C.A.R.E.
Guidelines for Requesting Research Support Services

Objective

The objective of this policy is to provide guidelines for requesting research support services from the Center for Anesthesia Research Excellence (CARE) in the Department of Anesthesia, Critical Care and Pain Medicine at Beth Israel Deaconess Medical Center (the Department).

Definitions

Research support services include, but are not limited to, assistance with study design, submissions to the institutional review board, data analysis, and abstract, poster and manuscript preparation.

Process for Reviewing Requests for Research Support

All requests will follow a multi-step review:
1. Item written up by staff member, submitted to CARE Director and Administrator
2. Reviewed by Director and Administrator. If necessary, return to staff member with comments and requests for modifications.
3. Draft reviewed by Director and Administrator forwarded to Physician Review Panel
4. Physician Review Panel meets monthly during faculty hour. Staff member presents proposal. Feedback given in person by Physician Review Panel and other interested members of the department who are present. Written summary of review, suggestions, and status are provided to applicant.
5. Staff member modifies proposal as necessary, resubmits to Director and Administrator.
6. Director and Administrator provide written determination of resources that will be provided by CARE.

Requests for Research Support Services

All requests for research support services should be made to CARE’s Medical Director of Research.

- Project Development (soup to nuts): Applicants must submit a written summary of their proposal using the New Project template provided by
CARE. Proposals will then be returned with feedback, or scheduled for review by the Physician Review Panel. The Physician Review Panel meets at regular intervals; the applicant will be asked to come to the scheduled review session and present the proposal to the Panel and discuss the project in greater detail. The Physician Review Panel, in conjunction with the Director, determines whether a submitted project will be supported by CARE, specifies which services are available and whether the applicant is eligible for free support or will be bound by the established fee schedule.

- **IRB/CCI Assistance:** Applicants must submit a written summary of their proposal using the CCI Part B template provided on the BIDMC Portal. This will be reviewed by CARE’s Director and Administrator for Clinical Research. Feedback will be provided, supplemented with in-person meetings as necessary. If assistance is requested with crafting the entire application and preparing the paper submission in its entirety, the CARE Director will determine if the applicant is eligible for free support from CARE Research Coordinators, or if the services will be provided according to the published fee schedule. Please see additional details in following section.

- **Statistical Assistance:** Applicants must submit a written summary of their needs using the Statistical Help template provided by CARE. CARE statistical support includes sample size calculation, statistical analysis plan development, interim analyses, final analyses, report preparation for Data and Safety Monitoring Boards, and other biostatistical topics.

- **Grant Submission and Planning:** All grant applications must be developed by the applicant in conjunction with the Office of Sponsored Programs. CARE personnel can assist with the Resources page (particularly if CARE will be a resource for the project), and with outside consultant editing assistance for the scientific portion.

- **Publication Assistance:** Applicants may request assistance with publications for work done outside of CARE by submitting a summary of the publication guidelines, deadline, and estimation of assistance needed to the CARE Director and Administrator. Please see additional details in the last section of this guidance document. For studies conducted with CARE assistance, publication preparation will typically be built into the initial support sheet provided by CARE when accepting the project.

- **Non-Clinical Time Request:** All Non-Clinical Time requests must be research-related, and come as part of a project proposal. The Physician Review Panel considers each request as part of the project feasibility.

**Guidelines for Requesting Assistance for Submission to the Institutional Review Board**
Before a research proposal originating from the Department is submitted to the Committee on Clinical Investigations (CCI), it must be reviewed by the Department’s designated Scientific Review Officer. If the Scientific Review Officer is a co-investigator on the proposal, then he or she cannot perform the scientific review, and the alternate reviewer should perform the review and complete the Scientific Review Form. The investigators should allow up to two weeks for the scientific review process.

Research proposals that require full board review must be submitted to the CCI approximately one month before the scheduled CCI meeting. The schedule of meeting dates and submission deadlines can be found on the CCI website. Both the Spark and Bushnell committees may be used.

In order to receive assistance with submitting a research proposal to the CCI, the project team should meet with a member of CARE at least four weeks before the research team intends to submit the proposal to the Scientific Review Officer. For a proposal requiring full board review, this would be approximately six weeks in advance of the submission deadline.

**Guidelines for Requesting Assistance for Publications**

Below is a list of items to bring to the initial meeting.

- Data, which should be in REDCap, Microsoft Access or a SAS, SPSS or STATA dataset. CARE will not analyze data that is collected and stored in Microsoft Excel.
- Guidelines for the abstract, including the deadline, word or character limit, whether tables and figures are permitted and whether there is a limit on the number of authors per abstract or a limit on how many abstracts one author can submit.
- A list of all authors on your abstract. Each author must meet the criteria for authorship as outlined in the Department’s policy and will need to approve the work before it can be submitted.
- A draft of the abstract. Abstracts are short; thus, an abstract should aim to address one primary objective. Additional objectives likely will need to be addressed in another abstract or reserved for the manuscript. The Results section of the draft abstract should have blanks where results need to be filled in. For example: *There were ___ women enrolled in our study with a mean/median age of ____*. The Conclusions section also can be sparse given that it is driven by the results.
- In order to receive assistance with an abstract submission, the project team should meet with a member of CARE at least four weeks before the abstract is due. All data collection should be complete by this time.