

MEMORANDUM

DATE: November 8, 2019

TO: Tripp Shealy III, Pamela Kryschal, Kaitlyn Emily Franczek, Emma Walker, Erin Kissner, Lauren Carlson, Heather Rigdon

FROM: Virginia Tech Institutional Review Board (FWA00000572, expires January 29, 2021)

PROTOCOL TITLE: RNS 18-11: Driver Response to Dynamic Message Sign Safety Campaign Messages

IRB NUMBER: 18-977

Effective November 8, 2019, the Virginia Tech Institution Review Board (IRB) approved the Amendment request for the above-mentioned research protocol.

This approval provides permission to begin the human subject activities outlined in the IRB-approved protocol and supporting documents.

Plans to deviate from the approved protocol and/or supporting documents must be submitted to the IRB as an amendment request and approved by the IRB prior to the implementation of any changes, regardless of how minor, except where necessary to eliminate apparent immediate hazards to the subjects. Report within 5 business days to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.

All investigators (listed above) are required to comply with the researcher requirements outlined at:

<https://secure.research.vt.edu/external/irb/responsibilities.htm>

(Please review responsibilities before beginning your research.)

PROTOCOL INFORMATION:

Approved As: **Expedited, under 45 CFR 46.110 category(ies) 4,7**
Protocol Approval Date: **May 23, 2019**
Progress Review Date: **May 22, 2020**

ASSOCIATED FUNDING:

The table on the following page indicates whether grant proposals are related to this protocol, and which of the listed proposals, if any, have been compared to this protocol, if required.

SPECIAL INSTRUCTIONS:

This amendment, submitted August 28, 2019, updates research protocol through revising sections: 6, 8.1, 9.5, 11, 15.1, 15.3, 24.1, and 26.1. Research personnel was updated through adding Lauren Carlson, Erin Kissner, and Heather Rigdon. Recruitment materials were updated to say "40 minutes" instead of "1 hour". Consent forms were updated to make the timing and location consistent.

Date*	OSP Number	Sponsor	Grant Comparison Conducted?
10/26/2018	PCA66S34	Virginia Center for Transportation Innovation & Research (Title: RNS 18-11: Driver Response to Dynamic Message Sign Safety Campaign Messages)	Not required (Not federally funded)

* Date this proposal number was compared, assessed as not requiring comparison, or comparison information was revised.

If this protocol is to cover any other grant proposals, please contact the HRPP office (irb@vt.edu) immediately.

MEMORANDUM

DATE: May 23, 2019
TO: Tripp Shealy III
FROM: Virginia Tech Institutional Review Board (FWA00000572, expires January 29, 2021)
PROTOCOL TITLE: RNS 18-11: Driver Response to Dynamic Message Sign Safety Campaign Messages
IRB NUMBER: **18-977**

Effective May 23, 2019, the Virginia Tech Institution Review Board (IRB) approved the New Application request for the above-mentioned research protocol.

This approval provides permission to begin the human subject activities outlined in the IRB-approved protocol and supporting documents.

Plans to deviate from the approved protocol and/or supporting documents must be submitted to the IRB as an amendment request and approved by the IRB prior to the implementation of any changes, regardless of how minor, except where necessary to eliminate apparent immediate hazards to the subjects. Report within 5 business days to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.

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Consent to Take Part in a Research Study

Title of research study: RNS 18-11: Driver Response to Dynamic Message Sign Safety Campaign, 18-977

Principal Investigator: Tripp Shealy, 540-231-6478, tshealy@vt.edu

Other study contact(s): Pamela Kryschal, (202) 549-9054, pamelak@vt.edu

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are 18 years old or older.

What should I know about being in a research study?

- Someone will explain this research study to you
- Whether or not you take part is up to you
- You can choose not to take part
- You can agree to take part and later change your mind
- Your decision will not be held against you
- You can ask all the questions you want before you decide

Why is this research being done?

The purpose is to study the effectiveness of roadside safety campaigns, particularly ones designed to change negative driving behavior.

How long will the research last and what will I need to do?

