Maximizing Your Time with a CBHDS Biostatistician

Overview

The CBHDS team is excited to contribute our expertise in biostatistics, data science, programming, and data management to your health- and medically-related research projects. With this expertise, we can facilitate your grant proposal submissions, peer-reviewed manuscript preparations, and presentations at professional conferences. Specifically, please look to us for support in study design, grant proposal development, data coordinating center needs, data analyses and programming, and dissemination of your research findings. This overview highlights information needed to move projects along more expeditiously. Please be sure to check out our more detailed guidance documents related to grant proposals, data organization, and manuscript preparation as you engage with our team. Finally, as you peruse our website, please check out our Frequently Asked Questions (FAQs), lead time policy, and authorship policy.

Are you looking for help with a grant proposal? If so, please see our detailed guidance for grant proposal preparation here. Broadly, please be prepared to answer the following questions:

- What are your study aims and hypotheses? What is your primary research question(s)?
- What outcome measures will you use to answer your research question(s)? How will they be measured?
- Describe your study design (randomized controlled trial, observational cross-sectional study, observational longitudinal study, etc).
- How are you collecting data to support your research question(s)?
- Are there particular subgroups you are interested in studying? Do we need to consider potential confounding variables in our analysis?
- For power and sample size estimates, what would a clinically meaningful finding look like? Do you have estimates to use as the basis of your power calculations from the literature or pilot work of your own?
- What is your deadline for submission? What should our timeline look like for completing this work?

Are you planning to submit a data file to CBHDS for data analysis support? If so, please follow the general guidelines below written for Excel files, noting that they are applicable to other formats as well. For more details, please refer to our Data Preparation guide.

If your data has been entered in Excel, please use the following guidelines:

- The first row of the data file should contain only the column/variable name.
- Keep column/variable names short (≤ 12 characters) and make sure that they are unique. All variable names should contain no spaces and should not start with a number or symbol.
- Do not indicate any distinguishing patient group or characteristic with colored font or highlighted cells as these will not be transferred when data is imported into our statistical software. Instead, please include a separate column/variable to indicate the patient meets specific criteria.
- Do not mix character/string (text) and numeric data types when entering data (e.g., when measuring blood pressure, the entry of 120/80 should be split into two variables (one for

systolic and another for diastolic) and missing values should be left blank instead of entered as "n/a".

Prior to sharing your data with us, please ensure that your dataset is free of all protected health information (PHI). PHI may include: patient name, date of birth, phone number, address, email address, medical record number, health plan number, social security number, or other unique identifying number, characteristic or code. For a full listing of PHI, please refer to What is Considered Protected Health Information Under HIPAA?

Please note that for human research studies, before allowing CBHDS biostatisticians access to your data, you will need to add them as 'key personnel' in the IRB study protocol.

Do you need helping writing a manuscript? If so, please review our Manuscript Preparation guide. Additionally, please be prepared to discuss co-authorship, as we follow the International Committee of Medical Journal Editors (ICMJE) Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals.

Authorship is generally expected whenever a person contributes substantive input on the design or analysis. The ICMJE has set the following standards:

1. Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;
2. Drafting the manuscript or revising it critically for important intellectual content; and
3. Final approval of the version to be published.

Authors should meet all conditions. Often a statistical collaborator will be involved in all three levels of manuscript preparation, and when this occurs, co-authorship is appropriate.

Finally, for grants, analyses, and papers/presentations that we support outside of direct grant funding or contractual agreements with CBHDS, please acknowledge that your work was supported by core grant funding through the iTHRIV CTSA using the following language:

"Research reported in this publication/presentation/work was supported in part by the National Center for Advancing Translational Sciences of the National Institutes of Health under Award Number UL1TR003015. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

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