National-Level Quality Programs Research Policy

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Authority: American Heart Association National Quality Research Staff

Overview

The American Heart Association (AHA) Get With The Guidelines® (GWTG) is a hospital-based quality improvement program designed to close treatment gaps. Our Quality Programs include modules in atrial fibrillation, coronary artery disease, heart failure, resuscitation (adult and pediatric), and stroke. The COVID-19 CVD Registry powered by Get With The Guidelines is AHA's newest national quality improvement program and registry.

The AHA collects millions of patient records in our quality programs, creating vast databases for advancing scientific research. Data are collected at the patient level in hospitals participating in AHA Quality Programs. Clinical encounters entered in the database are from U.S. hospitals only. Patient and hospital data are de-identified at an aggregate level. With this vast collection of data, AHA can translate research into potential improved practices, validate and support guidelines, as well as identify novel unique scientific findings to further promote quality improvement.

Using the data that are collected through AHA's national GWTG programs, researchers can develop study questions and submit a proposal to conduct an investigator-led research project.

Purpose

The purpose of this policy is to provide overview and direction for the use of AHA GWTG National Program Data for research that is developed into abstracts and manuscripts of sound scientific merit, which are published at conferences and in peer-reviewed journals and may be used to drive the development of AHA Guidelines.

Hospital-Level Data Use and Research guidance can be found at Hospital-Level Research.

Responsibility

GWTG and Mission: Lifeline participating hospitals, AHA Quality, Outcomes Research and Analytics Staff, GWTG Volunteer Leadership all have a responsibility and role to ensure this policy is followed.

Scope

This policy applies to all abstracts, publications, or any public facing material using National-Level GWTG or quality program data. This policy document is in addition to the Science Research Policy and does not overlap or disregard it. This does not include industry funded narratives.

Policy Statement

The AHA has a responsibility to ensure National-Level Research is of high scientific merit, as it is often used to drive AHA clinical practice guidelines. National-Level Research proposals must be submitted using a standardized process outlined below and approved abstracts and manuscript

drafts must be reviewed by AHA National Quality Research staff, the Systems of Care Advisory Group (SOCAG), and AHA Science.

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I. General Information

A. Definitions

- Designated Analytic Center: A center commissioned by the AHA and/or its volunteer leadership which may perform statistical analysis on Get With The Guidelines® datasets for strategic analyses.
- Early Career Investigator (ECI): PhDs and/or MDs who are current residents, fellows in training or have completed training within the last five years, or other doctoral prepared professionals who are early in their career development and have interest in cardiovascular or stroke research. Certain citizenship designation does apply.
- Get With The Guidelines® (GWTG): Get With The Guidelines® (GWTG) is a hospital-based quality improvement program designed to close treatment gaps. Our Quality Programs include modules in atrial fibrillation, coronary artery disease, heart failure, resuscitation (adult and pediatric), and stroke. The COVID-19 CVD Registry powered by Get With The Guidelines is AHA's newest national quality improvement program and registry.
- Researcher (Principal Investigator): The individual responsible for the preparation, conduct, and administration of the research study.
- Statistical Analysis Plan (SAP): A document that provides detail on the scope of planned analyses, population and data definitions, and methodology.
- Systems of Care Advisory Group (SOCAG): American Heart Association volunteer leadership committees that guide the direction of the quality programs.

B. Data availability and statistical analytics:

1. Data is available for research from the following GWTG modules:
    - Atrial Fibrillation (AFIB)
    - Coronary Artery Disease (CAD)
    - COVID-19 CVD
    - Heart Failure
    - Stroke
    - Resuscitation (Adult and Pediatric)
2. Analytic channels:
    - AHA Precision Medicine Platform – A strategic AHA initiative that is a cloud-based analytic workspace with access to datasets and is comprised of common tools and software used for statistical analysis.
        - Approved statistical analyses can be performed on the Precision Medicine Platform by the Researcher's Biostatistical Team, by the AHA Data Science Team, or a combination of the two teams.
    - American Heart Association Data Science Team - May be contracted to provide full-service analytic support or consultation services for approved statistical analyses.
    - Researcher's Institution/Biostatistical Team – Although limited, certain institutions may be granted permission for a copy of deidentified data to be delivered for statistical analysis to be performed. Facilities must meet AHA data security standards prior to receiving a data extract. If a facility does not meet the requisite security standards, the investigator will need to conduct the analysis on

