Health Services/Programmatic Research Protocol Template

(HRP-582 – TEMPLATE – Health Services/Programmatic Research Protocol)

PROTOCOL TITLE:

AccessKCTeen 2.0: Increasing teen access to care using peer social networks and mobile health services.

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IND/IDE NUMBER:

N/A

VERSION NUMBER/DATE:

V8 09/07/2022

V12 12/15/2023

REVISION HISTORY

This Revision History table is provided for the benefit of study team version control. If this table will not be useful please delete it.

Revision #	Version Date	Summary of Changes	Consent Change?
1	11/4/21	Initial submission	
2	2/17/22	Revision	Yes
3	4/18/22	• Removal of the THO arm • Addition of Event Day participants	Yes
4-7	4/26/22	• Peer leader compensation choice • Addition of data collected • Social Media Recruitment • Assent Discussion	Yes
8	7/18/22	• Addition of virtual meetings to gain feedback from Peer Leaders • Change of compensation for Peer Leader • Addition of notification of compensation to Peer Leaders • Addition of retroactively compensating Peer Leaders	Yes
9	8/15/2022	• Change of messaging for Peer Leader participants • Addition of risk for unsecure two-text messages	
10	9/7/2022	• Program activities: Mobile Unit Clinical Care Events • Research activities: Intervention Trail Participants (Event Day Survey)	

		• Event Day Participant: change in wording from study drugs to clinical care medications • Table of Events for enrolled intervention trail participants • 8.0- Event Day Participants study medications to clinical care medications and Event Day Survey	
11	11/16/2022	• Data Collection: Record deidentified data from the electronic health record.	
12	12/15/2023	Adding community partner and letter, adding method to share study information with potential participants	

Table of Contents

STUDY INFORMATION

1.0 Study Summary*

1.1 Synopsis

Study Title	AccessKCTeen 2.0: Increasing teen access to care using peer social networks and mobile health services.
Study Design	Open Clinical Trial
Primary Objective	To evaluate our novel multi-level intervention to increase access to care called TeenHealth Outreach+ (THO+).
Secondary Objective(s)	N/A
Study Population	• Adolescent participants: clinical trial (intervention trial participants as friend network or peer leader) and/or event day participants
	Up to 250 adolescent participants, including up to 40 peer leaders.
Study Duration for Individual Participants	Up to 7 months for adolescent clinical trial participants, event participants complete single survey
Study Specific Abbreviations/ Definitions	(SRH) Sexual and Reproductive Health (MH) Mental Health (CM) Children's Mercy (MHU) Mobile Health Unit

2.0 Objectives*

1. **Purpose, specific aims or objectives:**

To evaluate our novel multi-level intervention to increase access to care called TeenHealth Outreach+ (THO+).

2. **Hypothesis to be tested/Exploratory study design:**

Adolescents receiving THO+ will report that the intervention was feasible. This outcome is assessed at the end of the intervention period (which will be about 6 months after enrollment).

Background*

We propose research to evaluate our novel approach to increase adolescent access to sexual and reproductive health (SRH) and mental health (MH) care during and beyond the COVID-19 pandemic. As adolescents now face new and exacerbated access barriers, we seek to expand our work to evaluate a community-based intervention to ameliorate the negative impact of the pandemic on SRH and MH outcomes.

In the pandemic's wake, ambulatory clinic visits decreased by 71% for youth aged 7-17 years and remain uncharacteristically low. Further, mitigation efforts reduced youth engagement with schools and community programs, limiting opportunities for outreach and linkages to care. Decreased access is of particular concern for groups with long-standing disparities. Pre-pandemic, racial and ethnic minority adolescents had higher rates of sexually transmitted infections and unintended pregnancy and reported more persistent or severe mental illness. Consistent with national trends, adolescents in our pilot work reported increased pandemic-related stress, and many also reported sexual risk-taking. They also had unmet needs for SRH and MH care as typical pathways to care have been severed, raising concerns that existing disparities may worsen.

One challenge in responding to COVID-19 is that novel models for care delivery, such as telemedicine, are less likely to be used by those with limited familiarity and those not already connected to care. Mobile health units (MHUs) hold promises to reach adolescents in need of care. However, MHUs are often hosted at schools. In many regions, including ours, adolescents have been physically absent from most schools for more than eight months. Interventions that leverage adolescent social networks to share health information and resources with peers have been successful in reducing substance use and MH risk factors. To build on this work, we propose engaging with peer leaders, connected to

trusted community organizations, to share tailored information about SRH, MH, and novel, community-based, care sources within their networks.

Study Design

Study Design: Open Clinical Trial

PROGRAM ACTIVITIES:

AccessKCTeen 2.0 is an outreach program that deploys Children Mercy's Staff and Mobile Unit into the community to increase access to SRH and MH care and resources. *AccessKCTeen 2.0* will focus on education, peer leaders, and community partnership. All events are optional for adolescents to attend.

Mobile Unit Demonstration Events: The CM mobile unit will go to community sites where members of the CM *AccessKCTeen* team will do the following: provide education on telemedicine, SRH, and MH, answer questions on accessing care, SRH, and MH, and help adolescents get registered for telemedicine or other care at CM.

Mobile Unit Clinical Care Events: The CM mobile unit go to community sites where members of the CM *AccessKCTeen* team will provide direct clinical services, such as testing for infections or pregnancy, birth control counseling, and birth control.

Any teen can attend these events. If they choose to attend an event, they must enroll in our Event Day Survey, to receive clinical medications (e.g., emergency contraception, birth control pills, birth control patch) or testing as this is a requirement for pharmacy documentation. This survey will ask for contact information which is required to track clinical medications and provide testing results.

THO+: Teens as part of a friend network, where peer leaders in each network work with health professionals and trusted adults to connect adolescents in their networks to health information and sources for care.

RESEARCH ACTIVITIES:

INTERVENTION TRIAL PARTICIPANTS:

All adolescents will have access to THO+ activities and materials shared by the peer leaders.

All adolescents will be asked to complete an eligibility screening survey and baseline survey online or in-person. They will complete short surveys at 2, 4 and 6 months via Twilio text, call, or email.

PEER LEADER

We will enroll up to 40 Peer Leaders. In addition to the above activities (under intervention trial participant), if a teen is a "peer leader" they will attend a training session in-person or online with our study team to learn about sexual and mental health information and how to share information with their friends (like text or social media). The peer leaders will answer the same surveys described above and will be asked about their Peer Leader experience and how they are sharing the study health information. The Peer Leader will complete check-ins online, in-person, or through text message to gain feedback on their participation.

EVENT DAY TRAIL PARTICIPANTS

Adolescents not already in the trial as interventional trail participants who attend demonstration and clinical care and have received clinical medications or testing. They have the option to be consented for a single survey.

