Psychiatry Biostatistics and Methodology Core Procedures and Policies
Updated 1/8/2012

1. Scope of Services
   We are currently able to assist researchers with preparation of grants (including assistance with specific aims, sample size calculations, and data analysis plans), and analysis of data for papers and presentations. Other services that may be available in the future include database management and preparation of specialized tables and figures.

2. Timelines
   Please note that these guidelines exist so as to allow departmental researchers to take advantage of the limited biostatistical resources available in a manner which is as fair and efficient as possible.
   - New Grants: Researchers should make an initial appointment as soon as they begin to consider writing a grant, preferably 2-6 months before the Johns Hopkins internal deadline (ID). We won't be able to assist with grants first brought to us less than 30 calendar days before the ID. At the first meeting, we will talk about background and hypotheses, pilot data, possible statistical methods, sample size, and the timeline for completion of the work. Typically, we ask that you finalize hypotheses/specific aims, provide pilot data (if necessary), and .pdf files of relevant research papers 14 days before the ID. We will aim to finalize sample size calculations and data analysis sections 3 days before the ID. We can't guarantee on-time completion of work in situations where we don't receive the materials we need on-time. Grants submitted during peak periods or which involve specialized methods may require earlier deadlines; we will talk about this at the first meeting.

   - Resubmitted Grants: Please contact us as soon as your summary statements are available to schedule a meeting to discuss your resubmission. Typically we will require the same timeline as for a new grant, though this may be relaxed.
   - If at any point you decide to cancel or postpone a grant submission please let us know as soon as possible so that we can release the time we have budgeted for your submission to other faculty members.
   - Papers and Presentations: An initial meeting should be scheduled as soon as possible, at least 30 calendar days in advance of planned paper submission. Timelines will vary as a function of current workload and project requirements.

3. Grant and Manuscript Feedback
   We ask that you share with us summary statements from grants and reviewer feedback from manuscript submissions. This helps us look for trends that may be helpful for other investigators, and also helps us determine if we are using the kinds of methods that reviewers would like to see. If you choose to share these with us, they will be kept completely confidential.

4. Priorities
   When the workload of the core exceeds its capacity, certain projects will be given priority. Priority is decided by the core director in consultation with the department chair and departmental research director. Typically, projects already underway* will be given priority over new projects. Grants will often supersede

papers. Other factors will include need, merit, and ability of the researcher to assist in the funding of the core. We will try to make time for lower-priority projects during non-peak periods.

*Note: it is usually much easier when data analysis projects are begun and finished within a short period of time (e.g., within weeks). When projects are revisited after a long break, it becomes necessary to re-orient oneself to the data and the project aims, which results in duplicated effort, and also increases the likelihood that key facts are forgotten or misremembered. For this reason, we will typically not begin a project until all necessary data and information required to complete it is available. We also request that you work with us toward the goal of completing projects as quickly as possible. In cases where long breaks are unavoidable, your project may be given lower priority after it is revisited. In cases in which we have not received support (either through salary support or other payments), If more than 12 months pass between contacts regarding a given project, we reserve the right to rescind our agreement to perform the analyses.

