

**Study Title:** A Cluster Randomized Trial to Improve Adolescent Bicycling Safety

**NDT #:** [not yet assigned]

**Document Date:** February 1, 2022

## INFORMED CONSENT DOCUMENT

**Project Title:** A cluster randomized trial to improve adolescent bicycling safety

**Principal Investigator:** [REDACTED]

**Research Team Contact:** [REDACTED]

This consent form describes the research study to help you decide if you and your child want to participate. This form provides important information about what you and your child will be asked to do during the study, about the risks and benefits of the study, and about you and your child's rights research subjects.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you and your child want to be part of this study.

### **WHAT IS THE PURPOSE OF THIS STUDY?**

This is a research study. We are inviting you and your child to participate in this research study because your child rides a bicycle on public roads, sidewalks, or bike paths/trails and is willing to participate in a portion of the Neighborhood Centers of Johnson County summer school program.

The purpose of this research study is to find out how child bicyclists interact with the transportation system and with other road users when bicycling.

### **HOW MANY PEOPLE WILL PARTICIPATE?**

Approximately 200 children and 200 parents will take part in this study conducted by investigators at the University of Iowa.

### **HOW LONG WILL I BE IN THIS STUDY?**

If you and your child agree to take part in this study, your involvement will last for approximately 4-6 months.

- A total of 4 in-person meetings
  - 1 initial meeting to complete baseline surveys and set up the camera system on your child's bicycle (30-45 minutes)
  - 1 meeting to pick up the camera system and trip diary after a 1-week data collection period (15 minutes)
  - 1 meeting approximately 3 months after the initial meeting to set up camera system on your child's bicycle again (15 minutes)

- 1 final meeting to pick up the camera system and trip diary and have you and your child complete follow-up surveys (30-45 minutes)
- If your child is in the Neighborhood Centers of Johnson County (NCJC) Bike Club Plus program you will also complete a 45-minute virtual parent training session within one week of your child completing that program.

## **WHAT WILL HAPPEN DURING THIS STUDY?**

You and your child will be contacted by a member of the project team to schedule a time to meet in-person to complete parent and child questionnaires, set-up the camera system, and teach you and your child how to record your child's bicycling trips during two, one-week periods. The questionnaires will include questions about demographics, you and your child's bicycling experience and knowledge, and your child's temperament and perceptions related to bicycling. This meeting will take approximately 30-45 minutes. We will ask you to bring your child's bicycle and helmet to this meeting.

After the camera system is installed on your child's bicycle it will be ready to record trips. Your child will need to ride the bicycle equipped with the camera system during the 1-week data collection periods. The camera system should only be used to record trips on public roads, sidewalks, or bike paths/trails. You will need to contact the research team to replace the camera system battery if it becomes low or replace the memory card in the camera if it becomes full. Your child will also be asked to keep a written trip diary of all their trips throughout the 2 weeks to record information on the trip purpose and any accidents, near misses, or safety-relevant events.

At the end of the first week of data collection we will meet with you and your child again, in-person, collect the study equipment and collect and go over the trip diary with your child to get details on any accidents, near misses, or safety-relevant events experienced. This meeting will take approximately 15 minutes.

Your child or your child's summer school program site will be randomly assigned to receive one of three study treatments, either a control group (no bike club programming), NCJC Bike Club, or NCJC Bike Club Plus. This means that whichever study treatment your child or your child's summer program site receives will be determined purely by chance, like flipping a coin. Each summer program site or child will have a 1 out of 3 chance of receiving any one of the study treatments.

If your child or your child's summer school program site has been randomized to the NCJC Bike Club or NCJC Bike Club Plus program study treatment group, they will complete a 4-day, 12-hour course in bicycle safety education within 1 to 2 months after the first week of data collection. If your child is in the NCJC Bike Club Plus program you will be asked to complete a 45-minute virtual parent training session (via Zoom or preferred platform) within a week of your child completing the NCJC Bike Club program. This session will provide you feedback on your child's bicycling performance during the program, bicycle safety and child development information, and tips for practicing at home.

