



Memo

To:

Louis O Rabinowitz

From:

Site Support Team

Date:

February 10, 2014

Re:

The Impact of Driver Compensation on Commercial Motor Vehicle Safety Survey

IRB ID#:

4609-001

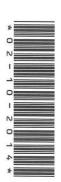
Attached is approval documentation for the above-referenced study.

- ☐ Check all addresses (sites) and phone numbers for accuracy in the Approval Document and Informed Consent. Let our office know ASAP if there are any inaccuracies.
- □ Please note the due date listed on the Approval Document for the Site Continuing Review Status Report. A Site Final Report should also be submitted once the study at your site is completed. These reports are required by the Board and by Federal Regulations.
- ☐ Please include the <u>IRB ID #</u> on <u>all</u> correspondence pertaining to this study.
- ☐ Sterling IRB forms for use by the Principal Investigator/Site are available on our website, www.sterlingirb.com.
- □ Sterling IRB has developed an Investigator Handbook that outlines the responsibilities of the Principal Investigator. The Investigator Handbook should be read by all key personnel on the research team. It can be located on the Sterling website, www.sterlingirb.com.
- □ Sterling IRB requires Principal Investigators to <u>promptly</u> report all events that may constitute unanticipated problems involving risk to subjects or others and new or updated safety information relating to the study or study product. Please refer to Chapters 7 ('Reportable Events') and 10 ('Research Conflicts and Noncompliance') of the Investigator Handbook (located on our website at www.sterlingirb.com) for additional information regarding reporting quidelines.

If you have any questions please call our office at 888-636-1062.









office 770.690.9491 toll free 1.888.636.1062 fax 770.690.9492 6300 Powers Ferry Road Suite 600-351 Atlanta, Georgia 30339 url www.sterlingirb.com e-mail info@sterlingirb.com

Date Issued:

February 10, 2014

Study

Expiration Date: February 6, 2015

Site Continuing **Review Status**

Report Due:

January 6, 2015 (form available at www.sterlingirb.com)

Principal Sites(s):

Investigator:

Louis O Rabinowitz

Street Legal Industries, Inc. Corporate Headquarters 102 Jefferson Court

Oak Ridge, TN 37830

Protocol:

The Impact of Driver Compensation on Commercial Motor Vehicle Safety Survey

IRB ID:

4609-001

Sponsor:

US Department of Transportation, Federal Motor Carrier Safety Administration

TYPE OF REVIEW: Expedited Review - Study Approval - Initial

- Protocol (Date and Version of the Protocol: January 20, 2013, Version 1)
- Survey Introductory Letter (Version Date: 22 January 2014)
- Waiver of Documentation of Informed Consent under 45 CFR 46.117(c)
- See Attachment A for Additional Approved Materials, including Recruitment Materials if applicable
- Investigator's Qualifications

APPROVED WITHOUT MODIFICATION

This study was reviewed and approved on February 7, 2014.

Sterling IRB has determined that this study represents the following category(ies) of research eligible for expedited review: research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation or quality assurance methodologies

Sterling IRB has approved this Principal Investigator to conduct this study at the above-listed site(s). Approval will expire on the study expiration date listed above, and if the study is to continue the Principal Investigator must receive Sterling IRB approval for study continuation prior to the expiration date. The Principal Investigator should submit the Site Continuing Review Status Report not less than one month prior to the last Sterling IRB meeting preceding the expiration date. If approval for study continuation is not obtained prior to the expiration date, the study will be considered to be in noncompliance with Federal Regulations and IRB requirements, may be suspended, and may be subject to termination.

A Site Final Report will be due at the conclusion of the study (form available at www.sterlingirb.com).

Any changes to the research must be submitted in writing to Sterling IRB for review and approval prior to implementation. Sterling IRB should be informed immediately of any serious adverse reaction or should any unanticipated problems involving risks to the subject or others occur or should the Sponsor provide safety information. Local prejudices or negative attitudes in the community toward the conduct of research projects must be reported immediately. State laws pertaining to Patient/Volunteer Bill of Rights and specific state laws concerning research which affect the conduct of clinical research must be enforced. Non-English speaking subjects enrolled in this study must be provided with an informed consent written in their fluent language, which must be approved by Sterling IRB before use.

