NCDR®

NATIONAL CARDIOVASCULAR DATA REGISTRY

Investigator's Guide

to

NCDR® Research

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Dear Investigator:

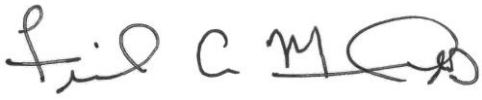
Welcome to the NCDR® Research Network. The National Cardiovascular Data Registry (NCDR®) is the American College of Cardiology's suite of data registries designed to help hospitals and private practices measure and improve the quality of cardiovascular care they provide. Since its inception in 1997, the NCDR has expanded to include nine hospital-based registries (with one more coming soon) and two outpatient registries. More than 2,400 hospitals and 2,100 outpatient providers participate in the registries. This participant base, coupled with a growing patient population, allow the NCDR Research Network to pose critical questions pertaining to cardiovascular health care and its delivery.

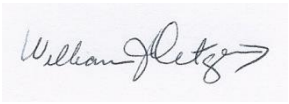
NCDR Mission: *To improve the quality of cardiovascular patient care by providing information, knowledge and tools; implementing quality initiatives; and supporting research that improves patient care and outcomes.*

We welcome research proposals from a variety of individual investigators and groups, as well as government agencies and industry representatives. All proposals undergo rigorous scientific review and those that make it through the review process are then considered for analysis. While the majority of studies are supported by external funding, the NCDR does supply funding for a limited number of studies each year. Competition for NCDR support is steep, however, and final decisions must consider available resources and each registry's agenda for strategic research.

We welcome your participation in NCDR Research and encourage you to use this Investigator's Guide throughout the research process.

Sincerely,





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Chair, NCDR Management Board
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OVERVIEW

NCDR DATA REGISTRIES

The registries focus on clinical characteristics, processes of care, and outcomes in high impact cardiovascular conditions or procedures as follows:

- **Chest Pain - MI Registry™** *(Formerly the ACTION Registry):* High-risk hospitalized STEMI/NSTEMI patients.
- **AFib Ablation Registry™:** Patients undergoing atrial fibrillation (AFib) ablation procedures. This registry captures data to assess prevalence, demographics, acute management and outcomes.
- **CathPCI Registry™:** Patients undergoing diagnostic catheterization and/or percutaneous coronary intervention (PCI).
- **Diabetes Collaborative Registry™:** Longitudinal view of the presentation, progression, management, and outcomes of patients with diabetes.
- **ICD Registry™:** Patients receiving implantable cardioverter defibrillators (ICDs). Although participation is CMS-mandated, 80 percent of participating hospitals report data on all implantations —regardless of payer or indication.
- **IMPACT Registry™:** Pediatric and adult patients with congenital heart disease who undergo diagnostic and interventional catheterizations.
- **LAAO Registry™:** Patients undergoing left atrial appendage occlusion (LAAO) procedures. This registry captures data to assess real-world procedural outcomes, short and long-term safety, comparative effectiveness and cost effectiveness.
- **PINNACLE Registry™:** Outpatients with coronary artery disease, hypertension, heart failure and atrial fibrillation.
- **PVI Registry™:** Patients undergoing lower extremity peripheral arterial catheter-based interventions; this registry also includes data collection for carotid artery stenting (CAS) and carotid endarterectomy (CEA).
- **STS/ACC TVT Registry™:** Patients undergoing aortic and mitral transcatheter valve replacement and repair procedures. This registry includes longitudinal follow up of outcomes after hospital discharge, including vital status and quality of life.

Visit the NCDR website (www.cvquality.org) to find Data Collection Forms (DCFs) and Data Element Dictionaries for each registry.

NCDR RESEARCH

Depending on funding source, the NCDR offers two distinct pathways for engaging in hypothesis-driven research:

NCDR-Supported: The Research & Publications (R&P) pipeline is the portal through which individuals and organizations can submit research proposals based on the analysis of NCDR data. These proposals are reviewed for scientific merit and undergo a competitive approval process for NCDR funding. All analyses are conducted by NCDR-contracted Data Analytic Centers (DACs).

Non-NCDR Supported: In addition to studies supported by the NCDR, hospitals, practices, cardiac care facilities, and industry can participate in a growing number of government and privately-funded NCDR research projects. For example, these projects can focus on outcomes research, comparative effectiveness research, longitudinal studies and surveys.

NCDR DATA ANALYTICS

NCDR custom analytics is a service that offers interested parties the opportunity to gain a broad understanding of issues, including safety, effectiveness and quality. Ad hoc data analytic requests are typically not hypothesis-based and are not intended for publication. However, the related data analysis is derived from the same data sets that are analyzed when completing approved research projects. To learn more about our data analytics, and how to submit a request for ad hoc data analysis, please visit the NCDR website. Table 1 outlines the differences between hypothesis driven research and custom data analytics.

Table 1: NCDR Data Use Opportunities

NCDR Research Pipeline and Research Studies
Purpose: Hypothesis-driven research that will ultimately appear in peer-reviewed research journals.
Dataset: Based on analysis of (HIPAA-compliant) limited datasets.
Source of Submission: Principal investigators of NCDR RPAs, which includes representatives from academia; industry; government agencies, and NCDR participating institutions and facilities.
Examples: • Published manuscripts • Presented abstracts • Chapters in books & other media
NCDR Data Analytics
Purpose: Descriptive and/or univariate statistics, trending, and/or data comparisons. **This work does not include hypothesis-driven research, and is not published.**
Dataset: Based on analysis of (HIPAA-compliant) limited datasets.
Source of requests for data analysis: NCDR participants; government and industry officials; consulting groups in ways that are not feasible for participants via individual dashboards and outcomes reports.
Examples: • Trending in device or medication usage • Enhanced comparisons between individual NCDR participant data and NCDR aggregate data • Use of descriptive statistics to answer clinical quality questions

HUMAN SUBJECT RESEARCH AND THE NCDR

In operating the NCDR, the American College of Cardiology (ACC) understands the importance of protecting human research subjects. The ACC has signed a Federal-Wide Assurance with the Department of Health and Human Services that requires all human subject research to be conducted in compliance with the Common Rule (45 CFR 46). The ACC has designated Chesapeake Research Review Incorporated as its institutional review board (IRB) of record. Each registry has submitted a protocol to the IRB, which governs all human subject research conducted by that registry. All registry protocols on file have currently been granted a waiver of informed consent. ACC staff will evaluate each Research Proposal Application (RPA) to ensure that the research proposed is consistent with the protocol on file for the registry. In the event that ACC staff determines an RPA is outside the protocol scope, they will work with the investigator to outline the best course of action. If the project requires a separate protocol and IRB review, the ACC will generate a cost estimate to cover related expenses. If separate approval is

required, it must be obtained prior to the commencement of research. Questions concerning the College's Human Research Subject Protection Program should be directed to cvquality@acc.org.

NCDR RESEARCH PROPOSAL APPLICATIONS

NCDR RESEARCH & PUBLICATIONS PIPELINE: OVERVIEW

As part of its mission, the NCDR encourages the submission of RPAs from individual researchers and organizations interested in improving the care of patients with cardiovascular disease by analyzing registry data and publishing the results in peer-reviewed journals. These guidelines were developed to provide investigators an overview of the NCDR research and publications process, from submission of a research proposal to publication of a manuscript. Principal investigators are required to adhere to these guidelines when preparing proposals, abstracts and manuscripts. Figure 1 is a representation of how the NCDR's R&P process is conducted.

Figure 1: Overview of the NCDR R&P pipeline process

PREPARING AND SUBMITTING A RESEARCH PROPOSAL APPLICATION

Information about the application process can be accessed on the NCDR website. Research proposals are submitted electronically through the online NCDR Research Management System (http://rp.acc.org/). An ACC username and password are required to log in and a variety of resources are available to assist in navigating the system. Additional tips are included in this guide to help prepare an RPA for submission and review.

* Please note that the individual identified on the RPA as the "Primary Author" is considered the research team's Principal Investigator (PI).

Choose the Appropriate Registry for Your Research

The Data Collection Forms (DCF) and Data Dictionaries for each of our registries are posted on the NCDR website. As ideas are developed for a research proposal, investigators should review the appropriate DCF and related dictionary to confirm that the registry collects the data needed for the study. See Appendix A to review additional information pertaining to NCDR datasets.

Rule Out Overlap

Investigators are required to determine whether a topic has been previously studied before moving forward with a new research proposal. Registry-specific listings of published manuscripts, presented abstracts, and unpublished works in progress are posted in the "R&P Resources" section within the online NCDR Research Management system, or on the NCDR website. Typically, research proposals that substantially overlap with existing work are not reviewed or approved.

Funding

Various funding options are available to support research studies using NCDR data:

NCDR (and DAC-Supported) Research: The NCDR supports a limited number of proposals for retrospective, observational research each year. Competition for NCDR support is steep and final decisions must consider available resources and each registry's agenda for strategic research. In addition, NCDR-contracted DACs may contribute in-kind analytic support for specific RPAs, which are also known as DAC-supported RPAs. NCDR will select proposals based on priority scores generated from the R&P Subcommittee meetings, which will then be matched against planned funding via clinical research agreements and in-kind analytic support.

Non-NCDR-Supported Research: Potential investigators may wish to use NCDR data in larger, more complex research projects. Many of these projects require linking NCDR data to an external data source, such as another registry, a claims database, an EHR database, a clinical trial, a survey database or other prospectively collected data. These projects include funding outside of NCDR, such as federal grants, foundation grants, task orders, industry support or even the investigator's own departmental or institutional funding. Review of these non-NCDR-supported RPAs occurs via a separate mechanism involving NCDR leadership (termed "ACC Scientific & Strategic Peer Review"), as well as separate contractual and financial agreements to support a set number of aims and RPAs to move forward to manuscripts. For additional information on how to pursue non-NCDR-supported research, please refer to Appendices H, I, and J. Approved externally-funded RPAs still must be submitted to the R&P pipeline for tracking purposes (via the online NCDR Research Management System, http://rp.acc.org/). Contracted RPAs that pose an issue in terms of overlap will be navigated on a case-by-case basis, but in general, contracted RPAs take precedence. Approval by NCDR does not constitute approval by governing bodies for the proposed external data source. The investigator must work with those organizations directly for any necessary approvals.

