

REQUEST FOR PROPOSALS:

QUANTITATIVE ANALYSIS OF INSULIN ACTIVITY PURCHASED FROM PHARMACIES IN THE UNITED STATES

PURPOSE

JDRF International, American Diabetes Association, and The Leona M. and Harry B. Helmsley Charitable Trust (Helmsley) are requesting proposals from analytical laboratories based in the United States (US) to analyze insulin activity in vials and pen cartridges that will be purchased from retail pharmacies in diverse locations throughout the US.

SCOPE OF WORK

The work requested would consist of the following:

- 1) Establishing a protocol/statement of work for the project summary and process to be followed, with budget and timelines.
- 2) Executing on the project i.e., analyzing the activity of insulin in vials/cartridges. All major basal and bolus analog insulins to be analyzed for activity.
- 3) Writing a paper on the outcomes of the study, submitting the paper to a peer-reviewed journal, and shepherding the paper through the peer-review process.

BACKGROUND

In December 2017, data published online by Alan W Carter, Pharm. D., of MRI Global and the University of Missouri–Kansas City, and Lutz Heinemann, Ph.D., of Science & Co, Düsseldorf, Germany in the [Journal of Diabetes Science and Technology](#), found that the average amount in 18 10-mL vials of NPH and regular insulin from the two major manufacturers was 40.2 U/mL, ranging from 13.9 to 94.2 U/mL. None met the 95-U/mL standard at the time of testing. This data was based on analysis of insulin vials randomly purchased in US pharmacies. However, the standards established by the US Pharmacopeia and Food and Drug Administration (FDA) require that insulin vials and cartridges contain a minimum of 95% intact insulin (95 U/mL).

This report has generated considerable concern among insulin users and has generated controversy among manufacturers, clinicians, and biochemists. A larger study is needed to further investigate and verify the findings from this study.

FULL PROPOSAL

The full proposal should comprise of a single project. It should include the following information:

- Title, project lead investigator, brief description of proposed project
- Project Plan, including details of proposed process for procurement of insulin vials and cartridges (major basal and bolus analogs) including locations, timing for obtaining samples (seasonality), and range of manufactures and retailers.
- Laboratory analytic methods (two or more methods should be proposed, including the method utilized by Carter and Heinemann).

- Statistical approach to sample size determination, statistical analysis plan, and completion of final report and manuscript.
- Project Timeline and Milestones:
 - In the timeline, please allow 2-3 weeks for review of the planned protocol and statistical analysis plan before proceeding.
- Project Governance
- Deliverable Descriptions
- Past experience working on such a project
- Estimated budget
- Biosketches for all investigators and co-investigators and key personnel

TIMELINES

- **Funding Opportunity Launch:** Wednesday March 21st, 2018
- **Full Proposal Submission Deadline:** Wednesday April 18th, 2018
- **Response to Applicants:** June 2018
- **Anticipated Earliest Start Date:** July 2018

SUBMISSION INSTRUCTIONS

Applicants should register and submit their completed proposals in RMS360 (<http://jdrf.smartsimple.us>).

All applicants are strongly advised to discuss their proposed project with Shachi Vyas before submitting.

If you have any grant-specific questions as you work within RMS360, please contact the administrative contact listed below. 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.

REVIEW CRITERIA

JDRF, ADA and Helmsley will review and select the proposals. Proposals will become the confidential property of the funding organizations.

SCIENTIFIC CONTACT

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ADMINISTRATIVE CONTACT

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ABOUT JDRF INTERNATIONAL

JDRF is the leading global organization focused on type 1 diabetes (T1D) research. Driven by passionate, grassroots volunteers connected to children, adolescents, and adults with this disease, JDRF is now the largest charitable supporter of T1D research. The goal of JDRF research is to improve the lives of all people affected by T1D by accelerating progress on the most promising opportunities for curing, better treating, and preventing T1D. JDRF collaborates with a wide spectrum of partners who share this goal. For more information, visit www.jdrf.org.

ABOUT THE LEONA M. AND HARRY B. HELMSLEY CHARITABLE TRUST

The Leona M. and Harry B. Helmsley Charitable Trust aspires to improve lives by supporting exceptional efforts in the U.S. and around the world in health and select place-based initiatives. Since beginning active grantmaking in 2008, Helmsley has committed more than \$2 billion for a wide range of charitable purposes. For more information, visit www.helmsleytrust.org.

ABOUT THE AMERICAN DIABETES ASSOCIATION

Nearly half of American adults have diabetes or prediabetes; more than 30 million adults and children have diabetes; and every 21 seconds, another individual is diagnosed with diabetes in the U.S. Founded in 1940, the American Diabetes Association (ADA) is the nation's leading voluntary health organization whose mission is to prevent and cure diabetes, and to improve the lives of all people affected by diabetes. The ADA drives discovery by funding research to treat, manage and prevent all types of diabetes, as well as to search for cures; raises voice to the urgency of the diabetes epidemic; and works to safeguard policies and programs that protect people with diabetes. In addition, the ADA supports people living with diabetes, those at risk of developing diabetes, and the health care professionals who serve them through information and programs that can improve health outcomes and quality of life. For more information, please call the ADA at 1-800-DIABETES (1-800-342-2383) or visit diabetes.org.