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Human Subjects Division
Box 359470 UW

HUMAN SUBJECTS REVIEW COMMITTEE APPLICATION

BOX FOR COMMITTEE USE ONLY
MASTER ☐ COMM. ☐ INVESTIGATOR ☐
APPLICATION NO. 38176 EB

Send three one-sided copies of this form (including one copy with original inked signatures) and three one-sided copies of all relevant materials (consent forms, questionnaires, instruments, drug information summary, data collection forms, debriefing statement, advertisements, etc.) to the Human Subjects Division, Box 359470. Do not leave blanks. Attach one one-sided copy of each research proposal, grant or contract, and/or one one-sided copy of the protocol and investigator's brochure for clinical trials. Students should attach one one-sided copy of thesis or dissertation proposals. For information and assistance, visit our web site at http://www.washington.edu/research/hsd/index.php or call (206) 543-0098. We will not accept handwritten forms, incomplete forms, or forms printed on both sides of the paper. Use 10 point type or larger throughout application. The contents of this application and attachments will be kept confidential within the limits of the law.

☒ **Check this box if your project falls into one or more of the minimal risk ("expedited") categories of research (see web site for listing of categories) and send us only two copies of all your materials.**

I. PRINCIPAL INVESTIGATOR (Provide all the information requested. Correspondence will be directed to this person. You may designate a contact person other than yourself in section II., below.)

Name Linda Boyle Title Ph.D Position Associate Professor
Department Industrial and Systems Engineering Division
Mail box or address Box 352650
Telephone 206 616 0245 Fax 206 685 3072 e-mail linda@u.washington.edu

II. CONTACT PERSON (Provide all the information requested. This person does NOT have signatory authority with regard to this application.)

Name Title Position
Mail box or address
Telephone Fax e-mail

III. TITLE OF PROJECT:
Evaluating the safety benefits of an on-board monitoring system in commercial vehicle operations: independent evaluation and data analysis (Pilot study)

IV. SIGNATURES: The undersigned acknowledge that: 1. this application represents an accurate and complete description of the proposed research; 2. the research will be conducted in compliance with the recommendations of and only after approval has been received from the Human Subjects Review Committee (HSRC). The principal investigator is responsible for reporting any serious adverse events or problems to the HSRC, for requesting prior HSRC approval for modifications, and for requesting continuing review and approval.

A. Investigator: Linda Boyle — Mar 03, 2010
TYPED NAME PLUS SIGNATURE — DATE

B. Faculty sponsor (for student): — Mar 03, 2010
TYPED NAME PLUS SIGNATURE — DATE

C. The Chair, Dean, or Director signing below acknowledges that this proposed activity has received intra-mural review and approval of scientific merit and investigator qualification.

Richard L. Storch Richard L. Storch (KS) 3-3-2010
TYPED NAME PLUS SIGNATURE — DATE

APR 13 2010
HUMAN SUBJECTS REVIEW COMMITTEE SIGNATURE — DATE — APPROVE ☒ DISAPPROVE ☐

Subject to the following conditions:

Period of approval is one year, from APR 13 2010 through APR 12 2011

VALID ONLY AS LONG AS APPROVED PROCEDURES ARE FOLLOWED

V. CO-INVESTIGATORS (Provide all the information requested for each co-investigator. Add sheets if necessary.)

Name Yiyun Peng Title BS Position Graduate student
Department Industrial and Systems Engineering Division
Mail box or address Box 352650
Telephone 206 616 0277 Fax N/A e-mail yiyunp@u.washington.edu

VI. LIST EACH PROPOSED AND FUNDED GRANT OR CONTRACT RELEVANT TO THIS APPLICATION. IF NONE, CHECK HERE ☐. FOR CENTER OR PROGRAM PROJECT GRANTS LIST P.I. AND TITLE FOR EACH SEPARATE PROJECT OR CORE. ADD SHEETS IF NECESSARY.

