| | |
|---|---|
| Title: | **Way to Safety: Cellphone Blocking Technology to Reduce Cellphone Use While Driving Among Teens** |
| Short Title | Way to Safety Cellphone Blocking |
| eIRB Number: | 14-011234 |
| Protocol Date: | 6/6/2016 |
| Amendment 1 Date: 10/3/2014 | Amendment 3 Date: |
| Amendment 2 Date: | Amendment 4 Date: |

**Sponsor**

TAPITMAT-CHIBE Pilot Grant Program -
Perelman School of Medicine, University of Pennsylvania


**Study Principal Investigator**

M. Kit Delgado, MD, MS
Department of Emergency Medicine
934 Blockley Hall
423 Guardian Drive
Philadelphia, PA, 19104
Phone 215-746-8256
email: mucio.delgado@uphs.upenn.edu

**Site Principal Investigator**

Catherine C. McDonald, PhD, RN
University of Pennsylvania School of Nursing
Claire Fagin Hall
418 Curie Blvd, Room 414
Philadelphia, PA 19104
The Children's Hospital of Philadelphia
The Center for Injury Research and Prevention
3535 Market Street, Suite 1150
Philadelphia, PA, 19104
PENN Phone: 215-746-8355
CHOP Phone: 267-427-1236
Email: mcdonalc@nursing.upenn.edu

# TABLE OF CONTENTS

## ABBREVIATIONS AND DEFINITIONS OF TERMS

| | |
|---|---|
| AE | Adverse Event |
| CHOP | Children's Hospital of Philadelphia |
| SAE | Serious Adverse Event |
| UPenn/Penn | University of Pennsylvania |
| PMACS | Penn Medicine Academic Computing Services |
| SQL | Structured Query Language |
| PHP | Hypertext Preprocessor |
| SSL | Secure Sockets Layer |
| HTTPS | Hypertext Transfer Protocol Secure |
| PHI | Personal Health Information |

## ABSTRACT

Context:

Motor vehicle crashes are the leading cause of death in teens in the U.S.[2], and for drivers aged 15-19 involved in fatal crashes, 21% of distracted drivers were distracted by the use of cellphones.[1] Nearly 90% of teens expect a response to a text message within 5 minutes, and the compulsion to respond is stronger for messages from close social contacts.[6] This suggests that behavioral-economic interventions such as immediate and frequent incentives are needed to offset the disutility caused by not being able to communicate by cellphone while driving.[7] If proven to be effective, incentives could be scaled up via auto insurance discount contributions, school programs, and parental contributions.

Objectives:

The objective of this study is to measure whether activation of a cellphone blocking device results in a decrease in the frequency of drives in which the phone is unlocked and the total proportion of time in which a cellphone is being used at non-zero speeds by teen drivers and to determine the incidence of handheld cellphone use while driving and its relationship to incoming text messages and driving conditions in a teen driver cohort.

Study Design:

Research participants will be recruited to take part in a randomized control trial. Participants' cellphone use will be observed during an initial baseline period. Participants will then be randomly assigned to one of four conditions (education only (control), opt-in blocking, opt-out blocking, and opt-out blocking with parental notification).

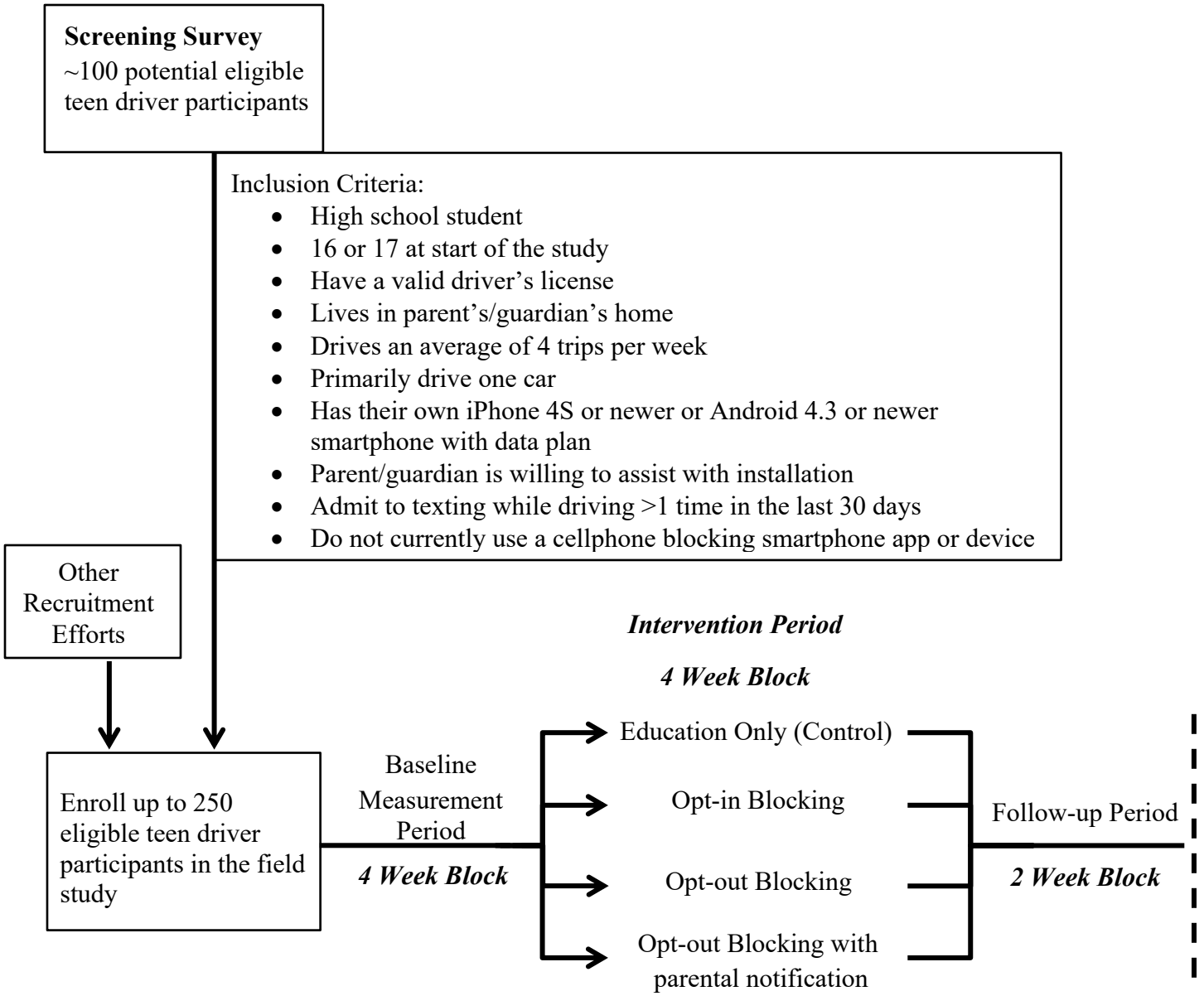
Setting/Participants:

