Investigator's Guide to NCDR® Research

Version 2.0

AMERICAN COLLEGE of CARDIOLOGY®

Heart House
2400 N St. NW, Washington, DC 20037
1-202-375-6000 | 1-800-253-4636 | Fax: 1-202-375-6842
ACC.org

Dear NCDR Investigator:

Welcome to the American College of Cardiology's (ACC) NCDR® (National Cardiovascular Data Registry) Research Network. The NCDR was established to empower hospitals and private practices to measure and enhance the quality of cardiovascular care. For over 25 years, ACC's NCDR registries have enabled hospitals, health systems, centers, and practices to access data-driven insights, analysis, and research. These resources guide clinical and operational decisions, helping cardiovascular care teams deliver optimal care to every patient, every time. With a growing patient population, the NCDR Research Network continues to explore critical questions about cardiovascular health and care delivery.

Primary investigators, research groups, government agencies, and industry representatives are encouraged to submit research proposals utilizing data from the NCDR registries. Each proposal receives a thorough scientific review. Proposals that pass the initial review are considered for analysis and potential peer-reviewed publication. The NCDR provides funding for a limited number of studies annually. Due to high demand, support is competitive. Funding decisions are based on available resources and each registry's strategic research priorities.

We welcome your participation and ask that you review these policies and procedures to apply them throughout the research process.

Sincerely,

Fred Resnic, MD, FACC
Chair, NCDR Oversight Committee

Fran Thorpe, DrPH, MPH
Senior Director, NCDR Research & Analytics
Clinical Registries & Accreditation

President
Christopher M. Kramer, MD, FACC

Vice President
Roxana Mehran, MD, FACC

Immediate Past President
Cathleen Biga, MSN, MACC

Treasurer
Akshay K. Khandelwal, MD, MBA, FACC

Secretary and Board of Governors Chair
David E. Winchester, MD, MS, FACC

Board of Governors Chair-Elect
Renuka Jain, MD, FACC

Trustees
Lee R. Goldberg, MD, MPH, FACC
Bonnie Ky, MD, MSCE, FACC
Sandra J. Lewis, MD, FACC
Thomas M. Maddox, MD, MSc, FACC
Andreas Merkl, MBA
Pamela B. Morris, MD, FACC
Hani K. Najm, MD, MSc, FACC
Samuel O. Jones, IV, MD, MPH, FACC
Geoffrey A. Rose, MD, FACC

Chief Executive Officer
Cathleen C. Gates

The Mission of the American College of Cardiology and the American College of Cardiology Foundation is to transform cardiovascular care and improve heart health for all.

CONTENTS

1 | Overview 4
2 | NCDR Registries 5
3 | NCDR Policies 7
4 | NCDR Procedures: Requesting NCDR Funding 11
5 | Applying with Non-NCDR Funding 19
6 | Applying For NCDR Data Request 25
7 | Industry Collaborative Pathway 27
8 | Publication Requirements 28
9| Responsibilities of the Primary Author 34
10 | Conclusion 38
11| Bibliography 39
Appendix A: Additional References and Helpful Links 40
Appendix B: Datasets and Linked Data Information 41
Appendix C: NCDR Research Proposal Application Frequently Asked Questions 47
Appendix D: NCDR Brand and Style Guide for Research and Publications 49
Appendix E: NCDR Funded Research Proposal Application 51
Appendix F: Suggested Language for NCDR Methods and Limitations 55
Appendix G: External Access to NCDR Data 56
Appendix H: Externally Funded Project Application Form 57
Appendix I Real World Evidence Data Request Form 61
Appendix J: Grant Funded Project Application Form 63
Appendix K: NCDR Funded Research Checklist 67
Appendix L: ACC Externally Funded Research Checklist 68
Appendix M: Memo of Understanding for Externally Funded Research 70
Appendix N: Letter of Support Request Form 73

1 | OVERVIEW

This guide offers prospective authors a comprehensive overview of research opportunities within NCDR. It introduces the application, review, and publication processes for research proposals, and is organized by sections that describe the eight cardiovascular data registries and the ACC's overall research approach. The document details the policies that research applications must follow and outlines expectations for primary authors upon approval. Appendices provide essential resources for authors at every stage of the Research Proposal Application (RPA) process, including Frequently Asked Questions (FAQ) and required style guides. Additionally, links to helpful external resources are included.

NCDR RESEARCH AND PUBLICATIONS OVERVIEW

Aligned with its mission, NCDR invites individual authors and organizations to submit Research Proposal Applications (RPAs) to advance cardiovascular care through the analysis of registry data and publication in peer-reviewed journals. This resource offers authors a clear overview of NCDR research and publication process, guiding them from proposal submission to manuscript publication. **All authors must follow these guidelines** when preparing proposals, abstracts, and manuscripts.

RPAs are hypothesis-driven studies using secondary analyses of NCDR data, aiming to produce manuscripts suitable for peer-reviewed publication. All analyses utilize HIPAA-compliant Limited Data Sets and are conducted by ACCF -approved Data Analytic Centers (DACs). Patient, hospital, and physician confidentiality are strictly maintained. Every project is overseen by the NCDR Research & Publications committees to ensure compliance with data access and use policies, as well as all relevant regulations.

Authors interested in conducting studies must submit a formal RPA through the NCDR's online research portal using ACC.org credentials. To maximize the likelihood of acceptance, follow the guidelines below before drafting your research proposal application.

2 | NCDR REGISTRIES

AFib Ablation Registry™: Assesses prevalence, demographics, acute management, and outcomes from patients undergoing atrial fibrillation (AFib) ablation procedures

CathPCI Registry®: Captures data on patients undergoing diagnostic catheterization and/or percutaneous coronary intervention (PCI)

Chest Pain - MI Registry®: Captures data on acute myocardial infarction (AMI) patients and patients with acute coronary syndromes

The CV ASC Registry Suite®: is the first-of-its kind to easily provide data-driven insights on cardiac procedures performed in the ambulatory setting

EP Device Implant Registry®: Captures data on patients receiving implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy (CRT) devices

IMPACT Registry®: Captures data on pediatric and adult patients with congenital heart disease who undergo diagnostic and interventional catheterizations

LAAO Registry™: Assesses real-world procedural outcomes, short- and long-term safety, comparative effectiveness and cost effectiveness from patients undergoing left atrial appendage occlusion (LAAO) procedures

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

CHOOSE THE APPROPRIATE REGISTRY FOR YOUR RESEARCH

ACC's suite of NCDR registries focuses on clinical characteristics, care processes, and outcomes across a wide range of cardiovascular conditions and procedures. Data Collection Forms (DCF) and Data Dictionaries for each registry are available on the NCDR website. When developing a research proposal, primary authors should review the relevant DCF and data dictionary to ensure the necessary data are collected by the registry.

**See Appendix B to review additional information pertaining to NCDR datasets.*

3 | NCDR POLICIES

POLICIES GOVERNING ALL NCDR RESEARCH

CHECK FOR OVERLAP

NCDR does not approve RPAs that substantially overlap with topics previously studied. Registry-specific lists of published manuscripts, presented abstracts, and ongoing unpublished projects are available in the "Resources and Supplemental Documentation" section of the online NCDR Research Portal or at ACC.org. If externally funded RPAs submitted during a review cycle raise concerns about potential overlap with a proposed NCDR-funded RPA, these situations are evaluated on a case-by-case basis. Generally, externally funded RPAs are given priority over proposed (not yet awarded) NCDR-funded RPAs.

THE "RULE OF TWO"

To promote equitable access and analytic opportunities for all researchers, NCDR established the "Rule of Two." This policy limits each primary author to a maximum of two (2) active proposals in the NCDR research pipeline at any given time. An active proposal is defined as one that has been submitted for committee review under any of the four general NCDR research opportunities or has been approved but not yet published. A proposal remains active until it is formally closed, declined, or results in publication of an approved manuscript in a peer-reviewed journal.

If a primary author has submitted two proposals for review, both need to go through the appropriate review process before submitting another proposal. If both RPAs are approved and move forward to analysis, the primary author cannot submit another RPA until at least one of the 'active' proposals has resulted in a manuscript publication or been closed out through the appropriate channels.

USE OF ARTIFICIAL INTELLIGENCE (AI) IN RESEARCH PROPOSAL DEVELOPMENT

Disclosure Requirement Applicants must disclose any use of artificial intelligence (AI) tools, techniques or systems in the development of their research proposal, including but not limited to assistance with writing, editing, statistical analysis, data summarization, literature synthesis, or methodological design. This disclosure must be included in the designated section of the application.

Purpose of Disclosure The purpose of this requirement is to ensure transparency in the proposal development process and to maintain the integrity, originality, and accountability of all submitted materials.

Acceptable Use AI tools may be used to support proposal development; however, applicants remain fully responsible for the accuracy, validity, and originality of all content submitted. AI-generated text or analysis must be reviewed, verified, and appropriately integrated by the applicant.

Prohibited Use AI tools may not be used to fabricate data, generate false citations, or create misleading or unverifiable scientific claims. Any such use will result in disqualification from the application process and may impact eligibility for future submissions.

Applicant Responsibility By submitting a proposal, applicants affirm that:

- All AI use has been fully disclosed.
- All content has been reviewed and validated by the applicant.
- The proposal reflects the applicant's own intellectual contributions and scientific judgment.

Non-Disclosure Failure to disclose the use of AI tools may result in administrative action, including rejection of the proposal or removal from consideration.

ONE MANUSCRIPT PER RESEARCH PROPOSAL APPLICATION

Each approved RPA may yield only one manuscript. If research leads to multiple manuscripts, separate RPAs must be submitted for each. Primary authors cannot request additional analyses that fall outside the original RPA's scope. Grants, industry collaborations, or other projects intending to produce multiple manuscripts are evaluated individually. However, no individual is permitted to have more than two manuscripts in progress at any time.

NCDR DEVICE POLICY

Research proposals examining comparative effectiveness or comparing generic device categories (e.g., drug-eluting versus bare-metal stents, or ICD versus CRT) are permitted, provided that no specific product can be identified.

Examples of identification methods not permitted include, but are not limited to:

- When a product type is exclusive to a single manufacturer.
- When a product size (diameter, width, or length) is exclusive to a single manufacturer.
- When a product's specific use or location is exclusive to a single manufacturer.
-
- Research proposal applications (RPAs) that primarily analyze manufacturers or brands.
- When a specific product, product type, or manufacturer can be identified through any of the following:
    - Name identification,
    - Brand identification,
    - Market share,
    - Indication for use,
    - other method(s) not listed here

Proposals that include direct comparisons between specific devices are not permitted. Research proposal applications that focus on manufacturer- or brand-specific analyses will be rejected and not reviewed through the NCDR process. However, these RPAs may be resubmitted for consideration if manufacturer- or brand-specific variables are removed.

Collaborative research between manufacturers or brands may occur outside the ACCF's standard NCDR research review process. These projects are conducted independently and are not reviewed or supported by the ACCF.

HUMAN SUBJECTS RESEARCH AND NCDR

Protecting human research subjects is of utmost importance. The ACC maintains a Federal-Wide Assurance with the Department of Health and Human Services (HHS), requiring all human subjects research to comply with the HHS Common Rule (45 CFR 46). Advarra, Inc. (formerly Chesapeake IRB) serves as the institutional review board (IRB) of record for all NCDR registries. Each registry has an approved protocol on file with Advarra, governing all human subjects research conducted through the registries.

All current registry protocols have been granted a waiver of informed consent. NCDR staff liaisons regularly review projects to ensure proposed research aligns with the protocol on file for each registry. If a research proposal falls outside the scope of the existing protocol, the staff liaison will collaborate with the primary author to determine the next appropriate steps. Any required separate approvals must be obtained before research can begin. For questions regarding the ACC's Human Research Subjects Protection policies, contact ncdrresearch@acc.org.

GUIDELINES FOR CONDUCTING SCIENTIFIC RESEARCH ON RACIAL AND ETHNIC DISPARITIES

Since 2022, NCDR has required all RPAs addressing racial and ethnic disparities to comply with the American Heart Association's Disparities Research Guidelines. These guidelines establish a consistent framework for language and scientific methods in health equity research.

Primary authors must review the Disparities Guidelines Checklist and incorporate its steps before submitting their RPA. All research must align with these guidelines, which will also be used by reviewers when evaluating proposals, abstracts, and manuscripts.

