

F.M. KIRBY FOUNDATION SOLICITATION EVALUATION FORM

DATE: November 20, 2019

REQUEST DATE: October 18, 2019

Last grant acknowledgement: Yes

Program Area: Health

APPLICANT:

JDRF International
14th Floor
26 Broadway
New York, NY 10004

Mail copy to: Ms. Sarah Cunningham

Executive Director
JDRF Triangle/Eastern North Carolina
Suite 202
3739 National Drive
Raleigh, NC 27612

CONTACT: Mr. Peter H. Roche, National Director, Leadership Giving

PHONE: (203) 584-1123

PAYEE OTHER THAN ADDRESSEE:

AMOUNT REQUESTED: \$200,000 **NATURE OF REQUEST:** Toward Beta Cell Replacement research

GRANT HISTORY

LAST GRANT DATE: 9/17/2018 **LAST GRANT AMOUNT:** \$200,000 **AFS DATE:** 10/16/2018

2014	\$150,000	9/15/2014	Toward the Beta Cell Restoration program
2015	\$175,000	9/14/2015	Toward Beta Cell Restoration and Beta Cell Replacement research
2016	\$175,000	9/12/2016	Toward Beta Cell Restoration and Beta Cell Replacement research
2017	\$200,000	9/15/2017	Toward Beta Cell Restoration and Beta Cell Replacement research
2018	\$200,000	9/17/2018	Toward Beta Cell Replacement research

See attached site visit report. LHV endorsement received.

DLK COMMENTS: Of all the medical research that the Foundation funds, this feels the closest to reaching a cure. As Aaron Kowalski outlined during our site visit in July, JDRF in recent years targeted some easier, quality of life solutions that included better devices and insulin. Now they are redirecting these dollars back to their core research. Dr. Dutta stated that some of the seeds they had planted years ago are truly paying off and cited the Anti-CD3 drug (teplizumab) as a prime example. That research involved a 20+ year investment and is now helping delay or stall the onset of T1D by up to two years. JDRF has been instrumental in building consortia that involve hospitals, researchers, big pharma and universities. This multi-dimensional approach has moved the research (and deliverables) forward in a large way. The beta cell replacement therapies continue to advance, and beta cell regeneration seems promising. Stewardship has always been strong with this organization. No surprise given the strong family support. I will note that JDRF invested equity capital totaling \$11.3M into four pharmaceutical companies. While programmatic, there was no research grant related expenses recorded, which made the allocation to research (on paper) decrease. Financial analysis attached.

JJK COMMENTS: As we have seen with our other large medical partner, American Cancer Society, JDRF has organized their work around three pillars: preventing, curing, and improving. As the site visit report captured well, JDRF sees this as a propitious moment to allocate more resources to the "curing."

APPLICANT: JDRF International

I share DLK's enthusiasm about this approach, as the myriad partnerships and collaborations of JDRF have led to a tipping point where significant breakthrough may be within reach.

This request has a sharp focus on Beta Cell Replacement and Regeneration and for good reason. One lead researcher, Doug Melton, Ph.D. of Harvard, says that "a tablespoon of beta cells has kept people T1D free for more than 17 years."

Even in just the last two years, the world of diabetes research went from having only one viable approach to creating pancreatic islet cells to now having four possibilities. More importantly, JDRF-funded researchers are as optimistic as ever that they can minimize immune response to these cells – through localized delivery – without the kind of widespread immune system suppression that was previously required.

As we have seen in some other medical projects, there are therapies that we know work – the key for JDRF will be making it work better. JDRF has invested a total of \$140M in beta cell research, a signal of their bullish perspective on the science. Investments like these have yielded five clinical trials that are currently under way.

While we have chosen to focus on the Beta Cell Replacement and Regeneration, it is equally fascinating to read of the progress made on Artificial Pancreatic technologies.

The fundraising here is truly impressive. While lacking the household-name-brand recognition, JDRF remains a powerhouse in development. If the enthusiasm and dedication of LHV and her family is any indication, JDRF's supporters must be incredibly motivated and engaged.

I recommend the budgeted \$200K toward Beta Cell Replacement research.

SDK COMMENTS: I can't really add to DLK's/my site visit report comments, team's EF comments, and LVH's endorsement. I agree with renewal and look forward to the 4/30/20 FMKF/KA joint presentation.

FM KIRBY FOUNDATION
Financial Statement Analysis

Grantee Name:	JDRF International	Date:	11/8/2019
Prepared By:	DLK		
Grant Request Amt.	\$ 225,000	Type of Financial Report Submitted	Audit
Budgeted Amt.	\$ 200,000	Period Covered in Financial Report	6/30/2018
Audit Firm	KPMG	Date of Report Issuance	10/16/2018
Opinion	Present Fairly		
Basis of Acctg.	GAAP		

Current Ratio (Liquidity Ratio/Working Capital Ratio)	1.74	Amount of Unrestricted Net Assets (Operating Reserve)	\$ 57,009,000
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Note: A current ratio measures an organization's ability to pay short-term and long-term obligations. The higher the ratio, the more capable the organization is of paying its obligations. A ratio under 1 indicates that the organization's liabilities are greater than its assets.

