AACVPR Data Analytic Center
Request for Applications

Letter of Intent Deadline: August 13, 2018
Application Deadline: September 10, 2018
Introduction

The American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) is a multidisciplinary organization consisting of health care professionals who are committed to improving quality of life and reducing mortality in patients with cardiovascular and pulmonary diseases. AACVPR provides education and other resources to healthcare professionals working in cardiac rehabilitation (CR) and pulmonary rehabilitation (PR) and has published guidelines/core components for CR and PR delivery. Based on these core components, AACVPR certifies CR and PR programs as a way to ensure the delivery of high quality CR and PR services. In order to monitor patient outcomes and identify opportunities to improve the quality of care delivered in CR and PR, AACVPR developed CR and PR data registries. These data registries represent the only national data registries of patients participating in CR and PR in the United States.

Overview of the Data Registries

The CR registry launched in 2012 and has a total of 505 programs included with over 350,000 patient records. Likewise, the PR registry launched in 2013 and has a total of 240 programs included with over 40,000 patient records. Participating programs enter data into the data registries via a web based data entry system. Some programs utilize an application programming interface (API), which is available from some telemetry vendors, that is able to submit data directly into the registries. The data in the registries are stored on a cloud based server which is compliant with all Health Insurance Portability and Accountability Act (HIPAA) requirements. The registries are
funded through program user fees and additional financial support from industry vendors.

The data registries collect a wide range of data on CR and PR participants which are summarized in Appendixes 1 and 2. These data include information on basic patient demographics, anthropomorphic measurements, co-morbidities, risk factor levels, functional capacity, quality of life, psychosocial measures, etc. Each data element has hard and soft limits for the range of allowable values to minimize incorrect data entry. Data are collected at baseline (enrollment in CR or PR), at completion, and in a limited number of participants at 1 year following completion. In order for programs to monitor the quality of care delivered in their individual program and compare it to their peers, automated reports are available to programs to view aggregate data on their patients’ performance relative to national averages for each data field.

**Need for a Data Analytic Center**

Currently, data from the CR and PR registries are only being utilized by individual programs to monitor their own patient outcomes and compare them to national averages as a way of identifying opportunities to improve quality of care. Programs have the right to publish research using data limited to their patients only, but no registry data at the national level has thus far been used for research purposes. However, there is increasing interest in utilizing these data within the CR and PR national registries for research purposes. Given their size, scope, and national reach, the AACVPR registries provide a major research opportunity. However, AACVPR would like for all analyses on
registry data to be conducted centrally to protect the security of these data and to
ensure that high quality statistical methods are utilized when analyzing these data.
Thus, AACVPR is releasing this request for applications (RFA) to establish a Data
Analytic Center.

Composition and Duties of the Data Analytic Center

The main purpose of the Data Analytic Center will be to conduct all statistical
analyses on data from the AACVPR CR and PR registries. The routine, day to day
functioning of the registries such as program data entry, the data entry interfaces,
maintenance of the hardware and software of the registries, registry reports, etc. will not
be the responsibility of the Data Analytic Center. These are managed by the Cissec
Corporation. The Data Analytic Center will only be responsible for data management
and statistical analyses for AACVPR or investigator initiated analyses.

Composition

We expect that the Data Analytic Center would be composed of a PhD
statistician, masters level statistician, and a primary investigator (PI) with some
experience or expertise in cardiac and/or pulmonary rehabilitation. We anticipate that
most analyses will be able to be conducted by a masters level statistician. In some
cases, a PhD level statistician may be needed, at least in an advisory role, if the
analyses are particularly complex or if there are questions on how to proceed, although
the time commitment of the PhD statistician is expected to be small. The PI could be
the PhD statistician or another faculty member with research expertise, who could add
content expertise to the team. We would envision that the PI would become a member of the AACVPR research committee to serve as a liaison between the research committee and the Data Analytic Center.

