

American Heart Association (AHA) Research Goes Red Research Policy

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Authority: American Heart Association Data Science Leadership and

Staff

Overview

Almost 30 years ago, the American Heart Association (AHA) recognized the importance of focusing on women's risks of heart disease and overall Cardiovascular disease (CVD) and the urgent need for deliberate strategies to prevent and treat CVD in women.¹ Over the next 3 decades, the AHA sustained its commitment and advocacy to prevent CVD (1997–2011)^{2,3,4,5} and launched the Go Red for Women campaign in 2004 to increase awareness of heart disease risk in women. In 2015, the AHA started the Go Red for Women Strategically Focused Research Network to study CVD risk in women while accounting for the sex specificity of the genesis, presentation, and management of CVD.⁶

With the aid of expert volunteers, AHA conducted an assessment of the research and clinical gaps for women and CVD. To directly address the identified gaps in women, the AHA launched the Research Goes Red registry (RGR) in collaboration with Verily's Project Baseline. Project Baseline is an effort to expedite evidence generation in clinical research.⁷ Established in 2019, RGR is a novel online platform designed to be participant-centric, customizable and scalable. It positions women at the center of clinical research processes to accelerate scientific discovery by fostering active engagement. Our goal herein, is to report on the first 2 years. We will review the demographics and health concerns of participants to date and delineate future direction for research, participants engagement, and advocacy collaborations.

A deidentified copy of the RGR data from Verily is encrypted and transferred to a secure workspace on the AHA Precision Medicine Platform (<https://precision.heart.org>), which is a cloud-based platform that provides powerful tools to support data analysis. AHA maintains an audit process enabling comprehensive review of processing and harmonization. An overview of the data elements and corresponding data documentation is available online on the AHA Precision Medicine Platform, which also includes resources to analyze and interpret the data. This open approach is consistent

¹ Eaker ED, et al. *Circulation*. 1993; 88:1999–2009. doi: 10.1161/01.cir.88.4.1999

² Mosca L, et al. *Circulation*. 1997; 96:2468–2482. doi: 10.1161/01.cir.96.7.2468

³ Mosca L, et al. *Circulation*. 2004; 109:672–693. doi: 10.1161/01.CIR.0000114834.85476.81

⁴ Mosca L et al. *Circulation*. 2007; 115:1481–1501. doi: 10.1161/CIRCULATIONAHA.107.181546

⁵ Mosca L, et al. *Circulation*. 2011; 123:1243–1262. doi: 10.1161/CIR.0b013e31820faaf8

⁶ St-Onge MP, et al. *J Am Heart Assoc*. 2021; 10:e019519. doi: 10.1161/JAHA.120.019519

⁷ Arges K, et al. *NPJ Digit Med*. 2020; 3:84. doi: 10.1038/s41746-020-0290-y

with the Findable, Accessible, Interoperable, and Reusable guiding principles for data management.⁸

RGR is guided by a **Science Advisory Group (SAG)** comprised of volunteer experts across multiple disciplines including cardiology, neurology, epidemiology, cancer, obstetrics and gynecology, cardio-obstetrics, genetics, preventive medicine, data science, and more. Guided by a volunteer principal investigator, the Science Advisory Group is further delineated into 3 subcommittees. The 3 subcommittees include publications, engagement, and communications. Operationally, RGR is overseen by the AHA's Chief Medical Officer and Chief of Data Science with support from AHA's Precision Medicine Platform, Quality, Outcomes Research & Analytics, and Consumer Health teams.

Purpose

The purpose of this policy is to provide an overview and direction for the use of data from the Research Goes Red Registry 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.

Scope

This policy applies to all abstracts, publications, or any public facing material using the Research Goes Red Registry data.

Policy Statement

The AHA has a responsibility to ensure all AHA research is of high scientific merit. Research Goes Red research proposals must be submitted using a standardized process outlined below and approved abstracts and manuscript drafts must be reviewed by AHA Research Goes Red Scientific Publishing committee.

⁸ Wilkinson et al. **Sci Data**. 2016; 3:160018. doi: 10.1038/sdata.2016.18

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I. General Information

A. Definitions

- Research Goes Red: Research Goes Red (RGR) is a participant-centric Registry to accelerate scientific discovery by fostering active engagement of women. RGR was launched by AHA in collaboration with Verily's Project Baseline in 2019.
- 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.
- RGR Scientific Advisory Group (SAG): A volunteer committee made up of experts that review all public facing RGR material.

