report or collateral ratings. When some task-based measures, such as computerized executive function tasks, are included in initial validation, it may give a detailed picture of functional aspects that affect mental health and well-being (Toplak et al., 2012). Most available universal mental health screeners are based on the current level of symptoms. At the same time, studies in resilience provide insights into core human factors, such as Psychological Flexibility being the most powerful predictor of mental health (Cobos-Snchez et al., 2020; Twiselton et al., 2020). Psychological Flexibility involves sub-constructs such as acceptance, mindfulness, defusion, contextual self, value & purpose, and committed actions(Hayes et al., 2006). We hypothesize that when Psychological Flexibility is included as part of a universal mental health screener, it will offer more profound insights into the current level of functioning and the ability to handle mental health challenges.

Even though there are many valid and reliable universal screeners available today, they do not offer ecological validity that tests the screener against day-to-day life events. Ecological Momentary

Assessment (EMA) using psychophysiological measures, such as Heart Rate Variability (HRV), adds validity to the screener under development. HRV can reflect an individual's emotional state and tap into emotional self-regulation.

The EMA is a group of methods used in various settings to collect real-life contextual data more frequently and flexibly across time. Event-based sampling and time-based samplings are some of the primary sampling schemes used in EMAs. It helps reduce recall bias, offers the ability to track fluctuation variables (e.g., emotional states), tests theoretical assumptions, and insights into interventions. Additionally, EMA has the edge over retrospective reports as it offers more frequent assessments that are less biased and a nuanced view of emotional states, thoughts, and behaviors. Responses to such variables may be affected with time otherwise (Davidson et al., 2017).

Reliability of a measure refers to the accuracy of measuring construct over a period. We are developing a screening measure that serves as a tool to monitor mental health throughout the year. When we test a newly developed screening measure using longitudinal panel data with the full sample and intensive longitudinal data with the stratified randomly selected sample, it offers much higher validity and reliability.

In conclusion, we aim to develop a measure that is 1. Based on current tools of mental health 2. Offers assessment of mental health strengths and challenges 3. Offers insights into cognitive and affective aspects of mental health 3. Offers predictive validity of resilience when in relation to distress 4. Has strong ecological validity 5. Offers feasibility and flexibility to administer it multiple times in the semester.
We also believe in creating a research study with an equal social impact. In order to achieve the aims, weve created a School Well-being and Youth Mental-health (SWAYM) program. SWAYM aims to develop a comprehensive multimodal screener based on understanding mental health, well-being, resilience, and cognitive science using correlational, longitudinal, and intense longitudinal modeling approaches. The goal is to create a robust screener offering higher construct, concurrent, and ecological validity. The program also offers schools resources that can be used for the multitiered system of support service to students. Although the SWAYM program objectives of helping schools with intervention and support are not a part of the research study, they are imperative in building a win-win relationship with participating organizations.

References

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Hayes, S. C., Luoma, J. B., Bond, F. W., Masuda, A., & Lillis, J. (2006). Acceptance and Commitment Therapy: Model, processes and outcomes. Behaviour Research and Therapy, 44(1), 125. https://doi.org/10.1016/j.brat.2005.06.006

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Shastri, P. (2008). Future perspective of planning child guidance services in India. Indian Journal of

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Twiselton, K., Stanton, S. C. E., Gillanders, D., & Bottomley, E. (2020). Exploring the links between psychological flexibility, individual well-being, and relationship quality. Personal Relationships, 27(4), 880906. https://doi.org/10.1111/pere.12344

Yadav, P. (2017). Counseling in India: Issues and Challenges. Indian Journal of Health and Well-Being, 8(8), 918-920.

3. Describe the data collection procedures sequentially. (Upload all interview questions, measurements, images, examples, etc. on page nine. Do not just provide a list of procedures, but rather this section must include enough information for the IRB to understand what the participants will be asked to complete.)

To develop a universal screener as a part of the SWAYM program, the PI and coinvestigators will develop a close relationship with the participating schools. The PI will verbally orient parents and caregivers about the study; the PI will attend the schools annual function (on 12/23 at site-1) and Parent-teacher meeting (on 12/20/22 at site-2). Parental consent forms will be distributed. Parents will be encouraged to read the consent form and contact the investigators if they have questions.

The study will be conducted in three phases.

Phase 1
In Phase 1, student participants will fill out various questionnaires and complete computerized tasks using the school computer lab. Additionally, parents will fill out three questionnaires using their personal devices. This procedure will occur from January 1st to January 22nd when the PI will be physically present at the sites.

The student participants will attend their scheduled computer class in the school's computer lab and log into the computer using the credentials provided by their institutions. After login, participants will navigate to the Qualtrics link using a web browser on the computer.

The Qualtrics form will first record assent from the students (see student assent in section 9). After providing their permission, over the course of a total of three sessions, the participants will fill out the demographic information, self-report measures, essay questions, and computerized tasks (Please refer to the list of inventories and descriptions of the tasks on page 9).