We expect that your participation in this research study will last for total of one hour. You will be asked to wear the functional near-infrared spectroscopy (fNIRS) cap for 18 minutes and read 16 series of 5 messages. During the time that you are wearing the cap, in between the 16 series, you will be asked two questions which you will answer out loud to the researcher. Afterwards, you will fill out a survey about your experience and yourself.

More detailed information about the study procedures can be found under “*What happens if I say yes, I want to be in this research?*”

Is there any way being in this study could be bad for me?

There is a risk that you might experience minor discomfort from the fNIRS device. The cap is the shape and approximate weight of a bicycle helmet. The fNIRS device will be cleaned between each participant with an alcohol swab.

Consent to Take Part in a Research Study

Will being in this study help me in any way?

There are no benefits to you from your taking part in this research. We cannot promise any benefits to others from your taking part in this research. However, possible benefits to others include the understanding of how to design roadside safety campaigns that help the general public.

What happens if I do not want to be in this research?

Taking part in research is completely up to you. You can decide to participate or not to participate.

If you are a student, the decision whether to participate or not participate will have no effect on your grades or relationship with Virginia Tech.

If you feel any discomfort from the fNIRS cap at any point, please inform the research team and they will be removed.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 540-231-6478.

This research has been reviewed and approved by the Virginia Tech Institutional Review Board (IRB). You may communicate with them at 540-231-3732 or irb@vt.edu if:

- You have questions about your rights as a research subject
- Your questions, concerns, or complaints are not being answered by the research team
- You cannot reach the research team
- You want to talk to someone besides the research team to provide feedback about this research

How many people will be studied?

We plan to include about 75 people at this location out of 300 people in the entire study across the state.

What happens if I say yes, I want to be in this research?

- The length of the process will be approximately 1 hour.
- You will interact with the research team conducting the study over the next hour.
- The research will take place in the Mobile Human Factors Laboratory.
- Participant recruitment will continue through August 2019. However, your involvement in data collection will occur just over the next hour.
- The procedure involves sitting for approximately 18 minutes with the fNIRS cap on and reading 16 sets of 5 roadside safety messages.
- In between each set, you will be asked two questions which you will answer out loud. The answers to these questions will be audio recorded by the research.
- After the 18 minutes, you will remove the fNIRS cap and complete a short survey about yourself and your experience with highway safety.
- The study will require you to wear a device on your head called an fNIRS cap. The cap is the size of a bicycle helmet and has non-invasive probes that touch the outside of your head and measure the change in light in the blood in your brain.

Consent to Take Part in a Research Study

What happens if I say yes, but I change my mind later?

You can leave the research at any time, for any reason, and it will not be held against you. There are no adverse effects for leaving the research.

Is there any way being in this study could be bad for me? (Detailed Risks)

There are no known risks to participating in this study.

What happens to the information collected for the research?

We will make every effort to limit the use and disclosure of your personal information, including research study records, only to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the IRB, Human Research Protection Program, and other authorized representatives of Virginia Tech.

If identifiers are removed from your private information or samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

The results of this research study may be presented in summary form at conferences, in presentations, reports to the sponsor, academic papers, and as part of a thesis/dissertation.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include faults in the physiological data collected during the experiment due to machine error.

What else do I need to know?

This research is being funded by Virginia Transportation Research Council.

If you agree to take part in this research study, we will reimburse you \$30 for your time and effort. To receive the \$30, you will sign a form with your name and address indicating that you received the compensation; this personal information will be destroyed after the data collection.

One of the team members conducting this research has a relationship with Toxcel, LLC. The team member is the owner of Toxcel, LLC. The compensation received by the team member is in addition to salary received from the institution. This disclosure is made so that you can decide if this relationship affects your willingness to participate in this study. If you have questions, tell the study coordinator you wish to discuss this with someone and they will make the necessary arrangements.

Consent to Take Part in a Research Study

Signature Block for Capable Adult

Your signature documents your permission to take part in this research. We will provide you with a signed copy of this form for your records.

Signature of subject

Date

Printed name of subject

Signature of person obtaining consent

Date

Printed name of person obtaining consent