ClinicalTrials.gov Data Entry Cover Sheet

Protocol ID: 22811 **Clinical Trials.gov ID**: NCT05988398

Project Title: Preventing Commercial Sexual Exploitation of Children (Project LIVE)

Principal Investigator: Katie M. Edwards, PhD, University of Nebraska-Lincoln

NUgrant

University of Nebraska-Lincoln Institutional Review Board (IRB) 402-472-6965 irb@unl.edu	**FOR OFFICE USE ONLY** IRB #: 20221122322EP IRB Decision Date: 11/09/2022 Date Received: 09/30/2022 NUgrant Project ID: 22322 Form ID: 59444 Status: Approved by the IRB

The UNL 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 irb@unl.edu 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.

Rigorous Evaluation of the READY to Stand Curriculum as a Tool to Prevent the Commercial Sexual Exploitation of Children Among Racially and Ethnically Diverse Urban Youth (PHASE I: FOCUS GROUPS AND COG INTERVIEWS)

*** 2. Principal Investigator is:**

Faculty

*** Principal Investigator:**

Katie Edwards - katie.edwards@unl.edu - 6034223207

*** Principal Investigator's Department**

Nebraska Center for Research on Children, Youth, Families and Schools

3. Secondary Investigator is:

Faculty

Secondary Investigator:

Rochelle Dalla - rdalla1@unl.edu - 4028810091

Secondary Investigator's Department

Department of Child, Youth and Family Studies

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.**

Yes, there are numerous people working on this project who are not affiliated with UNL. These include:
Stephanie Olson, CEO and Founder of The Set Me Free Project, will implement the curriculum in the schools; stephanie@setmefreeproject.net
Jennifer Stalder, SUCCESS specialist, Des Moines Public Schools, consultant; jennifer.stalder@dmschools.org
Stacie Nessa, Social Worker with Des Moines Public Schools, consultant; Stacie.Nessa@dmschools.org
Dr. Justin Ingels, Research Associate Professor, University of Georgia-- will serve as a consultant on cost documentation portion of the study; ingels@uga.edu

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

No

Project

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

Yes

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

Institution/Agency

*** 1. Name of Institution/Agency:**

Des Moines Public Schools

*** 2. Contact Information for the site:**

Stacie Nessa
Educational Liaison Consultant
stacie.nessa@dmschools.org

*** 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?

No

*** 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.).**

Recruitment and participation will take place within eight public (5 traditional and 3 alternative) high schools within the Des Moines Public School System (DMPS).

*** 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).**

Data will be collected in a private office, in an empty classroom, and/or within a private area of the library or gym of one of the DMPS high schools.

Funding

*** 12. Funding source:**

Present source

*** 12.a. Funding source type:**

Federal

*** 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.**

Centers for Disease Control and Prevention.

RCS Update: 11/09/2022: Federal, Centers for Disease Control and Prevention (CDC), Sponsor Award Number: 1

U01CE003405-01-00; UNL OSP project ID #55872, OSP form #143481. Grant congruency review conducted by RW on 10/10/2022. NOTE: This project approves only a portion of the proposed research in the grant referenced here. The approval only oversees Component A, Phase I. Future phases are expected to be submitted for review and approval building upon what is learned in this phase. No human subjects research related to future phase may begin until UNL IRB approval has been completed.

12.c. Related OSP Projects

ID :55872 click for more details
Title : Rigorous Evaluation of the READY to Stand Curriculum as a Tool to Prevent the Commercial Sexual Exploitation of Children Among Racially and Ethnically Diverse Urban Youth
Lead PI : Katie Edwards - katie.edwards@unl.edu - 6034223207
Department : Department of Educational Psychology
Sponsor : DHHS-Ctr for Disease Control

* 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)

11/01/2023

* 14. Project end date:

12/31/2023

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 irb@unl.edu or 402-472-6965 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	28	28	4	60
Children	45	45	10	100
Totals	73	73	14	160

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

☒ **Adults, non students**

☐ **UNL Students**

☐ **Students attending external institutions (i.e., not UNL)**

☒ **Children (under age 19)**

☐ **Persons who are institutionalized**

☐ **Prisoners**

☐ **Pregnant women/fetuses/neonates**

☐ **Persons who are experiencing restricted or inequitable civil rights (including parolees and LGBT people in certain states)**

☐ **Persons with HIV/AIDS**

☐ **Employees**

☐ **Persons currently serving in the military**

☐ **Veterans**

☐ **Persons with language impairment(s)**

☐ **Persons with mental disabilities**

☐ **Persons with physical disabilities**

☐ **Persons with psychological impairment**

☐ **Persons who are decisionally-impaired**

☐ **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.**

We are collecting focus group data from school personnel and high school students. We are collecting cognitive interview data with youth only.