☐ **American Recovery and Reinvestment Act (ARRA) – also known as the Stimulus Package or Recovery Act**

If you checked this box, please attach the ARRA cover sheet to your submission. (http://www.washington.edu/research/link.php?id=9)

A. Type of proposal: ☒ Research ☐ Contract ☐ Fellowship ☐ Training grant ☐ Subcontract ☐ Other, specify

B. Name of principal investigator: Linda Boyle

C. Name of funding agency: US DOT Federal Motor Carrier Safety Administration

D. Agency's number (if assigned):

E. Title of proposal: Evaluating the safety benefits of an on-board monitoring system in commercial vehicle operations: independent evaluation and data analysis

F. Inclusive dates: from 04/1/2010 through 10/1/2010

G. Status: ☒ New ☐ Competing renewal ☐ Non-competing renewal

H. Submitted through UW Office of Sponsored Programs? ☒ Yes ☐ No, (attach explanation)

VII. SUMMARY OF ACTIVITY. Answer in spaces provided (add numbered, referenced, single-sided sheets when necessary). Do not refer to an accompanying grant or contract proposal.

A. BACKGROUND AND PURPOSE OF RESEARCH. Provide relevant background information and explain **in lay language** why this research is important and what question(s) or hypotheses this activity is designed to answer.

Of the people killed in motor vehicle crashes in 2005, 12% (5,212) died in crashes that involved a large truck. Another 114,000 people were injured in crashes involving large trucks. About 15% of those killed and 24% of those injured in large truck crashes were occupants of large trucks.

The objective of the OBMS program is to determine whether on-board monitoring will reduce at-risk behavior among commercial drivers and improve driver safety performance. The at-risk commercial drivers for this study will be defined by the number of safety critical events observed with the OBMS that are in the upper third quartile (or at the greatest risk when compared to other drivers in the study). More specifically, the project will determine if recording and reporting of safety critical events, followed by coaching drivers (by safety managers) using these safety events as feedback, will enhance safe driving behavior. This system is also being proposed with on electronic on-board recorder (EOBR) and the independent evaluation will examine the human factors aspects of this system function as well.

Hypothetically, successful implementation of the OBMS program may significantly reduce the number and severity of crashes involving CMVs. More specifically, the goal of the OBMS project is to answer the following research questions:

- Does individual driving performance (lane deviations, braking) improve over time with OBMS feedback?
- Does the OBMS and feedback program improve safety (e.g., number of safety-critical events)?
- How do the drivers' attitudes towards the OBMS and feedback program change over time?
- Can the OBMS accurately distinguish "good" (safe) drivers from "at-risk" (unsafe) drivers?
- If driving performance improves, does the improvement persist?
- What are the fleet safety manager's attitudes about the OBMS?
- What is the business case for implementing an OBMS program?
- What differences are observed in how a driver records HOS data between the EOBR that is integrated into the OBMS and the carrier's previous method for recording HOS data?

A pilot study will be conducted prior to the commencement of full OBMS installations on all carrier vehicles. This IRB application is therefore for the pilot study only. An application for the full study will be submitted separately.

B. RESEARCH PROCEDURES INVOLVED.

1. Provide a complete description of: a. the study design, and b. sequence and timing of all study procedures that will be performed, e.g., volume of blood, size of biopsy, drug administration, questionnaire, name of psychological test. Provide this information for each phase of the study (pilot, screening, intervention and follow-up). **Use lay language**. Attach study flow sheet, if available.

   This study is conducted by the study team which includes VTTI (project manager), Transecurity (Technology vendor and data collector) and Linda Boyle (independent evaluator).

   The purpose of this pilot study is to help ensure the OBMS is working reliably and the data collection and reduction process works as planned. This will also give the fleet safety managers an opportunity to work with sample data to assess how the systems work in their vehicles and how the coaching process should be conducted. In general, pilot testing will demonstrate the OBMS is reliably collecting data and the back-end processing of the data is being handled correctly. Additionally, this pilot testing will provide the Independent Evaluator with a sample dataset that can be used to ensure that the data collected is at the level necessary to develop the analytical models.

