



1. The investigator works with the CRU leader to prioritize new requests or submits a request through the Core website.
2. An initial meeting with the biostatistician and investigator is scheduled.
3. The investigator sends meeting materials (e.g. study objective, preliminary hypotheses; relevant publications; list of relevant variables) prior to the meeting.
4. As the collaboration progresses (via meetings/correspondence with the biostatisticians), the nature of the project, study design, objectives, and hypotheses are clarified.
5. Expertise and advice on randomization, data collection, database design, and data provenance are provided.
6. A statistical analysis plan (SAP) is created, discussed, and agreed upon, derived variables are defined, and data consistency checks are specified.
7. The statistician and investigator meet/correspond regularly to ensure that the project is progressing and to keep the team updated.
8. Data collection is finalized, an analysis dataset with derived variables is created, and final data consistency checks are implemented.
9. Analyses per SAP are conducted, properly documented, and a statistical report is provided.
10. Results are discussed with the investigator. Additional data requests may be addressed – but the main hypotheses are expected to remain unchanged.
11. When a project results in a publication, the statistician writes the statistical methods section, and critically reviews the entire manuscript to ensure correct reporting and interpretation of results. Statisticians are generally included as coauthors on the manuscript.

Submit collaborative requests to the  
Biostatistics Core by visiting our website,  
<http://biostat.duke.edu/biostatistics-core>

