Immune Tolerance Network

REQUEST FOR PROPOSALS

CLINICAL TRIALS OF IMMUNE TOLERANCE IN TRANSPLANTATION USING DECEASED-DONOR ORGANS

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 Type 1 Diabetes, autoimmune diseases, 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 proposals for clinical tolerance trials in transplantation using solid organs or islets from deceased donors. Proposals should meet the following criteria:

1. There is strong support with preclinical data and/or evidence from clinical pilot studies; if preclinical studies alone are used to support the proposal, these studies should include brain dead donors or discuss why such studies are not needed with the proposed protocol

2. The donor and recipient are HLA mismatched;

3. Biomarker use and/or discovery should be incorporated into the immunosuppression withdrawal plan.

The ideal proposal would have *a testable mechanism of tolerance induction and a strategy for assays investigating this mechanism.* The ITN is particularly interested in proposals for phase II trials (with approximately 5-30 patients). 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.

Immune Tolerance Network
A clinical research consortium sponsored by NIAID

Benaroya Research Institute
1201 Ninth Avenue
Seattle, WA 98101-2795

Tel: 206.342.6562
Fax: 206.342.6588
immunetolerance.org

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 August 29th 2014.*

The letter should include:

- Name, title, and institution of principle 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 pilot human study) data

Based on evaluation of the Letter of Inquiry, the ITN will then invite more detailed formal applications. Invited Concept Proposals (upon notification in early September) will be due in early October.

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

Philip Bernstein, PhD
Executive Director of Strategic Review and Planning
Tel: (240) 235-6132
Email: pbernstein@immunetolerance.org

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 the Juvenile Diabetes Research Foundation.

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