

# Request for proposals to evaluate the role of health-related social needs in hypertension outcomes in women at risk

#### Contents

Key Dates	1
Overview	2
Social Determinants of Health, Social Risk Factors, and Health-Related Social Needs	2
Advancing women's health through Research Goes Red	2
What we're looking for	4
Who we're looking for	4
Before you apply	5
How to apply: letter of intent	6
How to apply: invited proposal	6
Peer Review	
Details and requirements	8
Duration	8
Number of Awards	8
Award Amount	8
Precision Medicine Platform, research environment	8
Interim assessment	g
Public access	g
Open data	g
Additional requirements	g

# Key Dates

Request for proposals (RFP) Posted:

Letter of Intent (LOI) Deadline:

American Heart Association LOI invitations:

Application Deadline for invited participants only:

January 10, 2022

February 14, 2022

April 1, 2022

pplication bedatine for invited participants only: April 1, 2021

Peer Review: April – May 2022

Notification of Awards: May 20, 2022
Award Start Date: July 1, 2022

# Overview

# Social Determinants of Health, Social Risk Factors, and Health-Related Social Needs

Medical care alone is insufficient to ensure better health and well-being. Understanding the role of factors such as social determinants of health, social risk factors, and health-related social needs is a crucial component of establishing equitable health for all.

The World Health Organization recognized the social determinants of health (SDOH) as the structural determinants and conditions in which people are born, grow, live, work, and age that affect health, functioning, and quality of life.<sup>2</sup> There are currently five main domains of SDOH, including *economic stability*, *neighborhood and built environment*, *education*, *social*, *and community context*, and *health and health care*. Each of these domains may have relevance at the individual, neighborhood, and environmental level. Social risk factors are specific adverse conditions associated with poor health, such as social isolation or housing instability.<sup>3</sup>

Health-related social needs is a term developed by the Centers for Medicare and Medicaid Services for use in the Accountable Health Communities Screening Tool.<sup>4</sup> There are five core domains and eight supplemental domains of health-related social needs. The five core domains include housing instability, food insecurity, transportation problems, utility help needs, and interpersonal safety. The eight supplemental domains include financial strain, employment, family and community support, education, physical activity, substance use, mental health, and disabilities. The patient's perspective, preferences, and priorities for connections or next steps are an important inclusion in health-related social needs screening.

Research has begun to explore the role of SDOH, social risk factors, and health-related social needs on cardiovascular health and well-being. Early studies have often been limited by small sample sizes and underrepresentation of ethnic and racial groups, women, and LGBTQ communities.

# Advancing women's health through Research Goes Red

The American Heart Association and Verily's Project Baseline joined forces to launch <u>Research Goes Red</u>, an initiative focused on improving women's health. Research Goes Red is a unique online participant-centric

<sup>&</sup>lt;sup>1</sup> Magnan S. Social Determinants of Health 201 for Health Care: Plan, Do, Study, Act. NAM Perspect. 2021;2021.

<sup>&</sup>lt;sup>2</sup> Commission on Social Determinants of Health, 2008. Closing the Gap in a Generation: Health equity through action on the social determinants of health. Final report of the Commission on Social Determinants of Health. Geneva, World Health Organization. Available at: https://www.who.int/social\_determinants/final\_report/csdh\_finalreport\_2008.pdf 3 Alderwick H and Gottlieb LM. Meanings and Misunderstandings: A Social Determinants of Health Lexicon for Health Care Systems. Milbank Q. 2019;97:407-419.

<sup>4</sup> Billioux, A., MD, DPhil, Verlander, K., MPH, Anthony, S., DrPH, & Alley, D., PhD. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. National Academy of Medicine Perspectives, 1-9. https://nam.edu/wpcontent/uploads/2017/05/Standardized-Screening-for-Health-Related-Social-Needs-in-Clinical-Settings.pdf

registry. Over 13,000 women have already joined Research Goes Red, connecting women in the United States with scientists and clinicians to involve more women in research. The current Research Goes Red cohort demographics are listed in **Table 1**. Young females are under-represented in the cohort, as are Non-Hispanic Black and Black females. The median age of Non-Hispanic Black and Black females enrolled in Research Goes Red is 50.0±0.6 and 42.0±3.2, respectively.

