



**Foundation for Sarcoidosis Research
Clinical Studies Network (FSR-CSN)
Request for Proposals**

Purpose:

To address research needs in the sarcoidosis disease space, in 2015 the Foundation for Sarcoidosis Research launched the world's only **Sarcoidosis Clinical Studies Network (FSR-CSN)**, bringing together an international partnership of world-renowned medical institutes and researchers for unprecedented collaboration in drug trials toward the treatment of sarcoidosis.

The development of a sarcoidosis Clinical Studies Network provides a forum to address a range of important but unanswered questions in sarcoidosis, facilitate a move towards broader consensus about clinical endpoints, and enables pharmaceutical industry entrance into the sarcoidosis space with less perceived risk. The initial phase of the CTN was 2015-2017 (with an extension to Oct 2018), and includes 8 national and international partners who collaborate in multi-site studies, trials, and data-sharing.

The Grant Award

This RFP invites applicants to apply for the grant award (inclusion and funding) via this competitive process. **The initiative is open to sites seeking renewals for first grant period as well as expanding to consider additional partners who can fully demonstrate major impact in the sarcoidosis research field.** The award grant period is July 2018 – June 2020 and funding is \$40,000 per year (total \$80,000). Funding is unrestricted and does not allow overhead.

FSR Clinical Studies Network: FSR-CSN

The FSR Clinical Studies Network is charged with:

1. Developing a core set of shared protocols and clinical outcomes measures that can be used to address various questions
2. Conducting multicenter clinical research experiments or observational studies that are unlikely to be addressed by industry or government funding priorities
3. Serving as a mechanism for rapid recruitment of centers for pharmaceutical trials

Structure

The FSR Clinical Studies Network (FSR-CSN) is led by a Steering Committee composed of the Principal Investigators from each participating institution. The purpose of the Steering Committee is to formulate and perform clinical studies. The FSR Research Manager facilitates the committee and will collect progress reports from sites on a quarterly basis. FSR will report quarterly to the FSR Scientific Advisory Board and will include information about the level of commitment and the participation (e.g. recruitment) of each participating site, as well as information about ongoing and planned projects.

Continuing participation in the Network is contingent on an annual basis on the performance of each individual site. FSR-CSN will meet at least four times annually by teleconference, and at least once annually in person, typically in conjunction with a scientific meeting. Additionally, there will be at least one mandatory in-person meeting at the outset of the funding period.

Application for Participation for NEW Applicants

The application is composed of several elements considered for selection: information about the site as well as a proposed study to be facilitated by the CSN group for this grant period. The study ultimately selected as the CSN project for the second grant period will be one of those from proposed applicants, so even if a site gets selected for the grant for CSN participation, their study proposed in the application may not be selected. Current members of the CSN are also invited to re-apply via a separate RFA.

Interested parties should apply for inclusion in the FSR-CSN by formulating a brief proposal that could be completed during the next 24-month study project (July 2018 - June 2020) for the Network. The proposal should:

- 1) Be no more than four pages in length (excluding budget).
- 2) Include a statement about the problem to be addressed, the methods to be used, and the impact of the research on the field.
- 3) Include a detailed budget for the proposed project with consideration for typical center feasibility
- 4) Include (within the four-page limit)
 - a. substantial information about the applicant's center:
 - b. number and demographics of sarcoidosis patients seen annually in the applicant's division;
 - c. names and expertise of relevant personnel at the center (e.g. a uveitis specialist);
 - d. enumeration of clinical trials and enrollment over the past 5 years (include whether internally funded or sponsored, and role of the applicant); and,
 - e. other relevant information to define the overall capacity of the institution to perform clinical research.
- 5) NIH-style bio sketch for all of the key personnel at the site (separate from the four-page narrative).

Please send applications electronically to the Foundation for Sarcoidosis Research to CSN@stopsarcoidosis.org. Include an NIH-style bio sketch for all of the key personnel at the site as attachment. Applications must be received by 8 p.m. CST on November 30, 2017.

Funding

The anticipated date for selection of site is by January 15th, 2018, and the funding period will commence in July 2018. Centers will be funded for a two-year period, but continued inclusion in the Network will be contingent annually on performance. After two years, a new round of applications will be needed to continue in the Network. The Network will be funded as a contract, with 50% of the funds designated for core costs (i.e., coordinators), and the other 50% of the funds designated for capitated quarterly payments for the studies. It is expected that some of

these funds will be used to cover costs for non-standard-of-care testing that is included in the protocol. The award will be \$40,000 per site annually (no indirects are included in the award).

Information

For more information about the FSR-CSN, please visit www.stopsarcoidosis.org or contact Ginger Spitzer at ginger@stopsarcoidosis.org.