Regardless of the funding mechanism, the principles of scientific oversight (RPA review, feasibility, appropriate methodology, etc.) apply to all NCDR research studies. In addition, all abstracts and manuscripts must undergo review by the related R&P Committee for that registry. If the proposal relates to more than one R&P Committee, NCDR will determine the lead committee for managing these processes.

No other bodies or groups may supplant the review and approval responsibilities of the relevant NCDR R&P Committee. For example, if a potential investigator proposes a special project that links the IMPACT Registry with Children's Hospital ABC Database, it is reasonable for the investigator to form a scientific group to guide the research or lead individual RPAs on the linked dataset. However, the existing appointed IMPACT Registry R&P Committee is still responsible for reviewing and approving the resultant RPAs, abstracts and manuscripts. Correspondingly, the Children's Hospital ABC may have its own policies that apply here as well.

Research Project Volume (the "Rule of Two")

The NCDR "Rule of Two" applies across all registries and states that a principal investigator may not have more than two active proposals ongoing at the same time in the pipeline. An active proposal is one that has been submitted to NCDR for R&P Committee review (or if pertaining to an externally funded proposal, one that has been submitted to the ACC for Scientific & Strategic Peer Review), but has not yet resulted in the publication of a manuscript to a peer-reviewed journal. For example, if a principal investigator has submitted two proposals for review, both need to go through the appropriate process

before submitting another proposal. If both RPAs are approved and move forward to analysis, the investigator cannot submit another RPA until at least one of the 'active' proposals has resulted in a manuscript publication. Please note that the rule of two applies to all principal investigators, regardless of the funding source.

One Manuscript per RPA

NCDR policy states that only one manuscript may be produced from each approved RPA. If multiple manuscripts are desired, then separate RPAs must be submitted. Also, principal investigators may not request additional analyses that extend beyond the scope of the original RPA. Grants, industry, or other projects that expect to produce multiple manuscripts will be examined on a case-by-case basis, but under no circumstance is one individual permitted to have more than two manuscripts in-progress.

RPAs with Direct Comparisons of Medical Products (e.g., specific drugs and devices)

Proposals that focus on comparative effectiveness and/or safety of medical products (e.g., drugs and devices), as well as those that propose comparisons among generic categories of devices (e.g., drug-eluting vs. bare-metal stents or ICD vs. CRT), are allowed for submission. RPAs in which the analysis of an individual manufacturer or brand is not a crucial component of the proposal can be submitted and reviewed via the standard pipeline process as described above.

However, proposals in which manufacturer or brand analysis is the central focus, and integral to the scientific validity and novelty of the proposal, will generally not be reviewed via the standard pipeline. This is because NCDR has a longstanding relationship with the U.S. Food and Drug Administration (FDA) to assess product safety and effectiveness with respect to specific manufacturer/brand, as part of the core mission of NCDR programs (above and beyond research proposals).

RPA Submission Deadlines

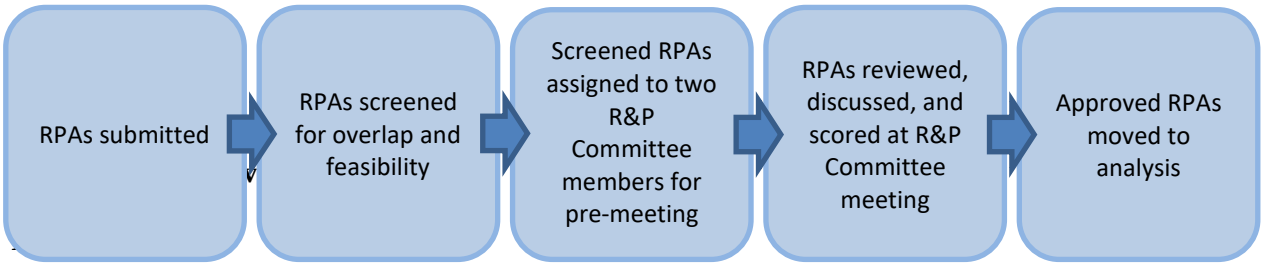
Each NCDR registry has its own R&P Subcommittee that meets two times per year to review new RPAs. Deadlines for RPA submission are generally **10 weeks** prior to a scheduled R&P meeting in which RPAs are being reviewed. Any RPAs received fewer than 10 weeks in advance of the upcoming meeting will not be reviewed until the subsequent meeting. Submission deadlines for each registry can be found on the NCDR Research Calendar, which is posted to the NCDR website. Extensions will not be granted. Since due dates are publicly posted, it is expected that interested investigators will abide by these dates.

For non-NCDR-funded research, RPAs are not expected to adhere to the above mentioned publicly posted schedule. A separate contract will denote the turnaround time for ACC Scientific & Strategic Peer Review, typically 3 weeks per RPA.

Once a proposal is submitted online and subsequently processed, an email is sent that contains the assigned RPA ID number. This ID number should be used in the subject line of all email correspondences pertaining to that RPA.

RPA Review

Figure 2 provides an overview of the RPA review and approval process for NCDR-funded proposals.



All submitted RPAs undergo an initial screening process by R&P staff, committee chairs and the assigned DAC to evaluate for overlap, feasibility, priority, and the "Rule of Two." RPAs that are deemed inappropriate to move forward will not receive committee review and applicants will be informed of the justification for this decision.

RPAs that are deemed appropriate to move forward will first be evaluated by two R&P Committee members (pre-meeting review), and then the entire committee at the next scheduled meeting, using the following criteria:

- **Significance:** The extent to which the project, if successfully carried out, will make an original and important contribution to the field.
- **Feasibility:** The likelihood that the proposed work can be accomplished in the project period by the investigators, and via an analysis that uses data from the fields suggested in the proposal.
- **Methodology:** The extent to which the conceptual framework, design, methods and analyses are properly developed, well-integrated and appropriate to the aims of the project. The review process strives to ensure that methods appropriate for observational research are employed, and that framing of questions, analyses and results will be in terms that describe "association" rather than those which assume that statistical association in observational studies imply causation.
- **Overall Score:** Committee members provide an overall score of the RPA, based on a ten-point scale.
- **Comments:** Committee members and primary reviewers (the two members who performed the pre-meeting reviews) provide specific comments.

*Please note that Registry Members do not have the authorization to independently review and/or approve RPAs.

Approved RPAs: If a proposal is passed approved by the R&P Committee, it will move forward to analysis at the assigned DAC. At this time, the principal investigator will be asked to review and sign the Terms and Conditions Letter which describes the roles and responsibilities of the principal investigator. See the section below, *Data Analysis for Approved RPAs*, for more information on the analysis process.

Revise & Resubmit: If a proposal is not approved, but scores high enough to warrant further consideration after completion of suggested revisions, the principal investigator may be invited to resubmit the proposal online within a specified timeframe (usually 30 days). When submitting the revised proposal, please specify this in the "Background/Significance" section of the online application and include the date of the original review. A letter addressing reviewer comments may also be submitted and is highly encouraged.

Declined RPAs: RPAs that are declined by the committee should not be revised and resubmitted.

DATA ANALYSIS FOR APPROVED RPAS

The NCDR has contractual agreements with participating hospitals that allow only assigned DACs to work with NCDR data. After committee approval of an RPA, NCDR staff will notify the designated DAC and a due date for analysis completion will be agreed upon. DAC staff will contact the principal investigator within several weeks of receiving the proposal to schedule the initial phone call for discussion of the analytic plan. Table 2 outlines the analysis process, including the responsibilities of the principal investigator. During preparation of drafts, the statistician assigned to work on the proposal will review tables and statistics and will be available to provide assistance as necessary. Once the bulk of the

analyses are sent to the principal investigator, he/she is expected to produce a manuscript that is suitable for submission to a scientific journal within four months.

Table 2: Analysis Process for Approved NCDR-Supported RPAs

Steps	Assumptions
1. Resubmit final RPA to NCDR	• Once an RPA is approved, the principal investigator should make revisions, if feasible, to the RPA based on comments from the committee's review. The revised RPA should be sent to NCDR R&P staff and the DAC. If there are no comments, the existing RPA will be considered the final version. • The principal investigator must communicate the following to all co-investigators: the background, hypothesis, intended tables, figures, summary statistics and testing in the RPA based upon the R&P committee review and comments.
2. DAC receives the revised final RPA; statistician may write a draft of the statistical analysis plan.	• If needed, the statistician will contact the principal investigator to discuss any outstanding questions or issues.
3. Statistician and DAC staff member discuss the analysis plan with the principal investigator. Once the plan is finalized, the principal investigator is responsible for sharing the analysis plan with the co-investigators.	• A conference call with the principal investigator is scheduled to discuss the draft analysis plan. • The statistician will finalize the analysis plan according to the revisions discussed during the conference call. • The principal investigator is responsible for circulating the final analysis plan among the co-investigators listed on the manuscript draft, which generally includes the investigators listed on the approved RPA. • If an abstract is to be written, the statistician will prepare and send a reduced statistical report to the principal investigator.
4. Statistician prepares and sends the results of the data analysis to the principal investigator.	• The data analysis contains all of the information specified in the analysis plan (e.g., information, summary data, and statistical tests). • The principal investigator should plan to prepare the first draft of the manuscript with the set of data included in the data analysis, with no additional analyses until after the first draft of the manuscript is reviewed by all co-authors and the R&P committee.
5. Principal investigator sends an email to NCDR and DAC to acknowledge receipt of analysis plan and data analysis.	• The principal investigator is required to send an email to NCDR R&P staff and the DAC confirming receipt of analyses.
6. The primary author will write the first manuscript draft in a timely manner, usually within one month of receiving the results of the data analysis.	• First draft of the manuscript is circulated by the principal investigator to the DAC, then to all co-authors and NCDR. • All manuscripts must be ready for submission to a journal within four months of receiving the initial data analysis. This includes review by the DAC and co-authors, in addition to NCDR R&P review and approval.

