Plan Overview

A Data Management Plan created using DMPTool

DMP ID: https://doi.org/10.48321/D1K34S

Title: Computerized Neurocognitive Tests for Aeromedical Safety

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Funder: United States Department of Transportation (DOT) (transportation.gov)

Template: U.S. Department of Transportation: Data Management Plan (DMP)

Project abstract:

Computerized neurocognitive tests are a non-invasive way to measure cognitive function (e.g., attention, working memory, information processing speed, reaction time). The Federal Aviation Administration (FAA) uses neurocognitive tests as part of the FAA's overall aeromedical physical exam process to determine if an aviator is safe to operate an aircraft within the National Airspace System. Neurocognitive tests are required only for aviators with certain medical conditions associated with aeromedically significant cognitive impairments (i.e., not all aviators are tested). The purpose of this research study is to obtain normative data from approximately 1,000 medical class 1, 2, and 3 aviators for three computerized neurocognitive tests under consideration as alternatives to supplement the FAA's current (i.e., legacy) neurocognitive test. Data and analyses will be used to potentially revise the FAA's Aviation Medical Examiners (AME) Guide, update clinical practices, and make changes to aviator medical certification protocols.

Start date: 01-28-2020

End date: 01-31-2025

Last modified: 01-18-2024

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Computerized Neurocognitive Tests for Aeromedical Safety

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Change Log:

2022-05-15: Initial Data Management Plan (DMP) written

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0. Dataset and Contact Information:

- Name of the dataset or project for which data is being collected -- Computerized Neurocognitive Tests for Aeromedical Safety
- Project number, contract number, or other number used to link this DMP -- A11J-AM.12
- Name of the person submitting this DMP -ORCiD of the person submitting this DMP -- Susan M. Jay; ORCiD: 0000-0002-1331-0396
- Email and phone number of the person submitting this DMP -- susan.m.jay@faa.gov; (405) 954-5500
- Name of the organization for which the person submitting this DMP is working for -- Performing Organization: Civil Aerospace Medical Institute (CAMI)
- Email and phone number for the organization -- Mailing Address: Civil Aerospace Medical Institute (CAMI) P.O. Box 25082 Oklahoma City, OK United States 73125
- Link to organization or project website -- https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/cami
- Date the DMP was written -- 15 May 2022

1. Data Description: These data sets and technical reports are derived from the research project "Computerized Neurocognitive Tests for Aeromedical Safety"

The purpose of this research study is to obtain normative data from approximately 1,000 medical class 1, 2, and 3 aviators for three computerized neurocognitive tests under consideration as alternatives to supplement the Federal
Aviation Administration's (FAA) current (i.e., legacy) neurocognitive test. Data and analyses will be used to potentially revise the FAA's Aviation Medical Examiners (AME) Guide, update clinical practices, and make changes to aviator medical certification protocols.

The anticipated data that will be generated from this research project include:

- De-identified research participant demographic, medical history, and flight time hours in survey format
- Numerical data sets (raw and aggregate data [pooled data, group averages]) for the three neurocognitive tests
- Technical report with recommendations summarizing the data analysis and results,

The methods used for creating the data will include computer-based software for survey data collection and aviator normative data collection for the three neurocognitive tests.

Data collection is projected from July 2023 to July 2024. This is a one-time data collection effort for each research participant.

The Principal Co-Investigators are not using existing data in this current research project.

Potential users of this data include:

- The Federal Aviation Administration's (FAA) Office of Aerospace Medicine
- The FAA's Aviator Medical Certification Division
- FAA neuropsychologists and psychologists, FAA-designed Aviation Medical Examiners (licensed medical providers who conduct pilot aviation medical exams on behalf of the FAA)
- Neurocognitive test developers
- Academic institutions, and
- The public.

The potential long-term value of the data will allow FAA neuropsychologists, psychologists, and FAA-designated Aviation Medical Examiners to make informed medical screening decisions for aviators with medical conditions associated with aeromedically significant cognitive impairments (e.g., traumatic brain injury, stroke, certain types of medications). These medical screenings are used to determine if an aviator is safe to operate an airplane within the National Airspace System, which in turn affects aviation safety for the flying and ground-based public.

De-identified aggregate data (i.e., groups means, standard deviations, standard errors) will be made publicly available through the National Transportation Library, as well as through links on the FAA's Civil Aerospace Medical Institute (CAMI) website.

The FAA/CAMI Principal Co-Investigators will be responsible for data management during the data collection and data analysis phases. Once the research project is complete, the de-identified aggregate datasets and final technical report will be transferred to the National Transportation Library for permanent, long-term storage and public access.

Adherence to this data management plan (DMP) will be made at least once per quarter.

