



Request for Expressions of Interest for Innovative Clinical Trials in Type 1 Diabetes

This Expression of Interest (EOI) is for information and planning purposes only and should not be construed as a solicitation or as an obligation on the part of the ITN

Purpose of Request

The purpose of this EOI is to gather information from the scientific community about novel ideas for tolerogenic immunotherapeutic trials in type 1 diabetes (T1D).

Background

The mission of the JDRF-ITN Partnership in Immune Tolerance is to encourage and support early-stage development of tolerogenic clinical protocols in T1D. The specific objective is to build relationships between academia and industry that foster appropriate pre-clinical drug development and early clinical efforts by supporting phase I safety and phase IIa proof-of-principle trials.

Specific Goals of Request

The current EOI is targeted towards the identification of novel and important clinical trial ideas, rather than detailed scientific treatments of the precise methodologies. As such, the EOI aims to gather information about the scientific basis for the innovative project, and its implications in terms of clinical benefit and our understanding of tolerance. Of particular interest to the JDRF-ITN Partnership are projects that hold significant potential to increase our understanding of, and our ability to induce and maintain a state of clinical tolerance in autoimmune diabetes.

Examples of pertinent topics include, but are not limited to:

- Combination therapy trials, such as those involving antigen-specific and immunomodulatory approaches
- Islet antigen-specific monotherapy trials with or without the use of tolerogenic adjuvants
- Antigen non-specific monotherapy trials

Expressions of interest should be no more than two pages in length and should include the following information:

- Name, title and institution of principal investigator (PI), co-investigator and/or key collaborator(s)
- Brief details of proposed clinical trial, including 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/collaborators (does not count towards page limit)
- Total estimated budget and project duration

Inquiries in this area should be referred to Philip Bernstein, Ph.D., tel: +1-240-235-6132; pbernstein@immunetolerance.org;

Key Dates:

- Expressions of interest should be submitted as attached pdf files via e-mail to Philip Bernstein (pbernstein@immunetolerance.org) under the subject line "EOI-Innovative T1D Trials" no later than **April 13, 2009** at noon EST.
- Submitted expressions of interest will be acknowledged with brief responses as to their suitability for further development by the ITN, by no later than June 1, 2009.