High school students who are age 16 or 17 at the start of the study that drive an average of 4 trips per week and hold a valid driver's licenses will be recruited. Other inclusion criteria include living with a parent/guardian, having their own smartphone (iPhone 4S or newer or Android 4.3 or newer) with data plan, primarily driving one car, admitting to texting while driving at least once in the past month, do not currently use a cellphone blocking app or device, and that a parent will be willing to install the device and adjust the settings as necessary.

Study Interventions and Measures:

A cellphone blocking device (DriveID) will be mailed or given directly to participants. DriveID will measure all teen participant cellphone use while the cellphone is in the car for the first four weeks. During the intervention period (Weeks 5-8), participants will be placed into one of the four conditions (one control, three blocking) that they have been randomized to. At the beginning of Week 5, the participant's DriveID will either be flipped into a cellphone blocking mode where the phone will lock when being used while driving or remain in a control mode. A two week follow-up phase will occur after the intervention, during which participants may choose which group they would like to try. Surveys and an interview will also be administered as part of this study.

## FIGURE 1: STUDY DIAGRAM




**Measurements:**

| | | | |
|---|---|---|---|
| Cellphone use while driving | → | → | → |
| Participant Survey | X | X | X* |
| Educational Information | | X | |
| Interview | | | X |

* Participant chooses mode for follow-up phase

# 1 BACKGROUND INFORMATION AND RATIONALE

## 1.1 Introduction

In the U.S. in 2012, 3,328 people were killed in crashes involving a distracted driver, and an additional 421,000 people were injured (up from 387,000 in 2011).[1] Drivers under the age of 20 represent the largest proportion of drivers who were distracted. Motor vehicle crashes are the leading cause of death in teens in the U.S.,[2] and for drivers aged 15-19 involved in fatal crashes, 21% of distracted drivers were distracted by the use of cellphones.[1] In a recent New England Journal of Medicine study, the risk of crashes in teen drivers was 3 to 8 fold higher if the driver was dialing or texting their cellphone,[3] an effect similar to having a blood alcohol concentration of 0.1 (above the legal limit of 0.08).[4] Nearly half of U.S. high school students admit to texting while driving in the last 30 days, despite the majority knowing that texting while driving is harmful.

Legal bans, public awareness campaigns, pledges, and a myriad of smartphone apps to reduce cellphone use while driving have had little effect on curbing the epidemic.[5] One reason these efforts have had limited success is that texting has been shown to be a compulsion in teens driven by present biased-preferences. Nearly 90% of teens expect a response to a text within 5 minutes, and the compulsion to respond is stronger for messages from close social contacts, such as a significant other.[6] This suggests that behavioral-economic interventions such as immediate and frequent incentives are needed to offset the disutility caused by not being able to communicate by cellphone while driving.[7] If proven to be effective, incentives could be scaled up via auto insurance discount contributions, school programs, and parental contributions.

## 1.2 Name and Description of Intervention

DriveID was released in December of 2013 as a device to overcome a technological barrier in being able to accurately measure whether a driver's cellphone is being used while driving. It is a solar-powered Bluetooth signaling technology placed on the car windshield. DriveID can measure type of cellphone use while driving and be configured to block a driver's cellphone use while the vehicle is in motion. There is no physical interaction with the DriveID device other than installation.

The device is placed on the windshield and an app is downloaded on to the phone. Online configuration of the device settings takes approximately 3-5 minutes. After the initial installation, the device is always on and interacts with the user's cellphone in the background. Only the cellphone with the corresponding DriveID application is monitored by the DriveID device. The DriveID device directly accesses the vehicle's driving metrics and can be set to lock the phone at speeds as low as 1 mph. Device setup is flexible to allow for specific smartphone applications like navigation and maps. The blocking function cannot be deactivated without permission of the account holder.

The study intervention involves randomization into one of four conditions: 1 control condition and 3 blocking conditions (opt-in blocking, opt-out blocking, and opt-out blocking with parental notification). For the control condition, the device will collect information about cell phone use, but no blocking functions will be activated. For opt-in blocking, the

participants will have to initiate the app when entering the vehicle; the blocking settings will be pre-set to block incoming calls and text messages only. For opt-out blocking, the device will automatically turn on when the teen begins driving and will be set to the same pre-set blocking configuration as opt-in blocking. For opt-out blocking with parental notification, the device will automatically turn on when the teen begins driving. The blocking settings will be pre-set to block all incoming calls and text messages. If teens override the blocking feature, a parent/guardian will receive an instant notification in the form of an email. Parents/guardians will also have the ability to increase the settings to block outgoing calls and all other cellphone functions (i.e. applications). Furthermore, if teens in any condition tamper with the DriveID device, delete the corresponding application from their smartphone, or disable Bluetooth capabilities, an email will be sent to the parent/guardian and a member of the study team.

