The intent of this instruction is to guide the research investigator when developing his/her study specific protocol.

1. General Information
   1. Formatting Instructions:
      * Use Times New Roman font 12 pt.
      * Allow space in the footer for the AFRL IRB approval period, version number and/or date to be included. The AFRL IR administrators will manage and insert the final version and approval period.
   2. The protocol should include other categories that may pertain to your specific research, i.e. HIV, pregnancy, long-term storage of samples, genetic testing, and data sharing practices.
   3. Shaded areas are instructional text only, and should be deleted in the final protocol version.
   4. A HIPAA waiver request is required if the medical records of subjects are going to be accessed without the subject’s consent. If subjects will be signing an ICD and the investigator wants to access the subject’s medical records then the subjects should also sign a HIPAA authorization form at the time of consent.
2. TITLE: The title on the research protocol must be identical to the title on the consent form, unless a specific justification (e.g. confidentiality issue, planned deception) for a different title is addressed in the research protocol.
3. INVESTIGATORS:
   1. A list of all investigators with their contact information must be included on the title page.
   2. Rank/Name, DSN 000-0000 and COMM, Organization/Office Symbol and Official Email address (no personal email accounts are permitted).
   3. Ensure email addresses and phone numbers are current.

**DELETE THIS FIRST PAGE OF INFORMATION AND ALL INSTRUCTIONAL TEXT OR NON-APPLICABLE TEXT PRIOR TO FINALIZING YOUR PROTOCOL**

1. **Principal Investigator**

Dr. Scott Graham, Assistant Professor, Air Force Institute of Technology Department of Electrical and Computer Engineering (AFIT/ENG), (937) 255-3636 ext. 4581, scott.graham@afit.edu.

1. **Associate Investigators**

Second Lieutenant (2LT) David Crow, Masters Student, Air Force Institute of Technology Department of Electrical and Computer Engineering (AFIT/ENG), david.crow@afit.edu.

Todo: Dr. Borghetti?

Name/Rank/Title, Organization/Office Symbol, Phone Number, Email address, contractor affiliation if applicable.

Todo: Dr. Mullins?

Name/Rank/Title, Organization/Office Symbol, Phone Number, Email address, contractor affiliation if applicable.

1. **Research Monitor**

Todo: Dr. Ries?

Name/Rank/Title, Organization/Office Symbol, Phone Number, Email address, contractor affiliation if applicable.

1. **Facility/Contractor**
   1. **Sponsor:**

Todo: Col Sweeney?

* 1. **Funding Source and Funding Amount:**

This experiment is unfunded. All necessary equipment has already been obtained.

* 1. **Contract #/CRADA #/Cooperative Agreement #:**

Not applicable

* 1. **Activity location(s) (where activity will be conducted):**

Air Force Institute of Technology, Wright-Patterson Air Force Base, Ohio

1. **Conflicts of Interest**

None.

1. **Background Information and Scientific Rationale**

Todo:

Briefly describe pre-trial data, current experience with procedures and any other relevant information to justify and support the research. Include detailed literature review with most current citations that serves as the foundation for your research.

* 1. **Investigative Question 1**

*Hypothesis: Todo*

Todo: description

* 1. **Investigative Question 2**

*Hypothesis: Todo*

Todo: description

* 1. **Investigative Question 3**

*Hypothesis: Todo*

Todo: description

1. **Study Objective(s) and Purpose** 
   1. **Purpose:**

Todo

* 1. **Primary Objective:**

Todo

* 1. **Secondary Objective(s):**

Todo

1. **Study Design**
   1. **Description of Study Design:**

Todo:

* Include the sequence and timing of study procedures.
* Consider including schemas of the study visit schedule/timetables.
* Distinguish research procedures from those that are clinical standard of care if applicable.
* Study duration and number of study visits, total time commitment for each visit and for the study overall that is required of the research participants.
* Blinding, randomization including justification or decision for not blinding and justification if applicable.
* Justification of placebo or non-treatment/control group.
* Definition of participant removal criteria.
* Description of what happens if study ends or participant’s participation ends prematurely (either participant choice or PI choice).

1. **Subject Selection**
   1. **Inclusion Criteria:**

A subject who meets all of the following criteria is eligible for participation in the study:

* Owns or has authorization to operate the motor vehicle
* Possesses a valid driver’s license
* Appears to be mentally and physically able and prepared for the driving task (e.g. not under the influence of substances; not experiencing undue emotional stress or physical limitations)
  1. **Exclusion Criteria:**

A subject who meets any of the following criteria is disqualified from participation in the study:

* Is pregnant or believes to be pregnant
* Is under the age of 18 years old
* Is not a United States citizen
* Is unable to maintain clear verbal communication with the researcher
  1. **Recruitment Plan**

Recruitment method:

For the purpose of this study, recruitment will be accomplished within the Air Force Institute of Technology, the Air Force Research Laboratory, and other major Air Force organizations located at Wright-Patterson Air Force Base (WPAFB). All participants will be service members, employees of the Department of Defense, or contractors working on WPAFB. An email will be sent to the group distribution mailing address by a person not directly in the chain of command (e.g. a secretary). Additionally, the recruiting advertisement will be posted on the electronic AFIT announcement board on the intranet.

