The Impact of Co-Administration of Alcohol and Cannabis on Impairment

Persistent Link

Include the persistent identifier (PID) that is associated with the dataset.

Persistent Link:

TBD.

Recommended Citation

The recommendeded data citation to be used when citing the dataset.

Recommended Citation:

TBD.

Change Log

Document the changes that are made to the DMP, any and all changes should be noted to ensure a more complete documentation.

Change Log:

2022.12.06: Initial DMP written

Table of Contents

Optional table of contents included here, in order to better organize the DMP.

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0. Dataset and Contact Information

Please provide the following information:

- **Name of the dataset or project for which data is being collected.**
- **Name of the FAA Line-Of-Business/Office for which the associated dataset is being generated.**
- **Email for the FAA Line-Of-Business/Office (key field).**
- **If applicable and as reference, project number, contract number, or other number used to link this DMP.**

0. Dataset and Contact Information:

Project Title: The Impact of Co-Administration of Alcohol and Cannabis on Impairment

FAA Line-Of-Business/Office: AAM-612

FAA Line-Of-Business/Office Email: Genomics@faa.gov

1. Data Description

Name the data, data collection project, or data producing program. Provide high level narrative.

The FAA-administered aspects of this study are still in the planning stages and as such the data set does not yet exist. The proposed study will consist of RNA-seq data consisting of approximately 840 samples collected from approximately 32 study subjects in the form of .fastq files along with corresponding cognitive task data.

Describe the purpose of your research and whether results will be documented in a published document or report. How will it be used?

It is the intent of the FAA Functional Genomics Team to analyze samples and data from the project to research molecular biomarkers associated with cannabis use, alone and concomitant with alcohol consumption. This may include biomarkers associated with cognitive performance, driving simulator performance, field sobriety tests, and survey scores. The data will be documented in a FAA report, which will be available at the FAA Aerospace Medicine Technical Reports library at FAA.

Describe the data that will be generated in terms of nature and scale (e.g., numerical data, image data, text sequences, video, audio, database, modeling data, source code, etc.).

RNA-seq and downstream analysis data (alignments, differential gene expression, functional and pathway analysis) and cognitive task data. The data consist of numerical data, scripts, and R Markdown notebooks.

Describe methods for creating the data (e.g., simulated; observed; experimental; software; physical collections; sensors; satellite; enforcement activities; researcher-generated databases, tables, and/or spreadsheets; instrument generated digital data output such as images and video; etc).

Drugs will be administered in a double-blind and double-dummy fashion (i.e., participants will always receive both active or placebo cannabis and active or placebo alcohol). During each session, a battery of assessments including blood collection, subjective questionnaire administration, cognitive performance testing, and simulated driving will be conducted.

Blood samples will be collected at baseline (prior to drug administration) and again at 1.5, 3.5, 5.5, and 7.5 hours after oral cannabis, alcohol, or placebo ingestion. Tubes will be labeled with a study code, and submitted to the FAA CAMI for functional genomics research such as RNA-Sequencing and bioinformatics analysis.

Describe the period of time over which the data will be collected and frequency at which it will be updated.

This study will be conducted at the Johns Hopkins Behavioral Pharmacology Research Unit. Participants will complete a screening visit, and, if eligible, will then complete 7 experimental drug administration sessions in randomized order where they will consume a cannabis-infused brownie (containing 0, 10, or 25mg THC) with a drink that contains no alcohol or alcohol (alcohol-containing drinks will be calculated to produce a breath alcohol concentration, BAC, of 0.05%). There is also a positive control session where participants will ingest placebo cannabis with an alcohol drink calculated to produce a BAC of 0.08%. Each session will last approximately 10 hours and will be separated by at least 1 week to allow for sufficient drug washout.

If using existing data, describe the relationship between the data you are collecting and existing data.

Not applicable.

Describe potential users of the data and the expected manner in which they may use it.

Typical users of the data include research analysts and the principle investigators. Also, the research sponsor (policy makers) may refer to the data to confirm their understanding of the results as they develop safety guidance.

Discuss the potential value of having the data available not only to your institution but also for the public, e.g., might be renewed interest and value in reanalyzing the data with updated and more universally comparable metrics or recently developed analytical methods.

The data to be collected and analyzed in the proposed study has heretofore been unavailable within the wider scientific literature due to the nature of cannabis research in the United States.

State clearly if data can be shared publicly or not. If you request permission not to make data publicly accessible, explain rationale for lack of public access.

