

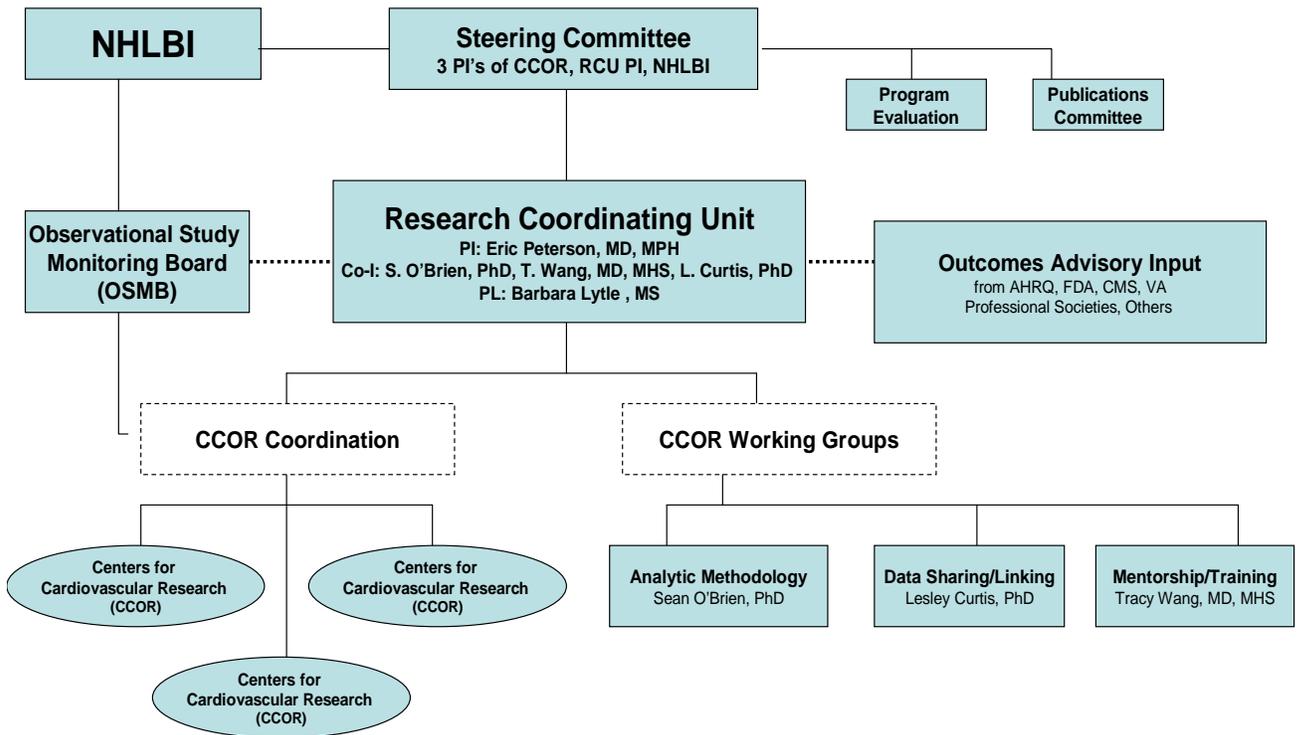
Proposal for the Duke NHLBI RCU for the CCOR

A. Vision for the RCU

As stated in the RFA, the primary goal of the NHLBI RCU is to facilitate coordination of research activities and communications between and among CCOR awardees and the NHLBI. In addition, the RCU will be responsible for conducting a number of tasks including the promotion of common measures and data sharing, meeting planning and coordination, dissemination of study findings, facilitating cross-center research collaborations, and overall program evaluation. Furthermore, the RCU, alone and as part of the Steering Committee, is expected to review CCOR research proposals, track project and CCOR progress, promote research collaborations beyond the individual CCOR to include the external outcomes community, and support the development and mentorship of junior investigators. Finally, though not explicitly stated, the RFA suggests that the selected RCU will help the NHLBI guide future development of the CCOR program and will provide input as well into where and how best NHLBI might support the development and application of CV outcomes research more generally.

B. RCU Organization

The coordination and planning of the NHLBI cardiovascular outcomes research agenda will require high levels of collaboration and communication among the CCORs, RCU, the NHLBI, Steering committee, and the Observational Study Monitoring Board (OSMB). Beyond these parties, we believe that external outcomes collaborators may provide important input to the program and projects in specific areas.



IV. Roles and Tasks of the RCU

A. Promoting Common Measures and Data Linking and Data Sharing

The creation and collection of standard CV data elements and definitions provide

Data Linking: The Duke RCU will also assist CCORs who want to link to existing clinical and administrative data sources in their applied projects. Potential existing databases include clinical data from the ACC, AHA, and STS registries and administrative claims data such as Medicare, social security death index, and health provider network files. The use of these linked data sources reduces need and costs for de novo data collection and promotes larger studies with longer, more complete patient follow-up.