B. Data availability and request

- How to get to access to the RGR data?
 - De-identified data is available on the AHA Precision Medicine Platform from the Research Goes Red Registry. You can learn more about the data characteristics through the [data snapshot page](#). All analyses are performed on the [AHA Precision Medicine Platform](#), which is a cloud-based platform with access to data and workspaces equipped with software and tools for data analysis and collaboration.
 - The steps to request RGR data are as follows:
 - Step1: The lead researcher completes an [online application form](#) to initiate the data request.
 - Step2: Before getting access to the Research Goes Red data, the investigator needs to sign a Non-Disclosure and Data Use Agreement (NDA/DUA). The AHA RGR team will review the application and contact the investigator to confirm NDA/DUA details. The filled NDA/DUA form will be sent out to the investigator via AHA's esign system for signature.
 - Step3: 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. The researchers will create an account on the AHA Precision Medicine Platform ([PMP](#)). Login to the PMP and go to the **Explore & Request** page to click on the RGR dataset and request the dataset and workspace.
 - Step 4: Once the workspace request has been approved and provisioned by the AHA, the Researcher can use the tutorial notebooks to explore the RGR data and prepare a statistical analysis plan for the proposal form.
- Approved statistical analyses will be performed on the AHA Precision Medicine Platform in one of the following ways:
 - Data Science Team at AHA - May be contracted to provide full-service analytical support or consultation services for approved statistical analyses.
 - Researcher's Institution/Biostatistical Team - The investigator can have their

own biostatistical team or data scientist to perform the data analysis via AHA Precision Medicine Platform.

II. Proposal Submission, Review, and Approval

A. Submitting a proposal

1. Upon applying for a PMP workspace, researchers must submit a manuscript proposal to the RGR Science Advisory Group within 30 business days.
2. Developing a proposal:
 - a. Review the data characteristics through the [data snapshot page](#) and data elements collected from the PMP RGR data documentation page to ensure the outcome of interest is collected.
 - b. Review [PubMed.gov](#) to avoid overlap with any existing publications.
 - c. Login into the assigned PMP workspace to explore and visualize the RGR data.
 - d. Fill out the [Research Proposal Form](#) completely, including sample tables and/or charts for the study.
3. Submit the completed Research Proposal Form to datascience@heart.org

B. Proposal review

1. Each proposal will be reviewed by SAG members.
2. Proposals are reviewed for feasibility, overlap with other approved proposals or existing publications, scientific merit, novel contribution to scientific literature, the strength of the analysis plan, and alignment with the AHA and RGR mission.
3. Approved proposals are considered final; projects are limited within the approved scope. Requests for additional analyses or expanded scope must be reviewed and approved.
4. Decisions: AHA staff will notify the lead author of the committee's decision to approve, request revisions or decline.
5. Resubmission:
 - a. Proposals for revised manuscripts may only be resubmitted for up to 2 more standard review cycles.

III. Project Development for Approved Proposals

Once a Research Proposal is approved, the investigator is notified by the AHA Staff of the approval, project timelines, requirements, and next steps.

1. 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.

2. Once the AHA has confirmed that the Researcher's project has been published, the AHA will take the necessary steps to decommission the Researcher's workspace on the Precision Medicine Platform, which includes access to the AHA dataset. Researchers should take the necessary steps to save any analyses, and notebooks prior to decommissioning.

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 Chairs of the RGR SAG Committee will determine authorship, in consultation with AHA scientific staff.
5. Plagiarism will not be tolerated and, if detected, will lead to the removal of the author from all RGR writing processes.

B. AHA Reviews Process

1. Abstract and manuscript drafts must be reviewed and approved by all authors prior to being sent to the RGR Publications committee for review.
2. All abstract and manuscript drafts must be reviewed by the RGR Publications committee. Each abstract review period is one week (5 business days), and each manuscript review period is four weeks (20 business days).
3. A summary of committee feedback and decision will be emailed back to the primary author.
4. Abstracts may not be submitted to a conference /meeting /journal without prior AHA review and approval.
5. Manuscripts may not be submitted to a journal without prior AHA review and approval.

C. Conferences

1. Conference posters or presentations must represent approved abstracts and require approval by co-authors, mentors, the RGR SAG committee, and AHA staff.
2. Posters/presentations must be submitted to datascience@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, acknowledgment and disclosures, and consistency with the approved abstract.