   After carrier selection, Transecurity support personnel will install one OBMS system on a truck at each selected carrier. Carrier maintenance personnel will observe the installations to provide a reference for the company of the required level of effort to install OBMS. The installed OBMS system will then be assigned to carrier-selected test drivers and Transecurity will provide information to selected drivers on the study. There will be up to 4 drivers participant in the pilot study (up to 2 drivers each carrier) and each driver will experience one week of Baseline phase (no-feedback), two weeks of Intervention phase (feedback) and one week of Withdrawal phase (no-feedback).

   Web-based (password protected) Baseline, Intervention, Withdrawal questionnaires and an exit interview will be administered to drivers to determine if they felt the system was useful and provided the expected outcomes. The questionnaires will assess each user's expectation, usability, and perceptions related to system effectiveness. A demographic questionnaire will also be given to gather information on age, gender, marital status, and other socioeconomic characteristics. This demographic questionnaire will be filled out by all drivers administered during the information session before the pilot study started. The Baseline questionnaire will be administered before and at the end of the first week; the Intervention questionnaire will be administered at the end of the second and third weeks; and the Withdrawal questionnaire will be administered at the end of the fourth week along with the exit interview. The questionnaires will be designed such that each one can be completed within 15 minutes. All questionnaires are included in the attachments.

Data collected on the pilot systems will be transferred from the OBMS to Transecurity"s data center using a combination of WiFi and cellular communications as would be expected during the full data collection activity. The results will prove that communications processes work effectively at the carrier's facility and in their normal operating area. During the pilot test period, Transecurity will make one data reductionist available to conduct data reduction on safety epochs. Incoming safety epochs will be reduced by the data reductionist and the results will be stored back into the Transecurity data center. Software (DriveMetrix Pro) developed by Transecurity will summarize the data and provide summary information about each incident (per driver, per shift), such as: Date of Incident, Time of Incident, Type of Incident, Location of Incident, Peak Recorded Performance Values for each Sensor, and other measures to be determined . Transecurity will be tracking the hit and false alarm rate of captured epochs and will adjust safety epoch trigger thresholds to optimize the capture process. The carrier and members of the entire OBMS FOT team (University of Washington) will have access to the collected data for review and assessment of validity using the DriveMetrix Pro software. University of Washington will receive any custom data exports they have requested to provide an opportunity to assess the data and verify that it will support the analytical models they plan to use in the subsequent analyses..

Prior to the pilot study, Transecurity will provide the carriers with access to their online issues and defects tracking system. Carrier personnel and OBMS FOT team members will have the ability to generate support tickets on aspects of the system they feel are incorrect or may need tweaking prior to conducting the study. The tracking system will be used to track the resolution of high priority items that need to be fixed before the main data collection activity begins.

In addition to normal, commercial OBMS operation, the pilot test will also include the collection of continuous naturalistic data to verify data quality management and data handling procedures. The entire data collection and transfer process will be exercised completely from collection on DriveMetrix Pro to the end goal of storing the data at VTTI"s data warehouse facility using the same methods and equipment as will be used in the main data collection activity. The Independent Evaluator (University of Washington) will be working with the FOT data only, and not the continuous, naturalistic dataset.

2. Would subjects undergo these or similar procedures (medical, psychological, educational, etc.) if they were not taking part in this research? ☒ No ☐ Yes If "Yes," describe how the study procedures differ from what subjects would otherwise undergo.

C. DECEPTION: If any deception or withholding of complete information is required for this activity, explain why this is necessary and attach a protocol explaining if, how, when, and by whom subjects will be debriefed.

No.

