The Consortium for Food Allergy Research (CoFAR) consists of two distinct entities, the CoFAR Leadership Center (LC) and the CoFAR Clinical Research Units (CRUs). The objectives of the CoFAR LC are to provide scientific strategy and organizational structure to CoFAR for the conduct of ground-breaking research in the areas of prevention, management and understanding of the mechanisms of IgE-mediated food allergy. To advance these objectives, the CoFAR LC will work closely and in collaboration with the CoFAR CRUs to conduct all CoFAR clinical trials and clinical studies. Clinical monitoring, data collection, data management, and statistical support for this effort will be provided by the NIAID-DAIT: Statistical and Clinical Coordinating Center. Standardized biomarker measurements across studies will be conducted by the CoFAR LC through a Central Biomarker Facility. In addition to the biomarker studies conducted by the Central Biomarker Facility, the CoFAR LC will select and support state-of-the-art mechanistic research linked to the CoFAR clinical trials and studies through an Opportunity Fund open to both CoFAR members and outside investigators. The CoFAR LC is expected to develop close interactions between basic scientists and clinical investigators to accelerate the translation of basic research advances into clinical applications. All research developed by the CoFAR LC will involve human subjects. The CoFAR LC will also be responsible for distributing protocol funds to the CoFAR CRUs to conduct CoFAR clinical trials and studies.

The scope of research that the CoFAR LC may conduct includes, but is not limited to, the following:

- Phase I and/or Phase II clinical trial(s) for either treatment or prevention of food allergy. Clinical trials should focus on immune-based approaches such as preventative early allergen exposure, new forms of allergen immunotherapy including immunotherapy in combination with adjuvants, anti-cytokine treatment, or other immunomodulatory agents/approaches.
- Phase III clinical trials will be allowed only following successful completion of a phase II trial.
- Applicants are strongly encouraged to contact NIAID Scientific/Research Contact(s) prior to including such a trial as part of the response to this FOA.
- Birth cohort studies of individuals at high risk vs. low risk of food allergy.
- Cross-sectional or long-term clinical studies in individuals with food allergy.
- The role of the microbiome in the pathogenesis of food allergy.
- Identification of the route of allergen sensitization in food allergy.
- Interactions between immunologic, environmental and genetic or epigenetic factors underlying food allergy.
- Proteomic and/or metabolomic profiling in association with the clinical presentation of food allergy.
- Molecular mechanisms (e.g. analysis of signaling pathways) in association with the clinical presentation of food allergy.
- Mechanisms underlying the severity of allergic reactions and anaphylaxis in food allergy.

The CoFAR LC will be responsible for oversight and completion of two ongoing CoFAR clinical trials.

- CoFAR 6: “Epicutaneous Immunotherapy (EPIT) for Peanut Allergy: A Randomized, Double-Blind, Placebo-Controlled, Phase II Study in Children and Adults” (www.clinicaltrials.gov/ct2/show/NCT01904604). CoFAR 6 is fully enrolled with 75 participants between the ages of 4 and 25 years. CoFAR 6 reached its primary outcome in August, 2015. Currently, CoFAR 6 continues to assess its participants in a follow-up phase on open treatment. Final assessment oral food challenges are expected to be complete by June of 2018, with last patient, last visit (a telephone assessment) in September 2018.

- CoFAR 7: “Oral Desensitization to Egg with Subsequent Induction of Sustained Unresponsiveness for Egg-Allergic Children using Baked Egg or Egg Oral Immunotherapy (OIT)” (www.clinicaltrials.gov/ct2/show/NCT01846208). CoFAR 7 is fully enrolled with 92 participants between the ages of 3 and 16 years. Assessment of the primary endpoint is anticipated to be complete in October 2017, with the last patient, last visit (a telephone assessment) in September 2018.

- CoFAR 6 and CoFAR 7 are each supported by: a statistical and data coordinating center that provides clinical monitoring, data management and analysis services; and an NIAID medical officer, an NIAID nurse/project manager, and an NIAID regulatory officer. The CoFAR LC will provide the funds to this center to continue its services for the completion of these two trials and the publication of their results.
**ELIGIBILITY**

Institutions may submit an application to both the CoFAR Leadership Center (RFA-AI-15-050) and the CoFAR Clinical Research Units (RFA-AI-15-051). However, the same clinical trial cannot be proposed in both applications.

**LIMIT ON NUMBER OF PROPOSALS PER ORGANIZATION**

Only one application per institution (normally identified by having a unique DUNS number or NIH IPF number) is allowed.

**KEY DATES**

If you are interested in this funding opportunity, please send a one-page summary of the proposed research and your biosketch to Eric Boberg (e-boberg@northwestern.edu) by February 23, 2016.

The sponsor application due date is June 30, 2016, by 5:00 PM.

**COLLABORATION OPPORTUNITIES**

The Office of Research Development offers assistance in identifying and facilitating collaborations, putting together interdisciplinary teams, programmatic and administrative development of large, cross-school proposals, and leveraging institutional resources for outreach and education. Contact Fruma Yehiely (yehiely@northwestern.edu), Associate Vice President for Research, for more information.

**CONTACT AND ADDITIONAL INFORMATION**

Fruma Yehiely, Associate Vice President for Research, 847-491-1074, yehiely@northwestern.edu

Limited Submissions web site: www.research.northwestern.edu/ord/funding/limited-submissions/