ABSTRACT AND MANUSCRIPT PREPARATION

GENERAL INFORMATION

Please keep in mind the following:

- Refer to the Brand and Style Guide in Appendix D for detailed information on NCDR branding guidelines for abstracts and manuscripts. This guide includes information on the correct use of "NCDR" (abbreviated vs. spelled out), registry names, partner and sponsor statements, disclaimers, and slide and poster templates.

- All abstracts and manuscripts must be reviewed and approved by the corresponding R&P committee before submission to a scientific conference or journal. One round of committee review is standard; however exceptions can occur if reviewers ask for substantive changes in a draft. In that case, R&P chairs may ask for a second round of review after the changes have been made. If more than two 'rounds' of revision are needed and review does not lead to an approval, there will be further adjudication and resolution. In rare cases of disapproval that cannot be resolved, the final decision (regarding any publication) lies with the NCDR officers. Please note that review and approval must occur **before** the abstract or manuscript is submitted. If an abstract or manuscript is submitted prior to approval, the NCDR will require the author to withdraw the submission; this may also result in immediate termination of the RPA.
- For non-NCDR-funded research, R&P review turnaround times for both abstracts and manuscripts will be mutually agreed upon in a separate contractual agreement.
- The primary statistician will review tables and statistics and be available to assist principal investigators in drafting statistical methods sections. Drafts cannot be submitted for NCDR R&P review until after accuracy is verified by the analytic center staff. The principal investigator will incorporate comments from the statistician when preparing the draft that is submitted for NCDR R&P review.
- A change in principal investigator does not reset timelines or due dates.
- Principal investigators are responsible for choosing the journal for manuscript submission.

Abstracts

It is widely accepted within the research community that the process of manuscript publication often includes the initial publication of an abstract. DACs and principal investigators should discuss the option of producing an abstract, and then target a specific scientific conference for submission. Principal investigators should monitor meetings of interest and their respective abstract submission deadlines. Before submission to a conference however, abstracts must be reviewed and approved by the R&P committee. When the abstract draft is finalized, including review by the assigned statistician at the DAC as well as co-authors, it should be submitted for R&P review via the online NCDR Research Management System. The NCDR Research Calendar provides specific submission dates for R&P review that correspond with the major scientific conferences each year. In general, these R&P deadlines **are 3-4 weeks prior to a scientific conference abstract submission deadline**. If a conference is not listed on the calendar, the abstract draft must be submitted for R&P review, at the very latest, three weeks prior to that conference's abstract submission deadline.

Upon completion of R&P review, the principal investigator then incorporates reviewer feedback into a revised abstract before submission to the conference. If the abstract is accepted for presentation, principal investigators must notify NCDR and specify the presentation type (poster, oral, etc.). NCDR staff will provide templates for presentation use, which can also be accessed and downloaded through the NCDR Research Management System (under "R&P Resources Page"). Principal investigators are encouraged to adhere to NCDR formatting for all abstract presentations (see the Style Guide in Appendix D) and should send the final presentation to the DAC and NCDR R&P Team for a last review and approval **no later than three weeks** before the conference. For poster presentations, final NCDR approval must be granted before printing. NCDR does not provide support for costs relating to presentation and publication of abstracts. Principal investigators should bear in mind that abstract preparation does not alter the timeline for manuscript submission, which is four months after delivery of the data analysis.

Manuscripts

Similar to the process for abstracts described above, when a manuscript draft is finalized (including review by the DAC and co-authors) and is ready for journal submission, the principal investigator submits the draft for R&P review through the online NCDR Research Management System. **R&P review of manuscripts usually takes 3-4 weeks.** The principal investigator then incorporates any committee feedback into a revised manuscript before submitting to the desired journal. The four-month timeline for manuscript production and submission ensures that data reported are up to date, and that the analysis stays within resource constraints. Again, principal investigators are encouraged to adhere to NCDR formatting rules for all manuscripts (see the Style Guide in Appendix D). NCDR does not provide support for costs pertaining to publication of manuscripts.

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR: AUTHOR GROUP COMMUNICATIONS-DRAFT PREPARATION

The principal investigator is responsible for the following:

1. Ensure the integrity of the work as a whole, from conception to published manuscript.
2. Communicate all expectations in a timely manner.
3. Establish and communicate with co-authors about timeline expectations for completion of the manuscript.
4. Obtain, from all investigators and DAC statisticians, timely approval of manuscript and abstract drafts prior to submitting to NCDR for R&P review.
5. Manage all communications with NCDR and DAC staff and respond in a timely fashion.
6. Oversee the completion of any changes required during NCDR R&P review of abstract and manuscript drafts.
7. Determine an appropriate listing of co-authors. NCDR encourages the principal investigator to follow International Committee of Medical Journal Editors guidance regarding identification of co-authors[1,2], specifically:
    - "*Authorship credit should be based on: 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3.*
    - *All persons designated as authors should qualify for authorship, and all those who qualify should be listed.*
    - *Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.*"

    In determining who to list as co-authors, the primary author should consider individuals involved in:

    - RPA concept and design
    - Abstract and manuscript writing
    - Data analysis and/or interpretation
    - Literature search
    - Critical review
8. Ensure that all co-authors receive and review this document, including updated versions as they are released (which are posted to the NCDR website).
9. Create an "Acknowledgements" section in the manuscript, if needed. Since NCDR does not permit inclusion of 'honorary' authors as co-authors, the principal investigator may consider including an acknowledgements section to cite contributors who do not meet the criteria for authorship, but whose assistance the authors would like to acknowledge. Examples of those who might be cited in a listing of acknowledgements include:

- A person who provided purely technical help or writing assistance;
- A mentor who provided only general support;
- Colleagues, reviewers and staff who do not qualify as authors;
- Groups of persons who have contributed materially to the paper but whose contributions do not justify authorship.

The acknowledgement should disclose the identity of the individual, his or her organizational affiliation, and the function or contribution to the paper (e.g., "served as scientific advisor," or "critically reviewed the research application proposal"). Financial and material support should also be acknowledged. The principal investigator is responsible for allowing individuals identified in the acknowledgement section opportunity to review the draft and consent to being listed on the paper prior to submitting the final draft to NCDR.

10. Provide the names of all co-authors and individuals cited in the acknowledgement section to NCDR at the time of NCDR R&P review of the abstract or manuscript. The principal investigator should also provide the names of any individuals who met the criteria for authorship or acknowledgement, but who declined to be included. This identification is an important step in ensuring transparency in the NCDR peer review process, managing potential conflicts of interest, and assigning R&P subcommittee reviewers. No individual should appear in the author panel or acknowledgement section for an abstract presentation or published article that has not been disclosed to NCDR.

The overarching goal of the primary author is journal submission within four months of the date upon which the analysis is completed, and submission to a journal not more than two months after NCDR R&P review is complete.

11. Allow co-authors and individuals listed under the acknowledgements section sufficient time to review and respond to the final draft prior to submission to R&P review. In general, it is good practice to give co-authors a minimum of one week and a maximum of two weeks for reviews of manuscripts, and a minimum of three business days for review of abstracts.
    - Co-authors and individuals listed under the acknowledgements section must be timely with reviews and responses. Occasionally, individuals are not able to meet stated timeline expectations for reviews set by the principal investigator. When an individual notifies the principal investigator regarding conflicts that will prevent timely review and response, the principal investigator should grant reasonable requests for extension (generally not longer than two additional weeks for manuscripts). If the principal investigator has not received any response from an individual or acknowledgement of receipt of a draft for review, the principal investigator should attempt to reach the individual via another communication mechanism (e.g., call the individual if the draft was sent via e-mail), and should allow the individual up to three business days to respond or request an extension. If the individual still has not responded, the principal investigator should remove the individual from the author panel or acknowledgement section, and should communicate this information, including the name of the individual and contribution to the paper or abstract, to the NCDR at the time the final draft is submitted for review.
    - If co-authors submit comments after a draft has been reviewed by the NCDR R&P committee and approved for journal submission, the principal investigator may add the individual back into the author panel or acknowledgement section without informing the NCDR. If the individual recommends substantive changes to the approved draft, the principal investigator must update NCDR and wait for a final dispensation regarding whether to proceed with presentation or publication.

12. Allow sufficient time for NCDR R&P review. Timelines for R&P review are discussed in detail above, under *Abstract and Manuscript Preparation*.

RESPONSIBILITIES OF THE PRINCIPAL INVESTIGATOR: COMMUNICATIONS WITH NCDR & JOURNAL EDITORS

When the analysis is complete, the principal investigator is responsible for the following activities:

1. **NCDR R&P Review:** NCDR policy states that the R&P Subcommittees must review the final manuscript (or abstract) draft before submission to a journal (or scientific session). This approach allows the best and most accurate review prior to journal submission, while also minimizing the time committee members must devote to review of drafts. Committee members do not have the authority to independently review and/or approve a manuscript. Principal investigators are responsible for uploading the final draft to the NCDR Research Management system for R&P review. See above: *Abstract and Manuscript Preparation*.
2. **Initial submission to a Journal or Scientific Session:** Submitting the final, NCDR-reviewed draft to a journal or scientific session. Once submitted, the principal investigator will notify NCDR, and include the name of the journal/scientific session, the date upon which the submission was made, and a copy of the submitted draft.
3. **Revisions of submitted manuscripts:** If the journal requests revisions to the manuscript, the principal investigator is responsible for informing the author group and biostatisticians, making revisions as needed, and resubmitting to that journal. It is also the principal investigator's responsibility to ensure that revision of a manuscript remains within the scope of the initial RPA, uses the same dataset, and does not create overlap with any RPA in process. If there are questions with regard to these issues, principal investigators must notify NCDR staff for formal evaluation.

