Main Doc

Einstein Aging Study

Data Access, Publication, and Data Sharing Guidelines

---

1. Publication, Data Access, and Data Sharing Guidelines

1.1. Introduction

Effective data sharing is essential to advancing the Einstein Aging Study's (EAS) mission.

This document outlines the policies and procedures governing data access, usage, sharing, and publication policies across all affiliated investigators and collaborators. Any usage of data is governed by this document.

It ensures adherence to NIH Data Management and Sharing (DMS) policies, promotes transparency, and upholds scientific integrity in all research outputs derived from EAS data.

By using Einstein Aging Study data, you are acknowledging receipt and acceptance of these policies, over and above existing Reliance Agreements and Data Use Agreements.

All investigators working on or with the Einstein Aging Study are required to fill out the short 4 question investigator survey: https://airtable.com/appypbLAeYU3hfUKB/paghGvLNtEFTgT9c2/form (no password)

2. Internal Workflow: From Proposal to Data Access

2.1. Overview of Workflow

To support transparency, a step-by-step flowchart will be provided on the EAS website articulating this process. This section outlines the sequential process:

1. **Submission of Concept Proposal:**
    - **All data requests and proposed presentations/manuscripts/theses/etc based on EAS data and grant proposals must submit a concept proposal for approval.**
    - **https://www.einsteinagingstudy.com/**
        - i. Submit a Concept Proposal
        - ii. **https://airtable.com/appypbLAeYU3hfUKB/pagMD2epOlRJBuPy0/form**
2. **Assignment of a unique concept ID**
    - Sequentially from last concept ID (aka Writing Group #).
3. **Passes Pre-Review for Completeness**
    - The pre-review process ensures that all required fields are appropriately completed and that the variables selected align with the stated research questions.
    - Proposals that include variables extending beyond the scope of the research questions will be returned for revision.
    - Please note that if a proposal does not pass pre-review, it must be fully resubmitted beginning with Step 1.
    - This pre-review will be conducted by Niliette Bravo (neb5486@psu.edu) in collaboration with Dr. Roque at Penn State.
4. **Assignment to a reviewer (Based on quarterly roster)**
    - Each assigned reviewer will evaluate the assigned concept proposal by completing the designated electronic review form.
        - i. Link: https://airtable.com/appypbLAeYU3hfUKB/pag9sEvgKA7g37aau/form
        - ii. Password: eas2025
    - The review will be conducted according to the criteria outlined below and must result in a final recommendation.
    - The reviewer will evaluate the following elements of the concept proposal:
        - i. Project Summary: Provide a brief summary of the proposed project in the "Short Summary" field. This should succinctly describe the research objectives and scope.
        - ii. Data Source Verification: Identify the types of data requested by the proposal (e.g., EMA: Cognition, Survey, Blood Analytes, Glucose Monitor, Air Pollution, etc.).
            1. Identify if variables exist in codebooks (eventually will be blocked at submission step if mismatch).
        - iii. Ensure that selected data types are appropriate for the stated research aims.
        - iv. Data Vintage
            1. Confirm the time periods of data requested (Pre-2017, 2017–2023, 2023+).
            2. Verify that data vintages align with study design requirements.
        - v. Overlap Issues
            1. Assess whether the proposed project overlaps with any previously approved or ongoing projects.
            2. Flag potential issues to avoid duplication or data misuse.
        - vi. Scientific and Methodological Review
            1. The reviewer will respond to several quality checks via the Airtable form.
        - vii. Statistical Plan Adequacy
            1. Evaluate whether the proposed statistical analysis plan is appropriate for the research question and data type.

viii. Need for Statistical Consultation
    1. Indicate whether the Statistical Core should be consulted for additional review or support.
ix. Variable Clarity
    1. Assess whether the independent and dependent variables are clearly defined and aligned with the hypothesis.
x. Clarity of the Study Question
    1. Confirm that the research question and hypotheses are clearly stated and answerable based on the proposal.
xi. Definition of Study Sample
    1. Determine whether the inclusion and exclusion criteria for participants are adequately specified.