As Principal Investigator you are responsible for following all policies of Sterling IRB as described in the Investigator's Compliance Agreement which you signed with study submission. It is your responsibility to ensure this research is conducted in accordance with applicable regulations (local, state and federal) as well as any requirements established by the IRB at the time of the approval. Refer to the Investigator Handbook at www.sterlingirb.com for details of these responsibilities.

Authorized Signature

Copy:

Sponsor and/or CRO

Attachments (if applicable): Attachment A, Sterling IRB Membership List, Approved Informed Consent / Approved Recruitment Material(s)



office 770.690.9491 toll free 1.888.636.1062 fax 770.690.9492 6300 Powers Ferry Road Suite 600-351 Atlanta, Georgia 30339 url www.sterlingirb.com e-mail info@sterlingirb.com

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Principal

Investigator:

Louis O Rabinowitz

Protocol:

The Impact of Driver Compensation on Commercial Motor Vehicle Safety Survey

IRB ID:

4609-001

Sponsor:

US Department of Transportation, Federal Motor Carrier Safety Administration

ATTACHMENT A: ADDITIONAL APPROVED MATERIALS

Study Materials:

 Email Thank You Message to CMV Carriers Who Participated in the Impact of Driver Compensation on Commercial Motor Vehicle Safety Survey

Online questionnaire item set and process logic

Recruitment Materials:

 Email Message Inviting CMV Carriers to Participate in the Impact of Driver Compensation on Commercial Motor Vehicle Safety Survey

 Email Follow-Up Message Encouraging CMV Carriers to Participate in the Impact of Driver Compensation on Commercial Motor Vehicle Safety Survey

For these approved materials, you may insert or change site-specific information without resubmitting to the IRB.

The following may apply dependent upon approved item:

Federal Regulations require that Sterling IRB be supplied with an actual copy of the advertisement (MP3, CD, DVD, tear sheet, cassette, VHS, etc.), when applicable, for review and approval prior to use. Approved print advertisements are authorized for internet use without being resubmitted to the IRB provided that they remain true to scale and are in no way modified.

If the above-referenced recruitment and/or study material(s) contain(s) a reference or link to a website, Sterling IRB assumes that the link(s) provided do/does not contain any information which would violate either Sterling IRB requirements or applicable regulations. It is your responsibility to submit any research-related content, including any information which pertains to a study under the review of Sterling IRB, for review and approval prior to use.



www.sterlingirb.com e-mail info@sterlingirb.com

Sterling IRB Membership Roster

Term: July 25, 2012 - July 24, 2014 IRB Registration Number: 00001790

Primary Members

Steven L. Saltzman, M.D., F.A.C.O.G., Chairman

Scientific

Maziar Rezvani, M.D., F.A.A.A.A.I., Vice-Chairman

Scientific

Melody Palmore, M.D., Medical Director

Scientific

George A. Kramer, M.D., MPH

Scientific

Robert L. Stahl, M.D., F.A.A.H.P.M.

Scientific

Jennifer R. McGaughey, RN, BSN, CIP

Scientific

Arin Neely, BS, CIP

Scientific

Lisa K. Kuklinski, BBA, CPMSM, CPCS, CAP

Non-Scientific

Rev. Dcn. Georgia A. Newman, PhD

Non-Scientific

Alternate Members

Mark Cavitt, M.D.

Scientific

Harvey DuBiner, M.D.

Scientific

Paula S. Hickman, MHA, CPMSM, CPCS

Non-Scientific

Arthur J. Powell, PhD

Non-Scientific

Lauren S. Surden, MSW

Scientific

Area of Expertise / Representative Capacity

Obstetrics and Gynecology / College Educator Pregnant Women / Prisoners / General Participant

Perspective

Allergy and Immunology

Children / General Participant Perspective

Infectious Diseases / College Educator

Pregnant Women / Cognitively Impaired Persons /

Prisoners / General Participant Perspective

Cardiology

Cognitively Impaired Persons / General Participant

Perspective

Hematology/Oncology

Cognitively Impaired Persons

Human Research Protection / Nursing

Children / General Participant Perspective

Human Research Protection / Biology

Children / General Participant Perspective

Credentialing / Medical Staff Management

General Participant Perspective

Pastoral Care and Education

Pregnant Women / Cognitively Impaired Persons /

Prisoners / General Participant Perspective

Area of Expertise / Representative Capacity

Psychiatry / Pediatric Psychiatry

Children / Cognitively Impaired Persons

Ophthalmology

Health Information Systems & Technology /

Credentialing

General Participant Perspective

Ethics

Clinical Research / Social Work General Participant Perspective STUDY: The Impact of Driver Compensation on Commercial Motor Vehicle Safety Survey

