FARE CLINICAL NETWORK MEMBERSHIP APPLICATION

FARE's mission is to improve the quality of life and the health of individuals with food allergies, and to provide them hope through the promise of new treatments.

FARE believes that every food-allergic individual deserves the best care and treatment possible. To that end, we created the FARE Clinical Network (FCN) to raise the quality of care for food-allergic patients nationwide; reduce discrepancies in care among providers; make comprehensive care accessible and available for all food-allergic patients; investigate the biology of food allergy; and develop new therapies and new diagnostics for food allergy. FARE believes that clinicians, physician scientists, family members and patients should know which clinics provide and maintain the highest standards in clinical and sub-specialty food allergy services; which clinical centers are leaders in conducting food allergy-related clinical trials and are facilitating the rapid dissemination and implementation of new evidence-based knowledge; and which centers are actively engaged in food allergy research and discovery. FARE now embarks on an effort to enhance and expand the FCN and believes that through collaborative efforts, the new FCN will provide benefits to its members as well as to patients by advancing our understaning of the biology of food allergy.

FCN MISSION

To bring top institutions together to ensure that patients with food allergies have access to state-of-the-art diagnosis and treatment, short-term and long-term care, and research that addresses factors from discovery to application along the entire clinical and translational spectrum.

FCN GOALS

- Develop and disseminate best practices for the care of patients with food allergies
- Serve as sites for clinical trials for the development of new therapeutics and diagnostics
- Engage in cutting-edge research to better understand the biology of food allergy and disseminate the findings to advance the fields of food allergy treatment and prevention
- Contribute to the development of the FARE Patient Registry and food allergy biorepositories

The centers of excellence selected as part of the FARE Clinical Network provide high quality clinical and sub-specialty food allergy expertise and services, and are focused on applying new evidence-based knowledge to this important field. All centers also meet high standards for clinical care and teaching, and some also are involved in cutting edge research. Traditional academic centers, as well as allergists' offices with academic affiliations, may apply to become members of the FARE Clinical Network.

MEMBER BENEFITS

For sites approved to be part of the FCN consortium, benefits will include the prospect to collaborate with other FCN investigators, opportunities to be a part of a strong clinical research network aimed at new therapeutics and diagnostics, access to biorepository samples and patient registry data, as well as clinical operations and regulatory support services at the FCN Data & Coordination Center (see below). All sites will also receive extensive educational materials and training. For discovery centers of distinction, annual stipends will also be provided (see below).

FARE will also create a forum where clinicians, researchers, industry representatives, regulators, payers and patient advocates will exchange ideas and opportunities for the advancement of research, prevention and treatment of food allergies. FCN members will be invited to participate in this forum, as appropriate. New information and opportunities arising from this forum will be made available to FCN members.

Furthermore, as part of our effort to encourage collaboration and share resource materials, FARE intends to make key educational materials available to, and/or co-brand these materials with, FARE FCN members. Information about the FARE Clinical Network and its members will be featured on FARE's website, in a variety of digital communications, and in materials distributed at special events, such as galas, luncheons, and conferences, as well as the annual meetings of professional associations and societies. This will further expose the FCN members to new opportunities for funding and collaboration.

GOAL OF THE COMPETITION

The competition is open to all sites, present and new, that meet the requirements. The goal is to retain the most successful of our current sites and add new sites that enhance the overall function of the network to provide excellent care to patients with food allergy, and to assist in the conduct of basic, clinical and translational research in food allergy. The overall objective is for the FCN to be a robust collaboration of centers that conduct studies on all aspects of food allergy while providing patients with the latest diagnostic and therapeutic options as well as education and support.

FCN STRUCTURE

Created by FARE in 2015 with an initial investment of more than $2 million, the FARE Clinical Network is a bold initiative that aims to accelerate the development of therapies for patients with food allergies as well as improve the quality of care for this serious illness. The FARE Clinical Network, which now comprises more than 30 centers of excellence across the country, brings members together for a common goal of ensuring that patients with food allergies have access to state-of-the-art diagnosis, care, research and clinical trials.

The current FCN model will be restructured towards one that enables expansion of the number of sites with a focus on the strengths of each participating site. FARE, along with its advisors, will develop food allergy-specific common standard operating procedures (SOPs), protocols and tracking metrics for each site, and train the sites for best practices and research efforts.