Funded studies must enroll new research participants into the Research Goes Red registry and collect data and engage with participants through Verily's online Clinical Studies Platform. To be eligible for the funded study, each study participant must be a new member of the Research Goes Red Registry.

Table 1. Demographic profile of the participants enrolled in Research Goes Red

Participants (n=13,413)	Percent
Sex at Birth	
Female	99.2%
Male	0.7%
Intersex	0.1%
Age (median ± SE)	48.0 ± 0.2
Derived Race and Ethnicity	
Non-Hispanic White	75.7%
Non-Hispanic Black	10.5%
Hispanic	6.9%
Non-Hispanic Asian	2.5%
Non-Hispanic Mixed	2.8%
Non-Hispanic American Indian or Alaskan Native	0.5%
Non-Hispanic Native Hawaiian or Pacific Islander	0.1%
Other	0.7%
Hypertension (n = 5,062)	
No	62.7%
Yes	30.8%
Prehypertension	6.4%

To be eligible for this funding opportunity, proposals *must* use the Verily Clinical Studies Platform to recruit new female participants who are at significant risk of hypertension into the proposed study as well as into the Research Goes Red Registry and collect data.

## What we're looking for

At the American Heart Association, equity and science are at the center of everything we do. The goal of this RFP is to unite researchers across disciplines to address unmet health needs and disparities in health-related social needs.

The American Heart Association is looking to fund investigators who will recruit populations at risk of hypertension including, but not limited to, young Black and/or Hispanic women, and evaluate the role of need-specific interventions on blood pressure control. Recruited participants must join the Research Goes Red Registry in order to be eligible for the proposed study.

Proposals should be focused on health-related social needs in under-served female populations, for example: housing instability, food insecurity, transportation problems, interpersonal safety, financial strain, employment, family and community support, education, physical activity, substance use, mental health, and disabilities.

## Who we're looking for

We are looking for a cross-disciplinary team of experts, community partners, and organizations with expertise in qualitative and quantitative sciences, hypertension, women's health, or data science.

Applicant teams or organizations are required to:

- Use the Verily Clinical Studies Platform currently used by the Research Goes Red Registry to recruit, engage, and collect data on participants in the proposed study. To be eligible for the study, each study participant must be a new member of the Research Goes Red Registry.
- To leverage the American Heart Association <u>Precision Medicine Platform</u> to harmonize, analyze, and interpret data
  - Self-reported data from consenting participants in Research Goes Red is de-identified, standardized and harmonized and uploaded into the Precision Medicine Platform on a regular basis, along with data documentation for use by approved researchers.
  - Note: research study data is not routinely shared with approved researchers in the public domain until after publication. However, as the Principal Investigator of this funded research study, you will have a private secure workspace that is equipped with your research study data and any additional approved data from the broader Research Goes Red cohort.
  - The American Heart Association Data Science team is available to assist with opening a workspace once a project has started.
  - o All applications are highly encouraged to include a data scientist with coding experience as a team member.

# Before you apply

All investigators, regardless of gender identity, are highly encouraged to join Research Goes Red to more fully understand the process and platform prior to sending in a Letter of Intent.