These inventories are intended to collect demographic information (see demographic_pdf for a list of complete questions) and information regarding their psychological state.

Child Participants will complete the following questionnaires,

Children's Psychological Flexibility Questionnaire (CPFQ)
Acceptance and Fusion Questionnaire-Youth (AFQ-Y8),

Secondary Social-Emotional Scale (SHES)
Difficulty in Emotional Regulation Scale (DERS),
Questionnaire on Self-Transcendence (QUEST),
PROMIS
Social Emotional Disstress Survey (SEDS)
Emotional Regulation Questionnaire (ERQ)
The School Connectedness Scale (SCS)
Claremont Purpose Scale (CPS),
UCLA PTSD Reaction Index,
Columbia Suicide Severity Interview,
Pediatric ACEs and Related Life Events Screener (PERLS)
Outcome Rating Scale (ORS)

Student Participants will complete the following tasks
Stroop task
Emotional Stroop task
Digit Span Task
go/no-go task
Wisconsid Card Sorting Task

Participants will be prompted to launch a web-based PsychToolkit application to launch a program that will administer cognitive tasks. These cognitive tasks measure executive functions.

The parents will be filling out the following questionnaire using a weblink sent to their email.

Barkley's Difficulty in Executive Function Scale (BDEFS)
Big-Five Inventory (BFI)
Caregiver's Psychological Flexibility Questionnaire (PFQ-Caregiver)
CompACT

Phase 2
In Phase 2, the PI will invite a small group (N~40) of Navrachna Vidyani Vidyalaya (site -1) students to participate in guidance lessons during the zero period. These students will be selected based on their scores for the CPFQ and QUEST surveys. Specifically, from the students in the highest and lowest quartiles for scores on these measures, we will select equal numbers of students, matching as closely as possible for gender and age.

The zero period is when no class is scheduled. The group will be selected using a stratified random sample based on their psychological flexibility and emotional distress scores. During the guidance class, the PI will interact with students on their excellent and challenging life experiences (see rainbow & clouds protocol in section 9), followed by offering some strategies on social-emotional learning. This activity will take place between 1/9/23 to 1/20/23 for five sessions. During the guidance lesson (phase 2), the participants will be given a wearable wrist or chest strap device that measures their heart rate variability during the session. In addition, the participants will be asked to fill out a brief five-question survey (see EMA survey in section 9) up to four times a day for 15 days using their personal device (i.e., cellphone, digital tablet, etc.).

Phase 3
Phase 3 will again involve all consenting students from both schools and is targeted towards collecting periodic panel data where all the participants will be asked to fill out a newly developed brief screener every month using their personal devices. The screener will be sent monthly between

2/2023 and 12/2023 (for total 11 times). Although the PI will not be present during the whole of Phase 3, the PI plans to visit sites in March 2023 (spring break), August 2023, and December 2023. The co-investigators will be visiting the site a day after sending the monthly screener. Phase 3 will be implemented in all participating school sites. For Phase 3, the monthly screener, students will be sent the survey as a WhatsApp (if available) message and their email. The student will be free to use whatever method is available to them (cellphone or computer.)

Precautions for the pandemic
While lockdowns in India have been lifted and students now receive in-person education, we may pivot to an "online-only" approach if the situation in India changes. In case of movement restrictions (lockdowns) recommended by the government, the students will complete the Qualtrics survey (including the cognitive tests) using the digital infrastructure of the institution (e.g., Google Classroom).

We note that nothing mentioned in the initial phase, and the follow-up phase changes in the "online-only" approach. For example, all the inventories and cognitive tasks will be present in the "online-only" approach. The only change that will occur is the physical location and the participants' device to answer the Qualtrics survey. Participants will be answering the Qualtrics survey remotely and using their devices.

The participating schools are some of the best private schools in the region. Most parents come from affluent backgrounds. We anticipate that all the parents will have a smartphone. However, if any parents do not have access to a personal device, The PI will carry some smartphones capable of web browsing with him and offer them to the parents to use to complete the online questionnaires. In addition, parents will be offered to use school Wi-Fi if they lack a personal internet connection. Also for the students, the school counselor reported that most students own a smartphone. However, if any students do not have access to a personal device, The PI will carry some smartphones capable of web browsing with him and offer them to students to use through the duration of the study.

4. Briefly describe the data analysis plan.
This study aims to develop a universal screener that identifies at-risk students, flourishing students, and their underlying factors, such as psychological flexibility and executive functions (Aim 1). The study also aims to establish the ecological and psychophysiological validity of the newly developed screener (Aim 2). Finally, the study team value providing meaningful information to schools that can be utilized to develop school-wide interventions by school administrators.

We will first run the descriptive statistics and correlations to establish relationships among various constructs and create a school profile based on the dual factor mental health model and psychological flexibility. To develop a short and feasible screener, we will analyze items from various questionnaires that account for the most variance for a given construct in a population. To achieve that, a confirmatory factor analysis will be used to determine the factor loadings on items.