The following statements must be included in the RPA:

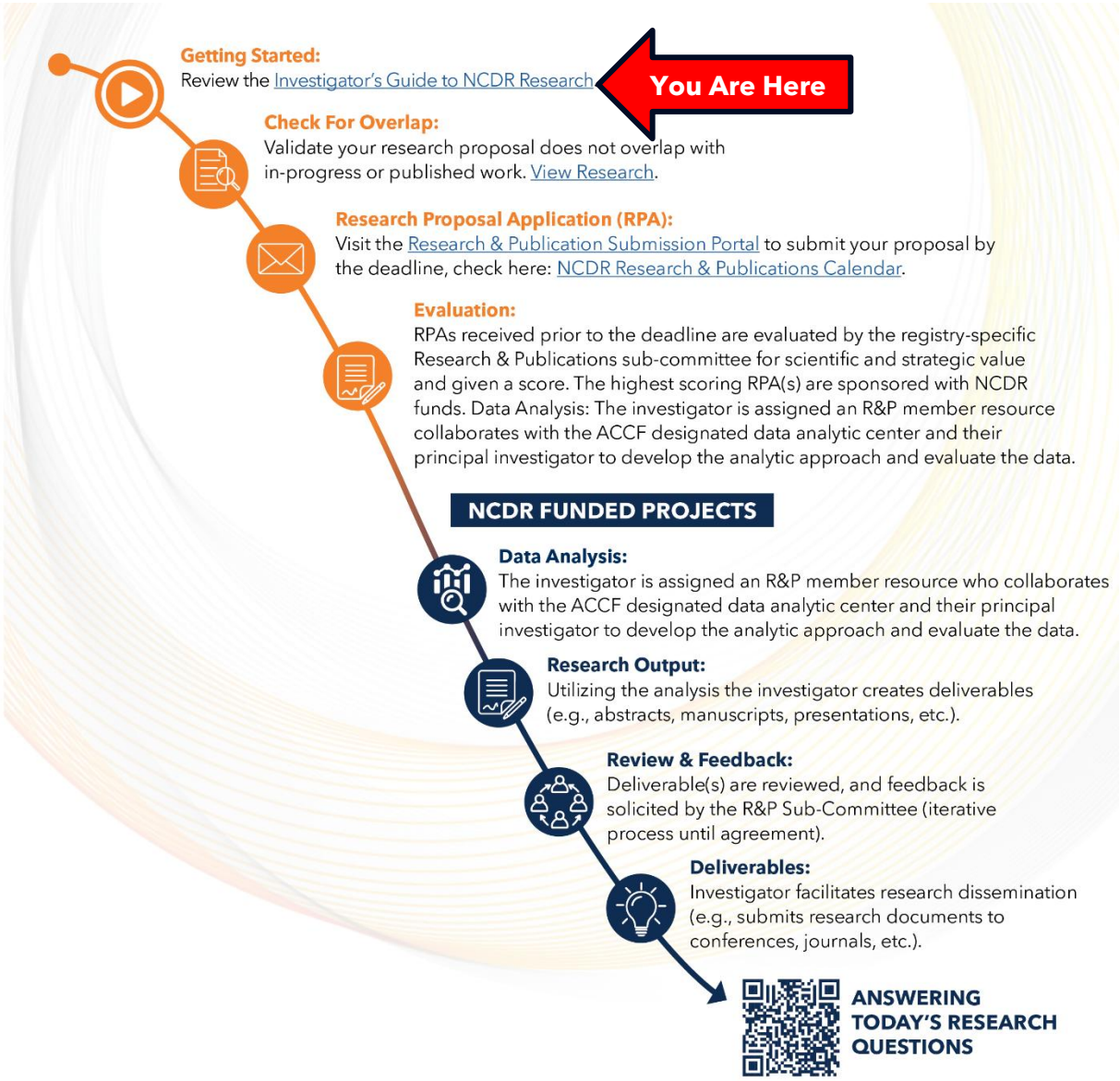
My RPA focuses on reporting health disparities by race and/or ethnicity.

☐ *Yes* ☐ *No*

I acknowledge that I have reviewed the American Heart Association's Disparities Research Guidelines and will align research proposals addressing race and/or ethnicity with these guidelines.

☐ *Yes* ☐ *No*

4 | NCDR PROCEDURES: REQUESTING NCDR FUNDING



PREPARING TO SUBMIT A RESEARCH PROPOSAL APPLICATION

ACCF funds a limited number of research proposals each year. Competition is intense, and final funding decisions are based on multiple factors, including scientific merit, novelty of the research question, methodological rigor, feasibility, available resources, and alignment with each registry's strategic research priorities.

Primary authors seeking **NCDR funding** must review the following sections:

3 | Independent Investigator Pathway
4 | Applying for NCDR- Funding
9 | Responsibilities of the Primary Author

SUBMITTING A RESEARCH PROPOSAL APPLICATION

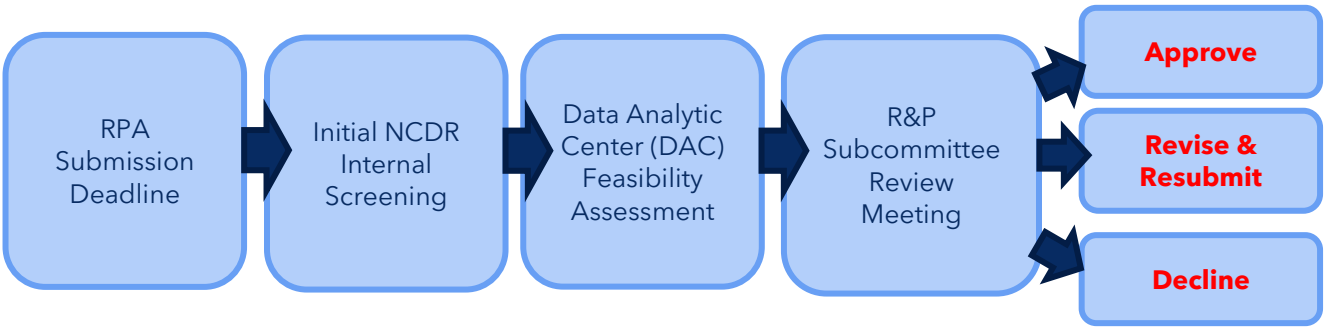
Research proposals must be submitted electronically through the NCDR Research Portal (rp.acc.org) using an ACC username and password. The portal provides a range of resources to help users navigate the submission process.

After a proposal is submitted and processed, the Primary Author will receive an email with the assigned RPA ID number. Include this ID in the subject line of all related email correspondence.

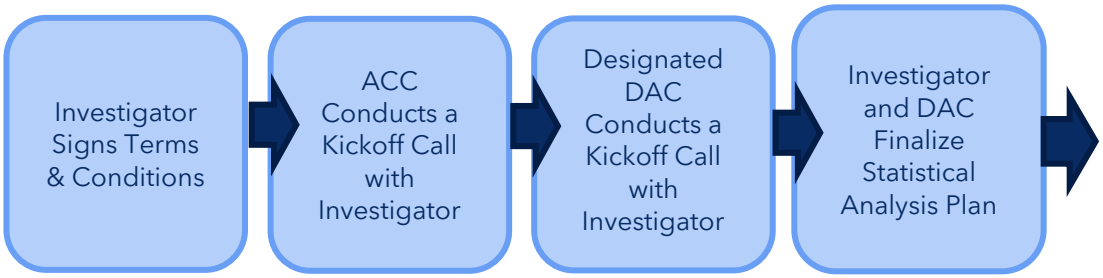
**Note: The "Primary Author" listed on the RPA is considered the research team's Primary Investigator (PI).*

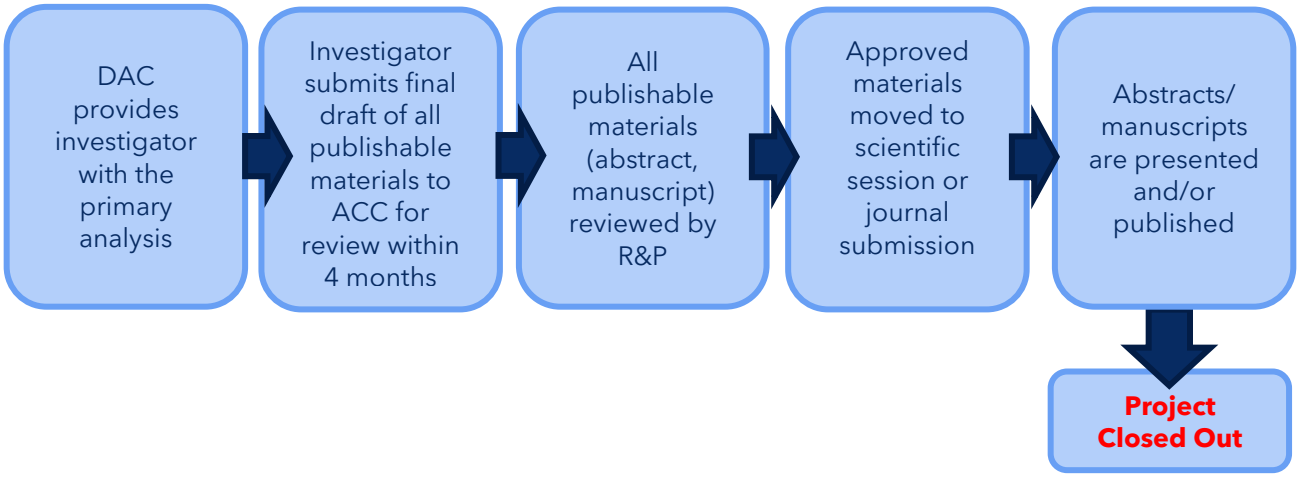
RESEARCH AND PUBLICATIONS PIPELINE

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



Approved RPAs:





RESEARCH PROPOSAL APPLICATION SUBMISSION DEADLINE

Each NCDR registry has its own Research & Publications (R&P) Subcommittee, which reviews research applications one to two times per year according to the annual NCDR Research Review Calendar. RPAs received after the submission deadline are held for review in the next submission cycle. Specific deadlines for each registry are posted on the NCDR Research Calendar at the ACC Research website. Applications must be submitted **by 11:59 PM EST** on the deadline day. As these deadlines are publicly posted, authors are expected to comply; **no extensions will be granted**. Any interested authors may submit a research proposal through the ACC Research Portal.

Primary authors are strongly encouraged to use the checklist in Appendix K before submitting their application and throughout the research process.

INITIAL SCREENING

All submitted RPAs undergo an initial screening by NCDR staff liaisons and R&P subcommittee chairs to assess duplication, priority, and compliance with NCDR policies and agreements. This review includes, but is not limited to, linkage requests, direct comparisons of medical device or pharmaceutical data, and the "Rule of Two" (i.e., a lead author may have no more than two active proposals at any time). RPAs deemed inappropriate at any screening stage will not proceed further; applicants will be notified of the decision without additional review.

RPAs approved during initial screening are forwarded to the designated NCDR Data Analytic Center (DAC) for evaluation of feasibility and overlap. This serves as the final screening step before R&P subcommittee review.

R&P SUBCOMMITTEE REVIEW

R&P subcommittee members evaluate each RPA before the next subcommittee review meeting using the following criteria:

- Significance: The potential for the project to make an original and meaningful contribution to the field if completed successfully.
- Feasibility: The availability of required data fields, adequacy of reporting rates, and the likelihood that the project can be completed within the proposed timeline and budget.
- Methodology: The degree to which the conceptual framework, study design, methods, and analyses are well-developed, integrated, and appropriate for the study's aims. The review ensures that methods suitable for observational research are used, and that findings are framed as associations rather than implying causation from statistical relationships.

- Overall Score: Committee members assign an overall score to the RPA on a ten-point scale, considering all criteria above.
- Comments: Committee members and primary reviewers provide specific feedback on the RPA.

Approved: Each year, ACCF funds a limited number of proposals, with the total varying based on the annual budget. Proposals are selected to move forward with analysis and publication based on their priority scores of an 8 or above (out of 10) from the R&P subcommittees.

After approval, the primary author must review and sign the NCDR Terms and Conditions, outlining their roles and responsibilities during the research process. Once approved, the proposal topic or analytic scope cannot be changed without resubmitting an updated RPA for review. For more details, see the section below on Additional *Data Analysis for Approved RPAs*.

Revise & Resubmit: If a proposal is not approved but scores between 4 and 7 (out of 10), the committee may invite the author to revise and resubmit the proposal within **30 days of receiving the revision request**. Authors should carefully review the committee's feedback, focusing on critical issues identified during discussion. Recommended actions may include refining the research rationale or feasibility analysis, adjusting specific aims, or revising the study design, statistical methods, or author team. Revised proposals must be submitted at rp.acc.org within 30 days. Proposals not resubmitted within this window will be declined and closed.

Declined RPAs: Proposals that receive a score of 4 or below are not approved. The primary author receives an unedited copy of the committee's reviews explaining the decision. These proposals are closed in the system, and revision is not permitted.

The table below provides the analysis process for R&P Committee approval of NCDR Funded RPAs.

Table 1: Analysis Process for Approved NCDR Funded RPAs

	Steps	Assumptions
1	Resubmit final RPA to NCDR	• Once an RPA is approved, the author 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 liaisons and the DAC. If there are no comments, the existing RPA will be considered the final version. • The primary author must communicate the following to all co-authors: the background, hypothesis, intended tables, figures, summary statistics and proposed

		analytic approach in the RPA based upon the R&P committee review and comments.
2	DAC receives the final RPA	• If needed, the statistician will contact the primary author to discuss any outstanding questions or issues.
3	Statistician and DAC staff member discuss the analysis plan with the primary author	• DACs schedule a conference call with the primary author to discuss the draft analysis plan. • The DAC statistician will finalize the analysis plan according to the revisions discussed during the conference call. • The author is responsible for circulating the final statistical analysis plan among the co-authors listed on the manuscript draft, which generally includes the primary authors listed on the approved RPA. • If an abstract is to be produced, the statistician will prepare and send a reduced statistical report to the primary author to support an abstract submission.
4	Statistician prepares and sends the results of the data analysis to the primary author	• The DACs perform a data analysis that contains all the information specified in the analysis plan (e.g., information, summary data, and statistical tests). • The primary author is required to send an email to NCDR R&P staff liaisons and the DAC confirming receipt of analyses. • The primary author should plan to prepare the first draft of the manuscript based on the results of the original primary data analysis. No additional analyses can be requested or conducted until after the first draft of the manuscript is reviewed by all co-authors and the R&P committee.
5	Primary author writes the first manuscript draft within one month of receiving the results of the data analysis	• The primary author is required to circulate the draft of the manuscript to the DAC first, then to all co-authors. NCDR should only receive final manuscripts for review. • All manuscripts must be ready for journal submission <u>within four months</u> of receiving the initial data analysis. This includes reviews by the DAC and co-authors before NCDR R&P review and approval.