Duties

We consider the work of the Data Analytic Center to fall into 2 broad categories. The first category would include the routine day to day function of the Data Analytic Center. These primary routine duties would include 1) routine data management for research purposes, 2) the conduct of internal AACVPR analyses, and 3) the acquisition and maintenance of Institutional Review Board (IRB) approval. The second category of work would include the conduct of investigator initiated analyses approved by the AACVPR Research Committee. As will be explained in more detail below, a fixed amount of financial support will be provided to support the routine day to day functioning of the Data Analytic Center, and additional funding will be provided for each investigator initiated analysis performed.

The Data Analytic Center would be provided with an analytic data set from the CR and PR registries that would be used to perform these analyses. This data set will be updated periodically (once or twice a year) to incorporate newly entered data. Appropriate security safeguards would need to be made by the Data Analytic Center to protect these data. In addition, AACVPR would want to enter into a Data Use Agreement with the Data Analytic Center to govern the use and security of these data.
**Routine Data Management**

Once a Data Analytic Center is chosen and prior to beginning analyses, there will likely need to be a period of time to examine the data sets to “clean” them and investigate for missing data or other apparent errors in data entry. As new data are incorporated, similar processes will need to be followed. As previously mentioned, there are hard and soft limits on data entry already incorporated into the registry that should minimize or prevent any significant data entry errors. Thus we do not think the data cleaning process will be very time consuming. We envision establishing a small group of AACVPR member volunteers who could work along with the members of the Data Analytic Center and meet regularly via teleconference to assist with this process. The member volunteers would not have access to the data sets themselves but would be able to review summary data from the data sets and would be familiar with the registries so that they would be able to provide guidance to the statisticians as necessary.

**Internal AACVPR Analyses**

AACVPR will periodically have internal analyses that we will need the Data Analytic Center to conduct such as quick analyses to answer questions that come up in committee meetings or more detailed analyses to support performance measure endorsement or AACVPR commissioned manuscripts, etc. We expect that most of these will be simple and quick requests that will not be very time consuming.
Institutional Review Board Approval

Given that the CR and PR registries were developed for quality improvement and not for research, individual patients have not given informed consent to participate in research. It is our belief that these data should be able to be utilized for research purposes with appropriate IRB approval and waiver of informed consent. As such, we will require that the Data Analytic Center obtain IRB approval through their own institutional IRB to manage the release of the analytic data sent from AACVPR to the Data Analytic Center and to govern the data management and data analyses that will be conducted by the Data Analytic Center. In addition, we will require that individual authors obtain local IRB approval for any investigator initiated analyses that they ask the Data Analytic Center to conduct, although these will likely be considered exempt from IRB review as the individual authors will not have access to raw data.

Investigator Initiated Analyses

AACVPR has a Research Committee which consists of volunteer members of the association with research expertise in CR and PR. All requests for investigator initiated analyses will first be submitted to the AACVPR Research Committee utilizing a manuscript proposal form as shown in Appendix 3. The Research Committee will review these requests for scientific validity and priority. The PI of the Data Analytic Center should participate in these discussions as well. Those proposals which are approved by the Research Committee to move on to the analytic phase will be passed on to the Data Analytic Center to conduct the analyses. Currently, there is not sufficient funding available from the registry to support investigator initiated statistical analyses.
Therefore, authors who request that analyses be performed will be responsible for providing funds to support these analyses. Thus, after proposals are accepted by the Research Committee, the Data Analytic Center will be able to assign a cost for these analyses and a time line for the completion of the work based on the complexity of the analyses needed and the estimated time needed for completion. It is also our expectation that members of the Data Analytic Center who participated in the completion of these analyses will be able to serve as co-authors on abstracts and manuscripts if interested. AACVPR will handle the collection of money from the investigators and will set up a payment schedule with the Data Analytic Center for work performed, perhaps on a monthly or quarterly basis.