   Each approved RPA is expected to produce a single manuscript.
4. **De Novo Submissions:** If the manuscript is not accepted at the journal to which it was initially submitted (referred to as de novo submission #1), the principal investigator is responsible for communicating this information to the author group and biostatisticians, forwarding them copies of any reviewer comments, revising as needed, and moving forward to a second de novo submission within one to two months of a rejection.
5. **NCDR R&P Status Updates:** Inform NCDR the manuscript status. Informing staff at the analytic center is not a substitute for informing NCDR staff. The principal investigator is responsible for, and required to, provide regular updates to NCDR staff, including:
   - Using the ID Number of the RPA upon which the manuscript is based (add this ID number to the subject line of e-mailed updates and all other communications regarding your proposal);
   - Providing a brief status report on progress in writing the manuscript;
   - Providing an expected date of completion;
   - Naming a journal targeted for publication.
6. **Publication:** When a manuscript is accepted for publication (or an abstract for presentation), the principal investigator is responsible for the following:
   - **Notification of acceptance:** Upon acceptance, informing NCDR of the date of acceptance and projected date of publication, if known. Remember that informing staff at the analytic center is not a substitute for informing NCDR staff. In the case of abstracts, the type of presentation (e.g., poster or oral presentation) is also needed.

- **Working with the ACC Marketing and Communications Team:** Upon acceptance, the principal investigator is responsible for working with the ACC Marketing and Communications team as needed. See also: *Promotion of Selected Manuscripts and Abstracts*, below.
- **Providing the Published Paper:** Sending NCDR a PDF of the published paper, once the edited version of the paper is posted online or is in print in hard copy. When an abstract is presented, sending NCDR a copy of the poster or slide presentation.

BARRIERS TO MANUSCRIPT COMPLETION & SUBMISSION

On occasion, a principal investigator or writing group may encounter difficulties that will hamper progress toward either completion or submission of a manuscript. The following are some scenarios that may occur, and any action that will be taken by the NCDR to mitigate such barrier(s). (See Table 3)

Table 3: Barriers to Manuscript Completion & Submission

Barrier	Policy
Results of the data analysis are not adequate to support the hypothesis, and subsequently affect the ability to write a manuscript.	The principal investigator, after conferring with the DAC, should notify the analytic center and NCDR research of their intention not to proceed, and include the justification for this decision.
Principal investigator has not communicated updates or has not responded to repeated requests for updates.	If the principal investigator does not reply after repeated inquiries, the project will either be closed or reassigned. This is a last resort, and occurs if, after two email messages, one phone call, and one certified letter, there is still no reply from the principal investigator.
Manuscript draft has not been developed or submitted within an adequate timeframe.	When manuscript development does not meet targeted goals, NCDR staff will contact the principal investigator to provide assistance as needed. If manuscript development continues to lag, a date for next steps in the development process will be targeted (e.g., submission for NCDR R&P review; journal submission after review; de novo submissions following rejection from a journal). If the new date is not met, NCDR staff will work with the chair of the R&P Subcommittee and the senior author to determine new lead authorship.
Resubmission to another journal has not occurred within two months.	In such cases, principal investigators will be required to submit an explanation for the delay in resubmitting their manuscript to another journal.
Approval is not obtained prior to submission of abstract or paper	The paper will be withdrawn; NCDR staff will consider if termination of the RPA is appropriate.

ACKNOWLEDGING THE LIMITATIONS OF OBSERVATIONAL DATA

Investigators may be inappropriately inclined to infer that associations in observational data imply a causal effect. It is essential that principal investigators acknowledge that observed associations in non-randomized studies (such as those conducted using registry data) cannot be construed as definitively causal. While associations may be due to cause/effect, no method can eliminate the possibility of bias, chance, or confounding. In general, causal language should be avoided in abstracts and manuscripts, and wording should be consistent with the Editors of the HEART Group Journals' *Statement on Matching Language to the Type of Evidence Used in Describing Outcomes Data* (See Appendix A; *JACC 2012;*

60:2420), and the sister paper behind this editorial: *Payal Kohli, MD and Christopher P. Cannon, MD. The Importance of Matching Language to Type of Evidence: Avoiding the Pitfalls of Reporting Outcomes Data. Clin. Cardiol. 35, 12, 714–717 (2012)*. Authors may want to reference the NCDR's data quality program from the following paper: *Messenger JC, Ho KL, Young CH, et al. The National Cardiovascular Data Registry (NCDR) Data Quality Brief: The NCDR Data Quality Program in 2012. J Am Coll Cardiol. 2012 Oct 16;60(16):1484-8.*

Additional considerations include limited outcomes data and variations in commitment and quality of data collection. See below for several examples of how to describe constraints of data:

a. *An unequal geographic distribution of participating hospitals leads to selection bias, which limits the proportion of the Acute Coronary Syndrome population that was evaluated during the period described by this study.*

b. *NCDR-participating facilities vary in terms of the types and number of procedures they provide. This variability can impact on the data that are accrued.*

c. *The extent and types of data each NCDR registry collects varies, and authors will need to address this limitation within the context of their research study.*

d. *NCDR data are collected during acute hospitalizations, and authors may need to address this constraint if their analysis is focused on in-hospital-stay data.*

Suggested language for referencing the NCDR data as a source in the methodology section as well as the limitations section with citations is located in Appendix F.

CITATION OF NCDR'S IRB

The College has designated Chesapeake Research Review Incorporated as its internal institutional review board (IRB) of record (see also *Human Subject Research and the NCDR)*. If an investigator's RPA is within the scope of the NCDR protocol on file, and she/he wishes to cite this IRB in their manuscripts (in general, this is not required), the following format should be used:

> *Waiver of written informed consent and authorization for this study was granted by Chesapeake Research Review Incorporated.*

PUBLICATION

ADHERENCE TO EMBARGO POLICIES

Content of manuscripts and abstracts is considered confidential and embargoed until publication. The ACC has policies governing embargoes and the disclosure of scientific research results contained in late-breaking clinical trial presentations and abstracts. The premature unauthorized disclosure of embargoed results and/or data in any format constitutes a breach of the embargo policy. Authors, presenters, reviewers, committee members, members, company sponsors, and/or anyone who violates the embargo policies shall be subject to ACC's disciplinary procedures and sanctions related to embargo violations. The policies are available on the ACC website. The NCDR has a policy regarding external access to NCDR research undergoing peer review, which is located in Appendix G. Investigators preparing for abstract presentation should familiarize themselves with the Common Statement on Prior Publication Policy (http://www.hsr.org/hsr/information/authors/ppublication.jsp).

PROMOTION OF SELECTED MANUSCRIPTS AND ABSTRACTS

When a manuscript or abstract has been accepted for publication (e.g. when the paper reaches "in press" status), the principal investigator may be asked by the ACC's marketing and communications team to provide the following:

- A completed **NCDR Manuscript Communications Strategy Questionnaire**. When requested, the form will be used to promote the article on the ACC website, to summarize findings in other ACC communications channels, and when applicable, in the development of a press release or comments to the media (handled by ACC's media relations team). After the embargo has lifted, the marketing and communications team will promote the findings of the research through appropriate vehicles.
- **Advance notice of publication date**. It is the principal investigator's responsibility to inform the NCDR staff of online and print publication dates. Principal investigators should notify the NCDR staff the same day a publication date is communicated by the publication or journal.
- **A draft of the article**. Please forward any drafts received to the NCDR staff. Embargoes will be honored, and drafts will only be used in the development of promotional and media messaging.
- **Power point slides summarizing the research and findings** (optional). Authors who are preparing oral presentations with slides should plan to submit them within one week of presentation. All slides must be created using the NCDR PowerPoint template and must include the following statement in the second slide position:

  > "This research was supported by the American College of Cardiology's National Cardiovascular Data Registry (NCDR).The views expressed in this presentation represent those of the author(s), and do not necessarily represent the official views of the NCDR or its associated professional societies identified at CVQuality.ACC.org/NCDR."

  Please do not use university or other logos on slide sets and avoid the use of pharmaceutical/medical device brand names. Appropriate rights from the publisher for any graphs, charts, or other visuals taken from the published article should also be obtained.

NCDR papers in various stages of manuscript development and publication acceptance are regularly reviewed internally by ACC for promotion planning. Decisions regarding the specific plan for each NCDR research paper are based on a number of factors and specific tactics are not guaranteed. There are three potential avenues for promotion of research findings: 1) promotion to NCDR participants, 2) promotion to ACC members, and/or 3) promotion to trade or mainstream media outlets. Promotions to NCDR participants and ACC members include mentions in "News and Views" (NCDR's monthly e-newsletter) and other applicable ACC member e-newsletters, news stories on *ACC.org* and promotion across ACC's various social media channels.

Decisions about coverage on ACC.org and other ACC member vehicles (e.g., newsletters, blogs, social media outlets, etc.) are made on a case by case basis. News covered on ACC.org is determined through an independent editorial process, and NCDR recommendations for coverage are advisory in nature and coverage cannot be guaranteed.

If a paper is determined to be "newsworthy," which means it is determined to be of interest to trade or mainstream media outlets, the ACC media team will either prepare a press release or conduct less formal outreach to individual outlets. If a press release is prepared, the media will contact the author for comments and/or consult the author questionnaire if the author has completed and submitted one.

Timely completion of the NCDR Manuscript Communications Strategy Questionnaire and notification of a manuscript's acceptance by a journal for publication are important sources of information to help the media team determine the potential news value of the study and for developing a promotion plan.