The performance tasks for executive functions, such as Stroop, go no/go, digit span, and Wisconsin card sorting task, will be analyzed with a repeated-measures ANOVA, including emotion type (neutral, positive, negative) as the factor of interest. Similarly, a repeated-measures ANOVA will be used to evaluate the interactive effects of cue type (valid, invalid) and emotion (neutral, happy, sad, fearful) on reaction times and accuracy during the cueing paradigm. A p-value of .05 will be used. Post-hoc contrasts for significant findings will be corrected for multiple comparisons.

For each student, we will compute a score for the difference in performance between emotional and neutral stimuli and correlate this with their scores for the emotion regulation, executive function, and

anxiety/depression measures to determine whether individual differences in task performance correlate with these measures. Covariates such as gender, sleep quality and health will also be considered. A p-value of .05 will be used.

For the longitudinal panel data (Phase 3 screener), we will use repeated measure ANOVA to evaluate mean differences during various time points.

For the intensive longitudinal HRV and EMA survey, we plan to employ the Dynamic Structural Equation Modeling approach and model the relationship between HRV, psychological flexibility, well-being, and emotional self-regulation.

To offer schools meaningful information, we plan to use descriptive statistics and data visualizations to provide aggregate school-wide and grade-wide results.

5. Does this project involve deception?
No

6. Describe how long, in terms of time, the procedures will take a participant to complete. The description should include the duration of a session, the number of sessions, over what period of time and the total time required to complete the procedures.
The total estimated time to complete the screening assessment (Phase 1) is 2 hours. In January 2023, four computer classes (40 min. Each) will be assigned for the data collection. However, if any student cannot complete everything in three sessions, the school will arrange an additional computer lab session.

The total time for guiding sessions (Phase 2) will be 3 hours and 20 minutes (40 minutes each day X 5 days). In addition, students will receive a five-question brief EMA survey four times a day for 15 days. We estimate 1 minute per survey totaling 4 minutes per day. The short survey will take up to 60 minutes over 15 days between 1/9/2023 and 1/20/2023.

The monthly screener (Phase 3) is estimated to take 5 minutes to fill out. The monthly screener will be sent 11 times. The required time will be 55 minutes between February 2023 and December 2023.

The parental questionnaires are estimated to take 30 minutes. The questionnaire will be sent one time in January 2023.

7. Will there be any follow-up with the participant or will reminders be sent to the participant?
Yes

> **7.a. Describe how the follow-up/reminder(s) will be completed (e.g. in-person, email, text-message, etc.). Describe the number of follow-up/reminder(s) that will be completed. (Upload all applicable scripts, templates, email, etc. on page nine.)**
> In Phases 2 and 3, surveys will be sent to the participants multiple times. The survey link will be sent to the participants via their email and on the WhatsApp phone application. Phase 2 EMA survey will be sent to selected participants (N=40) up to four times a day for 15 days. Phase 3 screener will be sent to all the participants every month until December 2023.

8. Describe any procedure not being done solely to achieve the project's proposed purpose. For example, a student will always complete the assignment described in the

procedures during their classtime but the survey evaluating the assignment is done strictly for the project.
On the school's recommendation, all the students will be invited to participate in Phase 1 and Phase 3 data collection, regardless of parental consent and student assent. The rationale behind this decision is to 1. treat all students equally, 2. reduce workload for schools to make special arrangements for students who are not participating 3. Provide the school with results that cover the entire school population. However, the data without parental consent and student assent will be deleted after the school report (descriptive results and data visualization) is generated. Data with parental consent and student assent will be analyzed for all the proposed research aims.

Once the data is collected and the aggregate report is generated for the school, the PI will match the data cases with parental consent and student assent and delete the rest of the data. The data, with parental consent and student assent, will be shared between the PI and Secondary PI at the UNL supervisor for analysis purposes.

9. Describe the research team's available time allocated to conduct and complete the project. Essentially, the IRB would like to know if your time available would be sufficient to achieve the results successfully in a responsible manner.
The PI will be responsible for most administrative activities involved in the study (e.g., communicating with schools, attending parents' meetings, assisting students in the computer lab during phase one, and uploading and deleting task-based data from the lab computer to the server). During Phase I data collection, the PI will be on the site-1, with 100% time allotted to study-related activities. The PI will be devoting 20 hours a week in December '22, 40 hours a week in January, and 7 hours a week from January to December 2023.

Dr. Hardik Joshi will be on site-2 100% of the time while Phase I data is being collected. He will devote 30 hours a week from January 1st to January 23rd. After that, he will be providing consultation as needed throughout the study.

The technology consultant will be responsible for technological activities (e.g., developing surveys on Qualtrics, developing task-based assessments, developing syntax for analyzing HRV, and responding to technical queries). He will be allocated 20 hours a week during November and December 2022 to prepare for Phase 1 and 2 data collection. In January, he will be allocating 10 hours a week. From February to December, he will allocate 5 hours weekly or as needed.