**Funding**

In order to support the initial data management function that will need to occur before analyses are begun, the acquisition and maintenance of IRB approval, ongoing data management as the analytic data sets are updated, and internal AACVPR analyses, AACVPR will provide a total of $50,000 annually, inclusive of all direct and indirect costs, to the statisticians and/or their institution to support this work. It is important to note that this funding will not include the performance of investigator initiated non-AACVPR commissioned analyses. As such, additional funding will be provided for analyses conducted for investigator initiated projects that are approved by the AACVPR Research Committee. The amount of funding provided for each of these analyses will be determined on a case by case basis depending on the complexity of the analyses needed and the estimated time required to complete them.
Application Requirements

Individuals interested in responding to this RFA should submit an application to AACVPR for review. Although there are no formal font or page limitations, we would expect that a 3-5 page application should be sufficient to respond to the RFA. We would expect that this application would include a description of the proposed team, prior experience with this type of data analysis, and a plan for data security and IRB approval.

In addition to the 3-5 page application, we would also like to receive the NIH biosketches of any personnel included on the team and a proposed budget explaining how the $50,000 in annual support for the routine day to day component of the scope of work will be utilized. This budget should list the salary including fringe benefits and estimated time on the routine day to day portion of the project (percent effort) as well as any equipment or other miscellaneous or indirect costs.

Applications can be sent via email to Kate Maude (kmaude@aacvpr.org) by September 10, 2018. In addition, we are requesting that a one page letter of intent to apply be submitted to the same email address by August 13, 2018. This letter of intent to apply needs to only include the institution name and the names and degrees of proposed members of the research team. The letter of intent will only be used by AACVPR to determine the number of applications that we expect to receive and the individuals and institutions who are applying to assist in preparing the review committee. The content of the letter will not influence the final selection of the Data Analytic Center.
Questions

Any questions related to this RFA can be submitted to Kate Maude (kmaude@aacvpr.org).
Data Analytic Center Application Checklist

One page letter of intent to apply submitted to Kate Maude (kmaude@aacvpr.org) by August 13, 2018.

Requirements:

1. Institution name
2. Names and degrees of proposed members of the Data Analytic Center

Full application submitted to Kate Maude (kmaude@aacvpr.org) by September 10, 2018.

Requirements:

1. Approximate 3-5 page application including description of proposed team, experience, and plans for data security and IRB approval
2. NIH bio-sketches of proposed members of the Data Analytic Center
3. Budget
The following is a list of data elements contained in the registry. Please note that this list is subject to change. Registry subscribers will be notified if there are any major changes made to the list. Please note that for the assessment tools listed, fields will be provided for scores. AACVPR will not provide actual tools. Participating programs may choose which fields to track within the registry; only the Medical Record ID field is required to save a record.

**Demographic Information**
- Registry ID (system)
- Record creation date (system)
- Program ID (system)
- Hospital medical record ID
- Last name
- Gender
- DOB
- Health insurance plan
- Insurance Copay
- Race
- Ethnicity
- ZIP code
- Education level

**Medical History Information**
- CR admission diagnoses and dates
- Pre-existing diagnoses
- Risk factors (hyperlipidemia, hypertension, diabetes T1/T2/IGT/IFG)
- Past history of CHD
- Comorbid conditions
- Revised Charlson Comorbidity Index (calculated)
- Heart Failure Status
- Tobacco use status:
  - Current status
  - Packs/day
  - Years of use
  - Pack-year history (calculated)
  - Oral tobacco use

**CR Intake Information**
- Referral date
- Age at time of referral (calculated)
- Enrollment status
- Enrollment date
- Prescribed number of sessions and how determined
- AACVPR Risk Category

**Pre/Post Clinical Assessments**
- Lipids (total cholesterol, triglycerides, HDL, LDL, non-HDL (calculated))
- Point-of-care qualifier
- Lipid panel date
- Fasting blood glucose
- Fasting blood glucose date
- Hemoglobin A1C
- Hemoglobin A1C date
- Blood pressure
- Height
- Weight
- Waist circumference
- BMI (calculated)
- Metabolic syndrome (calculated)
- Medications adherence (Aspirin, Beta-antagonists, ACEI/ARBs, Statins, PCSK9)

**Tobacco Use Status:**
- Current status
- Packs/day
- Years of use
- Pack-year history (calculated)
- Oral tobacco use

**Functional Measures**
- Maximal METs (from GXT)
- Peak Exercise METs (from CR session)
- 6-minute cycle distance
- 6-minute walk distance

**Supported Assessment Tools**

**Dietary Assessments**
- Diet Habit Survey
- MEDFICTS
- Block Dietary Fat Screener
- Rate-Your-Plate - Heart
Depression/Psychosocial Risk
- CES-D score
- BDI-II score
- PHQ-9 score
- Psychosocial Risk Factor Survey
- HADS

Health-related Quality of Life
- MacNew
- Medical Outcomes Trust-Short Form 36-v2 and SF-12 v2 (Standard)
- Ferrans & Powers Quality of Life Index–Cardiac Dartmouth COOP
- EQ-5D

Functional Status
- Duke Activity Status Index score
- DASI-METs (calculated)

Exercise Behaviors
- Exercise minutes/day
- Exercise days/week
- MET-mins/week (IPAQ)
- Steps per day (from pedometer)

Heart Failure
- LVEF
- NYHA Class
- MLHFQ Score
- KCCQ

Health Care Utilization
- Hospital readmissions and reasons for readmissions
- Number of days in hospital
- Emergency room visits
- Adverse events
- Unexpected events
- Influenza vaccination
- Pneumococcal vaccination

Discharge Information
- Completion status
- Non-completion reasons
- Program discharge date
- Number of sessions completed
- Number of ECG-monitored sessions
- Number of non-center sessions
- Vaccination Status

Follow-Up Information
- Follow-up date
- Follow-up method

Note: Some of the definitions for the above data elements are unique and have been standardized specifically for the registry. They may be different than what you are currently using. The definitions and timing of data collection will be reviewed during the principal user training sessions.
The following is a list of data elements contained in the Registry. Please note that this list is subject to change. Participating members will be notified if there are any major changes to this list. Please note that for the assessment tools listed, fields will be provided for scores. AACVPR will not provide actual tools. Participating programs may choose which fields to track within the registry; only the Medical Record ID field is required to save a record.

**Demographic Information**
- Registry ID (system)
- Record creation date (system)
- Program ID (system)
- Hospital medical record ID
- Last name
- Gender
- DOB
- Health insurance plan
- Session Copay
- Health insurer(s)
- Race
- Ethnicity
- ZIP Code
- Education level
- Social support/living arrangement

**Medical History Information**
- PR admission diagnoses
- Last Hospital Admission for COPD
- Comorbid conditions
- Revised Charlson Comorbidity Index (calculated)

**PR Intake Information**
- Referral date
- Enrollment date
- Reason for non-enrollment
- Age at enrollment (calculated)

**Pre/Post Clinical Assessments (tracked at intake, discharge, and follow-up)**
- Height
- Weight
- BMI (calculated)
- Fat-free mass/method used
- BODE Index (calculated)

**Spirometry**
- FEV₁ (actual, % predicted)
- FVC (actual, % predicted)
- FEV₁:FVC (ratio, entered in the form of a number to the nearest 2 decimal points.)
- DLCO (actual, % predicted)
- FRC (actual, % predicted)
- RV % Predicted
- TLC % Predicted
- RV/TLC % Predicted
- IC/TLC % Predicted
- Obstruction/restriction and severity

**Tobacco use status:**
- Packs/day
- Years of use
- Pack-year history (calculated)
- Years Using Oral Tobacco
- Tobacco Intervention Method
- Quit date

**Medication**
- Long-Acting Beta Agonist
- Short-Acting Beta Agonist
- Long-Acting Anticholinergics
- Short-Acting Anticholinergics
- Inhaled corticosteroids
- Oral corticosteroids

**Functional Capacity Measures**
- 6-Minute Walk Test parameters:
  - Distance (feet/meters)
  - Test type
  - METs (calculated)
  - Borg Rating of Perceived Exertion
  - Borg Dyspnea Rating
- Peak METs during PR

**Physical Activity**
- Exercise minutes/day
- Exercise days/week
- Patient Steps per Day
- MET-mins per week (IPAQ)
Supported Assessment Tools