DATA ANALYSIS FOR APPROVED RESEARCH

NCDR maintains contractual agreements with participating hospitals, permitting ACCF-approved Data Analytic Centers to access and analyze registry data. After an RPA is approved, the NCDR staff liaison coordinates with the assigned DAC to establish an analysis completion date. DAC staff will reach out to the primary author within several weeks to schedule an initial call and discuss the analytic approach and statistical analysis plan.

The assigned statistician will review tables and statistical outputs during draft preparation and provide ongoing support, including validating variable counts, interpreting data, and reviewing abstract and manuscript content as needed.

ADDITIONAL DATA REQUESTS FOR APPROVED RESEARCH

Discussion with the DAC during statistical analysis plan drafting may result in the author wanting to pursue additional statistics outside of the original scope of the project. Any statistical requests outside of the original scope of the approved research proposal must be resubmitted to the NCDR R&P subcommittee for review and approval prior to any work being done. DACs will not provide additional statistics without NCDR approval first.

Journal reviewers may sometimes request additional statistical analyses. If these requests fall outside the original project scope, authors must submit a new RPA following the resubmission process described above. For requests within the original research scope but outside the allocated budget, an Ad Hoc Request must be submitted by the DAC to the NCDR for review and approval. Ad hoc hours for journal requests are limited and highly competitive; **ad hoc hour requests for projects older than three years will not be considered**. This policy highlights the importance of following the NCDR's four-month drafting policy to ensure timely submission of data to journals.

STRATEGIC NCDR FUNDING PROCESS

STRATEGIC RESEARCH APPLICATION PROCESS

ACCF has established a separate review process for research considered strategic to the NCDR's mission of helping hospitals and private practices measure and enhance the quality of care. There is no predetermined number of strategic manuscripts; instead, proposals are evaluated and selected on a rolling basis to ensure optimal allocation of available resources.

All strategic research proposals are submitted to the NCDR Oversight Committee, as well as the relevant registry Steering and Research & Publications Sub-Committees. NCDR staff liaisons will coordinate to identify and combine overlapping or duplicate RPAs. No single committee's decision takes precedence; if any committee determines a proposal is not strategic or feasible, that decision stands - particularly in cases of potential conflicts of interest. Two approaches are used to review these proposals:

- Funding is awarded on a first-come, first-approved basis. If funds are exhausted within the first two months, subsequent projects will not receive strategic research funding.
- ACC recognizes the importance of promptly disseminating strategic research. Accordingly, this separate review process is designed to enable faster turnaround

times compared to the traditional NCDR-funded process. Both administrative review and, if approved, the subsequent analysis and manuscript drafting phases are accelerated. The primary author is contractually required to submit a manuscript draft within two months of receiving the analysis. If this timeline is not met, ACC reserves the right to reassign the project to a new primary author.

5 | APPLYING WITH NON-NCDR FUNDING

PREPARING TO SUBMIT A RESEARCH PROPOSAL APPLICATION

Primary authors who have secured **external funding** are required to review the following sections:

2 | Research Proposal Application Publication Requirements
4 | Responsibilities of the Primary Author
5 | Externally Funded Research

Primary authors interested in obtaining a **letter of support** are required to review:

2 | Research Proposal Application Publication Requirements
4 | Responsibilities of the Primary Author
5 | Externally Funded Research
6 | Letter of Support for Grant Funded Research

SUBMITTING A RESEARCH PROPOSAL APPLICATION (RPA)

Primary authors may leverage NCDR data for projects supported by external funding, including federal or foundation grants, industry support, or institutional funding. Externally funded RPAs are reviewed through a distinct process overseen by NCDR leadership and governed by separate contractual and financial agreements.

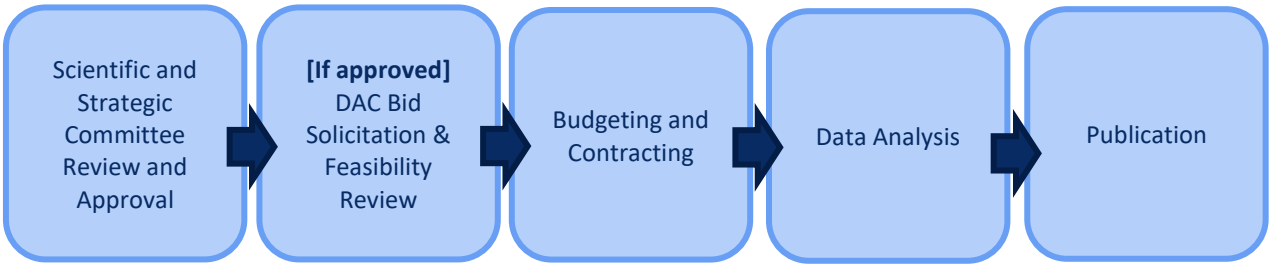
Externally funded projects are accepted on a rolling basis and may be submitted at any time. Primary authors must complete the Externally Funded RPA Form (Appendix H) and submit it to NCDRresearch@acc.org.

Primary authors are should use the checklist in Appendix L throughout the research process to ensure compliance with all requirements.

EXTERNALLY FUNDED RESEARCH PROPOSAL APPLICATION REVIEW

Figure 3 provides an overview of the RPA review and approval process for externally funded proposals.

Figure 3: Externally Funded RPA Review and Approval



SCIENTIFIC AND STRATEGIC COMMITTEE REVIEW AND APPROVAL

Externally funded research proposals must undergo Scientific and Strategic (S&S) review and approval. This process ensures that proposals demonstrate scientific merit, involve credible partners, and provide strategic value to NCDR. Contractual agreements with participating NCDR sites require scientific oversight of all secondary uses of NCDR data and associated research.

If an NCDR author's RPA requests linkage between NCDR and an external database, ACCF approval does not substitute for approvals required by governing bodies of the external data source. The primary author is responsible for obtaining and providing written proof of all necessary approvals directly from those organizations.

EXTERNALLY FUNDED RESEARCH OVERSIGHT

Following S&S approval, the Chair of the NCDR Oversight Committee may appoint an ACC member to oversee the proposal. This individual will offer subject-matter expertise and guidance on NCDR requirements. Primary authors will be provided with the appointed member's name and contact information after approval.

DATA ANALYTIC CENTER (DAC) BID SOLICITATION & FEASIBILITY REVIEW

Following S&S approval, the NCDR staff liaison will request bids from contracted DACs. During the bidding process, each DAC conducts a feasibility review of the RPA. If the project is found feasible, the DACs can submit bids, which are then used to inform the overall budget and contract development process.

The decision on which a DAC is selected is the purview of ACC. Authors are not permitted to request a specific DAC.

BUDGETING AND CONTRACTING

BUDGET

NCDR will provide a budget estimate to the primary author, based on the complexity of the request and including both data analytic center and ACC fees. Before receiving a budget estimate, primary authors should be prepared to answer the following questions:

1. What is the funding source? *(e.g., industry, grant, institutional, etc.)*
2. Has funding been secured? If not, when is it expected to be available?
3. Are there any deadlines for spending the funding? If so, please specify and indicate whether these deadlines are flexible.

TYPES OF SUPPORT

LETTER OF SUPPORT FOR GRANT FUNDED RESEARCH

Primary authors applying for grant funding may be required to submit a Letter of Support (LOS) from ACCF. Because the LOS request process can be time-consuming, primary authors should plan ahead. Before **submitting a request to NCDR**, **authors must review the full and provisional LOS procedures outlined in Figures 4 and 5 below.**

PROVISIONAL LETTER OF SUPPORT

If a requester can only provide limited project information, ACCF may, at its discretion, issue a ***provisional*** Letter of Support (LOS).

To receive a provisional LOS, the following documents are required:

- Grant Funded Project Application Form (Appendix J)
- Memo of Understanding for Externally Funded Research (Appendix M)
- Letter of Support Request Form (Appendix N)
- High-Level Protocol Summary

Primary authors interested in submitting a request for a Provisional LOS must submit the Grant Funded Project Application Form, Memo of Understanding for Externally Funded Research, High-Level Protocol Summary forms, and a Letter of Support Request Form together to NCDRresearch@acc.org.

FULL LETTER OF SUPPORT

To obtain a ***full*** Letter of Support (LOS) from the ACCF, the requester must provide the following documents:

Required documents for a full LOS:

- Externally Funded RPA Form (Appendix H)
- Letter of Support Request Form (Appendix L)
- Complete Study Protocol

Once all required documents are submitted, the ACC will convene an NCDR Scientific Peer Review Panel to evaluate the project and make an approval recommendation. Primary authors should consult Figure 4 for an overview of the full LOS process.

For questions or additional information, please contact: NCDRresearch@acc.org.

Figure 4: *Provisional* Letter of Support Process

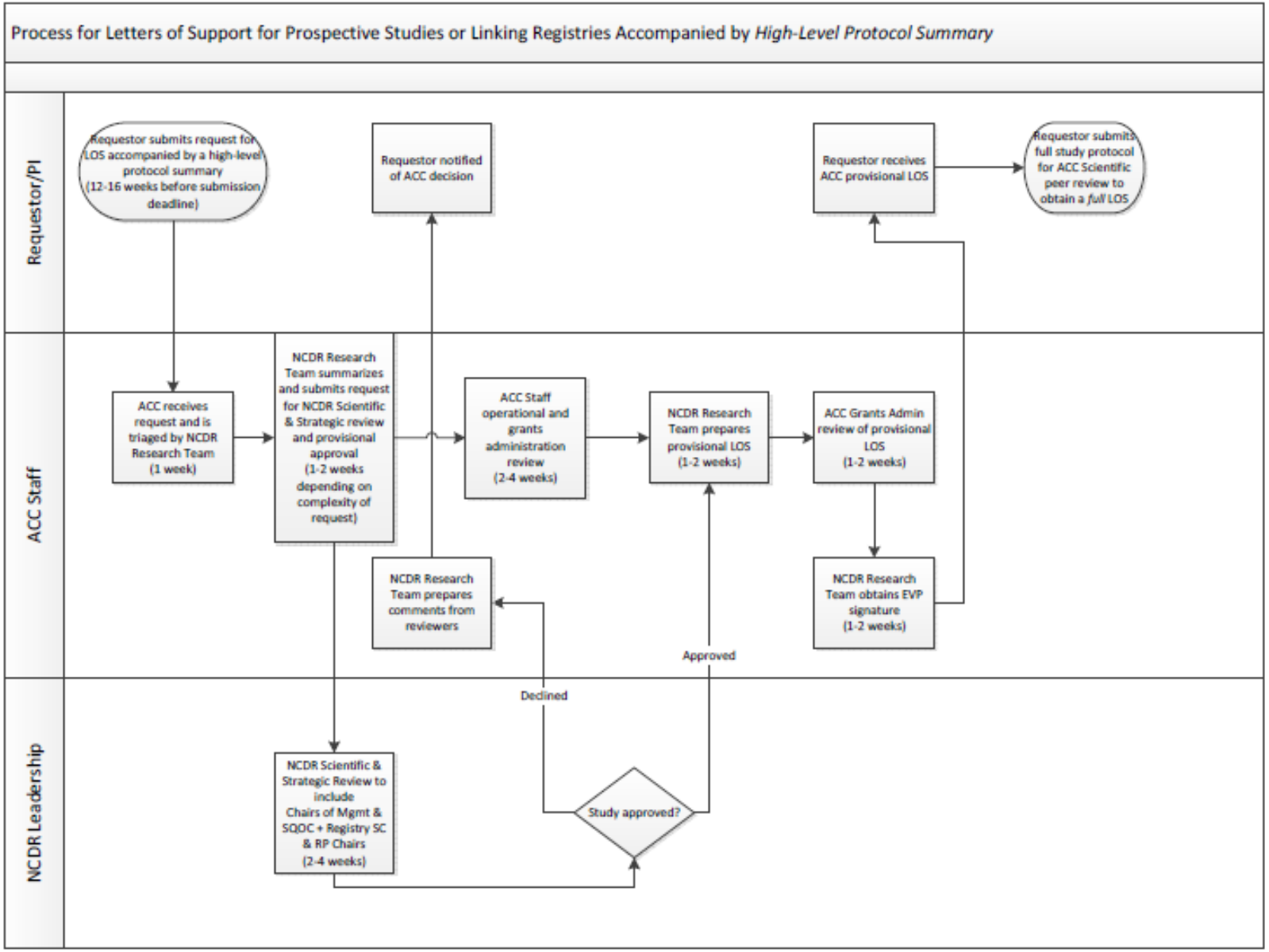
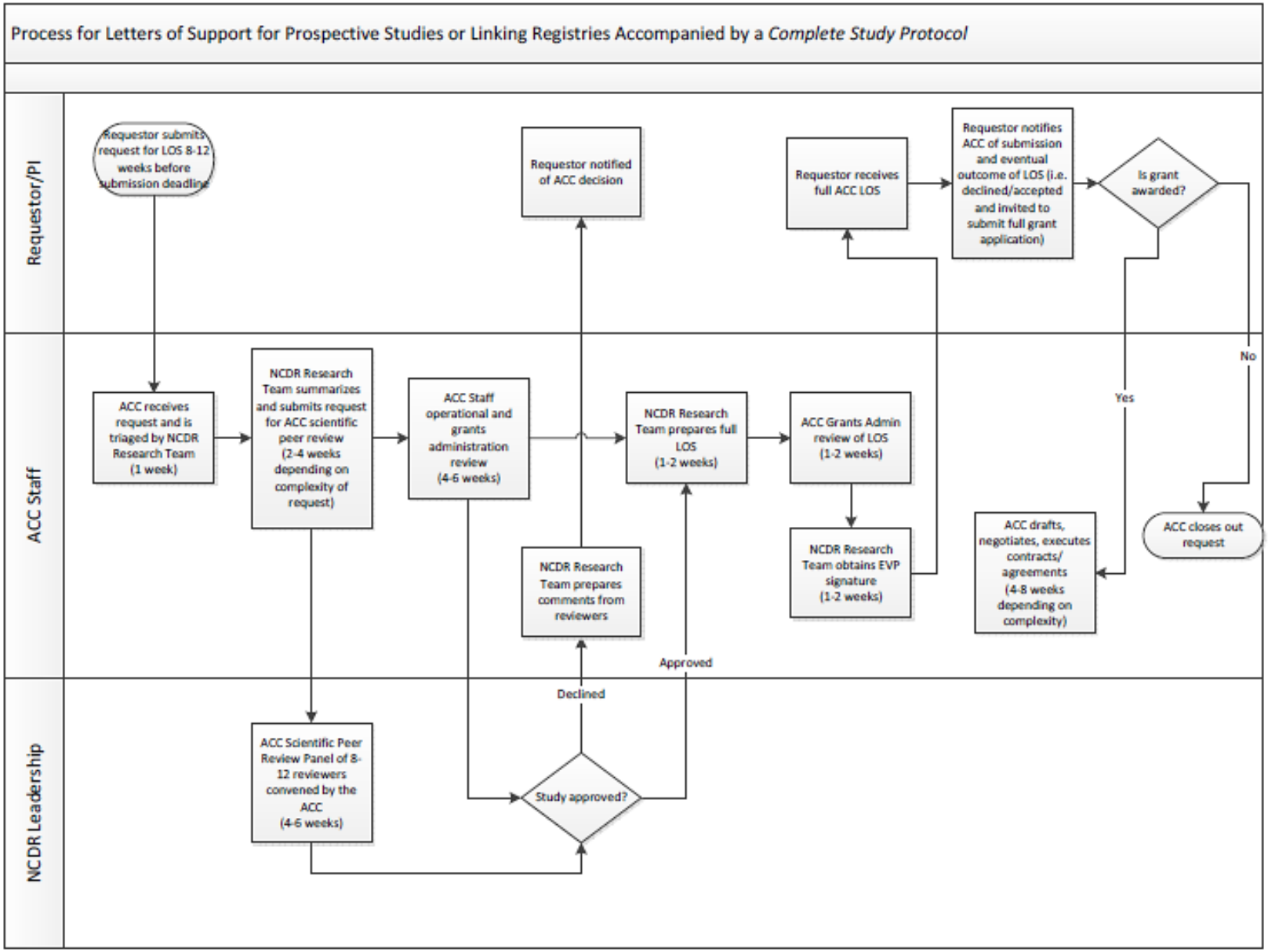


