

Bayview Psychiatry Data Core Procedures and Policies

1. Scope of Services

At this time, the data core is 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, data entry supervision, and preparation of specialized tables and figures.

2. Timelines

- **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 will not be able to assist with grants first brought to us less than 30 calendar days before the ID. At the initial meeting, we will discuss background and hypotheses, pilot data, possible statistical methods, sample size, and the timeline for completion of 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. Grants submitted during peak periods or which entail specialized methods may require earlier deadlines, negotiated at the initial meeting. We cannot guarantee on-time completion of work if we do not receive these materials by the agreed upon deadline.
- **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.
- **Papers and Presentations:** An initial consultation should be scheduled as soon as possible, at least 30 calendar days in advance of paper submission. Timelines will vary as a function of current workload and project requirements.

3. Priorities

In the event that the potential workload of the data core exceeds its capacity, certain projects will be given priority. Priority will be decided by the data 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 data core. We will try to make time for lower-priority projects during non-peak periods.

4. Data Files and Documentation

- **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, 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 do not currently have the resources to assist you in this. We advise 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 the use of personally identifying information, all such information (names, account numbers, JHH history numbers, etc) should be removed before the data core receives 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 data 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 data 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 data core will retain ownership of any documentation, and researchers may not distribute computing code or programs without express written permission (e-mail is sufficient). Occasionally the data core faculty may wish 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.

5. 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 such 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.

6. 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 data core staff; any data 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 data core agree. The data core and its staff reserve the right to decline authorship at any time.

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

7. Responsibilities of the Data Core and Researchers

The relationship between the data 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 Data 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 data core staff as appropriate.
- Accurate and ethical reporting of all results
- Meeting deadlines for data delivery, specific aims, literature reviews, and drafts