SHORT TITLE:

PROTOCOL TITLE:

Walking to school at Banneker Elementary

PRINCIPAL INVESTIGATOR:

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REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?
2	8/27/19	Updates to include Phase 2 details	N
3	9/24/19	Updates eligibility and screening	N
4	11/1/19	Updates to inclusion/exclusion criteria	N

Table of Contents

1.0 Study Summary

Study Title	Walking to school at Banneker Elementary
Study Design	Phase 1: cross-sectional survey Phase 2: behavioral Intervention
Primary Objective	Phase 1: to identify students and families interested in walking to/from school Phase 2: to provide support to students and families interested in walking to/from school
Secondary Objective(s)	
Research Intervention(s)/ Investigational Agent(s)	Phase 2 involves a behavioral intervention involving health coaching delivered over the phone and through email messaging.
IND/IDE #	N/A
Study Population	Children enrolled at Benjamin Banneker School and their parent(s)
Sample Size	Phase 1: the survey will be sent home with all students enrolled at Banneker; estimated response is 600 parents Phase 2: 30 parent/child dyads
Study Duration for Individual Participants	Phase 1: one survey that takes approximately 10 minutes to complete Phase 2: approximately 6 weeks
Study Specific Abbreviations/ Definitions	

2.0 Objectives

Phase 1: to identify students and families interested in walking to/from school.
Phase 2: to provide support to students and families interested in walking to/from school, and determine acceptability and appropriateness of the supports.

3.0 Background

Increasing rates of walking to school can lead to improvements in children's overall physical activity and health. Yet, few children walk to school. Walking school bus programs, often included in Safe Routes to School efforts, provide children an opportunity to walk to school in a group accompanied by an adult. This improves safety and support for walking to school. Our community partner, BikeWalkKC, provides walking school bus programming at some local schools in the Kansas City area. However, it is difficult to engage students and families to join these walking school buses and walk to school in general.

The purpose of this study is to test the acceptability and appropriateness of a novel behavioral coaching intervention for increasing the number of students who participate in a walking school bus or walk to school through other means. This study will be conducted at one local school, Banneker Elementary School in KCPS, where BikeWalkKC is providing a walking school bus in the fall of 2019. The walking school bus and BikeWalkKC's involvement is not part of the research study. The research activities, which are being conducted by our team at CMH, involve a cross-sectional survey of all students in the school (Phase 1), and a behavioral coaching intervention to up to 30 students, aimed to transition them from driving to school to walking (either with the walking school bus or through other means).

4.0 Study Endpoints

4.1 Completion of Phase 1, then Phase 2 if selected.

4.2 No primary safety Endpoint.

5.0 Study Intervention/Investigational Agent

5.1 Description: behavioral intervention only. See below:

Intervention
In general, Phase 2 will involve a behavioral coaching intervention. This will include handouts, text messages via Redcap and Outlook (see Jaylene Weigel's letter of support and the Texting Protocol in IRB submission), phone/skype calls, and email message communications with families (students and parent(s)) for delivering motivational content. The content will be theoretically based and cover skills building, goal setting, and problem solving.

6.0 Procedures Involved

6.1

Overview and study design

Phase 1 is a cross-sectional survey.
Phase 2 is a single group intervention design with purposeful selection of participants.

6.2

Study measures

Phase 1. The survey asks about current mode of transportation to school, barriers to walking to school, and interest in walking to school through various means. They survey also asks for the student's name, home address, parent email, and parent phone number. The survey is included in this IRB application. It was designed specifically for this study and some items were adapted from the National Safe Routes to School Center's parent survey.

Phase 2. At the end of the intervention, a survey will be administered to families (student and parent(s)) to assess their acceptability and preferences around the intervention content, and its appropriateness.

6.3 Describe:

- Source surveys, slides with scripts (these will include PowerPoint slides that are turned into videos by doing a voiceover and accessible from a study website), parent handouts, and module protocols will be uploaded to myIRB.
- Materials will be accessible here (*www.ciparesearchteam.org/walk-to-school*) and the URLs will be sent to participants each week via text/email:
    - Module 1: *https://www.ciparesearchteam.org/mod1*
    - Module 2: *https://www.ciparesearchteam.org/mod2*
    - Module 3-5: *https://www.ciparesearchteam.org/mod35*
    - Nonwalker Module 3: *https://www.ciparesearchteam.org/mod3*
    - Nonwalker Module 4: *https://www.ciparesearchteam.org/mod4*
    - Nonwalker Module 5: https://www.ciparesearchteam.org/mod5

6.4 Data collected during the study includes: Student name, address, and parent phone number and email address. This information will be collected via the Phase 1 School Travel Survey to determine

eligibility of families for Phase 2 or via response to a recruitment flier (if not already obtained from the screener survey).

