International Quality Programs Research Policy

Effective: March 20, 2024

Authority: American Heart Association National Quality Research and International Staff

Overview

The American Heart Association (AHA) Get With The Guidelines® (GWTG) and International Certification programs are facility-based quality improvement programs designed to close treatment gaps and facilitate delivery of care with the goal of improving outcomes for patients. The quality suite of programs includes modules in atrial fibrillation, coronary artery disease, heart failure, resuscitation, and stroke.

Quality program data is entered into AHA managed databases, creating a growing database within each country or region to advance scientific research. This data can be translated into the potential for improved practices, validating and supporting guidelines, and identifying novel scientific findings to further support quality improvement.

Additionally, data has been collected through several international collaborative quality improvement programs. These programs create be-spoke registries that are closely aligned with the GWTG data set and provide opportunity to evaluate how implementation science programs can impact processes of care and the translation of science into practice outside of the United States.

Using the data that are collected through AHA's international quality improvement programs, PIs can develop study questions within a country or region of interest 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 international quality 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 International Guidelines.

Responsibility

International hospitals, health systems, and sites that participate in AHA Quality Programs, AHA Quality, Outcomes Research and Analytics (QORA) staff, and international and domestic AHA Quality Programs 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 International GWTG or quality program data. This policy document is in addition to the Science Research Policy and does not overlap or disregard it.

Policy Statement

The AHA has a responsibility to ensure International Research is of high scientific merit. International Research proposals must be submitted using a standardized process outlined below and approved abstracts and manuscript drafts must be reviewed by appropriate AHA staff, assigned International Research Workgroup, and appropriate AHA department(s).

American Heart Association.

Contents

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 AHA Quality Program 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, and stroke.
- International Research: Research that utilizes data from an AHA collaborative quality program outside of the United States or associated U.S. Territory, regardless of additional datasets that are used in conjunction such as U.S. data
- International Research Workgroup: American Heart Association volunteer research Workgroup that reviews and approves international quality research proposals, abstracts, and manuscripts.
- Principal Investigator (PI): The individual responsible for the preparation, conduct, and administration of the research study.

- 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.
- Quality Programs: AHA quality improvement program designed to close treatment gaps and facilitate delivery of care with the goal of improving outcomes for patients including GWTG, Certification, and other special initiatives.
- 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 Workgroups that guide the direction of the U.S. based quality programs.

B. Data Availability and Analytic Options:

Access to AHA datasets will occur only through AHA-approved, secure platforms to ensure compliance with data security standards. AHA reserves the right to audit access logs to monitor data usage and enforce adherence to data sharing policies.

1. Data is potentially available for research from the following modules:
    - Atrial Fibrillation (AFIB)
    - Coronary Artery Disease (CAD)
    - Heart Failure
    - Stroke
    - Resuscitation

- Certification
- Data availability and access: QCT: De-identified, aggregated, event level data captures
  - GWTG -HF (from HF A.S.I.A.)
  - GWTG -CAD
  - International Stroke Certification
  - International Chest Pain Center Certification
  - International Heart Failure Certification
- International Research Platform (IR): Patient level data (housed on a server owned and operated by Outcome Sciences, LLC, an IQVIA subsidiary ("IQVIA"), and AHA's third party vendor for GWTG)
  - Mexico
  - Middle East (UAE)
- Patient Management Tool (PMT): Patient Level Data (housed on an IQVIA server in the Kingdom of Saudi Arabia ("KSA"))
  - KSA
- In-Country Databases: Access as allowed by regulations through in-country project teams.
  - Brazil
  - China

Analytic channels:

- AHA Precision Medicine Platform – A strategic AHA initiative that is a cloud-based analytic workspace with access to AHA owned 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 PI'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. Can only be utilized for analyses on the Precision Medicine Platform.
- PI's Institution/Biostatistical Team – Institutions may be granted permission to statistically analyze a limited and/or deidentified dataset at their own institution or on the Precision Medicine Platform.

Types of Analyses

- Regional: Individual, deidentified patient level analysis conducted on a regional basis.
- Combined or Comparative Country: Each country applies standardized analytic file and data cleaning processes/procedures. A single analysis protocol is agreed upon and performed and sharable deidentified, aggregate data is reviewed and analyzed. Alternatively, a new data file may be created using multiple countries data and housed on the Precision Medicine Platform for analysis.
- QCT: Event level data files provided for aggregate analysis.

C. Data Privacy and Protection Compliance

The AHA is committed to processing all personal data and health data collected in compliance with applicable US and international privacy laws. All international research data will be handled and processed according to AHA's Privacy Statement and Privacy Policy, which outline data subject rights, cross-border data transfer safeguards, and data handling practices.

AHA Privacy Statement: https://www.heart.org/en/about-us/statements-and-policies/privacy-statement

AHA Privacy Policy: https://www.heart.org/en/about-us/statements-and-policies/privacy-policy--standards

D. Project funding

- External funding via the PI, which may include grants, awards, industry, or institutional funds is accepted on a rolling basis. AHA will have final determination on which external funding sources are acceptable.
- Self-Analysis research proposals, where the investigator or a qualified statistician performs the required analysis and pays the required fees, are accepted on a rolling basis.

Strategic publications may be commissioned on behalf of the AHA.

II. Proposal Submission, Review, and Approval

A. Submitting a proposal

- Visit the following website for up-to-date information and submission deadlines:
    - International Research

Developing a proposal:

- Review the data elements collected for the applicable International research module to ensure the outcome of interest is collected.
- Review the Quality Research Publications database, PubMed.gov or other resources to avoid overlap with any existing publications.
    - The Quality Research Publications website includes international publications that use AHA Quality Programs data.
- PI is responsible for ensuring co-authors affiliations, financial interests, or other relationships that could influence the study's outcomes must be disclosed at the time of submission.