### 1.3 Findings from Non-Clinical and Clinical Studies

The largest, most rigorous study of the crash risk associated with distraction from cellphone use was published in the New England Journal of Medicine in January 2014. The authors conducted two studies on the relationship between the performance of secondary tasks, including cell-phone use, and the risk of crashes and near-crashes. To facilitate objective assessment, accelerometers, cameras, global positioning systems, and other sensors were installed in the vehicles of 42 newly licensed drivers (16.3 to 17.0 years of age) and 109 adults with more driving experience.

During the study periods, 167 crashes and near-crashes among novice drivers and 518 crashes and near-crashes among experienced drivers were identified. The risk of a crash or near-crash among novice drivers increased significantly if they were dialing a cell phone (odds ratio, 8.32; 95% confidence interval [CI], 2.83 to 24.42), reaching for a cell phone (odds ratio, 7.05; 95% CI, 2.64 to 18.83), sending or receiving text messages (odds ratio, 3.87; 95% CI, 1.62 to 9.25), reaching for an object other than a cell phone (odds ratio, 8.00; 95% CI, 3.67 to 17.50), looking at a roadside object (odds ratio, 3.90; 95% CI, 1.72 to 8.81), or eating (odds ratio, 2.99; 95% CI, 1.30 to 6.91). Among experienced drivers, dialing a cell phone was associated with a significantly increased risk of a crash or near-crash (odds ratio, 2.49; 95% CI, 1.38 to 4.54); the risk associated with texting or accessing the Internet was not assessed in this population. The prevalence of high-risk attention to secondary tasks increased over time among novice drivers but not among experienced drivers.

The authors concluded that the risk of a crash or near-crash among novice drivers increased with the performance of many secondary tasks, including texting and dialing cell phones. The study was funded by the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Highway Traffic Safety Administration.

There is one previous field study using Cellcontrol's cellphone blocking/filtering technology to reduce cellphone use while driving, which was funded by the National Highway and Traffic Safety Administration (NHTSA Contract DOT HS 811 863) and carried out by investigators at the University of Michigan. The abstract of the full report published online in December 2013 states:

Forty-four participants each received a cell phone filtering/blocking application on their employer-provided cell phones for 9 weeks. During the first and last 3 weeks, cell phone activity including calling, text messaging and application use was simply recorded in the background. During the middle 3 weeks, the cell phone filtering/blocking software was active, meaning that anytime the application sensed that the phone was moving faster than the pre-set speed threshold, all phone activity was blocked. Objective data on participants' phone use behavior and subjective data (from a questionnaire) on participants' acceptance were collected. Additionally, the impact on an organization attempting to implement a similar program employing cell phone filtering/blocking was examined. During the blocking period, participants initiated a higher proportion of their calls when stopped than when the blocking software was inactive. Also, during the blocking period, participants answered a much smaller proportion of incoming calls while driving, and outgoing calls were placed at a lower mean speed. Participants were neutral in their opinions on whether they received a safety benefit from the cell phone blocking.

### 1.4 Compliance Statement

This study will be conducted in full accordance of all applicable Children's Hospital of Philadelphia Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46. All episodes of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol and will report unanticipated problems involving risks to subjects or others in accordance with The Children's Hospital of Philadelphia IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

## 2 STUDY OBJECTIVES

The purpose of the study is to demonstrate feasibility of conducting a field trial of cellphone blocking technology in teen drivers to calculate sample sizes for future trials and generate preliminary data for funding applications. Primarily, the proposed is measuring whether activation of a cellphone blocking device results in a decrease in the total proportion of time in which a cellphone is being used at non-zero speeds by teen drivers.

### 2.1 Primary Objective (or Aim)

The primary objective of this study is to determine the feasibility of conducting an on-road driving study studying cellphone blocking technologies.

### 2.2 Secondary Objectives (or Aim)

The secondary objectives are to:

- Measure whether activation of a cellphone blocking device (DriveID) results in a decrease in the total proportion of time in which a cellphone is being used at non-zero speeds by teen drivers compared with baseline cellphone use while driving.

- Measure the reasons cellphones are being used while driving at non-zero speeds among teens (calls, texts, smartphone apps, etc.)
- Measure teen satisfaction with the cellphone monitoring and blocking device
- Determine the incidence of handheld cellphone use while driving and its relationship to incoming text messages and driving conditions in a teen driver cohort.
- Measure the number of phone unlocks per hour of drive time
- Measure the speed of the car, acceleration, and spatial characteristics of phone unlocks (ex. on highways vs. at intersections)

# 3 INVESTIGATIONAL PLAN

## 3.1 General Schema of Study Design

This is a randomized control study of control vs. cellphone blocking conditions.

### 3.1.1 Screening Phase

Participants will also be recruited through posted flyers, postcards, email blasts, through the Recruitment Enhancement Core (REC), social media, and by word-of-mouth/colleague referrals at Penn and CHOP. The flyers will be posted in a variety of public and private locations, including but not limited to, local public and private high schools in suburban and local Philadelphia, summer camps, universities, etc. No recruitment will occur through schools or public places without first obtaining permission. Postcards will be mailed to potentially eligible families identified by the REC and the Penn Social Media & Health Innovation Lab.

The Penn Social Media & Health Innovation Lab will assist with recruitment through a variety of social media outlets including Facebook and Craigslist. Language for these postings have been included with the application.

Interested participants will be directed to the Way to Health platform. A parent will create an account and consent online. Once consent is obtained, teens will be able to create their own account and assent online. Once consent and assent are obtained, teens will be screened for eligibility with an eligibility survey presented on the Way to Health platform. Only eligibility criteria will be asked. If a participant responds “yes” to all questions, teens will be presented with an intake survey on the Way to Health platform. Questions will cover demographics, opinions, perceptions and experiences with texting and driving. The teen will be asked to email the study team a picture of their driver’s license. A member of the study team will also contact the teen to answer any questions and to mail out the CellControl device. If a teen is not eligible, the participant will be informed that they are ineligible for the current study.

If participants turn 18 during the duration of the study, they will be re-consented as an adult through Way to Health.

