

F. M. KIRBY FOUNDATION SOLICITATION EVALUATION FORM

DATE: April 11, 2024
Program Area: Health
Grant Type: Board Grant

REQUEST DATE: February 27, 2024

APPLICANT:
JDRF International
200 Vesey Street, 28th Floor
New York, NY 10281

CONTACT: Aaron Kowalski, Chief Executive Officer

AMOUNT REQUESTED: \$200,000
BUDGETED AMOUNT: \$300,000

NATURE OF REQUEST: Support of the Center of Excellence in New England and reserved for future decision

GRANT HISTORY

SUPPORT: 2013-2023

OF APPROVED GRANTS: 11

TOTAL DOLLARS: \$2,000,000

LAST GRANT DATE: 05/01/2023

LAST GRANT AMOUNT: \$200,000

FYE DATE: 06/30

AFS DATE: 12/19/2023

Year Approved	Approved Amount	Approval Date	Grant Purpose
2023	\$200,000	05/01/2023	Support of the Center of Excellence in New England
2022	\$200,000	09/12/2022	Support of the Center of Excellence in New England
2021	\$200,000	12/20/2021	Toward Beta Cell Replacement research and Regeneration work
2020	\$200,000	09/14/2020	Toward Beta Cell Replacement research and Regeneration work
2019	\$200,000	12/16/2019	Toward Beta Cell Replacement research

LAST SITE VISIT DATE: N/A

ENDORSEE: Laura H. Virkler

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FINANCIAL ANALYSIS COMMENTS: The FY24 expense budget for JDRF International (JDRF) projects a 10% increase over the prior year actuals. The FY24 revenue budget projects a \$17.5M deficit – as compared to a \$7.1M surplus in FY23 – and a 2% decrease from the prior year actuals. The largest revenue decrease is attributable to the “other income & royalties” line. The FY23 audit shows unrestricted net assets totaling \$247.1M, and a cash position of \$13.1M – a cash decrease of \$25.2M from FY22. Investments are valued at \$334.8M – a \$48.1M increase from FY22. Total endowment value is \$7.8M. Total assets have increased by 4% from FY22. Financial assets available for general expenditures within 12 months are \$185.8M. As per the FY23 audit, supporting services represented 22.9% of functional expenses. As of June 30, 2023, JDRF had a \$10M line of credit on which there were no draws. FMKF last approved a grant to JDRF in FY23. The amount accounted for less than 1% of core fundraising revenue.

ORGANIZATION DESCRIPTION: Type 1 Diabetes (T1D) is an autoimmune disease that strikes both children and adults suddenly. It has nothing to do with diet or lifestyle. There is nothing you can do to prevent it. And, at present, there is no cure. In T1D, your pancreas stops producing insulin – a hormone the body needs to get energy from food. This means a process the body does naturally and automatically becomes something that now requires daily attention and manual intervention. If you have T1D, you must regularly monitor your blood-sugar level, inject or infuse insulin through a pump, and balance these insulin doses with your eating and activity throughout the day and night. However, insulin is not a cure for diabetes. Even with vigilant disease management, a significant portion of your day is spent with either high or low blood-sugar levels. These fluctuations place people with T1D at risk for potentially life-threatening hypoglycemic and hyperglycemic episodes as well as devastating long-term complications such as kidney failure, heart attack, stroke, blindness, and amputation.

JDRF has led the search for a cure for T1D since its founding in 1970s. In those days, people commonly called the disease “juvenile diabetes” because it was frequently diagnosed in, and strongly associated with, young children. Thus, the organization began as the Juvenile Diabetes Foundation. Later, to emphasize exactly how they planned to end the disease, they added a word and became the Juvenile Diabetes Research Foundation. We now know that adults are just as likely to be diagnosed with T1D, so a few years ago the decision was made to undergo another name change to JDRF, to better reinforce the organization’s commitment to improve life for people at all ages and stages of the disease.

JDRF works every day to change the reality of this disease for millions of people – and to prevent anyone else from ever knowing it – by funding research; advocating for government support of research and new therapies; ensuring new therapies come to market and are recommended by healthcare providers; and connecting, engaging, and educating the T1D community. JDRF is a powerhouse in the scientific community with dozens of U.S. locations and five international affiliates – Australia, Canada, Netherlands, Israel, and United Kingdom. They have funded about \$2.5B in research to date and have made significant progress in understanding and fighting the disease.

EMILY PRINCE COMMENTS: In FY24, JDRF is seeking a \$200K grant in support of its Center of Excellence in New England. FMKF first approved a grant in support of the Center in FY22. JDRF Centers of Excellence represent a new research model aimed at accelerating science in

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curing T1D and improving lives. Each represents a novel partnership with leading universities and research institutions, whereby JDRF funds the work, connects the research – each Center focuses on a key area of research such as immunology, stem cell biology, gene editing, etc., then JDRF links them to each other to ensure maximum collaboration – and propels advances forward with the aim of getting solutions to market as quickly as possible. Much of what JDRF is doing with this model is unique, but I would like to highlight their funding model, which is particularly remarkable. The Centers are designed to foster dynamic, nimble work that will drive discovery with maximum speed. By providing researchers with long-term funding, they are removing the red tape, restrictions, and reporting that accompany standard research grants. This allows scientists to focus on research rather than grant writing, and gives them the freedom to quickly change paths to pursue an alternate, promising direction without worrying about lost funding or filing new/amended applications. Centers are located at/in New England, Northern California, University of Michigan, Australia, and University of British Columbia.