- For teams that are invited to submit a full application, the project lead must be an American Heart Association professional member.
  - o Join or renew when preparing an application in Proposal Central, online or by phone at 301-223-2307 or 800-787-8984.
  - Membership/Partnership processing takes 3 to 5 days; *do not wait* until the application deadline to renew or join.
- Projects can include collaborators from across sectors and countries; however, the project proposal must be submitted by a project lead representing an academic or non-profit organization based in the United States.
- Any member of the team can serve as the project lead. Projects may include co-investigators
  from other collaborating organizations. We strongly recommend that organizations identify only
  one project lead per project.
- Preference will be given to applicant organizations that are institutes of higher education, public entities, or nonprofits that are tax exempt under Section 501(c)(3) of the Internal Revenue Code and are not private foundations or Type III supporting organizations. Other types of nonprofit and for-profit organizations are also eligible to apply. The American Heart Association may require additional documentation.
- Preference will be given to projects received from organizations with expertise in the following
  areas: qualitative and quantitative sciences, hypertension, women's health, health impact
  assessment and policy, social environmental disciplines, technology, and experts in quality of
  life and public health.
- Awardees will be selected based on health impact, scientific merit, feasibility, and scalability.
   Projects will be considered that:
  - o Are aligned with the American Heart Association's mission and goals
  - o Provide a clear plan of action for leveraging:
    - Research Goes Red Infrastructure including Clinical Studies Platform for recruitment into the study (required)
    - The American Heart Association Precision Medicine Platform (required)
- Organizations that are currently funded through other American Heart Association funding mechanisms can apply.
- Organizations can submit multiple proposals.

# How to apply: letter of intent

- 1. Letters of Intent are due February 14, 2022 at 3:00pm Central.
- **2.** Please save your submission as a <u>single pdf</u> using the following naming convention "LastName\_Institution\_Health-related social needs\_LOI.pdf".
- 3. Email final PDF format to pmp@heart.org to submit your letter of intent.
- 4. Your letter of intent should include the following information about the proposed project:
  - Project title
  - Names, titles, affiliations, relevant expertise, any collaborating organizations
  - Contact information for organizational representative with signing authority
  - Percent effort for all key project personnel, including project lead
  - Approximate budget per year of the study
  - Institutional data collection and security standards, including any relevant information on Institutional Review Board for Human Subjects research
  - Planned approach and activities to achieve the goals including how you will leverage
     Research Goes Red and the American Heart Association Precision Medicine Platform
  - Biosketch of project lead
  - How you learned about this RFP funding opportunity
- 5. The Letter of Intent does not have a word limit. It is recommended that sufficient detail is provided for reviewers to understand your approach and goals for your project. This could be completed in about 2-3 pages, with additional pages for the biosketch, references, and other documents as needed.

Letters of Intent that do not include a description of the use of the Research Goes Red Infrastructure and the American Heart Association Precision Medicine Platform will not be reviewed.

# How to apply: invited proposal

Applicants who are invited to submit a full proposal will be asked to provide information for the below points. See *Details and requirements* (page 7) for additional guidance.

Applications must be submitted using <u>ProposalCENTRAL</u>, the American Heart Association's online submission portal.

The deadline to submit invited proposals is April 1, 2022 at 3:00pm Central.

Late submissions will not be reviewed.

All full applications must include the following:

A research plan (6 page limit) (12-point font, 1-inch margins on all sides) to include:

- I. Hypothesis and Specific Aims
- II. Rationale/Background/Preliminary Work in the field
- III. Methodology describing how the Specific Aims will be successfully tested

- What is being evaluated
- How is it being evaluated
- What is the time frame
- o Anticipated outcomes upon successful completion of the study, if funded
- o What are the potential challenges and alternative optons
- Detailed description of how Research Goes Red Clinical Studies Platform and the American Heart Association Precision Medicine Platform will be leveraged
- IV. Information on instutitional data collection and security standards, including any relevant information on Institutional Review Board for Human Subjects research

**References** (pages for references are not included in 6-page limitation)

#### Biosketches of all key personnel

#### **Budget information including:**

- Salary and fringe benefits of the project lead, collaborating investigators, clinical study coordinator and other participating research staff or faculty.
- Clinical study-related expenses, such as salaries of technical personnel essential to the conduct of the project, in accordance with institutional and American Heart Association policies. Please note that the American Heart Association does not fund the costs of program implementation or operations beyond what is established in an approved budget.
- Each project is required to budget \$5,000 annually to subsidize the cost of technical assistance, licenses, and fees associated with the Precision Medicine Platform.
- Consultation services are available from American Heart Association experts in data science, computation, and metrics and evaluation to improve the rigor and impact of the proposed research study.
- o Maximum of 10% institutional indirect costs may be claimed on the award.
  - The awardee will be responsible for overseeing the total budget for the grant. If awarded, the project lead and the institution assume an obligation to expend grant funds for the research purposes set forth in the application and in accordance with all regulations and policies governing the grant programs of the American Heart Association.