Allocation of Functional Expenses	6/30/2018	%	Must Read Financial Statement Notes
A. Program Service Expenses	\$ 164,075	79%	Ideally program expenses should be at least 70% of total budget.
B. Management and General	\$ 15,918	8%	
C. Fundraising	\$ 27,985	13%	
D. Total Expenses	\$ 207,978	100%	
	(in thousands)		

Comments/ Notes:

Budget: The FY20 budget projects a \$2.4M surplus vs a projected surplus of \$5.7M for FY19. Total revenues are budgeted slightly higher, coming in \$1.3M (0.6%) above FY19. US public support revenues show a large increase of \$17M but it may be a function of not breaking the split out between US and Other revenues. Per the audited financial statements, JDRF has had a growing International contributions line. Expenses are budgeted to increase by \$4.7M or 2%. Program expenses account for \$2.5M (53%) of the increase, with fundraising and administrative expenses also budgeted for increases.

Audit: FY18 had an operating surplus of \$19M, up from \$13.4M for FY2017. Contributions were up \$19M (30%). Events revenue was fairly flat while contributions from international affiliates grew by \$600K (8%). Investment returns were down 3.3% (\$198K). Program expenses increased by \$11.4M (8%) while supporting services grew by \$2.4M (6%). JDRF had investments of \$90M, of which \$7.6M were endowment-related. Included within the investments are \$11.3M in preferred stock of four private companies (to provide equity capital to help accelerate the development of drugs, etc to treat, prevent and cure T1D. JDRF has a \$5M line of credit and there was no balance outstanding as of June 30, 2018. Overall, no red flags as a result of my review.

APPLICANT: JDRF International

DISPOSITION:

- Rejection
- Hold for review on/about:
- Approval for: **\$200,000**
- Hold for Board Review
- Insert Information: **Toward Beta Cell Replacement research**
- Other: **Send copy of check and insert to JDRF-NC**

Initials: *idc* Date: 11/21/19

Check #: _____ Date: _____

SITE VISIT REPORT

Report No: 18

Grantee:

JDRF International
190 Cider Hill Road
P.O. Box 70
Newport, VA 24128-0070

Program Area: Health

Most Recent Grant Amount and Date: \$200,000.00 - 9/17/2018

Primary Contact: Mr. Peter H. Roche, National Director, Leadership Giving

Phone: (540) 544-6978

Met With: Tom Brobson, Leadership Giving National Director; Aaron Kowalski, Ph.D, President & CEO; Andrew Rakeman, Ph.D., Assistant Vice President for Research; Sanjoy Dutta, Ph.D., Associate Vice President, Research and International Partnerships

Location: 26 Broadway, 14th Floor, New York, NY – 212-785-9595

Date Visited: July 30, 2019

F. M. Kirby Foundation Representative: S. Dillard Kirby, President; Diana L. Kostas, Treasurer and Secretary

Site Visit Guide: Matrix Score [Rating Scale from a high of 4 to a low of 1]

	'19	'14
<i>A. Personnel: Turnover, Professional Development and Career Advancement</i>	3.0	2.5
<i>B. Board: Involvement, Development, and Training</i>	3.0	3.0
<i>C. Financial: Net Assets, Fundraising Performance and Capacity</i>	2.75	3.0
<i>D. Strategic Planning, Review and Implementation</i>	3.5	3.5
<i>E. Program Evaluation and Quality Assurance</i>	3.0	3.0
Total:	15.5	15.0
Average Score:	3.1	3.0

Comments: The meeting kicked off with Dillard noting that FMKF's last site visit had occurred exactly five years prior. Dillard inquired about Tom Brobson's role at JDRF and whether he would be the primary point of contact for the Foundation. Tom stated that he was now handling Foundation Relations and would manage our relationship. Peter Roche would stay in touch with the Horton/Virkler/Kirby contacts in the North Carolina area. He emphasized that we could always reach out to either contact.

Aaron Kowalski then took the reins. His overall goal is to drive the mission faster, with immunotherapies and beta cell therapies being the primary pillars of their research portfolio. He reviewed the shifts in research approaches over the years. Due to the long-term nature of finding cures, JDRF moved toward finding simple solutions to quality of life type issues such as better insulin and better devices. With those in place, they have slowly been shifting more research dollars back towards a cure-based focus.

	Cure-Based	Quality of Life
2004	90%	10%
2009	66%	34%
Current	70%	30%
5 Years from Now	75-80%	20-25%

Upon Dillard’s comment about the overall research funding levels staying fairly flat since FMKF’s last visit, Aaron responded rather defensively that JDRF funded over \$100 million in 2018. Note that at the time of the 2014 site visit the research spending was close to \$120 million.

