



*dedicated to finding a cure*

## Request for Expressions of Interest for Developing an “ultra fast-acting” Insulin

### Background and Purpose of Request

In 2006 the JDRF Artificial Pancreas Project was launched to accelerate the development and delivery of a commercially available closed-loop system. One significant challenge that remains is the pharmacokinetic and pharmacodynamic profile of insulin delivered subcutaneously. Even with rapid-acting insulin analogs the kinetics fail to replicate pancreatic insulin action, being far too slow in the early minutes and far too long in leaving the bloodstream. We believe that these insulin kinetics complicate obtaining good blood sugar control, increase the risk for hypoglycemia, may increase cardiovascular risk and limit the ability to produce an artificial pancreas. The JDRF is exploring the possibility of launching a major initiative aimed at significantly accelerating the delivery of an “ultra fast-acting insulin” to market. This could come in the form of a modified insulin an improved or novel delivery system or some other method. The purpose of this EOI is to gather information from the scientific community (both academia and industry) on innovative strategies for developing insulins and/or delivery mechanisms that would more closely approximate native insulin delivery. Expressions of interest should be submitted no later than April 6, 2009.

### Specific Goals of Request

The current EOI is targeted towards the identification of novel insulin formulations and improved strategies for delivery. As such, the EOI aims to gather information about innovative insulin molecules or delivery approaches that may mimic the postprandial action of endogenous human insulin better than existing formulations.

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

- Molecular modifications of insulin molecules (eg. amino acid substitutions) to generate a novel ultra rapid-acting molecule
- Addition of adjuvants to improve pharmacokinetics
- Alternate modes of delivery that improve pharmacokinetics

### Instructions

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 insulin formulation or delivery approach, including scientific basis and rationale, evidence for improved glycemic control, clinical implications, 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 Marlon Pragnell, Ph.D. ([mpragnell@jdrf.org](mailto:mpragnell@jdrf.org)) (212)479-7690 or Aaron Kowalski Ph.D. ([akowalski@jdrf.org](mailto:akowalski@jdrf.org))

### Key Dates

- Expressions of interest should be submitted as attached pdf files via e-mail to Marlon Pragnell ([mpragnell@jdrf.org](mailto:mpragnell@jdrf.org)) under the subject line “EOI-Novels insulins” no later than April 6, 2009 at noon EST.
- Submitted expressions of interest will be acknowledged with brief responses as to their suitability for further development by the JDRF, by no later than May 6, 2009.