Health Services/Programmatic Research Protocol Template

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

PROTOCOL TITLE:
Adolescent Health Care Access

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IND/IDE NUMBER:
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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	11/4/2021	Initial submission	
2	11/27/2021	revision	Consent form was modified

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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	Cluster randomized clinical trial among peer networks
Primary Objective	To evaluate our novel approach to increasing access to care by comparing our community-level intervention, TeenHealth Outreach (THO) to our multi-level intervention TeenHealth Outreach+ (THO+).
Secondary Objective(s)	N/A
Study Population	• Adolescent participants for trial (intervention trial participants) • Adult stakeholders to provide feedback on intervention
Sample Size	Up to 200 adolescent participants for clinical trial, including up to 25 peer leaders in the THO+ arm. Up to 25 adult stakeholders to provide feedback on intervention
Study Duration for Individual Participants	Up to 7 months for adolescent participants; adult stakeholders 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*

2.1 Purpose, specific aims or objectives:

To evaluate our novel approach to increasing access to care by comparing our community-level intervention TeenHealth Outreach (THO) to our multi-level intervention, TeenHealth Outreach+ (THO+).

2.2 Hypothesis to be tested/Exploratory study design:

Adolescents receiving THO+ will have higher rates of health care utilization at six months after enrollment, compared to those receiving THO. This outcome is assessed 6 months after enrollment.

3.0 Background*

4.0 Study Design

4.0 Study Design:

5.0 Research Interventions*

☐ 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

Children/Minors (7-17 years of age): 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 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.

Economically or Educationally Disadvantaged Persons: 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 in regard to 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 also acknowledging 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

7.1 We will enroll up to 200 adolescents in this study. Of these, up to 25 will be asked to participate as peer leaders.

7.2 We will enroll up to 25 adult stakeholders

8.0 Identification and Recruitment of Potential Participants*

8.1 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

☒ 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

☐ Past subject list

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

☒ Other: __ We will also attend regular meetings conducted at community partner organizations and our team will share approved information sheet and verbal information to potential subjects.

8.2 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***

8.3 Recruitment of Potential Subjects:

- *Describe when, where, and how potential participants will be recruited.*
    - *INVERVENTION TRIAL PARTICIPANTS:* Once adolescents have decided to join the educational outreach program, they will receive written/digital information about the study and we will approach them to join our study. We will meet with potential participants (in-person or virtually) to describe the study and ask if they would like to participate. The written/digital information sheet is not yet created and will not be shared until it is IRB approved (via future modification).
    - *ADULT STAKEHOLDERS:* We will recruit trust adults from community partner organizations and word of mouth. We will meet with potential participants (in-person or virtually) to describe the study and ask if they would like to participate.

- *Upload any recruitment materials, including telephone scripts, in the myIRB application, Recruitment Materials section. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape or transcript. Wording of the advertisement may be submitted prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.)*
    - *Adolescent and Adult PARTICIPANTS:* We will develop a digital or paper flyer about participation in this research study that will be distributed to our community partners and interested adolescents and trusted adults. Informational flyers will not be shared until they have been reviewed and approved by the IRB.
- *If recruitment strategy involves contacting individuals' multiple times, describe how frequently and in what manner individuals will be contacted and the maximum number of attempted contacts for any one individual.*
    - *INTERVENTION TRIAL PARTICIPANTS:* 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.
    - *ADULT STAKEHOLDERS:* Adults will not be contacted more than three times for survey participation at the end of the study.

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 intervention measures)*: baseline, contact form, and 2, 4, 6 follow-up, and Post Mobile Unit survey (optional). Surveys will include both closed-ended and open-ended questions (see measures and table below)

- **Trust in Medical Profession Scale** (included in Baseline and 2, 4, 6 month Follow-Up). Sources:
  - Kao, Audiey C., et al. "The relationship between method of physician payment and patient trust." Jama 280.19 (1998): 1708-1714.
  - Hall, Mark A., et al. "Trust in the medical profession: conceptual and measurement issues." Health services research 37.5 (2002): 1419-1439.
- **Forgone care:** "Has there been any time over the past year when you thought you should get medical care, but did not?"
  - Lehrer, J. A., Pantell, R., Tebb, K., & Shafer, M. A. (2007). Forgone health care among US adolescents: associations between risk characteristics and confidentiality concern. Journal of Adolescent Health, 40(3), 218-226.
- **Mental Health:** Selected items from the CES-D and the GAD-7, as recommended by PhenX assessment for COVID-19 mental health: https://www.phenxtoolkit.org/protocols/view/960101
  - Kohout, F. J., Berkman, L. F., Evans, D. A., & Cornoni-Huntley, J. (1993). Two shorter forms of the CES-D depression symptoms index. Journal of aging and health, 5(2), 179-193.
  - Spitzer, R. L., Kroenke, K., Williams, J. B., & Löwe, B. (2006). A brief measure for assessing generalized anxiety disorder: the GAD-7. Archives of internal medicine, 166(10), 1092-1097.
- **Sexual Health**
  - Centers for Disease Control and Prevention. National Center for Health Statistics. National Survey of Family Growth. 2014. https://www.cdc.gov/nchs/nsfg/index.htm