COLLABORATING WITH OTHER ORGANIZATIONS ON MEDIA

Each author's affiliated organization or university is welcome to distribute their own press release when a paper is published. If those organizations would like to consult with the ACC media team, they are welcome to at any time. The ACC media staff requests advance notice and a copy of the release to allow for coordination of media promotion and embargo times, to ensure the release correctly portrays the ACC and its registries, and to allow the ACC to anticipate questions from media that may arise as a result of the release.

CONCLUSION

This investigator's guide to the NCDR represents years of knowledge gained from administering a robust research program. The information provided is intended to assist investigators in navigating the unique data obtained through the patient outcomes registry programs, as well as processes established to ensure appropriate direction and oversight of research activities. The appendices contain additional information about NCDR registries. ACC staff and NCDR volunteer members welcome any comments and questions you may have as you consider pursing research endeavors with the ACC.

BIBLIOGRAPHY

1. International Committee of Medical Journal Editors. Publication Ethics: Sponsorship, Authorship, and Accountability. Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication, Updated April 2010. www.icmje.org .
2. Steneck NH. *Introduction to the Responsible Conduct of Research,* U.S. Department of Health Services Office of Research Integrity, August 2007. A free copy of this document is available in a variety of formats at the Dept. of Health and Human Services: Office of Research Integrity, at: http://ori.dhhs.gov/ori-intro

APPENDIX A: ADDITIONAL REFERENCES AND HELPFUL LINKS

1. National Institutes of Health, Office of the Director. Guidelines for the ethical conduct of research. 4th edition, May 2007. Available online at http://www.nih.gov .
2. National Institutes of Health: Office of Research Integrity. Promoting Integrity Through "Instructions to Authors": A Preliminary Analysis. M.D. Sheetz. Available free online (PDF) at: http://ori.hhs.gov/images/ddblock/instructions_authors.pdf .
3. Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publications. International Committee of Medical Journal Editors. Reader note: The ICMJE does not publish print copies of the current Uniform Requirements. The official and most current document is freely available to the public at on the ICMJE website: http://www.icmje.org/ .
4. National Institutes of Health: Research Involving Human Subjects: http://grants.nih.gov/grants/policy/hs/ .
5. Academy Health is a nationally-recognized organization whose focus is health services and related policy research. They offer excellent training and professional resources at: http://www.academyhealth.org/index.cfm .
6. Payal Kohli, MD and Christopher P. Cannon, MD. The Importance of Matching Language to Type of Evidence: Avoiding the Pitfalls of Reporting Outcomes Data. Clin. Cardiol. 35, 12, 714–717 (2012).
7. The Heart Group. Statement on Matching Language to the Type of Evidence Used in Describing Outcomes Data. JACC. Vol. 60, No. 23, 2012.

APPENDIX B: DATASETS AND LINKED DATA INFORMATION

Datasets and Data Collection Forms

Current data collection forms and data dictionaries are posted on the NCDR website. Related launch dates for each data collection form are provided in the table below.

Table 3: Data Collection Forms and Related Launch Dates

NCDR Registry Version[1,2]	Content/Focus[3]	Devices	Launch Date
CathPCI Registry[4]	Procedure-Based (Diagnostic Cath & PCI)	Intracoronary Vascular closure	
V 2.x			2002
V 3.x			2005
V 4.x			2009
Chest Pain- MI Registry	Disease-Based (STEMI, N-STEMI)		
V 1.x			2007
V 2.x			2008
V 2.1			2010
V 2.4			2015
ICD Registry	Procedure-Based (Implantable Cardioverter Defibrillators)	ICD ICD lead	
V 1.x			2005
V 2.1			2011
V 2.2			2016
PINNACLE Registry	Disease-Based (Patients with CAD, Heart Failure, Atrial Fibrillation)		
V 1.x			2008
V 1.x			2008
IMPACT Registry	Procedure-Based (Congenital Heart Disease)	Congenital heart defects Vascular closure	
V 1.x			2010
V 2.0			2016
STS/ACC TVT Registry	Transcatheter aortic valve replacement (TAVR)	Transcatheter aortic and mitral valve replacement and mitral leaflet repair	2011
V 2.0			
Diabetes Collaborative Registry	Disease-Based (Patients with Diabetes Mellitus)		
V 1.0			2015
AFib Ablation Registry	Procedure-Based (Atrial fibrillation catheter ablation procedures)		
V 1.0			2016
LAAO Registry	Procedure-Based (Left atrial appendage occlusion procedures)		
V 1.0			2016
PVI Registry	Procedure-Based (Lower extremity peripheral arterial catheter-based interventions)		
V 1.0			2016

[1]Analyses are based upon discharge date within a given date range.

[2] The letter x designates minor changes that may occur within the lifespan of a given version of a registry's data collection form.

[3] Limited datasets (HIPAA-compliant) may vary slightly from the data cited in a given Data Collection Form.

[4] Not all CathPCI Registry participants submit all cardiac catheterization data, which may impact the feasibility of research proposals focused on cardiac catheterizations.

Quarterly Submissions and Call for Data Schedule: HIPAA-compliant limited datasets are uploaded from the NCDR data warehouse to the contracted data analytic centers on a quarterly basis. These uploads constitute refreshed datasets based on submissions received from registry participants by a call for data submission deadline. Participants may submit a new quarter's worth of data by this deadline as well as re-submit previous quarters of data going back as far as the launch of the current version. A sample Call for Data schedule is included in Appendix E.

Data Quality Reports (DQR): Each Data Quality Report – commonly referred to as a "DQR" – is prepared after data files are submitted to the NCDR. Participants use their data collection tool software to create a submission file which is uploaded to the NCDR website. After uploading, the data in the file are automatically assessed for errors (e.g. accuracy) and completeness. Passing the DQR ensures well-formed data and a statistically significant submission.

- **Assessment:** Data meets the NCDR-defined submission threshold for each data element (e.g., coding for Diabetes in CathPCI Registry needs to be answered 100 percent of the time; coding for CABG date only needs to be answered 80 percent of the time).
- **Completeness:** Data meets the NCDR-defined thresholds for composites of data elements. For instance, in the CathPCI Registry, 100 percent of all elements in Composite A (also known as Core Elements) must meet their thresholds; 90 percent of the elements in Composite B (also known as Supporting Elements) must meet the threshold.

HIPAA-compliant limited datasets include data that pass both assessment and completeness ("green light" DQR status) and data that pass assessment but fail completeness ("Yellow light" DQR status). DQR status is applied to the entire quarterly submission, not just individual patient records. In general, analyses are based only on green light submissions.

International Datasets: Although NCDR registries do have participants from U.S territories, as well as countries outside the U.S., only U.S. data are included in the data set used for outcomes reporting and research. The table below provides a registry-specific listing of our current international participants.

IMPACT Registry and the CDC National Death Index

A data linkage has been established between the IMPACT Registry and the National Death Index (NDI). This linkage includes information pertaining to cause of death. The match rate reflects mortality of the general, non-congenital cardiovascular population, indicating that mortality in the latter group is quite low. This data linkage was a one-time only project.

NCDR-CMS Data Linkage Overview

The ACC has centralized the linking of NCDR data with Centers for Medicare and Medicaid Services (CMS) administrative claims data. The current NCDR-CMS linked dataset combines data from the CathPCI Registry, Chest Pain-MI Registry, ICD Registry, STS/ACC TVT Registry and PINNACLE Registry with the following CMS files:

CMS Research Identifiable Files	Years Available
Inpatient Claims (IC)	2012-2014

Outpatient Claims (OC)	2012-2014
Skilled Nursing Facility (SNF)	2012-2014
Home Health Agency (HHA)	2012-2014
Hospice	2012-2014
Carrier File	2012-2014
Durable Equipment File (DME)	2012-2014
Part D Drug Event File (PDE)	2012-2014
Master Beneficiary Summary File (BSF) Base, chronic conditions, and cost and utilization segments	2012-2014
Master Beneficiary Summary File (MBSF) NDI segment	2012-2014
Part D drug, plan, prescriber, and pharmacy characteristics	2012-2014
Part D formulary characteristics	2012-2014

NCDR data have been deterministically linked to CMS data.

Research studies that wish to leverage the NCDR-CMS linked data must fall under the scope of the ACC's research study protocol that was approved by CMS. The ACC's study protocol focuses on the impact of pre-procedural, peri-procedural, and post-hospitalization treatment patterns on short-term re-hospitalizations and mortality among Medicare beneficiaries. The NCDR captures patient demographics, procedural details, and facility and physician information, which provides insight into clinical practice patterns and patient outcomes. However, additional detail on the sequence of care and events occurring post-discharge are not available through the NCDR. The combined NCDR-CMS dataset will allow researchers to evaluate the predictors of hospital compliance with optimal discharge planning, patient adherence to those protocols, and resulting patient outcomes such as mortality and re-hospitalization.

In order to examine the factors related to post-discharge patient outcomes following a major cardiovascular event, the cohort will include patients from the CathPCI Registry, ICD Registry, Chest Pain-MI Registry and the PINNACLE Registry who:

1) Receive a PCI at a hospital that is part of the CathPCI Registry
2) Have been admitted to either the CathPCI Registry or Chest Pain-MI Registry
3) Have had an ICD or CRT covered by CMS in the ICD Registry
4) Have been treated in an ambulatory setting by a physician who participates in the PINNACLE Registry

The NCDR-CMS linkage will be updated annually with the most recently available CMS data.

APPENDIX C: RPAS: FREQUENTLY ASKED QUESTIONS

NCDR Research Proposal Application (RPA)
Frequently Asked Questions (FAQ's)

Submitting Research Proposals to NCDR® Research:

1. **Where do I find a listing of the data elements and related dictionaries?**
   You will find the data elements and data dictionaries posted for each registry on the NCDR website. Be sure to review these documents before starting an RPA. Ask yourself if the NCDR actually collects the data needed for the study you are proposing. If not, you will need to reconsider your plan.

