



REQUEST FOR PROPOSALS

Combination Therapy Tolerance Trials in Allergy and Asthma

The Immune Tolerance Network (ITN) is an international clinical research consortium founded by the National Institutes of Health, with additional support from the Juvenile Diabetes Research Foundation, 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.

The ITN is currently seeking short “Concept Proposals” for novel combination therapy clinical trials designed to induce immune tolerance in allergy and asthma. The ITN is especially interested in the following:

- 1. Studies with a tolerance endpoint that combine allergen-specific approaches with other immunomodulatory agents.**
- 2. The development of novel tolerance assays to investigate allergen-specific mechanisms of clinical tolerance.**

The ideal proposal would have 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.

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).

Proposals should be submitted by **August 17, 2012**; successful proposals will be discussed at the fall (October) Network Steering Committee Meeting.

Please direct all proposal submissions and any questions concerning this RFP to **Philip Bernstein, PhD**: pbernstein@immunetolerance.org

