# Human Subjects Research Determination Form

SAINT LOUIS UNIVERSITY. — EST. 1818 —

Investigators needing an official determination of whether or not proposed activities are human subjects research requiring IRB review should complete this form. Decisions on whether IRB review is required for activities can only be made by the SLU IRB. Submit completed forms to irb@slu.edu.

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|---|---|---|
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| Department: Biostatistics | E-mail: srigdon@slu.edu | Degree: PhD |
| Additional Contact Person: | E-mail: | Phone: |
| Project Title: GOALI: Human Maintenance – A Prognostics Framework to Model Changes in Driver's Safety Performance and Optimize Dispatching Policies | | |
| Will this activity take place at an SSM facility? Yes ☐ No ☒ | | |

## Is it human research under DHHS Regulations?

**A. "Human"**

1. Does activity involve human subjects (***living*** individuals about whom an investigator conducting research collects data)? Click if using PHI for research on deceased persons. Yes ☒ No ☐

2. Does activity involve the prospective collection of data or information through **intervention** or **interaction** with the individual? (**Intervention**: physical procedure by which data are gathered **or** manipulations of the subject or the subject's environment that are performed for research purposes. **Interaction:** communication or interpersonal contact with the individuals, including electronic interaction) Yes ☐ No ☒

3. Does activity involve the collection or use of **individually identifiable** and **private** information? (**Individually identifiable:** information contains one or more elements that identify the individual **or** can be combined with other available information to ascertain the identity of the individual. **Private information:** information provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (e.g., medical or psychological information) **or** information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place) Yes ☐ No ☒

If "Yes" to Q1 and Q2 **or** Q1 and Q3, activity involves human subjects per DHHS regulations.

**B. "Research"**

4. Is the activity **systematic**? (**Systematic:** activity that involves data collection, either quantitative or qualitative, and data analysis to answer a question) Yes ☒ No ☐

5. Is the activity an **investigation**? (**Investigation:** activity that involves development, testing, evaluation, and/or search for information) Yes ☒ No ☐

6. Is the activity designed to **generate or contribute to generalizable knowledge**? (**Generalizable knowledge:** activity that draws general conclusions (knowledge gained may be applied to other populations outside of study), informs policy, or is universally or widely applicable; contributing to generalizable knowledge normally involves public dissemination of that knowledge) Yes ☒ No ☐

If "Yes" to Q4, Q5, **and** Q6, activity meets the definition of research per DHHS regulations.

* If activity involves "human subjects" and "research" per A & B, DHHS regulations apply.*

## Is it human research under FDA Regulations?

**7.** Are any of the following statements true?

**a.** Activity is conducted in the United States and involves use of a drug in one or more human subjects (as recipients of a test article or as controls, patient or healthy, 21 CFR 50.3), but is **not** the use of an approved drug in the course of medical practice. Yes ☐ No ☒

**b.** Activity is conducted in the United States and evaluates the safety or effectiveness of a device in one or more human subjects. Yes ☐ No ☒

**c.** Data regarding subjects (including controls) will be submitted to or held for inspection by FDA as part of an application for a research or marketing permit. Yes ☐ No ☒

**d.** Data regarding the use of a device (IVD) on human specimens (including de-identified/anonymous specimens) will be submitted to or held for inspection by FDA as part of an application for a research or marketing permit. Yes ☐ No ☒

If "Yes" to **any** of 7a-7d, the activity is human research per FDA regulations.

## Retrospective Data/Specimen Analysis Considerations

Yes ☒ No ☐

**8. Does the project involve retrospective data/specimen analysis?** *If no, skip to next section*
If Yes, provide a data collection sheet to the IRB and check one of the following:
Note: all research with newborn blood spots requires IRB review.

**a.** The provider of the data/specimens will remove all identifiers, including any codes, before sending data/specimens to SLU. Yes ☐ No ☐

**b.** Data/specimens to be obtained qualify as a Limited Dataset (only city/state/zip code, dates, and/or age are being obtained). Provide copy of internal or external data use agreement (DUA) for IRB records. By clicking yes, you assure you will not attempt to re-identify any individuals. Yes ☐ No ☐

**c.** Data/specimens to be obtained are coded, but the holder of the key to identifiers and the SLU investigator enter into an agreement (such as a code access agreement) prohibiting the release of the key to the investigator. Submit copy of agreement. Yes ☒ No ☐

**d.** SLU agent has documentation of written policies from a repository/data source that prohibits the release of the key to SLU agent. Submit documentation to IRB. Yes ☐ No ☐

**e.** There are other legal requirements prohibiting release of identifiers to SLU agent or the data (with or without identifiers) are all publicly available. Yes ☐ No ☐

If "Yes" to **any** of 8a-8e, the activity may not be human research for SLU agent.

## Quality Improvement Considerations

**9. Does the project involve quality improvement, not research?** *(If no, skip to next section)* Yes ☐ No ☒
If Yes, answer the following:

**a.** The goal of the project is to inform/improve the performance of the unit/site, not to establish scientific evidence to share beyond the scope of the unit/site. Yes ☐ No ☐

**b.** The unit/site administrators approve this as a QI project to be systematically implemented; activities do not require the consent of individual participants. Yes ☐ No ☐

**c.** If there is a possibility of publishing the outcomes of the QI initiative, the personnel involved will include the following statement with manuscripts, "This project was undertaken as a QI initiative, and as such was not approved by an IRB". Yes ☐ No ☐

If "Yes" to 9a-9c, the activity may not be human research for SLU agent.

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Project Description

**Please provide a brief project description.** State the project's purpose and explain how you will be gathering or obtaining project information/data/specimens.

This is a project that was favorably reviewed by the National Science Foundation and will likely be funded for approximately $83K for SLU and $200K for Auburn University. This Grant Opportunity for Academic Liaison with Industry (GOALI) project will investigate opportunities for incorporating analytical tools for modeling truck driver's safety performance and subsequent optimization of dispatching policies. Our research is motivated by the fact that transportation incidents remain a pressing public safety issue in the United States and throughout the world. Fatigue-related deterioration of driver's performance is a major factor contributing to fatal road incidents, especially among those involving commercial semi-trailer trucks. Truck drivers operate in a complex and dynamic environment, and currently there is not enough understanding of how various factors interact with the driver's ability to safely perform the required duties. At the same time, large amounts of data are either routinely collected by trucking and transportation companies or are available elsewhere. These data include route and rest schedule details, hours logged by the drivers, traffic and weather conditions, driving-related outcomes, etc. The research project aims to understand how changes in driver's performance develop as a function of driving conditions represented by those datasets, and subsequently, how this information can be used in practical decision making. The research is integrated with an education plan whose cornerstone is an online platform that will allow for the dissemination of the research outcomes to current and future practitioners.

The industrial partner is J. B. Hunt Transport, who will supply data on trucks and truckers, including GPS information and some demographic information about the driver (age, BMI, driving experience, and years with JB Hunt). In the data set that J. B. Hunt provides, the driver's identity will be coded and only J. B. Hunt will have to key to identifying the drivers.

## FOR IRB USE ONLY

**THIS DOES NOT REQUIRE SUBMISSION TO THE IRB**

Emily Harrison
**Signature of SLU IRB Reviewer**

6/24/2016
**Date**

**Justification for IRB Decision (if deemed necessary to provide):**