D. SUBJECTS

1 How many subjects will you need to **complete** this study? Number up to 6 Age range 25 and above

2. Explain how you will achieve equitable subject representation in the following categories. If not applicable, justify exclusions.

a. Age (minors, elderly): The participants in this study are required to have a commercial driver's license.

b. Gender: The majority of participants will be male as the majority of truck drivers are male.

c. Ethnic and racial minority populations: People who meet the inclusion criteria, in spite of ethnic and race, would have the same opportunity to participate in the study.

3. What characteristics (inclusion criteria) must subjects have to be in this study? (Answer for each subject group, if different.)

Subjects must have a commercial driver license. However, drivers who participant in this pilot study will be selected by the carrier but not the study team. As this is a data collection reliability test, the purpose of recruiting participants is to help evaluate the reliability of the system for the full study, but not to evaluate participants' behavior.

4. What characteristics (exclusion criteria) would exclude subjects who are otherwise eligible from this study? (Answer for each subject group, if different.)

Subjects who do not have commercial driver license will be excluded from this study.

5. Describe the subject recruitment strategies you will use for each group of subjects. (Attach advertisements, flyers, contact letters, telephone contact protocols, Health Sciences recruitment web site template, etc.)

Drivers will be recruited by carriers to help evaluate the reliability of the system.

6. Explain who will approach subjects to take part in the study and how this will be done to protect subjects' privacy. (Attach letters of cooperation from agencies, institutions or others involved in subject recruitment.)

Transecurity will train and approach subjects in this study with support of independent evaluator staff and VTTI. Independent evaluator staff and VTTI will make occasional site visits to meet with the drivers and safety managers.

The data will be transcribed by a member of the research team and stored on a secure server and released to the independent evaluator with participant's written consent. A unique number, and not participant name, will be attached to all data. Access to the files will be under the supervision of the PI and lead researcher involved in the project. The data will not be released to unauthorized individuals without participant's written consent.

7. Explain what steps you will take during the recruitment process to minimize potential coercion or the appearance of coercion.

Participation in this research is voluntary. Participants' voluntary permission to send their questionnaires regarding their opinions of the OBMS will be asked. Participants are free to withdraw at any time without penalty. Non-participation or withdrawal from this study will not adversely affect participants' employment status. Furthermore, participants are free not to answer any question in the questionnaires without penalty. They have the right to withdraw their consent for the study team to access/evaluate their data at any time. Withdrawal from the study indicates the study team will not have access to the data collected by the OBMS. Withdrawal from the study also indicates the study team will not send them questionnaires.

8. Will you give subjects gifts, payments, services without charge, or extra course credit? ☐ No ☒ Yes If yes, explain:

Each driver will be given $50 for participating in the pilot study.

9. Will any of the subjects or their third-party payers be charged for any study procedures? ☒ No ☐ Yes If yes, explain:

10. Where will the study procedures be carried out? (Attach copies of IRB approvals or letters of cooperation from non-UW research sites, if necessary.)

The study will be carried out at two carriers out of Washington State. The study is incorporated with VTTI as well as University of Wisconsin-Madison and therefore their IRB approvals are attached.

E. RISKS AND BENEFITS

1. Describe nature and degree of risk of possible injury, stress, discomfort, invasion of privacy, and other side effects from all study procedures, drugs and devices (standard and experimental), interviews and questionnaires. Include psycho-social risks as well as physiological risks. Include risks of withholding standard care or procedures if this is the case. Do not reference the consent form.

There are some risks and discomforts to which participants will be exposed in volunteering for this research. These risks include:

1. The risk of a crash associated with driving a truck as participants usually do.

2. Possible adverse consequences for violating company and/or traffic rules.

2. Explain what steps you will take to minimize risks of harm and to protect subjects' rights and welfare. (If you will include protected groups of subjects (minors, fetuses in utero, prisoners, pregnant women, decisionally impaired or economically or educationally disadvantaged subjects) please identify the group(s) and answer this question for each group.)

