



REQUEST FOR PROPOSALS

Peanut Allergy Tolerance Trials for Difficult-to-Treat Patients

The Immune Tolerance Network (ITN) is an international clinical research consortium supported by the National Institute of Allergy and Infectious Diseases, NIH with the mission to accelerate the clinical development of immune tolerance therapies through a unique collaborative model.

The ITN develops, implements, and conducts trials of novel immune tolerance therapeutics in solid organ and islet transplantation, autoimmune diseases, and allergy & asthma. ITN trials look beyond the traditional endpoints of safety and efficacy, actively investigating the mechanisms of tolerance induction and maintenance by integrating hypothesis-driven, mechanism-based research into all our clinical trials. The goal is to improve our understanding and establish tolerance in the human clinical setting and to develop new biomarkers of tolerance in human disease.

A major effort in our food allergy portfolio has been early dietary introduction for children at risk of developing peanut allergy (LEAP) as well as intervention with oral immunotherapy in young children with established peanut allergy (IMPACT). While early intervention with peanut immunotherapy appears to be very effective in inducing desensitization and possibly a higher rate of clinical tolerance, there is an additional need to study adolescents and older children who are more “difficult-to-treat” (i.e. do not tolerate the higher doses of peanut oral immunotherapy or do not respond to oral immunotherapy alone). The goal for such studies would be to identify a supporting therapeutic that would allow peanut immunotherapy to be effective for the induction of tolerance in this difficult-to-treat cohort. Complex trial designs, such as umbrella trials where different therapeutics are combined with peanut OIT into a single protocol are encouraged, as are other adaptive trial designs.

The ITN is currently seeking short “Concept Proposals” for novel combination therapy clinical trials designed to induce immune tolerance in peanut allergy for a difficult-to-treat cohort. The ITN is especially interested in the following:

- 1. Studies that combine peanut immunotherapy with other agents to enhance safety and efficacy leading to sustained unresponsiveness and ideally tolerance.**
- 2. Proposed trials must have a testable mechanistic hypothesis.**

The ideal proposal should be supported by strong preclinical data, some safety and efficacy experience, and a fully described, testable mechanism of tolerance induction. The ITN is particularly interested in proposals for phase II trials.

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Request for Proposals**

Proposals should be brief, no more than five pages. **The deadline for submission is March 31, 2021.** The proposal review process will focus on evaluating the conceptual framework of the proposed trial and its significance and suitability for further development; it does not require submission of a detailed clinical protocol (which would be invited only upon acceptance of the Concept Proposal).

Please direct all proposal submissions and any questions concerning this RFP to **Philip Bernstein, PhD:**
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