2. Standards Employed:

Data are anticipated to be collected and developed electronically on secure (i.e., government only access card),
government furnished equipment. Data formats will include:

- Comma-separated values (.csv) raw data output files generated by the neurocognitive test(s) software; open format
- Excel data files (.xlsx) for the aggregate data generated during the data analysis; open format
- Word files (.docx) generated by the survey software; open format
- Word files (.docx) generated during the report process; open format
- Portable Document File (.pdf) for the final technical reports; open format

Proprietary data format are not anticipated for inclusion at this time.

Data versions will be maintained by the FAA/CAMI Principal Co-Investigators using a standardized naming convention. Electronic data files will be maintained on secure (i.e., government only access card), government furnished equipment.

The anticipated file formats are standard for the Principal Co-Investigators' field(s).

Anticipated documentation will include datasets (e.g., Excel spreadsheets) with explanatory notes, and a technical report with charts, data tables, and graphs as necessary to explain the study data analysis and results.

A specific metadata schema has not yet been selected for this research project.

The metadata will be managed by the FAA/CAMI Principal Co-Investigators and stored on secure (i.e., government only access card), government furnished equipment. Once the research project is complete, the de-identified aggregate datasets and final technical report will be transferred to the National Transportation Library for permanent, long-term storage and public access.

A computer, or other internet-connected electronic device, with Microsoft Office applications (e.g., Word, Excel) and Adobe PDF Reader will be required to access the data sets and technical reports.

At the end of a data collection day, the FAA/CAMI Principal Co-Investigators and/or government trained research support staff, will perform quality control checks of the raw data generated by neurocognitive test(s) software. These data quality control checks will look for missing data fields and aberrant/spurious data (e.g., missed keystrokes) prior to raw data upload to secure (i.e., government only access card), government furnished data back-up/storage devices. The raw data will be reviewed by the research project Data Manager prior to upload to the secure (i.e., government only access card), government furnished data analysis computer.

The FAA/CAMI Principal Co-Investigators will ensure that the final datasets and technical report are maintained and retained on government furnished equipment in accordance with Department of Transportation (DOT) and FAA data accessibility policies. The FAA/CAMI Co-Investigators will ensure that the files open and have retained the entered data.

3. Access Policies:

All de-identified aggregate data, study results, and final technical report will be made publicly available through the National Transportation Library website, as well as through a link on the Civil Aerospace Medical Institute (CAMI) website.
• Discuss how will you guard against disclosure of identities and/or confidential business information. --
Potential research participants who volunteer for the study and who meet the study inclusion criteria, will access a URL link (provided by the FAA/CAMI Principal Co-Investigators) to the Informed Consent Form. The Informed Consent form will have a randomly generated unique identifier that will be used to identify the research participant and their collected data (i.e., demographic survey responses and neurocognitive test(s) scores/results) throughout the remainder of the study. The Informed Consent form will be the only form on which research participants will identify themselves by name. Only the FAA/CAMI Principal Co-Investigators and government trained research support staff, will have access to the "Master Key" linking an Informed Consent form with a research participant's unique identifier. The "Master Key" and scanned Informed Consent forms will be stored on a secure (i.e., government only access card), government furnished equipment. The demographic surveys will have input fields only for the research participant's unique identifier; there will be no data entry fields for a participant to inadvertently enter personally identifiable information (PII) (e.g., name, date of birth, social security number). The neurocognitive test(s) "Welcome" screen/test instructions screen will have an input field only for the research participant's unique identifier; there will be no data entry fields for a participant to inadvertently enter PII. Survey response data and neurocognitive test(s) scores/raw data will be reported as numerical frequencies and/or group averages (i.e., aggregate data). The final datasets for public access will contain only aggregate data.

• List what processes you will follow to provide informed consent to participants. --
Potential research participants who volunteer for the study and who meet the study inclusion criteria, will access a URL link (provided by the FAA/CAMI Principal Co-Investigators) to the CAMI Institutional Review Board (IRB)-approved Informed Consent Form. The Informed Consent Form will provide the participant with an overview of the study, its voluntary nature and the ability to opt-out at any time, and will inform participants of the study purpose, and how the FAA will use the study results. The informed consent will also state that any PII collected (e.g., participant's name) will not be associated with the participant’s demographic survey responses or neurocognitive test(s) scores. All participants must provide their informed consent prior to completing any of the demographic surveys or neurocognitive test(s). A paper copy of the informed consent will also be available for the participant to retain for their records.

• State the party responsible for protecting the data. --
The FAA/CAMI Principal Co-Investigators will be responsible for protecting the data in accordance with FAA data management policies and procedures.

It is anticipated that the de-identified, aggregate data will not contain private or confidential information. Only de-identified, raw and aggregate data will be shared with the neurocognitive test developers. Only de-identified aggregate data will be made accessible to the public.