Key findings are expected to be described in one or more reports and published. Per standard journal requirements and potentially public access requirements, it is expected that this will include archival of some or all of the data and genetic information in online repositories, e.g., deposition of sequences in dbGaP (https://www.ncbi.nlm.nih.gov/gap/).

Indicate the party responsible for managing the data.

Unless otherwise noted, refer to "Section 0: Dataset and Contact Information", the FAA line-of-business (LOB) is identified, which is responsible for generating the data, and is also responsible for managing the data initially, and by default long-term, the FAA's Enterprise Information Management (EIM) will manage and catalog the data. Refer to the FAA Data Governance Center, this is landing page and access point to EIM uploaded datasets.

Describe how you will check for adherence to this data management plan.

Unless otherwise noted, refer to "Section 0: Dataset and Contact Information," the FAA line-of-business (LOB) is identified, which is responsible for generating the data, and is also responsible for managing the internal project management processes to ensure adherence to the published data management plan (DMP). Details of the particular FAA LOB's DMP adherence processes can be provided on-demand. Typical processes require management review and sign-off at project start and close-out.

2. Standards Employed

List in what format(s) the data will be collected. Indicate if they are open or proprietary.

2. Standards Employed:

Unless otherwise noted, this FAA research project has descriptive project data posted in https://rip.trb.org/ at project launch and while under development and https://researchhub.bts.gov/ database beyond. These databases have published standards. The project's metadata will be posted in Catalog.Data.Faa.Gov. This catalog follows the DCAT-US Schema v1.1 (Project Open Data Metadata Schema) https://resources.data.gov/schemas/dcat-us/v1.1/ – a set of required fields (Title, Description, Tags, Last Update, Publisher, Contact Name, etc.) for every data set displayed on Catalog.Data.FAA.gov.

If you are using proprietary data formats, discuss your rationale for using those standards and formats.

The proposed data will be in the form of .fastq and .csv files.

Describe how versions of data be signified and/or controlled.

Unless otherwise noted, refer to "Section 0: Dataset and Contact Information", the FAA line-of-business (LOB) is identified, which is responsible for generating the data, and is also responsible for version control initially. Once uploaded by default upon project completion and long-term, the data is managed by FAA's Enterprise Information Management (EIM), which also applies configuration control on dataset versions. Refer to the FAA Data Governance Center. This is the internal FAA landing page and access point to EIM uploaded datasets and processes.

If the file format(s) you are using is(are) not standard to your field, describe how you will document the alternative you are using.

Unless otherwise noted, this project's metadata will describe the data and formats whether open source or non-standard to the particular field domain of the research. if additional description is required for non-standard formats, the researcher will list references and/or definitions here.

List what documentation you will be creating in order to make the data understandable by other researchers.

Unless otherwise noted, this project's metadata will describe the data and formats and by default should be understandable by other researchers and on the FAA's Enterprise Information Management (EIM), which requires application of published standards like DCAT-US Schema v1.1 (Project Open Data Metadata Schema) https://resources.data.gov/schemas/dcat-us/v1.1/ – a set of required fields (Title, Description, Tags, Last Update, Publisher, Contact Name, etc.). Most data sets use open standard and common formats (e.g., CSV, XML, JSON) and if not, described in this DMP.

Indicate what metadata schema you are using to describe the data. If the metadata schema is not one standard for your field, discuss your rationale for using that scheme.

This project's metadata and associated data schema is posted with its data on the FAA's Enterprise Information Management (EIM), which requires application of published standards like DCAT-US Schema v1.1 (Project Open Data Metadata Schema) https://resources.data.gov/schemas/dcat-us/v1.1/ – a set of required fields (Title, Description, Tags, Last Update, Publisher, Contact Name, etc.).

Describe how will the metadata be managed and stored.

Unless otherwise noted, refer to "Section 0: Dataset and Contact Information", the FAA line-of-business (LOB) is identified, which is responsible for generating the data, and is also responsible for generating the metadata. Once uploaded by default upon project completion and long-term, the data and its associated metadata is managed by FAA's Enterprise Information Management (EIM). Refer to the FAA Data Governance Center. This is the internal FAA landing page and access point to EIM uploaded datasets and processes.

Indicate what tools or software is required to read or view the data.

Unless otherwise noted, open data formats are used as much as possible. If not possible, the researcher shall list proprietary data formats and associated tools and software required to read/view the data here. Citations to the required tools and software would be included.

Describe your quality control measures.