Subject recruitment message:

“The Air Force Institute of Technology (AFIT) is conducting a study in which participants will operate a researcher’s personally-owned vehicle for brief periods of time. Data will be collected from the vehicle’s Controller Area Network (CAN) via its On-Board Diagnostics (OBD-II) port located under the steering column. No data will be transmitted to the vehicle and no electronic modifications of any kind will be made. Additionally, participants will operate a vehicle simulator on the AFIT campus. Data will also be collected from the simulator.

The main goal of this study is to compare a driver’s real-world driving fingerprint with their simulated-world driving fingerprint. Participation in this study is voluntary and compensation will not be provided. However, participation in this study will allow you to participate in important research about vehicle network defense and help the investigators develop meaningful suggestions for the automotive industry and legislators. Volunteers will be asked to operate the researcher’s motor vehicle in a parking lot and along a two-mile course. Participants will be asked to follow three scripted scenarios for up to 30 minutes. Participants will be asked to do the same in a vehicle simulator.

This research project has been approved for the use of human subjects by the Air Force Research Laboratory’s Institutional Review Board in accordance with AFI 40-402 and AFRLI 40-402.”

* 1. **Consent Plan**

Information concerning the informed consent document will be presented by the primary investigator or one of the associate investigators. Consent will be obtained from the participant before any data is collected.

* 1. **Compensation**

There are no plans to provide compensation for participation in the research.

1. **Experimental Plan**
   1. **Equipment:**

Todo:

* If you are using a device or drug that could fall under FDA device/drug regulations, supply discussion of FDA status and supporting FDA documentation. Also include the manufacturer’s specifications as an attachment. Discuss whether the device/drug is being used within the manufacturer’s specifications. Include as an attachment the manufacturer’s user guide or package insert of product or device.
* Consider attaching a photo of any equipment that will be used.
* If multiple sub-experiments, discuss in detail each experiment (i.e., number of MRI visits, number and volume of blood draws, number of days/hours, etc.). If conducting surveys, questionnaires, interviews, reference AFI 38-501, Air Force Survey Program. If applicable AF survey office documentation must be submitted.
* Incidental Findings: for activities that could result in the discovery of an incidental finding that may have substantive or clinical importance; for example findings from (1) Imaging procedures such as MRI, (2) records review, (3) EEG, (4) genetics, (5) surveys, questionnaires that may ask about illegal activity, describe the plan that will be followed if an incidental finding is detected. Plans should include sufficient detail such as the specific time frame for follow up of any clinical readings, reporting to the subject and/or the primary medical provider as applicable. The proposed time frame should be justified.

1. **Risk/Benefit Analysis**
   1. **Benefits:**

There is no benefit to the subjects.

* 1. **Risks:**

Todo:

* List all research procedures, their major and minor risks and expected frequency.
* Include all foreseeable risks or discomforts to the participant (physical, emotional, social, and financial, loss of employability, reputation and breach of confidentiality) as applicable.
* Include steps that will be taken to minimize risks.

1. **Statistical Consideration and Plan**

Todo:

Use the minimum number of subjects needed to meet the research objective or answer the research question**.**

1. **Safety Monitoring and Reporting**

The participants will be monitored by research personnel throughout the entire test session. Participants will be told (verbally by the experimenter, as well as in the informed consent form) that they are free to terminate their participation at any time. Participants will be informed of the study’s procedure and the requirements to employ standard vehicle safety features. The primary investigator or one of the associate investigators will act as the on-site monitor and will notify participants in person in the case of emergency. For example, participant notification is necessary if they became unconscious, if there are dangerous driving conditions they don’t notice, or if they are driving dangerously or illegally. In the case of an adverse incident, WPAFB emergency services will be notified immediately. The PI will ensure that mishaps or injuries sustained during research will be reported as required pursuant to AFI 91-204.

1. **Confidentiality**

No data regarding the participants will be collected or maintained. No contact will be made with participants after their participation in the study. With the exception of the potential presence of vehicle identification numbers (VIN), vehicle data is generic. All vehicle network data collected will be scanned for VINs. If whole or partial VINs are found, they will be replaced by a generic VIN of all zeros.

1. **Data Management / Data Sharing Plan**

Vehicle network data will be sorted by make, model, and observation state. The data will be copied to and stored securely on an access-controlled folder on AFIT’s internal network, and access will be managed by the principal investigator and enforced by AFIT/SC via network policy. Dual protection for this folder requires CAC-and-PIN network login plus account-based access to the folder. Only researchers listed on this document will have access to the folder.

All data will be maintained beyond the completion of this study in order to support related work in the future. Vehicle data will also be analyzed, and the results will be used for publication via conference and journal papers as well as theses and dissertations. No published results will identify participants or the vehicle, and no published results will associate the participants or the vehicle with any findings.

1. **References**

Todo

1. **Attachments**

Todo:

* Informed Consent Document (required unless waiver granted).
* Consent waiver request.
* HIPAA waiver request.
* Current Curriculum Vitae of investigators (Appropriate to experience/education).
* Questionnaires or surveys (if applicable).
* Subject recruiting materials (if applicable).
* Other attachments if applicable, such as: letters of collaborative support (data use agreements, CRADA, etc.), IND/IDE supportive documents, contractor assurances, and any other supportive documentation.
* Safety, Radiation, Laser, IBC Board reviews etc.