3. Table of Events for enrolled intervention trial participants:

	Completed at enrollment	Mobile unit event (optional)	Completed after enrollment
Eligibility Screen (Survey Measures Interventional Subjects and Mobile Unit Event)	X	X	
Informed Consent	X	X	
Contact Information (Survey Measures Interventional Subjects)	X		
Baseline Survey (Survey Measures Interventional Subjects)	X		
Event Day Survey (administration of clinical cares to possibly include clinical care medicine and testing)		X	
2-month Follow-up survey (Intervention Measures)			X
4-month Follow-up survey (Intervention Measures)			X
6-month Follow-up survey (Intervention Measures)			X

Research Interventions*

4. Description:

- This intervention will examine the impact peer leaders have in mobilizing their networks to engage in health events and care for MH and SRH. We will examine intervention feasibility. We will examine our primary outcome through surveys.

SUBJECT MANAGEMENT

6.0 Inclusion and Exclusion Criteria*

2.

1. **Eligibility Criteria**:

(1) INTERVENTION TRIAL PARTICIPANTS (ADOLECENTS)

Inclusion Criteria

- Aged 14-18 years and 364 days old

a. **Exclusion Criteria**

- Younger than 14 years old or older than 18 years and 364 days at the time of enrollment
- Does not speak/understand English
- Not recruited from an already nominated or enrolled adolescent

(2) Event Day Trail PARTICIPANTS (ADOLECENTS)

Inclusion Criteria

- Aged 14-18 years and 364 days old
  - **Exclusion Criteria**
- Younger than 14 years old or older than 18 years and 364 days at the time of enrollment
- Does not speak/understand English

2. **Equitable Selection***:*

1. Adolescents within the social networks of enrolled adolescents will be selected for our sample population since peer networks heavily influence adolescents' health behavior choices. Peer networks that diffuse reliable information and positively influence norms have efficacy in connecting under-resourced adolescents to care.

3. **Vulnerable Populations:** *Check any vulnerable populations <u>that are being targeted</u> for enrollment into the study: (Members of the following populations may not be included as participants in the research unless selected here.)*

☐ Children/Minors (under 7 years of age)

☒ Children/Minors (7-17 years of age)

☐ Neonates (infants less than 30 days old)

☐ Neonates of Uncertain Viability (infants less than 30 days old)

☐ Non-Viable Neonates (infants less than 30 days old)

☐ Wards of the State

☐ Fetuses

☐ Pregnant Women

☐ Adults with impaired decision-making capacity

☐ CM Employees

☐ CM Students/Residents/ Fellows

☒ Economically or Educationally Disadvantaged Persons

☐ Prisoners

<u>Children/Minors (7-17 years of age):</u> Our research involves no more than minimal risk to children aged 7-17 years. To participate in this research study, adolescent participants must be between the ages of 14-18 years and 364 days of age. For adolescents this age, guidelines from national medical organizations support allowing for waiver of parental permission for minimal risk studies to support adolescent autonomy and since teens have the capacity to understand and consent for research studies. Adolescents will be provided as much time as they want to make their decision and can involve a trusted adult if they so choose. Further, state laws enable adolescents to have access to confidential SRH and MH care and to make decisions regarding their care. Because of this, we are requesting a waiver of parental permission to help maintain confidentiality around sensitive health care and to follow best practices to support adolescent autonomy.

<u>Economically or Educationally Disadvantaged Persons:</u> Our research is designed to address health disparities; thus, we involve communities experiencing these disparities such as those

that are economically disadvantaged. We are mindful of the history of abuse experienced by some of these communities regarding research participation. We will follow best practices for engaging in research with disadvantaged communities which include involving community members in research design and implementation (as planned for our community action boards) and acknowledge the important contributions of community members by providing appropriate gift cards or tokens of appreciation (refreshments) and bringing the study findings back to stakeholders.

7.0 Local Number of Subjects

1.

    1. We will enroll up to 250 adolescents in the trial. Of these, up to 40 will be asked to participate as peer leaders.

8.0 Identification and Recruitment of Potential Participants*

2.

    1. **Identification of Potential Participants:**

How will participants be identified? (Check all that apply)

☐ Chart reviews

☐ By their treating physician who will then provide the study team's contact information to the potential subject/family

☐ By their treating physician who will obtain patient/family permission to share contact information with the study team

☒ By a partnering community-based organization who will then provide the study team's contact information to the potential subject/family

INTERVENTION TRIAL PARTICIPANTS:

Community organizations and partners will be given a paper or digital flyer (*titled Peer Leader Flyer*) about the program and see if any adolescents are interested. They will then let a study team member know which adolescents would like to be in the study. A study member will approach the interested adolescents to see

if they would like to be a part of the study. After interested adolescents are enrolled, adolescents will turn to their social networks to recruit more adolescents to participate in the trial. After networks are formed, networks in the THO+ arm will nominate a peer leader to work with our team to disseminate health information related to SRH and MH.

Event Day Participants

Community organizations and partners will host our team and may share information through their own networks. A study team member will approach teens who are interested in receiving clinical care medications or testing at events. If they choose to receive clinical care services they must enroll as an Event Day participant.

We will create a QR code that community partners may share with potential event day participants. Once scanned, the code will reveal this text:

Get healthy with Children's Mercy!
We hope to talk with you about our study to learn about getting care on a mobile health unit.
Your health and your voice matter!

☐ By a partnering community-based organization who will obtain patient/family permission to share contact information with the study team

☒Self-refer in response to IRB approved advertisements or websites

☐ Through Cerner or other CM sources (e.g. databases, billing records, pathology reports, admission logs, etc.) May involve access of records by individuals not involved in the patient's care.

☐ List of candidates provided through the Data Report Request Form

☒ Registry of individuals interested in research opportunities

INTERVENTION TRIAL PARTICIPANTS:

Community organizations and members of our CAB can give study staff a list of interested adolescents who we can contact to participate in this program.

☒Past subject list

☐ Participants will roll-over from another research study: Study #_____

☒ Other: __

2. Pre-Screening prior to HIPAA Authorization

Will any of the identification methods checked above involve access to Protected Health Information (PHI) prior to obtaining HIPAA Authorization?

☐ Yes

☒ No

If yes, a "Partial Waiver of HIPAA Authorization" is required. Be sure to make this selection in the "HIPAA & Confidentiality" section below and complete ***Addendum E: Waiver/Alteration of HIPAA Authorization***

3. Recruitment of Potential Subjects:

1. *Describe when, where, and how potential participants will be recruited.*

INVERVENTION TRIAL PARTICIPANTS: Community organizations and partners will be given a paper or digital flyer (*titled Peer Leader Flyer*) about the program and see if any adolescents are interested. They will then let a study team member know which adolescents would like to be in the study. A study member will approach the interested adolescents to see if they would like to be a part of the study. After interested adolescents are enrolled, adolescents will turn to their social networks to recruit more adolescents to participate in the trial. After networks are formed, networks will nominate a peer leader to work with our team to disseminate health information related to SRH and MH.