2. **How do I avoid overlap between what I am proposing and what is already published or underway at NCDR?**

Please visit the NCDR website to find links for registry-specific listings of manuscripts, abstracts, and unpublished projects. Reviewing these lists will help avoid overlap with other projects already in the pipeline. Note that the RPA form requires that an investigator do this before submitting an RPA.

As an RPA is prepared, the Rule of Two must be considered, which applies across all NCDR registries. If two proposals are submitted, investigators will need to wait for those to go through review before submitting additional proposals. If both proposals are approved and move forward to analysis, another proposal cannot be submitted until at least one of those proposals has resulted in a manuscript that has been submitted to a peer-reviewed journal for possible publication.

3. **The institution where I am doing my fellowship training is not a member of NCDR. Will I be able to use the NCDR database for research?**
   NCDR participation is not required to engage in research that is based upon analysis of NCDR data. In fact, the ACC no longer asks about participation on RPAs.

4. **Do I receive the raw data or is data analyzed by a NCDR designated team?**
   NCDR does not share raw data. Proposals that are approved to move forward are assigned to one of the NCDR's contracted Data Analytic Centers (DACs). The DAC, in turn, will contact the principal investigator to discuss the analytic plan. Once the initial analysis is complete, the DAC will send the results to the principal investigator. It is expected that investigators will produce a final manuscript (including input from all co-authors and statisticians, and review by NCDR) and be ready to submit to a journal within four months of the date upon which the analysis was delivered.

5. **How do I enter my RWI (Relationship with Industry) through ACC's website?**
   You can enter or update your RWIs through the ACC's Disclosure System, http://disclosures.acc.org/. You will be asked a series of questions about any relationships you may have with various entities. If you answer "yes" to any of the questions, the system will ask you to complete information regarding the relationship(s). If you have problems with the website, please call our toll-free number for assistance: (800) 253-4636. If you are not a member, please also call our toll-free number for assistance. Normal business hours are Monday thru Friday, 9:00 AM to 5:00 PM EST.

6. **Are there financial costs associated with using NCDR databases (from protocol submission until publication)?**
   The NCDR supplies funding for a set number of research studies per year. However, if an applicant has his or her own source of funding, it should be noted on the application (at the funding source question). Applicants with their own source of funding will receive a separate review process and may apply at any time.

7. **How do I submit my RPA form and is there an application fee?**
   Submit your RPA through the NCDR Research Management System, which can be accessed at http://rp.acc.org/. This website also contains many useful documents under the "R&P Resources Page," including a brief overview of how to use the system, as well as user guides to assist investigators when navigating the system. No fee is required when submitting an RPA.

8. **How soon will I be notified of the outcome?**
   After an RPA is submitted, NCDR staff will process it and applicants will receive an email confirmation containing a unique ID number. For internally funded proposals, processing usually occurs right after an RPA submission deadline, or about 10 weeks prior to the next R&P Committee meeting. Dates for all RPA submission deadlines and R&P Committee meetings are posted on the NCDR website on the Research Calendar. Applicants are typically notified of the outcome of their submissions within six weeks after a committee meeting. For externally funded proposals, processing usually occurs within a few weeks of receiving the RPA in the online system.

9. **How can I connect with other investigators interested or experienced in working with NCDR data for research purposes?**
   ACC has established a networking forum on LinkedIn®. ACC in Touch has expanded to include the NCDR Research Network Subgroup, created for physicians, researchers, and other individuals interested in cardiovascular research. The group serves as a forum for the exchange of ideas, networking and discussions centering around cardiovascular research findings and opportunities to conduct research based on NCDR data.

   To join, go to LinkedIn Groups, search for "NCDR Research Network" and click the "Join Group" button. Once you have joined the NCDR Research Network community, you will also be accepted into its parent group, the American College of Cardiology, if you are not already a member.

10. **How do I submit a non-NCDR-funded research proposal that links NCDR data to an external data source?**
    Investigators may complete the preliminary proposal for non-NCDR funded research form, located on the NCDR website, Research section, Steps for Submitting a Research Proposal and email it to *ncdrresearch@acc.org*. The NCDR will follow up with investigators to initiate the process for evaluating the request. Non-NCDR-funded research requests for linking the NCDR with an external data source requires additional information and documentation that will be provided to the investigator by the NCDR upon receipt of their preliminary proposal.

APPENDIX D: NCDR BRAND AND STYLE GUIDE FOR RESEARCH AND PUBLICATIONS

NCDR® Brand and Style Guide for Research and Publications

NCDR branding guidelines must be followed in all written communications, including research manuscripts, abstracts, posters, and presentation slides.

I. Correct Use of "NCDR" in Abbreviated vs. Spelled Out Form

- Use of "ACC's NCDR" or "NCDR" is preferred over individual registry names in manuscript and abstract titles.
- NCDR as an acronym is preferred over the spelled out form (National Cardiovascular Data Registry) in manuscript and abstract titles.
- Upon first reference in the body of manuscripts and abstracts, the spelled out form followed by the abbreviation in parentheses is appropriate, "National Cardiovascular Data Registry (NCDR)."

II. Correct Use of Registry Names

- Authors are required to use the appropriate registry name, as shown below, whenever the name is used. As stipulated by branding and partner guidelines, there are no acceptable abbreviations for NCDR registries.

  Chest Pain-MI Registry

  CathPCI Registry

  Diabetes Collaborative Registry

  ICD Registry

  IMPACT Registry

  LAAO Registry

  PINNACLE Registry

  PVI Registry

  STS/ACC TVT Registry ("TVT Registry" may be used after first reference)

- Authors may refer to a registry as "the registry" once the full name has been established in a document.
- When referring to a risk model or analysis of a registry's data in a research paper, do not refer to the risk model or data as that of NCDR. Rather, specify the name of the registry whose data were used in the analysis/risk model. Example: *The CathPCI Registry model for risk-adjusted mortality (RAM; v 4.0 data) was used to assess…*

III. Partner and Sponsor Statements

At the end of the manuscript draft (before the References section), authors should insert the following statement to describe the registry on which their research is based:

- Chest Pain-MI Registry® is an initiative of the American College of Cardiology with partnering support from the American College of Emergency Physicians.
- CathPCI Registry® is an initiative of the American College of Cardiology with partnering support from the Society for Cardiovascular Angiography and Interventions.
- Diabetes Collaborative Registry® is an initiative of the American College of Cardiology, American Diabetes Association, American College of Physicians and Joslin Diabetes Center. The registry is sponsored by AstraZeneca (Founding Sponsor) and Boehringer Ingelheim Pharmaceuticals, Inc.
- IMPACT Registry® is an initiative of the American College of Cardiology with partnering support from the Society for Cardiovascular Angiography and Interventions, and the American Academy of Pediatrics.
- PINNACLE Registry® is an initiative of the American College of Cardiology. Bristol-Myers Squibb and Pfizer Inc. are Founding Sponsors of the PINNACLE Registry.
- PVI Registry™ is an initiative of the American College of Cardiology with partnering support from the Society for Cardiovascular Angiography and Interventions.
- STS/ACC TVT Registry™ is an initiative of The Society of Thoracic Surgeons and the American College of Cardiology Foundation.

IV. NCDR Disclaimer for Abstracts and Manuscripts

- Authors must incorporate the following disclaimer statement within their manuscript:

  This research was supported by the American College of Cardiology's National Cardiovascular Data Registry (NCDR). The views expressed in this manuscript represent those of the author(s), and do not necessarily represent the official views of the NCDR or its associated professional societies identified at CVQuality.ACC.org/NCDR.

V. Use of NCDR Slide and Poster Templates

- PowerPoint slide and poster templates have been developed for authors who are visually presenting NCDR research findings. To ensure NCDR branding guidelines are followed and logos are used in accordance with ACC branding policy, authors are required to use ACC approved templates.
- Authors must include the following disclaimer in their abstract presentations:

  Oral Presentations and Slides: This research was supported by the American College of Cardiology's National Cardiovascular Data Registry (NCDR). The views expressed in this presentation represent those of the author(s), and do not necessarily represent the official views of the NCDR or its associated professional societies identified at *CVQuality.ACC.org/NCDR.*

  Poster Presentations: This research was supported by the American College of Cardiology's National Cardiovascular Data Registry (NCDR). The views expressed in this abstract represent those of the author(s), and do not necessarily represent the official views of the NCDR or its associated professional societies identified at *CVQuality.ACC.org/NCDR.*

APPENDIX E: SAMPLE CALL FOR DATA

How to read the Call for Data Schedule:

1. Quarter: Defined by the Discharge Timeframe or timeframe of follow-up (if applicable).

2. Patients Discharged: Patients with discharge or follow-up dates falling within each defined timeframe should be entered into the associated quarter. *Note: When editing/adding data for a previous quarter, the data for that quarter must be resubmitted to the DQR.*

3. Data Submission Deadline: The last day data can be submitted in order to be included in the Outcome Report for the quarter.

Call For Data	Discharge/Follow-up Timeframe	Data Submission Deadline 11:59PM EST
Q4	Oct 1, 2012 - Dec 31, 2012	Apr 15, 2013
Q1	Jan 1, 2013 - Mar 31, 2013	July 1, 2013
Q2	Apr 1, 2013 - June 30, 2013	Sept 30, 2013
Q3	July 1, 2013 - Sept 30, 2013	Jan 10, 2014
Q4	Oct 1, 2013 - Dec 31, 2013	Apr 15, 2014

APPENDIX F: SUGGESTED LANGUAGE FOR NCDR METHODS AND LIMITATIONS

NCDR Registry-Wide

Methods

The American College of Cardiology operates the National Cardiovascular Data Registry (NCDR), a comprehensive, outcomes-based cardiovascular quality improvement program encompassing both in-patient and ambulatory clinical registry programs. The NCDR programs use clinical data for the development and assessment of performance and quality metrics, quality improvement programs, and peer-reviewed outcomes research. The methods and quality metrics implemented in the NCDR have been published previously[1,2].

