FARE
Food Allergy Research & Education

Request for Applications

Food Protein-Induced Enterocolitis Syndrome (FPIES)

The objective of this RFA is to advance the understanding of the pathogenesis of FPIES and to provide a rational foundation for new, effective treatments and prevention strategies. Applications may be organized around:

1. Immunologic mechanisms/pathways that are hypothesized to play an important pathobiologic process, or
2. One or more clinical trials or clinical studies to test a novel therapeutic approach or mechanistic hypothesis, or to aim at elucidating disease phenotypes and endotypes.

Proposals responsive to this RFA (non-exhaustive list) may evaluate:

- The role of innate and adaptive immune functions in the development and pathogenesis of FPIES
- The impact of the microbiome
- The mechanisms of desensitization and sustained tolerance
- Genetic variations and epigenetic alterations
- Clinical, immunologic, and physiologic phenotyping and endotyping
- Standardization of the FPIES challenge protocol for diagnosis and disease monitoring
- Biomarker discovery or studies to aid early detection and diagnosis
- Prevalence, epidemiology, and long-term outcomes of FPIES

Eligibility & Project Requirements

- Principal Investigators (PIs) must hold a faculty-level appointment or equivalent. Whereas residents, fellows, and post-doctoral associates are **NOT** eligible to serve as PIs, they are eligible to serve as co-investigators.
- More than one PI, or multiple PIs, may be designated on the application for projects that require a "team science" approach.
- Applicants are strongly encouraged to establish collaborations across the FARE Clinical Network and utilize the consortium's resources such as the FARE Data Coordination Center (DCC) and FARE Biobank & Biomarker Discovery Center (BBDC) as appropriate.

Funding Level

- FARE intends to commit a total of $1 million to this funding opportunity. The $1 million may be awarded to a single applicant or spread across multiple proposals.
- The maximum allotted budget for any given proposal is $1 million inclusive of indirect costs. Indirect costs of grant recipient(s) are capped at 10%.
- The project award period shall be determined by the scope of the proposed project, but is not to exceed three years. Cost extensions (at most six months) must be requested within 45 days of the budget period's end date and are not guaranteed.

Key Dates

Request for Applications released	May 2023
Letter of Intent deadline	July 17, 2023
LOI review/notification to proceed with full application	August 2023
Full application deadline	October 13, 2023
Scientific review	November 2023
Earliest award announcement	December 2023

Mandatory Letter of Intent

Prospective applicants are REQUIRED to submit a 1-page Letter of Intent (LOI) by **July 17, 2023, at 11:59 p.m**. **ET**.

The single-page document should include the following information:

- Title and brief summary of the project
- Names and affiliations of the Principal Investigator(s), co-investigators, and collaborators
- Names of potential non-conflicted reviewers with appropriate scientific expertise

The letter should be submitted per the application procedure noted in the following section.

Following review of the LOI, applicants will be notified if their proposal is selected to advance to a full proposal.

Application Procedure

Proposals shall be submitted via FARE's online grant submission system.

- To apply visit https://foodallergy.fluxx.io/user_sessions/new and click on "Create New User" (or log in if you already have an account).
- A step-by-step user's guide for applying via a web-based portal will be made available.
- For questions concerning user accounts, passwords, or system issues, please contact Gilla Camden, FARE Senior Grant Manager at gcamden@foodallergy.org or 615-906-9933.

For those advancing to full proposal submission, applicants will enter general project information via the web-based form and upload the documents listed below under **'Proposal Sections'**:

- Project Title
- Amount Requested
- Investigator Information: Name, title, institution, department
- General Project Information: Applicants will be asked to answer general questions regarding the project

Proposal Sections

Applications should include the sections detailed below.

1. **Scientific Abstract (500 words maximum)**
   The abstract, which is limited to 500 words in the respective text field, is a succinct and accurate description of the proposed project. The abstract must state the application's broad, long-term objectives and specific aims; design and methods for achieving the stated project goals; and alignment with the goals of the RFA. The abstract should be informative to other people working in

the same or related fields and understandable to a scientifically or technically literate reader. Avoid using first-person language or describing past accomplishments.

2. **Lay Abstract (200 words maximum)**
   The general audience summary provides an overview of the proposed research for people who are not trained in the sciences. Summaries may be shared with the public and thus should not include proprietary/confidential information. The general audience summary should not duplicate the structured technical abstract and should be written in an understandable way for a lay audience. Describe concisely the background, significance, question(s) being asked, information to be obtained, and potential impact of your proposed research.

3. **Research Plan (5-page limit, excluding tables and figures)**
   The Research Plan should follow the standard National Institutes of Health (NIH) format with the following mandatory sections:
   a. **Rationale and Specific Aims:** List the objectives and goal(s) of the research proposed and describe the Specific Aims briefly and succinctly.
   b. **Background & Significance**
   c. **Innovation**
   d. **Approach, Methods, and Analysis**: Include [if applicable] preliminary studies/data that support the feasibility of the application, stage of the project/product, hypotheses, design, procedures, sample recruitment, methods/measures, potential pitfalls and alternatives, and data management and analysis plan.