A Children's Mercy social media account will be used in accordance to CMH requirements if needed to facilitate follow-ups for AccessKCTeen surveys, and to inform Peer Leaders of AccessKCTeen events for them to share with their peer networks for recruitment.

a) *ADOLESCENT INTERVENTION TRIAL PARTICIPANTS:* We will develop a digital or paper flyer *(titled Peer Leader Flyer)* about participation in this research study that will be distributed to our community partners and enrolled adolescents.
   - Adolescents will not be contacted more than three times for initial study participation. For each follow-up survey, study staff will make up to three attempts to reach these teens by phone, text (reminder of appointment for survey through Twilio/Spark or CM approved messaging), and/or email.

b) *ADOLESCENT EVENT PARTICIPANTS:* We will recruit adolescents using paper or digital information sheets on the day of the event. We will create a QR code that community partners may share with potential participants. The text will read:

   Get healthy with Children's Mercy!
   We hope to talk with you about our study to learn about getting care on a mobile health unit.
   Your health and your voice matter!

9.0 Surveys and Psychometric Testing:

- *Describe any surveys or psychometric testing that will be conducted as part of the study. Address whether the instruments used have been previously validated.*
    - *INTERVENTION TRIAL PARTICIPANTS:* Surveys include:
        - (*Titled Survey Measures Interventional Trial Participants*) Eligibility Screen, contact form, baseline survey
        - *(titled Survey Measures Intervention Trail Participant)*: 2, 4, 6 follow-up
        - Event Day Survey Measures (optional).
        - Surveys will include both closed-ended and open-ended questions (see table below). When possible, we will use previously validated measures.
        - Peer Leaders in the THO+ arm will complete check-ins by text message, on-line or in-person.

    - ADOLESCENT EVENT PARTICIPANTS: Survey (*titled Event Day Survey Measures*) at the event day survey (optional).

Feasibility constructs (Bowen et al.) and sample measures		
Construct	**Source**	**Sample Measure***
Acceptability - How do stakeholders react?	Adolescent	Satisfaction**; Recommend to friends**;
Demand - To what extent is the intervention likely to be used?	Adolescent	Likelihood to use again**; proportion of friends who would use
Implementation - To what extent can the intervention be implemented as planned?	Adolescent	Engagement**; "What toolkit ideas worked well/not so good?"
	Study Record#	Fidelity to peer leader training, engagement, attendance
Practicality - What factors make intervention delivery challenging or facilitate delivery?	Adolescent	Ease of talking with friends about health**
	Study Record#	Field notes

Integration - To what extent can intervention be integrated within community?	Adolescent	Frequency of network health information exchange** "What was it like to learn about SRH/MH health at community partner?"
Expansion - To what extent can model be expanded?	Adolescent	Openness to vaccine information using intervention**
Limited efficacy - Does the intervention show promise?	Adolescent, Study/Medical Record#	Health care utilization (yes/no; also where accessed, what type);[74] new patient registration (yes/no); care-seeking intention**
*Appendix has complete list of closed- and open-ended items; **Likert responses range from 1 ("strongly disagree") to 5 ("strongly agree"); #Additional assessments: proportion enrolled, attendance for study activities		

- *List the names of each instrument (survey, questionnaire, test, etc). Upload copies of any surveys, psychometric tests, or other instruments that will be administered for research purposes in the myIRB application, Other Attachments section.*
    - We will submit the following attachments:
        - *INTERVENTION TRIAL PARTICIPANTS:* Survey Measures for intervention participants (titled *Survey Measures Interventional Trial Participants*) includes Eligibility Screen, Contact Information and Baseline Survey, (titled *Survey Measures Interventional Trial Participants*), includes 2, 4, 6 Follow-Up Survey and Event Day Survey Measures (optional)
        - ADOLESCENT EVENT PARTICIPANTS: Survey Measures for Event Day Participants includes Eligibility Screen, Contact Information (titled Event Day Survey Measures) (optional).

10.0 Additional Research Activities

N/A

11.0 Follow-up

c) *INTERVENTION TRIAL PARTICIPANTS: Adolescents* will interact with us for 6 months as this is the duration of the intervention period. After *enrollment*, adolescents will complete a follow-up survey at 2, 4, and 6 months. Study staff will make up to three

attempts to contact the participant and the follow-up survey will be administered via phone call, text message (Twilio/Spark) or Email.

d) Event Day Participants: N/A

12.0 Genetic Analysis Information

13.0 Sharing of Results with Subjects

3.

1. *Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with participants or others (e.g., primary care physicians) and if so, describe how the results will be shared. See Research Documentation in the Electronic Health Record for details on what must be included in the EMR.*

We intend to share study results with participants and community partners through informational meetings and flyers and other forms of communication used by partners (email, newsletters).

We intend to share study results in the academic community though presentations and a peer-reviewed publication.

We will share only aggregated results, never any individual subject results.

14.0 Risks to Subjects*

- Risk of emotional distress: Participants may experience increased stress over survey questions asking about mental or sexual health. However, we feel this risk is minimal and will include information in the consent process that reminds participants that they are not required to answer questions that make them feel uncomfortable. We will have a list of other community resources for participants needing services. During the consent process, we will inform participants that most of the information they share during the study will be kept confidential except in rare cases where their safety is at risk or mandated reporting is in effect.
- Risk of Unsecure two-way texting: Participants and member of the community have a risk of breach of confidentiality when using two-way messages. Information security is a top priority for both the investigators and the hospital. When any PHI (name, address, date of birth etc.) or sensitive information is received through an unsecure two-way messaging platform, a member of the research team will contact the participants or members of the community directly by phone call to gather all information on a secure platform.

- Risk of breach of confidentiality: There is potential for loss of confidentiality. Information security is top priority for both the investigators and the hospital. We believe that all identifying and clinical information will be secure, and a security breach is highly unlikely to occur. We will store participants' names and contact information on a REDCap project accessible only to the study team. Name and contact information will be kept on a separate REDCap instrument within the main project and marked as "identifiers". Thus, data downloaded for analysis will not include any identifying information, and all names and phone numbers will be destroyed at the end of the study.

We believe the risks involved in this study are minimal.

- *If applicable, indicate which activities may have risks to the subjects that are currently unforeseeable.*

N/A

- *If applicable, indicate which activities may have risks to an embryo or fetus, should the participant be or become pregnant.*

N/A

- *If applicable, describe risks to others who are not participants (e.g. pregnant partner of a male subject)*

N/A

15.0 Potential Benefits*

- *Describe the potential of any direct benefits that individuals may experience from taking part in the research. Include the probability, magnitude, and duration of the potential benefits as this will be useful to the IRB in making their risk/benefit determination.*

  There may be no direct benefits to participating in this study. Some participants may benefit from learning about health information and care sources in their community.

