Immune Tolerance Network

REQUEST FOR PROPOSALS

Clinical Trials in Immune Tolerance

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 Type 1 Diabetes, autoimmune diseases, solid organ and islet transplantation, and allergy and 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 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 Concept Proposals for novel clinical trials designed to induce immune tolerance in Type 1 Diabetes, transplantation, autoimmune diseases, and allergy and asthma. In addition, the ITN accepts applications for the development of novel tolerance assays or mechanistic studies for the purposes of establishing new surrogate biomarkers of immune tolerance and investigating the mechanisms of clinical tolerance.

Successful proposals will be those that describe innovative approaches to studying tolerance that will advance both clinical care and our understanding of tolerance. The ideal strategy would have strong preclinical data, with a known mechanism of tolerance induction and/or be amenable to mechanistic assays investigating this mechanism. The ITN is particularly interested in proposals for phase I/II and 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.

Proposals are welcome from academic, government and industry-based investigators throughout the year. 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.

NIAID JDRF

Proposal Instructions

Proposals should be submitted via our website: (http://www.immunetolerance.org/professionals/proposals/guidelines) and contain the following information on the concept proposal form provided:

- Name, title, and institution of principle investigator (PI), co-investigator and/or key collaborator(s)
- Brief description (no more than two pages in length) of proposed clinical trial, including the scientific basis and rationale, evidence for tolerance induction, clinical implications, feasibility, potential mechanistic studies and tolerance assays that should accompany the trial, and references to published or preliminary data (preliminary data need not be presented in detail)
- Biosketches of PI and co-investigators and collaborators (does not count toward page limit)

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

Philip Bernstein, PhD
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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 is headquartered at the University of California, San Francisco, and is sponsored by the National Institute of Allergy and Infectious Diseases, with support from the Juvenile Diabetes Research Foundation.

www.immunetolerance.org