Data Sharing: Once federally-funded studies are complete, it is important to consider how these data may be shared with other interested investigators to promote further science and discovery. Typically, the NIH provides a public use dataset from these studies to interested investigators (e.g., Framingham). However, outcomes research projects can be complex as they often use existing data sources whose formation was not based on public funding. In these cases, a mandate to make all the data public may ultimately reduce the willingness of owners of existing data to provide access to researchers. Thus, our RCU proposes a two-fold plan for data sharing. First, data supported solely with federal funds will be made directly available as de-identified data to qualified researchers after the completion of the study (with Steering Committee review of research proposals). Alternatively, for studies that rely on existing databases, we propose that researchers might gain access via a separate research committee that includes a representative of the database owner (e.g. professional society). Once approved, a qualified external researcher could ask important research questions either by obtaining a de-identified database directly from the external database owner or by having his/her research query run internally by the database owner.

B. Communications, Meetings and Cross-Center Collaboration

The RCU should also promote collaborations among the three funded CCORs. While the full scope of intercenter collaboration must await Center selection, we have outlined several potential strategies to promote such goals and to work towards creating a unified “network” for multi-center outcomes research. Effective and timely communications is critical to multicenter collaboration. On an operational basis, we will strive to optimize communications between the NHLBI, RCC, CCOR and key leadership bodies. Such communication will utilize webinars, teleconference calls, and frequent email between teams to facilitate rapid responses when issues arise. In addition, we propose a variety of mechanisms for building cross-center collaborations, and enhancing the overall national recognition of this NHLBI Outcomes Research Network:

NHLBI Outcomes Research Network Website: We plan for our RCU to host and maintain a dedicated website. The site will make CCOR study information, protocols, forms, and other pertinent materials available from a central location and will inform investigators and other study participants of new developments. The website will have multiple levels of access for the public, CCOR members and study leadership. The public website with unrestricted access will be useful for informing the public about the Outcomes Network, its progress and important findings to date. A secure website with log-on identification and password protection will be created for investigator and NHLBI use. Typical content may include a project tracking system, common measures and data definitions, study protocols, manual of procedures, training materials, electronic versions of the data forms, the answers to frequently asked questions (FAQs), committee

schedules and minutes, and past newsletters and operational materials. There also will be separate secure Web sections for the Steering Committee and OSMB Committee that provides information about past and upcoming meetings and other relevant information.

CCOR Communications: Minutes of committee calls and meetings will be written promptly with an appropriate summary of action items, distributed to appropriate study constituents and archived for future reference. In addition to a directory of study personnel, the RCU will facilitate electronic communication among the different subcommittees and working groups via the website. An account will be established at the RCU for an overnight delivery system for rapid dissemination of study materials.

Study Meetings and Conference Calls: The RCU will assume responsibility for organizing meetings of the Steering Committee and the Observational Study Monitoring Board. This function includes determining the location of meetings, providing proper audio-visual equipment support, agendas and other support materials, as well as preparation of meeting minutes. In addition, the various committees can be expected to hold scheduled conference calls to discuss issues and chart progress towards goals. RCU will assume responsibility for facilitating calls and establishing dial-in telephone numbers.

C. Promoting Cross-Center Research Collaborations: While each CCOR will have proposed 1 to 2 individual free-standing research projects, a stated goal for the program is to develop multicenter research efforts over time. This collaboration can be facilitated in a stepwise fashion. First, after CCOR selection, we propose that the Steering Committee quickly convene all parties to review the proposed research portfolio and evaluate shared interests and commonalities across projects. If overlap exists among project and subject content among CCOR, then the involved CCORs, in consultation with the Steering Committee and RCU, may elect to revise their proposals to facilitate hybrid multi-center research projects. The review may also identify CCOR study proposals whose study design and findings could be enhanced from multi-site expansion. Assuming other Centers had interest in such research, then the Center and the Steering Committee could seek out additional funding sources to support this expanded research. Such support could come from federal or foundation grant support or from a public-private partnership. Second, we propose to further facilitate collaborative research by creating methodological and operational “interest communities” among the CCORs to share analytic approaches and to solicit feedback on research or project challenges. For instance, statisticians across centers may form a working or writing-group to advance a particular analytic discipline. Alternatively, project leaders across Centers may create a group to discuss methods for assessing patient-reported functional outcomes. We also propose mechanisms to encourage the CCOR investigators to create more collaborative data access and publication policies within their specific projects. Specifically, we propose that the individual CCOR studies solicit interest and involvement in their projects from other CCOR researchers.

D. Dissemination of Research

We will work with the Steering Committee and investigators to effectively communicate CCOR findings. We have suggested that an important first step will be the formation of a publication subcommittee. In conjunction with the RCU and its statistical team, the Steering committee-run publication subcommittee will develop the “Access and Publications Policies” for the NHLBI Outcomes Research Network. This policy will

provide internal as well as external interested investigators with a set of guidelines on the types of permissible queries, process for data access, and the costs (if any) required to support the query. This policy will also guide the manuscript process (author requirements, Publications and Steering Committee oversight etc). Support within the current budget for analysis is finite, thus there should be an explicit prioritization of addressing the most important questions first. Once approved and the analysis complete, the DCRI can provide editorial and technical support for study publications. Findings will be disseminated in scientific peer-reviewed publications, and at scientific meetings. We will also pursue partnerships with major cardiovascular, heart failure and surgical associations to disseminate results more rapidly and to a wider audience, as approved by the Steering Committee.