Refer to "Section 0: Dataset and Contact Information", the FAA line-of-business (LOB) identified is responsible for managing quality control standards in the data generation and initial creation of the associated metadata. Once uploaded by default upon project completion and long-term, the data and its associated metadata is managed by FAA's Enterprise Information Management (EIM). Refer to the FAA Data Governance Center. This is the internal FAA landing page and access point to EIM uploaded datasets and processes. Thus, all data uploaded to the EIM platform follows the quality control measures set forth in managing FAA datasets, where EIM states “FAA Data Stewards publish data thru the FAA Data Governance Center hosted and managed by the FAA Chief Data Office. Here the metadata is curated and validated for quality and accuracy. The FAA Data Steward enters metadata and verifies quality and accuracy before publishing to data.faa.gov.”

3. Access Policies

Describe what data will be publicly shared, how data files will be shared, and how others will access them.

Consistent with the previous two sections, "Section 1. Data Description" and "Section 2. Standards Employed," the default long term storage and access location for the data documented in this DMP is the FAA's Enterprise Information Management (EIM). Refer to the FAA Data Governance Center., which is the internal FAA landing page and access point to EIM uploaded datasets and processes.

Indicate whether the data contain private or confidential information. If so:

- **Discuss how will you guard against disclosure of identities and/or confidential business information.**
- **List what processes you will follow to provide informed consent to participants.**
- **State the party responsible for protecting the data.**

For this DMP's particular dataset, "Section 1. Data Description" Question #9 the researcher already delineated if the data was able to be publicly accessible or restricted and reason associated with the latter. Restricted data is identified upon upload to the FAA's Enterprise Information Management (EIM) and details of the protections in place are documented at the FAA Data Governance Center, which is the internal FAA landing page and access point to EIM uploaded datasets and processes.

Collection of raw data and raw biospecimens will be performed by JHUSOM, and sent to the FAA Functional Genomics Team. It is anticipated that some analyses may be conducted and published in collaboration with JHUSOM researchers. The FAA will establish a legal agreement to receive samples and/or data from JHUSOM.

The FAA will receive data and biospecimens with de-identified subject codes. However, the FAA does expect to receive some data that may have date/time of study events (such timestamps may be considered a HIPAA identifier).

Ultimately the FAA intends to publish key results and findings from the research, such as a list of biomarkers that are associated with cannabis and alcohol use and cognitive impairment (pending study findings of such biomarkers). Key findings are expected to be described in one or more reports and published. Per standard journal requirements and potentially public access requirements, it is expected that this will include archival of some or all of the data and genetic information in online repositories, e.g., deposition of sequences in dbGaP (https://www.ncbi.nlm.nih.gov/gap/).

JHUSOM has obtained a Certificate of Confidentiality and the study is listed on clinicaltrials.gov with the identifier NCT04931095.

If applicable, describe how you will deidentify your data before sharing. If not:

- **Identify what restrictions on access and use you will place on the data.**
- **Discuss additional steps, if any you will use to protect privacy and confidentiality.**

Unless otherwise noted, all concerns and mitigations associated with the need to deidentify fields in the data are addressed in the previous question.

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

Name who has the right to manage the data.

Unless otherwise noted, the data described in this DMP is generated and managed by the Federal Aviation Administration. The data are in the public domain, and may be re-used without restriction.

Indicate who holds the intellectual property rights to the data.

Unless otherwise noted (e.g., data is partially proprietary by an external entity, where intellectual property is shared), this data is required to be made available in open, machine-readable formats, while continuing to ensure privacy and security in accordance with the OPEN Government Data Act, which is Title II of the Foundations for Evidence-Based Policymaking Act.

Cognitive task data is owned by the Johns Hopkins University School of Medicine and will not be deposited here. RNA-seq and downstream analysis data is owned by the Federal Aviation Administration.

List any copyrights to the data. If so, indicate who owns them.

Unless otherwise noted, there is no shared copyrights on the data described in this DMP.

Cognitive task data is owned by the Johns Hopkins University School of Medicine will not be deposited here. The JHUSOM retains the right to publish this data and any independent analyses performed on it.

Discuss any rights that are transferred to a data archive.

There are no rights transferred to the permanent archive or repository to accompany this dataset described in this DMP.

Describe how your data will be licensed for reuse, redistribution, and derivative products.

Unless otherwise noted, there is not a need for the data in this DMP to be licensed for reuse, redistribution, and/or its derivative products.

5. Archiving and Preservation Plans

Discuss how you intend to archive your data and where (include URL).