Mr. Ghosal will be present 100% of the school time during Phase 1 and 2 data collection and will be available by phone on an as needed basis during Phase 3.

Dr. Dhvani Patel will facilitate the school and research team relationship and monitor the project's ethical implementation in India. She will also provide free mental health services to the needed students through her organization if the need for clinical intervention arises that cannot be fulfilled by the school or the Mental Health Consultant. Dr. Patel will make a site visit and ensure students' well-being a day after the Phase 3 screener survey is sent. Dr. Patel will also act as an in-charge investigator if the PI cannot be present during Phase 1 data collection due to situational reasons. Dr. Patel will devote her time to the project on a need basis.

The Secondary investigator (Dr. Carrie Clark) will supervise the project and analyses and will be available on an as needed basis.

Note: In India school week is 25 hours a week.

10. Describe the process followed to ensure that all persons assisting with the research (e.g. data collectors, transcriptionists, research assistants, etc.) are adequately trained, have the qualifications and appropriate training to perform the procedures included in the research. Describe the communication plan that the research team will follow to ensure that all personnel members , are informed about the protocol, any changes to the protocol, research-related duties and functions, etc.
Most of the data collection work will be done by the PI. The PI will work with the research team to ensure that the study is performed to the highest ethical standards. Specifically, all members working on the study will receive a copy of this protocol to read. All data analysis will be closely monitored and checked by the PI, who will serve as the first author on all publications related to the research. In addition, the secondary investigator serves as a supervisor to oversee the overall project and ensure that the highest ethical standards are maintained throughout the different phases of the study.

Recruiting Procedures

1. Describe how potential participant names and contact information will be obtained. For example, a list of names will be obtained from the telephone directory.
Participants' names and their parent's email addresses will be obtained through schools.

2. Describe how potential participants will be approached or told about the opportunity to participate in the project. Ensure all phases of recruitment are described. Upload all applicable recruitment documents such as scripts, flyers, templates, etc. on page nine.
The PI will attend the school's annual function and parent-teacher meetings to inform parents about the research participation opportunity and obtain informed consent. The PI will be visiting classrooms to inform students about the research opportunity.

Benefits and Risks

3. Describe any direct benefits to participants, if any.

Note:

Payments or incentives (including credit) should be discussed in section 6.9.a.

There are no direct benefits to the participants.

4. Will any individual results of the research or procedures/tests completed, be provided back to the participant?
Yes

4.a. What results will be provided to the participant and can the results be used for clinical or diagnostic purposes?
The individual result will be provided to the school counselor upon parental request. Due to the complexity of the interpretation of the research results, the result must be explained by the school counselor to the parents rather than being given directly to the parent. The result will not be used for clinical or diagnostic purposes; however, if a student shows clinically significant symptoms, a school counselor will be alerted for needed assessment and intervention.

We will practice extra vigilance and caution for any student who answers yes to suicide-related questions. The Email Task function is an automation function within Qualtrics that alerts the responsible parties if the respondent selects a particular response. The Email Task will be activated for the suicide-related questions. When a student selects yes to any of the suicide questions, an automated email alert will be sent to the PI, Mr. Ghosal, and the school counselor. This automation allows the PI, Mr. Ghosal, and the school counselor to immediately follow up with the student and ensure that the responsible party has been contacted, a suicide risk assessment is performed, a safety plan is created, a professional referral is made, and parents/legal guardians are provided with needed resources.

A major goal of this study is to develop a screening process to help schools in India identify at-risk youth and offer them early intervention to prevent suicide and mental health challenges. Suicide is the second leading cause of death for teens and young adults (CDC, 2022) and a public health emergency. We believe that preventing suicide should be a priority of any mental health screening instrument. Research has established that asking students about suicide does not increase their suicidal ideation (Dazzi et al., 2014). Instead, evidence suggests that repeated assessment of suicidal risk resulted in a significant decline in suicidal ideation and encouraged participants to talk about it (Mathias et al., 2012, Dazzi et al., 2014). Asking about suicidal thoughts and ideation creates an opportunity for communication and lays the path to treatment and recovery. Therefore, we believe that the benefits of asking questions about suicide risk outweigh the risks to the participants.

In the Republic of India, the central government governs the laws. With the exception of Indian penal code section 306- Abetment of suicide [If any person commits suicide, whoever abets the commission of such suicide, shall be punished with imprisonment of either description for a term which may extend to ten years, and shall also be liable to fine], attempt to suicide is not an offense. Furthermore, the Indian Mental Health Act 2017 states that Notwithstanding anything contained in Section 309 of the Indian Penal Code, any person who attempts to commit suicide shall be presumed, unless proved in any case to have extreme pressure, to have severe stress and will not be attempted and rebuffed under the said Code. The Mental Health Act further states that any attempted suicide victim shall be provided with care, therapy, treatment, and rehabilitation by the government for free. To our knowledge, there is no law related to suicidal ideation in India. In India, practice of Clinical Psychology is governed by the Rehabilitation Council of India (RCI). To our knowledge, there is no practice model in place by the RCI for minors with suicide ideation and there is no legal obligation to alert authorities.