### 3.1.2 Baseline Measurement Period (4 Week Block)

DriveID will monitor all cellphone use while the teen driver's cellphone is in the car in which DriveID is installed. The application will run in the background, so there will be no observable changes to participants' cellphone functions. DriveID will capture GPS data throughout the baseline, intervention, and follow-up periods. At the completion of the fourth week, the teen participant will be instructed to complete an online survey administered through Penn's Way to Health IT platform asking about driving behaviors for the first thirty days of the study. Participants will have 2 weeks to complete this survey.

### 3.1.3 Intervention Period (4 Week Block)

At the beginning of the intervention period (this will start within 2 business days of baseline measurement period survey completion), all participants will receive an email with a link to an educational website that raises awareness of the dangers of distracted driving (http://enddd.org). The Children's Hospital of Philadelphia has performed an independent evaluation of the educational content of the website and found it to be evidence based, and scientifically guided[8].

DriveID will be used as a cellphone blocking device for those in the three cellphone blocking conditions where the phone will lock while driving, but the locking function can be overridden according to pre-set settings. DriveID will continue to monitor cellphone use while driving including how often the teen unlocks the cellphone as well as if they are using the phone for a call or other phone features. However, DriveID is not able to differentiate which phone features are being used.

The study team does not promote texting and driving and encourages all participants to drive safely.

### 3.1.4 Follow-up Period (2 Week Block)

At the end of the intervention period, participants will be able to choose a configuration of the Cellcontrol (no blocking, opt-in blocking, opt-out blocking, and opt-out blocking with parental notification. Participants will have up to 1 week to choose mode (via phone call, survey on Way to Health, or via text message). If a participant does not choose mode, the setting will default to remain in what setting the participant was randomized to for the intervention period. We will continue to measure our primary and secondary endpoints. At the completion of the follow-up period or upon voluntary withdrawal from the trial, the teen participant will be instructed to complete an online survey administered through Penn's Way to Health IT platform asking about user satisfaction with the device and its configurations. Members of the study team may also contact the teen participant to participate in a semi-structured phone interview conducted by a member of the study team. The interview will be audio recorded.

## 3.2 Allocation to Treatment Groups and Blinding

Participants will be randomized to one of four groups. The randomization chart will be maintained will be maintained on a secure server that is only accessible by key study personnel.. Participants and study staff will be aware of which group they have been assigned to. A minimum of five participants will be enrolled into each group.

## 3.3 Study Duration, Enrollment and Number of Sites

### 3.3.1 Duration of Study Participation

The study duration per subject will be approximately 3 months , with up to four weeks of Phase 1 (baseline period), up to four weeks Phase 2 (intervention period), and up to two weeks Phase 3 (follow-up period).

### 3.3.2 Total Number of Study Sites/Total Number of Subjects Projected

The study is being conducted at the Children's Hospital of Philadelphia and the University of Pennsylvania. It is expected that up to 250 people will participate in this research study.

## 3.4 Study Population

### 3.4.1 Inclusion Criteria

1) High school student (16 or 17 at start of the study)
2) Holds a valid driver's license
3) Lives in parent/guardian's home
4) Drives an average of 4 trips per week
5) Primarily drive one car
6) Has their own iPhone 4S or newer or Android 4.3 or newer smartphone with data plan
7) Parent/guardian is willing to assist with installation
8) Admits to texting while driving at least once in the last month

### 3.4.2 Exclusion Criteria

1) Already uses a smartphone app or hardware device to limit cellphone use while driving

Subjects that do not meet all of the enrollment criteria may not be enrolled. Any violations of these criteria must be reported in accordance with IRB Policies and Procedures.

# 4 STUDY PROCEDURES

## 4.1 Screening Procedure and Online Consent/Assent Process

Potential participants will either be recruited directly from the eligible participant pool surveyed under IRB protocol (#14-11072) or they will be recruited through methods discussed in section 9.5. Eligible participants from the previous survey study will be contacted by study team members with information about the study. Interested participants outside of that study will be directed to the Way to Health Platform to get more information on the trial and complete the online consent/assent process.

Teens and parents will be instructed that the parent first needs to create a username and password, and create a profile through the WTH platform and then review a consent and sign prior to their teen being screened for the trial. The profile on Way to Health asks for parent's contact information and date of birth. We are not collecting this as data, but it is required in order to create a WTH profile. After a parent consents for their teen to participate they will be instructed to have their teen go to the WTH site and register. Teens will then review and sign an assent for the trial. Following this they will be screened with an eligibility survey presented on the WTH platform. If a participant responds "yes" to all questions they will be allowed to continue in the trial and will be asked to complete the intake survey immediately. Questions will cover demographics, opinions, perceptions and experiences with texting and driving. They will then continue on with their trial participation. If they are not eligible, the participant will be informed that they are ineligible for the current study and will not complete any study procedures. These teens will be documented as screen failures

Teens will be asked to email the study team a copy of their driver's license. A member of the study team will then contact the teen and parent/guardian to schedule an in person meeting or a phone meeting. During this meeting the study team will answer any questions pertaining to the consent or the study and distribute the DriveID device in person or by mail. If a participant turns 18 years old during their participation in the study, a member of the study team will email the teen a link to complete the online consent via WTH in order to re-consent. Participants will receive an email or a text message reminder regarding incomplete steps in WTH depending on their preference selection for communication.

The validation of the online consent/assent process will be met during this meeting and allow for the fulfillment of one of the study aims: to demonstrate the feasibility and effectiveness of an online consent process in order to remotely recruit a larger number of participants in future studies among those who purchase the Cellcontrol product. During the meeting, a member of the study team will ensure that the participants truly understand the risks and benefits of the study. If any participants wish to withdraw, they may do so at this time.

## 4.2 Device Installation

Parents will install the DriveID device for the teen participant via instructions provided with the device. The DriveID device is installed behind the rearview mirror as to not impede vision of the road; the size of the device is approximately 3 inches by 5 inches. The parent and teen will also complete online registration of the device. When installation is completed correctly, a confirmation message is sent to Cellcontrol. If Cellcontrol receives an error message, noting incorrect installation, a member of the study team will contact participants to troubleshoot.

