V2.0

Protocol for Research Projects Using Existing ERGO Study Data

This document outlines the necessary steps to follow when conducting a research project using existing ERGO Study data. For proposals involving the use of stored biospecimens or new data generation, please contact Dr. Tamarra James-Todd (tjtodd@hsph.harvard.edu) and Marlee Quinn (mquinn@hsph.harvard.edu).

Step 1: Project Proposal & Approval

1. Fill out and submit "ERGO Study Data Interest" form found on the ERGO Study website.
    a. If you have questions about the ERGO Study or data availability, please email ergo@hsph.harvard.edu. Otherwise, a study team member will contact you within one month of submitting your request.
2. Download the "ERGO Study Analysis Plan_Template.ppt" and prepare an analysis plan for your proposed project.
    a. Include a drafted list of invited coauthors in your analysis plan for discussion to ensure all necessary co-investigators are included. Please ask Dr. James-Todd and/or Marlee Quinn for a list of possible co-investigators.
3. Present/share your analysis plan with the ERGO Study team for their feedback.
    a. **Preferred option:** Present analysis plan at an upcoming Study Team meeting.
        i. Presenting at a team meeting facilitates more rapid feedback.
        ii. Contact ergo@hsph.harvard.edu for upcoming meeting dates/to be added to the agenda.
    b. **Alternative option:** Circulate your analysis plan for review via email.
        i. Send your analysis plan via email to ergo@hsph.harvard.edu. We will then circulate your proposal to a subgroup of relevant ERGO Study team members for review.
    c. You will receive written feedback and any necessary revisions within 2-4 weeks, depending on reviewer availability.
4. If requested, revise and (re)circulate your analysis plan via email for additional review.
5. Once approved, please contact ergo@hsph.harvard.edu to determine any necessary administrative steps which can include but are not limited to:
    a. Being added to the IRB protocol
    b. Shared network drive access
    c. Harvard Sponsored Role (HSR) credentialing (e.g., added to IRB protocol, shared drive, etc.)
6. Please send necessary documents, such as a copy of the IRB Approval for your analysis. Additional documentation may be requested based on the nature of your proposal.
7. **Progress updates –** Please keep ERGO staff informed of project progress by providing status updates to the list of active ERGO projects, circulated via email every 2-3 months.

Step 2: Authorship

1. Identified co-authors should be invited to participate and author order should be determined/reviewed and be included in your analysis plan and presentation.
2. The order of authors on scientific products, beyond first and last authorship, should be determined based on the order of contribution (highest to lowest). First or senior authors who have provided equal contributions to the project are encouraged to share first/last authorship.
3. All projects should include **"The ERGO Study Team"** at the end of the author list.

Step 3: Data Access & Analysis

1. Download and complete the "ERGO data request template.xlsx" and email your request to ergo@hsph.harvard.edu. The ERGO data manager will reach out to you with any questions and will compile your resulting dataset and data dictionary.
2. **Data access for INTERNAL/HARVARD COLLABORATORS**
    a. Coordinate with Marlee Quinn to gain Harvard network/Shared drive (S:) access and to create a project folder. Once you have access, Marlee will send you the path to your drive folder.
    b. The ERGO data manager will save your dataset(s) and accompanying files (e.g., data dictionary, blank data collection forms, etc.) to your project folder.
    c. **IMPORTANT**: Your ERGO dataset **MUST remain in the S: drive**. You **CANNOT** save ERGO data to your computer or other storage devices/network folders.
    d. To analyze the data, you will need to call to the dataset from its location in the S: drive, making sure that you save any additional analytic datasets you create in the same folder.
3. **Data access for EXTERNAL/NON-HARVARD COLLABORATORS**
    a. External collaborators will need to work with Marlee Quinn to determine if a data use agreement with the investigator and their institution is needed and if their institutional IRB has reviewed and approved the project prior to gaining access to ERGO data.
    b. Once all approvals are in place, the ERGO data manager will send the corresponding dataset(s) and files via secure email and file sharing (Kiteworks)
    c. Data must be stored in a secure location and never stored on portable USB drives or similar devices.
4. **Data Analysis**
    a. **Causal diagrams & confounders** – We strongly recommend constructing a causal diagram/framework (e.g., Directed Acyclic Graph, DAG) based on your research question in order to select potential confounding factors based on a priori assumptions and knowledge about underlying relationships between measured and unmeasured

factors. Variable selection processes and justifications should be clearly stated in your methods section.

b. **Use of race/ethnicity in analyses** – Race is a social construct, and while many exposures and outcomes vary by race/ethnicity, the observed differences are results of current and historic sociopolitical factors and structural racism rather than fixed or biological differences between groups. As such, investigators should think critically about how they incorporate race/ethnicity data in their analyses and provide corresponding justifications for their use.

