JDRF Request for Expressions of Interest:
Studies Relevant to the Prevention of Human Type 1 Diabetes

Key Dates:

January 31, 2013: Expressions of interest (EOI) due date

(must be submitted via proposalCentral: https://proposalcentral.altum.com)

February 15, 2013: EOI decision notification

March 27, 2013: Full application due date (for accepted EOIs)

July 2013: Award notification

Purpose of Request

JDRF is soliciting expressions of interest (EOI) for studies in the at-risk and 'pre-diabetic' setting of human T1D that address the topics of natural history/immunopathogenesis, biomarkers, or mechanism-based therapeutic trials.

Background

The incidence of type 1 diabetes has been increasing worldwide with the disease occurring earlier in life. In addition to this earlier age of onset of type 1 diabetes, the disease is occurring increasingly in individuals who had been previously considered to be at low to moderate genetic risk, lowering the threshold for developing the disease. Although it is generally accepted that the etiology of type 1 diabetes arises from contributions of both genetics and environmental factors, the exact immunopathogenesis of human T1D, from birth (including the impact of prenatal events), to autoantibody positivity and then on to insulin dependence, remains largely unknown. As such, we do not have reliable biomarkers that mark the early stages in the natural history of the disease or that can serve as surrogate endpoints in prevention trials. While disease progression may manifest differently in individuals, the period from autoantibody positivity to overt T1D, provides a window of opportunity for testing secondary prevention interventions.

Specific Goals of Request

Expressions of interest (EOI) are sought from investigators interested in pursuing studies using existing study cohorts aimed at:

- Understanding the immunopathogenesis/natural history of human T1D in the at-risk or pre-diabetic setting.
- Mechanism driven secondary prevention trials.
- Discovery and/or validation of biomarkers that represent early events in the disease as well as those that may serve as surrogate read-outs or endpoints for efficacy of specific interventions.

This initiative encourages collaborations between clinicians and basic scientists and applications with promising assays or novel expertise that could accelerate T1D prevention efforts.

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

- Understanding the basis of slow, fast, and non-progression to disease.
- Identification and validation of biomarkers associated with slow, fast, and non-progression to disease.
- Understanding whether human T1D is a relapsing/remitting disease with the purpose of defining its basis and defining biomarkers for its detection.
- Predictive modeling of risk of T1D progression.
- Understanding the role of prenatal events and maternal environment on the development of T1D.
- Secondary prevention clinical trials, including the identification/validation of intermediate endpoint biomarkers.

Please note JDRF will NOT support the establishment of any new study cohorts as part of this solicitation. Also, intervention trial proposals for pregnancy or primary prevention will not be considered.

Please also note that all proposals involving the discovery and development of antigen specific therapies, must be submitted to a concurrent JDRF EOI call on this topic. Please refer to the **JDRF website** for deadlines regarding this RFA.

Levels of Funding and Grant Mechanism:

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, budgets proposed 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 including the following information:

- Name, title and institution of principal investigator (PI), co-investigator and/or key collaborator(s).

- Brief details of approach proposed, including the scientific gap being addressed, hypothesis if relevant, scientific rationale, and references to published or preliminary data (preliminary data need not be presented in detail).

- Specifics of bio-samples to be utilized if applicable (including matching and blinding criteria) and projected time-lines for sample access (Please note: for the full application, applicants will be asked to provide: i. documented proof of sample access/approval/pending approval, or copies of applications to sample access committees and ii- power calculations for the selected sample/cohort size, where applicable).
- Specifics of clinical trial cohorts.
- Bio-sketches 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 bio-samples from T1D clinical studies through NIH: PAR-13-013.