## 4.3 Study Treatment Phase

The study treatment phase will consist of three parts: a baseline measurement period, an intervention period, and a follow-up period.

### 4.3.1 Baseline Measurement

DriveID will measure participants' cellphone use while the cellphone is in the car in which the DriveID device is installed. DriveID will also record GPS data. This data will not be accessed in real time by the study team and will only be viewed after the completion of the drive. The participants will not have access to the usage data during the baseline period and will have no interaction with the device as the monitoring occurs.

Coded data on primary and secondary endpoints will be automatically uploaded daily whenever the phone has a Wi-Fi or cellular data connection to the Cellcontrol server and then exported through an encrypted, secure internet connection to Penn's Way to Health IT Platform for management and analysis via linkage of a study ID.

### 4.3.2 Intervention

At the completion of the baseline phase, all participants will receive an email to an educational website where they can learn about the dangers of distracted driving (http://enddd.org). Teens will also complete a survey.

Cellcontrol will remotely flip the participant's DriveID into a cellphone blocking mode for those in the three blocking conditions of the study on the first day of the intervention period. Teens randomized into the control group will continue with DriveID as is (information regarding cell phone use will continue to be collected, but no blocking will occur). In the blocking conditions, the phone will lock when being used while driving, but the locking function can be overridden.

Coded data on primary and secondary endpoints will be automatically uploaded daily whenever the phone has a Wi-Fi or cellular data connection to the Cellcontrol server and then exported through an encrypted, secure internet connection to Penn's Way to Health IT Platform for management and analysis via linkage of a study ID.

All parents will have the option to check teen's phone use while the vehicle is in motion on the website (https://account.cellcontrol.com/login.php) during weeks five to ten. Parents in the opt-out blocking with parental notification group will receive a notification every time the phone is being used while the vehicle is in motion.

### 4.3.3 Follow-up Phase

At the completion of the Intervention phase, participants will receive a text message and/or email notification that they are eligible change the configuration settings to any of the four conditions tested in the trial. Changes can be made by logging into the Cellcontrol online portal. We will collect data on what configuration the participants choose to make during the 2-week follow-up phase. If a participant does not choose a configuration for the follow-up phase after 1 week, the default setting will be to stay in the configuration they are currently in.

### 4.3.4 Debriefing

At the completion of the follow-up phase or upon voluntary withdrawal from the trial, the participant will be instructed to complete an online survey administered through Penn's Way to Health IT platform asking about user satisfaction with the device. They will receive a link

to the survey through email. If necessary, they may receive reminder calls, emails, or text messages from members of the study team for a one month period following study completion. The purpose of the survey will be to debrief the participant's experience with the trial, cellphone blocking technology, and suggestions for designing a better trial. For subjects that withdrawal prematurely, we will ask about what factors contributed to their decision to withdraw early.

For participants who complete the trial, a member of the study team may contact them to complete a brief phone interview.

### 4.4 Subject Completion/Withdrawal

Participants may withdraw from the study at any time. They may also be discontinued from the study at the discretion of the Investigators at any time.

## 5 STUDY EVALUATIONS AND MEASUREMENTS

### 5.1 Confirmation of Eligibility

Members of the research team will confirm the eligibility of potential subjects based on the inclusion/exclusion criteria noted in Section 3.4 after the online assent process. A parent or guardian will first need to create an account on the Way to Health platform and complete consent online. Once consent is obtained, teens will need to create an account on the Way to Health platform and complete assent. After the participant provides assent, they will be presented with a survey to confirm eligibility. If they are eligible, an intake survey will be available for teens to complete. A study team member will contact participants to confirm eligibility (which will be recorded and retained for all individuals). If subjects are not eligible, no other study procedures will occur.

### 5.2 Intake Survey

We will collect the following information on each subject:

- Demographic characteristics
- First two digits of the teen's driver's license number
- Month and year of birth
- Last four digits of the teen's social security number (for UPenn's reporting purposes)
- Opinions and perceptions on texting while driving and associated technology

### 5.3 Cellcontrol Data

Cellcontrol requires users to enter in basic information to set up the account policy. This includes:

- Username
- Password
- Name
- Phone number

- Email

The Cellcontrol app currently tabulates the following data which are uploaded securely to the Cellcontrol server:

- Phone talk time while driving
- Phone usage time while driving (non-talk time phone unlocked and being used for apps, texts, email, etc).
- Phone unlocks while driving
- Speed the car is traveling when the phone is unlocked
- Incidence of hard decelerations converted to a "driving score" and hard accelerations converted to an "eco score"
- Number of incoming calls and texts that are blocked
- GPS, accelerometer, and timestamp data

### 5.4 Post-Baseline Survey

We will collect self-report information on each subject's driving behaviors for the past thirty days in which they were driving in the baseline period. Information includes how often they report driving and self-report cell phone use.

### 5.5 Teen End of Study Survey

We will survey participants via the Way To Health platform. The survey will be constructed in Qualtrics, an online survey tool used by Way To Health, to elicit feedback on the cellphone locking technology. Teen subjects will be asked to report:

- Their feedback on using the cellphone blocking technology
- Feedback on settings/configurations of the cellphone blocking technology
- Perceptions of whether their safety had improved with the use of the technology
- Suggestions for improving the technology and the research study
- Suggestions for future interventions to promote engaged driving

A member of the study team may contact participants over the phone to elaborate upon responses to the end of study survey questions.