- *ADULT STAKEHOLDERS:* Survey *(titled Trusted Adult Stakeholder survey)* will include both closed-ended and open-ended questions (see measures and table below)

- *Engagement* To what extent were you able to…(1 = Not at all to 5 = To a great extent) Engage teens in your group in study related activities? Get teens in your group to share their opinions about mental health? Encourage teens in your group to get a check-up or see a doctor? Use language and terms about sexual health that teens in your group could understand?

Feasibility constructs (Bowen et al.) and sample measures		
Construct	**Source**	**Sample Measure***
Acceptability - How do stakeholders react?	Adolescent	Satisfaction**; Recommend to friends**;
	Stakeholders	Satisfaction**; Recommend to others**
Demand - To what extent is the intervention likely to be used?	Adolescent	Likelihood to use again**; proportion of friends who would use
	Stakeholders	"How much future interest would there be among community members?"
Implementation - To what extent can the intervention be implemented as planned?	Adolescent	Engagement**; "What toolkit ideas worked well/not so good?"
	Stakeholders	Engagement**; "How did mitigation efforts impact intervention delivery?"
	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**
	Stakeholders	Ease of toolkit use**; "What was hard about engaging with adolescents?"
	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?"
	Stakeholders	"How can a program like this be sustained?"
Expansion - To what extent can model be expanded?	Adolescent	Openness to vaccine information using intervention**
	Stakeholders	"How could the intervention build community trust for future vaccination?"
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		

10.0 Additional Research Activities

N/A

11.0 Follow-up

- *N/A*

12.0 Genetic Analysis Information

N/A

13.0 Sharing of Results with Subjects

12.1 *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 with 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*

13.1 *List the research risks. Research risks are any potential physical, psychological, social, legal, privacy, confidentiality risks or economic harms that may come from participating in the study. This does not include the risk of any procedures conducted as part of clinical care.*

- *Where applicable, describe the probability, magnitude, duration, and reversibility of the risks.*
- *Describe the measures taken to minimize these risks as this will be useful for the IRB in making their risk/benefit determination.*
- *If collecting or accessing sensitive data which may pose legal, economic, or reputational harm, describe this risk in detail.*

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 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.

13.2 *Indicate whether the researchers believe the risks involved in this study are minimal, or if the study poses greater than minimal risk of harm to subjects.*

We believe the risks involved in this study are minimal.

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

N/A

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

N/A

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

N/A

15.0 Potential Benefits*

14.1 *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.*

This study is not designed to benefit the research participant.

14.2 *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)*

16.1 ***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:

- *The total amount anticipated*
- *The study time points when payments will be made and the amount of compensation at those time points.*
- *To whom payments will be made (i.e. to subjects, to parents/LAR, or will this be based on some criterion such as age of subject).*
- *If total amount of payment and/or tangible property for an individual subject may exceed $600, include plans for the collection of Social Security Number (SSN) or Individual Tax Identification Number (ITIN) as required by CM policy.*
    - *Intervention Trial Participants:* Adolescents will have an opportunity to receive up to $75. 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. If an adolescent attends a mobile unit event, they will receive $15 for the post mobile unit survey (optional).
    - *Peer Leaders:* Teens can earn an additional $100 for being a peer leader. They will get $50 at the end of month 3 (for extra training) and $50 at the end of month 6 (for completing additional survey questions).
    - *Adult stakeholders:* Will receive $20 gift care to thank them for their time to complete the survey.

16.2 Reimbursement: *If providing reimbursement (repayment to research participants and/or their families to cover out-of-pocket expenses they incur), select the form of reimbursement:*

☐ Greenphire/ClinCard
☐ Check
☐ Other: _____

N/A

16.3 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:*
  - **.1 *Emergency Contraception Plan B (Levonorgestrel) for future use***
- *How and when the item(s) will 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***
- *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

17.1 *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

18.1 *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.*

Written Informed Permission/Consent

☐ **Written informed permission of parent/LAR for pediatric participants**

Study group(s) to which this method applies:

☐ **Written informed consent of adult participants**

Study group(s) to which this method applies:

☐ **Written informed consent of participants turning 18**

This includes the continued access to and use of their PHI by the study team.