The new FCN model will include *three different levels* that sites can apply for: *Discovery Centers of Distinction*, *Clinical Research Centers of Distinction*, and *Care Centers of Distinction*. In addition, there will be a Data and Coordination Center (DCC) and biorepository center to facilitate and integrate all research efforts. The FARE Patient Registry system will be enhanced and placed under the direction of the DCC. The DCC will be at the center of the FCN and will provide the following services to FCN sites:

- Statistical support, design and analyses, including interim and final analyses of study data, both clinical and mechanistic
- Clinical trial design, implementation and management
- Development of protocols, manuals of operations and manuals of procedures
- Regulatory activities as needed including assistance in the preparation, submission, tracking and archiving of all regulatory submissions and communications and Investigational New Drug (IND) applications with National Regulatory Health Authorities.
- Data management and reporting
- Safety oversight and reporting
- Handling of investigational and/or regulated study products (investigational and/or registered)
- , including product receipt, distribution and quality control
- Preparation of reports and analyses for presentations and publications
- Institutional Review Board (IRB) submissions
- Biospecimen tracking
- Administrative support

- Overhaul and oversight of the FARE Patient Registry
- Preparation of per protocol budgets in collaboration with clinical centers, with these centers providing additional monetary support to the DCC by budgeting for its services in their grant applications

All clinical sites will be expected to provide excellent care to patients with food allergy and contribute to the FARE Patient Registry. Below are the basic activities of each of the new levels of commitment for the FCN sites. A site can apply to one or more FCN levels, providing the relevant information in the application (see below).

Discovery Centers of Distinction and Clinical Research Centers of Distinction must be not-for-profit and preferably will be sited at academic institutions with adequate institutional support for the necessary infrastructure. Each center will have a Principal Investigator whose background and experience indicate competence in research in food allergy. A consortium of more than one institution/site may comprise a center; however, one of the institutions/sites must be identified as the lead site. These awards will be subject to administrative review along with the submission of progress reports annually. The review will include applicable criteria such as tracking of center recruitment goals, as well as maintaining compliance with award Terms and Conditions.

FCN LEVELS

Discovery Centers of Distinction (Level I)

Must have a demonstrated record of funded basic and/or translational clinical research focused on food allergy. Priority will be given to sites that have a track record of collaborative research.
Conduct basic/translational research: expected to apply for R34, RO1 and UO1 grants from NIH as well as other grants from foundations and federal sources via collaborative research efforts with other FCN sites, e.g. Discovery & Clinical Research.

- Are expected to work within FCN towards the betterment of basic and/or translational clinical research aimed at diagnosing, preventing and treating food allergy
- Proposed support: Up to $100,000 per year for 5 years for infrastructure and training, e.g., research staff, equipment, supplies, travel to support maximum of three in-person meetings per year and salary support. We expect to fund up to 10 sites at this level.

Clinical Research Centers of Distinction (Level II)

Must have a demonstrated record of funded clinical research focused on food allergy. Priority will be given to sites that have engaged in industry-funded and/or federally funded investigations of new therapies or diagnostics for food allergy. Sites should be capable of or have a history of collaboratively functioning in a clinical research network, as well as active or planned approaches for regional coverage and involvement.

- Can attract large numbers of subjects from a racially and culturally diverse population with food allergy
- Have well-trained and experienced clinical research staff
- Can conform to FCN-wide SOPs
- Possess the infrastructure (including but not limited to clinical operations, patient safety, data management and biostatistics, and legal and administrative resources) to perform industry-sponsored as well as federally funded clinical trials examining new therapeutics and novel diagnostics for food allergy
- Demonstrate proven experience and track record with patient recruitment, management and follow-up
- Have access to and experience with a central IRB
- Proposed support: Possible small annual stipends for infrastructure and training of no more than $10,000 per site. We expect to award up to 30 sites at this level.

Care Centers of Distinction (Level III)

Must have a demonstrated record of caring for food allergy patients and their families. Priority will be given to sites that have a demonstrated track record of educating patients and families about food allergy and can implement the latest FDA-approved therapies.

- Provide excellent food allergy clinical care
- Collaborate with FCN Clinical Research Centers for patient access to clinical studies, and information on new approaches to treating food allergy
- Agree to contribute to the FARE Patient Registry. Prior to submission, the individual submitting this application ("the applicant") must verify must verify with internal stakeholders (e.g., legal and administrative authorities) their site's ability to contribute to the registry
- Proposed support: Although no financial commitment will be provided, FARE will support via online training, advertising and educational materials for patients and their families and assessment of quality care. Furthermore, the FCN Care Center will have access to scientific and clinical information emerging from the Discovery and Clinical Research sites as well as the FARE forum.

