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Gertrude Campbell Dr. Ronald J. Stoney, Co-Founder The Foundation to Advance Vascular Cures is issuing an RFA for pilot projects, following on the heels of the success of the 2023 Vascular Health Innovation Summit: *"Precision Medicine and Patient-Centric Vascular Health: Present and Future State"*. The pilot projects are envisioned to leverage existing datasets, biospecimens and imaging in new ways to address gaps in the field and stimulate the next stage of translational research (e.g., clinical trial, NIH or large foundation support, translation to patients) – always with the goal of improving patient outcomes.

Participants at the Summit discussed the implications of precision medicine across vascular disease types, such as peripheral artery disease (PAD) and Abdominal Aortic Aneurysm (AAA), and examined different approaches, including big data omics-based discovery and validation research, and use of AI and deep learning to analyze data from imaging, biobanks, and electronic health records. Attention to diversity and social determinants of health was a clear, stated priority throughout. Based on Summit discussions, the following priority project areas for pilot research funding are:

- Disease risk prediction and progression models, applying precision medicine approaches. Examples include quantitative assessment of vascular calcification from CT imaging to predict intervention outcomes, or investigation of historical vascular lab data to identify at-risk patients and model disease progression.
- Identification of novel vascular disease phenotypes based on clinical trajectory, morphology, or responses to treatment
- Insights into mechanisms underlying disparities in vascular disease, identifying data and/or methods for obtaining such data, and analytical approaches to assess disparities in treatment and/or outcomes.
- Exploration of new (or new interpretations of) biomarkers of vascular disease.
- Medical management best practices, including timing and frequency of screening, scans, genetic testing, based on computer modeling and deep learning. Examples include assessing viability of ultrasounds and CT scans as clinical decision support tools for dialysis readiness, viability of supervised exercise therapy, and pharmacological responses.
- Translation of risk prediction metrics to providers and patients, including assessing requirement for uptake, validation studies, and patient preferences. This covers studies that focus on lifestyle and behavioral changes.

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Scope and Requirements

- The RFA call is for pilot projects, with the expectation that the data gathered in the pilot project will support larger, future grants that are innovative and impactful. Proposals for large scale RCTs or basic laboratory science with longer timelines are not eligible. Planning grants are likewise not responsive to this call.
- Pilot projects should address gaps in the field, focus on one vascular disease area, and include strategies to address underrepresentation of diversity.
- The funded project will have a maximum of 16 months duration and a total award of \$75K. Proposals must demonstrate feasibility within the timeframe and budget, and must demonstrate that it can achieve optimal impact with minimal resources.
- All proposals should include a roadmap to next stage research, including ways that the Foundation to Advance Vascular Cures can support pilot project success and continuity. All must be patient-centric and impact oriented.
- Proposals must be milestone based. At least one milestone achievable in the first 6 months is required. Additional milestones must be achievable in 16 months.
- Budgets for each milestone using the <u>CPCR 2023 RFA Budget Worksheet</u> must be provided and may not include capital equipment.
- The Foundation to Advance Vascular Cures does not fund indirect costs.
- Collaboration between 2 or more investigators and institutions is required. Institutions are defined as academic research and care (any specialty), allied health professionals, community- or faith-based. organizations, payers, managed health organizations/health systems, regulators and industry (drug or device developers).
- Inclusion of at least one patient advisor in the design and execution of the project is required.
- Projects should seek to develop key resources for future sharing with the vascular healthcare community, which may include de novo resources or enhancing the scope/value of existing resources.
- Only attendees at the 2023 Vascular Health Innovation Summit are eligible to apply as primes for the current RFA call.

Review Criteria

• Impact: How will the results of the study impact patient care or future research? What will be learned from the study, regardless of the outcome?

- Innovation: Does the proposal develop a novel approach or technology? Does it create a paradigm-shift in research?
- **Research strategy:** Are the milestones meaningful and is the approach based on solid scientific premise and methodology? Are the milestones achievable within the proposed timeframe and budget?
- Investigators: What are the qualifications and commitment of the investigators? What is the contribution of each collaborator and why are they essential to its success?
- **Patient engagement:** Is the patient advisor/s being engaged in a way that is meaningful to ensuring the project is aligned with patient needs and preferences?
- **Resources available:** Are all the necessary resources available to the project team?
- Implications: Based on the outcome of the study what would be the logical next steps and how will they be achieved?

Proposal Guidelines

Proposals may not exceed 5 pages, single spaced, 11 pt. type, excluding supplemental appendices (which may not exceed 4 pages) and biosketches.

Key sections:

- 1. Key unmet need addressed by the proposal
- 2. Project goals/specific aims
- 3. Innovation
- 4. Milestones and deliverables
- 5. Research strategy specific approaches and methods
- 6. Shared resources and how they will be used or developed
- 7. Impact of the project results (success or failure) and future directions
- Investigators specify their specific roles and efforts; NIH biosketches (4-page maximum per investigator)
- 9. Budget worksheet: overall and for each collaborator/center by milestone, using the 2023 RFA Budget Worksheet as an appendix

Eligibility

Eligibility is limited to those investigators invited to apply by the Foundation to Advance Vascular Cures. Applications from other investigators will not be considered.

Application Process

Proposals must be submitted electronically to the Foundation to Advance Vascular Cures at <u>grants@vascularcures.org</u> by **midnight Pacific Time on December 22, 2023.** All submissions must be in Microsoft Word or PDF and conform to the guidelines listed above. Proposals will be reviewed upon receipt to ensure all required information has been provided before receipt is confirmed.

Key Dates

- November 1, 2023: RFA announced
- December 22, 2023: Proposals due to Vascular Cures by midnight Pacific time
- January 31, 2024: Awardees announced
- Grant award period April 1, 2024 to July 31, 2025
- July 31, 2025 Final report due
- Payment timeline: Oct. 1, 2024 50% payment based on achievement of milestone #1; August 31, 2025 - Final 50% payment based on achievement of all milestones

Budget

Note: All awards may be used for direct costs only

Please include a <u>2023 RFA Budget Worksheet</u> for each collaborator (see Budget Worksheet document for a template).