University of Pittsburgh

School of Medicine
Department of Emergency Medicine

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Official Title of Study: Utilizing Text Messaging to Improve Vehicle Safety Among At-Risk Young Adults (SaVE)

NCT number: NCT03833713

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CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Utilizing Text Messaging to Improve Vehicle Safety Among At-Risk Young Adults (SaVE)

SOURCE OF SUPPORT: National Highway Traffic Safety Administration (NHTSA)

Researchers at the University of Pittsburgh are conducting a research study to understand vehicle safety behaviors of young adults. Research studies include only people who choose to take part. Please take your time in deciding whether you want to be involved in the clinical trial. You are encouraged to discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you should ask the research assistant for more explanation. If you decide to do this study, you will be asked to sign and date this form.

Who is being asked to take part in this research study?

You are being asked to participate in this study because you are an Emergency Department (ED) patient between 18-25 years of age and have reported a history of a risky vehicle behavior. About 250 people will take part in this study.

Why is this research being done?

This is a research study to find out how best to help young adults develop safe vehicle habits.

What procedures will be performed for research purposes?

If you choose to take part, we will ask you to:

(1) Provide us with your contact information (name, phone number, email). We will also ask you to provide your social security number.

(2) Answer a survey <u>today</u> and <u>8 and 14 weeks from today</u> including some questions about risky vehicle behaviors like not wearing a seat belt, drinking and driving, and distracted driving. The survey requires access to a personal computer and internet connection. These surveys each take about 5 minutes to complete.

(3) <u>For the next 2 weeks</u>, respond to 2-3 text message queries <u>1 day per week (Sunday)</u>. These queries could include some questions about risky vehicle behaviors like not wearing a seat belt, drinking and driving, and distracted driving.

(4) If you respond to at least 50% of these texts, 2 weeks from now, you will be randomly assigned to either a 6-week text message intervention or weekly text message queries (same as the first 2-weeks). The intervention provides feedback on some of your text responses.

a. **If you do not complete at least 50% of these texts over the next 2 weeks, you will be removed from the study and not eligible for further payments. We will notify you by text if you do not meet this eligibility criteria.

For the text messaging: We ask that you reply as accurately as possible and as soon as possible, but not to text while driving. You can text STOP at any time to withdraw, at which time you will not receive any further text messages. **We will not be able to respond to any immediate or emergency concern you have that is sent to our phone number, nor any text message outside the scope of the questions we ask.** We will not send any private information through texts unrelated to your drinking reports.

What are the possible risks, side effects, and discomforts of this research study?

The possible risks of this research study may be due to breach of confidentiality in information associated with text-message communication and web-based communication. It also includes research data being accessed/seen by people outside of the study team. Only the study investigators and Jack Doman, the Director of the Office of Academic Computing at WPIC, will be able to link your research data with your phone number.

Risks associated with Mobile Phone Text-Message Interactions:

Text message are unencrypted. As such, transmissions may be unknowingly and/or unintentionally intercepted by third parties. Someone not associated with the research study may see the messages on your phone. **We ask that you minimize this risk by (1) setting up a password protection on your cellular phone and (2) immediately erasing messages after responding to our queries.**

Risks associated with Mobile Apps and Web-based Surveys:

There is also a possibility of breach of confidentiality in sending or entering data into apps or website. We will minimize this potential risk by assigning you a unique ID. All data sent from the phone to servers will be identified only by this ID.

What are possible benefits from taking part in this study?

There are no direct benefits. Participating in this study may help determine how best to help young adults improve vehicle safety. We hope the information learned from this study will benefit other young adults in the future.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?

We will promptly notify you if any new information develops during the course of this study that could cause you to change your mind about continuing to participate in this study.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?

You and/or your health insurance will be charged for any portion of your care that is considered standard care (that is, these expenses would have happened even if you were not in the study). You may be responsible for any co-payments and deductibles that are standard for your insurance coverage. You will not be charged for any of the procedures that occur as part of this research study.

Will I be paid if I take part in this research study?

If you choose to participate in the trial, you will be paid as follows: 1) $15 for completing the initial questionnaires, 2) $15 for completing the 8-week web-based assessment, 3) $15 for completing the 14-week web-based assessment. The most you could be paid is $45. There are no additional payments for messaging fees.

Who will know about my participation in this research study?

In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following people may have access to your research records:

(1) Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information for the purpose of monitoring the appropriate conduct of this research study.
(2) If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate authorities.

Any information about you obtained from this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet or password-protected computer database that only authorized study personnel can access. Your identity on these records will be indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. You will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission (release).

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?

The investigators may continue to use and disclose, for the purposes described above, identifiable information related to your participation in this research study for a minimum of seven years after final reporting or publication of a project.

Is my participation in this research study voluntary?

Your participation in this research study, including the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to participate or not will have no effect on your current and future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provide.

May I withdraw, at a future date, my consent for participation in this research study?

You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. Any identifiable research data resulting from your participation in this research study prior to the time you formally withdraw your consent may continue to be used and disclosed by investigators for the purposes described above.

To withdraw from text messaging, simply text “stop” to our phone number. To formally withdraw your consent for participation in this research study, you should provide a written and dated

notice of this decision to the Principal Investigator of this research study at the address listed on the first page of this form. If you want to stop being in the study, it will have no effect on your current or future relationship or medical care with your insurer, your doctor, the University of Pittsburgh, or any UPMC hospital or affiliated health care provider.

If I agree to take part in this research study, can I be removed from the study without my consent?

At any time, the study doctor may discontinue your participation in this study. The study doctor may decide to take you off this study if your health or safety may be at risk; you have not been following study instructions or because of a study administrative decision by the study sponsor or the study doctor.

WHAT IS THE CLINICAL TRIALS REGISTRY?

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that a listed investigator address my questions, concerns or complaints.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that have occurred during my participation.

By signing this form, I agree to participate in this research study. A copy of this consent form will be given to me.

_____	_____	_____
Participant's Signature	Printed Name of Participant	Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

Printed Name of Person Obtaining Consent	Role in Research Study
Signature of Person Obtaining Consent	Date