SITE SELECTION

Members of the FARE Clinical Network will be selected through a comprehensive, rigorous application process. Candidate sites are required to address criteria in a number of key areas, including food allergy patient base, staff credentials, implementation of state-of-the-art diagnostic and clinical practice guidelines, facilities, operational oversight, training, and research experience. Candidate sites will also indicate on their application which FCN level(s) they are applying to join (*Discovery Centers of Distinction*; *Clinical Research Centers of Distinction; Care Centers of Distinction)*. After review of applications received, FARE leadership might approach individual applicants to consider a different level of engagement.

A FARE-organized and -supervised review committee will evaluate each site's application to become a member of the FARE Clinical Network, as well as its annual renewal, and will work with centers on any needed remediation efforts.

The review process for FCN sites will consider the following factors depending upon the level designation:

Criteria	*Discovery Centers of Distinction*	*Clinical Research Centers of Distinction*	*Care Centers of Distinction*
Scientific excellence of the application, and the extent to which it addresses the goals and objectives of the RFA	X	X	NA
Availability of and access to a suitable patient population, and the ability of proposed recruitment strategies to provide an adequate number of patients to support participation in the network and/or FARE Registry	X	X	X
Demographic and geographic distribution of the patient population	X	X	X
Demonstrated experience, ability and willingness to carry out common protocols; adequacy of plans for	X	X	NA

effective cooperation and collaboration with other centers in the network			
Qualifications and research experience of the Principal Investigator and other investigators carrying out multi-center investigations and other clinical research, as well as experience and success in training junior investigators	X	X	NA
Proven experience and ability to disseminate new knowledge to health care professionals, patients and families	X	X	X
Proven experience and ability to collect, process, ship and receive biospecimens	X	X	NA
Availability of adequate facilities and support personnel	X	X	X
Availability of infrastructure (including but not limited to clinical operations, patient safety, data management and biostatistics, legal and administrative resources) to perform clinical studies	X	X	NA
Proven experience with and access to IRB approval	X	X	NA
Demonstrated collaborations with FARE or similar organizations for information dissemination	X	X	Optional

TERMS AND CONDITIONS OF AWARDS

All awardees will be notified in early 2020. Commencement of awards will begin on or about April 1, 2020, subject to available FARE funding.

A. Annual Review

Each FCN site will undergo annual review (see Progress Reports below) to ensure compliance with the terms and conditions of the award. FARE may terminate an award and/or association with an FCN site at any time for any center if basic, translational or clinical research and/or patient care are not being conducted according to applicable guidelines such as the *Current Good Clinical Practice Guidelines.*

B. Award Recipient

These awards will be made to the institution and not to the Principal Investigator. In the event the PI leaves the center, funding will not necessarily follow that individual to a different institution.

C. Dissemination of Information

Each center is expected to participate at both the local and national level in programs to disseminate information developed through center activities. Each center is also expected to function as a partner in the network according to the direction established by the Steering Committee (FARE leaders and select members of the FCN and Data Coordinating Center). Furthermore, Discovery Centers and Clinical Research Centers will be responsible to register their clinical trials on www.clinicaltrials.gov within the federally required timeframe as applicable.

D. Publications

Publications based on any study or research done through funding obtained from FARE must acknowledge the support of FARE and be presented to the FCN Steering Committee for approval in advance of submission. Centers are encouraged to publish with venues that allow for open access to publications.

E. Progress Reports

Annual progress reports will be mandated and must be completed to assist FARE in shaping future policies with respect to its awards program.

F. Changes in Budget

Requests for changes in budget will require prior approval by FARE. All requests must be in writing and directed to the Chief Medical Advisor for Operations, FARE. No additional financial commitments should be taken prior to formal authorization from FARE.

G. Award Payments

FCN award payments will be issued quarterly.

H. Renewals

Renewals of FCN awards are based on a demonstration of satisfactory progress and the availability of FARE funds.

I. Patent Policy

Inventions and discoveries from research performed during the term of an FCN award will be subject to the current FARE patent policy as well as to the patent policies of the institution where the work is performed.

J. Adherence to Regulations

Sites are solely responsible to adhere to all relevant local, state and federal regulations. Specifically, for the conduct of clinical studies, FARE will not assume responsibility as a sponsor for a clinical trial application such as a US FDA IND.

K. Malpractice Liability

FARE will not assume responsibility for, and the institution will indemnify and hold FARE harmless from, any lawsuit, claim, judgment, damages, awards or malpractice arising from treatment, research or investigations related to an award or association with the FCN.

L. Overhead/Indirect Costs

FARE allows for up to 10 percent of overhead. In any case, overhead charge should be embedded into the overall budget, which should not be above the proposed level of support listed above. Please provide information on your organization's overhead charge in the budget justification section below.