5. **Iterative feedback and revision (as needed)**
    - Reviewer, Executive committee and investigator submitting proposal will go back and forth until concerns are resolved.
    - *Logging current status of concept proposal approval and feedback provided into Airtable.*
6. **Approval of concept proposal**
7. **Logging of concept proposal approval and feedback provided into Airtable**
8. **Manuscript/abstract/poster submission accompanied by:**
    - Concept ID
    - Versioned dataset filename
    - Software/code used (e.g., R, SAS, SPSS, Mplus)
    - Manuscript checklist (via Airtable)
9. **Review of Manuscript/abstract/poster by designated reviewer**
10. **Final approval and archiving of all materials and metadata by the TDM Core**

2.2 Data Availability Language and Definitions

1. **STAGE 1: Submitted:** deposited into the central data deposit location for relevant Core/Project on Dropbox.
    a. **This data stage is not available for writing papers.**
2. **STAGE 2: Processing:** adjudication of various column checks, range checks, etc. as applicable for the data stream. A Dataset Review is completed and sent to data generating entity.
    a. This data stage is not available for writing papers.
3. **STAGE 3: Frozen:** snapshot of processing step to test data integration and check rules for merging, data quality.
    a. **This data stage is not available for writing papers.**
4. **STAGE 4: Internal release only for the investigative team:** available to internal investigators only for project aims.
5. **STAGE 5: Dissemination / Broader release:** available for the public once publications available as per NIH guidelines.

2.3 Final Documentation Requirements

All materials—manuscripts, posters, abstracts—must be submitted to the TDM Core delegate for final approval and archiving.

https://airtable.com/appypbLAeYU3hfUKB/pagiAaIRBlLc6FMqa/form (password: eas2025)

Review outcomes are logged, and the tracking database is updated accordingly.

3. Concept Proposals

3.1 Purpose and Requirements

An approved concept proposal is **required for all analyses involving EAS data**. No datasets will be released without a proposal that clearly defines the research question, specifies required data, and outlines the analysis plan. **No concept proposals may be approved which involve data which have not been released/frozen, with the exception of those pertaining to grant submissions that will collect new data.**

This applies to:

- Principal Investigators
- Secondary Data Users
- Individuals submitting a grant proposal that relies on the EAS data - must be submitted and approved PRIOR to the grant submission
- Students and Trainees of EAS Investigators
- Users of Highly Identified Data

To proceed,

- Submit the completed form via our Airtable
  - **https://www.einsteinagingstudy.com/**
    - Submit a Concept Proposal
    - **https://airtable.com/appypbLAeYU3hfUKB/pagMD2epOlRJBuPy0/form**
- Proposals will be assigned a tracking ID upon receipt and reviewed within one week.
- All sections of the form must be completed. Incomplete forms will be returned without review.

3.2 Overlap and Transparency

Investigators and also TDM members must conduct a search for overlapping projects and report their findings in the designated section of the proposal form. Search by investigators is expected amongst published literature. Search by TDM members will be of EAS Publications and submitted concept proposals.

If overlap is found, the proposal should describe how it has been addressed or resolved. If the submitter omits this step, the proposal will be returned.

The mPIs and Executive committee will adjudicate unresolved issues.

If unclear how to search for overlap, submitters may contact: Dr. Nelson Roque (nur375@psu.edu).

3.3 Amending Approved Proposals

If during the course of research:

- New variables are proposed
- The analysis plan changes
- The study is split into multiple papers

...an amended proposal is required to be submitted via the website. Changes are to be submitted as a new concept proposal submission, and should be highlighted in **UPPER CASE** and accompanied by a rationale letter. This helps maintain scope consistency with the original approved work.

4. Publications and Grant Submissions

This section covers all academic works, including: Manuscripts, Grant Proposals, Theses, and Conference Submissions (posters, talks, symposia).

4.1 Pre-Submission Requirements for Manuscripts/Conferences

Presentations (posters, talks, symposium) should be based on **already approved concept proposals.**

Scope, Requirement, & Timeline: All manuscripts, and long-form derived works stemming from an approved concept proposal must be reviewed **at least one month prior** to external submission. Material for abstracts, posters, talks, stemming from an approved concept proposal must be reviewed **at least two weeks prior** to submission.

To submit a manuscript or conference material for review or archiving, please visit: https://airtable.com/appypbLAeYU3hfUKB/pagiAaIRBILc6FMqa/form (password: eas2025)

4.2 Pre-Submission Requirements for Grants

All investigators intending to submit a grant proposal involving EAS data (already collected, or to-be-collected) must first obtain concept proposal approval.