- *Describe the potential of any benefits to society/science or others related to the possible knowledge gained.*

  The knowledge gained from this study will help inform future local efforts aimed to connect teens in Kansas City to the healthcare they need and will inform the wider scientific/public health community of opportunities and effective strategies for integrating peer leader and mobile health intervention models.

16.0 Investigator Assessment of Risk/Benefits Ratio*

16.1 Please provide an assessment of risk and benefits in the table below. Note, the IRB makes the final determination based upon responses in the two preceding sections.

Select as applicable:	**Pediatric Risk Category:**	
☒	Category 1	Research not involving greater than minimal risk (45 CFR §46.404 and 21 CFR §50.51)
☐	Category 2	Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. (45 CFR §46.405 and 21 CFR §50.52)
☐	Category 3	Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. (45 CFR §46.406 and 21 CFR §50.53)
☐	Category 4	Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. (45 CFR §46.407 and 21 CFR §50.54)
Select if applicable:	**Adult Risk Category:**	
☒	Not Greater than Minimal Risk	
☐	Greater than Minimal Risk	

17.0 Payment, Reimbursement and Tangible Property provided to subjects*

Is payment, reimbursement, or tangible property part of the study?

☒ Yes ☐ No *(If No, delete the following subsections)*

- ***Payment to Subjects:*** *If providing payment for participation (e.g., cash equivalent for participation, payment for time off work), select the form of payment:*

☒ Greenphire/ClinCard (will be used for in

☒ Gift Card: (Merchant: Rybbon electronic cards will be used as a primary compensation method. Physical Target/Walmart cards may be used for teens that prefer physical gift cards over electronic)

☐ Other: _____

Note: "Gift Card" and "Other" options require approval by Research Administration. Upon submission in myIRB, ORI staff will initiate the Research Administration approval process.

Payment Schedule: Describe the payment schedule (if the payment schedule is involved, consider using a table to display this information) including:

Intervention Trial Participants: Adolescents will have an opportunity to receive up to $60. They will be given a $30 gift card after completing the baseline survey. A $10 gift card will be given for each follow-up survey that is completed at 2, 4, and 6 months after enrollment.

Peer Leaders: Teens can choose to earn an additional $225 for being a peer leader or they can choose to earn up to 30 hours of academic volunteer or community service hours.

Teens that choose to earn an additional $225 for being a peer leader will receive $100 for Peer Leader Training, $25 recruiting the first teens to the research study and $ 5 for each teen recruited after the first teen (Maximum of $50 for 10 additional friends enrolled), and they will get up to $5 for each text message check-in or virtual meeting check-in ($50 for up to 10 check-ins).

All Peer Leaders enrolled prior to protocol version 7.18.2022 will be contacted via phone and notified of compensation changes. The notification of change of compensation for Peer Leader participants will be documented in REDCap under the note section. For those who have already enrolled more than one friend will be retroactively compensated following the new compensation changes.

Teens can earn up to 30 hours of academic volunteer or community service hours for participating in the training, Peer Leader virtual meeting check-ins, helping study staff to prepare for events (inventory, setup and takedown), attending events, text message check ins, and recruiting other teens to enroll in the study.

For teens who choose academic volunteer or community service hours, they must follow the guidelines of their academic institutions to ensure the hours gained through AccessKCTeen 2.0 would count towards their requirement. If their academic institution does not allow the volunteer or community service hours, they have the option to join the research study and earn up to $225 (as listed above) for their participation.

Teens will have the flexibility to change the type of compensation received, (up to $225 or Academic Community Service Hours) at any time during the study.

Event day Participants: Adolescents will have an opportunity to receive study medications and/or testing. At demonstration events, they may receive emergency

contraception for future use. At clinical events, they may receive contraception (emergency contraception, depo-provera, birth control pills/patch) and/or testing for pregnancy/sexually transmitted infections.

- **Tangible Property:** If *providing tangible property or any item of value given for participation (e.g., a toy, a tote bag, a water bottle, an electronic device), describe:*
  - *The item(s) to be offered to research participants at some of the mobile unit events include the following:*
  - *Demonstration event:*

    Emergency Contraception Plan B (Levonorgestrel) for future use

  - *How and when will the item(s) be distributed*

    This item will be given to any research participant who feels the need to have it after a mobile unit event (optional)

  - *The estimated total maximum value of the item(s).*

    *$**19***

  - *Clinical event:*
  - ***Emergency Contraception Plan B (Levonorgestrel); birth control pills/patch/depo shot, testing for pregnancy and/or sexually transmitted infection.***
  - *How and when will the item(s) be distributed*

    These items will be given to any research participant who wants to start medication or get tested at a clinical event (optional)

  - *The estimated total maximum value of the item(s).*

    Emergency contraception = $19

    birth control pills = $78.80

    birth control patch= $113.60

    depo shot= $37.81

    testing for pregnancy =$15.26

    testing for Chlamydia=$115.33

    Testing for Gonorrhea=$24.69

- *If the estimated total maximum value of payment and/or tangible property provided to an individual subject may exceed $600, include plans for the collection of Social Security Number (SSN) or Individual Tax Identification Number (ITIN) per CM policy.*

18.0 Compensation for Research-Related Injury

4.

- *If the research involves more than Minimal Risk, describe the available compensation in the event of research related injury. NOTE: For industry sponsored studies, this must match the agreed upon language in the Clinical Trial Agreement (CTA).*

N/A

19.0 Economic Burden to Subjects

5.

- *Describe any costs that participants may be responsible for because of participation in the research. This may include transportation to appointments, time away from work, parking, additional lab tests, et cetera.*

N/A

20.0 Parental Permission and Adult Consent Process*

20.1 Indicate below all methods of Permission/Consent that will be used in this study.

- *If the study includes **multiple study groups**, be sure to indicate which method is being used with each group.*
- *If requesting a **Waiver of Documentation**, a complete **Waiver**, or an **Alteration**, complete the required regulatory addendum noted below.*

Waiver of Documentation of Permission/Consent

Permission/Consent form provided but signature will **NOT** be obtained (e.g. verbal consent)

Must complete *Addendum A: Waiver of Documentation of Permission/Consent*

☐ **Waiver of written documentation of permission of parent/LAR for pediatric participants** N/A

☒ **Waiver of written documentation of consent of adult participants**

Study group(s) to which this method applies: We will obtain ***verbal*** consent for any participants who are aged 18 or older upon enrollment. This includes adolescents that may be 18 years and 364 old upon enrollment and adult stakeholder participants.