the Precision Medicine Platform or contract with AHA's Data Science Team or approved analytic providers.
    - Analytic Partners – The AHA partners with Designated Analytic Centers which may perform statistical analysis on GWTG datasets for strategic analyses commissioned by the Association and its volunteer leadership. Individual investigators may be able to request and contract for these services on an *ad hoc* basis, if the investigator is unable to complete the analysis through one of the above means.
        - Analyses are delivered to Researchers as charts and graphs.

C. Project funding

1. AHA provides funding for a limited number of commissioned strategic analyses, including Early Career Investigator Awards, each year. Funded proposals are competitively reviewed and commissioned through AHA's volunteer leadership committee (see Proposal Submission, Review, and Approval).
2. External funding via the Investigator, which may include grants, awards, industry, or institutional funds, are accepted on a limited basis. AHA will have final determination on which external funding sources are acceptable.
3. Government- and foundation-funded grants require additional review time. Investigators may want to include analyses of AHA's datasets in a research grant proposal.
    - Proposals for federal funding must be submitted 6 months prior to due date.
    - Proposals for other foundation funding must be submitted 3 months prior to due date.

II. Proposal Submission, Review, and Approval

A. Submitting a proposal

1. Visit the following websites for up-to-date information and submission deadlines:
    - AFIB, Coronary Artery Disease, Heart Failure, and Stroke- National-Level Research Publications
    - Resuscitation- GWTG - Resuscitation Research
    - COVID-19 CVD- Research Opportunities AHA COVID-19 CVD Registry
    - Early Career Investigators (ECI) - Research Opportunities
        - Note: Original proposals only – no resubmissions
2. Developing a proposal:
    - Review the data elements collected for the applicable GWTG module (Case Report Form) to ensure the outcome of interest is collected.
    - Review the GWTG Publications database and PubMed.gov to avoid overlap with any existing publications.
3. Fill out the Research Proposal Form completely, including sample tables and/or charts for the study.
4. Submit the completed Research Proposal Form
    - Atrial Fibrillation, Coronary Artery Disease, COVID-19 CVD, Heart Failure, and Stroke modules: Submit to QualityResearch@heart.org
    - Resuscitation module: Submit to GWTGResuscitationResearch@heart.org
5. Limitations and project scope:

- A lead author may have a total of 2 active projects across all the modules; additional proposals will not be accepted. Manuscripts submitted to journal are not considered an active project.
- Resuscitation: If the lead author has not complied with the data destruction policy for previous projects, additional proposals will not be accepted until the requirements have been fulfilled.
- Only one manuscript may be produced per approved proposal. If the scope of a proposal is too broad for a single manuscript, an additional proposal can be submitted for approval.

B. Proposal review

1. Proposals are reviewed by expert clinical volunteer groups specific to each module.
2. Review Criteria: Proposals are reviewed for feasibility, overlap with other approved proposals or existing publications, scientific merit, novel contribution to scientific literature, strength of the analysis plan, and alignment with the AHA mission.
3. Decisions: AHA staff will notify the lead author of the committee's decision to approve, request revisions or decline.
4. Approved proposals are considered final; projects are limited within the approved scope. Requests for additional analyses or expanded scope must be reviewed and approved.
5. Proposals that are revised may only be resubmitted for up to 2 more standard review cycles.
6. Declined ECI proposals, if feasible, can be revised and may be resubmitted for up to 2 more standard review cycles standard review cycles.