Proposals for grants that require biospecimens must indicate specifically what samples are required (specimen type, participant characteristics and dates/visits, volume needed). Approval will depend on sample availability and other leadership considerations.

Scope: Applies to all grant proposals that involve EAS data (whether already collected or to be collected).

Requirement: Investigators must obtain concept proposal approval before beginning any internal or institutional steps toward grant submission.

Timeline: Approval should be secured at least three months prior to the intended grant submission date.

Exceptions: Deviations from this timeline may be permitted only under extraordinary circumstances, subject to review and approval by EAS leadership.

4.3 Finalization and Archiving

Authors are responsible for submitting their manuscript for review, and keeping the TDM Core informed of submission status and final outcomes. Failure to comply with the review timeline may result in the withdrawal of the submission.

Required Submission Materials:

- Final draft approved by all authors (paper, poster, talk, symposium)
- Concept proposal ID
- Versioned dataset name(s)
- Event name, date, and location
- Submission deadline
- (If requested) Code used for analysis

Final manuscripts, along with full citations, must be archived with the TDM Core. The TDM Core is responsible for providing a list of publications and professional presentations to the Administrative Core each year for progress reporting to NIH.

To submit a conference material (poster, talk, symposium), or manuscript for review or archiving, please visit:

https://airtable.com/appypbLAeYU3hfUKB/pagiAaIRBILc6FMqa/form (password: eas2025)

4.4 What If X Happens?

If a usage of data is not approved, the Einstein Aging Study can request withdrawal of conference materials or published works.

In circumstances where an abstract is submitted simultaneously with a concept proposal the abstract must be pulled from submission if the proposal is not approved.

---

5. Guidelines for Oversight and Administrative Structure

To ensure the process operates efficiently and maintains the highest standards of scientific integrity, an oversight model is essential. This model provides clear structure, accountability, and transparency throughout all stages of proposal development and data use.

The oversight model consists of several key components, including:

- an Executive Committee, which offers strategic direction and final approval authority;
- a quarterly, rotating, Scientific Review Panel, responsible for evaluating the scientific merit and feasibility of proposed projects; and
- The Technology and Data Management Core, which ensures that data use aligns with ethical guidelines and established priorities.

Together, these components work in concert to support responsible stewardship of EAS data and facilitate high-quality, impactful research.

5.1 Executive Committee

The Executive Committee is responsible for high-level oversight of all data access and sharing activities. This includes approving concept proposals, resolving conflicts, and ensuring alignment with the study's aims and existing grants. Some responsibilities are formally defined in EAS grant documents and implemented by the TDM Core (e.g., creation and sharing of files).

5.2 TDM Core Delegate

The day-to-day administration of the data sharing process is overseen by a designated member of the Technology and Data Management (TDM) Core.

Currently, this role is held by **Niliette Bravo (neb5486@psu.edu**) at Penn State, who coordinates communication, manages tracking via Airtable, and ensures documentation is maintained and archived for all proposals and reviews.

Please always CC in emails: einsteinagingstudy@psu.edu for broader communication with the full set of Technology and Data Management core members.

5.3 Proposals for presentations/manuscripts/theses/ grant proposals: Rotating Reviewer Model-

The proposal review process is described below. The review process is distributed across core and project investigators on a rotating quarterly basis.

Each investigator contributes to the review workload to promote equitable participation. Long-term, a data-driven report and visual dashboard of reviewer participation may be developed to monitor balance and transparency.

The present list of reviewers for 2025 is available here:

Available at: https://www.einsteinagingstudy.com/docs/investigators/policies
https://docs.google.com/document/d/1LxLQE7wyF0UnT6iTwd6kvMK0_dgscv7tsgQD68HwqbA/edit?tab=t.0

6. Reviewer Guidelines

Reviews should be turned around within 2 weeks.

If you foresee an issue with this, we ask that you reach out to Niliette Bravo (neb5486@psu.edu) for reassignment of the proposal.

6.1 Concept Proposal Reviews

Reviewers should ensure that:

- The research question and hypotheses are clear.
- Rationale for multiple papers (if applicable) is provided (and why not separate proposals).
- Variables, data versions, and calculated fields are described.
- Clear inclusion/exclusion criteria are defined.
- The analysis plan is methodologically sound.
- The person submitting has verified that no duplication exists with other ongoing projects, and the reviewer is not aware of overlap.
- Application denotes compliance with all policies of the EAS.