6.5 Once Phase 2 is complete, no long term follow-up will be completed.

6.6 N/A – no biologic or radiation review

7.0 Data and Specimen Banking

7.1 N/A not using biorepository

8.0 Genetic Analysis Information

8.1 N/A no genetic analysis

9.0 Sharing of Results with Subjects

9.1 N/A results will not be shared with participants

10.0 Study Timelines

10.1 Describe: For Phase 1, the survey will be administered at the beginning of the school year (approximately during the week of Aug 12, 2019). Within 3-8 weeks of the survey administration, a select group of families will be contacted to offer them the intervention (Phase 2). The intervention (Phase 2) will last approximately 6 weeks.

11.0 Inclusion and Exclusion Criteria

11.1 Describe the criteria that define who will be included or excluded in your final study sample.

<u>Inclusion Criteria</u>

- Phase 1: Parents of children enrolled at Benjamin Banneker school
- Phase 2: Parents/child dyads who completed the Phase 1 survey OR respond to recruitment attempts and express interest in walking to school. Included parent/child dyads will be:
  - Those who do not participate in LINC program both before **and** after school 4+ days per week (child);
  - Those who live within the school boundary and south of Meyer Blvd (i.e., close enough to an existing walking school bus route) or are willing to drop off and/or pick up the child at a place along an existing walking school bus route (i.e., remote drop off).

Exclusion Criteria

- Children not enrolled at Benjamin Banneker school
- Those who participate in LINC program both before **and** after school 4+ days per week (child);
- Those who do not live within the school boundary and south of Meyer Blvd (i.e., close enough to an existing walking school bus route) or are not willing to drop off and/or pick up the child at a place along an existing walking school bus route (i.e., remote drop off).

11.2 We will exclude each of the following special populations: (You may not include members of the following populations as subjects in your research unless you indicate this in your inclusion criteria.)

- Adults unable to consent
- Prisoners
- Wards of the state
- Pregnant women may be included, but only in such capacity as parents of other children enrolled at Benjamin Banneker school

12.0 Vulnerable Populations

12.1 If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.

- HRP-416 Checklist has been reviewed.

13.0 Local Number of Subjects

13.1 Phase 1: anticipated that 600 parents will respond to the survey

Phase 2: up to 30 parent/child dyads

13.2 N/A

13.3 N/A

14.0 Screening and Recruitment Methods

14.1 Phase 1: The survey will be sent home with all students. Banneker staff will give the survey to each student to take home.

Phase 2: We will purposefully select survey respondents based on their survey responses to reach out to via various means to offer the intervention (Phase 2). If the desired enrollment numbers are not reached using this approach, recruitment fliers will be send home

with students living within walking distance of the school. We will try to target those living close to the school but it is likely that some students living further away will receive the flier.

We did not receive very many returned screeners. Thus, we are going to recruit more broadly as described above. We will screen those who respond to the recruitment flier to determine their eligibility. These eligibility questions were asked in the Phase 1 screener survey, but need to use the Phase 2 phone script as a screener because we won't have Phase 1 data on everyone who we send the recruitment flier to.

14.2 The participants will come from Banneker elementary school.

14.3 Phase 1 will include all students at Banneker. Phase 2 will involve a select group of students selected based on their survey responses. A Letter of Support from the school is included in this IRB application.

14.4 No identifiers will be collected prior to p/a/c by the CMH study team.

14.5 For Phase 2, study staff will contact a select subset of survey respondents up to three times to offer the intervention, and share the flier with other families (including those who did not respond to the screener) until up to 30 dyads agree to receive the intervention. First, a recruitment letter will be sent in the mail and email. Next, we will call the parent on the phone and go over the details of the study and screening (if interested). At this time, the parent and child will either agree to participate or decline. The intervention will start the Sunday after enrollment.

15.0 Reimbursement, Payment and Tangible Property provided to subjects

15.1 N/A – no reimbursement

15.2 Phase 1: No incentive. Phase 2: $50 for responding to at least 80% of the daily tracking text messages and another $50 for completing a close-out interview.

15.3 N/A – no tangible property

16.0 Withdrawal of Subjects

16.1 Withdrawal of participants is not anticipated for any one reason.

16.2 N/A

16.3 When a participant decides to withdraw data obtained up to the time of withdrawal will be kept.

17.0 Risks to Subjects

17.1 The main risk of this study is a loss of confidentiality.

17.2 The risks involved in this study are minimal.

17.3 Walking to school may have some unforeseeable risks but the decision to walk to school is ultimately up to the dyads. BikeWalkKC is working with the school to minimize dangers potentially associated with walking and our assessment of risks is that they are minimal and do not outweigh the benefits of walking to school.