School personnel will include anyone who working in administration (e.g., principal), teaching (e.g., academic subject matter instructor) or support service (e.g., counselor) capacity within any of the eight high schools encompassed within Des Moines Public School (DMPS) system.

All youth/student participants will be enrolled in one of eight high schools (grades 9 - 12) within DMPS. The first youth who express interest from each school, who meet eligibility criteria and who have parental consent 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.**

Eligibility will be determined by a verbal screening process conducted by the Project Coordinator or member of the research team when potential participants contact him/her/them to learn more about the study. (See recruitment script, attached)

The first who express interest and meet eligibility criteria will be selected for inclusion. In terms of youth, the first who express interest, meet criteria, and have parental consent will be included.

*** 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 PIs (Drs. Edwards and Dalla) have a professional relationship with the DMPS administration including the superintendent (see Letter of support), Executive Director of Student Services, Jake Troja, Director of School Climate Transformation, Mike Vukovich, Director of High Schools, and Mary Grinstead, Executive Director of Data and Assessment. We are working directly with Stacie Nessa (DMPS Educational Liaison Consultant), and Jennifer Stalder (DMPS SUCCESS Supervisor). This group will work with us to coordinate recruitment.

*** 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.

We will be collecting focus group discussions (FGD) with school personnel (n=60) and youth (n=80) and cognitive interviews with youth (n=20). All FGD will include groups of ~10 people and occur in a private space in a DMPS library or empty classroom. Responses from FG participants will be anonymized (no names associated with responses). All FGD participants will be asked to maintain privacy of all information shared within the discussion--however, there is no guarantee that FG participants will not share information outside the discussion (and this is in the consent/assent forms). Cognitive interviews (n=20) will occur one-on-one (between participant and research staff member trained by Dr. Edwards). These will occur in a private room in a DMPS library, office or an empty classroom. Cognitive interview data/transcripts will be de-identified by a member of the research team.

In terms of youth: the first from each school who express interest, meet inclusion criteria, and have parental consent will be included.

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.**

No

Research Methodology and Data Sources

*** 1. Will the project involve audio recording?**

Yes

*** 1.a. What will be recorded? How long will the recordings be stored? How will they be stored? Where will they be stored? Who will have access to the recordings? When will the recordings be destroyed? How will the recordings be destroyed?**

Focus group discussions and cognitive interviews will be recorded using a digital audiotape. Recordings will be saved in a restricted UNL OneDrive folder that only the PI, Co-I, trained research assistants (RAs) will have access to. The recordings will be deleted after they are transcribed by Rev.

*** 1.b. Will the audio recordings be transcribed?**

Yes

*** 1.b.1. How will the audio and transcripts be transferred between the research team and the transcriptionist or transcription services organization? Will the audio and/or transcripts contain identifying information? Who is completing the transcription? If being completed by an online service, what protocols are in place to ensure data security? As a recommendation, transcriptionists external to the research team should complete a confidentiality agreement.**

Note

Depending on the sensitivity of the data and the vulnerability of the participants, additional requirements for transcription services may be necessary. A template confidentiality agreement is available on the IRB website.

FG and cognitive interview recording files will be uploaded to REV (a professional transcription service). The recordings will be de-identified by research staff before uploading to Rev. All REV professionals have signed NDAs and confidentiality agreements (see attached).

*** 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?**

Demographic surveys will be completed using qualtrics; data will be sent to a secure UNL onedrive folder. IP addresses will not be collected. Names or other identifying information will not appear on the demographic forms (see Demographic Forms- youth and school personnel). No one but members of the research team [PI, Co-I, research assistants trained by PI Edwards] will have access to the 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?**

Recruitment, as it relates to GDPR, is restricted to the US only and does not apply.