D. Manuscript and journal submission

1. Conference Poster or Presentation Requirements:

- Conference posters or presentations must represent approved abstract and require approval by co-authors, mentors, the RGR SAG committee and AHA staff.
- Ensure use of AHA-approved template.
- Ensure AHA Representation – trademarks and acronyms.
- Before printing, ensure poster or PPT is reviewed and approved by co-authors, mentors, and AHA staff.
- Include the following Acknowledgement Statements where appropriate:
 - Sources of Funding American Heart Association's (AHA's) Research Goes Red is funded, in part, by the Bugher Trust Foundation, the AHA, and in-kind donations from Verily.
 - The American Heart Association Precision Medicine Platform (<https://precision.heart.org/>) was the cloud-based research platform used for data analysis.
 - (If appropriate) The American Heart Association (Dallas, TX) served as the data analytic center.

2. Abstract and Manuscript Requirements

- 1) Reference the original manuscript, [Research Goes Red: Early Experience with a Participant-Centric Registry](#)⁹ that provides all information on registration, consent, recruitment, engagement, and the Baseline Privacy Policy.
- 2) Include these statements in manuscripts.
 - To directly address the identified gaps in women, the AHA launched the Research Goes Red registry (RGR) in collaboration with Verily's Project Baseline. Project Baseline is an effort to expedite evidence generation in clinical research¹⁰ Established in 2019, RGR is a novel online platform designed to be participant-centric, customizable, and scalable.

⁹ Gilchrist SC, Hall JL, Khandelwal A, Hidalgo B, Aggarwal B, Kinzy C, Mallya P, Connors K, Stevens LM, Alger HM, Mehta L, Wexler L, Mega JL, Hernandez A, Hayes SN, Mieres JH, Jessup M, Roger VL. Call to Action for Cardiovascular Disease in Women: Epidemiology, Awareness, Access, and Delivery of Equitable Health Care: A Presidential Advisory From the American Heart Association. *Circulation* doi: 10.1161/CIR.0000000000001071. Review. PubMed PMID: 35531777.

¹⁰ Arges K, Assimes T, Bajaj V, Balu S, Bashir MR, Beskow L, Blanco R, Califf R, Campbell P, Carin L, et al.. The Project Baseline Health Study: a step towards a broader mission to map human health. *NPJ Digit Med.* 2020; 3:84. doi: 10.1038/s41746-020-0290-

- Individuals register for RGR from the Project Baseline website (projectbaseline.com). The website and Clinical Studies Platform are provided by Verily.
- All authors have reviewed and approved the abstract/manuscript.
- We utilized data from participants enrolled in the AHA Research Goes Red Registry, an online research platform powered by Verily.

3) Acknowledgement Statements

- Sources of Funding American Heart Association's (AHA's) Research Goes Red is funded, in part, by the Bugher Trust Foundation, the AHA, and in-kind donations from Verily.
- The American Heart Association Precision Medicine Platform (<https://precision.heart.org/>) was the cloud-based research platform used for the data analysis.
- (if appropriate) The American Heart Association (Dallas, TX) served as the data analytic center.

4) AHA Representation - Includes use of the Research Goes Red registry

- a) Ensure proper use of RGR
 - When the following first appear in the document, they must be spelled out like this:
 - Research Goes Red registry
 - After first use, you may use RGR

3. **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. For OAA, please indicate it is the authors own work which means 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.
 - Please use the following statement if TOP requested:

Participants in Research Goes Red consented to share data with researchers. Data are de-identified and stored securely by the American Heart Association. Interested researchers can submit proposals to utilize RGR for research purposes. including for validation purposes.

- Institutional Review Board (IRB): The IRB information for Verily's Project Baseline:
 - Western Institutional Review Board (WIRB).
<https://www.wcgirb.com/about/>
 - Sponsor: Baseline Study LLC
 - Protocol Title: The Project Baseline Community Study
 - Protocol Number: 101143

4. **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.
- The final PDF of the publication should be sent to AHA staff after publication.

Important Websites and References:

- [Research Goes Red](#)
- [RGR data snapshot](#)
- AHA Precision Medicine Platform - <https://precision.heart.org/>
- [Project Baseline by Verily](#)
- [Baseline Privacy Policy](#)

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