Sanjoy Dutta referred to the seeds they planted years ago that are now reaping benefits and breakthroughs. The Anti-CD3 drug (teplizumab) involved a 20+ year investment and is now helping delay or stall the onset of T1D by up to two years. A brief discussion ensued regarding JDRF’s work with industry players. As T1D impacts a relatively small part of the population, JDRF works on de-risking the research and incentivizing the companies to take part in the studies. Andrew Rakeman commented that JDRF is now taking a more active role by requesting proposals that target research gaps, reaching out to investigators directly and making T1D more attractive to pharma companies that are involved with autoimmune therapies by working on the initial proof of concept, mapping out targets and designing regulatory pathways for the FDA.

Sanjoy then pointed out that when the regulatory pathways don’t exist, they build a consortium. The Artificial Pancreas Consortium would be one such example. The Beta Cell Replacement Consortium consists of 50 investigators, Eli Lilly and Novo Nordisk. 50% of JDRF’s grants are focused on beta cell regeneration. The Encapsulation Consortium includes companies such as Sigilon Therapeutics, academic scientists from University of Florida and industry scientists from Lockheed Martin. At this point, JDRF has 5 or 6 consortia in place.

In response to our inquiry about governance and safe guards against inappropriate use of tax-exempt dollars for commercial gain, we may have caught them off guard a bit. That said, we had a generally satisfactory discussion of how JDRF handles the industry partnerships and potential pitfalls from the monetization of commercial drugs. Both Aaron and Sanjoy stated that any “profitable” monies made from transactions are plowed back into research funding as far as JDRF is concerned. Research offices (ROs) must sign terms and conditions that protect the investigators while also requiring a small payback to funnel into research if a profit is made. The terms are revisited every couple of years and have a strict policy on funding overhead (10% for indirect costs). There are

checks and balances at the university level as well. It was noted that the current terms and conditions can be found on the JDRF website.

Andrew gave a quick overview on “replacement” versus “regeneration”. Replacement refers to beta cells that are coming from outside the body. Regeneration refers to beta cells inside the body.

Aaron discussed some changes to the overall structure of JDRF’s Board and Leadership teams. The Board was sized down from 35 people to 15 people. There is a new Mission Board that is non-governing and focuses on fundraising. The Research Committee was also downsized.

Aaron then segued to the topic of prevention and how genetics play a role in the disease. He stated that the average American has a 1 in 300 chance of getting T1D. Children of diabetics have a 5 in 100 chance. Currently, it is possible to slow the progression of T1D but not prevent it. However, there are blood tests that can identify patients at risk. JDRF works with the EMA (the European version of the FDA). Israel, Denmark and Finland are all moving towards standard screening for diabetes in children. Finnish people have a 1 in 100 chance of getting T1D. Aaron seemed to make a soft pitch, that given the Kirby family’s history of T1D, we might naturally wish to consider support for prevention efforts. We shared with him, our basic research inclination and comfort in our general area of focus now. He seemed to respect that but did provide further education on their screening programs.

Researchers are learning that people have T1D much earlier than when their symptoms present. Screening programs are very expensive and Sanjoy stated the need for government support. JDRF expanded a T1D screening program based on evidence that early intervention can slow disease progression and dramatically reduce the risk of diabetic ketoacidosis, also known as DKA. The ASK Program at the Barbara Davis Center for Diabetes at the University of Colorado is now screening children ages 2-17, becoming the largest T1D screening program in the United States. Early diagnosis can impact treatment 10 years out. Sanjoy pointed out that most therapies can be curative and preventative but that T1D is very heterogenous so they must analyze each study and determine who will respond well to a given therapy.

Both Sanjoy and Andrew are in constant communication with the JDRF team, as well as NIH and the Helmsley Foundation (the Big 3 T1D funders). They also work on leveraging relationships with competent partners and pointed out a new partnership with the Parker Institute for Cancer Immunotherapy. In conjunction with the Helmsley Charitable, JDRF and The Parker Institute have launched a collaborative research initiative to understand, predict and prevent T1D following checkpoint therapy for cancer. The three nonprofits are jointly funding \$10 million in autoimmunity research over a three-year period.

We wrapped up the meeting with a quick review of how JDRF decides to deploy its resources. Aaron stated that annually JDRF reviews 3 key pillars from a resource perspective:

1. Curing
2. Preventing
3. Treating it better

The Board and Research Committee create roadmaps for each of the 3 pillars and set annual targets. It was an informative 90-minute session with all JDRF representatives taking an active part in the conversation. The most exciting takeaway is that the many years of research appear to be paying off in an acceleration of FDA-approved T1D therapies, more biotech companies entering the beta cell replacement therapy field and new drugs demonstrating the ability to preserve beta cells and potentially prevent T1D in people at risk. This is an investment worthy of our significant FMKF funding to date, and we anticipate a further request (well before our month-end October deadline), to be considered at our December Board meeting.