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 CRUs are to provide the CoFAR with clinical trial and study opportunities, in order for the CoFAR to conduct ground-breaking research in the areas of prevention and treatment of food allergy and understanding of its underlying mechanisms. To advance these objectives, the CoFAR CRUs will work in collaboration with the CoFAR LC to conduct the CoFAR clinical projects, whereby the CoFAR LC will provide scientific strategy and organizational structure. Each CoFAR CRU will also propose a multi-center, cutting edge clinical trial. Clinical monitoring, data collection, data management, and statistical support for this effort will be provided by the NIAID-DAIT: Statistical and Clinical Coordinating Center. CoFAR CRUs will also be expected to provide a rich environment for New and Early Stage Investigators to develop research skills and to assist them in progressing to more senior status through their work in CoFAR.

It is anticipated that at least three clinical projects will be implemented during the course of the CoFAR awards. At least two will be clinical trials and the third project may be either a clinical trial or a clinical study.

The scope of the multi-center clinical trial proposed under this FOA includes but is not limited to, the following:

- Phase I or Phase II clinical trial for either treatment or prevention of food allergy focused 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.

The scope of clinical trials and studies that the CoFAR CRUs will implement for the CoFAR LC 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.
• 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.

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/