

NAPRTCS Participating Centers Committee (PCC) Operations Manual

Effective 5-04-05

1.0 Aims and Objectives

- 1.1 NAPRTCS PCC activities will be focused upon generating and prioritizing studies undertaken by NAPRTCS member sites, establishing center guidelines for study participation and Principal Investigator eligibility, and ensuring fairness and transparency with regard to the process utilized for site selection, Principal Investigator selection and authorship for studies arising from NAPRTCS research endeavors.
- 1.2 The processes utilized and guidelines proposed pertaining to 1.1
 - 1.2.1 Require NAPRTCS Board approval to become effective
 - 1.2.2 Will be reviewed at least annually by the PCC and amendments, or lack thereof, be noted in PCC meeting minutes and submitted to the NAPRTCS Board for approval.

2.0 Core PCC Functions-Overview

- 2.1 The NAPRTCS PCC is charged under NAPRTCS Bylaws resolution to
 - 2.1.1 Generate, review, and prioritize responses to the request for applications (“RFA”) and industry initiatives, including the selection of principal investigators and study sites, subject to the approval of the Board
 - 2.1.2 Solicit, originate, select, and suggest special analyses intended for presentation as abstracts at major meetings
 - 2.1.3 Prepare annual report manuscripts for each registry, and
 - 2.1.4 Work with The EMMES Corporation (the “Data Coordination Center”) to develop an annual data report for each registry.
- 2.2 The NAPRTCS PCC will define the guidelines for centers in good standing, which is a necessary requisite for its members to participate in any NAPRTCS study or analysis and Principal Investigator eligibility. Requisites for member in good standing status will be listed in the PCC Operations Manual, posted on the NAPRTCS Website and presented at the NAPRTCS Annual Meeting. Current criteria for centers in good standing criteria are
 - 2.2.1 A signed and active Registry Participation Agreement **AND**
 - 2.2.2 Active local Institutional Review Board Approval for patient enrollment **AND EITHER**
 - 2.2.3 A minimum of 10 patients enrolled annually over the previous 3 years **OR**
 - 2.2.4 An average record currency score (defined by EMMES corporation) of at least 75% over the past 2 years

Centers may fulfill 2.2.3 or 2.2.4 by addressing their backlog of incomplete prevalent patient records and/or by enrolling all incident patients. A signed

and active Facility Agreement is required to participate and/or serve as Principal Investigator for all NAPRTCS studies including those funded by an RFA mechanism or industry, Special Studies and Special or Quick Analyses.

3.0 Response to RFA

3.1 The NAPRTCS PCC will evaluate and prioritize all RFAs generated by government or industry sources relevant to NAPRTCS. RFAs deemed appropriate by the PCC for a NAPRTCS response will be submitted to the Board for approval prior to initiating the response process.

3.2 The PCC will disseminate to all NAPRTCS members of centers in good standing a request for a response to the RFA. The following timeline will govern the proposal evaluation process, unless more expedient terms are required by the RFA under consideration.

3.2.1 Members will be given 14 days from the PCC request to submit a letter back to the PCC indicating their intent to respond to the RFA.

3.2.1.1 The response will comprise completion of the one-page NAPRTCS RFA response form, which provides a synopsis of the research plan and budget in accordance with the guidelines pertinent to the RFA.

3.2.1.2 All PCC members will review all responses submitted within 7 days after the 14-day response deadline

3.2.2 Factors to be assessed in evaluating RFA responses include but are not limited to:

3.2.2.1 Scientific Merit Score (30%)

3.2.2.2 Research is a novel idea (20%)

3.2.2.3 PI has resources available to fulfill proposal (10%)

3.2.2.4 PI has track record in conducting multi-center Research (1-10) (10%)

3.2.2.5 PI has track record in completing multi-center Research (10%)

3.2.2.6 Experience in clinical research (10%)

3.2.2.7 Potential to Lead to NIH Funding (10%)

3.2.2.8 The PCC will vote to prioritize the submitted RFA responses and then select the individual or team to prepare the official NAPRTCS response for each RFA within 7 days after the 14-day member response deadline.

3.2.2.9 Each PCC member will receive one equal vote.

3.2.2.10 If a one or more PCC member(s) submitted a response to be considered, they will be prohibited from the RFA response evaluation and selection process.

- 3.2.2.11 If two or more responses receive equal vote counts, a maximum of three runoff-voting rounds will be conducted between those responses.
- 3.2.2.12 If the PCC is unable to select between two or more responses, those responses will be sent to the Board for final resolution.
- 3.2.3 PCC discussion and voting results will be noted in PCC meeting minutes. PCC member names will be removed from voting tallies.
 - 3.2.3.1 The author of each RFA response not selected will receive written comments from the PCC Chair and Vice-Chair as to the PCC assessment as to the merits and weaknesses of their responses.
- 3.2.4 The PCC proposal rank order will be submitted to the Board on the day following the vote.
 - 3.2.4.1 The response selected by the PCC will require Board approval prior to proceeding with a formal response to the funding entity.
 - 3.2.4.2 If the Board does not approve the response selected by the PCC, the Board will submit their rationale for their decision to the PCC in writing.