Study group(s) to which this method applies:

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**

☒ **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 old upon enrollment and the adult stakeholder participants.

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

Study group(s) to which this method applies: Any adolescent turning 18 during the course of study participation. 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 consent with that participant before the 2, 4, 6 month follow-up call/text/email.

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:

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, eConsent, 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 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 that are 18 years old, we will review a study information sheet in-person or virtually (*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.

Adult Stakeholders: For adults that are 18 years or older, we will review a study information sheet in-person or virtually *(titled Adult Stakeholder Verbal Consent)*

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 post Mobile unit survey (optional) and on the 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.**

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 over the phone, or 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.

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 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 a signature.

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*

a) 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*

a) 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*

19.1 *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

19.2 *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.

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

N/A

19.4 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 messaged via Twilio/Spark to engage peer leaders. Date of birth will be recorded to assess age of intervention trial participants. Zip codes will be recorded to identify if we are serving economically or disadvantage youth based on their location.

1. Name/Initials	☐ Accessed only	☒ Recorded
2. 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
3. Medical record number	☐ Accessed only	☐ Recorded
4. Account number	☐ Accessed only	☐ Recorded
5. Health plan identification number	☐ Accessed only	☐ Recorded
6. Social Security Number	☐ Accessed only	☐ Recorded
7. Device identifiers and serial number	☐ Accessed only	☐ Recorded
8. Certificate/License number	☐ Accessed only	☐ Recorded
9. Telephone number	☐ Accessed only	☒ Recorded
10. Fax number	☐ Accessed only	☐ Recorded
11. Email addresses	☐ Accessed only	☒ Recorded
12. Web addresses (URLs); Internet IP addresses	☐ Accessed only	☐ Recorded
13. Street address, city, county, precinct, zip code or equivalent geographical codes	☐ Accessed only	☒ Recorded
14. Full face photographic images and any comparable images	☐ Accessed only	☐ Recorded
15. Biometric identifiers, including finger and voice print	☐ Accessed only	☐ Recorded
16. Vehicle identifiers and serial numbers, including license plate number	☐ Accessed only	☐ Recorded

17. 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
18. Elements of date, including year, for persons 90 years or older	☐ Accessed only	☐ Recorded
19. Other:	☐ Accessed only	☐ Recorded

26.0 Adverse Events and Unanticipated Problems*

Intervention Trial 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.

20.1 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.

20.2 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*

21.1 *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 step-wise 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.

Sample size and power: We compare rates of any health care utilization at 6 months. Based on previous work,[13,56] we estimate this difference between arms: THO = 15% and THO**+** = 60%. Using an intra-class correlation of 0.30, we will have a minimum of 83% power (two-sided test, alpha=0.05) to detect this difference using 20 networks (four members each, range 2-8). To handle probabilistic instances where members of a network have no health need, we will increase networks by 20% and recruit 12 networks/arm (N ~ 78 - 192).

28.0 Data and Specimen Management*

22.1 Data Management: *Describe how data will be handled, including:*

- *What information will be included with data?*
    - *Intervention Trial Participants:* Survey information included as data will be questions from our eligibility screen, baseline survey, post Mobile unit survey (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.
    - *Adult stakeholders:* We will include all survey data that is related to engagement and feasibility
- *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 the data will 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.

22.2 Specimen Management:

N/A

22.3 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

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

STUDY MANAGEMENT

31.0 Setting & Locations*

25.1 *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 event 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 have not been identified yet. We will adjust protocol and submit an agreement from community partners when partners have been identified. No study procedures with participants will begin prior to updating our IRB submission with this information.

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

26.1 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.

26.2 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

27.1 *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

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.*
The below table provides an explanation for a waiver of parental permission for participants 14-17 years of age.

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 participate if we could not maintain privacy on the potentially sensitive survey questions. 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 if inaccurate findings were implemented.
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).
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.
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 providing study information to parents of teens answering questions about and mental health may put some teens at risk. One example would be if parents do not support medical guidelines that advise teens should have access to accurate and age-appropriate health information. Teens may chose to share their decision to participate with parents and trusted adults.

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: a. Plan to protect PHI from improper use and disclosure: b. Plan to destroy PHI at the earliest opportunity, unless there is a health or research justification for retaining the PHI: c. 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 without the waiver/alteration, i.e. explain why a signature for HIPAA Authorization cannot be obtained.	We have requested an alteration for HIPPA 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.