

HANDLS Data Analysis and Manuscript Proposal Form

1. Submission Date:

2. Title Information

a. Proposal Title:

b. Abstract

(Summarize background information and literature, and state how they lead to the questions(s) of interest. Include a concise justification and explanation of the research question(s) to be addressed. End by stating the aim of the data analysis and summarizing the method(s) that will be used to address the questions.)

c. Suggested key words:

3. Lead Author Name & Title:

Institutional Affiliation:

Address:

Telephone:

Email:

4. Co-Authors Name & Title, Institutional Affiliation, Contact Information, and Responsibilities:

Examples of responsibilities include design and concept of study, statistical analysis, data acquisition, methodological expertise, funding acquisition, literature review, writing.

Also indicate who will have access to the individual level data (statistical analysis & preparation of tables and figures). Items not assigned to a co-author are assumed to be the responsibility of the lead author. Corresponding author should also be identified if it is not to be the lead author. NIA IRP Investigators Michele K. Evans, MD & Alan B. Zonderman, PhD should be listed as co-authors.

Name Contact Information Responsibilities

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Contact Information** | **Responsibilities** | **Access to individual level data (Y or N)** |
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| Alan B Zonderman | [zondermana@mail.nih.gov](mailto:zondermana@mail.nih.gov) | Principal investigator | Y |
| Michele K Evans | [evansm@grc.nia.nih.gov](mailto:evansm@grc.nia.nih.gov) | Principal investigator | Y |

Co-Authors outside of the lead author’s institution with access to individual level data will be required to sign the collaborative agreement and obtain institutional approval.

5. Background/Rationale: (Include the relevance of this proposal to African Americans and justify the need for the HANDLS cohort to answer the research question):

6. Research Hypotheses/Specific Aims:

7. Data: Variables required including waves needed, sample inclusions/exclusions. (See <https://handls.nih.gov/06Coll-w00dataDocR.cgi> for names) Please justify any need for personally identifying information (PII; e.g., date of birth, address). An example table is provided below. Please edit and only include variables necessary for the proposed study. Check the website to ensure that variables are available at the waves listed.

|  |  |  |
| --- | --- | --- |
| Variable | Wave | Description/Use |
| HNDid | 1,3,4 | Identification variable |
| Sex | 1 | Sex |
| Race | 1 | Race |
| Age | 1,3,4 | Age at time of visit |
| BMI | 1,3,4 | Body mass index |
| ACE03 | 4 | Before you were 18 years old was anyone in your household depressed or mentally ill? |
| Cope01:Cope23 | 1,4 | Brief-COPE |

8. Brief Statistical Analysis Plan and Methods: (Including power

calculations)

9. References: (Maximum 15)

10. Have all co-authors reviewed and approved this document? [ ] Yes [ ] No

(required)

11. Location of Statistical Analysis:

NIA IRP Staff:

Local (list site):

12. Conflict of Interest

a. Are these analyses to involve a for-profit corporation? [ ] Yes [ ] No

b. Do you or any member of your Writing Group intend to patent any process, or aspect of outcome from these analyses? [ ] Yes [ ] No

13. Collaborative Agreement for Research

Are the Lead Author and any co-authors who will have direct access to HANDLS data aware they will need to sign the HANDLS Collaborative Agreement before they will receive the data? [ ] Yes or [ ] No

14. HANDLS Manuscript Overlap

The Lead Author has reviewed all existing HANDLS manuscripts /manuscript proposals and found (Check one):

[ ] No similar manuscripts / proposals

[ ] The following manuscripts / proposals with similarities: (List MS # title and Lead Author below)

15. Timeline Note: Completion of manuscript preparation is expected in less than TWO years. The manuscript proposal will expire if no manuscript draft is submitted for HANDLS review at the end of the TWO years from date of approval. If additional time is needed after TWO years, please contact HANDLS for extension.

16. We encourage collaborators to adhere to the JAMA guidelines for reporting race and ethnicity in medical and science journals in their proposals and publications (Flanagin A, Frey T, Christiansen SL, AMA Manual of Style Committee. Updated Guidance on the Reporting of Race and Ethnicity in Medical and Science Journals. JAMA. 2021;326(7):621–627. doi:10.1001/jama.2021.13304).