STERLING IRB ID: 4609-001 DATE OF IRB REVIEW: 02/07/14

[OFFICIAL LETTERHEAD]

CMV Carrier Company Name Attn: Contact Name or Generic Title Contact Address 1 Contact Address 2 Contact City, State, Zip

Dear [Contact Name or Generic Title]:

The primary mission of the Federal Motor Carrier Safety Administration (FMCSA) of the US Department of Transportation is to reduce crashes, injuries and fatalities involving large trucks and buses. Recent reports show declines in both truck and bus crashes over a ten-year period. While these findings are encouraging, much work needs to be done to prevent commercial motor vehicle-related fatalities and injuries. An important group FMCSA works with to improve highway safety is the motor carrier industry. FMCSA works with companies like yours to advance our mutual goal of maximizing the well-being of your drivers and others who share the nation's highways.

FMCSA has contracted with Street Legal Industries, Inc. (Street Legal), to conduct a research study to determine if there is a correlation between safety and the way drivers are paid and we are asking that you consider participating. Street Legal is conducting a two-part survey as part of the study. FMCSA will use study findings to develop guidelines commercial motor vehicle carriers can use in determining best practices for compensating drivers and to provide information that will be useful to FMCSA as policy issues are considered. The study report will be made available to the public on the FMCSA website. About 2,500 commercial carrier companies will participate in this study.

Your participation in the study is voluntary. You may refuse to participate or withdraw from the study, at any time, without penalty or loss of benefits to which you are otherwise entitled. There is no alternative to study participation. There is minimal risk expected with participation in the study. You will be informed in a timely manner if new information that may influence your willingness to continue participation in the study becomes available. You will not personally benefit from your participation in the study, but information may be learned that could benefit others in the future.

Data collected by Street Legal will be coded and your answers will be kept in strict confidence. The resulting report and dataset provided to FMCSA will be reported only in the aggregate. Personally identifiable information and information identifiable by participating company will *not* be provided to FMCSA.

The method for collecting data will be a two-part survey. The first round will consist of a short phone interview to determine how your company pays drivers. Depending on your response to that item, you may be asked additional questions. The total time anticipated for completing the first interview is anticipated to be less than ten minutes.

Page 1 of 2 – Survey Introductory Letter Version Date: 22 January 2014 STUDY: The Impact of Driver Compensation on Commercial Motor Vehicle Safety Survey

STERLING IRB ID: 4609-001 DATE OF IRB REVIEW: 02/07/14

You may be asked to participate in a second round of data collection. Should you be selected to participate in the second round, you may be required to pull information from drivers' records. Depending on your recordkeeping system, it may take up to an hour complete the collection of driver information. You will have the option of receiving a second phone call to respond to interview questions or to complete an online, web-based form to complete a short questionnaire. It is anticipated that the interview or completing the online questionnaire will take no longer than fifteen minutes.

Your participation may be stopped without your consent by the study investigator for any reason. For example, your participation may be stopped:

- if it is deemed to be in the best interest of your health and welfare.
- if you fail to follow instructions.

There is no cost to participate in the study. You will not be compensated to participate in the study. You do not waive any of your legal rights by participating in the study.

Should you have questions about the research study described in this letter, please contact the FMCSA contracting officer for the project:

US Department of Transportation Federal Motor Carrier Safety Administration Office of Acquisition Management ATTN: Ms. Theresa Hallquist 1200 New Jersey Avenue, SE W66 – 6th Floor Washington, DC 20590-0001

If you have questions regarding your rights as a research participant, or if you have questions, concerns, complaints about the research, would like information, or would like to offer input, you may contact the Sterling Institutional Review Board Regulatory Department, 6300 Powers Ferry Road, Suite 600-351, Atlanta, Georgia 30339 (mailing address) at telephone number 1-888-636-1062 (toll free).

STERLING IRB ID: 4609-001

This document has 2 pages.

Thank you in advance for your participation in this important research.