Due to unclear laws and the absence of a national model of suicide risk intervention by the

Government of India, we have followed the American Psychological Association (APA) and National Association of School Psychology (NASP) model to address students at risk of suicide. This model includes detailed suicide risk assessment, safety planning, parental/caregiver involvement, referral to a hospital, and monitoring of students mental health. We believe the procedures we have set to address students who express suicidal ideation surpass the general conventional practice in India. We have created a robust infrastructure and the capacity to consult when there is a student in need. We plan to proactively support the at-risk student and their family until they receive services from an accessible government-run facility or private facility of their choice. In addition, we plan to monitor at-risk students mental health by school counselors checking in periodically with students.

Centers for Disease Control and Prevention, National Center for Injury Prevention and Control. (2013). Web-based Injury Statistics Query and Reporting System (WISQARS) [online]. Available from http://www.cdc.gov/injury/images/lc-charts/leading_causes_of_death_by_age_group_2013-a.gif

Dazzi, T., Gribble, R., Wessely, S., & Fear, N. T. (2014). Does asking about suicide and related behaviours induce suicidal ideation? What is the evidence?. Psychological medicine, 44(16), 33613363. https://doi.org/10.1017/S0033291714001299

Mathias, C. W., Michael Furr, R., Sheftall, A. H., Hill-Kapturczak, N., Crum, P., & Dougherty, D. M. (2012). What's the harm in asking about suicidal ideation?. Suicide & life-threatening behavior, 42(3), 341351. https://doi.org/10.1111/j.1943-278X.2012.0095.x

4.b. If test results performed on biospecimens will be provided back to the participant, all testing must be completed by a lab that is CLIA or CAP certified. Please identify the lab that will perform the tests. If this is not applicable, please respond with N/A.
N/A

4.c. Who will present and discuss the results with the research participant? How they will discuss the results (i.e., face-to-face, via phone, etc.)? What qualifications or training do they have to do so?
A school counselor will discuss the result with the parents of the participants face-to-face if requested by parents. The school counselors are trained mental health professionals with credentials necessary to practice counseling in India.

5. Describe the benefits of the research to society, if any.
This research aims to develop a universal mental health screener for identifying students' strengths and mental health problems. In addition, the study aims to study the relationship between psychological flexibility, mental health, executive functions, and well-being, informing society about how psychological flexibility can affect mental health. The results of this study can be vital in intervention design for a particular population. Finally, the study is also assessing the ecological validity of the measure using two unique approaches, ecological momentary assessments and psychophysiological measures. This approach may inform future research studies regarding associations between broader screening and more intense EMA and psychophysiological measures.

6. Describe all risks to the participant including a breach of confidentiality, if applicable. What will be done to minimize the risk(s)? If there are no known risks, this should be stated.

The participants may feel discomfort with specific questions. The PI will encourage the student to talk to the school counselors or the on-call psychologist from the research team. In addition, the PI will visit each class to debrief the students and to ensure that students are mentally healthy. Mr. Goshal will immediately reach out to any student expressing extreme distress, suicidal thoughts, or behavior. Mr. Ghosal, along with the school counselor, will determine the necessary steps to safeguard the child/children, including but not limited to suicide risk assessment, safety planning, resource sharing, and professional referral. Given that Mr. Ghosal is a qualified mental health practitioner, he can immediately implement support systems for these students.

While Minor Data Breach is always possible, we have taken steps to minimize such an occurrence. From the guidelines established by UNL Research Compliance Services (https://research.unl.edu/researchcompliance/research-data-security/) all data from sponsored research activity is recorded and made accessible only to PI and supervisory secondary PI in accordance with all applicable federal, state, and university requirements.

Furthermore, we ascertain that in the event of the breach, the risk to the participants and the loss of confidentiality, integrity, availability, or inappropriate access generally will not have a negative or significant impact on the participants, University, or research area as most of our data is focused on student's general life with a few exceptions of sensitive data about their mental health.

7. Does this research involve procedures, equipment or tests that could reasonably result in an incidental finding?
Yes

7.a. Will the study team provide incidental finding results to the research subject?
Yes

7.a.1. Will the participant be able to choose if they wish to receive incidental finding results?
No

7.a.2. Will the participant be excluded from the research if they choose not to receive incidental findings?
No

7.a.3. Describe the plan for identifying and assessing which incidental findings are of possible clinical significance. Since identification of an incidental finding may be outside the PI's expertise, this could include a plan for obtaining clinical expertise from outside the research study team.
Since most student participants are minors, we do not plan to provide incidental finding results to students themselves. Instead, the school counselor will be alerted immediately. The school counselor will follow the school protocol which may include informing parents and providing additional student support. From the research team, Mr. Ghosal will immediately reach out to the school counselor and ensure that the student is safe, further mental health evaluation is planned, risk management and safety procedures are in place, and parents/legal guardians are well informed about their role as well as locally available resources.

