QMC Guidelines for Grant Application with Data Coordinating Center (DCC)

If you are proposing a multi-center and/or multi-national study, the funding organization (typically NIH) will expect a Data Coordinating Center to organize the study and monitor performance. For these applications, which typically are allowed extra pages (depending on the FOA), we will do the following (as for other grants) with noted additional responsibilities.

What we do include, but not limit to, the following

1. Assistance in refining specific aims particularly from statistical analysis perspectives
2. Involvement in study design development
3. Power/sample size calculation
4. Statistical analysis plans development and write up
5. Participation in data management plans development
6. Development of QA/QC plans
7. Assistance in developing data safety monitoring plans
8. Involvement in determining necessary personnel and efforts for the proposed works
9. DCC: randomization process
10. DCC: study document development process
11. DCC: integration with PI and clinics and communication approaches

When to contact us

1. At least **3 months** before submission deadline for new proposals – Proposals that start the planning early and allow time for internal peer review will likely to be better quality
2. At least **1.5 months** before submission deadline for resubmission, renewal or recycled proposals

Percent efforts guidelines

1. The PI (or Director) of the Data Coordinating Center is expected to be a Ph.D.-level biostatistician with experience leading DCCs. A minimum average of **20%** per year for the PI/Director and reasonable efforts for other required faculty statisticians
2. Yearly average of at least **10%** for faculty statisticians (in addition to the PI/Director) for projects with intensive statistical analysis (e.g., analysis for longitudinal data, large number of variables, missing data, cluster data, etc.) as specified by the DCC PI/Director
3. Efforts for statistical analysts should be included in addition to faculty statisticians; at least **25% efforts** of analyst for the year when data analysis (including DSMB reports) is conducted
4. Similar levels for data management must be included to develop the central study database, develop the data entry approach, tailor the interactive voice/web response system (IVRS) system for patient randomization to treatment and, if necessary, monitor study drug inventory at clinical sites, etc.
5. Typically, the DCC will have a separate budget from the main study, which will be developed by the QHS financial administrators, and there is an implicit understanding that indirects from the DCC budget will be returned to QHS
6. Any exceptions should be discussed with the QMC leadership and department chair

What we need from you includes, but not limited to, the following

1. On line request at QMC website
2. In person meeting(s) for new proposals to explain your research and proposal ideas and discuss integration of the DCC with the clinical leadership and sites
3. **Final** version of specific aims should be provided before we draft statistical analysis plans --- A proposal with analysis plans that do not match specific aims will affect scores from reviewers
4. Pilot data that can be used to calculate effect sizes for power calculation; if pilot data are not available then need to provide effect sizes from the literature
5. Discussions related to the logistics of the study, such as who will be authorized to request a patient treatment randomization and at what point in patient eligibility screening
6. Work out the percent efforts with the study statistician to be consistent with DCC requirements and to pass on to the financial administration team at QHS for paper work and final budget