Sincerely yours,

[NAME OF APPROPRIATE DOT OFFICIAL] [TITLE OF DOT OFFICIAL]

Approved by Sterling IRB IRB ID 4609

Attachment K

Survey Introductory Letter, Questionnaire Email Invitation, Follow-up remind for non-response or incomplete questionnaire, Thank you email, Online Questionnaire and Process Logic Flow

Email Message Inviting CMV Carriers to Participate in the *Impact of Driver Compensation on Commercial Motor Vehicle Safety Survey*

Dear CMV Carrier Representative:

The Federal Motor Carrier Safety Administration (FMCSA) recently sent you an email message to tell you about a study that Street Legal Industries (SL) is administering for FMCSA. As you may recall from that message, the study is being conducted to determine the ways in which CMV carrier companies pay their drivers and whether pay methods correlate to driver safety.

We would like to invite you to participate in this important study by completing an online survey questionnaire. Should you participate, your information will be kept in strictest confidence. Data obtained from the survey will be coded and reported in the aggregate. Individuals completing survey questionnaires will not be identified and no individual company's data will be reported.

The survey questionnaire and instructions for completing the questionnaire can be accessed at <WEBSITE ADDRESS HERE>. The survey is presented in two parts. Every survey participant will fill out the Part 1 questionnaire. Part 1 of the questionnaire should take no longer than thirty (30) minutes to complete.

Depending on your response to certain items on Part 1 of the questionnaire, you may be asked to complete Part 2. Filling in Part 2 will also take less than thirty (30) minutes, but you will be asked to provide demographic information about your company's drivers such as average age and the numbers of drivers who are paid using various methods. The amount of time it will take for you to research information required for Part 2 will depend on your accessibility of your company's driver information.

Note that you will be able to complete part of the questionnaire, save it, and return to the survey website to complete the survey at a later time. There is an email link at the survey website to send questions about questionnaire items to the research team. You will also have the option of sending questions to the FMCSA about the study to Ms. Terri Hallquist, FMCSA <WHAT TITLE SHOULD GO HERE?> through another the email link available at the survey website.

We certainly hope that you'll participate in this important study. Thank you for your consideration.

< SIGNATURE HERE>

FMCSA Project Manager

Approved by Sterling IRB IRB ID 4609

Attachment K

Survey Introductory Letter, Questionnaire Email Invitation, Follow-up remind for non-response or incomplete questionnaire, Thank you email, Online Questionnaire and Process Logic Flow

Email Follow-Up Message Encouraging CMV Carriers to Participate in the Impact of Driver Compensation on Commercial Motor Vehicle Safety Survey

Dear CMV Carrier Representative:

We recently transmitted an email message to you containing an invitation to participate in a study that Street Legal Industries (SL) is administering for the Federal Motor Carrier Safety Administration (FMCSA). The study is being conducted to determine the ways in which CMV carrier companies pay their drivers and whether pay methods correlate to driver safety.

We urge you to participate in this important study by completing an online survey questionnaire. Should you participate, your information will be kept in strictest confidence. Data obtained from the survey will be coded and reported in the aggregate. Individuals completing survey questionnaires will not be identified and no individual company's data will be reported.

A few reminders about the survey:

- The survey questionnaire and instructions for completing the questionnaire can be accessed at <WEBSITE ADDRESS HERE>. The survey is presented in two parts. Every survey participant will fill out the Part 1 questionnaire. Part 1 of the questionnaire should take no longer than thirty (30) minutes to complete.
- Depending on your response to certain items on Part 1 of the questionnaire, you may be asked to complete Part 2. Filling in Part 2 will also take less than thirty (30) minutes, but you will be asked to provide demographic information about your company's drivers such as average age and the numbers of drivers who are paid using various methods. The amount of time it will take for you to research information required for Part 2 will depend on your accessibility of your company's driver information.
- You will be able to complete part of the questionnaire, save it, and return to the survey website
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 questions about questionnaire items to the research team. You will also have the option of
 sending questions to the FMCSA about the study to Ms. Terri Hallquist, FMCSA <WHAT TITLE
 SHOULD GO HERE?> through another the email link available at the survey website.

We certainly hope that you'll participate in this important study. Thank you for your consideration.

<SIGNATURE HERE>

FMCSA Project Manager