III. Project Development for Approved Proposals

Once a Research Proposal is approved, the investigator is notified by AHA Staff of the approval, project timelines, requirements, and next steps. All proposals will have a GWTG Volunteer from the Advisory Group act as a mentor throughout the project.

A. Non-disclosure and data use agreements

1. Non-disclosure, Data Use, and or Terms of Service agreements are required to access GWTG data and/or utilize statistical output for publication. Usage is limited to the scope of the approved project proposal. Changes to the analysis plan that require additional data usage may require an amended agreement and potential fees.

B. Data analysis process and requirements

2. Projects with analysis being completed on the Precision Medicine Platform:
    - When an investigator-led project is approved to be completed using the Precision Medicine Platform, investigators must indicate whether their institution's statisticians will complete the analysis independently or whether the AHA Data Science Team will be contracted to conduct the analysis.
    - Once a Non-disclosure agreement/data use agreement (NDA DUA) is complete, the lead Researcher will receive instructions on how to request a workspace on the Precision Medicine Platform. Once the workspace request has been approved and provisioned by the AHA, the Researcher can begin to use the platform and any authorized datasets for their analysis. The American Heart Association will

deliver the necessary data to conduct the approved analyses directly to the workspace.
    - For analyses that will be completed by AHA's Data Science Team, a Statistical Analysis Plan (SAP) will be developed based on the approved proposal and delivered to the researcher. Analyses will not begin until the SAP has been approved by the investigators. No additional research questions or analyses will be added once the SAP has been approved.
    - For self-analyses using the Precision Medicine Platform, the SAP will be reviewed and approved by the SOCAG liaison and others as needed.
    - Completed analyses will align with the approved SAP and be used to develop a manuscript.
    - Access to the Precision Medicine Platform and the AHA dataset will expire in conjunction with the term date of the NDA/DUA or once the Researcher's manuscript has been published in a journal (authorized purpose for the project), whichever comes first.
    - Once the AHA has confirmed the Researcher's project has been published, the AHA will take necessary steps to decommission the Researcher's workspace on the Precision Medicine Platform which includes access to the AHA dataset. Researcher should take necessary steps to save any analyses, notebooks prior to decommissioning.
3. Projects with self-analysis at the investigator's institution:
    - After the NDA DUA is signed, the specified dataset will be provided directly to the designated data recipient. A copy of deidentified data will be delivered for statistical analysis to be performed to facilities that meet AHA data security standards. The lead Researcher and co-authors are responsible for data security and statistical analysis of the data provided.
4. Projects with analysis being completed at an approved Designated Analytic Center:
    - The Designated Analytic Center will develop the SAP in consultation with project investigators based on the approved proposal to ensure the key questions of the proposal are answered.
    - Project investigators must review the SAP carefully to ensure it describes all analyses, outcomes, figures, and tables that will be needed to prepare a high-quality manuscript. Approved SAPs are considered final.
    - Once the SAP is approved, additional analytic requests may not be completed until after a review of the manuscript by either co-authors or the journal to ensure limiting scope-creep.
    - Additional requests may also need to be reviewed for approval by AHA and the SOCAG. Additional charges may be billed to the investigator for additional analyses.
    - After final SAP is approved by Author Group, the Designated Analytic Center sends the completed analyses to the lead Researcher.

IV. Conference Abstract and Manuscript Preparation

A. Authorship guidelines

1. In accordance with the International Committee of Medical Journal Editors (ICMJE) guidelines, authorship credit is based on the following conditions:

    - Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data.
    - Drafting or critically revising the content.
    - Final approval of the version to be published.
    - Accountability regarding accuracy or integrity of the content.
2. The order of authorship on the byline should be a joint decision of the co-authors.
3. AHA staff can serve as co-authors if authorship requirements are met.
4. In the event of a disagreement regarding authorship, the Chair of the Systems of Care Advisory Group or Research Task Force will determine authorship, in consultation with AHA scientific staff.
5. Plagiarism will not be tolerated and, if detected, will lead to removal of the author from the GWTG writing process. Sentences should not be cut and pasted from other published works, including works by the author or co-authors or in prior GWTG publications.