3. Data Files and Documentation
   - Data Entry: While we cannot currently assist in database management, we do recommend the use of RedCap, a web-based database creation, management and entry tool. See http://project-redcap.org/ for more info, or contact Andre Hackman, the JHU RedCap contact: ahackman@jhsph.edu.
   - Format: Data (including pilot data) can be delivered in virtually any format, but data files must be cleaned and documented. A "Cleaned" data file is reasonably free of errors and ready to be analyzed. A "Documented" data file means that it is accompanied by a codebook or data dictionary, listing each variable name, description (e.g. the variable named v1mmseq1 refers to the first item of the MMSE administered at study visit 1), format (numeric vs. string/text), and coding (e.g. 0 = 'no', 1 = 'yes'). We can advise you on the preparation of your data and documentation files, but we don't currently have the resources to assist you in this. We recommend that you meet with us prior to data collection and entry to ensure that the necessary data will be available and in an appropriate format for each specific aim/hypothesis.
   - Security: Unless the nature of the project requires that we use personally identifying information, all such information (names, addresses, phone numbers, account numbers, JHH history numbers, etc) should be removed before the data core receives it. **Please note, DO NOT transmit datafiles via e-mail which contain personally identifiable information. If this occurs, it will constitute a HIPAA violation and we will be obligated to report it.** Investigators should retain their own files in which unique identifiers (e.g., patient ID numbers) with links to identifying information to be kept for purposes of quality control. Data files received by the data core will be stored on a shared University drive accessible by staff members of the core. It may also be stored on statisticians' laptops to facilitate offsite work. Unless otherwise agreed upon, data files will be stored indefinitely on the University server for documentation purposes and to facilitate future analyses.
   - Analysis Documentation: The core will document all analyses such that they could be replicated by an independent statistician. This documentation, along with any syntax, log files, or computing code will be provided to researchers. The core will retain ownership of any documentation, and researchers may not

distribute computing code or programs without express written permission (e-mail is sufficient). The reason for this policy is that we do not want to be held responsible if the code is misused. Occasionally the core faculty may want to use completed or ongoing projects for teaching purposes. In these cases, no data or analyses will be shared with a third party without express written permission from the investigator.

4. Ethics

   Faculty and staff of the data core will abide by the American Statistical Society's 'Ethical Guidelines for Statistical Practice'. http://www.amstat.org/committees/ethics/index.html (Accessed 11/15/09). To prevent breaches of ethics (or the appearance of breaches), data analysis plans specifying primary and secondary outcomes will be agreed upon prior to the start of analyses. In the case of strictly exploratory analyses, published reports must specify that analyses were conducted in an exploratory fashion, without an *a priori* plan.

   Any core staff who will be working on your project should be added to the IRB protocol. All staff have completed human subjects training.

5. Authorship/Acknowledgement

   Researchers will be expected to adhere to the authorship guidelines of the International Committee of Medical Journal Editors. A full discussion may be found here: http://www.icmje.org/ethical_1author.html . The key requirements are:

   "Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3."

   Collaboration with us will typically warrant authorship for one or two members of the core staff; any core staff who meet these authorship requirements should be included as authors. Order of authorship will be agreed upon early in the collaboration, but may be revised if both the researcher and core agree. The data and its staff reserve the right to decline authorship at any time.

   Acknowledgements (in papers or presentations) of the core and/or specific members are greatly appreciated. Because such acknowledgements imply endorsement, researchers should notify the core in advance of any acknowledgements, and provide a copy of the paper or presentation for review if requested.

6. Financial Support of the Data Core

   Our salaries and supplies are supported mostly through NIH grants. This makes it important that we are included appropriately on grant submissions for which we will be expected to provide statistical support. Our supply needs are relatively modest but we do request that you budget a certain dollar amount per % effort for each year. Typically we will agree on % effort at the first meeting, and we can provide you with information on how to include our salary support and supplies in your grant budget. Since we are not a cost center, we can't bill on an hourly basis for services.

8. Responsibilities of the Core and Researchers

The relationship between the core (methodological researchers and practitioners) and substantive (non-methodological) researchers is intended to be a collaborative one. In other words, you are the "what" and we are the "how" in our shared business of making scientific inferences. Some of these responsibilities have been described in previous sections, but they are summarized here again.

Responsibilities of the Core

- Frank discussions of capabilities and timelines
- Methodological teaching, substantive learning
- Clear explanations of all methods and results
- Sufficient documentation to allow replication by an independent statistician
- Accurate and ethical reporting of all results
- Meeting deadlines for grants and paper submissions

Responsibilities of the Researcher

- Frank discussions about expectations and timelines
- Substantive teaching, methodological learning
- Provision of accurate data and answers to all questions about study design and conduct
- Authorship or acknowledgement of the core staff as appropriate.
- Accurate and ethical reporting of all results
- Meeting deadlines for data delivery, specific aims, literature reviews, and drafts