6.2 Manuscript, Abstract, and Poster Reviews

Key review criteria include:

- Consistency with the approved concept proposal.
- Use of correct data.
- Acknowledgements are included appropriately.
- Overall clarity, writing quality, and data interpretation.
- No overlap with other approved or ongoing work.

7. Data Usage, Preservation, and Attribution

7.1. General Data Guidelines

- All EAS data are stored on secure institutional servers.
- Closed datasets will be shared via Dropbox hosted at Albert Einstein College of Medicine.
    - Box was the previously approved storage warehouse for AECOM, but decommissioned in April/May 2025.
- Emailing of datasets is strongly discouraged and in some instances prohibited.
    - Please contact Dr. Nelson Roque and Niliette Bravo for consultation on appropriate sharing if any questions.
- Only **.edu** addresses are eligible to receive data, unless otherwise stated in a formal DUA/MTA/Reliance Agreement.

7.2. Usage Expectations

- Use data only for approved concept proposal purposes.
- Do not redistribute data at all without authorization.
- Maintain compliance with ethical and institutional guidelines.
- All data to be used for any analytic purpose, are only to be provided by the EAS TDM Core. If you received a dataset otherwise, you will need to repeat your work on a final dataset.

7.3. Metadata and Documentation

All data shared to the central database maintained by the EAS TDM Core must be accompanied by:

- Appropriate documentation.
- Data dictionary, Codebooks or variable explanations.
- Version information.

7.4. Citation and Acknowledgement

Researchers must acknowledge EAS using the following language:

> The Einstein Aging Study (EAS) has grant support from the National Institutes of Health National Institute on Aging Grant AG003949 {and if sleep data collected prior to 2023 are used - R01AG062622}.
>
> The content of this (article, paper, abstract, etc) is solely the responsibility of the authors and does not necessarily represent the official views of the NIA or the NIH.
>
> We thank the study staff and all of the participants who have enrolled in the EAS.
>
> Data were from the Einstein Aging Study (EAS): Study information, codebooks, and a form to request data access are available through the Einstein Aging Study website, https://einsteinagingstudy.com

7.5. Roles and Responsibilities by User Group

7.5.1. Principal Investigators (PIs)

PIs are responsible for:

- Managing lab member access to data and removal on exit of lab.
- Coordinating IRBs/DUAs/MTAs for staff transitions.
- Ensuring continual compliance with proposal approvals.
- Communicating about staff departures within 7 days to ensure data access is cutoff to remain compliant with university standards.

7.5.2. Secondary Data Users

These users must:

- Submit a concept proposal.
- Abide by all institutional and study-specific requirements.

7.5.3. Ancillary Study Data

Ancillary study data has two meanings: (1) computing new metrics from existing data; (2) collecting or assaying a new data stream.

Ancillary study investigators are encouraged to connect with the original PI that collected the data stream or blood samples they are interested in to ensure awareness of any overlap or pending work. The original PI, to the extent appropriate, should be at least invited to be a part of writing groups.

Ancillary study investigators should coordinate access via their PI and may require Executive Committee approval for overlap or special cases. Ancillary studies generating new data metrics or assay results are required to deposit finalized data into the Albert Einstein College of Medicine central database within 3 months of data processing completion.

Failure to deposit prior to publication may result in bypassing centralized data quality and standardization checks, increasing the risk of undetected errors in the published work.

7.5.4. Users of Highly Identified Data

- Require a formal reliance agreement.
- Must follow data protection and de-identification protocols.
- May need to conduct analysis in a secure enclave. This is to be determined by Albert Einstein College of Medicine and the respective institution at the time of signing contractual agreements.

---

8. Data Compliance and Regulations

8.1 Data Use Agreements (DUAs)

8.1.1. Who Needs a DUA?

- A DUA is required for all users and consortia outside of Albert Einstein College of Medicine. Please allow **a minimum of 12 weeks** for processing.