### 5.6 Teen Semi-Structured Interview

We may call participants upon completion of the follow-up period to complete a semi-structured phone interview. The interview will be conducted by a member of the study team and will be recorded by the Penn Mixed Methods Research Lab. The interview will last approximately twenty minutes. Teen subjects will be asked questions regarding:

- Feedback on each intervention phase of the study (baseline, intervention, and follow-up)
- Suggestions for preventing cellphone distractions while driving

- If they will continue to use this technology

### 5.7 Safety Evaluation

This is a minimal risk, behavioral intervention study. Physical risk is no more than the risks already caused by distracted driving from handheld cellphone use. The intervention directly lowers the risk of distracted driving by blocking incoming phone calls and texts and locking the phone while the participant is driving. The participant may unlock the phone in any of the conditions with the swipe of a finger where they will then be brought to their typically screen. If participants have their phone password protected, they will still need to enter their password in order to use the phone. The extra swipe to dismiss the cellphone blocking technology is no more dangerous than unlocking the phone normally.

Participants will have no interaction with the physical DriveID device after installation. There are no expected serious adverse events related to the intervention or participation in this study.

## 6 STATISTICAL CONSIDERATIONS

This is a pilot trial with the purpose of demonstrating the feasibility of conducting this type of research and generating data in order to estimate sample sizes for future trials.

### 6.1 Primary Endpoint

Frequency of phone unlocks while driving (unlocks/hour)

### 6.2 Secondary Endpoints

Total proportion of time the phone is in use at non-zero speeds

Seconds of phone use at non-zero speeds

Seconds of phone use while stopped

Number of incoming calls and texts that were blocked

Number of times participants make or receive a phone call, send or read a text message, and use any application while driving at non-zero speeds

Proportion of participants who switched to another blocking configuration in the Follow up period

Participant acceptance of cellphone blocking technology based on post-study survey

Incidence of handheld cellphone use and its relationship to incoming text messages and driving

In determining feasibility the following will be measured:

- Proportion of screen eligible who enroll
- Number enrolled per month
- Retention rates by study arm
- Proportion of surveys completed

## 6.3 Statistical Methods

### 6.3.1 Baseline Data

Baseline and demographic characteristics will be summarized by standard descriptive summaries (e.g. means and standard deviations for continuous variables such as age and percentages for categorical variables such as gender).

### 6.3.2 Efficacy Analysis

The primary analysis will be based on an intention to treat approach and will include all subjects randomized at the beginning of the intervention period.

The primary efficacy endpoint will be the difference in frequency of cellphone unlocks per hour of driving between weeks 5 and 8 compared with baseline period weeks 2 to 4. The statistical analysis will use relative change models adjusted for age, sex, state, and presence of in-vehicle navigation and phone connectivity systems will compare % change in unlocks per hour with 95% confidence intervals in each intervention arm relative to control arm.

# 7 STUDY INTERVENTION

## 7.1 Description

The study intervention will involve four different conditions to which participants may be randomized: 1 control group and 3 blocking groups.

### 7.1.1 Education Only (Control) Group

Participants in the control group will complete the Baseline driving period, but at the end of Week 4, instead of DriveID flipping into a blocking mode, the device will remain at baseline settings. It will continue to collect information regarding cellphone use while driving in the background. There will be no observable changes to cellphone functions.

### 7.1.2 Opt-in Group

The blocking settings for opt-in group participants will require participants to "opt in" to using the blocking features. Blocking settings will be pre-set to block all incoming calls and text messages while the vehicle is in motion, but participants will have to initiate the blocking when they begin driving by activating the device via the phone app. Participants have the ability to override the blocking function while the vehicle is in motion. Number of unlocks can be monitored through logging in to the DriveID website.

### 7.1.3 Opt-out Group

The blocking settings for opt-out group participants will turn on by default while driving. Blocking settings will be pre-set to block all incoming calls and text messages while the vehicle is in motion, but participants will have the ability to override the blocking. Number of unlocks can be monitored through logging in to the DriveID website.

### 7.1.4 Opt-out Blocking with parental notification Group

The blocking setting for the opt-out blocking with parental notification group participants will turn on by default while driving. The restrictions will be pre-set to block all incoming calls and text messages while the vehicle is in motion. Parents/guardians will receive a notification every time the teen overrides the block at non-zero speeds. Parents/guardians will have the option to also block outgoing calls as well as all other cellphone functions (i.e. applications). Number of unlocks can also be monitored through logging in to the DriveID website.

# 8 SAFETY MANAGEMENT

## 8.1 Adverse Event Reporting

Since the study procedures are not greater than minimal risk, SAEs are not expected. If any unanticipated problems related to research involving risks to subjects or others happen during the course of this study (including SAEs) they will be reported to the IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. AEs that are not serious but that are notable and could involve risks to subjects will be summarized in narrative or other format and submitted to the IRB at the time of continuing review.

Enrolled participants will be provided with contact information of a study team member for reporting of any adverse events that occur during data collection. They will be told to contact regarding any occurrence they feel is an adverse event, including but not limited to, moving violations/citations while participating, traffic accidents, DriveID malfunction, etc.

# 9 STUDY ADMINISTRATION

## 9.1 Treatment Assignment Methods

### 9.1.1 Randomization

Participants will be randomized to one of the four condition groups.. A statistician who is not involved with enrolling subjects will be responsible for creating the randomization chart. We will do block randomization for 8 assignments at a time. Each block will contain the four arm assignments repeated once in a random order. We will create a string that is 250 assignments long. As participants reach the intervention phase they will be assigned to the next available assignment in this string. Once an assignment has been used it is no longer available to be used. Study staff and participants will not be blinded to the condition. Individuals conducting data analyses will use data which blinds them to which group participants are in.

## 9.2 Data Collection and Management

**Confidentiality, Security, and Anonymization**

### 9.2.1 Way To Health

All personal information that the participant is asked to provide will be collected via *Way To Health. Way To Health* collects subjects' names, dates of birth, addresses, email addresses, phone numbers, and the last four digits of their social security number. They also request the name and phone number of an alternate contact. To assure that participant confidentiality is preserved, individual identifiers are stored in a single password protected system that is accessible only to study research, analysis and IT staff. The last four digits of participants' social security numbers will be stored in a locked cabinet to be destroyed at a later date. An investigator or statistician who logs in will be able to access only non-identifiable data. The *Way To Health* administrative group and research coordinators responsible for contacting participants for follow-up study visits or responding to questions about the study are able to view participant names and contact information. The WTH web development team and Project Director currently have administrative access to PHI. All of these personnel will have completed Human Subjects Protection and HIPAA privacy training. The system automatically generates logs of all data queries which can be reviewed by research staff to ensure that no unauthorized persons have gained access to identifiable information. This system is hosted on site at The University of Pennsylvania (UPenn) and is protected by a secure firewall and several layers of operational security. Once a participant has been entered into this system, they are given a unique study identification number (ID). Any datasets and computer files that leave the firewall are stripped of all identifiers and individuals are referred to by their study ID. The study ID is also used on all analytical files.