B. Conference abstract process

1. Generation of a conference abstract may be the initial step in development of the analyzed data to answer the approved proposal research questions.
2. It is not required to develop an abstract for potential conference submission and you may go directly to manuscript development.
3. All co-authors must review and approve the abstract draft.
4. Abstracts must be submitted at least 2 weeks in advance to be reviewed for approval by AHA before submitting to conference.
5. Atrial Fibrillation, Coronary Artery Disease, Heart Failure, Stroke and COVID-19 modules
    - Submit the abstract to QualityResearch@heart.org.
    - Abstracts are separately reviewed by the Systems of Care Advisory Group and AHA Science.
        - Abstracts going to AHA conferences only need Systems of Care Advisory Group approval.
    - AHA staff will send the committee's decision and feedback to the primary author.
6. Resuscitation:
    - Submit the abstract to GWTGResuscitationResearch@heart.org.
    - Abstracts are separately reviewed by the Adult/Pediatric Research Task Forces and AHA Science.
        - Abstracts going to AHA conferences only need Task Force approval.
    - AHA staff will send the committee's decision and feedback to the primary author.
7. Review Feedback should be incorporated into the abstract prior to submission to conference.
8. Notify AHA Staff of abstract acceptance.
9. Contact QualityResearch@heart.org to obtain the AHA-approved presentation or poster template for accepted abstracts.
10. Conference posters or presentations must represent the approved abstract and be approved by co-authors, mentors, AHA Staff and biostatistician or Designated Analytics Center.
11. Posters/presentations must be submitted for to QualityResearch@heart.org for approval prior to printing or presentation. AHA staff will review posters/presentations to ensure the appropriate use of AHA trademarks and acronyms, acknowledgement and disclosures and consistency with the approved abstract.

C. Manuscript process and journal submission

1. A manuscript draft should be developed in a timely manner. If the abstract is accepted for presentation at to a conference, the manuscript development should continue with the goal to publish the manuscript during the conference.
2. See "Publication Requirements" section following for additional information required in manuscript.
3. All co-authors, mentors and analytic provider must review and approve the final manuscript .
4. After the above review, a final Manuscript is submitted to AHA staff for review that includes review by AHA Staff, AHA Science and Program Advisory Group. This review and approval must be obtained before submitting to journal.
5. Manuscript timeline for projects utilizing a Designated Analytic Center or the AHA Data Science Team on Precision Medicine Platform (unless otherwise specified in the NDA/DUA):
    - Investigators must provide a final draft of the manuscript for AHA review within 6 months of completion/delivery of analysis.
6. Manuscript timeline for self-analysis project on the Precision Medicine Platform or Investigators Institution (unless otherwise specified in the NDA/DUA):
    - Investigators must provide a final draft of the manuscript for AHA review within 12 months of receiving the specified dataset.
    - Investigators that need additional time beyond the 12 months may request an extension from the SOGAG.
7. After manuscript is reviewed and approval is sent to lead Researcher, the manuscript must be submitted to journal within 30 days. Subsequent journal submissions or resubmission should be within 30 days of journal decline and or updated data.
8. AHA Staff should be notified of all journal activity including declines and acceptances.
9. AHA reserves the right to reassign or decommission projects if deadlines are not met.
10. Coinciding abstracts:
    - Author may submit abstract to conferences with AHA review, but the manuscript must still meet deadlines.
    - If the abstract is submitted and accepted to a conference, the goal is to have journal publication coincide with conference dates.