Figure 5: *Full* Letter of Support Process



EXTERNALLY FUNDED PROJECT CONTRACTING

NCDR policy requires that externally funded research projects be contracted between the primary author's institution and the ACCF. If the funding source is external to the author's institution, the ACCF will assist in determining the appropriate contract structure among all parties. Before a contract can be issued, primary authors should be prepared to answer the following questions:

1. Which entity will handle the contracting process? (e.g., *primary author's organization, funding sponsor, etc.)*
2. Who is the point of contact in the contracting department?
   - Name
   - Phone Number
   - Email Address

Note: The contracting process may take several weeks or months to complete.

DATA ANALYSIS

Unless otherwise approved, all data analyses must be conducted by an ACCF -approved Data Analytic Center. The DAC is selected based on registry assignment, budget, project timeline, and the center's capacity to complete the work.

After the contract is executed, an NCDR staff liaison will schedule a kickoff call with the primary author, DAC, and other stakeholders. During this call, the staff liaison will review the Investigator's Guide to NCDR Research, and the DAC will discuss the analytic plan with the primary author. The timeline for analysis completion will be negotiated during contract execution. Throughout the project, the staff liaison will monitor progress, checking in with the primary author and DAC to ensure milestones, deliverables, and deadlines are met. The DAC will provide the primary author with aggregated, de-identified data tables in accordance with the statistical analysis plan outlined in the approved RPA.

Anyone requesting access to NCDR data must review and comply with the External Access to NCDR Data Policy found in Appendix G.

PUBLICATIONS

All externally funded publications (e.g., abstracts, posters, manuscripts) **must** be reviewed and approved by the appropriate Research & Publications (R&P) Committee. Primary authors must comply with the guidelines outlined in the Research Proposal Application Publication Requirements section.

For questions or additional information, contact NCDRresearch@acc.org.

6 | APPLYING FOR NCDR DATA REQUEST

REAL WORLD DATA EVIDENCE REQUESTS

Real World Data Evidence requests provide custom, in-house analytics performed by the NCDR Data Analytics Team. These services offer stakeholders the opportunity to obtain tailored analyses of clinical data from real-world populations, delivering valuable insights into quality of care, geographic variations, patient demographics, trends, and market conditions.

Custom Analytics Services are utilized by:

- Pharmaceutical companies
- Medical device manufacturers
- Government agencies
- Medical specialty societies

Examples of available analyses include:

- Applying descriptive statistics to address clinical questions related to patient characteristics, medical therapies, cardiac procedures, or event rates
- Conducting comparative effectiveness research with real-world patient populations
- Examining the adoption and utilization of treatment options
- Understanding patterns of care by practitioner type, insurance type, and geographic region
- Analyzing factors influencing treatment selection based on patient characteristics and clinical conditions

*** Real World Data Evidence requests are not hypothesis-driven and are not intended for public dissemination unless explicitly approved by ACCF. Data provided through this process may not be used in abstracts, presentations, manuscripts, or other forms of public information release.**

To request custom NCDR Real World Data Evidence analytics, complete the Data Request Form in Appendix I and submit it to NCDRResearch@acc.org. An NCDR staff member will contact you after reviewing your request. Timelines and fees for custom data analytics depend on the complexity of the request. These projects are governed by separate contractual and financial agreements.

PARTICIPANT USER FILE PROGRAM PILOT

The ACC Participant User File (PUF) Research Program enables individual primary authors to access and analyze national-scale, de-identified NCDR data. Designed to offer competitive research opportunities for participating hospitals, the PUF Program supports the generation of real-world evidence. Its primary goal is to expand NCDR research by facilitating timely data access and publication.

Under the current PUF Program Pilot applications are only being accepted for the IMPACT Registry.

Note: this program will only be available for primary authors at participating NCDR hospitals.

7 | INDUSTRY COLLABORATIVE PATHWAY

Getting started: Be able to clearly quantify and articulate the research question you would like to solve.

Dataset Review: Find out What Each Registry Collects by visiting *ACC.org/WhatEachRegistryCollects* and identify the patient or procedure population that intersects with your interest area.

Contact us: Email *NCDRResearch@acc.org* to contact the NCDR Research Team.

Sign NDA: Sign a non-disclosure agreement to facilitate open discussion between you and the NCDR Research Team.

Share & Collaborate: Your team works directly with the NCDR Research Team to determine how best to address your research question.

Review & Contract: A proposal and analytic plan are drawn up; legal teams agree to and execute the contract.

Deliverables: NCDR Research Study Manager coordinates all project milestones and deliverables.

GET STARTED TODAY!

8 | PUBLICATION REQUIREMENTS

Scientific oversight—including RPA review, feasibility assessment, and appropriate methodology—applies to all NCDR research, regardless of funding source. Additionally, **all abstracts, posters, presentations, manuscripts, or other publicly shared materials using NCDR data must be reviewed by the appropriate R&P Subcommittee**. If a proposal involves more than one Research & Publications (R&P) Committee, ACCF will designate a lead committee to manage the process. The review and approval responsibilities of the relevant NCDR R&P Subcommittee cannot be delegated or bypassed.

PUBLICATION PREPARATION

Refer to the Brand and Style Guide in Appendix D for comprehensive NCDR branding guidelines for abstracts, presentations, and manuscripts. The guide details proper usage of "NCDR" (abbreviated versus spelled out), registry names, partner and sponsor statements, disclaimers, and templates for slides and posters.

The NCDR review and approval process must be completed before submitting an abstract or manuscript to a conference or journal. If submission occurs without prior NCDR approval, the author will be required to withdraw it. Failure to secure approval in advance may result in delays, reassignment, or termination of the RPA. Primary authors are responsible for planning ahead to accommodate the NCDR review timeline and any external deadlines. For further details, refer to the "Abstracts" section below.

Key considerations:

- The standard R&P Committee review process takes 3–4 weeks. The NCDR Research Calendar lists submission deadlines for R&P reviews that align with major cardiovascular scientific conferences. Abstracts must be submitted to NCDR **at least three weeks before the conference submission deadline**.
- All publications—including abstracts, presentations, and manuscripts—must be **reviewed and approved** by the relevant R&P Committee before submission to a conference or journal. Typically, one round of committee review is sufficient. However, if substantive changes are requested, a second round of review may be required after revisions.
    - If a publication is not approved after two rounds of revision, it will undergo further adjudication. In rare cases where disagreement persists, the final decision rests with the NCDR R&P Committee.
- A statistician from an approved DAC will review the statistical analysis plan, tables, and figures, and will assist primary authors in drafting and interpreting the statistical methods and results sections. Drafts cannot be submitted for NCDR R&P review until the analytic center staff have verified the accuracy of methods and results. Primary authors must incorporate the statistician's feedback when preparing drafts for committee review.
- Changing the primary author does not alter established timelines or due dates.
- Primary authors are responsible for selecting the scientific conference and journal for abstract and manuscript submissions.

ABSTRACTS

Within the research community, manuscript publication often begins with the submission of an abstract. Data Analytic Centers and primary authors should discuss whether to produce an abstract and identify a target scientific conference for submission.

Primary authors are responsible for monitoring relevant conferences and their abstract submission deadlines. Once the abstract draft has been finalized—including review by the assigned DAC statistician and co-authors—it must be submitted for R&P Committee review via the online NCDR Research Portal (see "Publication Preparation" for more details).

The NCDR Research Calendar lists submission deadlines for R&P review that align with major scientific conferences each year. R&P deadlines are always a minimum of **three weeks prior to the conference abstract submission deadline**. If a conference is not listed on the calendar, submit the abstract for R&P review at least three weeks before its deadline.

After R&P review, the primary author must incorporate reviewer feedback into a revised abstract before submitting it to the conference. If substantive changes are requested, the revised abstract must be resubmitted to NCDR for review. If the abstract is accepted for presentation, primary authors must notify NCDR staff liaisons and specify the presentation type (poster, oral, etc.).

NCDR staff liaisons provide presentation templates, which can also be downloaded from the NCDR Research Portal under "Resources and Supplemental Documentation." Primary authors are required to follow NCDR formatting for all abstract presentations (see the Style Guide in Appendix D) and must send the final presentation to the DAC and NCDR R&P Team for review and approval at least **three weeks** before the conference.

For poster presentations, final NCDR approval is required before printing. ACCF does not support costs associated with presenting or publishing abstracts. Preparing an abstract does not change the four-month timeline for manuscript submission following data analysis delivery.

Note: To be eligible for approval, abstracts must be submitted **no fewer than three (3) weeks in advance** of the scientific session's abstract submission deadline. Abstracts submitted after this deadline will **not be approved for submission**. The ACC will not grant exceptions.

Required NCDR Disclaimer for Abstracts and Manuscripts

Authors must include the following disclaimer statement in all abstracts and manuscripts:

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

MANUSCRIPTS

Once a manuscript draft is finalized—including review by the DAC and co-authors—and ready for journal submission, the primary author must submit the draft for R&P Committee review by emailing it directly to the appropriate registry staff liaison. If the staff liaison is unknown, materials should be sent to ncdrresearch@acc.org. R&P manuscript review **typically takes 3-4 weeks.** The primary author must incorporate any committee feedback into a revised manuscript before submitting it to the target journal. If substantive changes are requested (beyond basic formatting or grammar), the revised manuscript must be resubmitted to NCDR for an additional review.

A six-month timeline for manuscript completion and submission ensures that data reported from NCDR are current and that analysis remains within allocated resources. Primary authors are required to follow NCDR formatting guidelines for all manuscripts (see the Style Guide in Appendix D). NCDR does not provide funding for manuscript publication costs.

Table 2: 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.	After conferring with the DAC, the primary author must notify the DAC and NCDR staff liaison of their intention not to proceed and include the justification for this decision.
Primary author has not communicated updates or has not responded to repeated requests for updates.	If the primary author does not reply after repeated inquiries, the RPA will either be closed or reassigned to another author. This will occur if, after two email messages, one phone call, and registry R&P chair involvement, there is still no reply from the primary author.
Manuscript draft has not been developed or submitted within an adequate timeframe.	If manuscript development does not adhere to R&P deadlines, the NCDR staff liaison will contact the primary author to provide assistance as needed. If manuscript development continues to lag, the date for next steps in the development process will be determined (e.g., submission for NCDR R&P review; journal submission after review; de novo submissions following rejection from a journal). If the new deadlines are not met, the NCDR staff liaison will work with the chair of the R&P Subcommittee and the senior author to determine reassigning the manuscript to a new lead author.
Resubmission to another journal has not occurred within two months.	In such cases, primary authors will be required to submit an explanation for the delay in resubmitting their manuscript to another journal and provide a new target journal and deadline for submission. If the new deadlines are not met, the NCDR staff liaison will work with the chair of the R&P Subcommittee and the senior author to determine reassigning the manuscript to a new lead author.
Approval is not obtained prior to submission of abstract or paper	The lead author will be required to withdraw the abstract or manuscript. The NCDR staff liaison will work with the chair of the R&P Subcommittee to determine if termination of the RPA is appropriate.

