



JDRF Requests Expressions of Interest for Studies Relevant to the Discovery and Development of Antigen Specific Therapies for Human Type 1 Diabetes

Key Dates:

February 13, 2013: Expressions of interest (EOI) due date

(EOIs must be submitted via the proposalCentral website: <https://proposalcentral.altum.com>)

March 8, 2013: EOI decision notification

April 15, 2013: Full application due date (for accepted EOIs)

July 2013: Award notification

Purpose of Request

JDRF is soliciting expressions of interest (EOI) for the discovery, development, pre-clinical or pilot clinical testing of novel antigen-specific therapeutic approaches designed to induce durable immunoregulation for human type 1 diabetes (T1D). JDRF is committed to translation of research findings towards clinical results and is most interested in projects that have clinical translation potential.

Background

Immunotherapeutic approaches for preventing or halting T1D have involved both antigen-specific and antigen non-specific interventions. Because T1D results from a failure to maintain immune tolerance to beta cell autoantigens, targeting the immune response to these autoantigens may provide an effective means of preventing and controlling the autoimmune response and avoid the harmful effects associated with non-specific immunosuppression. Clinical data from several independent trials has provided compelling evidence that current immunomodulatory approaches are not effective at preventing T1D or at durably controlling beta cell loss in the recent onset T1D setting. In addition, islet transplantation trials show recurrence of beta cell antigen specific autoreactivity under the cover of immunosuppressive therapy.

Specific Goals of Request

Expressions of interest are sought from investigators interested in discovering and developing, or in evaluating in pre-clinical models or pilot clinical studies, novel antigen-specific therapies for T1D. Such therapies may have application for: 1) the at-risk, immune vs. immunologically unprimed setting with primary prevention of T1D and/or for the immune vs. immunologically primed setting with secondary prevention of T1D; 2) for control of autoimmunity in the new onset T1D setting; or 3) in combination with other immunomodulatory therapies or approaches to regenerate beta cells to restore insulin independence in the recent onset and established T1D setting. The clinical translation potential of the investigations should be emphasized. Of interest are also mechanistic studies and biomarker discovery/validation around antigen-specific T1D clinical trials.

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

- Discovery of novel antigen-specific therapies for T1D
- Validate and further develop existing antigen-specific approaches to enable and accelerate their clinical translation
- Dose finding studies, differences in unprimed vs. primed autoimmune responses, optimization of treatment regimens, and in silico modeling
- Elucidate mechanisms of action of antigen-specific approaches to improve efficacy and refine the therapeutic strategy

- Mechanistic studies for ongoing or recently completed antigen-specific clinical trials in T1D
- Combination therapies that augment efficacy of antigen-specific therapies
- Pilot clinical trials to establish proof of concept or optimize dosing or route of administration of antigen-specific therapies
- Investigators with ideas or resources that might benefit this initiative should also submit their ideas via an expression of interest

Levels of Funding and Grant Mechanisms:

Applications in response to this announcement can be submitted under one of the following three funding mechanisms:

- **Innovative Grants:** up to \$110,000 (including 10% indirect costs) for one year only.
- **Strategic Research Agreements (SRAs):** up to \$165,000/yr (including 10% indirect costs) for up to two years. For any research projects proposed for 3 years, applicants must provide STRONG scientific justification. For any budget that exceeds \$165,000/yr, JDRF scientific staff must be contacted with a strong justification, prior to EOI submission. SRAs require quarterly milestones, reporting against those milestones and will receive milestone-based payments.
- **Clinical grants for pilot trials:** up to \$500,000 total costs (including 10% indirect costs) for a maximum of 3 years. For any trials proposed for greater than 3 years or for a larger budget, JDRF scientific staff must be contacted prior to EOI submission. Clinical awards require pre-established milestones and will receive milestone-based payments.

For all submissions, proposed budgets should be well-justified and commensurate with the type of study and the research plan.

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

- Name, title and institution of principal investigator (PI), co-investigator and/or key collaborator(s), including industry
- Brief details of approach proposed, including hypothesis if relevant, scientific rationale, potential advantages over existing technologies, deliverables, and references to published or preliminary data (preliminary data need not be presented in detail)
- Relevant intellectual property, description of potential for translation into therapies including short and long-term development goals
- Specifics of bio-samples to be utilized, if applicable, (including matching and blinding criteria) and projected time-lines for sample access.
- Biosketches of PI and co-investigators/collaborators (does not count towards page limit)
- Total estimated budget and project duration

Eligibility:

Applicants must hold an M.D., D.M.D., D.V.M., Ph.D., or equivalent academic degree and a faculty position or equivalent at a college, university, medical school, or comparable institution. Applications may be submitted by domestic or foreign public or private non-profit organizations, such as colleges, universities, hospitals, laboratories, units of state or local governments or eligible agencies of the federal government. There are no citizenship requirements.

Inquiries:

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Note: Please be reminded that there are research resources for studies using biosamples from T1D clinical studies through NIH: [PAR-13-013](#).