☒ **Waiver of written documentation of consent of participants turning 18**

Study group(s) to which this method applies: (Active Participants) Any adolescent turning 18 during the study participation still actively participating in study activities. In the case a participant turns 18 from the time of the baseline survey through the time of the follow-up surveys, we will complete ***verbal*** adult informed with that participant before the 2, 4, 6-month follow-up call.

Waiver or Alteration of Permission/Consent

Adult consent will **NOT** be obtained, or you propose to alter a required element of consent.

Must complete *Addendum B: Waiver of Permission/Assent/Consent*

☒ **Waiver/Alteration of permission of parent/LAR for pediatric participants**

Study group(s) to which this method applies: All parents of adolescents between the ages of 14-17.

☐ **Waiver/Alteration of consent of adult participants**

Study group(s) to which this method applies:

☒ **Waiver of consent of participants turning 18**

Study group(s) to which this method applies: (Non-Active Participants) Adolescent participants that turn 18 during the study and have completed study activities for the continued access to and use of identifiable data.

Additional Methods

☐ **Obtaining permission/assent/consent of non-English speaking parents or participants**

Must compete *Addendum C: Non-English Speaking Subjects*

Study group(s) to which this method applies:

☐ **Surrogate decision maker consent form adults not capable of consenting for themselves**

Must complete *Addendum D: Surrogate Decision Maker Consent*

Study group(s) to which this method applies:

20.2 Permission/Consent/Consent at 18 Discussion: *If selected options for "Written" or "Waiver of Documentation" above, describe below how the informed permission/consent discussion will be conducted. Describe:*

- *Where and when the discussion will take place.*
- *Steps that will be taken to minimize the possibility of coercion or undue influence.*
- *Any supplemental materials that will be used to enhance the discussion (e.g. videos, sent, educational pamphlets).*
- *Any measures that will be taken to ensure that parent(s)/LAR have adequate time to ask questions and decide if they will permit their child to participate in the study (e.g., providing a copy of permission form in advance of visit).*
- *How comprehension of the permission form will be verified (e.g. teach back).*
- *If obtaining permission via telephone, confirm CM research policy will be followed.*
- *Process to ensure ongoing consent during the study.*

Intervention Trial Participants:

For adolescents**,** we will review a study information sheet in-person or online (*titled Study Information Letter for Intervention Participants).* This info sheet will be available for the participant to keep. We will use a teach-back method to ensure participant understanding and ensure that the participant has the opportunity to ask questions before agreeing to participate.

20.3 Documentation of Permission/Consent/Consent at 18: *If selected "Written" options above, explain how informed permission will be documented. Describe:*

- *Whether CM Research Policy "10.04 Obtaining Permission/ Assent/ Consent" and "Research Documentation in the Electronic Health Record" will be followed. If not, describe whether and how permission of the parent(s)/LAR will be documented in writing.*
- *Whether e-Consent will be used to document permission (non-FDA regulated studies only).*

N/A

20.4 Identification of participants turning 18: Explain *the process for tracking participants to ensure that consent is obtained to continue participation once they turn 18 years of age.*

INTERVENTION TRIAL PARTICIPANTS: We will build a REDCap alter to indicate to study staff on the Event Daysurvey (optional) and on the *Survey Measures Interventional Trial Participants* follow-up surveys whether the adolescent has turned 18 since the baseline survey according to their date of birth. If yes, we will proceed with adult consent processes and record having done so in the REDCap survey. If the participant attends a mobile unit event and has turned 18, they will be re-consented in-person at the event. If they have turned 18 by the follow-up surveys, they will be re-consented over the phone.

21.0 Assent of Pediatric Subjects

21.1 Select the option(s) that apply to the study:

☐ **Obtaining assent of pediatric participants is NOT POSSIBLE due to:**

☐ The *capability of the participants (considering the ages, maturity, physical and/or psychological state) is so limited that they cannot reasonably be consulted.*

☐ The *intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the participants and is available only in the context of the research.*

☐ **Obtaining assent of pediatric participants is NOT PRACTICLE given the context of this study** (e.g., minimal risk, no direct contact with subjects).

Must complete *Addendum B: Waiver/Alteration of Permission/Assent/Consent*

☒ **Assent of pediatric participants WILL BE SOUGHT following assessment of ability to assent: Waiver of written documentation of assent of pediatric participants (ages 14-17)**

.

21.2 Assessment of Ability to Assent*: If seeking assent from pediatric subjects, describe how the ability to assent will be determined.*

Intervention Trial Participants: Adolescents will have to be at least 14 years of age or older to participate. Study staff will determine ability to provide assent in similar manner as with adult consent.

21.3 Assent Discussion: *If seeking assent from pediatric participants, explain how the assent discussion will be conducted. Describe:*

- *Where and when the discussion will take place.*
- *Steps that will be taken to minimize the possibility of coercion or undue influence.*
- *Any age-appropriate supplemental materials that will be used to enhance the discussion (e.g., videos, eConsent, educational pamphlets).*
- *Any measures that will be taken to ensure that pediatric participants have adequate time to ask questions and decide if they want to participate in the study.*
- *How comprehension of the study will be verified (e.g., teach back).*
- *If obtaining assent via telephone, confirm CM research policy will be followed.*
- *Process to ensure ongoing assent during the study.*

The minor adolescents (ages 14-17) will be asked to provide ***verbal*** assent after the study is explained in detail in person. We will follow best practice guidelines established for adolescent participation in health research. This includes building a research team that is specially trained to work with adolescents, using age-appropriate language that is easy to understand and allowing adolescents ample time to consider participation and

ask questions. We will clearly state that participation is voluntary. Potential adolescents will be asked if they understood the information and if they have any questions.

For those adolescents who enroll virtually they will be provided with the study information sheet (titled Study Information Letter for Intervention Participants) from our REDCap to review by themselves. If the participant has any questions about the study, they can contact the PI listed on the information sheet or the research staff over the phone to ask questions prior to completing the study. If the adolescent does not have any questions about the study, they will use REDCap to agree to the study.

21.4 Documentation of Assent or Inability to Assent: If *seeking assent from pediatric participants, explain how assent, or a determination of inability to assent, will be documented. Describe:*

- *Whether CM Research Policy "10.04 Obtaining Permission/ Assent/ Consent" and "Research Documentation in the Electronic Health Record" will be followed. If not, describe whether and how assent, or inability to assent, will be documented in writing.*
- *Whether e-Consent will be used to document assent (non-FDA regulated studies only).*

For this mature group of minors (ages 14-17), we wish to document assent or inability to assent similarly to how we will document adult consent. Study staff conducting assent will document within REDCap that the participant indicated they understood all study procedures, had the ability to answer questions, and agreed to participate. However, we will not be collecting signatures.