Data are captured electronically and submitted into a secure, centralized database. NCDR programs include robust data quality processes, including an independent audit program[3]. Details of NCDR data elements and definitions and participating sites are available on NCDR's website. A waiver of written informed consent and authorization for this study was granted by Chesapeake Research Review Incorporated.

Limitations

NCDR programs are voluntary; however, individual sites may participate based upon requirements from external stakeholders, such as regulators or insurance payers. Thus, the data and related study results reflect the centers/practices participating, and may not be generalizable to larger U.S. or non-U.S. practice. Although sites are expected to submit comprehensive data for all patients meeting registry inclusion criteria, some eligible patients may not be included. While applied research can improve care and clinical decision-making, observational data are subject to unmeasured confounding. However, demographic, clinical, treatment, procedural, and institutional data elements are available to adjust for potential confounding.

1. Rumsfeld JS, Dehmer GJ, Brindis RG. The National Cardiovascular Data Registry: Its' Role in Benchmarking and Improving Quality. U.S. Cardiology 2009;6:11-15

2. Masoudi FA, Ponirakis A, Yeh RW, Maddox TM, Beachy J, Casale PN, Curtis JP, De Lemos J, Fonarow G, Heidenreich P, Koutras C, Kremers M, Messenger J, Moussa I, Oetgen WJ, Roe MT, Rosenfield K, Shields TS, Spertus JA, Wei J, White C, Young CH, Rumsfeld JS. Cardiovascular Care Facts: A Report from the National Cardiovascular Data Registry – 2011. J Am Coll Cardiol. 2013 ;62:1931-1947.

3. Messenger JC, Ho KK, Young CH, et al. The National Cardiovascular Data Registry (NCDR) Data Quality Brief: the NCDR Data Quality Program in 2012. J Am Coll Cardiol. 2012 Oct 16;60(16):1484-8

APPENDIX G: EXTERNAL ACCESS TO NCDR RESEARCH UNDERGOING PEER REVIEW

Policy: The American College of Cardiology Foundation (ACCF) and its partner societies direct research activities under the National Cardiovascular Data Registry (NCDR) programs. A key component of these research activities is the peer review process. To facilitate peer review, the ACCF established Research and Publications (R&P) Subcommittees for each of the NCDR registry programs to develop and oversee processes designed to 1) maintain the autonomy and independence of the investigator(s); 2) provide reviews of research proposals, abstracts, and manuscripts that are timely, thorough, constructive, free from personal or organizational bias, and maintain the need for confidentiality; and 3) appropriately represent to the public the integrity of the ACCF and its NCDR partner societies in directing research.

The R&P peer review process takes under consideration many scientific factors, including the appropriate use of research methods; accuracy of calculations and application of logic; support for conclusions by evidence presented; consultation/citation of relevant literature; quality of research proposed or presented; and significance of proposed or presented research in contributions to the field of cardiovascular medicine. These processes are consistent with externally recognized standard-setting bodies in the conduct of health care research, including the U.S. Department of Health Services Office of Research Integrity.

Divergence from the established R&P peer review processes and policies can have unintended negative consequences, and, therefore, is significantly limited. Requests to allow external access to research must be submitted to the NCDR for consideration, and decisions are made on a case-by-case basis, but remaining in compliance with R&P peer review processes and policies. External access is defined as access to information from the point of a research proposal application (RPA) submission through publication of final results, and may include requests both from within the ACCF and the professional society registry partners that are external to the R&P process (e.g., policy, marketing, communications, etc.) or external to ACCF (e.g., funding agency reviews, professional societies, etc.).

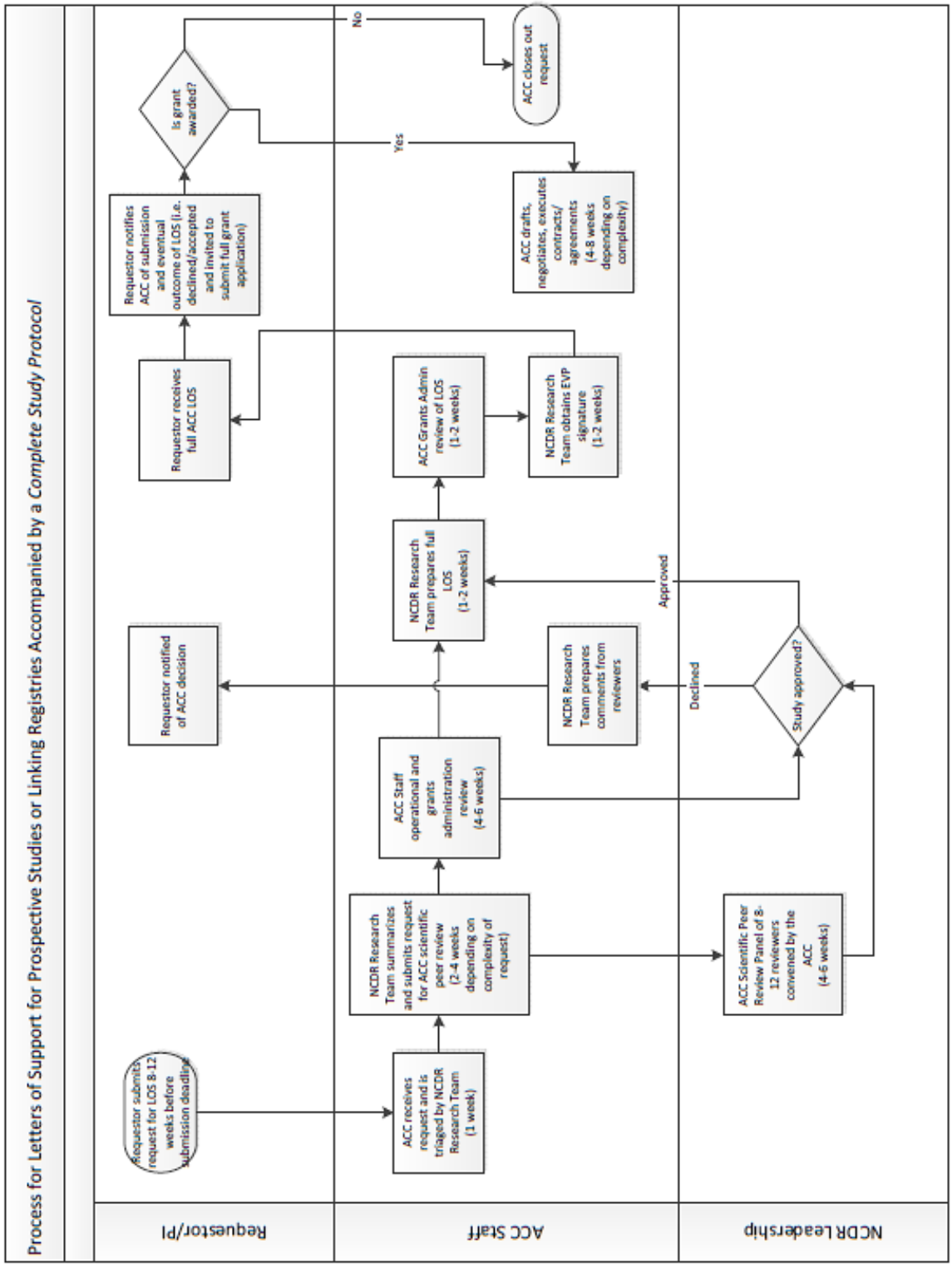
Requests must be submitted in writing stating the need and intended purpose(s) for access, the mechanism or processes by which external access will be managed, the proposed timelines, resources, and appropriate assurances of confidentiality. Any decision to allow external access must be unanimously approved by the NCDR Management Board Chair, the NCDR Chief Science Officer, the NCDR Science and Quality Oversight Committee Chair, and the Chairs of the relevant registry Steering Committee and R&P Subcommittee. The lead and senior authors will be informed of requests received and decisions made by NCDR. If a decision is made to allow external access, individuals involved in the external process may be required to provide information and assurances to ensure transparency and confidentiality are maintained, as well as compliance with the established NCDR R&P peer review processes and policies. In addition, the lead and senior authors will be notified when access to research is being granted at least 1 business day prior to the release of any information.

