

**Guidelines for data analysis projects in
The Department of Epidemiology and Biostatistics (DEB)**

1. Initiating Collaborations

- a. DEB strives for a respectful, friendly, mutually educational, and productive collaboration.
- b. All requests should be managed through or stored within a request tracking system.
- c. DEB will professionally and promptly reply to requests.
- d. Requests for initial consultations should be made at least two weeks prior to any deadline. More time is required for proposal development.
- e. Analysis projects are typically expected to result in some type of publication or disseminated work, or grant proposal.
- f. Taking data currently under analysis with DEB to other analysts (i.e., “Analyst shopping”) without prior disclosure to DEB (or vice versa) will not be tolerated.
- g. All conditions and warranties, express or implied, by operation of law or otherwise regarding the DEB, accuracy of data, acceptable performance or fitness of analysis or data for any purpose, or any other use of the DEB analysis tools are hereby disclaimed and excluded. UT Health and the DEB do not warrant that the services or deliverables provided under collaboration agreements will meet requirements or will perform, or be performed, without error or interruption, and UT Health and DEB expressly disclaim any implied warranties of merchantability and fitness for a particular purpose.

2. Authorship

- a. Discussion of authorship are best had early in the collaborative process before the analysis begins.
- b. The DEB complies with the requirements for authorship of the International Committee of Medical Journal Editors (ICMJE) criteria (<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>).
- c. Authorship is based on ICMJE criteria and is unrelated to and is not in lieu of payment for analysis.
- d. Faculty statisticians are typically included as authors because developing a analysis plan, conducting an analysis, and reporting the analysis typically meets authorship requirements.

3. Communications with collaborators

- a. Written summaries should be shared for all meetings in an electronic format. Notes or data on paper are not accepted unless scanned, and the DEB will not archive unsigned paper documents.
- b. Any analyses included in a DEB involved manuscript not performed by DEB will be well-described and may be reproduced or tested for accuracy to ensure consistency within the project.
- c. The DEB may use project management systems in order to improve the efficiency of collaboration. Any communications outside of the project

management system of the will disrupt efficient collaboration and cause analysis costs to increase.

4. Grants and proposals

- a. DEB typically does not charge for preparation of collaborative proposals because the proposals should benefit all parties.
- b. Level of support in terms of Full Time Equivalents (FTE) should be discussed prior to starting on the proposal and will be proportionate to the work expected.
- c. Preliminary data analyses may require a funding source and are not typically included without charge in proposal development projects.
- d. For data analysis proposals, a 2:1 staff to faculty ratio is typical. Every % FTE of faculty matched with x2% for staff.
- e. Requests to participate in proposals should allow sufficient time prior to deadlines. Requests made less than two weeks prior to deadlines can be refused.
- f. Program project grants typically require 5% faculty FTE per project
- g. Clinical trials require a of $\geq 5\%$ faculty FTE during the full length of the study.
- h. Proposals involving less than a 5% FTE commitment are difficult to manage and execute.
- i. Large projects ($> \$250,000/\text{year}$), especially those requiring evaluation of interventions with human subjects or clinical trials, typically require at least 10% faculty FTE over the course of the project for consistent engagement, monitoring, quality assurance, reporting, and to achieve timely publication within the funding performance period.

5. Estimation of costs

- a. A funding source should be identified prior to initiation of a data analysis project.
- b. DEB will not bill or charge for services without a written approval by responsible party of estimated costs.
- c. For estimating collaborations hours, a project requiring substantial statistical expertise resulting in a peer-reviewed manuscript is typically at least 100 hours.
- d. The minimal amount of time on a peer-reviewed manuscript is about 20 hours.
- e. The cost of a data analysis for a manuscript typically exceeds the publication fees for most journals with such fees.

6. Data sharing

- a. Existence of all project data shall be disclosed within the applicable laws and regulations. Collaborators shall not withhold data without knowledge of DEB analysts. If data are withheld or modified from the original then then the withholding party shall provide a rationale for nondisclosure.
- b. Protected health information (PHI) is handled consistent with institutional and governmental policies. Use of PHI is to be minimized as necessary.
- c. Data to be analyzed by the DEB should be shared in a manner that is analysis-ready by statistical software.
- d. DEB personnel are not solely responsible for identifying erroneous or irregular data
- e. DEB personnel are not responsible for correcting erroneous or irregular data.

- f. The principle investigator is responsible for providing correct data to the DEB. While the DEB will remove errors from analytical data, the DEB staff or faculty will not make corrections to data originating outside DEB.
- g. The DEB may refuse to analyze erroneous, incomplete, or non-representative data.
- h. DEB will not release any data without explicit knowledge and consent of the Principal Investigator or data owner.
- i. For the purposes of publication, if a dataset was obtained from public or DEB-developed datasets, then the DEB faculty who obtained the data are the data owner.
- j. Prior to data analysis, protocols and proposals will be shared.
- k. Institutional Review Board and <https://clinicaltrials.gov/> numbers will be given.

7. Clinical trials

- a. DEB involvement in clinical trial is predicated on the objective that the trial has been, is, and will be planned, conducted, analyzed, and reported in a manner that meets current standards for clinical trials.
- b. Clinical trials require a data management plan consisting of the statistical plan, a database designed and built to meet clinical trial standards with access controls in which data are promptly entered, and monitoring in place prior to enrollment.
- c. DEB involvement in a clinical trial is best initiated at the design stage and continues throughout conduct of the study, extending to the publication of results.
- d. Data from clinical trials should be shared in compliance within pertinent laws and regulations if requested by institutional authorities, journals or study sponsors.
- e. If the DEB is responsible for the final analysis then the DEB will conduct the interim analyses.
- f. Additional tests of efficacy, beyond the statistical analysis plan may be declined.

8. Data analysis

- a. The DEB adheres to the American Statistical Association ethical guidelines (<http://www.amstat.org/asa/files/pdfs/EthicalGuidelines.pdf>).
- b. The DEB will adhere to CONSORT, TRIPOD, and STROBE reporting guidelines (<http://www.equator-network.org/>).
- c. All analyses should be programmatically reproducible.
- d. DEB analysis programs should follow good programming practices.
- e. Version control systems are preferred for tracking analysis programs.
- f. Compliant with laws, institutional policies, and data use agreements, analytical data and data analysis programs will be archived on a server or a database accessible by more than one DEB employee.
- g. Disputes in analysis may be resolved by an agreed upon neutral third party.

9. Analytical and Technical staff

- a. Only DEB personnel can act as supervisors for DEB staff.
- b. Staff workload will be monitored for consistency with billing and commitments (e.g., to grants and contracts) and balanced among staff according to ability and availability.

- c. While it is not feasible to fully document all in-development programs, analytical programs should be accessible by, comprehensible to, and operable by more than one analyst.
- d. Analysts are encouraged to share analytical tools.
- e. DEB analytical and technical staff are given the opportunity for continuing education and professional growth.