22.0 HIPAA and Confidentiality

HIPAA regulations apply to this study if the data used or accessed relates to:

The past, present or future physical or mental health or condition of an individual; The provision of health care to an individual; OR The payment for the provision of health care.

22.1 HIPAA Authorization

Select all applicable methods of HIPAA Authorization that apply to this study.

☐ Full Written HIPAA Authorization will be obtained (within the p/a/c form or standalone form)

☐ Partial Waiver of HIPAA Authorization (e.g., waiver for recruitment and pre-screening purposes only)

Must complete *Addendum E: Waiver/Alteration of HIPAA Authorization*

- *Describe the PHI for which use, or access is necessary for research.*

☒ Alteration of HIPAA Authorization (some but not all required elements of an Authorization are present, e.g., signature will not be obtained)

Must complete *Addendum E: Waiver/Alteration of HIPAA Authorization*

- *Describe which proposed elements to be altered.*

We will not obtain a signature from adolescents

☐ Waiver of HIPAA Authorization (authorization will NOT be obtained)

☐ If Other, explain:

22.2 Indicate how the research team will protect the confidentiality of subjects' data during storage, use, and transmission (e.g., training, authorization of access, password protection, encryption, physical controls, and separation of identifiers and data [master list]). Remember: Sensitive CM data, including research data, must be stored on a file server on the CM network domain – not on a workstation hard drive.

We will store all data in REDCap on a CM secured device. Signatures on paper will not be obtained to avoid obtaining written PHI.

22.3 State whether a Certificate of Confidentiality has been issued for this study. Certificates are automatically issued for NIH funded research per *NIH policy. For non-federally funded research involving identifiable, sensitive information, investigators may apply for a Certificate if desired. See the NIH website on Certificates of Confidentiality for more details.*

This study is funded by the NIH and therefore is automatically provided a certificate of confidentiality.

23.0 Provisions to Protect the Privacy Interests of Subjects*

23.1 Describe the steps that will be taken to protect subjects' privacy during recruitment and while obtaining permission/assent/consent. For example, best practice is to obtain permission/assent/consent in a separate area where a private conversation can be had. If this is not possible, be sure to explain what steps will be taken to provide as much privacy as possible.

Assent/consent will be collected one-on-one in-person or virtually with all adolescents. For adolescents, study staff will make sure potential adolescent participants have access to privacy remotely or in-person.

23.2 Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.

Adolescents will be contacted by study staff with experience working with adolescent research participants. They will be told about the study and given as much time as necessary to decide if they want to participate. We will ensure that adolescents know they are free to choose whether to participate in all study-related activities and surveys.

23.3 Indicate how the research team is permitted to access any sources of information about the participants and how the research team will protect the confidentiality of the data.

We will input all survey data into REDCap that is on a secured server.

24.0 Withdrawal of Subjects*

24.0 Describe anticipated circumstances under which participants will be withdrawn from the research without their consent.

N/A

24.1 Describe procedures that will be followed when participants are withdrawn from the research, including data retention plans or partial withdrawal from procedures with continued data collection.

For adolescents that do not complete the follow-up surveys, we will still use their baseline data for analysis. Their contact information will be destroyed after the third attempt to reach them.

DATA MANAGEMENT

25.0 Data Collection*

6.

1. *Provide a general description of the types or categories of data that will be collected during the study (e.g., lab test results, procedure outcomes, length of stay, questionnaires, surveys). Details on identifiable data and sensitive data will be described below:*

- Survey data through REDCap
- For those receiving Clinical Care there will be data collection for feasibility of the mobile unit for the following: Biological Sex of Patient, Age of Patient, Participation in Pregnancy test, STI testing for gonorrhea/chlamydia (urine), and STI testing for HIV and Syphilis (blood). Results for the following: pregnancy test, STI test results for gonorrhea/chlamydia/HIV/syphilis (urine and blood). Record of if birth control was received and which type. Record of Condoms taken. Record if referral to Children's Mercy Hospital Adolescent or Teen Clinic was given. All services are optional for teens. All information collected will be de-identified.

2. *Describe the source of the data and how that data will be obtained.*

- All data will be collected directly from participants by entry into redcap via ipad, phone call, text (Twilio), or email.

3. **Sensitive Data:** If *collecting or accessing sensitive data which may pose legal, economic, or reputational harm, please specify here.*

   N/A

4. **Identifiable Data:** *To minimize risks, only the minimum necessary identifiable data should be accessed and/or recorded. Indicate below which identifiable data elements will be accessed only versus which data elements will be recorded, i.e., written down for the purposes of this research study.*

Names, phone number, and email addresses will be recorded for the purposes of the 2-, 4- and 6-month follow-up phone calls. We will also record phone numbers to send text messages to engage peer leaders. Date of birth will be recorded to assess the age of intervention trial participants. Zip codes will be recorded to identify if we are serving economically, or disadvantage youth based on their location.

a) Name/Initials	☐ Accessed only	☒ Recorded
b) All elements of date (except year) directly related to an individual (e.g. date of birth, admission date, discharge date, date of death)	☐ Accessed only	☒ Recorded
c) Medical record number	☒Accessed only	☒ Recorded
d) Account number	☒ Accessed only	☐ Recorded
e) Health plan identification number	☐ Accessed only	☐ Recorded
f) Social Security Number	☐ Accessed only	☐ Recorded
g) Device identifiers and serial number	☐ Accessed only	☐ Recorded
h) Certificate/License number	☐ Accessed only	☐ Recorded
i) Telephone number	☐ Accessed only	☒ Recorded
j) Fax number	☐ Accessed only	☐ Recorded
k) Email addresses	☐ Accessed only	☒ Recorded
l) Web addresses (URLs); Internet IP addresses	☐ Accessed only	☐ Recorded
m) Street address, city, county, precinct, zip code or equivalent geographical codes	☐ Accessed only	☒ Recorded
n) Full face photographic images and any comparable images	☐ Accessed only	☐ Recorded
o) Biometric identifiers, including finger and voice print	☐ Accessed only	☐ Recorded
p) Vehicle identifiers and serial numbers, including license plate number	☐ Accessed only	☐ Recorded

q) Any other unique identifying number, characteristic or code that may help identify individual participants including their initials (e.g. student or employee ID number)	☐ Accessed only	☐ Recorded
r) Elements of date, including year, for persons 90 years or older	☐ Accessed only	☐ Recorded
s) Other:	☐ Accessed only	☐ Recorded

26.0 Adverse Events and Unanticipated Problems*

Intervention Trial Adolescent Participants: In the unlikely occurrence of an adverse event or unanticipated problem, we will follow established practices for adolescents engaged in minimal risk research. It is possible that some of the intervention content may make some participants feel uncomfortable. We will clearly announce multiple times throughout the intervention duration that participation is voluntary, and adolescents may skip parts if they prefer. We have trained staff who are skilled in discussing sensitive topics like sexual health and mental health. While unlikely, someone may share information about a serious health risk to themselves or others (I.e., thoughts of hurting oneself). Our team has experience with these serious conditions and will work with community partner leaders and the parent or guardian to establish a safe care plan that may include referral to the CM emergency department for urgent evaluation.