ACKNOWLEDGING THE LIMITATIONS OF OBSERVATIONAL DATA

Primary authors must recognize that observed associations in non-randomized studies, including those using registry data, should not be interpreted as definitive evidence of causality. While associations may reflect underlying causal relationships, the potential for bias, chance, or confounding cannot be fully excluded.

In general, causal language should be avoided in abstracts and manuscripts. Authors should ensure their wording aligns 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 related paper by *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 wish to cite the NCDR's data quality program, as described in: *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.*

Primary authors should also consider referencing potential study limitations, such as limited outcomes data and variations in data collection quality or commitment. See below for examples of how to describe data constraints:

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 the accrued data.

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 inpatient 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 in Appendix F.

CITATION OF NCDR'S IRB

The ACCF has designated Advarra, Inc. (formerly Chesapeake IRB) as its institutional review board (IRB) of record (see also Human Subjects Research and the NCDR). If a primary author's RPA falls within the scope of the approved registry research protocol and an IRB citation is needed for a manuscript (though this is generally not required), use the following format:

Waiver of written informed consent and authorization for this study was granted by Advarra, Inc.

ADHERENCE TO EMBARGO POLICIES

All abstract and manuscript content is considered confidential and embargoed until publication. The ACCF has established strict policies governing embargoes and the disclosure of scientific research findings, including those in late-breaking clinical trial presentations and abstracts. Any premature or unauthorized disclosure of embargoed results or data, in any format, is a violation of this policy. Individuals, including authors, presenters, reviewers, committee members, sponsors, and others—who violate embargo policies are subject to ACCF s disciplinary procedures and sanctions. Detailed policies are available on the ACC website.

The NCDR also maintains a policy regarding external access to research under peer review, detailed in Appendix G. Primary authors preparing abstract presentations should review the Common Statement on Prior Publication Policy (http://www.hsr.org/hsr/information/authors/ppublication.jsp).

PROMOTION OF SELECTED MANUSCRIPTS AND ABSTRACTS

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

- A completed **NCDR Manuscript Communications Strategy Questionnaire**. This information helps ACC promote the manuscript on its website, summarize findings across communications channels, and, when appropriate, develop press releases or media comments. After the embargo lifts, ACC's marketing and communications team will promote the research findings through suitable media channels.
- **Advance notice of publication date**. The primary author is responsible for informing the NCDR staff liaison of both online and print publication dates and must do so on the same day the date is provided by the publisher or journal.
- **A draft of the article**. Primary authors should forward drafts to the NCDR staff liaison. Embargoes will be honored, and drafts will be used solely for developing promotional and media materials.
- **PowerPoint slides summarizing the research and findings**. Authors preparing oral presentations with slides must submit them within one week of the presentation. NCDR-funded projects are required to use the NCDR PowerPoint template or the NCDR Poster template; externally funded projects are encouraged to do so. If you are a TVT author please use these templates; ACC STS TVT PowerPoint template, ACC STS TVT Poster template.

All NCDR funded presentations must include the following statement as the second slide:

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

Primary authors must not include other logos on slides and should avoid using pharmaceutical or medical device brand names. Appropriate rights from the publisher must be obtained for any graphs, figures, charts, or visuals taken from published articles, and sources must be properly cited.

ACC regularly reviews NCDR papers at various stages of manuscript development and acceptance to plan for potential promotion. Decisions on specific promotional strategies are based on multiple factors, and particular tactics are not guaranteed.

There are three potential avenues for promoting research findings: (1) to NCDR participants, (2) to ACC members, and/or (3) to trade or mainstream media outlets. Promotions to NCDR participants and ACC members may include "News and Views" (NCDR's monthly e-newsletter), other ACC member newsletters, news stories on ACC.org, and posts across ACC's social media channels.

Timely completion of the NCDR Manuscript Communications Strategy Questionnaire and prompt notification of a manuscript's acceptance are vital for the ACC media team to assess the news value of the study and develop a promotion plan.

Decisions about coverage on ACC.org and other ACC member platforms (e.g., newsletters, blogs, social media) are made on a case-by-case basis. News coverage on ACC.org is determined through an independent editorial process; NCDR recommendations are advisory and do not guarantee coverage.

If a paper is deemed "newsworthy"—meaning it is of interest to trade or mainstream media—the ACC media team may prepare a press release or conduct targeted outreach to relevant outlets. If a press release is prepared, the media team will contact the author for comments and may reference the completed author questionnaire.

COLLABORATING WITH OTHER ORGANIZATIONS ON MEDIA

An author's affiliated organization or university may issue its own press release when a paper is published. However, the author is responsible for providing the ACC media team with advance notice and a copy of any press release prior to distribution, including those from third parties. This requirement enables the ACC to coordinate media promotion and embargo times, ensure accurate representation of the ACC and its registries, and prepare for potential media inquiries resulting from the release.

9| RESPONSIBILITIES OF THE PRIMARY AUTHOR

Primary authors are expected to submit their manuscript to a journal within six (6) months of receiving the primary analysis, and no later than two months after the NCDR Research & Publications (R&P) review is complete. Each approved RPA should produce a single manuscript.

All primary authors are responsible for the following:

1. Ensure the integrity of their work from proposal conception through to the published manuscript.
2. Adhere to all deadlines. Failure to meet deadlines may result in delays.
3. Clearly communicate all timelines and expectations for manuscript completion to co-authors. Obtain timely approval of abstract, presentation, and manuscript drafts from all co-authors and DAC statisticians before submitting materials to NCDR for R&P review (see Publication Requirements for review timelines and process).
4. Manage all communications with NCDR and DAC staff, responding promptly to avoid unnecessary delays during the review of abstracts, presentations, and manuscript drafts.
5. Determine the appropriate listing of co-authors. NCDR encourages primary authors to follow the International Committee of Medical Journal Editors (ICMJE) guidelines for identifying co-authors, 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 all three criteria.
    - All people designated as authors should meet all three criteria, 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 co-authorship, the primary author should consider individuals who contributed to:

    - RPA concept and design
    - Abstract and manuscript writing
    - Data analysis and/or interpretation
    - Literature search
    - Critical review
    - Data analysis and/or interpretation who contributed to research
    - Critical review
6. Ensure that all co-authors receive and review this document, including any updates as they are released.
7. Create an "Acknowledgements" section in the manuscript if needed. NCDR does not permit inclusion of 'honorary' authors as co-authors, but contributors who do not meet authorship criteria may be cited in the acknowledgements section. Examples include:
    - A person who provided technical help or writing assistance

- A mentor who provided general support
- Colleagues, reviewers, or staff who do not qualify as authors
- Groups or individuals who contributed materially but do not meet the authorship threshold

The acknowledgements section should disclose the individual's name, organizational affiliation, and 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 primary author must allow anyone listed in the acknowledgements section the opportunity to review the draft and consent to being named before submitting the final draft to NCDR.

8. Provide the names of all co-authors and individuals cited in the acknowledgments section to NCDR at the time of R&P review for the abstract or manuscript. Also, provide the names of any individuals who met authorship or acknowledgment criteria but declined inclusion. This ensures transparency, manages potential conflicts of interest, and assists with reviewer assignments. No individual should appear as an author or in the acknowledgments of an abstract or article without disclosure to NCDR.
9. Allow co-authors and individuals to be listed in the acknowledgments section with ample time to review and respond to the final draft before R&P review submission. As a guideline, provide co-authors at least five business days (ideally up to ten) to review manuscripts, and at least five business days for abstracts and presentations. Co-authors and individuals in the acknowledgments section must respond promptly to review requests. If someone cannot meet the established timeline, the primary author should grant reasonable extension requests (generally up to two additional weeks for manuscripts). If no response or acknowledgment is received, the primary author should follow up using an alternative communication method (e.g., a phone call if email was used initially) and allow up to three additional business days for a response or extension request. If there is still no response, the individual should be removed from the author panel or acknowledgments, and this information (including the individual's name and contribution) must be reported to NCDR when submitting the final draft for review. If co-authors provide comments after R&P committee review and journal approval, the primary author may add them back without notifying NCDR. However, if substantive changes are recommended, the primary author must inform NCDR and await a decision before proceeding.
    - If no response is received, the primary author should follow up using an alternative communication method (e.g., a phone call if email was used initially) and allow up to three additional business days for a response or extension request. If there is still no response, the individual should be removed from the author panel or acknowledgments, and this information (including the individual's name and contribution) must be reported to NCDR when submitting the final draft for review. If co-authors provide comments after R&P committee review and journal approval, the primary author may add them back without notifying NCDR. However, if substantive changes are recommended, the primary author must inform NCDR and await a decision before proceeding.

COMMUNICATIONS WITH ACC & JOURNAL EDITORS

When the analysis is complete, the primary author is responsible for the following activities:

NCDR R&P Committee Review: NCDR policy requires that the R&P Subcommittee review and approve the final abstract and/or manuscript draft before it is submitted to a journal or scientific conference. Primary authors must email these materials to the appropriate NCDR staff liaison. If the staff liaison is unknown, all publishable materials should be sent to ncdrresearch@acc.org.

Initial Submission to a Journal or Scientific Conference: Once the NCDR-approved final draft is submitted, the primary author must promptly notify NCDR. This notification should include the name of the journal or scientific conference, the submission date, and a copy of the submitted draft.

Revisions of Submitted Manuscripts: If a journal requests revisions, the primary author must notify the author group and biostatisticians, implement the required changes, and resubmit the manuscript to the journal. The primary author is also responsible for ensuring that any revisions remain within the scope of the initial RPA, use the same dataset, and do not overlap with other in-progress RPAs or published manuscripts. If questions arise or revisions require additional analytic work, primary authors must contact the NCDR staff liaison for evaluation and approval before proceeding.

De Novo Submissions: If a manuscript is not accepted by the initial journal (de novo submission #1), the primary author must promptly inform NCDR, the author group, and biostatisticians. Reviewer comments should be forwarded, revisions made as needed, and a second de novo submission (de novo submission #2) prepared within one month of the rejection.

NCDR R&P Status Updates: Primary authors must keep the NCDR staff liaison informed as revisions occur at the journal review level. Notifying DAC staff does not substitute for this requirement. Primary authors must provide monthly updates to the NCDR staff liaison, including:

- The assigned RPA ID number in the subject line of all communications
- A brief monthly status report on manuscript progress
- The expected date of manuscript completion
- The name of the target journal for publication

Publication: When a manuscript is accepted for publication (or an abstract for presentation), the primary author is responsible for the following:

- **Notification of acceptance:** Upon acceptance, the primary author must inform the NCDR staff liaison of the acceptance date and the projected publication date, if known. Notifying DAC staff does not fulfill this requirement. For abstracts, include the type of presentation (e.g., poster or oral).

- Coordination **with ACC Marketing and Communications: After** acceptance, the primary author should coordinate with ACC Marketing and Communications if contacted. This may involve providing information or materials for press releases, website features, or other promotional activities.

- **Providing the Published Paper/Presentation:** Once the final version of the paper is published online or in print, the primary author must send a PDF copy to the NCDR staff liaison. For abstracts, provide a copy of the presented poster or slide deck.

10 | CONCLUSION

The NCDR Research Investigator's Guide is designed to help primary authors navigate the NCDR research process and understand the policies and procedures governing all research activities. Any research or publishable material using NCDR data must follow the review channels outlined in this guide.

The appendices contain additional information about NCDR registries.

11| 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: https://ori.hhs.gov/ori-introduction-responsible-conduct-research.