Data will only be transferred through DriveID, Cellcontrol, Penn's Way to Health IT Platform, and the CHOP and Penn study teams. Data will be stored on secure servers both at

CHOP and Penn. Any data transferred between the CHOP and Penn study teams will be transferred via encrypted hard drive or secure email.

### 9.2.2 Cellcontrol

Data collected by Cellcontrol through the DriveID device will be manually uploaded by members of the study team or directly to Way to Health through secure CSV reports. Data will not be tracked in real time.

### 9.2.3 Semi-Structured Interview

The semi-structured interview will be completed by a member of the study team and will be recorded by Penn's Mixed Methods Research Lab. The MMRL provides verbatim transcription of individual and group data through *Accurate, Dependable, Affordable* (ADA) transcriptions services. ADA provides secure and confidential data transfers consistent with the University of Pennsylvania's Institutional Review Board data safety standard. ADA provides transcription services that are also consistent with federal Health Insurance Portability and Accountability Act (HIPAA) guidelines and regulations. The MMRL works with ADA to check for accuracy. Once accuracy in transcription is determined, original recordings are destroyed

## 9.3 Confidentiality

All data and records generated during this study will be kept confidential in accordance with Institutional policies on subject privacy and the Investigator and other site personnel will not use such data and records for any purpose other than conducting the study. The safeguards described above in Section 9.2 will be implemented to ensure subject confidentiality.

No identifiable data will be used for future studies without first obtaining IRB approval. The investigator will obtain a data use agreement between provider (the PI) and any recipient researchers (including others at CHOP) before sharing a limited dataset (dates and zip codes).

## 9.4 Regulatory and Ethical Considerations

### 9.4.1 Data and Safety Monitoring Plan

While there is no data monitoring safety board in place for this study as it is a study with minimal risk and without medical or biological intervention, the research teams at the University of Pennsylvania and the Children's Hospital of Philadelphia, led by the Investigators, will be aware of and will monitor possible areas of risk to the research participants. Weekly team meetings will include discussion of any safety and data issues that are observed. The PIs will be responsible for monitoring the data and safety.

### 9.4.2 Risk Assessment

Despite care taken in the study design to minimize risk exposure to participants, it is acknowledged that there is minimal risk to participants.

Loss of confidentiality is a potential risk of participating in this study; however, the safeguards put in place by *Way To Health* and the Mixed Methods Research Lab (Section

9.2) will reduce this likelihood. The members of the study teams will follow necessary precautions to ensure that all collected data is not shared with unauthorized individuals or groups.

As part of this study, teens will be driving with a cell phone blocking device present and operating in the vehicle. These teens are eligible for the study because they admit to texting while driving. This study will not require them to interact with their phones while driving any more than they would normally choose to on their own. We will encourage teens throughout the study to drive safely and not to use their cell phones while driving.

It is possible that participants may feel uncomfortable answering some of the interview questions. They will be made aware before the start of the interview that this is a risk associated with participation in the interview and will be reminded that they do not have to answer any questions which make them uncomfortable.

### 9.4.3 Potential Benefits of Study Participation

There are no direct benefits from participating in this study.

### 9.4.4 Risk-Benefit Assessment

The gathered information has the potential to increase the understanding of teen's opinions on cellphone blocking technology. The research has the potential to enhance the foundation of behavioral change models and improve the quality of continuing education about safety. The results may also speak to the benefits of using cellphone blocking devices in-vehicle for promoting positive safety behaviors; these benefits outweigh the minimal risk of participation in this study.

## 9.5 Recruitment Strategy

Recruitment may occur through a subject pool from IRB #14-11072. Potential participants will also be recruited through a variety of strategies. As we are not limited by geographic location we will all recruitment strategies on a national level unless otherwise noted. These strategies consist of on-the-ground recruitment strategies (posting posters and flyers in visible areas, recruitment through local school districts), direct mailer (email blasts, letter or postcard sent to home address), social media (facebook, craigslist, snapchat, etc), for-profit and nonprofit organization partnerships/mentions, media attention (mentions in local and national news sources), and word-of-mouth referrals.

On-the-ground recruitment strategies include posting flyers in areas where teen drivers and parents frequent and recruiting through local school boards. These locations will include parks, malls, and other after school hangouts. These materials will only be posted in the Philadelphia area rather than nationwide. We will also reach out to local school boards to ask about having flyers posted and/or sent to parents in the Philadelphia. We will contact persons in in the district superintendent office to investigate whether they will be willing to post theses flyers at schools in their district and/or are willing to mail letters to parents of teen drivers in their school district. This will only be done in the Philadelphia area. No recruitment will occur through schools or public places without first obtaining permission. Letters, postcards, and flyers will consist of the messaging in the letters, postcards, and flyer we have attached to this protocol.

We will also recruit participants by mailing letters and doing email blasts to parents of teen drivers. We will work with CHOP's Recruitment Enhancement Core (REC) to contact individuals who have visited CHOP and who have teen drivers through direct mailers of letter and/or postcards. The REC will also send email blasts to families on our behalf. These emails will consist of the messages included in the letters attached to this protocol.

