



## REQUEST FOR PROPOSALS

# Clinical Trials in Immune Tolerance in Autoimmune Skin Disease

The Immune Tolerance Network (ITN) is an international clinical research consortium founded by the National Institute of Allergy and Infectious Disease of the National Institutes of Health, with the mission to accelerate the clinical development of immune tolerance therapies through a unique collaborative model. Additional support is provided by the NIDDK and JDRF.

The ITN develops, implements, and conducts trials of novel immune tolerance therapeutics in autoimmune diseases, allergy & asthma, transplantation and type 1 diabetes. 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 its clinical trials. The goal is to improve our understanding of tolerance in the human clinical setting and to establish new biomarkers of tolerance in human disease. Supported by an unprecedented array of core facilities offering state-of-the-art genetic, cellular and immunologic assays, the ITN is generating some of the first combined clinical and mechanistic data on immune tolerance induction in humans.

**The ITN is currently seeking proposals for novel clinical trials with the goal of inducing tolerance in patients with autoimmune skin disease. We are particularly interested in trials where the antigen-specific immune response in the target organ (skin) can be assessed and compared to biomarkers in blood. The ideal proposal would meet the following criteria:**

- 1. There should be a strong mechanistic rationale for tolerance that is supported by preclinical data or clinical data from other disease settings;**
- 2. Disease-specific antigens should be known and a method for assessing the immune response they elicit should be available;**
- 3. Combination therapies (i.e. sequential administration of therapeutics) are encouraged. Therapeutic agents could be a combination of those that induce immune deviation and/or regulation, produce effector cell depletion or exhaustion, or those that are anti-inflammatory to create the appropriate environment for sustained suppression of autoimmunity in order to achieve durable clinical remission of disease.**
- 4. We will consider proposals in to any skin disease with clear immune pathogenesis (with higher priority given to those where an antigen has been identified/associated). Diseases of**

interest include (but are not limited to) vitiligo, alopecia areata and blistering diseases (i.e. pemphigus and pemphigoid). While proposals in any skin disorder will be considered, the ITN is looking to diversify beyond our current portfolio, which already places an emphasis on psoriasis (PAUSE; <http://www.pausestudy.org/>).

The ITN is particularly interested in proposals for phase II trials, safety studies (early phase I) will not be considered.

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. Proposals are welcome from academic, government and industry-based investigators. Funding will vary based on the type and scope of the trial.

For more information about the ITN's portfolio of clinical trials, please visit [www.immunetolerance.org](http://www.immunetolerance.org).

## Proposal Instructions

Proposals are welcome from academic, government and industry-based investigators. Funding will vary based on the type and scope of the trial. In the first stage of this application process, potential applicants must submit a one-page Letter of Inquiry (in advance of the formal proposal) that is due no later than **September 26<sup>th</sup> 2016**.

The letter should include:

- Name, title, and institution of principal investigator (PI), co-investigator and/or key collaborator(s);
- Brief description (no more than one page in length) of the proposed clinical trial, including the scientific basis and rationale, evidence for tolerance induction, and potential mechanistic studies and tolerance assays that will accompany the trial;
- References to published or preliminary (preclinical and/or human study) data.

Please direct all proposal submissions and any questions concerning this RFP to:

**Philip Bernstein, PhD**

Executive Director of Strategic Review and Planning

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## About the Immune Tolerance Network

The Immune Tolerance Network is a clinical research consortium dedicated to the development of immune tolerance therapies for transplantation, autoimmune diseases, and asthma and allergy. The ITN currently supports over 20 clinical trials, each with integrated investigations of the clinical mechanisms of tolerance. The ITN consortium is led by several institutions, including the Benaroya Research Institute at Virginia Mason, Seattle; University of California, San Francisco; and the Massachusetts General Hospital, Boston and is sponsored by the National Institute of Allergy and Infectious Diseases, with support from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and JDRF.