   1. Participants will be instructed to follow their company's safety protocols. Participation in this study will have no effect on what may happen if participants violate their company's safety protocol.

   2. Participants are under no legal obligation to mention that they are participating in this study.

   3. Participation (or withdrawal) in this study does not have any influence on their status as an employee with their current company. Whether participants allow the research team to access their data will have no effect on what may happen if they violate their company's safety policies or rules.

3. Is it possible that you will discover a subject's previously unknown condition (disease, suicidal intentions, genetic predisposition, etc.) as a result of study procedures? ☒ No ☐ Yes If yes, explain how you will handle this situation.

4. Describe the anticipated benefits of this research for individual subjects in each subject group. If none, state "None."

   The results from this pilot study may help the study team determine the reliability of the system and data collection plan.

5. Describe the anticipated benefits of this research for society, and explain how the benefits outweigh the risks.

   The purpose of the pilot study is to evaluate the reliability of the OBMS system and data collection plan for the full study. In this pilot study, participants' performance and behavior will not be the focus. Therefore, there is no anticipated benefit for society. However, in the full study, operator monitoring and feedback can be characterized as a behavior-based safety method. As safe behavior is rewarded and unsafe behavior is coached, overall safety will be proactively improved and thus successful implementation of the OBMS program may significantly reduce the number and severity of crashes involving CMVs.

F. ADVERSE EVENTS OR EFFECTS

1. Who will handle adverse events? ☐ Investigator ☐ Referral ☒ Other, explain:

   We are not the prime contractor.

2. Are your facilities and equipment adequate to handle possible adverse events? ☒ Yes ☐ No, explain:

3. Who will be financially responsible for treatment of **physical injuries** resulting from study procedures?

   ☐ Study sponsor ☒ Subject or subject's insurer ☐ UW compensation plan ☐ Veterans Affairs ☐ Other, explain:

G. CONFIDENTIALITY OF RESEARCH DATA

1. Will you record any direct subject identifiers (names, Social Security numbers, patient, hospital, laboratory or claim numbers, addresses, telephone numbers, locator information, etc.) ☒ No ☐ Yes If yes, explain why this is necessary and describe the coding system you will use to protect against disclosure.

2. Will you retain a link between study code numbers and direct identifiers after the data collection is complete? ☒ No ☐ Yes If yes, explain why this is necessary and for how long you will keep this link.

3. Describe how you will protect data against disclosure to the public or to other researchers or non-researchers. Explain who (other than members of the research team) will have access to data (e.g., sponsors, advisers, government agencies, etc.).

   All data records will be set up in password -protected files and will be viewed only by individuals listed on the project team. The data will be destroyed at some specified time after the project is complete (the receiving agency may request to hold the data for a period of time after the project is complete in case mistakes were made in the analysis or in case additional analyses are required to complete the final report).

4. Will you place a copy of the consent form or other study information in the subject's medical or other personal record?
   ☒ No ☐ Yes. If yes, explain why this is necessary.

5. Do you anticipate using any data (information, specimens, etc.) from this study for other studies in the future? ☒ No ☐ Yes
   If "Yes," explain and include this information in the consent form.

H. ADDITIONAL INFORMATION

1. If the study will involve radiation exposure to subjects, e.g., X-rays, radioisotopes, what is status of review by the UW Radiation Safety Committee (RSC): ☐ Pending ☐ Approved (Attach one copy of approval.) ☒ NA

2. Will you need access to subjects' medical, academic, or other personal records for screening purposes or during this study?
   ☒ No ☐ Yes. If yes, specify types of records, what information you will take from the records and how you will use them.

3. Will you make audio-visual or tape recordings or photographs of subjects? ☐ No ☒ Yes. If yes, explain what type of recordings you will make, how long you will keep them, and if anyone other than the members of the research team will be able to see them.

