



FARE CLINICAL NETWORK MEMBERSHIP APPLICATION FORM

APPLICATION COVER SHEET

Institution: _____

Respondent: _____

Position/Title: _____

Department: _____

Address (Street): _____

City, State/Province, Zip Code, Country: _____

Phone: _____ Fax: _____ Email: _____

Administrative Assistant (for Applicant)

Phone: _____ Fax: _____ Email: _____

Applying for:

Discovery Center of Distinction

Clinical Research Center of Distinction

Care Center of Distinction

All applicants must fill out sections A through G

A. NIH STYLE BIOSKETCHES

Principal investigator and all co-investigators/key members must be included in the application.

BIOGRAPHICAL SKETCH

Provide the following information for the senior/key personnel and other significant contributors. Fill a separate section A form for each additional person and send in with your application.

NAME: _____

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE: _____

postdoctoral training and residency training if applicable.

INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	Completion Date MM/YYYY	FIELD(S) OF STUDY

1. PERSONAL STATEMENT (LIMIT 250 WORDS)

2. POSITIONS AND HONORS (LIMIT 250 WORDS)

3. CONTRIBUTIONS TO SCIENCE (LIMIT 250 WORDS)

4. ADDITIONAL INFORMATION: RESEARCH SUPPORT AND/OR SCHOLASTIC PERFORMANCE (LIMIT 250 WORDS)

B. PATIENT DEMOGRAPHICS

Provide a short description of the patient populations under your supervision. Provide the approximate size of your food allergy patient populations (e.g., 100-150 patients attended clinic visits in past 12 months). Describe the demographics of your food allergy patient populations including race, gender, age, ethnicity, socio-economic status, level of educational, and other relevant information you collect. Provide a description of the processes for characterization of clinical status of your patient populations (e.g., food challenges, skin testing, other allergies, medications, etc.). (Limit 500 words)

C. INTERACTIONS WITH FARE

Please describe any experience or connection you may have to working with FARE. (Limit 250 words)

D. COLLABORATIONS

The FCN will benefit from a collegial and collaborative spirit. Please provide a short description of your experience and track record of working collaborations with external partners or multi-site clinical trials. (Limit 250 words)

E. CLINICAL

From the patient's perspective, describe the clinical setting, e.g., the physical space, examination room and waiting area; dedicated facilities for food allergy diagnosis, including food challenges; an appropriate space (or kitchen) to support food challenges; and an appropriate tertiary care hospital facility where inpatient care can be provided as necessary during anaphylaxis or other severe health issues. (Limit 250 words)

F. PATIENT INTERACTIONS

Describe how your center handles patient communication and patient follow-up. Please be specific regarding issues related to patient confidentiality such as HIPAA compliance infrastructure. (Limit 250 words)

G. INFORMATION INFRASTRUCTURE

As a minimum, participation in the FCN will require one PC running Microsoft Windows (7, 8, or 10), or an Apple/Mac computer running Windows software such as with Bootcamp, Parallels, VMWare Fusion, or VirtualBox, and at least one printer and high-speed internet connection. Please confirm that you can meet these requirements and that technical support is available at your institution. (Limit 100 words)

**Discovery Centers of Distinction and Clinical Research Centers of Distinction
Applicants Must Complete Sections H, I and J**

H. CLINICAL RESEARCH ENVIRONMENT AND RESOURCES

1. CLINICAL RESEARCH SUPPORT INFRASTRUCTURE

Describe the available clinical research support infrastructure at your site. This may include clinical operations, patient safety, data management and biostatistics, legal and administrative resources for clinical studies. (Limit 250 words)

2. INVESTIGATIONAL PRODUCTS AND PATIENT TOOLS

Describe the process for distribution of drugs and equipment to patients. Be specific regarding issues related to regulatory compliance. (Limit 250 words)

3. SPECIMENS

Describe how your center handles specimen collections, storage, receiving and shipping. Please include information on maintaining participant and data confidentiality. (Limit 250 words)

4. LABORATORY

Please note the make and model of relevant equipment used in your clinic and describe the availability of other specialized equipment that exists on site for testing. (Limit 100 words)

5. EQUIPMENT

List the most important equipment items already available for food allergy research. Indicate what is available at your institution that would support overall network activities and analyses. This can include special storage and equipment for processing and shipping samples (Limit 250 words).

6. CURRENT CLINICAL PROTOCOLS

List the most important safety and treatment protocols already available for food allergy research including those to respond to adverse events that may result from challenges (Limit 250 words). In addition, applicant can attach copies of protocols or provide links to them if available publicly.


I. TRAINING & MENTORSHIP

FARE aims to promote the next generation of food allergy investigators. Please provide a short description of your experience and track record of training and/or mentorship of junior investigators and how you envision the FCN as a conduit for future young investigator development (Limit 250 words).

J. PAST HISTORY OF CLINICAL TRIALS

Describe your participation in food allergy clinical research in the past five years. Please highlight randomized clinical trials. Indicate sources and amount of support, participants enrolled and completed, successful completion of study and resultant publications. Indicate performance in other multi-site trials (Limit 2500 words).

Discovery Centers of Distinction Applicants Must Complete Sections K, L and M

K. PROPOSED PROJECTS

Outline two clinical/translational research projects that would advance the mission of FARE and would benefit from access to FCN sites. Please provide a brief narrative description of two protocols in food allergy that the center would propose to the FCN for implementation. It should be recognized that most translational research and/or clinical studies that are proposed will not be initially undertaken, and it is possible that not all centers will participate equally in all studies. The studies proposed by the centers that are selected will be submitted to the FCN Steering Committee for further consideration. However, a decision to fund a particular center will not commit the network to develop that group's proposed studies. FARE identified areas of interest include but are not limited to: NATURAL TOLERANCE, MECHANISMS OF ORAL IMMUNOTHERAPY RESPONSE, NEW THERAPIES AND DIAGNOSTICS TO REPLACE FOOD CHALLENGES, EPIDEMIOLOGY AND CHARACTERISTICS OF THE FOOD-ALLERGIC PATIENT INCLUDING PSYCHOSOCIAL FEATURES, and PREVENTION STRATEGIES.

Please use the enclosed Word file for the proposal and send in with your application. Limit each proposal to no more 1500 words and follow the outline below:

1. BACKGROUND
2. SPECIFIC AIMS/ HYPOTHESIS
3. RATIONALE FOR STUDY
4. APPROACH/DESIGN. INCLUDING OBJECTIVES AND ENDPOINTS
5. STATISTICAL APPROACH
6. IMPORTANCE OF THE NETWORK
7. TIMETABLE
8. ESTIMATED COSTS (SEPARATE FROM INFRASTRUCTURE BUDGET SHEET)

L. FCN INFRASTRUCTURE BUDGET FOR DISCOVERY CENTERS OF DISTINCTION

Please complete the attached budget sheet (Excel format) and send in with your application.

M. BUDGET JUSTIFICATION

Please provide details on your institution's overhead in the budget justification. (Limit 250 words)