Social media sources will also be used for recruitment purposes. We plan to use Facebook, Craigslist, Twitter, Snapchat, Google, and Instagram in our social media campaign. The Penn Social Media & Health Innovation Lab will assist us in using the various social media outlets so that we can be as effective as possible in disseminating the recruitment message to the correct population. With many of these mediums we will be able to target teens and parents with separate ads. In those cases we will provide recruitment ads that are targeted for that specific population. In many cases the social media ad that we can use consists of a brief message (i.e., Twitter only allows a 160 character message). In these cases the message would direct the potential participant to the WTH landing page where they can register. On this page we will recreate the full message that is included in the recruitment letters so that all participants are well informed of the study details prior to registering for the study. Final advertisements and Twitter messages have been attached to this protocol.

We will be reaching out to many for profit and nonprofit organizations that might be willing to help us advertise this study. These organizations include but are not limited to MADD, insurance companies, and cell phone companies (other examples: madd.org<http://madd.org>, vsofa.org<http://vsofa.org>, stoptextsstopwrecks.org<http://stoptextsstopwrecks.org>, aaafoundation.org<http://aaafoundation.org>, enddd.org<http://enddd.org>, digitalresponsibility.org<http://digitalresponsibility.org>). We will ask these organizations if they would be willing to advertise to consumers using the flyer, letter, or brief mentions on their websites. Letters and flyers would be the same as those used for other recruitment strategies. Brief mentions would redirect potential participants to the WTH landing page where they would read the full recruitment message.

We will be working with the CHOP ad UPenn media relations offices to learn various ways we might get mentions for this study in the press. We hope that some local and nationwide news outlets (Penn News Today, NPR, and other print and online newsletters) will be interested in doing a story on the goals of this program and that this media attention will help with recruitment. If we are successful in getting media attention the lead Penn PI for this study, Kit Delgado, will conduct interviews and ensure that a link to the WTH landing page is included in any material produced around the study.

While all the above recruitment strategies may differ in terms of their approach, message length and type, each method will direct all potential participants to the WTH landing page where a standard message giving an overview of the program will be posted. That landing page text has been included in this protocol as well. It is important to stress that because of this method all potential participants will be exposed to the same recruitment message and study information prior to registering for the program.

The Recruitment Enhancement Core provides assistance with recruitment plan development and will identify and contact potential participants on our behalf using the CHOP Data Warehouse, and the CHOP Recruitment Registry.

## 9.6 Informed Consent/Assent

We will require parental consent and teen assent for this trial. Parental consent and subject assent for this trial will be obtained via Way to Health.

Interested participants will be directed to the Way to Health Platform to get more information on the trial and complete the online consent/assent process.

Teens and parents will be instructed that the parent first needs to create a username and password through the WTH platform and then review a consent and sign prior to their teen being screened for the trial. After a parent consents for their teen to participate they will be instructed to have their teen go to the WTH site and register. Teens will then review and sign an assent for the trial.

A member of the study team will then contact the teen and parent/guardian to schedule an in person meeting or a phone meeting. During this meeting the study team will answer any questions pertaining to the consent or the study and distribute the DriveID device in person or by mail. If a participant turns 18 years old during their participation in the study, a member of the study team will email the teen a link to complete the online consent via WTH in order to re-consent. Participants will receive an email or a text message reminder regarding incomplete steps in WTH depending on their preference selection for communication.

The validation of the online consent/assent process will be met during this meeting and allow for the fulfillment of one of the study aims: to demonstrate the feasibility and effectiveness of an online consent process in order to remotely recruit a larger number of participants in future studies among those who purchase the Cellcontrol product. During the meeting, a member of the study team will ensure that the participants truly understand the risks and benefits of the study. If any participants wish to withdraw, they may do so at this time.

A member of the study team will contact all enrolled participants to ensure understanding of study procedures. Electronic signatures will be obtained for both parent and child.

## 9.7 Payment to Subjects/Families

### 9.7.1 Payment for time and inconvenience (i.e. compensation)

Participants will be compensated for their time, effort, and inconvenience over the duration of the study:

- Completion of the intake survey
- Successful installation of DriveID
- End of Baseline Period (including completion of survey)
- End of Intervention Period(including completion of survey)

- End of Follow up Period(including completion of survey)
- End of Drive Survey Teen Interview

### 9.7.2 Gifts

All participants will receive a DriveID device for participation in the study.

## 10 PUBLICATION

We plan to publish the findings in conference proceedings and/or peer-reviewed journals.

## 11 REFERENCES

1) National Highway Traffic Safety Administration. Distracted Driving 2012. Traffic Safety Facts Research Note. Available at: http://www.nrd.nhtsa.dot.gov/CATS/index.aspx.

2) Query, C. W. B. I. S. (2010). Reporting System (WISQARS). Atlanta, GA: US Department of Health and Human Services, CDC. *National Center for Injury Prevention and Control*.

3) Klauer, S. G., Guo, F., Simons-Morton, B. G., Ouimet, M. C., Lee, S. E., & Dingus, T. A. (2014). Distracted driving and risk of road crashes among novice and experienced drivers. *New England Journal of Medicine*, *370*(1), 54-59.

4) Leung, S., Croft, R. J., Jackson, M. L., Howard, M. E., & Mckenzie, R. J. (2012). A comparison of the effect of mobile phone use and alcohol consumption on driving simulation performance. *Traffic injury prevention*, *13*(6), 566-574.

5) Cheng, C., & Meer, J. (2012). The Effect of Cell Phone Bans on Driver Behavior: Accidents and Casualties. *College Station, TX: Department of Economics, Texas A&M University*.

6) Atchley, P., & Warden, A. C. (2012). The need of young adults to text now: Using delay discounting to assess informational choice. *Journal of Applied Research in Memory and Cognition*, *1*(4), 229-234.

7) Loewenstein, G., Asch, D. A., Friedman, J. Y., Melichar, L. A., & Volpp, K. G. (2012). Can behavioural economics make us healthier. *BMJ*, *344*(7863), 23-25.

8) Feldman, J. (2014, May 5). *Evaluating the Effectiveness of Distracted Driving Presentations – Children's Hospital of Philadelphia (CHOP) and EndDD.org*. Retrieved from http://enddd.org/distracted-driving-research/childrens-hospital-of-philadelphiachop-report/