*** 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.

Yes

*** 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.)**

The overall goal of the 5-year project is to conduct both a process and rigorous outcome evaluation of The Set Me Free Projects (SMFP) READY to Stand (RTS) curriculumwith an eye toward widespread dissemination to other U.S. communities, if deemed effective.

The overall project is divided into Components A and B, and three different IRB Phases for IRB approval as follows:
1. Component A, Phase I: Focus groups with students (n = 80) and school personnel (n = 60); cognitive interviews with students (n = 20)

2. Component A, Phase II (Open Pilot Trial/OPT): Survey data from students (n = 878) and school personnel (n = 78) to further refine the surveys and procedures; and

3. Component B, Phase III (RCT): quasi experimental study

The current application is for Component A, Phase 1 aimed at planning and refinement of instruments through FG and cognitive interview data.

To date, no comprehensive, rigorously evaluated primary prevention programs for CSEC exist. Although a handful of programs have been developed to prevent CSEC, they are often awareness-based only programs (rather than skills-based programs), target select groups of youth (e.g., system-involved), seek to prevent revictimization (rather than initial perpetration) or focus on reducing victimization risk only (rather than focusing on perpetrators and/or bystanders), and are rarely (and never rigorously) evaluated. Experts have suggested that CSEC programming focus on healthy and unhealthy relationships, provide youth with general information about sex trafficking, factors related to sex trafficking, and identification of safe people and needed resources. Additionally, programs that include bystander intervention training as well as promoting social norms that protect against violence may help to reduce the incidence of CSEC. Further school personnel are likely critical partners in the prevention of CSEC.

The READY to Stand (RTS) Curriculum (which stands for Report anything dangerous; End the communication; Ask for help; Dont engage; and Your safety first) is a commercial sex trafficking prevention program created for 3rd to 12th grade students and includes programming for school personnel. The RTS for high school students provides students four, 45-minute modules with psychoeducation on CSEC, healthy relationship skills training, identification of safe people and resources, and programming components to enhance valuing of self and others. The RTS will be enhanced with two additional 45-minute modules that focus on bystander intervention training in situations of CSEC and shifting school and community norms to be intolerant of all forms of violence, including CSEC and glamorization of pimp culture.

*** 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.)**

For this phase of the research project (Component A, Phase I: Refinement and Planning), will we collect focus group data from

youth (n = 80 or until saturation is reached) and school personnel (n=60 or until saturation is reached), and cognitive interview data from youth (n=20).

High school students and school personnel associated with one of the eight public high schools (5 traditional and 3 alternative schools) in Des Moines will be included. We will conduct approximately one focus group per school for youth (10 participants per school x 8 schools) and one focus group per school for school personnel (10 participants per school x 5 regular high schools and an additional focus with school personnel from each of the 3 alternative schools.

The focus groups with youth will last approximately 90 minutes and engage youth in a discussion regarding perceptions of commercial sexual exploitation of children (CSEC) in their school and more specifically opportunities for bystander action in situations of CSES as well as social norms regarding the acceptability of CSEC. Youth will also be asked their ideas for how to enhance students engagement in bystander action in situations of CSEC as well as how to create school and community norms that are intolerant of CSEC and foster the belief that everyone has a role to play in ending CSEC. The role of glamorization of pimp culture in CSEC will also be examined as well as perceptions of survey research inquiring about CSEC (after explaining to youth why it is important to ask these questions and how they are used in research). Youth will be asked to provide ideas for ways to enhance safety of youth participation in CSEC research and ways to enhance enrollment and retention of youth in CSEC research (see Focus Group Script_Youth, attached).

The focus groups with school personnel will last approximately 90 minutes and engage school personnel in discussion regarding perceptions of how CSEC impacts students in DMPS and their ideas for the role that school personnel can play in preventing CSEC in DMPS, specifically around modeling programming messages specific to bystander action and shifting community norms to be intolerant of all forms of violence, including CSEC (see Focus Group Script_School Personnel, attached).

After the initial item pools for the survey instruments have been created following focus groups, research advisory input, and an updated and extensive literature review, the researchers will conduct cognitive interviews with students (N=20 across all 8 high schools).These will be used: to ensure that students understand the survey questions, to determine if questions need modifying to be more salient/relevant to the age group and local context, to ensure that the response options are meaningful, etc. More specifically, participants will be asked to read each question and response options aloud. We will ask probing questions such as, tell me in your own words what this means, does this question make sense and if not why, how could we make this question better, etc (see Cognitive Interview Script_Youth, attached).