APPENDIX A: ADDITIONAL REFERENCES AND HELPFUL LINKS

1. National Institutes of Health, Office of the Director. Guiding principles for ethical research. March 16, 2016. Available online at https://www.nih.gov/health-information/nih-clinical-research-trials-you/guiding-principles-ethical-research .
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	Launch Date	Starting Timeframe	Ending Timeframe	Notes
AFib Ablation Registry ™	Procedure-Based (Atrial fibrillat ablation proc				
V 1.0		2016	2016Q2	2024Q3	Initial release
V 2.0		2024	2024Q4	present	Major update - overhaul of dataset, added follow-up
CathPCI Registry®	Procedure-Ba (Diagnostic coronary angiograph y, percutaneo us coronary intervention procedures)				
V 1.0		1999	1998Q1	2001Q2	Initial release 1999 overlaps with v2 for 1 quarter
V 2.0		2002	2001Q1	2004Q4	overlaps with v1 for 1 quarter, overlaps with v3 for one year
V 3.0		2005	2004Q1	2009Q2	overlaps with v2 for one year
V 4.3		2009	2009Q3	2009Q4	supported by CATHPCIDM.CATHPCI.vProductVersionHistoryDIM
V 4.3.1		2010	2010Q1	2011Q1	Revasc AUC applied 2009Q3 supported by CATHPCIDM.CATHPCI.vProductVersionHistoryDIM
V 4.4		2018	2011Q2	2018Q2	supported by CATHPCIDM.CATHPCI.vProductVersionHistoryDIM
V 5.0		2023	2018Q2	present	Updated Revasc AUC for ACS & SIHD; intended to add AUC for diagnostic procedures
Chest Pain - MI	Disease-Based				

Registry® *(formerly the ACTION Registry)*	(STEMI, NSTEMI)				
V 2.0		2008	2008Q3	2008Q3	Initial Release
V 2.0.1		2008	2008Q4	2008Q4	Minor change
V 2.0.2		2009	2009Q1	2009Q1	Minor change
V 2.1		2009	2009Q2	2009Q2	Major change
V 2.1.1		2009	2009Q3	2011Q1	Minor change
V 2.2		2011	2011Q2	2013Q4	Major change
V 2.3.1		2014	2014Q1	2014Q4	Major change - new meds
V 2.4.1		2015	2015Q1	2015Q3	Major change – new meds
V 2.4.2		2016	2015Q4	2018Q4	Minor change
V 3.0		2023	2019Q1	2023Q2	Major change - new patient populations
V 3.1		2023	2023Q3	2024Q2	Minor change - new pt pathway flow & STEMI referral dataset for pt d/c between July 1, 2023 - June 30, 2024
V 3.1		2024	2024Q3	present	Corrective dataset - added coding selections to support metric reporting for pt d/c one/after July 1, 2024
EP Device Implant Registry® *(formerly the ICD Registry)*	Procedure-Based (Implantable cardioverter defibrillators)				
V 1.0		2005	2005Q2	2010Q1	Initial release
V 2.1		2011	2010Q2	2016Q1	Minor update - added leads and pediatric procedures
V 2.2		2016	2016Q2	2021Q1	Minor update
V 2.3		2021	2021Q2	2024Q4	Major update - Additional procedure type
V 2.4		2025	2025Q1	Present	Major update - procedure pathways, retired CMS-only option
IMPACT Registry®	Procedure-Based (Congenital heart disease)				
V 1.0		2010	2010Q4	2012Q2	Initial Release
V 1.0.1		2012	2012Q3	2016Q1	Minor update - v1 DCT retired 9/1/16
V 2.0		2016	2016Q2	2016Q2	Major

V 2.0.1		2016	2016Q3	present	Minor update - corrections to DCF layout/headings and TDD
LAAO Registry ™	Procedure-Based (Left atrial appendage occlusion procedures)				
V 1.0		2016	2015Q4	2017Q2	Initial release
V 1.1		2017	2017Q3	2018Q3	Minor update
V 1.2		2018	2018Q4	2019Q4	Minor update added medication strategy section (BSC/FDA request)
V 1.3		2020	2020Q1	2022Q3	Minor update new data elements, visual changes
V 1.4		2022	2022Q4	present	Minor update- removed medication strategy section, new data elements to align w/ platform upgrade
STS/ACC TVT Registry ™	Procedure-Based Transcatheter aortic valve replacement and repair				
V 1.0		2011	2011 Q4	2012 Q2	Initial Release
V 1.1		2012	2012 Q3	2012 Q4	Minor
V 1.2		2013	2013 Q1	2013 Q3	Minor
V 1.3		2013	2013 Q4	2014 Q2	Minor
V 2.0		2014	2014 Q3	2016 Q3	Added Mitral
V 2.1		2016	2016 Q4	2020 Q4	Minor
V 3.0		2021	2021 Q1	Present	Full upgrade added Tricuspid and BDS and FDS

[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 data sets (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.

CALL FOR DATA SCHEDULE

These uploads constitute refreshed data sets 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.

DATA QUALITY

The NCDR employs a multipronged approach to ensure the validity and accuracy of the data, with a focus on capturing high quality data from participating facilities. Enhancing data quality is at the forefront of many key registry processes, as detailed below.

- Data Dictionary Development: The selection of registry data elements is a result of input from clinical experts, regulatory agencies, and industry. The evidence-based elements are intended to measure clinical practice and patient outcomes. Included in these data elements are patient demographics, presenting clinical characteristics and medical history, treatment indications, technical details (such as medication dosing or devices utilized), and laboratory and other test results. These elements aim to identify patterns of clinical care and facilitate risk adjustment.

- Data Capture Software Rules: The NCDR utilizes clinical and technical specifications to create a standardized platform for data collection across multiple, diverse facilities. Examples include standardized drop-down menus for categorical variables, valid ranges for numeric variables, and parent-child data structure (where appropriate) to prevent erroneous data entry.

- Trained Data Collection Personnel: Facilities participating in the NCDR may employ various personnel or a certified vendor for data capture and data entry roles, and each facility has an assigned Registry Site Manager (RSM) to oversee data collection and registry reporting. To support enrolled facilities, the NCDR provides outreach and training that includes a comprehensive orientation and a continuing education program to address the ongoing educational needs of registry participants. This includes regularly scheduled new user conference calls, ongoing RSM calls, live and on-demand training webinars, online resources and documentation, and an annual meeting featuring registry-focused workshops and presentations. The NCDR's Clinical Quality Consultants, who are equipped with both clinical training and registry expertise, are available to assist individuals via a toll-free phone number or email support.

- Data Quality Checks and System Alerts: The Data Quality Check is executed after each patient record is entered. This function generates real-time alerts that identify out-of-range errors before the record is saved. Data Quality Checks also provide alerts for incomplete data, enabling facilities to promptly address any missing fields.

  The Data Quality Report is executed upon data submission and provides additional feedback to the facility. The report provides a series of additional completeness and logic checks, resulting in a green, yellow, or red status. DQR status applies to the entire quarterly submission, not just individual patient records.

  - Green Status indicates that the submission has passed all data and completeness assessments.
  - Yellow Status indicates that the submission has passed the data assessment but failed to pass the completeness assessment.
  - Red Status indicates that the submission did not pass the registry's data assessment.

- Data Outlier Reports: Data Outlier Reports provide programmatic analyses to compare facility data with all data reported by participants in the registry and identify those that fall outside of the expected parameters. Specific metrics are developed based on recommendations from the Registry Steering Committees and NCDR Registry Product Managers. The facilities who meet one or more of these outlier criteria receive a confidential report summarizing their data. Data Outlier Reports are provided solely for informational purposes and are intended to serve as a tool for reflection for process improvement opportunities.

- National Audit Program: Each registry within the NCDR has a data audit conducted on a regular basis. ACCF contracts with a Quality Innovation Network/Quality Improvement Organization (QIN/QIO) for audit services.

  Facilities are randomly selected for participation in the audit, with a goal of auditing 5-10% of facilities that are submitting data. The data elements selected for audit are approved by the Registry Steering Committee and Clinical Science and Quality Committee. The audit compares the medical record data captured by an auditor against the data collected in the registry. To ensure consistency, inter-rater reliability is integrated into the audit program, with a subset of records independently abstracted by another auditor.

  The audit also includes an adjudication phase, where facilities may contest their audit results and provide a reference to the medical record page where the data may be found. This information is then re-evaluated, and, if an audit finding is overturned, the facility's audit report is updated prior to issuing the final audit report.

- Case Submission Assessment: The NCDR evaluates submitted cases to ensure that all cases that should be included have been entered into the registry. A subset of facilities selected for the audit are asked to submit their medical billing records for procedures conducted during a specified timeframe. This data is then compared to the cases submitted to the registry, to verify that all cases that should have been entered are present and valid cases. A report is provided to facilities for informational purposes.

- Clinical Event Adjudication (Specific to the LAAO Registry): Any occurrence of strokes, transient ischemic attacks (TIAs), intracranial hemorrhages, bleeding events, or systemic embolisms reported in the LAAO Registry requires clinical event adjudication. When an event is reported, facilities are required to answer additional questions about the event. ACCF has contracted with an analytic center partner to develop the algorithmic adjudication process, which is used to ensure that reported events comply with the event definition as specified for the registry. The algorithmic evaluation was validated by a Clinical Event Committee (CEC) and the CEC has a ongoing review process, evaluating a subset of cases each year.

For additional information about NCDR Data Quality, please see The National Cardiovascular Data Registry Data Quality Program 2020.pdf

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. ACC maintains a Data Use Agreement with CMS to link data from the AFib Ablation Registry, CathPCI Registry, Chest Pain-MI Registry, EPDI Registry, LAAO and STS/ACC TVT Registry with the following Medicare Research Identifiable Files (RIF) files:

Table 4: CMS Research Identifiable Files

CMS Research Identifiable Files	Years Available
Inpatient Claims (IC)	2012-2022
Outpatient Claims (OC)	2012-2022
Skilled Nursing Facility (SNF)	2012-2022
Home Health Agency (HHA)	2012-2022
Hospice	2012-2022
Carrier File	2012-2022
Durable Equipment File (DME)	2012-2022
Part D Drug Event File (PDE)	2012-2022
Master Beneficiary Summary File (BSF) **Base, chronic conditions, cost and utilization segments**	2012-2022
Master Beneficiary Summary File (MBSF) NDI segment	2012-2022
Part D drug, plan, prescriber, and pharmacy characteristics	2012-2022
Part D formulary characteristics	2012-2022

Research studies utilizing the NCDR-CMS linked data **must align with the ACC's CMS-approved research protocol. This protocol centers on examining how** pre-procedural, peri-procedural, and post-hospitalization treatment patterns affect short-term rehospitalizations and mortality among Medicare beneficiaries. The NCDR-CMS linked dataset enables researchers to assess predictors of hospital compliance with optimal discharge planning, patient adherence to these protocols, and outcomes such as rehospitalization and mortality.

APPENDIX C: NCDR RESEARCH PROPOSAL APPLICATION FREQUENTLY ASKED QUESTIONS

NCDR RESEARCH PROPOSAL APPLICATION FREQUENTLY ASKED QUESTIONS (FAQ'S)

1. Where do I find a listing of the data elements and related dictionaries?

Data elements and data dictionaries are posted on the NCDR website for each registry. Review these documents before starting an RPA to confirm that NCDR collects the data required for your study. If the necessary data is not available, you may need to adjust your study aims.

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

Visit the NCDR website for registry-specific listings of published manuscripts, abstracts, and ongoing or unpublished projects. Reviewing these resources helps ensure your project does not overlap with others already in the R&P pipeline. Completion of this step is required on the RPA form before submission.

3. How many RPAs can I submit for consideration?

When preparing an RPA, keep the Rule of Two in mind: a primary author may have no more than two active proposals across all NCDR registries at one time. If you have two proposals under review, you must wait until they complete the review process before submitting another. If both are approved and proceed to analysis, you cannot submit another proposal until at least one results in a manuscript submitted to a peer-reviewed journal.

4. 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?

Your institution does not need to participate in NCDR for you to use the standard NCDR research process. All analyses are conducted at designated data analytic centers. To apply, simply create an acc.org account and log in at rp.acc.org.

Note: Fellows from non-participating institutions are not eligible for direct access to de-identified NCDR data through the PUF research process.

5. Do I receive raw data, or is data analyzed by an NCDR-designated team?

ACCF does not provide authors with direct access to row-level data. Approved proposals are assigned to one of ACCF's contracted data analytic centers. The DAC contacts the author to finalize the statistical analysis plan and, after completing the analysis, provides the results for manuscript drafting.

6. How do I enter my RWI (Relationship with Industry) through ACC's website?

Authors can enter or update their RWIs through the ACC's Disclosure System: http://disclosures.acc.org. You will be asked a series of questions about any relationships you 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 any problems with the website, please call

our toll-free number for assistance at (800) 253-4636. Normal business hours are Monday through Friday, 9:00 AM to 5:00 PM EST.

7. Are there financial costs associated with using NCDR data?

The ACCF provides funding for a limited number of research studies each year. If you have your own funding to cover analysis costs at a DAC, be sure to note this in your application. Primary authors with independent funding may submit proposals at any time for separate review.

There is no application fee for proposals submitted through the standard NCDR research process.

8. How do I submit my RPA form?

Submit your RPA through the NCDR Research Portal at http://rp.acc.org/. The portal also offers helpful resources, including an overview of the system and user guides to assist primary authors.

9. How soon will I be notified of the outcome?

After submitting an RPA, you will receive an email confirmation with a unique ID number. For ACCF-funded proposals, initial screening usually happens shortly after the submission deadline, and projects that pass are sent for feasibility assessment (about 10 weeks before the next R&P Committee meeting). Submission deadlines and committee meeting dates are posted on the NCDR Research Calendar. Applicants are typically notified of outcomes within six weeks after the committee meeting. For externally funded proposals, the review and approval process generally occurs within a few weeks of NCDR receiving the RPA.

10. How can I connect with other primary authors interested or experienced in working with NCDR data?

ACC has established a LinkedIn networking forum: the NCDR Research Network Subgroup. This group is designed for physicians, researchers, and others interested in cardiovascular research using NCDR data. The forum facilitates the exchange ideas, networking, and discussion of research findings and collaborative opportunities.

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

11. How do I submit an externally funded research proposal that links NCDR data to an external data source?

To submit an externally funded research proposal linking NCDR data to an external source, complete the Externally Funded Research Proposal Application Form (Appendix H) and email it to ncdrresearch@acc.org. NCDR will follow up to begin the evaluation process. Additional information and documentation will be requested as needed.

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.

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.
  - AFib Ablation Registry
  - CathPCI Registry
  - Chest Pain - MI Registry
  - EP Device Implant Registry
  - IMPACT Registry
  - LAAO Registry
  - STS/ACC TVT Registry ("TVT Registry" may be used after first reference)
  - CV ASC Registry Suite

- 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 must insert the following statement to describe the registry on which their research is based:

- **AFib Ablation Registry** is an initiative of the American College of Cardiology.
- **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.
- **The CV ASC Registry** is an initiative of the American College of Cardiology with partnering support from Society for Cardiovascular Angiography and Interventions.
- **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.
- **STS/ACC TVT Registry** is an initiative of The Society of Thoracic Surgeons and the American College of Cardiology.