4. **Environment (1-page limit)**
   Briefly describe the space and equipment available to carry out the proposed research (e.g., space designated specifically for your research program, shared space and/or core facilities).

5. **Project Timeline and Metrics (1-page limit)** Using a Gantt-like chart, list each project aim and related activities to benchmark progress toward stated goals and objectives.

6. **Subsequent Funding (1-page limit)**
   Detail a specific plan to obtain extramural funding including a timeline of grant submission(s).

7. **Project Budget**
   Using the NIH budget template (PHS 398, Form Page 4), the project budget should clearly indicate how the grant funds will be spent. Expenditures must:
   - be fully justified, reasonable and clearly related to the project's goals
   - reflect the activities listed in the proposal
   - explain the sources and amounts of any cash match or cost-sharing funds

   Requests should be made by expense type (salary and fringe benefits, services, travel, supplies, etc.) and should provide sufficient detail for individuals unfamiliar with the project.

8. **Budget Justification**
   A budget justification (using PHS 398, Form Page 5) is required for purposes of describing in detail the major budget line items: salary and fringe benefits, travel, services, and supplies and other expenses. The narrative should provide specific information about why an expense is necessary to achieve the project's goals and objectives. It must also describe the roles and responsibilities of the PI and collaborators, even if uncompensated. The Budget Justification should include sufficient detail for reviewers to assess whether appropriate resources have been requested.

9. **Human Subjects (no page limit)**
   Briefly describe any human subjects issues. If human subjects are involved, provide a description of their involvement and characteristics, study procedures, materials used in the research, potential

risks to subjects, the process for recruitment and informed consent, and protection against risks. Provide assurance that the project will be reviewed and approved by an accredited institutional review board (IRB) and comply with the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

10. **NIH Biographical Sketches**
    NIH-formatted biosketches should be included for key members of the research team. Biosketches must be submitted using the current format and are limited to five pages. The NIH biosketch form can be downloaded at https://grants.nih.gov/grants/forms/biosketch.htm.

11. **References**

12. **Letters of Support (if applicable)**
    Upload all Letters of Support as a single PDF file.

Submission Style Guide

Applications must adhere to the following formatting specifications:

- 11-point Arial font
- Single-spaced
- ½" margins on all sides
- 8½" x 11" (i.e., standard size) paper
- Number all pages

Review Process

All proposals will be triaged for feasibility and close alignment to the nature and purpose of the RFA, including completeness, feasibility, and budget compliance.

- Applications that meet all technical criteria will move forward to undergo scientific review.
- Each application will receive at least two independent reviews. Assigned reviewers will score the proposal utilizing the same criteria used in NIH peer review.
- Final funding decisions are based on reviewer scores and other RFA criteria and principles.
- Investigators will receive final notice of award or non-award.

Evaluation Criteria

Each proposal will be evaluated using the NIH 9-point rating scale (1 = exceptional; 9 = poor) scoring system. Each application will receive a separate score for each of five core review criteria (Significance, Investigator(s), Innovation, Approach, and Environment) and Overall Impact. Scientific merit will be determined by averaging these preliminary impact scores from two independent reviewers with appropriate expertise. Applications deemed of high scientific merit will be evaluated and ranked by a review committee.

Additional review considerations will include feasibility of the proposal, and plan for (and probability that) the project will lead to additional grant funding.

- Projects that entail collaborations across FARE Clinical Network sites and/or utilization of FARE Clinical Network services, such as the FARE Data Coordination Center and FARE Biobank and Biomarker Discovery Center, and FARE databases, including the FARE Patient Registry, are highly encouraged.
- Proposals from new, emerging investigators will be given priority. For the purpose of this RFA, a new investigator is defined as a faculty member or equivalent who is not tenured and who has not

been a faculty member for more than six years in aggregate. The review panel can assign extra weight to a proposal from a new investigator to enhance opportunity for funding.

Contact for Information, Questions & Consultations

Questions and requests for consultations should be directed FPIES@foodallergy.org.

Awardee Requirements | Terms and Conditions

- It is expected that all research supported by this RFA will result in one or more publications in a peer-reviewed journal and will provide critical preliminary data to support extramural applications.
- Compliance: Recipients of an award must adhere to federal, state, and local guidelines with respect to scientific conduct of research, conflict of interest policies, and human subject participation.
- Continued funding is contingent on keeping FARE apprised of the project's status. Awardees must submit general progress reports every six months after the notice of award.
- Awardees must notify FARE during the funding period if there is a significant change in the scope of work or personnel that would affect the outcome of the project or necessitate re-budgeting.
- All presentations and publications resulting from work funded by this award must acknowledge FARE funding.