[The measures that are to be used in the cognitive interview procedures will be submitted via a change request form once they are confirmed through the FG data analyses, lit review, and consultation with the research advisory board].

* 4. Briefly describe the data analysis plan.

All data will be transcribed (by Rev) and then analyzed by trained research assistants/project staff (supervised by Drs. Edwards and Dalla) using thematic analysis. Specifically, More specifically, audio files will be transcribed (using Rev, a speech to text on-line transcriptions service), deidentified by a member of the research team, and then read thoroughly to become familiar with the data. Initial codes are then created that represent the meaning and patterns evident in the data. A codebook is created simultaneously to keep track of the codes. The next step involves reading data again and applying codes to excerpts/passages that correspond to codes. Excerpts that represent the same meaning(s) receive the same code. Next, all excerpts with the same code are grouped together. The codes are then grouped into potential themes; with some themes having sub-themes. Themes are then reviewed and revised, ensuring that each theme has enough data to support it as a distinct concept. Themes are then arranged in narrative communicating results of analysis. Although school personnel data will be analyzed separately from student data, we will examine similarities and differences in themes across these populations. We will also examine variations in themes across subpopulations of students as well as subpopulations of school personnel. Themes will be shared with the research advisory board and their input on how to use this data to inform programming and research will be solicited.

* 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.

Each focus group participant (youth or school personnel) will engage in one ~90-minute group discussion.
Each cognitive interview participant will engage in one ~90-minute one-on-one interview.

* 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.)

Participants will each receive two reminders (via email or text) at one week and 3 days before their upcoming focus group or cognitive interview (see reminder script, attached).

*** 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.**

None

*** 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 PIs (Drs. Edwards and Dalla) have time allocated specifically for this project; research assistants will hired for the project as well as a project coordinator.

*** 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.**

Dr. Edwards will take lead on implementing data safety procedures. Regular study team meetings (e.g., PI, Co-Is, Project Coordinator) will dedicate time to the data safety and monitoring to ensure that all data quality and IRB policies and procedures are being followed. We will ensure that any study staff are following best practices for data storage. The research materials as part of Component A consist of focus group transcripts and interview transcripts. No identifying information will be included in the data. Focus group and individual interviews will be recorded and transcribed. Neither recordings nor transcripts will include names or other identifying information. Upon completion of transcription and data checking, all audio recordings will be destroyed.

We will ensure that all study staff complete CITI training prior to study participation, are aware of appropriate procedures, and are aware that we limit access to data to only study staff that are necessary. As needed, we will consult with IRB for help to ensure that best practices for ethical and safe practice of research are being followed.

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.**

Students and school/district personnel for the focus groups and cognitive interviews will be recruited through word of mouth, fliers posted throughout the schools including staff break-rooms, announcements in school outlets (e.g., school newspapers / school social media), and targeted recruitment through diverse student groups (e.g., Gay Straight Alliance) (see Recruitment Flyer, attached).

The recruitment flier indicates that students and school personnel are both needed for the project. Those interested are asked to contact the project coordinator (PC) who will provide more information, confirm that the individuals are eligible to participate, and then--
IF SCHOOL PERSONNEL:
If the caller is school personnel the project coordinator would move forward to schedule the FC (refer to PC_School Personnel Recruitment script).

IF YOUTH:
PC will determine if they are intersted in the FG or the cognitivie interview, obtain parental/guardian contact information and youth contact information. The PC will then contact the parent/guardian, explain the study, and then send a link to the parental consent form. Once this is received, the PC will contact the youth, schedule the FG or cognitive interview, and send a link to complete the youth assents. (refer to PC_Youth Recruitment script).

*** 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.**

Potential participants will contact the Project Coordinator (PC; see above)
The PC will:
1. Confirm eligibility (i.e., high school student at one of the 8 DMPS schools) or high school personnel aged 18 or more.
2. Answer questions about study.

If potential participant is school personnel, Project Coordinator will then (see PC_School Personnel Recruitment Script):
3a. Schedule the FG with the person;
3b. Obtain preferred contact method for reminder (text or email);
3c. Send link to qualtrics consent form.