8.1.2. How to Initiate DUAs?

- **The only person who may initiate DUAs is Mindy Katz at Albert Einstein College of Medicine. Please include all parties listed below in your DUA request to Mindy Katz.**
  - **Mindy Katz (mindy.katz@einsteinmed.edu);**
  - **and CC:**
    - Dr. Nelson Roque (nur375@psu.edu)
    - Niliette Bravo (neb5486@psu.edu)

8.2. Alignment with NIH Data Sharing Policy

Data will be shared with investigators receiving approval of their concept proposal and DUA as appropriate/necessary. Data is not to be posted to public-facing websites without Executive committee and TDM Core approvals.

Follow repository, funder, and journal guidelines for how long data should be preserved. Extensions are allowed if the award receives a no-cost extension.

8.3. Alignment with Consortia Goals

Data will be shared with relevant and approved consortia based on existing compliance requirements. Consortia have their own processes and goals towards harmonization.

---

9. Additional Notes and Next Steps

- The document will be revised based on continued input from EAS mPIs and NIH policy updates.
- A section on **data not yet collected**, including **MRI and genetics data**, will be added in future updates.
    - We anticipate updating this policy document within 1 month of each data stream released.

Addendum 1 (09/11/2025)

SOP: Secure Dataset Sharing & Access Guideline

Purpose

This SOP outlines the process for securely sharing datasets with approved researchers and ensuring compliance with project-specific data access policies.

This SOP applies to both: (1) external investigators that have an already approved concept proposal; (2) internal investigators that are formally part of the P01.

Scope

Applies to all dataset transfers conducted through Einstein Aging Study using secure Dropbox links. This policy covers:

- Data sharing procedures
- Access restrictions, Tracking and auditing

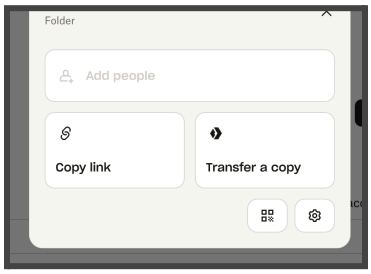
Procedure

1. Approval

- Data access is granted **only** to individuals with an **approved concept proposal**.
- The Project Manager (PM) must verify approval before initiating dataset sharing.
- If you have any concerns about whether you should or should not share data, or where to place it, please reach out to Dr. Nelson Roque and CC Niliette Bravo.

2. Data Transfer Process

1. Nelson generates a **Dropbox link** for the dataset via the 'Transfer a Copy' button.



   - **Password** = the recipient's **Proposal ID**.
   - **Expiration date** = 14 days from the date of sharing.
   - **Files only** are recorded in Airtable. **Passwords are NEVER stored.**

2. Nelson sends the following standardized email to the recipient:

Subject: [EAS] Secure Access to Requested Files for Concept Proposal [Add proposal ID]

Body:

Dear [Recipient Name],

You have been granted access to the requested data files via a secure Dropbox link. Please ensure you download the files before the expiration date.

For security purposes, **do not share this link or password with anyone.**

Access Instructions

- Files are available at: [Insert Dropbox Link]
- Password: [Insert Password]
- Link Expiration: [Insert Expiration Date]
  Please ensure you download the files before the expiration date.

Support & Issues

If you encounter any difficulties accessing the files, please contact: Dr. Nelson Roque – nur375@psu.edu and kindly copy: Mindy Katz (mindy.katz@einsteinmed.edu) and our Project Manager, Niliette Bravo (neb5486@psu.edu)

Policies & Guidelines: Please review and adhere to our data access and handling policies before working with these files:

https://docs.google.com/document/d/1tDgyRSRedqn4jLrwPerVJyWuuiCzxQ0k5ERoF85bTvE/edit?usp=sharing

On behalf of the EAS Tech and Data Management Core, we are excited to hear what you learn!

Available at: https://www.einsteinagingstudy.com/docs/investigators/policies

All the best,

Nelson & Mindy.

---

3. Airtable Tracking

- The Project Manager records each dataset transfer in the **Concept Proposal Table** in Airtable.
    - Fields logged:
        - Title
        - Submitter Name
        - Reviewers Recommendation
        - Resubmission
        - Affiliation
        - Email
        - Dropbox Link (files only, no password)
        - Expiration Date (default = 2 weeks)

Compliance & Enforcement

- Recipients must confirm acknowledgment of the restrictions upon receipt.
- Any violation of the sharing policy may result in:
    - Immediate revocation of access
    - Reporting to the PI
    - Potential suspension of future data access privileges