Version: 1.1

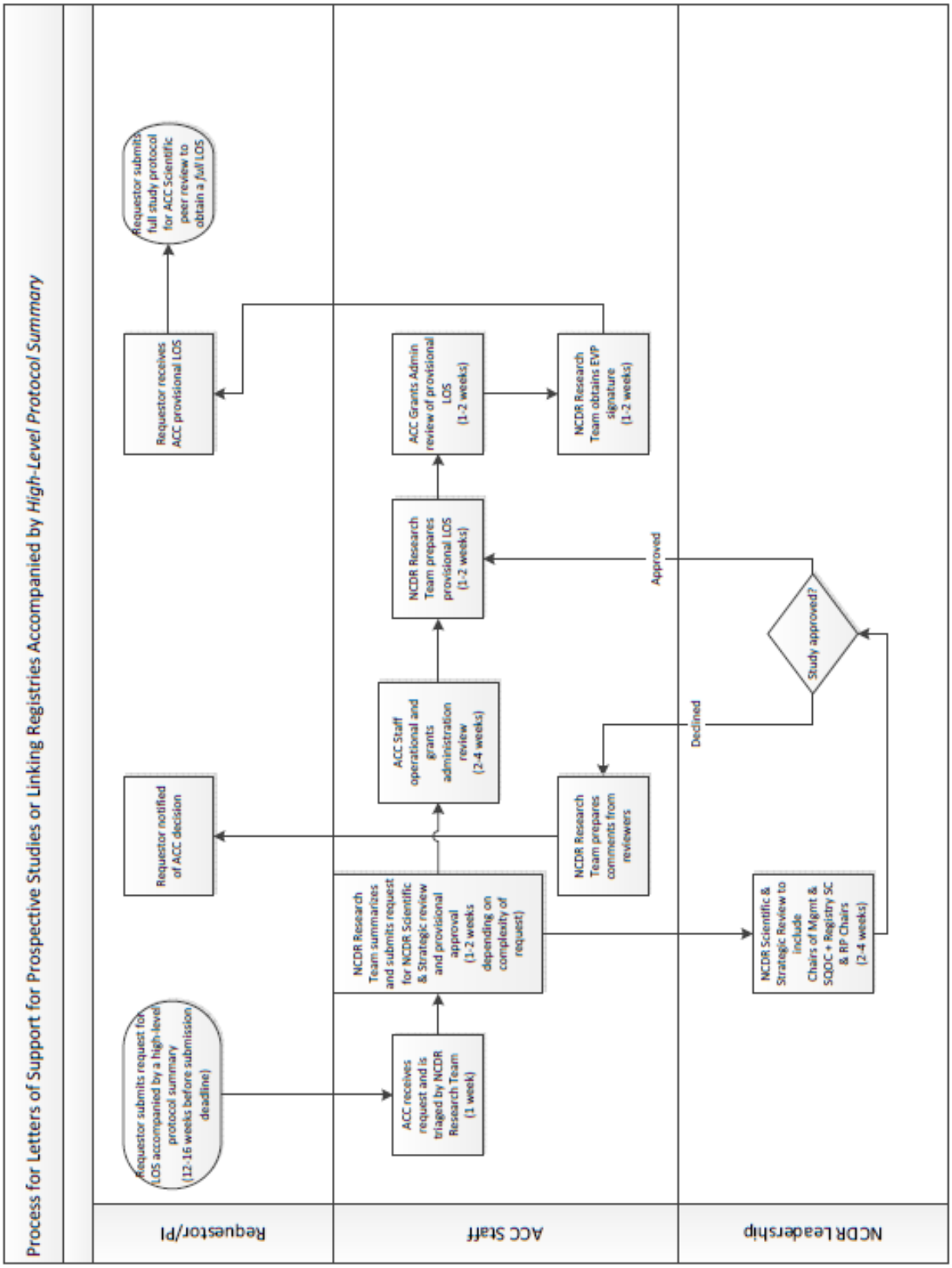
Effective Date: 8/24/11

APPENDIX H: PROCESS FOR OBTAINING A LETTER OF SUPPORT

When the potential investigator has a fully developed scientific protocol, a full Letter of Support from NCDR Leadership may be requested.



If a full protocol has not yet been developed, the potential investigator can submit a summary protocol that will be considered for a provisional letter of support.



APPENDIX I: LETTER OF SUPPORT CHECKLIST

Letter of Support Checklist

The following checklist is designed for individuals or organizations requesting a Letter of Support from the ACC for any study that proposes to link any ACC registry with an external data source, including but not limited to:

- Other registries
- Claims data
- EHR data
- Clinical trial data
- Survey data
- Prospectively collected data

The checklist is designed to help individuals or organizations understand and organize the necessary information and specific documentation required by the ACC in order to review these requests.

In order to receive a ***full*** Letter of Support from the ACC, the requestor is required to provide all of the information detailed in the tables below. Upon receipt of completed documentation, the ACC will convene an ACC Scientific Peer Review Panel that will evaluate the project and make a recommendation for approval.

If a requestor is only able to provide limited project information, the ACC may, at its own discretion, provide a ***provisional*** Letter of Support. The ACC will only provide a full Letter of Support for requests that are submitted with ALL required information and documentation and that have undergone the ACC's peer review process.

Please complete the following section:

Date of Request:	
Principal Investigator:	
Title of Project:	
RFA in response to: (Please provide RFA, PA or FOA Number)	
Application Due Date:	
PI's Internal Deadline:	
Co- Investigator(s):	
Key Personnel, if any:	
Human Subjects (Yes/No):	
Research Administration Contact:	

Please review the following list of required documentation. Please attach corresponding documents to address the information required in each section. If information is not available for a section, please include a document that provides an explanation or states "Not Applicable".

Required Documentation	Specific Information Required	ACC Comments to Requestor
Cover Letter to ACC Specifying Request	Request must include the following information: • What specific activity is the ACC being asked to support? • What are the expectations of the ACC regarding providing data? • How often would the ACC be required to provide data? • What is the total expected duration of the ACC's commitment to the project?	
Project Summary (Limited to 1-2 pages)	• Project Overview • Statement on the scientific merit of the proposed project. • Statement on the broader impacts of the proposed project.	Requestor must complete the Preliminary *Research Proposal Form Non-NCDR Funding Only*. This form can be found under Step 7 of this webpage: http://cvquality.acc.org/NCDR-Home/Research/Submit-a-Proposal/Steps-for-Submitting-a-Proposal.aspx

Full Project Description (Limited to 15-20 pages)	Request must include the following information:
	• Specific Aims
	• Research Strategy
	  ◦ Significance
	  ◦ Innovation
	  ◦ Approach
	• Limitations and Alternative Approaches
	• Timelines and Milestones, Expected Measurable Outcomes and Deliverables
	• Dissemination Plan
	• Bibliography	

Description of the External Data Source to be linked to the NCDR	The following questions should be addressed: • What is the external data source? Another registry, claims data, EHR data, survey data, clinical trial data, or other prospectively collected data? • Who owns the external data source? • What is the governance structure of the external data source? • Describe the proposed approach for linking the NCDR with the external data source. • Who will conduct the linkage? • How will the issue of missing or overlapping data elements be addressed?	
PI/Co-PI/Key Personnel Profile	Biosketches for the PI, Co-PI(s) and Key Personnel.	
Human Subjects	The following should be addressed: • Protection of Human Subjects? • Inclusion of Women and Minorities? • Inclusion of Children?	
Governance/Ownership of Resulting Linked Database	The following should be addressed: • Where will the resulting linked database reside? • What rights will the ACC have to the linked database? • How long will the linked database exist? • Is there a longer-term sustainability plan for the linked database?	The requestor understands that the governance, representation on any committees, authorship, operational and programmatic oversight will be mutually agreed upon by all parties.
Additional Consortium/Contractual Agreements	Please indicate if any additional consortium or contractual agreements will be required with any 3rd parties.	

Research & Publications	The following should be addressed: • How many manuscripts are expected from this project? • What additional Research and Publication policies apply? • What will be the funding source for publications? • What organizations and/or individuals will be conducting queries and/or statistical analyses?	• Requestor must review *Investigator's Guide to NCDR Research* document and ensure that ALL co-authors also receive and review the document. Below are highlights from the *Investigator's Guide* • Requestor must submit a Research Proposal Application (RPA) for *every* manuscript utilizing the online NCDR Research Management System well in advance of any intended journal submissions. • Requestor will be responsible for communicating to co-authors about RPA requirements, timeline expectations for completion of manuscript(s). • Requestor will communicate revisions resulting from the NCDR R&P review of abstract and manuscript drafts to co-authors and oversee completion of required revisions. • Requestor understands that it is ACC policy that NCDR R&P Subcommittees **review and approve** the final draft of a manuscript that is ready for submission to a journal. • If approval is not obtained prior to submission of abstract or paper, the paper will need to be withdrawn; ACC staff will determine if termination of the RPA is appropriate.

APPENDIX J: SCIENTIFIC REVIEW FOR NON-NCDR-PROPOSALS

Updated: 2014

1. NCDR scientific review and approval of all research proposals that involve the use of NCDR data is mandatory, based on ACC policy for scientific oversight and related to the legal obligation for oversight of all data and related research in NCDR program contracts with hospitals/practices.
2. ACC staff identifies when there is a need for scientific review of a **non-NCDR-supported** proposal or grant application.
3. The NCDR leadership team helps identify clinical and methodologic subject matter experts with grant review experience to serve on the ACC peer review group. Primary sources of peer reviewers are active NCDR committee members and data analytic center methodologists.
4. An invitation email is then sent from ACC staff to potential reviewers, specifying:
    a. Charge - primary goals of the review and any specific questions to address;
    b. Timeline - no less than two weeks is deemed a reasonable 'ask' of ACC volunteers.
    c. Feedback requested - reviewers are asked to provide overall comment(s) on proposal scientific priority and to provide specific comments for any scientific concern(s)/questions to be addressed. Where possible, reviewer comments should be classified as major or minor comments; reviewers may also note 'operational', comments to be addressed by ACC staff (e.g. regarding budget, governance, etc.). Reviewers may be asked to provide an overall recommendation whether ACC should pursue the project. Reviewers will disclose any relevant COI in serving as a reviewer for a given proposal.
5. ACC staff distributes the proposal to those who opt in to serve as reviewers. This initiates the proposal review period. Reviewers will be reminded of the confidential nature of the reviews, and that the proposal is not to be further distributed or discussed. Staff will offer an optional phone call to clarify process steps and timeline among reviewers, but this will not be a group discussion of proposal specifics, so that reviews remain independent.
6. ACC staff collects the individual reviews, which need to be collated and then reviewed in detail to identify common comments/themes, major comments, minor comments (or any comments that do not appear to be relevant to include in a summary), and overall recommendation from each reviewer, where provided. ACC staff will support the collation of reviewer feedback/comments, and the NCDR leadership team will then oversee the summation of comments to identify those that will be included in the overall review (major/minor), and synthesize the overall recommendation to ACC. Staff will identify if any reviewers are not able to meet timeline and work with NCDR leadership to consider whether to extend review period or forgo that reviewer's input.
7. If needed, ACC will seek clarifying comments from peer reviewers, or, if the situation dictates, may seek additional external review from a methodologic expert. Clarifying comments may also be sought from the proposal investigators, as needed (e.g. if the review group has points of clarification/confusion that may be more efficiently resolved than providing them as review comments).
8. The summary review and specific comments will be provided to the proposal investigators, and may be provided to the NCDR Management Board and /or ACC Board of Trustees Executive Committee, depending on the specific situation (e.g. if the project is a collaboration with external entities, versus being investigator-initiated).