If potential participant is a youth, Project Coordinator will then (see PC_Youth Recruitment Scrip):
3a. Determine if youth wants to be involved in Focus Group or Cognitive Interview;
3b. Obtain contact information for parent/guardian; obtain contact information for youth;
3c. Contact parent (via phone; see Parental Contact and Permission Script) to explain the study and their youth's interest in participating (in FG or cognitive interview) and answer questions. If parent is interested in having their child participate, Project Coordinator will send a link (via text or emial) to parent;
3d. Once the parental consent form is received, the Project Coordinator will contact the youth, schedule the FG or interview, and then email or text a link to the youth assent (see Youth_ParentPermissionReceived(PPR) Script).

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 of this research. However, participants may enjoy being part of the study and discussing the topics with others.

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

No

*** 5. Describe the benefits of the research to society, if any.**

The information provided in this research will strengthen the surveys and procedures for Component B-- the evaluation of the prevention program curriculum. Results will be valuable to help keep youth healthy and to prevent the CSEC.

*** 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 risks of this study are minimal. Participants may feel sad or anxious or award when we discuss sensitive topics however, none will be asked about their personal experiences. Instead, this study is intended to obtain perceptions about the issues in Component B (e.g., perceptions of CSEC in their school, school norms regarding the acceptability of CSEC; Focus group data) and to see if the surveys make sense (e.g., "does this question make sense and if not why?", cognitive interviews). A resource page for services in the Des Moines area related to, for example, sex trafficking, sexual violence, homelessness, physical/domestic violence etc... will be provided to each participant. (see Resource Sheet, attached).

Information has been included at the lead in to the FGs indicating that we will not be asking about personal experiences and asking that participants not provide information on personal experiences. If infomation is provided that requires mandatory reporting the following steps will be made:
1. the researcher will contact the PI
2. the PI will report the incident to the proper authorities (most likely Iowa Department of Public Health and/or law enforcement);
3. PI will report incident to IRB

An additional risk is that there is no guarantee that a member of a focus group won't share what is said as part of the focus group. However, we will stress that all information discussed in the FG is confidential and stress the importance of maintaining that confidentiality after the FG is over. Language to this effect has been included in all FG consent forms/assent forms. Because we are not asking about personal experiences, there are no negative consequences or known risks if a breach of confidentiality should occur.

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

No

*** 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.**

Data will be collected within the DMPS school system (library, gym, office, empty classroom). There are counselors on site at each school, as well as trained personnel (teachers, special education instructors, etc...). In addition, we will provide all participants with a list of resources available within the Des Moines community.

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?**

Yes

*** 9.a. Describe the amount and form of compensation. If providing research or course credit, please describe the alternate activity that will be available for students who choose not to participate in the project and still want to receive credit. If a lottery/raffle is offered, please describe the odds of winning and when the winning participant(s) is expected to be notified.**

If the project is supported through a form of funding, including department, internal, or start-up funds UNL accounting requirements must also be met when documenting receipt of participant payments. Describe how UNL accounting requirements will be met, specifically when handling payment receipts that include individual identifying information.

Each person will be provided a $25 gift card; they will sign a form indicating they received the gift card (see attached). These receipts will not be attached to any of the collected data.

*** 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.)**

YOUTH:
1. Project coordinator will go over the key parts of the study (purpose, risks, procedures) with the parent (while on the phone) to make sure they understand, answer all questions, and then email or text a link to the parental consent form.
2. Once the parental consent form is obtained, the PC will contact the youth, schedule the FG or cogn. interview, and send a link to the youth assent form via email or text. Phone number of PI and PC are included on the form with instructions to contact if they have questions.

SCHOOL PERSONNEL:
1. Project coordinator will send (via text or email) the consent form to school personnel.

*** 2. Describe the person(s) who will obtain participant consent/assent.**

The project coordinator will obtain consent, parental consent, and youth assent.

*** 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.**

School Personnel (18+) provide consent for themselves (see attached).

Parents/guardians will provide parental informed consent for their youth. On the consent form, the parent/guardian confirms that they are legally responsible for the youth they are consenting (see attached). After parental consent is obtained, youth will be contacted by PC, questions answered about the study, and then a link to the assent will be emialed or texted.