4.0 Member Initiated Studies

- 4.1 NAPRTCS members from a center in good standing can request to initiate different types of studies using the NAPRTCS registry and/or involving other NAPRTCS sites.
 - 4.1.1 Members interested in initiating a study should contact a member of the PCC to determine the most appropriate NAPRTCS study type and to assist the member with initiating the pertinent NAPRTCS process.
 - 4.1.1.1 The PCC member contacted will inform all PCC members by e-mail within 24 hours as to the specifics of the member's study request.
 - 4.1.1.2 This contact will be recorded as an addendum to the following PCC meeting minutes.
 - 4.1.1.3 The PCC Chair and Vice-Chair will report this contact to the Board no later than the following Board conference call.
 - 4.1.1.4 The PCC will direct the center member to the most appropriate NAPRTCS study type within one week of the initial contact
 - 4.1.1.5 A PCC member will be assigned to monitor and assist with the progress of the member initiated proposal.
- 4.2 Industry sponsored studies
 - 4.2.1 The PCC will evaluate a member initiated, industry sponsored study for its relevance to NAPRTCS. Studies deemed appropriate

by the PCC for a NAPRTCS response will be submitted to the Board for approval to proceed.

4.2.2 The member initiating the study reserves the right to serve as the study Principal Investigator.

4.2.3 The Board reserves the right to negotiate the contract terms with the specific industry funding entity

4.2.4 Terms with respect to authorship for any manuscripts and abstracts emanating from a member-initiated study will be established in the form of a written agreement between the PCC and the study member prior to study commencement.

4.3 Special Studies and Special Analyses

4.3.1 Member responses to requests for NAPRTCS Special Studies and Special Analyses will be referred to the Special Studies Committee Chair, who also serves as the PCC Vice-Chair.

4.3.2 The Special Studies Chair (PCC Vice Chair) will inform the PCC of the nature of all current Special Studies/Analyses and responses to Special Studies/Analyses requests at each PCC meeting or conference call.

4.4 Quick Analyses

4.4.1 Quick Analyses comprise NAPRTCS Registry queries of the existing database that require less than 3 hours of statistical analysis work by EMMES. EMMES is solely qualified to determine if a study request would require a Quick Analysis.

4.4.2 EMMES will notify the PCC of their decision with respect to each member-initiated request for a Quick Analysis.

4.4.3 Terms with respect to authorship for any manuscripts and abstracts emanating from a member-initiated Quick Analysis will be established in the form of a written agreement between the PCC and the study member prior to analysis commencement.

4.5 Templates for industry-sponsored studies, Special Studies/Analyses, and Quick Analyses will be available on the NAPRTCS Website and will be accompanied by help documents to facilitate proper completion and expedite the evaluation process.

5.0 NAPRTCS Abstract Requests

5.1 The Board will determine annually the number of abstracts NAPRTCS will be able to fund for various academic meetings.

5.1.1 The PCC will solicit requests for studies to be presented as abstracts from the membership four months prior to each meeting's abstract submission deadline.

5.1.1.1 These solicited abstracts do not include abstract reports emanating from current ongoing NAPRTCS studies; PI's for ongoing studies are expected to submit abstracts as part of their project's process.

- 5.1.2 NAPRTCS members from centers in good standing will have one month to respond to the request for abstracts.
- 5.1.3 The PCC will review and prioritize the abstract requests within one week of receipt and forward the top abstracts to EMMES to assess feasibility for collecting and analyzing data by the abstract submission guideline.
- 5.1.4 Authors of selected abstracts will work with EMMES and a PCC member to prepare the abstract. A first draft version of the abstract will be submitted to the PCC at least two weeks prior to the abstract deadline. The PCC will have 48 hours to make comments regarding the abstract.
- 5.1.5 Finalized abstracts will be forwarded to the PCC, but do not require PCC approval prior to submission.
- 5.1.6 Terms with respect to authorship for abstracts will be established in the form of a written agreement between NAPRTCS and the study member prior to analysis commencement.

6.0 Annual Report

- 6.1 The PCC is responsible for preparing the annual report for each registry.
 - 6.1.1 All PCC members representing each registry will participate in the preparation of their registry report. The PCC member in the final year of their term for each registry will be primarily responsible for preparing the annual report.
 - 6.1.2 The PCC member in the final year of their term for each registry will be primarily responsible for presenting annual report data at the NAPRTCS annual meeting.