# AACVPR Application for Registry Data Analysis

# Title and Contact Information

Date:

Project title:

Principal Investigator (PI): Is the PI an AAVCPR member? Yes No

PI email:

PI telephone #:

Research Sponsor (if project is a Graduate/Medical Student Thesis project): Research Sponsor email:

Research Sponsor telephone:

PI Institution: PI Address: City, state, zip:

Research Sponsor (if project is a Graduate/Medical Student Thesis project): Research Sponsor email:

Research Sponsor telephone:

1. **Research team:** please include a complete list of other members of the research team (collaborators, students, staff), who will participate in the research project.

|  |  |  |  |
| --- | --- | --- | --- |
| **Name** | **Affiliation** | **Position** | **E-mail & Telephone #** |
| **To Be Determined** | **Data Analytic Center** | **Statistician** | [**Research@aacvpr.org**](mailto:Research@aacvpr.org) **(312) 321-5143** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

1. **Research Proposal:** Attach a research proposal addressing the following items.
   1. **Background:** Describe the importance and rationale of the research and the potential knowledge to be gained. Please explain in detail, including key references.
   2. **Research Question and Objectives:** Clearly state the research question with primary and secondary objectives of the study. When possible, use pre-specified directional hypotheses.
   3. **Data Variables:** Describe the specific variables that are requested to answer the research question. Provide the date range needed for data extraction. Here is a link to the codebook:

# Cardiac:

* + 1. **Pulmonary:**
  1. **Methods and proposed analytical plan**

Clearly outline proposed statistical methods needed to analyze the research question(s). Include mock table(s) with precise outcomes to be measured and analyzed. If feasible, describe power calculations if the study involves comparisons on each of the primary and secondary objectives.

Proposals that expect to produce more than one manuscript should note this as part of the Research Proposal section of the application. Additional manuscripts that are created based on the data analysis will need to follow the AACVPR Policy on Publications and Presentations as well.

In the spirit of open science, this document will serve as a “pre-registration” of the study and will be retained by the Research Committee of AACVPR and the DAC. The more detailed and precise the application, the more evidence of transparency and rigor the research team will have when presenting/publishing the results.

Therefore, consider reviewing NIH’s **Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies** available here: [https://www.nhlbi.nih.gov/health-topics/study-quality-](https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools) [assessment-tools](https://www.nhlbi.nih.gov/health-topics/study-quality-assessment-tools) Consider incorporating elements from the RECORD statement: Benchimol EI, Smeeth L, Guttmann A, Harron K, Moher D, Petersen I, Sørensen HT, von Elm E, Langan SM, RECORD Working Committee. The REporting of studies Conducted using Observational Routinely-collected health Data (RECORD) statement. PLoS medicine. 2015 Oct 6;12(10):e1001885. <https://pubmed.ncbi.nlm.nih.gov/26440803/>

# Target manuscript/abstract/presentation submission:

Identify a due date for submission and the proposed venue(s) for dissemination of findings (e.g., professional meeting presentation. abstract, journal title, grant proposal). Please note: If the final

submission will not be ready six months after researcher receipt of data analysis, the researcher will be required to submit an Interim Report.

The publication must list the master’s level statistician that conducts the analyses as a co-author. If the analyses require additional significant support either from the supervising PhD statistician or any other member of the DAC, these individuals will need to be listed as co-authors as well.

For publications, consider consulting the ICMJE Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals ([www.icmje.org](http://www.icmje.org/)) to ensure that all necessary elements for publication in a medical journal will be available when the proposed study is completed Additional details regarding ICMJE recommendations and language to use for publications can be found in the AACVPR Registry Research Requests and Publications FAQs Document.

# Required attachments

* Research Proposal
* Biosketch (equivalent to NIH Biosketch format) of the primary investigator
* Following initial approval from the Research Committee and final confirmation of analytic plan by statistician, include proof of compliance with applicable state and federal laws related to research, including where applicable, IRB approval or an Exempt or Non- Human Subjects Research (NHSR) determination from their home institution as soon as the decision is obtained.

Principal investigator agrees to pay all costs associated with data procurement, use and analysis of the data. To confirm adherence to the above requirement, please have Lead Researcher provide their initials here:

# Confirmation of Adherence to AACVPR Policy on Applications for Registry Data & AACVPR Policy on Publications Using Registry Data

Principal Investigator is required to adhere to the AACVPR Policy on Applications for Registry Data, AACVPR Policy on Registry Data Publications and Presentations, and to confirm that they will submit an Interim Report and/or Final Report (See Appendix C/D) to the AACVPR Research Committee.

To confirm adherence to the above requirement, please have Lead Researcher provide their initials here:

# Confirmation of Requirement to Include Disclosure Statement & AACVPR Registry Funding Statement for Published Data

The lead researcher must confirm they understand they will need to include the following disclosure and funding statement as part of any abstract, presentation, or manuscript created using data analysis from the AACVPR registry:

*“This study was supported by data obtained, whole or in part, from the AACVPR Cardiac (or Pulmonary) Rehabilitation Registry. The opinions, results and conclusions reported in this paper are those of the authors and are independent from the AACVPR. No endorsement by AACVPR is intended or should be inferred. The AACVPR Registries are supported by registry participant program subscriptions and outside funding from LSI and ScottCare.”*

To confirm adherence to the above requirement, please have Lead Researcher provide their initials here:

1. **Completion of Application**

To finalize the application, please have the Principal Investigator sign and date the application using the spaces below.

Signature

Printed Name of Institution or PI

Position at Institution

Date