*** 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.**

SCHOOL PERSONLEL: All school personnel interested in the project will contact the Project Coordinator (PC) who will provide more information about the study and schedule the FG if s/he wants to participate. At that time, a link to the informed consent

form will be emailed (or texted) to the person to complete and submit. (no waiting period).
*If consent has not been received, the PC will remind of this and send a new link when the PC calls for the reminder of the scheduled FG.
*The PC will provide the researchers leading the FG a list of people who have provided consent and who are scheduled for that FG

YOUTH: All youth nterested in the project will contact the Project Coordinator (PC) who will provide more information about the study and determine whether the youth is interested in the FG or cognitive itnerview. The youth will provide contact information for his/her parent/guardian. The PC will then contact the parenta/guardian and explain the study and then email or text a link to the parental consent form if they are willing to allow their youth to participate. Once that has been completed, the PC will contact the youth, schedule data collection, and then send the link (text or email) to the youth to obtain youth assent. (minimal waiting period)
*Cognitive interviews & FG are scheduled after receiving parental consent. The PC will provide the researchers leading the FG a list of youth who have recieved parental consent and provided assent and who are scheduled for that FG. Anyone who arrives without the required documentation completed will be asked to leave.
*The PC will remind the youth about the assent form when s/he calls to remind about the scheduled interview/FG. If the youth still does not complete the assent by the day prior to the interview, it will be cancelled.

*** 5. Describe the primary language that will be used by those obtaining consent.**

English*

*Component A is planning and refinement (information gathering) if it is necessary to obtain consent/parental consent/youth assent in another language (e.g., Spanish) a modification will be sent to IRB in advance.

*** 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.**

English*

*Component A is planning and refinement (information gathering) if it is necessary to conduct a FG (or one-on-one interview); in another language (e.g., Spanish) modifications will be submitted to IRB in advance.

*** 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 UNL 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.**

Audio recordings will be uploaded to a private UNL OneDrive/Sharepoint folder. Only those associated iwth the projec (PI, Co-I, project coordinator or research assistants/staff ON THIS IRB PROTOCOL) will have access to these. Audio recordings will be uploaded to Rev where they will be transcribed. Once transcribed, all audio-recordings will be deleted. Transcript files will be uploaded to a private UNL OneDrive/Sharepoint folder. Only those associated with the project (e.g., PI, Co-I, project coordinator or research assistant) will have access to these.

*** 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.**

The Project Coordinator will maintain a list of all youth and school personnel who participate (as well as contact information-- this is necessary to arrange the Focus Groups and cognitive interviews as well as to send reminders). After participating, all youth and school personnel will also sign a "Research Participant Compensation Confirmation" form. However, none of these identifiers will be associated with the data provided by the research participants.

*** 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.**

A list of names associated with each focus group will be maintained by the Research Team members coordinating the focus groups (to identify who shows up/who does not). However, identifying information will not be associated with any of the focus group data collected. Lists of participants will be kept in separate files from the audio-recordings or transcripts. Lists of participants will be destroyed after data collection (other than participant payment forms kept on file).

The research conducting the one-on-one interviews will also know the name of the youth they are interviewing. However, this information will not be associated with the interview data, but in a separate file for record keeping purposes only.

Data will be stored online 7 years post publication.

*** 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.**

Audio recordings will be kept only until they are transcribed (no more than one year). De-identified transcripts will be kept for seven years and then destroyed.

*** 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 UNL servers vs. external servers possibly utilizing cloud computing must be provided, if applicable.**

A list of names associated with each focus group will be maintained by the Research Team members coordinating the focus groups (to identify who shows up/who does not). However, identifying information will not be associated with any of the focus group data collected. Lists of participants will be kept in separate files from the audio-recordings or transcripts. Lists of names will be destroyed following the completion of data collection although they will be maintained in payment and consent/assent forms).

The research conducting the one-on-one interviews will also know the name of the youth they are interviewing. However, this information will not be associated with the interview data, but in a separate file for record keeping purposes only.

Lists of participants will be kept in a password protected computer by the Project Coordinator and in a private UNL onedrive folder with access limited to project personnel. Participant lists will be kept for 7 years and then destroyed.

Signed consent forms / youth assent forms will be scanned and uploaded to a private UNL Onedrive folder; once scanned the original paper copies will be shredded; parental permission forms will kept in a private UNL Onedrive folder.