7.a.4. Describe the process that will be followed to identify which results will be reported to subjects and the communication procedure. This description should include, who will present the results, how they will discuss the results with the research participant, (e.g., face-to-face, via phone, etc.) and what qualifications or

training they have to do so.
A school counselor will discuss the result with the parents of the participants face-to-face if requested by parents. School counselors are trained mental health professionals with the credentials necessary to practice counseling in India.

The PI will present the aggregate school-level descriptive results using zoom meetings with the administrators. The PI is a Nationally Certified School Psychologist (NCSP) with 7 years of experience in needs analysis and planning and developing school-wide interventions.

8. Describe the availability of medical or psychological resources that participants might require as a consequence of the research and/or in the case of incidental findings, if applicable.
Participants who show clinically significant symptoms will be referred to the school counselor for further evaluation if any mental health symptoms appear elevated. The research team will give priority to suicide and trauma-related questions. If any participants show a higher level of symptoms or respond 'yes' to any suicide-related questions, the school counselor will be alerted immediately, and Mr. Ghosal will offer a free consultation. In addition, the investigating team will provide copies of a flyer with written information about available resources in the local city. The school counselor will be encouraged to distribute it to the parents needing it. Lastly, the PI is a trained school psychologist, certified trauma-focused CBT therapist, and trained in clinical suicidology. Mr. Ghosal is a practicing clinical psychologist. They can act as an interim resource until other professional help is arranged.

Compensation/Incentives and/or Cost for Participation

9. Will compensation or incentives (including money, gift certificates, extra credit, books, t-shirts, etc.) be provided to participants?
No

10. Will the research require the participant to pay for any aspects of the study or cost for participation, including cost for travel and transport to and from the study site?
No

Informed Consent Process

1. Describe how informed consent/assent will be obtained and the process that will be followed to ensure the participant understands the information presented. (Upload age appropriate consent/assent forms, if applicable, on page nine.)
Study participants include school going children and their parents. We will collect parental consent and child participants' assent. Parents will be explained the study during the school function or parent

teacher meeting session (see attached script) and provided with two printed copies of the informed consent form and an envelope. The PI will read the informed consent to them and encourage them to ask any questions they have. The PI will ask them to sign and return the consent in a sealed envelope within one week if they want their child to participate in the study. The parents who could not make it to the in-person session will be sent the informed consent forms home with the child. The PI will call them personally to explain the consent form and answer any questions they have. The parent will be requested to sign the form, seal it in the provided envelop and return it with their child back to school within one week if they agree for their child to participate in the study.

The PI will visit each classroom and explain the study to the student participants before beginning Phase 1. The assent form (first page) will appear on the computer during the first day of Phase 1 data collection. The PI will read that form to the student and request them to check the appropriate check box.

Separate consent and assent forms will be collected for the Phase-2 (EMA) participants (see Parental_Consent_EMA & Assent_EMA in section 9). These participants will be invited by phone to participate using similar procedures as above.

2. Describe the person(s) who will obtain participant consent/assent.
The PI will obtain consent forms. The co-investigator, Dr. Hardik Joshi, will hold consent forms that are "sealed in an envelope". As such, while Dr. Hardik Joshi will have access to consent forms, he will not be able to view them.

3. Describe who will provide consent/assent. If you have identified the inclusion of either child or adult wards or persons with a legally authorized representative (LAR) within section 3.2 of the protocol, describe the process that will be followed to ensure the LAR is providing the consent for the participant.
During the explanation of the study, we will make it clear that only a parent or legally authorized child guardian can provide consent for the child. This will also be made clear on the parent consent form.

4. Describe the waiting period, if any, between when the potential participant will be informed of the study and when consent will be obtained. If multiple data collection points are included within the project, describe the amount of time between each period.
There will be a one week waiting period between informing about the study and collecting the consent forms.

5. Describe the primary language that will be used by those obtaining consent.
The consent and assent will be in English.

6. Describe the primary language understood by the participant. If translation services (verbal and/or written) are needed, please describe that here. If written materials are necessary a Translation Certification Form is required.
We are selecting a school where the medium of instruction is English. Such a school communicates with the students and parents in English only. Also, English is the official language of India. Therefore, we use English as a communication language for all research-related communication.

7. Will any subjects be decisionally impaired so that they do not have the capacity to give consent?

No

8. In certain cases involving non-exempt research (i.e. Expedited or Full Board), a waiver of informed consent or a waiver of an element of informed consent may be requested. Additionally, for projects including NU students who are 17 or 18 years of age, a waiver of parental consent may be requested. Would you like to request a waiver of consent or a waiver of a consent element?
No

9. In certain cases involving non-exempt research (i.e., Expedited or Full Board), a waiver of informed consent documentation may be requested. Electronic consent may be a typical process where consent documentation might be waived.