Approximately 3 months after the first meeting or 1-2 months after the NCJC Bike Club or NCJC Bike Club Plus program, the study team will contact you and your child to schedule a time to set up the camera system for another week of data collection. This meeting will take approximately 15 minutes.

At the end of the second week of data collection we will meet with you and your child again, in-person, collect the study equipment and collect and go over the trip diary with your child to get details on any accidents, near misses, or safety-relevant events experienced. At this meeting we will also ask you and

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your child to complete follow-up questionnaires. Your child's questionnaire will include questions about their bicycle safety knowledge, perceptions, cues to action, and self-efficacy. Your questionnaire will include questions about bicycling safety knowledge, child development as it relates to bicycling, and practice at home. This meeting will take approximately 30-45 minutes.

The in-person meetings will take place wherever it is most convenient for you and your child to both fill out a questionnaire and have access to your bicycle to be able to practice recording during the equipment training session (e.g., your home, a park, neighborhood center, on the university campus, etc.).

On the questionnaires, you and your child will be free to skip any questions that you would prefer not to answer.

**IMPORTANT:** During data collection we ask that you inform us as soon as possible of any malfunctions with the camera system when you or your child become aware.

#### **Data Storage for Future Use**

As part of this study, we are obtaining data from you and your child. We would like to study your and your child's data in the future, after this study is over. You and your child's data may be placed in a central repository or other national repositories sponsored by the National Institutes of Health or other Federal agencies. If this happens, it will be stripped of identifiers (such as name, date of birth, address, etc). Other qualified researchers who obtain proper permission may gain access to your and your child's data for use in approved research studies that may or may not be related to the purpose of this study.

The tests we might want to use to study your and your child's data may not even exist at this time. Therefore, we are asking for your permission to store your and your child's data so that we can study it in the future. These future studies may provide additional information that will be helpful in understanding road safety and bicycling behavior, but it is unlikely that what we learn from these studies will have a direct benefit to you or your child. It is possible that you or your child's data might be used to develop products, tests, or discoveries that could be patented and licensed. In some instances, these may have potential commercial value and may be developed by the Investigators, University of Iowa, commercial companies, organizations funding this research, or others that may not be working directly with this research team. However, donors of data do not retain any property rights to the materials. Therefore, there are no plans to provide financial compensation to you should this occur.

Your data will be stored *without* your name or any other kind of link that would enable us to identify which are yours. Therefore, it will be available for use in future research studies indefinitely and cannot be removed.

We may contact you again about being in one of our future studies, therefore we plan to keep your contact information (stored separately from your data). Agreeing to be in this current study does not obligate you to participate in one of our future studies. You would sign a separate Consent Document for any future study participation.

#### **Audio/Video Recording**

One aspect of this study involves making audio recordings/video recordings of your child. By participating in this study, you consent to such audio and video recordings. These are necessary in order for the UI project staff to understand the context under which certain bicycling behaviors occur. These recordings will be made with cameras and will be recorded during your child's biking trips. They will be

uploaded from the camera memory cards to a password protected computer file at the end of the one week recording periods. Access to these data will be under the supervision of study investigators or as required by law. Data analysts assigned to work on this project will also have access to the data. Data gathered during the study will be kept indefinitely.

### **WHAT ARE THE RISKS OF THIS STUDY?**

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

There is a risk that information collected during the study may be used or seen by others. Persons who view the video data may be able to identify you or your child. You and your child's study information will be protected as described in the section about confidentiality.

**IMPORTANT:** As a participant, your child is expected to ride their bicycle on public roads, bike paths/trails, and/or sidewalks during the study period. All normal risks of riding a bicycle in these areas exist, including but not limited to the risk of being involved in a motor vehicle accident. There is a risk of being injured. Your child should always be safe and ride just as they normally do. Your child should not take any risks beyond what they normally would and should not place themselves in unusually dangerous situations during this study.

### **WHAT IF MY CHILD IS INJURED WHILE PARTICIPATING IN THIS STUDY?**

- The University's insurance does not provide medical payments coverage for injuries sustained while participating in this study.
- The University's insurance does not provide Uninsured/Underinsured Motorist coverage if your child is injured in a motor vehicle accident caused by a third party. You will be responsible for any claims you or your child may have against the responsible party.
- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

### **WHAT ARE THE BENEFITS OF THIS STUDY?**

We don't know if you or your child will benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because of the knowledge gained regarding bicycling safety and riding behaviors.