IV. 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 the ACC approved templates below.

Poster Template

PowerPoint Template

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 NCDR® (National Cardiovascular Data Registry). The views expressed in this presentation represent those of the author(s), and do not necessarily represent the official views of the ACC or its associated professional societies identified at CVQuality.ACC.org/NCDR.

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

APPENDIX E: NCDR FUNDED RESEARCH PROPOSAL APPLICATION

Preliminary Research Proposal Application

NCDR Funding Only

1. **Research Proposal Details**

   A. Registry

   ☐ AF Ablation ☐ CathPCI

   ☐ Chest Pain – MI ☐ IMPACT

   ☐ EP Device Implant ☐ STS/ACC TVT

   ☐ LAAO

   Select the registry that best fits your proposal

2. **RPA Title**

   A. RPA Title:

3. **Author Details**

   A. Primary Author's Name (one individual only, responsible for RPA):

   Author must have an ACC.org login. If not, go to https://www.acc.org/and create one.

   B. Primary Author's E-Mail

   This email will be listed with approved research proposals on CVQuality.ACC.org

   C. Is Primary Author currently a fellow-in-training or within five years of completing their fellowship? ☐ Yes ☐ No

   If yes, then a Senior Author, who is more than 5 years out of fellowship is required. If you do not have a Senior Author, email ncdrresearch@acc.org and one will be assigned.

   D. Primary Author's Affiliated Institution:

   E. Primary Author's Telephone:

   F. Primary Author's Street Address:

   G. Primary Author's RWI current as of date: MM/DD/YY

   Note that this cannot be a date in the future. Primary, senior, and co-authors must have entered and updated their RWI on Disclosures.ACC.org within the last 12 months. Members should go to the member center; non-members may go here.

   H. Primary Author RWI Expectations Communicated?

☐ Yes ☐ No

Investigator's Guide to NCDR® Research
Under 'Submitting an RPA', click 1. Review Investigator's Guide to NCDR® Research

4. Senior Author Details

A. Senior Author Name:

Please type senior author's name. If Primary Author is currently a fellow-in-training or within five years of completing their fellowship, Senior Author is required in this field.

B. Senior Author's E-mail:

The Primary Author will be responsible for most communications regarding this RPA. The Senior Author will be contacted only for confirmation of understanding of mentorship responsibilities if Primary Author is early career as defined above.

5. Co – Authors

A. Co-Author(s) Name (optional, if known):

Please enter Co-Author names separated by a comma,

6. Research Plan

A. RPA Keywords:
List briefly the main terms relevant to the Research & Proposal Application topic.

B. Background/Significance:
Provide a brief statement (maximum 1-2 paragraphs, not more than 1 typed page) describing the background and significance of the proposed research.

C. Hypothesis and/or Statement of Intent:
Provide a brief statement (maximum 1-2 sentences) describing the proposal's main hypothesis. Limit to no more than two aims. Analytic time typically supports only one manuscript.

D. Inclusion & Exclusion Criteria:
Briefly describe the proposal's patient and/or hospital inclusion and exclusion criteria.

E. Data Requested (Including Primary Outcomes and Covariates):
Please utilize the appropriate registry's data collection form as reference to delineate groups for comparison, list the primary and secondary outcomes of interest for this proposal and requests for modeling these outcomes, any covariates of interest, and any of the main variables that may need to be considered (e.g., for adjustment) in the analysis.

F. Data Request Type Description:

Please describe the type of dataset you intend to use (e.g., in-hospital only, linked data, etc.). Note that NCDR-funded research will only link to CMS data.

G. Brief Statistical Analysis Plan:

Provide a brief (no more than 1-2 paragraphs) description of the proposed statistical methodology that could be considered for your proposal based on the data requested above. If your proposal is approved, the assigned data analytic center will discuss the comprehensive details of the statistical analysis plan that will support your analysis. Please provide sample tables for how you plan to present the data. Kindly restrict the number of sample tables you may wish to provide to two (2). If necessary, you may upload an attachment using the link at the bottom of this form.

H. I acknowledge that I have reviewed the device-to-device research guidelines and agree my research proposal does align with the guidelines.

☐ Yes ☐ No

Please review the Guidelines for Conducting Device Research in the Investigator's Guide to NCDR® Research.

I. My RPA focuses on reporting health disparities by race and/or ethnicity.

☐ Yes ☐ No

I acknowledge that I have reviewed the race and ethnicity research guidelines and agree my research proposal does align with the guidelines.

☐ Yes ☐ No

Please review the Guidelines for Conducting Scientific Research on Racial and Ethnic Disparities in the Investigator's Guide to NCDR® Research.

J. Overlap Attestation:

☐ Yes ☐ No

Please click the link for Currently Approved Proposals and review:

- *NCDR Manuscripts by Registry*
- *NCDR Abstracts by Registry*
- *Unpublished Projects by Registry*

By selecting 'No', you are acknowledging you have reviewed the NCDR's list of current approved research proposals and published manuscripts for this database, and this proposal topic does not appear to overlap with any previously approved topics.

By selecting 'Yes', you are acknowledging you have reviewed the NCDR's list of current approved research proposals and published manuscripts for this database, and that overlap exists with a previously published work. To proceed with this submission, please provide a justification for the overlap in the text box below.

K. Overlap Review Date: MM/DD/YYYY

Note that this cannot be a date in the future.

L. AI Use Disclosure:

Did you use any artificial intelligence (AI) tools (e.g., ChatGPT, Copilot, Gemini, or similar) in the development, drafting, or editing of this Research Proposal Application?

☐ Yes ☐ No

If yes, please briefly describe:

- The AI tool(s) used
- The purpose or task for which AI was used
- How you verified the accuracy and originality of AI-generated content

M. References:

List relevant literature citations; maximum of 10.

7. <u>Funding Source:</u>

A. NCDR (requesting NCDR support, no cost to you or your institution)

Return completed form to: ***NCDRresearch@acc.org***.

APPENDIX F: SUGGESTED LANGUAGE FOR NCDR METHODS AND LIMITATIONS

NCDR REGISTRY-WIDE

METHODS

The American College of Cardiology operates the NCDR® (National Cardiovascular Data Registry) 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 Advarra.

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 DATA

Policy: The NCDR generally does not provide third parties with direct access to patient-level data. In rare cases where access to more detailed data is essential, requests may be considered. All external data requests must be submitted in writing and clearly explain the intended use. These requests undergo a comprehensive, case-by-case review that includes legal, privacy, security, scientific and strategic evaluations. This extensive review does not guarantee approval.

APPENDIX H: EXTERNALLY FUNDED PROJECT APPLICATION FORM

Preliminary Research Proposal Form

Non-NCDR Funding Only

8. Research Proposal Details

A. Registry

☐ AF Ablation ☐ CathPCI

☐ Chest Pain – MI ☐ IMPACT

☐ EP Device Implant ☐ STS/ACC TVT

☐ LAAO

Select the registry that best fits your proposal

9. RPA Title

A. RPA Title:

10. Author Details

A. Primary Author's Name (one individual only, responsible for RPA):

Author must have an ACC.org login. If not, go to https://www.acc.org/and create one.

B. Primary Author's E-Mail

This email will be listed with approved research proposals on CVQuality.ACC.org

C. Is Primary Author currently a fellow-in-training or within five years of completing their fellowship? ☐ Yes ☐ No

If yes, then a Senior Author, who is more than 5 years out of fellowship is required. If you do not have a Senior Author, email ncdrresearch@acc.org and one will be assigned.

D. Primary Author's Affiliated Institution:

E. Primary Author's Telephone:

F. Primary Author's Street Address:

G. Primary Author's RWI current as of date: MM/DD/YY

Note that this cannot be a date in the future. Primary, senior, and co-authors must have entered and updated their RWI on Disclosures.ACC.org within the last 12 months. Members should go to the member center; non-members may go here.

H. Primary Author RWI Expectations Communicated?

☐ Yes ☐ No

Investigator's Guide to NCDR® Research
Under 'Submitting an RPA', click 1. Review Investigator's Guide to NCDR® Research

11. Senior Author Details

A. Senior Author Name:

Please type senior author's name. If Primary Author is currently a fellow-in-training or within five years of completing their fellowship, Senior Author is required in this field.

B. Senior Author's E-mail:

The Primary Author will be responsible for most communications regarding this RPA. The Senior Author will be contacted only for confirmation of understanding of mentorship responsibilities if Primary Author is early career as defined above.

12. Co – Authors

A. Co-Author(s) Name (optional, if known):

Please enter Co-Author names separated by a comma,

13. Research Plan

A. RPA Keywords:

List briefly the main terms relevant to the Research & Proposal Application topic.

B. Background/Significance:

Provide a brief statement (maximum 1-2 paragraphs, not more than 1 typed page) describing the background and significance of the proposed research.

C. Hypothesis and/or Statement of Intent:

Provide a brief statement (maximum 1-2 sentences) describing the proposal's main hypothesis. Limit to no more than two aims. Analytic time typically supports only one manuscript.

D. Inclusion & Exclusion Criteria:

Briefly describe the proposal's patient and/or hospital inclusion and exclusion criteria.

E. Data Requested (Including Primary Outcomes and Covariates):

Please utilize the appropriate registry's data collection form as reference to delineate groups for comparison, list the primary and secondary outcomes of interest for this proposal and requests for modeling these outcomes, any covariates of interest, and any of the main variables that may need to be considered (e.g., for adjustment) in the analysis.

F. Data Request Type Description:

Please describe the type of dataset you intend to use (e.g., in-hospital only, linked data, etc.). Note that NCDR-funded research will only link to CMS data.

G. Data Requested Start Date/ End Date:

Please describe the start and end dates requested.

H. Brief Statistical Analysis Plan:

Provide a brief (no more than 1-2 paragraphs) description of the proposed statistical methodology that could be considered for your proposal based on the data requested above. If your proposal is approved, the assigned data analytic center will discuss the comprehensive details of the statistical analysis plan that will support your analysis. Please provide sample tables for how you plan to present the data. Kindly restrict the number of sample tables you may wish to provide to two (2). If necessary, you may upload an attachment using the link at the bottom of this form.

I. My RPA focuses on reporting health disparities by race and/or ethnicity.

☐ Yes ☐ No

I acknowledge that I have reviewed the race and ethnicity research guidelines and will align research proposals addressing race and/or ethnicity with these guidelines.

☐ Yes ☐ No

Please review the Guidelines for Conducting Scientific Research on Racial and Ethnic Disparities in the Investigator's Guide to NCDR® Research.

J. Overlap Attestation:

☐ Yes ☐ No

Please click the link for Currently Approved Proposals and review:

- *NCDR Manuscripts by Registry*
- *NCDR Abstracts by Registry*
- *Unpublished Projects by Registry*

By selecting 'No', you are acknowledging you have reviewed the NCDR's list of current approved research proposals and published manuscripts for this database, and this proposal topic does not appear to overlap with any previously approved topics.

By selecting 'Yes', you are acknowledging you have reviewed the NCDR's list of current approved research proposals and published manuscripts for this database, and that overlap exists with a previously published work. To proceed with this submission, please provide a justification for the overlap in the text box below.

K. Overlap Review Date: MM/DD/YYYY

Note that this cannot be a date in the future.

L. AI Use Disclosure:

Did you use any artificial intelligence (AI) tools (e.g., ChatGPT, Copilot, Gemini, or similar) in the development, drafting, or editing of this Research Proposal Application?

☐ Yes ☐ No

If yes, please briefly describe:

- The AI tool(s) used
- The purpose or task for which AI was used
- How you verified the accuracy and originality of AI-generated content

M. References:

List relevant literature citations; maximum of 10.

14. Funding Source

A. Externally Funded (grant, departmental, institutional, industry, pharma, medical device etc.)

Please note analysis begins at $50,000 and may increase depending on complexity. If you request NCDR support for your application, it will undergo scoring during review cycles to compete for a limited number of slots. If you plan to provide your own funding, your application will undergo a similar review via an expedited process.

B. Funding Description:

Please describe your funding sources: e.g., grant source and type, institution, industry name.

If Funding Source checked is 'NCDR', no written description is required.

Return completed form to: ***NCDRresearch@acc.org***.
Use the following in the subject line: New *[Insert Registry Name]* Externally Funded RPA

APPENDIX I REAL WORLD EVIDENCE DATA REQUEST FORM

This Data Request Form is to be completed for custom analytic requests that are *not* intended to support oral or poster presentations, manuscripts in peer review publications or other public release of information. Please complete the form below and e-mail to NCDRresearch@acc.org. Failure to complete all fields will result in the form being returned to you, which will delay processing your request.

CONTACT INFORMATION	
Requestor Name:	
Anticipated Collaborator(s):	
Requestor's Organization:	
Requester's Address:	
Requester's City:	
Requester's State:	
Requester's Zip Code:	
Telephone Number:	
E-mail Address:	

Please select the NCDR registry/ies relevant to this request:

☐ **AFib Ablation Registry™**

☐ **CathPCI Registry®**

☐ **Chest Pain – MI Registry®**

☐ **STS/ACC TVT Registry™**

☐ **IMPACT Registry®**

☐ **LAAO Registry™**

☐ **EP Device Implant Registry®**

PURPOSE OF REQUEST

Please state the purpose of this request. NOTE: This form is for custom analytic requests that are ***not*** *intended to support oral or poster presentations, manuscripts in peer review publications, or other public release of information. Providing as much detail as possible will help expedite your request.*

SOURCE OF FUNDING

Please provide a brief explanation of the source, description and amount of funding that will pay for this request (e.g., grant, industry, etc.).