Note

In the state of Nebraska, electronic signature must be individually identifiable to the person signing to constitute electronic signature.

Will this project request to waive consent documentation (e.g. signature)?
No

Note

Consent documentation cannot be waived when an authorization to access Protected Health Information is required under the HIPAA regulations.

Confidentiality

1. The project should make adequate provisions to maintain the confidentiality of the data. Describe how confidentiality of all records will be maintained.
All data will be collected by the Internet. Qualtrics and PsyToolkit are secure sites, with SSL encryption. No information will be saved on the computer itself. All data will be uploaded to a secured

UNL OneDrive folder after each phase of the data collection and deleted from the web-platform. At the end of the session, the participants will log out securely and close the browser.

Each student and parent participant will be assigned a numeric identification code. Only the PI will have access to master list that links participants' names and numeric codes. All survey data will be saved on UNL OneDrive secure server with two-factor authentication (i.e duo mobile). The master participant list will be saved on a secure server with two-factor authentication mainted by Holland Computing Center (HCC).

2. Will participants be identifiable during data collection or in the results? (This question should be answered "yes" if data collection is completed in an in-person setting or if data will be coded throughout the research process and a link is maintained between the code and participant identifiers.)
Yes

2.a. Describe how participants will be identified during the data collection procedures and in the data.
During data collection, the participants will be required to enter a numeric code on Qualtrics and PsychToolKit. The parent participants will be required to enter a numeric code on Qualtrics. Participants will not be entering their name or other identifying information during any phases of data collection.

During data collection, the participants must enter a numeric code on Qualtrics and PsychToolKit. The parent participants will be required to enter a numeric code on Qualtrics. Participants will not be entering their names or other identifying information during any phases of data collection.

During phase 2, the heart rate variability (HRV) data collection and EMA data collection, the HRV device will be identified with a numeric code (i.e., not with identifiable information). The data will be first downloaded on PI's computer with the numeric code name as a file name. The data will be uploaded to UNL's OneDrive folder right away, renamed, and it will be deleted from the computer.

2.b. If the data are coded, describe if a list linking names and codes will be used. The description should include the process that will be followed to keep the list secure during and after data collection and when the list will be destroyed. If the list will continue to be stored after all data collection procedures are complete and data has been verified, a justification for long-term storage must be provided.
Before data collection, the PI will assign a numeric code to each student and parent participant and create a master list. Qualtrics data will be de-identified with only the participant's ID number as the identifier. The master list file with names and corresponding numeric codes and without any data will be saved in a separate dual-authenticated password-protected server managed by Holland Computing Center. We plan to further the current study if we receive grant funding. We believe longitudinal research provides immense insights into human development and functioning. Therefore, we plan to keep the master list for 10 years from the beginning of the study for the purposes of following students if we receive funding. We will erase the master-list after 10 years from the beginning date of the study.

3. Describe how long the project records and data will be kept. The description should differentiate between the length of storage time for identifiable and de-identified records, if applicable.
The deidentified data will be retained indefinitely to support publications and research outputs. If the

PI and co-PI leave UNL, the data will be destroyed or a new IRB protocol will be put in place at the new institution.

4. Describe where and how records and data collected will be stored. The description should include how both electronic and/or paper/physical records and data will be stored. Specificity regarding secure NU servers vs. external servers possibly utilizing cloud computing must be provided, if applicable.
After each data collection phase, the de-identified data from the Qualtrics server will be downloaded and saved on the UNL secure server. A separate file with names and corresponding numeric codes will be saved on a dual authenticated password-protected UNL server managed by Holland Computing Center (HCC) and accessible to the PI only. Other paper records, such as the consent forms, will be stored in a locked file box while in India, separate from any data, and then transferred to a locked filing cabinet in Dr. Clark's research office on the UNL campus.

5. Describe all persons or entities planning to have access to the records and/or data.
Only PI (Om Joshi) and supervisory secondary PI (Dr. Carrie Clark) will have direct access to data. Only data that has no possibility of becoming identifiable will be shared with others, as described below.

6. Describe how data and/or research results will be reported. The description should include whether the data will be reported individually, identifiable, or in summary (aggregate) format. This description should also consider the possibility of deductive disclosure when reporting results or describing the research in a manuscript. If applicable, describe if masking procedures or certain descriptions would or would not be used. Also, describe if the data/results will be reported at conferences, in journals, in a thesis, in a dissertation, to the funding agency, back to the project site, etc.
The data will be reported only in aggregate/summary format in conference proceedings, journals, and school administration. A data set with individual summary scores will be collated specifically for sharing purposes that contains only data that could not be deduced to be from specific individuals, as below.