7.

1. **Monitoring:** Describe the process for monitoring participants and data to identify adverse events and other unanticipated problems.

Intervention Trial Participants: Study staff will review study data every month for any adverse events.

2. **Reporting:** *Confirm Policy 5.11 Reportable Events of the CM Research Program Policies and Procedures will be followed in regards to reporting adverse events and other unanticipated problems to the CM IRB. If deviating from, or expanding upon this policy, explain why the approved policy would not suffice for this study and the rationale for deviating/expanding*

27.0 Data Analysis*

8.

1. *Describe the data analysis plan, including any statistical procedures or power analysis.*

Describe how the sample size for the study was determined (e.g. formal sample size calculation, convenience sampling). To minimize the risks associated with a possible breach of confidentiality, appropriate sample size calculations limit the amount of patient data being recorded to the amount necessary to answer the research question.

Quantitative data: We will conduct descriptive analysis with inferential and graphical exploratory analytic techniques, presenting mean, median, and interquartile range [continuous variables] and frequency and percentage [categorical variables]. We will examine outliers and/or influential points, perform bivariate analyses to assess relationships, and summarize group data. We will use SAS 9.4 (SAS Institute Inc., Cary, NC, USA); the significance level will be 0.05. For our primary outcome, we calculate the proportion in each arm with any health care utilization at 6 months. We use logistic regression to assess intervention effect on utilization and explore differences in other outcomes. Models will include covariates to adjust for variables (e.g., sex, age) that may increase precision. We will explore heterogeneity of effects with stepwise addition on interaction terms to examine moderation by sex, age, or engagement. If >20% of data is missing, we will use complete cases or imputation, based on missingness pattern.

28.0 Data and Specimen Management*

9.

1. **Data Management***: Describe how data will be handled, including:*
   - *What information will be included with the data?*
     - *Intervention Trial Participants:* Survey information included as data will be questions from our eligibility screen, baseline survey, Event Day Survey Measures(optional) and 2-, 4-, and 6-month follow-up. We will ask adolescents about their health behaviors as well as some demographics to describe the group (age, gender identity, race). Attendance at study-related events, training, and group sessions will be included as data.
     - *Event day Participants:* Survey information included as data will be questions from our eligibility screen, and Event Day Survey Measures (optional). For those receiving Clinical Care

the information included as data: Participation in Pregnancy test, STI testing for gonorrhea/chlamydia (urine), and STI testing for HIV and Syphilis (blood). Results for the following: pregnancy test, STI test results for gonorrhea/chlamydia/HIV/syphilis (urine and blood). Record of if birth control was received and which type. Record if referral to Children's Mercy Hospital Adolescent or Teen Clinic was given. All services are optional to teens.

- *How the data will be collected and stored. (e.g., REDCap, Excel, paper forms)*
    - All data will be directly accessible and stored securely via REDCap at CMKC.
- *How long will the data be stored?*
    - Contact information for teens that would like to participate in future research will be kept for 5 years and then destroyed. For teens that do not want to participate in future research, we will destroy contact information as soon as the study is completed. De-identified data will be stored in accordance with CMRI guidelines and will be deleted once IRB project is closed
- *Who will have access to the data?*
    - CM study team, students from the University of Kansas Medical Center (KUMC) and University of Missouri – Kansas City (UMKC) will have access. A reliance will be obtained from both institutions.
- *Who is responsible for receipt or transmission of the data?*
    - Trained CM research team members and students from the University of Kansas Medical Center (KUMC) and University of Missouri – Kansas City (UMKC)
- *Methods for transferring data.*
    - All data that is shared will be de-identified using a secure data transfer system.

2. Specimen Management:

N/A

3. Biosafety Information

Will this study involve handling, transporting, or shipping any potentially hazardous biological material at/from a Children's Mercy location (e.g., blood, stool, saliva, tissue)?

☐ Yes

☒ No

Will this study involve processing any potentially hazardous biological material at a Children's Mercy location (e.g., blood, stool, saliva, tissue)?

☐ Yes

☒ No

If processing potentially hazardous biological materials, where will this work be conducted?

☐ Pediatric Clinical Research Unit (PCRU)

☐ Children's Mercy Research Institute labs (mySafety ID#: _____)

☐ Other location

If "Other location," identify the location and mySafety ID# of the corresponding IBC protocol:

Location: _____

mySafety ID#: _____

29.0 Storage/Banking of Data and Specimens for Future Research

N/A

10.

30.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

This section is required when research involves more than Minimal Risk to participants.

N/A: Our study involves no more than minimal risk to participants

11.

STUDY MANAGEMENT

31.0 Setting & Locations*

12.

- *Describe the sites or locations where the research will be conducted.*

- Research may be conducted in a variety of settings including the community, within CMRI, virtually on Microsoft TEAMS, as well as at mobile unit events at community partner locations.

Identify where research procedures will be performed including any non-CM affiliated locations. For any non-CM affiliated locations, upload a letter of support in myIRB which states that the site is aware that research will be conducted on their premises.

- Community Partners:

a) Mattie Rhodes Center

148 North Topping Ave

Kansas City, MO 64123

b) Front Porch Alliance

3210 Michigan Ave

Kansas City, MO 64109

Describe the composition and involvement of any community advisory board.

- For intervention refinement we will form a Community Action Board (CAB) to 1) refine proposed content,2) generate strategies for outreach (e.g., social media), education (e.g., group sessions), and support to inform peer leader training, 3) guide toolkit development (described below), 4) confirm sites to host the MHU for care and telemedicine demonstrations, 5) inform outcome measures. We will meet (virtually/in-person) biweekly then monthly (or as needed) during implementation. The CAB will be composed of key stakeholders from the community including about 10 adults and about 10 teens. The CAB participants are not engaged in research.
  - *For research conducted outside of CM and its affiliates describe:*
    - *Regulations or customs affecting the research*
      - *N/A*
    - *The local scientific and ethical review structure*
      - *N/A*
  - *Describe the availability of medical or psychological resources that subjects might need as a result of taking part in the study.*

32.0 Multi-Site Research

13.

1. **Students**: Describe *any student involvement in the protocol (only when a reliance is necessary).* ***Remove section or mark 'n/a' if students are not involved.***

- Student from KUMC will assist with recruitment, enrollment, and data collection through survey administration. They will also assist with data analysis and dissemination.