   Driver face video data will be collected while participants driving for data analysis and evaluation purpose. All data records will be set up in password- protected files and will be viewed only by individuals listed on the project team. And the data will be destroyed at some specified time after the project is complete (the receiving agency may request to hold the data for a period of time after the project is complete in case mistakes were made in the analysis or in case additional analyses are required to complete the final report).

4. Will your study involve use of equipment involving energy input to the subjects (EMG, EKG, MRI, ultrasound, etc.)?
   ☒ No ☐ Yes. If yes, attach documentation that all equipment will be tested regularly by the Scientific Instrument Division (call (206) 543-5580 for information) or describe safety testing procedures you will use.

5. Have all Investigators (i.e., all UW personnel responsible for the design, conduct or reporting of the proposed research) read and complied with GIM 10, the University's policy governing the disclosure of Significant Financial Interests? ☐ No ☒ Yes. (Note: This application can not be considered unless all Investigators have read and complied with GIM 10, which may be accessed at http://www.washington.edu/research/osp/gim/gim10.html.)

6. Does any Investigator have a Significant Financial Interest related to the proposed research that must be disclosed as provided in GIM 10? ☒ No ☐ Yes. If yes, each Investigator having a Significant Financial Interest must comply with GIM 10, including submission of a Significant Financial Interest Disclosure Form. Final review of this application cannot occur until the GIM 10 review is complete. Delays in complying with GIM 10 will result in delays in completing the final review of this application. Please list the name of each Investigator having a Significant Financial Interest below:

I. CONSENT FORMS ☒ **Written** (Attach copies of all consent and assent forms for each subject group. Include a footer identifying the version date of each form and a header or title that identifies each different form.)

☐ **Oral** (Attach written scripts of oral consent and assent for each subject group.)

☐ **Waiver** (Attach written justification of waiver of consent per 45 CFR 46.116(d) – see Web site (http://www.washington.edu/research/hsd/consent.php) for information on requesting a waiver of consent.)

J. DRUGS, SUBSTANCES, AND DEVICES

1. List **all** non-investigational drugs or other substances used to conduct this research (analgesics, anesthetics, drugs used to treat side effects, etc.). Include products used for standard clinical care if they are used in this study for research purposes.

Name	Source	Dose	How administered
N/A			
N/A			
N/A			
N/A			
N/A			

2. List **all** investigational new drugs or other investigational substances to be used in the study. Include marketed products used "off-label" (different formulation, dose, route of administration, or indication). Provide:

- **three** copies of a concise summary of information about the drug prepared by the investigator (including animal and human toxicity data, studies done in animals and humans to date);
- **one** copy of the Investigator's Brochure;
- **one** copy of the study protocol.

Important note: You must register an IND with the appropriate institutional pharmacy (**UWMC: 598-6054; HMC: 731-5448, VA: 764-2142**) before using the drug in research.

Name	Source	Dose	How administered	IND Number	Phase of testing
N/A					
N/A					
N/A					
N/A					

3. List all investigational devices you will use. Provide the information requested below and attach one copy of the company protocol. If there is no Investigational Device Exemption (IDE), explain why. Include a statement as to why the device qualifies as non-significant risk. Provide a copy of the FDA letter(s) which states the device classification (PMA, 510K, Class I, II, or II, or custom device) and categorization (Category A or B). "Category A" means that Medicare may **not** be billed for the device or for services related to its use. "Category B" means that Medicare may be billed for services related to its use **if** the U.S. Health Care Finance Administration (HCFA) grants authorization. **Important Note.** Register IDE devices with the UWMC Manager of Surgical Support Services (598-6538) or the HMC Business Manager of Surgical Services (731-8094) to obtain authorization for use.

   a. Name of the device: N/A

   b. Name of the manufacturer:

   c. Description of its purpose and how you will use it in this study:

   d. Descriptions of previous studies in humans and animals:

   e. Investigational Device Exemption (IDE) number or FDA status: