American Heart Association.
COVID-19 CVD Registry™
Powered by Get With The Guidelines®

COVID-19 CVD Registry Powered by Get With The Guidelines®*

Investigator-Initiated Research Proposal Form

American Heart Association Quality Improvement Programs

For questions or to submit this form, email: QualityResearch@Heart.org

Date Submitted to AHA:	Project # (assigned by AHA Staff):
Working Title of Research Proposal:	

Principal Investigator / Lead Author Information:

Name and Credentials:

Title/Position:

Institution/Company:

Mailing Address, City, State, Zip:

Email:

Phone Number:

AHA Professional Membership - status or number:

Early Career Investigator? ◯ Yes ◯ No ***See appendix for Early Career Investigator definition***

COVID-19 CVD Registry Participation

Is your hospital or health system enrolled in the COVID-19 CVD Registry and actively uploading patient records? ◯ Yes ◯ No

If yes, please provide name and contact information for site PI:

Target data analytics channel:

☐ Self-analyze data on AHA's Precision Medicine Platform (PMP)
☐ Collaborate with AHA Data Analytics Team on the PMP to conduct analysis.
See appendix for more details and for pricing.

For self-analyze projects, indicate who will be performing the statistical analyses:

*** Please note:** This form is specific to COVID-19 CVD proposals only and should not be used for other GWTG research proposals

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Diversity & Inclusion: "Strengthening all of us as individuals, as an organization and as one world" By marking the box below, please confirm that you will make every effort as the Project Lead to strive for AHA's commitment to diversity and inclusion in the Scientific and Healthcare Quality Community. This will include building a collaborative project team that is inclusive of individuals who are diverse across gender, race/ethnicity, career stage, and institution. If you are unable to find a collaborator for each of these groups, please contact the AHA team and we will help to build your project network. ☐ I have read and agree to the above Diversity and Inclusion commitment
Co-Investigator(s)/Author(s) – Name, Institution, Email address: Name: Institution: Email: Name: Institution: Email: Name: Institution: Email:
Expected or existing funding (check all that apply and specify source): ☐Federal Grant: ☐Non-Federal Grant or Foundation: ☐Not-for-profit or Academic Source: ☐For-profit/industry: ☐Institution/Self-Funded: ☐Other:
If Project is Grant or Foundation Funded: Project funding start and end dates: Total Funding budgeted for AHA GWTG Statistical Support:
Research Dissemination Target (check all that apply and specify target): ☐ Scientific Conference: ☐ Journal: ☐ Other:

Publication/abstract key words:
Goals/Objectives/Research Question:
Study Hypothesis:
Background and Rationale (1-2 paragraphs, with references):

Study Population (specify any subgroups):
Primary/secondary exposure variables:
Primary Outcomes/Endpoints:
Secondary Outcomes/Endpoints:
Description of Proposed Statistical Analyses. Provide sufficient detail including types of statistical tests to be performed so that the Research and Publications Subcommittee can assess the statistical expertise of the investigative team. Note: A more formal statistical analysis plan may be requested by the R&P prior to approval.

Sample Tables (please provide examples of the tables as you plan to present them in the space below):
Brief Description of Research Team Qualifications Related to Proposal:
Key References:

AHA Use Only:
Review notes and decisions

APPENDIX

The AHA Precision Medicine Platform (PMP) is a cloud-based data marketplace with secure, private workspaces equipped with data analysis tools. Users can work with the Get With The Guidelines data as well as upload their own data to the workspace. The Precision Medicine Platform uses a combination of security measures that meet or exceed FedRAMP low and HIPAA requirements, providing users with a comprehensive security, quality, and privacy framework.

- Learn more about the Precision Medicine Platform here.
- Explore the capabilities of Precision Medicine Platform workspaces here.

☐ Investigator-led Data Analysis on AHA's Precision Medicine Platform (PMP)

Select Career Level	PMP Annual License Fee for 2023	GWTG Data Administration Fee Per Proposal	$50,000 Computational Cloud Credits
☐ Early Career*	$1,250	$250	FREE
☐ Established	$5,000	$1000	FREE

- Each workspace owner will name an analytic team on the manuscript proposal, which will be provisioned with the PMP workspace and appropriate dataset files.
- Software available for basic statistical analysis include SAS, Python and R. Individuals may also use machine learning and AI tools as well as the many other visualization and software programs within the PMP workspaces.
- Investigator will be allotted up to $50,000 complimentary Amazon Web Services credits with their access to a workspace on the Precision Medicine Platform during the term of this Agreement.
- Invoices are sent via email.

☐ Collaborate with AHA Data Analysis Team to Conduct Analysis on the PMP**

- The AHA Data Analysis Team will work with the authors to estimate the number of hours per project. The authors will need to be available for questions and discussion as part of the estimation process. This information will also help inform the author of the expected length of time a PMP workspace will be needed, to enable a cost projection.
- The AHA Data Analysis Team includes statisticians and scientists with significant study design, epidemiology, and computer science capabilities.
- Typical analyses will range from 50 – 250 hours depending on the complexity of the analyses.
- Rates are $125 per hour in addition to the annual PMP license fees as noted above.
- Prioritization of manuscripts may depend on workflow.
- The investigator will be invoiced directly for analytical hours accrued per month.
- See following page for more detail regarding the AHA Data Analysis Team.

☐ Ad Hoc Support with AHA Data Analytics

- The AHA Data Science Team is available on an ad hoc basis to provide technical and analytic support for Self Service authors.
- Rates are $175 per hour.

☐ Early Career Investigator Database Research Seed Grant (ECI Grant) Recipient

- ECI Grants are competitively awarded each year for Get With The Guidelines national-level research.

- The following fees are waived for ECI Grant recipients that have been approved for research to be conducted using GWTG data on the PMP:
    - PMP Annual License Fee, up to one year,
    - GWTG Data Administration Fee for one proposal,
    - Collaboration with the AHA Data Analysis team (up to 150 hours).

*Early Career Investigator includes the following:

- Predoctoral fellows pursuing a post-baccalaureate doctoral degree including PhD, MD, DNP, or equivalent clinical health science doctoral degree program
- Postdoctoral fellows including trainees with post-baccalaureate PhD, MD, DNP, or equivalent clinical health science doctoral degree program. This includes MDs who are current residents, fellows in training or have completed training within the last 5 years.
- Research or Clinical faculty/staff up to and including the rank of assistant professor (or equivalent) for which no more than five years have elapsed since the first faculty/staff appointment.

**Collaborate with AHA Data Analysis Team to Conduct Analysis on the PMP

Obligations of AHA Data Analysis Team

AHA Data Analysis team will hold an initial call with the principal investigators (PI), and/or their appropriate research staff to assess and understand the statistical needs of the project. Topics to be discussed during the initial consultation call include but are not limited to: overview of expectations and accountability, description of project, research hypothesis, feasibility, primary and secondary objectives, definitions of exposure variables, end points, and cut off values, discussion of statistical techniques and methodologies, overview of desired and format of output including charts, graphs, tables etc, and estimation of hours and cost.

Within a week of the consultation call, the Data Analysis team will send a Statistical Analysis Plan (SAP) to the PI and their appropriate research staff detailing the planned analysis and agreed upon project deliverables with a time frame. Any changes to the planned analyses should be made prior to formal written approval of the SAP. Suggested changes must be within the scope of the approved proposal. The PI and their appropriate research staff will provide written approval of the Statistical Analysis Plan. Work on the project only will start after the contract has been agreed upon and signed by all necessary parties. The Data Analysis team will provide the PI and their appropriate research staff with regular status updates and communicate any statistical issues that may arise. A finalized Statistical Analysis Report within the prespecified time frame will be delivered via email to the PI. The Data Analysis team performing the analysis will be co-authors on the publication(s) to acknowledge the intellectual contribution to the work. The Data Analysis team will be given at least 1 week to review any final drafts of an abstract or publication prior to submission or resubmission to ensure study and statistical integrity.