Step 4: Manuscript Preparation

1. **Non-gendered language –** ERGO includes trans and/or gender non-conforming individuals so use of non-gendered language is required. For example, instead of "pregnant women" please use "pregnant participants/individuals/people/etc." and instead of "mom" or "maternal" use "parent" or "parental" or "previously pregnant individual", when possible.
2. **Reporting & interpreting results**
    a. **Emphasize strength, direction, and patterns of associations not statistical significance.**
        i. Analyses should examine the extent to which the exposure/predictor variable is associated with the outcome not a binary whether or not the exposure/predictor is associated with the outcome.
        ii. When reporting results, avoid excessive focus on p-values and statistical significance. Instead, we prefer to focus on the effect estimates and corresponding 95% confidence intervals (CI) to interpret study findings, focusing on the magnitude and precision of potential effects within the CI and not just whether it includes the null.
3. **Acknowledgments & Funding Support**

    a. The acknowledgements section should include a statement thanking ERGO study participants and well as Marissa Grenon, Francesca Yi, Autumn Hoyt, and the ERGO co-op students.
    b. **REMINDER:** The manuscript must acknowledge the original NIH grant funding ERGO (R01ES026166), as well as other possible grants that are needed. Please contact the ERGO study team (ergo@hsph.harvard.edu) to determine relevant grant numbers for inclusion in the Acknowledgement section.
4. **Co-author review**
    a. Prior to submission, manuscripts must be circulated among coauthors for review, revised, and approved by all coauthors. This process may include several rounds of revision.
    b. If not required by the journal as part of the manuscript, an author contribution document should be sent to ERGO staff to include with project files.
5. **CDC Clearance**
    a. Projects using biomarker data from analysis at the Centers for Disease Control and Prevention must obtain CDC clearance prior to journal submission. To submit your manuscript for CDC review and clearance you must have a near final manuscript draft

that has been reviewed by all co-authors and revised based on co-author feedback. Once ready, CDC review should be coordinated directly with Dr. Antonia Calafat at the CDC.

Step 5: Analytic Code Review

1. Before submitting your manuscript to a journal, you must complete the "ERGO Study Code Review Form" and submit it to the ERGO Study Data Manager for review (ergo@hsph.harvard.edu) along with the 1) manuscript and associated materials (figures, tables, supplemental) and 2) the code file (R, SAS, STAT, etc). The reviewer will either request revisions to your code as detailed in their response or approve it for journal submission.

2. During peer review, if changes are made to your results in response to reviewer/editor comments, an amended code review form must be submitted for an updated review prior to resubmission.

Step 6: Manuscript Submission

1. Unless otherwise arranged, investigators using ERGO study data are responsible for paying any associated manuscript publication fees or conference fees for submitted abstracts.

Step 7: Final Project Materials

1. **Lay summary/abstract** – Investigators must submit a brief summary (< 1 page) of their manuscript/project, especially highlighting study objectives, findings, and their implications written for a lay audience at or below an 8th grade reading level. Lay summaries are used to communicate study findings with ERGO participants and the general public.
2. **Final project files** – All final manuscript/project materials must be either saved in your project's S:\ drive folder or sent to the ERGO Study Data Manager in a zip folder (ergo@hsph.harvard.edu), in order to be archived in case they need to be referenced/reviewed in the future.

   Final Documents:
   - ☐ Analysis plan
   - ☐ Manuscript file(s)
   - ☐ Supplemental materials
   - ☐ Tables & Figures
   - ☐ Annotated code files
   - ☐ Code review form(s)
   - ☐ Lay summary
   - ☐ Reviewer comments & responses (If applicable)
   - ☐ Conference abstract(s) & details (*if applicable)* (e.g., Organization, date/location, etc.)
   - ☐ Other relevant documents (e.g., authorship contribution statement)
3. Researchers **MUST <u>destroy all ERGO datasets within 1 year after manuscript publication</u>** (or project completion).

Thank you for your interest in the ERGO study!

ERGO Co-Investigator Directory

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