REQUEST FOR LETTERS OF INTENT (LOI):

EXPLORATORY CLINICAL TRIALS TO PREVENT PROGRESSION OF DIABETIC NEPHROPATHY:

PURPOSE
JDRF is committed to facilitating the translation of preclinically validated targets to mechanistic, proof-of-principle and proof of concept clinical studies that may ultimately lead to large confirmatory studies for regulatory submission/clinical adoption of therapies for Diabetic Nephropathy with promise for treatment at chronic kidney disease (CKD) stages 1-3 including approved or investigational therapies. To this end, JDRF is soliciting letters of intent (LOI) for clinical trials from academic and/or industry groups with therapies to prevent progression of renal function loss in T1D (trials enrolling both T1D and T2D can be considered providing T1D population included).

BACKGROUND
Diabetic nephropathy is a complication of diabetes that contributes significantly to morbidity and mortality. Recent publications suggest that despite improvements in care, the risk of end stage renal disease (ESRD) is not substantially reduced. Diabetic nephropathy is the leading cause of kidney disease in patients undergoing dialysis. There is a paucity of validated interventions for clinical adoption to improve outcomes in those with diabetic nephropathy. Thus, identification of therapies with the potential to or reduce loss of kidney function is a high priority for JDRF.

OBJECTIVES
LOIs are sought from investigators with approved or investigational drug candidates to validate mechanism of action and/or efficacy in preventing progression or reversal of diabetic nephropathy in T1D. JDRF is particularly interested in clinical trials targeting patients with disease no more severe than CKD3 based on NKF definitions (reference), as well as, trials that use novel approaches to stratify entry population based on estimated risk of progression during the trial. LOIs in this category should ideally include the validation of mechanism of action of the drug or therapy with prior evidence of association with onset or progression of diabetic nephropathy.

Under exceptional circumstances, proposals that also include preclinical studies may be considered if needed to obtain regulatory approval to move forward with the proposed clinical trial. Please contact Dr. Helen Nickerson to discuss studies in this area.

Please note that therapies to improve treatment of ESRD / CKD5 are not within the scope of this request, unless being repurposed to earlier stages of chronic kidney disease. Trials which include a CKD4 population may be considered but the call is intended to solicit proposal for treatment of early stage disease.

MECHANISM
Accepted letters of intent from academic groups would be submitted as Clinical Strategic Research Agreements, (http://jdrf.org/grant-center/information-for-applicants/grant-mechanism-descriptions/strategic-research-agreements). Letters of intent from industry groups would be invited to submit applications to the JDRF Industry Partnership program, http://jdrf.org/grant-center/industry-partnerships/.
Clinical trials of up to 36 months duration will be considered. Investigators proposing trials exceeding this duration should contact Dr. Helen Nickerson (contact information below) to assess whether submission is possible. Total and annual budget should be concomitant with the trial proposed. However, it is unlikely that JDRF will support pivotal or Phase 3 trials, or trials exceeding $1,000,000 USD in total costs per year. Funded projects would be subject to quarterly progress reporting and payment according to pre-specified milestones.

ELIGIBILITY
Applications may be submitted by for-profit entities as well as nonprofit organizations, public and private universities, colleges, hospitals, laboratories, units of state and local governments. There are no citizenship requirements.

LETTER OF INTENT
An approved LOI is required prior to submission of a full proposal. Letters of intent should use the template provided.

DEADLINES
- Request for LOI Release Date: March 21st 2014
- LOI Submission Deadline: May 15th 2014
- LOI Notification: July 2014
- Full Application Deadline: September 15th 2014
- Response to Applicants Date: January 2015
- Earliest Anticipated Start Date: February 2015

SUBMISSION INSTRUCTIONS
Applicants should register and submit their completed LOI in RMS360 (http://jdrf.smartsimple.us). The deadline to submit a completed LOI is 15 May 2014.

REVIEW CRITERIA
JDRF will review and select LOIs to be developed into full proposals. Please direct queries about the suitability of your proposal to the scientific and administrative contacts below.

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<th>ADMINISTRATIVE CONTACT</th>
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<tr>
<td>Shachi Vyas, M.S., PGDIP IBM JDRF, 26 Broadway, 14th Floor New York, NY 10004 ☎️: 212-859-7844 📧<a href="mailto:SVyas@jdrf.org">SVyas@jdrf.org</a></td>
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If you have any grant-specific questions as you work within RMS360, please contact the administrative contact listed above. For any non-grant-specific inquiries or issues, please contact SmartSimple Support Services via email support@smartsimple.com or phone (866) 239-0991. Support hours are Monday through Friday between 5:00am and 9:00pm US Eastern Standard Time.