2. **Study-Wide Number of Subjects:** *If this is a multicenter study, indicate the total number of participants to be accrued across all sites. Additionally, list out the enrollment numbers planned for each site.*

- N/A

33.0 International Research

14.

1. *Describe any research conducted internationally by CM investigators that is part of this study. If research is conducted internationally, the project must also have been approved by the local equivalent of an IRB before it can receive final approval from the CM IRB. When there is no equivalent board or group, investigators must rely on local experts or community leaders to provide approval. Upload related correspondence in myIRB. Contact ORI at irb@cmh.edu*

to discuss further as there is a great deal of variation in requirements internationally and this assessment can take some time.

- N/A

Addendum A: Waiver of Documentation of Permission/Consent

Regulatory Criteria: *To qualify for a waiver of documentation of parental permission or adult consent, the study must fit into at least one of the three scenarios below. Indicate which scenario(s) applies.*

☐ **The only record linking the participant and the research would be the permission/consent form and the principal risk is potential harm resulting from a breach of confidentiality.** Each parent/LAR or adult participant will be asked whether they want documentation linking the participant with the research, and the parent/LAR's or adult subject's wishes will govern.

OR

☒ **The research presents no more than minimal risk of harm to participants and involves no procedures for which written parental permission or adult consent is normally required outside of the research context.**

OR

☐ **The parent(s)/LAR or adult participants are members of a distinct cultural group or community in which signing forms is not the norm**, the research presents no more than minimal risk of harm to subjects and an appropriate alternative mechanism for documenting that informed parental/LAR permission or adult consent was obtained will be provided. Describe the alternative mechanism provided:

Addendum B: Waiver/Alteration of Permission/Assent/Consent: Waiver of parental permission of adolescent and Waiver of adult consent at age 18 (Non-Active Participants) Adolescent participants that turn 18 during the study and have completed study activities for the continued access to and use of identifiable data.

What's the difference between a "waiver" and an "alteration" of parental permission, child assent, or adult consent?

A "waiver" of parental permission, child assent, or adult consent is when **all 9 required elements of permission/consent are waived.** If the IRB approves a waiver, then the study team does not need to obtain the parental permission or adult consent in order to include a participant in the study.

An "alteration" of parental permission, child assent, or adult consent is when **one or more of the 9 required elements are waived** because they are not relevant to the research activity. If the IRB approves an alteration, then the study team must still obtain parental permission or adult consent in order to include a participant in the study, but certain elements may not be required in the form/discussion.

NOTE: *If requesting a waiver of parental/LAR permission because parental permission is not a reasonable requirement to protect the subjects [e.g. research on neglected or abused children], contact irb@cmh.edu to discuss additional regulatory requirements.*

Regulatory Criteria: *To qualify for a waiver or alteration of parental permission or adult consent,* ***ALL*** *of the following must apply. Explain how the study meets each of the regulatory criteria below.*

Criteria	Explain how the study meets the criteria
The research involves no more than minimal risk to the subjects	Adolescents will be completing confidential surveys. Risks are minimal and mitigated by the option to skip any question that they do not want to answer and by the confidentiality procedures we have in place to protect personal information.
The research could not practicably be carried out without the requested waiver/alteration (i.e., explain why the study could not be done if permission/assent/consent were required)	Adolescents will be recruited virtually or in-person where parents may not be present. Also, some teens would not want to participation if we could not maintain privacy on the potentially sensitive research topics. Requiring parental permission would mean many teens interested and eligible would not be able to participate. This could lead to sample bias and inaccurate study findings and ultimately could cause harm to adolescents. Additionally, assent was obtained utilizing the Information Sheet. Continued access to and use of identifiable data is needed to meet the study aims for participants that turn 18 during the study and have completed study activities.
If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format	Because of the 2, 4, 6-month follow-up survey, we will need to collect at least one form of contact information (phone number, email). Additionally, continued access to and use of identifiable data is needed to meet the study aims for participants that turn 18 during the study and have completed study activities.
The waiver/alteration will not adversely affect the rights and welfare of the subjects	We have no reason to believe that this waiver will adversely affect the rights of participants. On the contrary, we believe it will protect their rights, as teens may be more comfortable participating in a study about sexual and mental health without the involvement of their parents. The Waiver will not adversely affect the rights of non-active participants that turn 18 during the study as assent was obtained utilizing the Information Sheet.

Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation	Because our participants are older minors (14 and up) we are including in the assent everything that would be typically included in an adult consent form. We believe not providing study information to parents participating in a study about their sexual and mental health, may protect teen rights and privacy without the involvement of their parents. They may choose to share their decision with parents and trusted adults. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation

Proposed Alteration (if applicable):

N/A

Addendum E: Waiver/Alteration of HIPAA Authorization

What's the difference between a "waiver" and an "alteration" of HIPAA Authorization?

A "waiver" of HIPAA Authorization is when **the requirement to obtain authorization is completely waived.** If the IRB approves a waiver then the study team does not need to obtain HIPAA Authorization in order to include a subject in the study.

An “alteration” of HIPAA Authorization is when **one or more of the required elements of authorization are waived.** If the IRB approves an alteration then the study team must still obtain HIPAA Authorization in order to include a subject in the study, but certain elements may not be required in the form/discussion.

Regulatory Criteria: *To qualify for a waiver/alteration of HIPAA Authorization,* ***ALL*** *of the following must apply to a study. Explain how the study meets each of the regulatory criteria below.*

Criteria	*Explain how the study meets the criteria*
The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals based upon the following: o Plan to protect PHI from improper use and disclosure: o Plan to destroy PHI at the earliest opportunity, unless there is a health or research justification for retaining the PHI: o Assurance that PHI will not be reused or disclosed to any other person or entity:	a. PHI will only be kept in the REDCap project, accessible only to authorized members of the study team b. We will remove all PHI from the REDCap database after the last contact. Names and contacts of participants that indicate they would like to be contacted for future research will be stored in a separate secure database away from study materials. c. PHI will not be reused or disclosed to any other person or entity
The research cannot practicably be conducted	We have requested an alteration for HIPPA

without the waiver/alteration, i.e. explain why a signature for HIPAA Authorization cannot be obtained.	Authorization to reduce stress and anxiety that could potentially occur if adolescents are asked to provide signature for minimal risk study. Participants may choose not to participate which could affect the sample size and bias results for the research. Some teens may have distrust in medical research based on a long history of abuse perpetrated against marginalized populations. In order to improve communication and reduce anxiety for this minimal risk study, we seek this alteration.
The research cannot practicably be conducted without access to and use of the PHI, i.e. explain why access to PHI is needed for this study.	Names, phone numbers and emails are needed in order to contact the survey participant for the follow-up surveys and to send educational messages to the peer leaders throughout the study.