National-Level Quality Programs Research Policy

Effective: September 5, 2024

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 GWTG programs include modules in atrial fibrillation, coronary artery disease, heart failure, resuscitation (adult and pediatric), and stroke. The AHA engages in quality programs such as Implementation Science, Healthcare Certification, Professional Certification and other AHA initiatives with data availability, researchClinical 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 and Quality Programs 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

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Responsibility

GWTG and quality programs 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

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.
- **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.
- Quality Certification Tool (QCT): The QCT is a portal used for maintaining compliance with the program requirements, document submission and storage, quality measure data entry and as a general resource for your chosen certification or quality improvement program or initiative.
- **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.

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

5. Atrial Fibrillation, Coronary Artery DiseaseCOVID-19 CVD, Heart Failure, Resuscitation and Stroke: Submit to Proposal Central (Quality Improvement Research Proposals | American Heart Association) or QualityResearch@heart.org
    - 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.
6. International investigators
    - Investigators without United States citizenship can submit proposals to conduct analyses on the AHA Precision Medicine Platform or for AHA-commissioned strategic analyses, including Early Career Investigator Awards.
    - After the proposal is approved, investigators will need to complete the international due diligence questionnaire (IDDQ) process.
    - Up to 10% of total AHA-funded analyses will be awarded to international investigators in the primary investigator role.

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.
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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

1. Projects [illegible]

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2. It is not required to develop an abstract for potential conference submission and you

6. Manuscript timeline for **self-analysis project on the Precision Medicine Platform or investigator's institution** (unless otherwise specified in the NIBD(u)14.9A(f)]TJ0 Tc 0 Tw 6.36.8 0 Td( )Tj-0.60

- Immediately notify coauthors and AHA staff of acceptance and provide a copy of the accepted manuscript.
- AHA staff will request additional information for promotional activities after publication.
- Final PDF of the publication should be sent to AHA staff after publication.

References

- Quality Research – www.heart.org/QualityResearch
- Online publications library – www.heart.org/QIPublications
- GWTG Early Career Investigator Award – www.heart.org/GWTGEarlyCareerInvestigatorAward
- National-level research – www.heart.org/GWTGResearch
- Precision Medicine Platform – https://precision.heart.org/

Contacts: AHA National Center Quality Research Staff

4. Email: QualityResearch@heart.org

V. Appendix

Precision Medicine Platform

The American Heart Association 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 HIPAA 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