Immune Tolerance Network

Concept Proposal Template Form

FOR CLINICAL TRIAL PROPOSALS

INSTRUCTIONS:

Complete this form only if you are proposing a Clinical Trial. There is a separate form for Tolerance Assay proposals that is available on the Submit a Proposal section of the ITN website.

Applicants should consult the Guidelines for Submission for information on the content required in each field in order to ensure that you are providing all information required for the review process.

When all information has been entered, save the completed form to your hard drive. Submit your concept proposal by emailing the completed form and any supporting materials as attachments to conceptproposals@immunetolerance.org.

SECTION 1: General Information

A. TITLE OF PROPOSED STUDY

B. PRINCIPAL INVESTIGATOR			
Last Name	First Name	Middle Initial	Degrees ☐ MD ☐ PhD ☐ Other: _____
Position/Title			

C. MAILING ADDRESS OF PRINCIPAL INVESTIGATOR			
Institution			Department
Street Address			
City	State/Province	Zip/Postal Code	Country
Office Telephone	Fax Number		E-Mail Address

D. COLLABORATORS / CO-INVESTIGATORS
In the space below, list any Co-investigators or collaborators to be involved in this study. i.e. *John Doe, University of Immunology, clinical collaborator*

E. OTHER CLINICAL TRIALS
List all clinical trial applications that have been submitted elsewhere, or currently in development or underway:

SECTION 2: Research Information

A. ABSTRACT

Please provide a short description of the proposed research, including Objectives, Basis/Rationale, Significance, Relevance to Immune Tolerance and Clinical Protocol Summary. Briefly describe the innovative aspects of the protocol and its potential for clinical benefit and for understanding clinical tolerance. DO NOT EXCEED THE SPACE PROVIDED.

B. PROPOSED MECHANISTIC STUDIES

Provide a brief description and rationale for mechanistic studies or tolerance assays you envision would complement the clinical portion of the research. Describe how you would utilize ITN core or existing assays if applicable. DO NOT EXCEED THE SPACE PROVIDED.

SECTION 3: Additional Project Information

A. CLINICAL SITES

How many clinical sites do you envision?

B. REAGENT / PARTICIPANT AVAILABILITY

Provide a brief comment on the sources and availability of both patients and key reagents/pharmaceuticals for this study. List any possible industrial collaborators. DO NOT EXCEED THE SPACE PROVIDED.

C. ETHICAL CONSIDERATIONS

Consult the Guidelines for Submission for detailed instructions on completing this section. DO NOT EXCEED THE SPACE PROVIDED.

D. CONFLICT OF INTEREST DISCLOSURE

In the space below, disclose any personal or professional involvement with industrial concerns or personal commercial interests held by yourself and your collaborators that are relevant to the current proposal. DO NOT EXCEED THE SPACE PROVIDED.

E. SUPPORTING PUBLICATIONS

List up to five (5) publications that have direct relevance to this proposal. Note that these publications are not necessarily required to be authored by the principal investigator. Include those publications which support and/or clarify the current proposal. Provide complete references listing all authors, title, publication, issue and year. DO NOT EXCEED THE SPACE PROVIDED.