# **Peer Review**

All Principal Investigators submitting a full proposal must:

- Serve on the peer review committee
- Submit scores within deadline

Failure to participate in peer review and submit scores by posted deadline will result in disqualification.

Proposals that receive the highest scores in the peer review will advance for final selection with a committee of American Heart Association volunteer leaders and experts in the field.

# Details and requirements

#### Duration

Up to 2 years from date of funding, contingent upon milestones and timelines being met.

#### Number of Awards

The American Heart Association anticipates awarding up to four grants for this RFP. The American Heart Association reserves the right to determine the final number of awardees.

#### **Award Amount**

- Up to \$225,000/year (\$450,000 total)
- An additional Amazon Web Services service credit for use of the American Heart Association
  Precision Medicine Platform may be provided for computational time, use of AWS tools and
  infrastructure, and storage. Credit amount will be determined based on estimated need over
  duration of the grant.

#### Precision Medicine Platform, research environment

All funded applications will leverage workspaces on the American Heart Association Precision Medicine Platform, powered by Amazon Web Services.

Each funded application will be eligible to receive Amazon Web Services computational credits to cover the cost of cloud computing for a secure and private workspace on the American Heart Association's Precision Medicine Platform to enable investigators in each team to collaborate and analyze data securely.

Data analysis is enabled in secure workspaces by a web interface that allows researchers to code in various languages, including R and Python, and to use statistical software including but not limited to SAS and R studio. The most up-to-date machine learning and artificial intelligence software available from Amazon Web Services is also included. Researchers are also able to install their own tools.

The American Heart Association asks that the grantees also accelerate collaboration through the sharing of data and code as well as the coordination for interoperability of data to facilitate findability and sustainability. The American Heart Association fully supports the FAIR (<u>F</u>indable, <u>A</u>ccessible, <u>I</u>nteroperable and <u>R</u>eusable) guiding principles of data stewardship.

The Platform is HIPAA and FedRAMP compliant. Learn more about the Platform's Security Information.

To learn more about the Precision Medicine Platform:

- Overview
- Full list of available analytical tools
- Videos:
  - o Learn more about the platform video 1
  - o Explore the capabilities of the platform video 2

#### Interim assessment

Awardees must report progress on a minimum annual basis. Progress reports may take the form of a required written report in addition to video conferencing, phone calls, and/or face-to-face visits. Reporting will be focused on achievement of stated milestones as indicated in the project timeline. The American Heart Association reserves the right to request additional updates, site visits, or reporting.

#### Public access

The American Heart Association's public access policy requires that all journal articles resulting from American Heart Association funding be made freely available in PubMed Central and attributed to a specific American Heart Association award within 12 months of publication. It is the responsibility of the awardee to ensure journal articles are deposited into PubMed Central.

## Open data

Any factual data that is needed for independent verification of research results must be made freely and publicly available in a repository approved by the American Heart Association within 12 months of the end of the funding period (and any no-cost extension).

For more information on the above policies, see the American Heart Association's Open Science Policy webpage.

## Additional requirements

- The projects submitted can have no scientific or budgetary overlap with other work funded by the American Heart Association or any other source.
- Any inventions, intellectual property, and patents resulting from this funding are governed by the American Heart Association's <u>Patent</u>, <u>Intellectual Property and Technology Transfer Policy</u>.
- The applicant/awardee and institution are responsible for compliance with all American Heart Association research award policies and guidelines for the duration of any awards they may receive.
- Visit the Research Programs Awards Policies page for more information on this topic: <u>American</u>
   <u>Heart Association Policies Governing All Research Awards</u>

For questions and assistance: pmp@heart.org