Fill out the Research Proposal Form via Proposal Central completely, including sample tables and/or charts for the study.

Submit the completed Research Proposal Form to InternationalQI@heart.org

Limitations and project scope:

- A lead author may have a total of 2 active projects across all the modules; additional proposals will generally not be accepted. Manuscripts submitted to journal are not considered an active project.

- 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

- Proposals are reviewed by expert clinical volunteer groups specific to each module.

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.
Decisions: AHA staff will notify the lead author of the Workgroup's decision to approve, request revisions or decline.

- Approved proposals are considered final; projects are limited within the approved scope. Requests for additional analyses or expanded scope must be reviewed and approved.
- Proposals that are revised may only be resubmitted for up to 2 more standard review cycles.
- Declined Early Career Investigator (ECI) proposals, if feasible, can be revised and may be resubmitted for up to 2 more standard review cycles .

Funding & Conflict of Interest (COI): AHA funded proposals are reviewed by the registry research team for conflict of interest.

- Non-AHA funded projects using AHA data must first apply/be approved prior to securing external funding.
- Journal/publications fees are the responsibility of the PI. Journal may require additional funding/COI review specific to their publication processes. AHA is not involved in this process.

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 an individual from the International Research Workgroup act as a mentor throughout the project. International Due Diligence Questionnaire (IDDQ)

- All first authors who reside outside of the United States will need to complete the Third Party International Due Diligence Questionnaire (IDDQ) Form for evaluation before the proposal can move on for further development and AHA staff must complete the Internal IDDQ Form.
- The IDDQ will need to be renewed every 3 years (if the investigator is still working on projects with the organization).

A. Nondisclosure and Data Use Agreements

- Nondisclosure, Data Use, and/or Terms of Service agreements are required to access GWTG data and/or utilize statistical output for publication. Usage is strictly 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.
- Third parties, including external consultants and subcontractors, are prohibited from accessing AHA data without explicit authorization through a Data Use Agreement. Third-

party data access is strictly limited to approved purposes, and unauthorized data linkage or re-identification attempts are prohibited and will result in immediate access termination.

B. Data analysis process and requirements

- 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 an IDDQ and Nondisclosure Agreement/Data Use Agreement (NDA DUA) are complete, the lead PI 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 PI 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 PI. 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 assigned International Research Workgroup mentor 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 associated dataset will expire in conjunction with the term date of the NDA/DUA or once the PI's manuscript has been published in a journal (authorized purpose for the project), whichever comes first.
    - Once the AHA has confirmed the PI's project has been published, the AHA will take necessary steps to decommission the PI's workspace on the Precision Medicine Platform which includes access to the dataset. The PI should take necessary steps to save any analyses and/or notebooks prior to decommissioning.

Projects with self-analysis at the investigator's institution:

- After the IDDQ and NDA DUA are 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 PI and co-authors are responsible for data security and statistical analysis of the data provided.

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 PI.

IV. Conference Abstract and Manuscript Preparation

A. Authorship guidelines

- In accordance with the International Workgroup 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.

The order of authorship on the byline should be a joint decision of the co-authors.
AHA staff can serve as co-authors if authorship requirements are met.
In the event of a disagreement regarding authorship, the Chair of the Systems of Care Advisory Group or will determine authorship, in consultation with AHA scientific staff.
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

- Generation of a conference abstract may be the initial step in development of the analyzed data to answer the approved proposal research questions.
- It is not required to develop an abstract for potential conference submission and you may go directly to manuscript development.
- All co-authors must review and approve the abstract draft.

Abstracts must be submitted at least 2 weeks in advance to be reviewed for approval by the International Research Workgroup before submitting to a conference.
  - AHA staff will send the Workgroup's decision and feedback to the primary author.

Abstracts must be submitted at least 2 weeks in advance to be reviewed for approval by AHA Science Review before submitting to a non-AHA conference.
  - AHA staff will send Science Review decision and feedback to the primary author.

Feedback should be incorporated into the abstract prior to submission to conference.
Notify AHA Staff of abstract acceptance.
Contact InternationalQI@heart.org to obtain the AHA-approved presentation or poster template for accepted abstracts.

Conference posters or presentations must represent the approved abstract and be approved by all associated co-authors, mentors, AHA Staff and biostatistician(s) or Designated Analytics Center if applicable.
Posters/presentations must be submitted for to InternationalQI@heart.org for approval prior to printing or presentation. AHA staff will review posters/presentations to ensure the appropriate use of trademarks and acronyms, acknowledgement and disclosures and consistency with the approved abstract.

C. Manuscript process and journal submission

- A manuscript draft should be developed in a timely manner. If the abstract is accepted for presentation at a conference, the manuscript development should continue with the goal to publish the manuscript during the conference.
- See "Publication Requirements" section following for additional information required in manuscript.
- All co-authors, mentors and analytic provider must review and approve the final manuscript.

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.
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.

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.

After manuscript is reviewed and approval is sent to lead PI, 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.
AHA Staff should be notified of all journal activity including declines and acceptances.
AHA reserves the right to reassign or decommission projects if deadlines are not met.
Coinciding abstracts:

- Author may submit abstract to conferences with International Research Workgroup 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

- The following are required when submitting to journal for publication:
  - AHA representation: Includes use of AHA GWTG and Certification 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.

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 PIs 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) or equivalent: 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.

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 International Quality Research Staff

InternationalQI@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/