*** 5. Describe all persons or entities planning to have access to the records and/or data.**

Only project personnel will have access to the data: Project Coordinator, PI, Co-I, research assistants/staff on this IRB protocol. Rev will have access to the audio-recordings as well in order to transcribe.

*** 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.**

All data will be reported in aggregate form only; names or particpant identifying information will not be used.

Data Monitoring & Sharing

*** 7. Does the project require data safety monitoring?**

Yes

*** 7.a. Describe the provisions for monitoring the data to ensure the safety of participants. For example, in a clinical drug trial study, the data is monitored as it is collected to detect adverse side effects. If participants are having serious reactions to the study drug, then the study is adjusted to protect the participants. A second example would be in a study on teen suicide, if a teen exhibits signs of suicidal tendencies, a process is in place to notify the appropriate people immediately rather than realizing the problem at the end of the study.**

At this point in the project, the research team will be monitoring the data for safety. This will involve de-briefing with all data collectors for both the FGs and cogntive interviews; having at least 2 researchers present at each FG; contacting the PI immediately if any problems or unexpected events arise at the FG or cogn. interviews.

*** 7.b. Identify what data will be reviewed.**

Information provided at the FG and cogntive interviews.

*** 7.c. Describe how often the data will be reviewed.**

The research team will be monitoring the data provided by participants for as the data are being collected (during FG or interviews). The PI will be contacted if any problems are detected (e.g., personal disclosures; individuals showing up without proper consent/parenal consent/assent; upset at the questions or emotional distress).

*** 7.d. Describe what actions would be considered during the review of the data.**

The PI will be contacted immediately. Actions will result depending on what the issue is (e.g., informing that a person was asked to leave a FG because he/she showed up without having received parental consent; pausing the cogntive interview if a break is needed, etc...). All incidents will be recorded. IRB will be notified in cases including, but not limited to: mandatory reporting required, person stopping the FG or cogn. interview because of being upset; person not allowed to participate in FG bc parental consent not obtained.

*** 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?**

No

Note

If data sharing plans change at any time, please contact your IRB coordinator to discuss the necessary steps, as applicable.

Questionnaires, Surveys, and Testing Instruments

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

Focus group script- school personnel
Focus group script- youth
Cognitive interview- youth
Demographics (school personnel and youth)

*Please note that we will come back with a change request form with the surveys for the cognitive interviews, branding for fliers/consents, and other edits after working more with our school partners to obtain their input. We are also in the process of discussing plans for putting together adult and youth advisory boards and will let the IRB know about these as well. Just like other boards in PI Edwards work, these individuals will provide guidance/input on all study protocols that are submitted to the IRB.

**The funded grant proposal is also uploaded.

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.

☒letter of support (2) from Tom for SMF-UNL project TA signed.pdf
☒Edwards CDC proposal 2-1-22.pdf
☒Rev.com Information Security Privacy Overview.pdf
☒Resource Sheet - Des Moines, IA.docx
☒Cogntive Interview Script_Youth.docx
☒Demographics, School Personnel.docx
☒Demographics, Youth.docx
☒PC_Youth Recruitment Script.docx
☒Recruitment Flyer.docx
☒Research Participant Compensation Confirmation.docx
☒Focus Group Scripts_School Personnel (2).docx
☒Focus Group Scripts_Youth.docx
☒Reminder Script.docx
☒Youth_ParentPermissionReceived(PPR) Script.docx
☒Parental Contact and Permission Script.docx
☒Caregiver Consent_Cognitive Interview_11.8.22.docx
☒Caregiver Consent_Focus Group_11.8.22.docx
☒Consent_School Personnel_11.8.22.docx
☒Youth Assent_Cognitive Interview_11.8.22.docx
☒PC_School Personnel Recruitment Script_11.8.22.docx
☒Youth Assent_Focus Group_11.8.22_RWedits.docx
☒Youth Assent_Focus Group_11.8.22_RWedits-Approved.pdf
☒Youth Assent_Cognitive Interview_11.8.22-Approved.pdf
☒Caregiver Consent_Cognitive Interview_11.8.22-Approved.pdf
☒Consent_School Personnel_11.8.22-Approved.pdf
☒Caregiver Consent_Focus Group_11.8.22-Approved.pdf