Unless otherwise noted, the data described in this DMP will be uploaded to the FAA's Enterprise Information Management (EIM) through the FAA Data Governance Center. This is the internal FAA landing page and access point to EIM uploaded datasets and processes. Here the metadata is curated and validated for quality and accuracy. The FAA Data Steward enters metadata and verifies quality and

accuracy before publishing to data.faa.gov, which is the FAA's clearinghouse site for publicly available FAA data and managed and hosted by the FAA's, IT Shared Services organization - Chief Data Office, see https://catalog.data.faa.gov/about for more information.

Per standard journal requirements and potentially public access requirements, it is expected that this will include archival of some or all of the data and genetic information in online repositories, e.g., deposition of sequences in dbGaP (https://www.ncbi.nlm.nih.gov/gap/).

Indicate the approximate time period between data collection and submission to the archive.

Data and all research products (e.g., reports) are expected to be submitted within the period-of-performance of the research, which is planned to conclude 05/2026.

Identify where data will be stored prior to being sent to an archive.

Unless otherwise noted, the permanent archive of the data described in this DMP shall be uploaded, stored, and managed permanently by the FAA's Enterprise Information Management (EIM) platform. However, until the upload upon completion of the project or at a convenient time before, the data will reside locally by the researcher. Refer to "Section 0: Dataset and Contact Information", the FAA line-of-business (LOB) is identified, which is responsible for generating the data, and is also responsible for managing the data initially.

Describe how back-up, disaster recovery, off-site data storage, and other redundant storage strategies will be used to ensure the data's security and integrity, initially and for the long-term.

Unless otherwise noted, the data described in this DMP shall be uploaded, stored, and managed permanently by the FAA's Enterprise Information Management (EIM) platform. This platform is managed and hosted by the FAA's, IT Shared Services organization - Chief Data Office and all back-up, disaster recovery, off-site data storage, and other redundant storage strategies are managed internally by this office and adhering to all FAA mission support policies. For more information and details on these processes, see FAA EIM Platform or contact the FAA line-of-business (LOB) that is identified in "Section 0: Dataset and Contact Information," which is responsible for generating the data.

Describe how data will be protected from accidental or malicious modification or deletion prior to receipt by the archive.

Unless otherwise noted, the data described in this DMP will initially (prior to receipt into the FAA's Enterprise Information Management (EIM) platform) be generated and managed by the FAA line-of-business (LOB), identified in "Section 0: Dataset and Contact Information." The FAA LOB will maintain (3) copies of the data within protected and monitored FAA government servers, facilities, and cloud platforms.

Indicate how long the chosen archive will retain the data.

Unless otherwise noted, the long term storage of the data described in this DMP will persist indefinitely in the FAA's Enterprise Information Management (EIM) platform following standard government policies and best practices.

Indicate if the chosen archive employs, or allows for the recording of, persistent identifiers linked to the data.

Unless otherwise noted for the FAA researchers in this DMP, the persistent identifiers can only be linked to the Catalog.Data.faa.gov, which provides access to metadata. Access to the research data itself currently requires secure access, including a secure government credentialed sign-on, referred to as MyAccess. This is a role based security profile and intrusion detection monitoring policy to maintain a secure boundary for the EIM Platform that hosts the data.

Discuss how your chosen data repository meets the criteria outlined on the Guidelines for Evaluating Repositories for Conformance with the DOT Public Access Plan page.

Unless otherwise noted, the data described in this DMP shall be uploaded, stored, and managed permanently by the FAA's Enterprise Information Management (EIM) platform. The EIM Platform is an FAA-developed, cloud-based, big data platform that consists of two key items: (1) “Data Mall” – this is a large repository for FAA data. It is organized and catalogued for easy access, but safeguarded to preserve its integrity and protect data from unauthorized access. And (2) an “App Mall” – this is a collection of curated technologies and tools to enable FAA personnel to transform data into information. For more information, see FAA EIM Platform. The platform's DATA.FAA.GOV is the FAA's clearinghouse site for publicly available FAA data and managed and hosted by the FAA’s, IT Shared Services organization - Chief Data Office. It is public gateway to the Enterprise Information Management (EIM) platform that is dedicated to managing data and information to improve efficiency, reduce costs, promote transparency, and enable business insight across the FAA. Thus, this FAA repository meets all the criteria outlined in the DOT Public Access Plan above.

6. Policies Affecting this Data Management Plan

Include policies that the data management plan was created to meet, such as the DOT public access 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 Month December 06, 2022.