Health-related Quality of Life
- Chronic Respiratory Disease Questionnaire
- St. Georges Respiratory Questionnaire
- Medical Outcomes Trust-Short Form 36-v2 (Standard)
- Ferrans & Powers Quality of Life Index- Pulmonary Global
- Dartmouth COOP
- COPD Assessment Test (CAT)

Depression/Psychosocial Risk
- Center for Epidemiologic Studies-Depression Patient Questionnaire
- Psychosocial Risk Factor Survey
- Hospital Anxiety and Depression Scale
- Geriatric Depression Scale (15- or 30-point)
- Beck Depression Inventory-II

Oxygen Usage
- Nasal cannula and/or mask usage at rest,
  ADLs, exercise, and sleep
- Oxygen percent at rest, ADLs, exercise, and sleep

Dyspnea Assessments
- Modified Medical Research Council Dyspnea Scale
- Baseline Dyspnea Index
- Transitional Dyspnea Index
- UCSD Shortness of Breath Questionnaire

Healthcare Utilization
- Exacerbations
- Untoward Events/Mortality
- Hospitalization

Discharge Information
- Completion status
- Non-completion reasons
- Program discharge date
- Number of exercise sessions completed

Follow-Up Information
- Follow-up date
- Follow-up method

Note: Some of the definitions for the above data elements are unique and have been standardized specifically for the Registry. They may be different than what you are currently using. The definitions and timing of data collection will be reviewed during the Principal User training sessions.
Application for Access to Outpatient Cardiac and/or Pulmonary Registry Data

For Research Purposes

Use of data obtained from the Outpatient Cardiac and Pulmonary Registries through the American Association for Cardiovascular and Pulmonary Rehabilitation (AACVPR) require researchers to complete this application followed by review and approval by the AACVPR Research Committee. The goal of this application process is to ensure that registry data are used to answer applicable and scientifically appropriate questions in a responsible manner by qualified research teams. The review process is overseen by the Research Committee with attention to scientific merit and feasibility. Applicants may be contacted with requests for additional information within the application review process.

AACVPR requires that a qualified statistician or analytical group with a business contract with AACVPR conduct the data analyses. No registry data will be released to the researcher. The Research Committee will review the application, and if the research concept is approved, more detailed discussion between the researcher and statistician will occur to finalize the analytic plan. It is the responsibility of the researcher to 1) pay the associated cost of the data analyses, and 2) provide proof of compliance with applicable state and federal laws related to research, including where applicable, IRB approval, following approval of the application and final analytic plan confirmed by the analytic center.

The researcher will be responsible for any costs associated with data procurement, use, and analyses provided by AACVPR or its contracted agents. No analyses will be conducted until all costs are paid in full. If additional analytic work is requested by the researcher beyond the original analytic plan, additional fees may occur based on the estimate provided by the analytic center.

Title and contact information

Date: _______________________

Project title:   __________________________________________________________

Principal investigator: ____________________________________________________

AAVCPR member:           yes            no

PI contact information:     email:                         Telephone #:

Institution ________________________________________________________

Address _________________________________________________________

City, state, zip ____________________________________________________
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.

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2. **Background:** Describe the importance and rationale of the research and the potential knowledge to be gained. Please explain in detail, including key references.


3. **Research Question and Objectives:** Clearly state the research question with primary and secondary objectives of the study.


4. **Data Variables:** Describe the specific demographic and outcome variables that are requested to answer the research question. Provide the date range needed for data extraction.


5. **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.

6. **Target submission:**

Identify due date for submission and proposed venue to disseminated findings (e.g., professional meeting presentation, abstract, journal title, grant proposal)

7. **Required attachments**

- 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.

______ Principal investigator or _____ Institution (check one) agrees to pay all costs associated with data procurement, use and analysis of the data. If signing on behalf of an Institution I represent and warrant that I have the authority to bind the Institution to this Agreement.
Signature

Printed Name of Institution or PI

Position at Institution

Date