

MANUSCRIPT ANALYSIS GUIDELINES

The Clinical Coordinating Center (CCC) provides information and resources to help the writing group develop an analysis plan.

Basic requirements to include:

- Designation of the WHI participant group to be used in the analyses: (OS,CT, HRT, DM or OS/CT)
- List of variables to include in the analysis.
- Dummy tables and templates for analysis.
- A list of analytic variables that need to be defined anew for use in your paper, as well as descriptions of how to create these variables.

Data Restrictions:

- The writing group may only carry out analyses that are directly related to and based on the main hypothesis of the approved paper proposal. If new hypotheses emerge or are of interest to the writing group, the P&P committee requires that a new or amended paper proposal be submitted.
- The Behavioral Committee recommends that validated behavioral construct summary variables be used for all analyses instead of the individual questions from the psychosocial forms (Form 36/37/38). Please see the "[Psychosocial/Behavioral Constructs](#)" document for a description of the behavioral construct variables.

Resources to help develop an analysis plan (many available in the "Publications" and "Data" sections of <http://www.whi.org/>):

- A list of published WHI papers categorized by broad topic area. You are encouraged to review the WHI literature in your area of interest to determine what has already been done. These papers also provide valuable examples of what variables are available, appropriate analytic techniques and sample layouts for tables and figures.
- A table showing baseline and follow-up forms and the frequency in which the data from these forms are collected. This table will help you determine the data that is available for your analyses.
- Tables and methods from the WHI Baseline Monograph papers (Ann Epidemiol 2003;13:S1- S86.) include a large amount of descriptive data that may help you decide on specific scientific approaches to use in the analysis. Also, the tables can help you determine which sample of participants to base your analysis on, because comparison of OS and CT women are provided for based on a large subset of variables collected at baseline.
- A document listing the physical activity summary variables. These summary variables are based on the physical activity data collected at baseline on Form 34 and Form 42. When possible, the same set of variables has been created for follow-up visits.
- A list of available FFQ nutrient summary variables. There are over 100 nutrient summary variables created from the Food Frequency questionnaire (FFQ) data. This final set of summary nutrient variables is available in the "Data" section of <http://www.whi.org/>.

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The CCC Statistician responsibilities:

- Perform statistical analyses with the guidance of the writing group.
- Provide statistical advice to the writing group.
- Distribute analysis summary tables to the Chair of the writing group.
- Provide the writing group with a time line to complete requested analyses.
- Participate on conference calls.
- Review final tables created for the manuscript.
- Write statistical methods for the manuscript, and assist with other sections as needed.
- Review the manuscript.

Time constraints of the CCC Statisticians:

- WHI CCC Statisticians have various projects ongoing at all times. When a proposal has been approved, it will be added to the queue. In most cases, proposals are done in the order they were approved.