D. Publication requirements and information

1. The following are required when submitting to journal for publication:
    - AHA representation: Includes use of AHA GWTG trademarks, acronyms and use of approved templates.
    - Acknowledgement statements: Included in the Methods section for data collection, coordination, and analysis providers.
        - Statement is based on how/where analytics performed:
        - Research letters or other works with smaller word count restrictions can include the acknowledgement statements in a note at the end.
    - Sponsorship Statements: All manuscripts should include the appropriate standard statement under the Sources of Funding or Funding Support section of the manuscript.
2. Other relevant information
    - Open Access Agreement (OAA): All manuscripts are considered the work of the authors even if an author is employed by AHA or an AHA vendor; thereby the authors retain the copyright.

- Transparency and Openness Promotion (TOP): AHA data is collected for clinical care and quality improvement, rather than primarily for research, data sharing agreements require an application process for other researchers to access the data.
- Ethics approval statement: Each participating hospital received either human research approval to enroll patients without individual consent under the Common Rule or a waiver of authorization and exemption from subsequent review by their Institutional Review Board.
- Institutional Review Board (IRB): Given that the primary purpose of the registry is quality improvement, each participating center either received human research approval to enroll patients without individual consent under the Common Rule or a waiver of authorization and exemption from subsequent review by their Institutional Review Board.

3. After Journal Acceptance
    - Immediately notify co-authors and AHA staff of acceptance including the final accepted manuscript.
    - AHA staff will request additional information that will be used for promotional activities after publication.
    - Final PDF of the publication should be sent to AHA staff after publication.

Important Websites and References:

Heart.org/QualityResearch – Main Page
Heart.org/QIPublications – Online Publications Library
Heart.org/EarlyCareerInvestigator – AHA Early Career Investigator
National-Level Research Website
https://precision.heart.org/ - Precision Medicine Platform

Contacts: AHA National Center Quality Research Staff

QualityResearch@heart.org

Modification History:

Revision Number	Description of Modification	Who	Date of Revision

V. Appendix

Precision Medicine Platform

The AHA Institute for Precision Cardiovascular Medicine created a new model for bringing together science and technology to drive breakthroughs in cardiovascular and brain health and disease.

Accelerate Precision Medicine with AHA's Precision Medicine Platform

Overview
The PMP is a secure HIPPA compliant and FedRAMP certified cloud-based ecosystem that facilitates data sharing, collaboration, and power computing. The PMP workspace is an interactive AWS cloud environment comprised of common tools and software used in biomedical analyses that enables users to easily store data, collaborate, and perform analyses while also having access to elastic power compute resources on demand.

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

Collaboration
The platform facilitates collaboration and reproducibility by enabling users to share workspaces and conduct analyses in a private, secure cloud environment. Users can also collaborate through traditional development methods such as github.

Collaboration is made easy with the PMP because all data and analyses reside in a secure workspace for which only the participant/team representative has access, unless the participant/team representative chooses to collaborate with colleagues and share the workspace on the PMP workspace portal.

Power Compute In the PMP
There are multiple ways to take advantage of power compute in the Precision Medicine Platform, namely:

- EMR, Automatic Scaling through Spark
    - Analyses that use spark based packages or software can leverage the EMR workspace auto-scaling cluster architecture to optimize performance
- Elastic, High Performance Computing
    - Analyses that need to optimize software through traditional parallel computing methods can leverage the EC2, GPU and CPU architecture options

Default workspace architectures are designed to fit the needs of most users, however architecture sizes can be increased and customized as needed. To increase compute resources in a workspace or get assistance with power computing on the PMP, please contact us

Videos
Learn more about the platform (video). and Explore the capabilities of the platform (video)

Terms of Use
Any inventions, intellectual property, or patents resulting from this funding are governed by the AHA Patent, Intellectual Property and Technology Transfer Policy

To request a Precision Medicine Platform (PMP) workspace

1. Register: Go here and Sign In In to Register
2. Go to Search and Request Workspace
    a. Do not click on any datasets on the Search page
3. Complete Form, understanding that billing will be based on the NDA/DUA
    a. Once the form is submitted and you have received a confirmation number, it can take up to 36 hours for the workspace to be provisioned

Be sure to use this https://precision.heart.org URL and not this one https://precision.heart.org/sso/