INTENDED USE OF DATA

Please state the intended use of data. If data are to be used for internal research purposes, please attach a copy of your study protocol with background, methods, and references.

SCOPE OF REQUEST

Please provide the following details to define the scope of your request: inclusion/ exclusion criteria, provide a list of the variables and the corresponding variable numbers (4-5 digit # next to each variable) as part of your request (go to the Registry website and review the available variables within the respective data collection form- https://cvquality.acc.org/NCDR-Home/Data-Collection/What-Each-Registry-Collects),time period to be analyzed, preferred statistical methods, and specify any sub-groups, special categorizations, pre-defined ranges, etc.

FORMAT SPECIFICATION

Please select your preferred output format:

☐ MS Excel Spreadsheet(s)

☐ Aggregated Analytic Data Tables

☐ Recurring, customized data exports

Specify the frequency of exports:

Please note: The HIPAA Privacy Rule states the Minimum Necessary Requirement applies when using or disclosing protected health information (PHI). The ACC takes reasonable steps to limit the use or disclosure of, and requests for, PHI to the minimum necessary to accomplish the intended purpose.

Submit application and/or questions to NCDRresearch@acc.org

APPENDIX J: GRANT FUNDED PROJECT APPLICATION FORM

PRELIMINARY GRANT FUNDED PROPOSAL FORM

GRANT PROJECTS ONLY

15. Primary author Details

- **A.** Primary author's Name:
- **B.** Is Primary author currently a fellow-in-training? ☐ Yes ☐ No
- **C.** Primary author's Institution:
- **D.** Primary author's Email:
- **E.** Primary author's RWI current as of date:
- **F.** Senior Primary author(s) (optional):
  - i. Name:
  - ii. Email:
  - iii. and Institution:

16. Grant Funding Details

- **A. Funding Agency** *(NIH, FDA, etc.)*
- **B. Type of Grant** *(R01, K23 etc.)*
- **C. Link to Funding Announcement** *(if available)*
- **D. Grant Submission Deadline**
- **E. Grant Duration** *(years)*
- **F. Primary author's Institution Deadline**

17. Grant Proposal Details

- **A. Registry** (*Please select the NCDR registry/registries relevant to this request:*

☐ AFib Ablation Registry™

☐ CathPCI Registry®

☐ Chest Pain – MI Registry®

☐ STS/ACC TVT Registry™

☐ IMPACT Registry®

☐ LAAO Registry™

☐ EP Device Implant Registry®

B. Title of Grant Proposal

C. Key Words (*optional*):

List briefly the main terms relevant to the Grant Funded Proposal Application topic.

D. Background/Significance

*Provide a brief statement (**maximum 1 paragraph**) describing the background and significance of the proposed research*

E. Grant Aims Hypotheses

Briefly outline the aims of the grant proposal and related hypotheses

***18.* Anticipated Research Proposal Applications (RPAs) stemming from Grant Aims** (*one RPA per aim*)**:**

***1.* Aim #1**

a. Inclusion & Exclusion Criteria

Briefly describe the RPA's patient and/or hospital inclusion and exclusion criteria

b. Data Requested, Including Primary Outcomes and Covariates

Please utilize the appropriate registry's data collection form as reference to delineate groups for comparison, list the primary and secondary outcomes of interest for this proposal and requests for modeling these outcomes, any covariates of interest, and any of the main variables that may need to be considered (e.g., for adjustment) in the analysis.

c. Brief Statistical Analysis Plan

*Provide a brief description (**maximum 1 paragraph**) of the proposed statistical methodology for your proposal (e.g., trends to be evaluated, clinical characteristics of patients/providers, changes over time, estimated study endpoints, etc.). Please also include sample statistics (i.e., table shells, mean T value, etc.) for ACC to fully assess for scientific and budgeting purposes.*

***2.* Aim #2**

a. Inclusion & Exclusion Criteria

Briefly describe the RPA's patient and/or hospital inclusion and exclusion criteria

b. Data Requested, Including Primary Outcomes and Covariates

Please utilize the appropriate registry's data collection form as reference to delineate groups for comparison, list the primary and secondary outcomes of interest for this proposal and requests for modeling these outcomes, any covariates of interest, and any of the main variables that may need to be considered (e.g., for adjustment) in the analysis.

c. Brief Statistical Analysis Plan

*Provide a brief description (**maximum 1 paragraph**) of the proposed statistical methodology for your proposal (e.g., trends to be evaluated, clinical characteristics of patients/providers, changes over time, estimated study endpoints, etc.). Please also include sample statistics (i.e., table shells, mean T value, etc.) for ACC to fully assess for scientific and budgeting purposes.*

3. Aim #3

a. Inclusion & Exclusion Criteria

Briefly describe the RPA's patient and/or hospital inclusion and exclusion criteria

b. Data Requested, Including Primary Outcomes and Covariates

Please utilize the appropriate registry's data collection form as reference to delineate groups for comparison, list the primary and secondary outcomes of interest for this proposal and requests for modeling these outcomes, any covariates of interest, and any of the main variables that may need to be considered (e.g., for adjustment) in the analysis.

c. Brief Statistical Analysis Plan

*Provide a brief description (**maximum 1 paragraph**) of the proposed statistical methodology for your proposal (e.g., trends to be evaluated, clinical characteristics of patients/providers, changes over time, estimated study endpoints, etc.). Please also include sample statistics (i.e., table shells, mean T value, etc.) for ACC to fully assess for scientific and budgeting purposes.*

19. AI Use Disclosure:

Did you use any artificial intelligence (AI) tools (e.g., ChatGPT, Copilot, Gemini, or similar) in the development, drafting, or editing of this Research Proposal Application?

☐ Yes ☐ No

If yes, please briefly describe:

- The AI tool(s) used
- The purpose or task for which AI was used

- How you verified the accuracy and originality of AI-generated content

Return completed form to: **NCDRresearch@acc.org**.
Use the following in the subject line: New *[Insert Registry Name]* Grant-Funded Proposal Application

APPENDIX K: NCDR FUNDED RESEARCH CHECKLIST

SUBMITTING AN RPA

- ☐ Read the NCDR Research Policies and Procedures
- ☐ Choose the appropriate registry for your research
- ☐ Rule out overlap
- ☐ "Rule of Two" (confirm you have no more than two active proposals in the R&P pipeline)
- ☐ Create and submit new RPA on NCDR Research Management System (ensure to select NCDR Funded under funding source)

PUBLICATIONS

- ☐ Refer to the Brand and Style Guide in Appendix D prior to drafting a publication (i.e. poster, abstract, or manuscript, etc.).

  Templates can be accessed and downloaded through the NCDR Research Portal (select the "Resources and Supplemental Documentation" link under "User Resources").
- ☐ Submit the draft publication to the appropriate NCDR staff liaison via the online NCDR Research Management System.
- ☐ Submit the publication to the desired conference or journal and notify the appropriate NCDR staff liaison upon acceptance/rejection.

APPENDIX L: ACC EXTERNALLY FUNDED RESEARCH CHECKLIST

PREPARING AN RPA

- ☐ Read the NCDR Research Policies and Procedures
- ☐ Choose the appropriate registry for your research
- ☐ Rule out overlap
- ☐ Confirm you have no more than two active proposals in the R&P pipeline ("Rule of Two")

SUBMITTING AN RPA

- ☐ Complete the NCDR Externally Funded RPA Form in Appendix H.

  Submit the form to NCDRresearch@acc.org and use the following text in the subject line:

  New [Insert Registry Name] Externally Funded RPA
- ☐ Be prepared to provide the NCDR staff liaison with the following information upon request:
  - ✓ Funding source
  - ✓ Timing of funding (i.e. is there a specific date the funds will become available) / deadlines
  - ✓ Entity responsible for contracting
  - ✓ Point of contact at the contracting organization

**The NCDR staff liaison will submit the RPA to the Scientific and Strategic (S&S) Committee once all required documents are provided. S&S Committee approval must be granted prior to moving forward.*

RPA ANALYSIS

- ☐ Provide the designated NCDR staff liaison with availability for a kickoff call.
- ☐ Provide monthly project updates to the designated NCDR staff liaison upon receipt of statistical analysis.

PUBLICATIONS

- ☐ Refer to the Brand and Style Guide in Appendix D prior to drafting a publication (i.e. abstract, poster, manuscript, etc.).

  Templates can be accessed and downloaded through the NCDR Research Portal (select the "Resources and Supplemental Documentation" link under "User Resources").
- ☐ Submit the draft publication to the appropriate NCDR staff liaison via email or the online NCDR Research Management System.

- ☐ Submit the publication to the desired conference or journal and notify the appropriate NCDR staff liaison upon acceptance/rejection.

APPENDIX M: MEMO OF UNDERSTANDING FOR EXTERNALLY FUNDED RESEARCH

MEMORANDUM OF UNDERSTANDING

BETWEEN THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION

AND _____

This Memorandum of Understanding ("MOU") is hereby entered into and made effective as of _____ ("Effective Date") by and between the American College of Cardiology Foundation ("ACCF") and _____ ("PI"). ACCF and PI may each be referred to herein as a "Party" and collectively, as the "Parties".

I. IN GENERAL

WHEREAS the ACCF and PI desire to collaborate on a research endeavor for which federal funding will be sought.

WHEREAS, ACCF has developed the American College of Cardiology's NCDR® (National Cardiovascular Data Registry), to collect and report on standardized national clinical cardiovascular data in connection with different cardiovascular procedures.

WHEREAS the PI wishes to use certain NCDR data and analysis in connection with the research endeavor titled *<Insert Title of Grant Application>* ("Project"); and

WHEREAS the Parties desire to enter into this MOU in order to set forth the expectations regarding ACCF's role in the PI's grant application for federal funding.

NOW, THEREFORE, based on mutual consideration, the receipt and adequacy of which are mutually acknowledged, ACCF and PI agree upon the following terms and conditions.

II. PI OBLIGATIONS. The PI agrees to the following terms and conditions governing the PI's development of the "Project" and the grant application(s).

1. PI agrees that based on the proposed statement of work, ACCF shall be designated as a contractor or vendor when referenced in the federal award application. ACCF shall not be designated as a sub-recipient consistent with the characteristics outlined at 2 CFR 200.331.

2. PI agrees that the number of research proposal applications ("RPAs") requested in the statement of work submitted by PI is equal to the number of manuscripts planned to be written by the PI over the course of the federal award.

3. PI agrees that pre-submission data requests will be reviewed by ACCF. PI understands that ACCF shall not be obligated to complete data requests without execution of the proper contract and financial consideration to ACCF.

4. PI agrees that the PI has confirmed that the proposed contractual and financial engagement with ACCF is consistent and permissible under PI's institution's policies.

5. PI shall submit required federal award applications forms to ACCF at least eight (8) weeks prior to the desired date of completion by ACCF.

6. PI understands and agrees that ACCF reserves the right to suspend participation in the federal award application if PI fails to submit required federal award application forms at least (8) weeks prior to the desired date of completion.

7. PI shall prepare the federal award application as required by the funding federal agency and ensure all documents/forms are complete and accurate.

8. PI understands and agrees that ACCF's approval of the statement of work and budget applies to the current submission of the application to the funding federal agency. PI must submit a revised statement of work and budget in the event that the application is not funded, and a resubmission is required or desired.

III. ACCF OBLIGATIONS

1. ACCF reserves the right to modify the level of effort and budget provided by ACCF if the originally proposed timeline, scope, or budget of the statement of work is modified.

IV. TERM, TERMINATION, MODIFICATIONS, AND CHOICE OF LAW

1. This MOU constitutes the entire agreement between the Parties with respect to the subject matter hereof. The PI acknowledges and agrees that additional agreements will be required if the Project is funded by a federal agency.

2. There are no representations, warranties, agreements or understandings, express or implied, written or oral between the Parties hereto relating to the subject matter of this MOU that are not fully expressed herein.

3. This MOU shall be governed exclusively by the laws of the District of Columbia, United States of America. Any suit or proceeding relating to this MOU shall be brought only in the District of Columbia. EACH PARTY CONSENTS TO THE EXCLUSIVE PERSONAL

JURISDICTION AND VENUE OF THE COURTS LOCATED IN THE DISTRICT OF COLUMBIA.

4. Either Party shall have the right to terminate this MOU, without cause, at any time upon thirty (30) days' advance written notice to the other Party.

5. ACCF shall have the right to immediately terminate this MOU if PI fails to provide required federal award application documents to ACCF within eight (8) weeks of the submission date, if budget limitations in an awarded federal application are inadequate or if the PI proposes substantive changes in the scope or budget that, in ACCF's sole discretion, are unacceptable.

6. This MOU, when accepted by the Parties, will commence on the Effective Date and will remain in effect for twelve (12) calendar months from the Effective Date except as modified or terminated.

V. SIGNATORIES

IN WITNESS WHEREOF, each of the Parties has caused this MOU to be executed by its duly authorized representative.

AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION	**PI**
Signature: _____	Signature: _____
Name: Cathleen C. Gates	Name:
Title: Chief Executive Officer	Title:
Date: _____	Date: _____

APPENDIX N: LETTER OF SUPPORT REQUEST FORM

Primary authors must complete the NCDR Externally Funded RPA Form in Appendix H, in addition to the Letter of Support Request Form, when requesting a Letter of Support for a grant submission.

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