### **WILL IT COST ME ANYTHING TO BE IN THIS STUDY?**

You will be responsible for the costs of operating and maintaining your child's bicycle during this study and for any repairs needed to maintain the bicycle. You will also be responsible for the costs associated with charging the camera battery during the two, one-week study periods.

## **WILL I BE PAID FOR PARTICIPATING?**

Your child will be paid for being in this research study.

Your child will be paid \$25 for the first questionnaire and training on how to use the camera and GPS system and \$50 for the two one-week data collection periods, interviews related to the trip diaries, and follow-up questionnaire. The total for completing the study will be \$75. Your child will receive these payments in the form of gift cards at the first and last in-person meeting.

## **WHO IS FUNDING THIS STUDY?**

The National Institutes of Health (NIH) are funding this study. This means that the University of Iowa is receiving payments from NIH to support the activities that are required to conduct the study. No one on the research team will receive a direct payment or increase in salary from the NIH for conducting this study.

## **WHAT ABOUT CONFIDENTIALITY?**

We will keep you and your child's participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of you and your child's participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you or your child.

- federal government regulatory agencies,
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect you and your child's confidentiality, we will

- Separate names and any identifying information from the data. A coding scheme will be used to identify the data by participant number only (e.g. Bicyclist 1). The list linking you and your child's name and study participant numbers will be stored in a secure location that is accessible only to the researchers.
- Any video and GPS files, as well as all other data, will be stored in a locked office on a password protected computer at the University of Iowa.
- If we write a report or article about this study or share the study dataset with others, we will do so in such a way that you or your child cannot be directly identified.
- We will truncate the GPS routes at the beginning and end of each trip if used in a zoomed in visual display so that the specific origin and destination locations cannot be directly identified.

Data collected from the video recordings and a report of the investigators' findings may be shared with

the UI General Counsel Office. The data will include information that could identify you or your child. Under extreme and extraordinary circumstances and under advisement from the General Counsel, law enforcement may be provided information that includes your and/or your child's identity. Authorities could subpoena the video recordings if accidents or illegal activities are recorded.

## **IS BEING IN THIS STUDY VOLUNTARY?**

Taking part in this research study is completely voluntary. You and your child may choose not to take part at all. If you and your child decide to be in this study, you may stop participating at any time. If you and your child decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

### **What if I Decide to Drop Out of the Study?**

If you and your child decide to leave the study early, we will ask you to contact the research staff to schedule a time to remove and return the recording equipment. This should take approximately 5 minutes.

### **Will I Receive New Information About the Study while Participating?**

If we obtain any new information during this study that might affect you and your child's willingness to continue participating in the study, we will promptly provide you with that information.

### **Can Someone Else End my Participation in this Study?**

Under certain circumstances, the researchers or study sponsor might decide to end you and your child's participation in this research study earlier than planned. This might happen because in our judgment it would not be safe for you or your child to continue, because funding for the research study has ended, because the sponsor has decided to stop the research, or other unforeseen issues.

## **WHAT IF I HAVE QUESTIONS?**

We encourage you and your child to ask questions. If you have any questions about the research study itself or if you experience a research-related injury, please contact: [REDACTED]

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail [irb@uiowa.edu](mailto:irb@uiowa.edu). General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, <http://hso.research.uiowa.edu/>. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

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This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you and your child decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you and your child agree to take part in this study. You will receive a copy of this form.

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Subject's Name (printed): \_\_\_\_\_

(Signature of Subject) \_\_\_\_\_ (Date) \_\_\_\_\_

Parent/Guardian or Legally Authorized Representative's Name and Relationship to Subject:

(Name - printed) \_\_\_\_\_ (Relationship to Subject - printed) \_\_\_\_\_

(Signature of Parent/Guardian) \_\_\_\_\_ (Date) \_\_\_\_\_

### **Statement of Person Who Obtained Consent**

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

(Signature of Person who Obtained Consent) \_\_\_\_\_ (Date) \_\_\_\_\_