E. Develop and Promote State of the Art Outcomes Research Methodology

The field of CV outcomes research provides multiple analytic and methodological challenges. Unlike a controlled experiment, outcomes researchers typically evaluate 'real life' -- typical patients receiving non-protocol driven care in community practice. From these uncontrolled data and settings, outcomes researchers attempt to glean insights into what structure-, process- or system-factors might lead to better (or worse) patient. Our statisticians would be ready to provide consultation to the individual CCOR investigators if such help was required. Our RCU investigators would play an active role in the review of potential publications to assure their quality and methodological rigor. We propose development of methodological "interest communities" among the CCORs to share analytic approaches or to solicit feedback on research or project challenges. For example, those with an interest in patient-centered outcomes assessment could meet and discuss issues related to measurement of quality of life or how to adjust these for socio-economic confounders or deal with missing survey data.

F. Mentorship and Training

Mentorship and training of junior faculty is a key stated goal of the NHLBI Outcomes program and also represents another means of promoting cross-institutional collaboration. At many institutions, the outcomes research community is limited, and thus, early career researchers can often be isolated in their local communities with little exposure to other researcher or centers performing similar work. Cross-institutional mentorship provides a well-rounded perspective, as well as opportunities for career development and facilitation of future collaborative relationships. Therefore, training the next generation of outcomes researchers is a shared goal embraced by the RCU and all Centers. While each CCOR will likely have their own internal training program, we envision leveraging the leadership and expertise across all CCORs as well as that of the RCU to provide additional avenues supporting training collaborations. We believe this can be facilitated by the creation of an early career advisory group. This would have representation from each of the CCOR, NHLBI, and be headed by Tracy Wang, herself a junior to midlevel faculty at the RCU at Duke. This group would review mentorship relations and plans established for each identified junior outcomes investigator at each CCOR. This group would also create a list of potential outcomes faculty mentors at each CCOR as well as at the RCU and at other outstanding national academic outcomes centers.

G. Evaluation of a Successful Network

Program evaluation is a necessary component of this NHLBI endeavor. In collaboration with the Steering Committee and NHLBI Scientists, we propose to establish a set of

metrics for benchmarking the research, and mentoring successes of the individual CCOR as well as the overall success of the program in stimulating cross-center collaborations, development of novel methodologies, and overall impact on the discipline and practice of medicine more generally. This process needs also to be measured incrementally so that it can provide useful feedback and stimulate course corrections when needed. Consonant with the Donabedian model, evaluation metrics can be divided into structure, process and outcomes. As an example, one goal of the CCOR is to encourage strong mentoring of junior faculty. *Structural metrics* might include the formation of appropriate mentoring teams (including clinical and methodological). *Process metrics* might include having the mentoring team meet regularly with the junior faculty to define a project including the deliverables and timeline, and then gauge progress over time toward completion. *Outcomes metrics* would include the junior faculty publications in peer-reviewed journals, presentations at national meetings, and eventually promotion and/or representation of these individuals on national research committees. CCOR metrics: Based on the stated goals in the RFA, each CCOR should be evaluated based on quality and impact of their science as well as the success of their mentored junior outcomes faculty. Benchmarks for the science might include whether or not their research projects are adhering to proposed study timelines, whether enrollment curves are being achieved, and other operational targets. Additional metrics could include number and quality of publications, as assessed by their citation index and impact factor of their published journals. Additionally, science that is incorporated into guidelines for care and/or have other policy changes should clearly be noted. Additional metrics for later success of a CCOR might be its ability to partner with other research communities, and obtain future federal-, foundation- or industry-funding for outcomes research, and/or the incremental growth in their outcomes faculty and staff. Junior investigator mentorship metrics have already been suggested above. Of note, given the marked under-representation of minority academic researchers, the diversity of CCOR center faculty and fellows trained may also be a target of assessment.

Program Metrics: Programmatic success could include an aggregate of the measures noted for individual CCORs but aggregated among the three centers. The scientific output of the combined centers (publications, citations etc) is straightforward to measure. More challenging is the ability to evaluate cross-center engagement and collaboration. Some markers may include the degree to which the program stimulates cross-center research (i.e., external investigators completing successful projects in collaboration with a given CCOR or Network research study). Evidence of cross-center bidirectional mentorship of junior faculty could be considered another metric of success. Third, the development of group products such as the on-line web-based outcomes research learning modules and the active participation in the CCOR research seminars and methodological interest groups are reflective of success. Fourth, the aggregate success of the individual CCOR to obtain subsequent federal or other outcomes research funding is a metric of programmatic success. Additional metrics may relate to how well this program's investigators, projects and centers interact and carry out collaborative research with the rest of the outcomes community (such as AHRQ CERTs or Decide or AHA PRT or NIH CTSA sites).