Potential research participants who volunteer for the study and who meet the study inclusion criteria, will access a URL link (provided by the FAA/CAMI Principal Co-Investigators) to the Informed Consent Form. The Informed Consent form will have a randomly generated unique identifier that will be used to identify the research participant and their collected data (i.e., demographic survey responses and neurocognitive test(s) scores/results) throughout the remainder of the study. The Informed Consent form will be the only form on which research participants will identify themselves by name. Only the FAA/CAMI Principal Co-Investigators and government trained research support staff, will have access to the "Master Key" linking an Informed Consent form with a research participant's
unique identifier. The "Master Key" and scanned Informed Consent forms will be stored on a secure (i.e., government only access card), government furnished equipment. The demographic surveys will have input fields only for the research participant's unique identifier; there will be no data entry fields for a participant to inadvertently enter personally identifiable information (PII) (e.g., name, date of birth, social security number). The neurocognitive test(s) "Welcome" screen/test instructions screen will have an input field only for the research participant's unique identifier; there will be no data entry fields for a participant to inadvertently enter PII. Survey response data and neurocognitive test(s) scores/raw data will be reported as numerical frequencies and/or group averages (i.e., aggregate data). The final datasets for public access will contain only aggregate data.

4. Re-Use, Redistribution, and Derivative Products Policies:

These data are managed by the Department of Transportation, Federal Aviation Administration. The data are in the public domain and may be re-used without restriction. Citation of the data is appreciated. Please use the following recommended citation:


The Federal Aviation Administration (FAA) holds the intellectual property rights to this data.

The datasets and technical report are in the public domain.

Any rights to be transferred to a data archive are unknown at this time.

The data will be available to the public for reuse, redistribution, and the creation of derivative products in accordance with Department of Transportation and Federal Aviation Administration policy regarding U.S. government funded research products (i.e., the data are in the public domain and may be re-used without restriction, with source citation appreciated).

5. Archiving and Preservation Plans: Data archiving will be accomplished through the National Transportation Library.

The approximate time period from completion of data collection and analysis to archive submission is anticipated to be less than one year.

During the data collection and analysis phases, the data will be temporarily stored on secure (i.e., government only access card), government furnished equipment prior to being sent to an archive.

The data security and integrity will be maintained by the Federal Aviation Administration, and the data management and protection will be subject to the standards and methodologies used by the Administration.

The data security and integrity will be maintained by the Federal Aviation Administration, and the data management and protection will be subject to the standards and methodologies used by the Administration.

The data security and integrity will be maintained by the National Transportation Library (NTL) and the data management and protection will be subject to the standards and methodologies used by the NTL.
The National Transportation Library will retain the data indefinitely.

The National Transportation Library allows persistent identifiers to be linked to the data.

It is understood that the National Transportation Library complies with the following attributes:

1. Promotes an explicit mission of digital data archiving;
2. Ensures compliance with legal regulations, and maintains all applicable licenses covering data access and use, including, if applicable, mechanisms to protect privacy rights and maintain the confidentiality of respondents;
3. Has a documented plan for long-term preservation of its holdings;
4. Applies documented processes and procedures in managing data storage;
5. Performs archiving according to explicit work flows across the data life cycle;
6. Enables the users to discover and use the data, and refer to them in a persistent way through proper citation;
7. Enables reuse of data, ensuring appropriate formats and application of metadata;
8. Ensures the integrity and authenticity of the data;
9. Is adequately funded and staffed, and has a system of governance in place to support its mission; and
10. Possesses a technical infrastructure that explicitly supports the tasks and functions described in internationally accepted archival standards like Open Archival Information System (OAIS).

6. Policies Affecting this Data Management Plan:

This data management plan was created to meet the requirements enumerated in the U.S. Department of Transportation's "Plan to Increase Public Access to the Results of Federally-Funded Scientific Research" Version 1.1 <<https://doi.org/10.21949/1520559>> and guidelines suggested by the DOT Public Access website <<https://doi.org/10.21949/1503647>>, in effect and current as of May 15, 2022.
Planned Research Outputs

Dataset - "[alternative neurocognitive test #1] Dataset"

De-identified, aggregate data (e.g., group means, standard deviations, standard errors) from the 1st alternative neurocognitive test.

Dataset - "[alternative neurocognitive test #2] Dataset"

De-identified, aggregate data (e.g., group means, standard deviations, standard errors) from the 2nd alternative neurocognitive test.

Dataset - "[alternative neurocognitive test #3] Dataset"

De-identified, aggregate data (e.g., group means, standard deviations, standard errors) from the 3rd alternative neurocognitive test.

Data paper - "Computerized Neurocognitive Tests for Aeromedical Safety"

Technical report with recommendations based on the data analysis and results of the research project.

Planned research output details

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