17.4 N/A no risk to embryo or fetus

17.5 Parents and dyads may also experience a small risk of loss of confidentiality.

18.0 Potential Benefits to Subjects

18.1 Participants may experience greater levels of physical activity, lower adiposity, as well as greater cognitive and academic performance associated with walking to school.

18.2 N/A

19.0 Investigator Assessment of Risk/Benefits Ratio: (IRB makes the final determination)

Select as applicable:	**Pediatric Risk Category:**	
X	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:**	
X	Not Greater than Minimal Risk	
	Greater than Minimal Risk	

Data Management and Confidentiality

20.1 The data analyses will be descriptive, to summarize the results of the surveys. Qualitative data will also be collected and summarized as part of Phase 2.

20.2 This is a pilot study and the sample size was selected to provide a sufficient number of dyads who complete the intervention and post intervention survey on acceptability.

20.3 All research staff will obtain the proper research training, authorization of access. Study data will be store using password protection, encryption, physical controls, and separation of identifiers and data [master list]) during storage, use, and transmission.

20.4 This study will not obtain a certificate of confidentiality.

20.5 Describe how data or specimens will be handled study-wide:

- Study data will be stored per the Record Retention and Management Policy and the Record Retention Schedule 2015 according to guidelines for NIH funded studies.
- The CMH study team will have access to the data.

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

- N/A – no more than minimal risk

22.0 Provisions to Protect the Privacy Interests of Subjects

22.1 Participants will be given study ID numbers, all information collected for the study will be done using that ID, not their name or any other identifying information. The participant's name will only be linked via a master list and on the permission/assent form. The initial study survey (Phase 1) will contain a verbal consent and some identifiers will be collected.

22.2 Participants will be given ample time to decide whether or not they would like to participate in the study. They will be able to come back to the initial verbal consent after a time (Phase 1) and decide to complete it or not.

22.3 The information accessed by the study team will come from the Phase 1 survey and responses to recruitment fliers. The information will be kept secure and not shared outside of the project team. The exception is that the information from the Phase 1 survey will be

shared with BikeWalkKC so that they can follow up with families interested in participating in the walking school bus that BikeWalkKC is providing. List all PHI to be accessed and/or recorded for this research study. Identifiers includes: name, street address, telephone number, and email address.

22.4 The HIPAA Authorization will be wrapped in with the permission/assent/consent form(s).

23.0 Compensation for Research-Related Injury

23.1 N/A

23.2 N/A

24.0 Economic Burden to Subjects

24.1 No economic burden for subjects other than time investment.

25.0 Permission/Assent/Consent Process

25.1 Indicate whether you will you be obtaining permission/assent/consent, and if so describe:

- The study staff requests an alteration of the permission/assent process, more specially to use a verbal permission/assent. They have reviewed the checklist for Waiver of Alteration of Consent process and have concluded that the study meets the criteria for number 1.
    - Since this survey collects minimally identifying information (name, address, phone number, and email) and the intervention is minimal (behavioral coaching) the study team is requesting an "opt out" permission/assent process where the participants indicate they do not wish to participate by not completing the form.
    - The recruitment/enrollment phone call for Phase 2 includes a script that explains that participation is voluntary and that withdraw will not affect their relationship with the school or CMH. The script also covers the details/requirements of the study. This script has been uploaded with this amendment submission.

26.0 Process to Document Permission/Assent/Consent

26.1 We will be requesting a waiver via 26.2.

26.2 This research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of permission/assent/consent is normally required outside of the research context. The IRB will generally waive the requirement to obtain written documentation of permission/assent/consent.

26.3 The study will obtain verbal permission/assent/consent, but not document permission/assent/consent in writing, therefore a permission, assent and or consent scripts (e.g., Study Information Sheet, in this case wrapped up in the study survey) will be developed and uploaded in myIRB in lieu of full permission/assent/consent forms.

Review HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent to ensure that you have provided sufficient information.

27.0 Setting

27.1 Describe the sites or locations where your research team will conduct the research.

- The survey will be sent home with students.
- The intervention will occur over the telephone/skype, text, and email.
- For research conducted outside of the organization and its affiliates describe:
    - A letter of support has been obtained from the participating school.

28.0 Resources Available

28.1 Describe the resources available to conduct the research: For example, as appropriate:

- Don Chisholm and the community have the appropriate resources (mainly meeting rooms and computers) to conduct the research.
- N/A
- All study staff will be trained on the protocol prior to study initiation and will undergo the proper research training.

29.0 Multi-Site Research – marked as collaborative in myIRB because Dr. Carlson works with GRAs from UMKC/KUMC

29.1 N/A
29.2 N/A
29.3 N/A
29.4 N/A

30.0 International Research

29.1. N/A