

Request for Applications (RFA)

Project title: Vasculitis Research Initiative to Assess Disease Impact (V-RIDI study)

Goals of the funding program: The VF Board of Directors has agreed that the patients for whom we advocate have diseases for which impact has not been adequately assessed. The goals of this RFA are to stimulate research that addresses scientific questions related to the impact of vasculitis to patients, their families, and society.

Background: What is known about the impact of vasculitis? What tools have been used in the past in the US to measure the impact of vasculitis? What tools may be useful now? Do tools exist in other diseases that would be relevant to vasculitis?

- a. Previously published examples of the utility of epidemiologic databases and approaches include:
 - i. National Hospital Discharge Survey (Cotch MF, Hoffman GS; Yerg DE; Kaufman GI; Targonski P, Kaslow FW. The epidemiology of Wegener's granulomatosis: estimates of the five-year period prevalence, annual mortality, and geographic disease distribution from population-based data sources. *Arthritis Rheum* 1996. 39:37-92).
 - ii. State databases that are similarly constructed (NYS – SPARCs), e.g. Statewide Planning and Research Cooperative System [SPARCS] - all nonfederal, non-psychiatric hospitals in the State of New York (Ibid).
- b. Other potential resources
 - i. Health and Human Services/CMS (Center for Medicare and Medicaid Services) and CDC databases
 - ii. Possible sources: large hospital system databases (e.g. Kaiser, VA Hospitals, Hospital Corporation of America (HCA), Mayo Clinic, Cleveland Clinic, others?)
- c. Examples of tools previously published to assess patient reported effects of disease
 - i. Hoffman GS, Drucker Y, Cotch MF, et al. Patient-reported effects of disease on health, function, and income. *Arthritis Rheum*. 1998; 41: 2257-62.
 - ii. Abdou NI, et al. Wegener's Granulomatosis: Survey of 701 Patients in North America. Changes in Outcome in the 1990s. *J Rheumatol* 2002; 29:309-16.

Types of research questions this RFA is meant to address.

There are unmet needs to acquire accurate data to determine:

- The epidemiology of vasculitis, including case incidence, prevalence, race, socio-demographic and geographic distribution.
- The impact of vasculitis on ability, disability, individual and family income.
- The costs of having or treating vasculitis from the viewpoint of any of the following: patient, family, employers, insurers, government, society.

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Such costs include direct costs (health care: medicines, doctor visits, laboratory, imaging and other diagnostic tests) and indirect costs of disease (e.g. travel for health care, loss of income to family members who must modify work routines, housing modifications etc) not only on the individual and the family unit, but also the health care system and the national economy.

- The impact of vasculitis on patients' quality of life, family dynamics and maintenance of established relationships with significant others including spouses, children, parents, employers, employees and friends.

Feasibility

The VF realizes that it is not possible to perform a comprehensive study of all known forms of vasculitis for the amount of funding available. However, it is hoped that by using available databases and modifying or designing new patient-reported outcomes tools, that useful information can be obtained for one or more of the most common forms of vasculitis (e.g. granulomatosis with polyangiitis (Wegener's), giant cell arteritis and/or microscopic polyangiitis) or rare forms that have highly characteristic features so inclusion of erroneous diagnoses is minimized (e.g. Takayasu's arteritis). A successful project would both produce important findings and publication(s) and, hopefully, lead to continuation of the work on a larger scale for other forms of vasculitis, supported by Federal, non-profit, and/or industry resources.

Furthermore, the VF realizes that not all of the aims stated above are equally attainable or, indeed, feasible, within the time and budget constraints or within a single project. It is hoped that a variety of approaches can be pursued simultaneously that can take advantage of newer technologies (such as social media) to address project goals. Where possible, methods should overlap to yield information on the reliability of estimates produced.

What is the VF prepared to do to stimulate interest in Vasculitis Epidemiology and Outcomes Research?

- In December 2012 the VF Board agreed to provide an RFA for \$100,000 to support a study that could be performed in one or more diseases for which the VF advocates.
- Support, through its members and partnerships with the Vasculitis Clinical Research Consortium (VCRC), the Rare Diseases Clinical Research Network (RDCRN, NIH), and others, access to patients for data acquisition.
- Direct the grant recipients (and applicants) to work in partnership with the V-RIDI study (Vasculitis Research Initiative to assess Disease Impact) Steering Committee to ensure study success.

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Who is eligible to apply for this grant?

- Investigators with a publication track record in the areas of epidemiology, outcomes and disease impact.
- Because these outcomes will vary between health systems and countries, this initial study will focus on these issues in the US. Future studies may be funded that will examine outcomes in other countries, for which this may serve as a template and basis for comparison.

Components to the application that will favor funding

- Prior experience in epidemiology and outcomes research
- A feasible plan that takes advantage of existing databases that track diagnoses and geographic distribution
- Use of validated survey tools that can be adapted from prior studies that examine health, damage, socio-economic, functional and emotional impact of disease in a representative sub-population of patients studied. If new tools are to be utilized, a plan for their validation should be included.
- Appropriate plan and expertise for substantive biostatistical analyses of the data.

Applications for the V-RIDI study can be accessed on the Vasculitis Foundation web site (www.VasculitisFoundation.org).

Letter of Intent

Interested parties are requested to submit a non-binding letter of intent (no longer than two pages) within six weeks of April 1, 2013. The letter of intent should include the following:

- Descriptive title of the proposed research
- Abstract that states hypothesis and anticipated new knowledge to be gained from the research
- Name, address and telephone number of the Principal Investigator(s)
- Names of other key personnel
- Participating institutions

Please submit letter to Joyce A. Kullman, Executive Director, Vasculitis Foundation: jakullman@vasculitisfoundation.org

In brief, the application will consist of

1. Project Abstract, Performance Sites & Personnel
2. Lay Person Summary (Maximum 300 words.)
3. Detailed Budget (Not to exceed two pages.)
4. Resources
5. Biographical Sketch—Principal Investigator (Not to exceed two pages.)
6. Research Activities (of the PI for the past three years – Limit one page.)
7. Other Support (as it applies to this grant – Limit one page.)

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8. Timeline: A half page description of the timeline from initiation to completion of the study (s), not to exceed two years.
9. Research Plan
 - A. Specific AIMS, hypotheses, expected results and impact. (Not to exceed one page.)
 - B. Background and Significance
 - C. Preliminary Studies
 - D. Research Design, Methods and Analysis (including analytical approaches, limitations of methods and contingency plans should one or more approaches prove not feasible.) (Not to exceed four pages.)
 - E. Expected findings: (One page statement of how expected findings may influence current concepts and lead to subsequent studies and discoveries.)
 - F. Timeline: A half page description of the timeline from initiation to completion of the study (s), not to exceed two years.
 - G. Literature Cited
 - H. Consortium/Contractual Agreements

Appendix (One collaged set; no page numbering necessary for Appendix.)

Investigator NIH style CVs (biosketches) will not be counted towards the page limit.

Application deadline: Friday, June 7, 2013

Selection Process:

Applications will be reviewed by a panel of VF selected experts in the areas of vasculitis, epidemiology and outcomes. The review process will occur over a 4-week period (June 2013). A single award will be provided by October 2013 to the most meritorious applicant(s) that meets committee objectives.