We now know that to cure T1D, you must restore or replace insulin-producing beta cells and protect them from autoimmune attack. JDRF has been at the cutting edge of this research for more than two decades, pioneering the development of stem cell derived beta cells in the lab and establishing that they can mature to release insulin in the blood. There are hundreds of people who have been living for years free from needing insulin injections after receiving transplanted donor islets as the source of insulin-producing cells. While these results have restored glycemic control and significantly improved people's quality of life, the current approach is available to a limited number of people and these individuals need to take immunosuppression drugs for the rest of their lives. JDRF's ambition is to build on these advances so that the broader T1D community can benefit from implanted beta cells and remove the need for chronic immune suppression drugs. Having developed a way to make an unlimited number of beta cells using stem cells and establishing the most advanced genome engineering tools and immunology expertise, New England Center Director David Harlan, M.D., and colleagues focus on the challenge of protecting these cells from the immune attacks that occur following transplantation. Since 2020, New England Center scientists have published 23 Peer Reviewed articles in well-known journals such as *Cell*, *Nature Immunology*, and *Diabetes*. This year's request highlights three projects continuing from last year, the results of which will benefit scientists worldwide aiming to treat and find cures for diabetes. Project One will create stem-cell derived beta cells and genetically engineer them to not be recognized as immune targets by the body. Project Two will test the ability of the cells engineered in Project One to induce an immune response in humanized models of T1D. Project Three will analyze the impact of the genetically modified cells on the immune system. While this work may seem disparate, it is all interconnected in its focus of addressing the need for immunosuppression of transplanted beta cells. Immunosuppression-free cell therapy would revolutionize diabetes care for many, eliminating the need for diabetes devices and insulin therapy.

The day when no one will need insulin to survive is not merely approaching, it is in sight thanks to the unwavering commitment of JDRF, its network of scientists, and funding partners like FMKF. Thanks to efforts of the collective, the first disease-modifying therapy has been FDA-approved, dozens of curative therapies are in clinical trials, biotech companies are investing capital like never before, and pharma companies are entering billion-dollar partnerships to bring new treatments to market. But, barriers to development, regulation, clinical adoption, and community access still stand in the way of JDRF reaching its ultimate goal of turning **Type One into Type None**. To supercharge their efforts, JDRF will be launching a comprehensive campaign in the coming year,

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the specifics of which are still in the planning stages. JJK, LHV, and I were able to get some advance details on a January call with Sarah Cunningham Jackson, Associate National Director, Leadership Giving & Kathleen Seitz, Chief Global Development Officer, the details of which are documented in GivingData. JDRF's various projects and operations require large fundraising goals - \$200M in FY24. With a campaign, JDRF can think beyond its annual raise, and do a major push into key pillars of its work – 85% will likely go towards Cures & Improving Lives, while 15% will go towards Advocacy & Access. So far \$115M has been raised, with 8 families making gifts of \$1M or more. It will be a 5-year campaign, but we don't know when the official time clock began/begins or the target goal - \$1B has been thrown out as a possibility. LHV has expressed a strong desire for FMKF to contribute to this campaign but has been candid that she is not ready to get behind a major number until the campaign has more concrete details flushed out.

A grant of \$200K in support of the Center of Excellence in New England will ensure that JDRF has the resources to continue being at the forefront of the science, its scientists have the resources to do the work, and patients benefit from the advancements coming out of their labs. A grant of \$100K to RFD will allow us to show a good faith commitment to the organization and the campaign, while awaiting finalization of the specific details. Therefore, in FY24, I recommend a grant of \$300K, as budgeted, in support of the Center of Excellence in New England and RFD.

RECOMMENDATION: In FY24, I recommend a grant of \$300K, to be allocated as follows:

\$200K in support of the Center of Excellence in New England
\$100K Reserved for Future Decision

JUSTIN J. KICZEK COMMENTS: I really appreciate the clarity of the mission of the New England Center of Excellence. The final paragraph spells out the stakes very clearly: “Dr. Harlan states the most significant focus of the Center in New England is to address the need for immunosuppression of transplanted islet cells – it is the single most crucial element of moving cures forward. [Harlan] states, ‘We have to devise a way to alter these cells genetically, so they don't require immunosuppression. That's the name of the game.’” A simple mission to explain, but one that, as ECP covers above, requires decades of research experience and experimentation, which this Center excels at, anchored by Dr. Harlan.

I concur with ECP that the day of “Type None” is in sight, especially considering there are T1D patients today who are off insulin altogether (though still require immunosuppression drugs).

Our plan seems measured and appropriate. I concur with the plan laid out by ECP and endorsed by LHV.

RECOMMENDATION: In FY24, I recommend a grant of \$300,000, to be allocated as follows:

- \$200,000 in support of the Center of Excellence in New England
- \$100,000 Reserved for Future Decision

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DISPOSITION:

- Declination
- Hold for review on/about:
- Approval for: **\$300,000**
- Recommended Grant Payment(s):
2024:
2025:
2026:
- Hold for Board Review: **April 26, 2024**
- Payee Other Than Addressee:
- Insert Information:
- Other: **Include grant letter with Reserved for Future Decision explanation and stipulation.**

Initials: JK

Date: 04/12/2024

Check # _____

Date: _____