Data Monitoring & Sharing

7. Does the project require data safety monitoring?
No

8. Do you plan to share the data collected during this project through public-use files, repositories or other means outside of your approved research team and/or sites?
Yes

8.a. Do you have an established data sharing plan?
No

8.b. Please describe the process in which data will be shared. For example, data will be stored in a repository such as the UNL Data Repository (UNLDR) through UNL Libraries; or, data will be made available to colleagues via Box in a de-identified folder. (These are only examples to illustrate possible answers. Please provide as much detail as possible when describing the data sharing process.)
Given that we are working with a small number of schools, we are cautious about sharing data that would in any way identify students or families. Therefore, while we will share data as required by 'open science'-adhering journals for publication, we will limit this to summary scores and basic demographic information that would not allow student identification. These data will be added to a file in a distinct 'SharePoint" folder. CEHS's IT team will manage the folder. The de-identified data will be made available to colleagues or other researchers using UNL OneDrives de-identified, password-protected folders secure link. The secure link means the data can be accessed only by the specific recipient via email.

8.c. Will all data be de-identified when shared? De-identified means the data does not contain information that would link a participant's identity with the data collected including the ID code if the master list still exists.
Yes

8.c.i. Describe the methods that will be used to ensure proper de-identification of all data. Please be cognizant of small sample sizes and how this may affect the possibilities of re-identification of a research participant.
Each student and parent participant will be assigned a numeric identification code. We will force Qualtrics to delete other identifiers, such as IP addresses and location details. Only the PI and co-PI will have access to the master list that links participants' names and numeric codes. All survey data will be saved on UNL OneDrive secure server with two-factor authentication (i.e, duo mobile).
After each data collection phase, the de-identified data from the Qualtrics server will be downloaded and saved on the UNL secure server. A separate file with names and corresponding numeric codes will be saved on a dual authenticated password-protected UNL OneDrive server. The master list will be saved separately on UNL OneDrive. Other paper records, such as the consent forms, will be stored in a locked file box in India, separate from any data, and then transferred to a locked filing cabinet in Dr. Clark's research office on the UNL campus.

Before sharing any data with external researchers or in repositories, we will strip out any variables that could potentially reveal participants' identities. If a variable has fewer than 5 cases with a specific demographic characteristic (e.g., non-binary gender), we will remove that information from the file. We will also share only summary scores (i.e., calculated scores rather than individual responses to items) and we will not share any responses related to suicidality, self-harm or rare psychiatric diagnoses, as these are potentially sensitive and could lead to speculation about participant identity.

Note

Information about data sharing must be consistently described to the research participant within the consent form.

Questionnaires, Surveys, and Testing Instruments

Please list all questionnaires, surveys, and/or assessment instruments/measures used in the project.
Inventories:

For Students:

Measures CPFQ
AFQ Y8
Cognitive Experiments
Go-No-Go Task (inhibitory control)
Digit Span task (working memory) Wisconsin Card Sorting Task (mental flexibility) Stroop Color-Word Task (selective attention)
DERS
SEHS-HE
Quest
PROMIS Anxiety PROMIS Depression SEDS
ERQ
CPS
Columbia Suicide Severity
UCLA PTSD
Pediatric ACEs and Related Life Events Screener (PEARLS)
ORS

For Parents:
Measures
CPFQ CAREGIVER REPORT BDEFS
BFI
CompACT

For Guidance Lesson Students
EMA Survey

Uploaded Attachments

Please submit copies of the following:

- Funding application
- Institutional Approval letters
- Data sharing plans
- Recruitment flyers, ads, phone scripts, emails, etc.
- Informed Consent Forms, emails, and/or letters
- If transcriptions are required, Confidentiality Agreement that transcriptionists will sign
- If this is a study utilizing PHI, Release of Authorization that will be used to obtain permission from the participant for the agency/institution to release protected health information for project purposes or a letter from the agency/institution documenting agreement to provide protected health information for project purposes
- All Instruments/Measures used in the project

Please upload all documents that would include the IRB approval stamp as a PDF. These documents could include recruitment materials AND informed consent/assent forms.
☒Vasu_School_Permission.pdf
☒Mathur_Screener_approval.pdf
☒Vidyani_Vidyalaya_Approval.pdf
☒Rainbow&Cloud_protocol.pdf
☒Demographies.pdf
☒Measures_Description_SchoolWB.pdf
☒EMA Survey.pdf
☒Screen_GU_Ethical_Defer.pdf
☒Vidyani_Permission Letter.pdf
☒SWAYM_Parents_PDFs.pdf
☒Child_Orientation_Script.pdf
☒Mental_Health_Resources.pdf
☒SWAYM_Student_Inventories.pdf
☒Assent Form_EMA.docx
☒Assent Form_Youth Well-being.docx
☒ParentalConsent_YouthWellBeing.docx
☒Parental_Consent_EMA.docx
☒Parent_Orientation_Script.docx