



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

Request for Proposals

Purpose:

Sarcoidosis remains relatively under-studied and under-funded, resulting in a lack of inter-institutional structure and support needed to address basic questions. For example, there are little data regarding the magnitude of change after treatment with medical therapies despite their use for several decades, there are no data assessing minimal important clinical differences for most of the metrics used to assess sarcoidosis, and there is a striking absence of information about long-term morbidity from the disease. Additionally, the absence of an organized body with common protocols and shared vision may be perceived as a barrier for pharmaceutical industry interest in sarcoidosis.

The development of a sarcoidosis Clinical Studies Network would provide a forum to address a range of important but unanswered questions in sarcoidosis, facilitate a move towards broader consensus about clinical endpoints, and enable pharmaceutical industry entrance into the sarcoidosis space with less perceived risk.

FSR Clinical Studies Network: FSR-CSN

The Foundation for Sarcoidosis Research (FSR) is creating a Clinical Studies Network that will be 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) will be led by a Steering Committee composed of the Principal Investigators from each participating institution. The purpose of the Steering Committee will be to formulate and clinical studies. The chair of the Steering Committee will be responsible for providing a progress report in writing to the FSR Scientific Advisory Board at least twice annually. The progress report 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.

At the outset, the FSR Clinical Studies Network (FSR-CSN) will be composed of 6-8 sites, but the intention of the FSR is to expand the size of the Network once it is established, and as funding allows. Continuing participation in the Network is contingent on an annual basis on the performance of each individual site.

FSR-CSN will meet at least six 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:

Interested parties should apply for inclusion as a site in the FSR-CSN by formulating a brief proposal that could be the inaugural project of the Network. The proposal should:

- 1) Be no more than four pages in length.
- 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 (within the four page limit)
 - a. substantial information about the applicant's center:

- b. number and demographics of sarcoidosis 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 sarcoidosis 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 involving sarcoidosis.
- 4) NIH-style bio sketch for all of the key personnel at the site (separate from the four-page narrative).

Some examples of questions that could be addressed in the RFP include: *what is the minimal clinically important difference in one of the sarcoidosis-specific QOL instruments?; what is the magnitude of response when treating pulmonary sarcoidosis with various agents?; what proportion of individuals will reach the clinical outcome measures proposed by WASOG within a given time after diagnosis, and what epidemiologic variable predict those?; what is the utility of HRCT for predicting treatment response, course of sarcoidosis, or need for biopsy to confirm the diagnosis?* For the initial iteration of the Network, studies will not include measurement of laboratory-based variables, such as HLA typing or candidate biomarkers, though these may be part of future projects.

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 January 5, 2015.

Funding

The anticipated date for selection of site is by March 1, 2015, and the funding period will commence in the spring of 2015. 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 \$30,000 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.



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