F.M. KIRBY FOUNDATION SOLICITATION EVALUATION FORM

DATE: August 27, 2019 **REQUEST DATE:** July 25, 2019

Last grant acknowledgement: Yes

Program Area: Health

APPLICANT:

Hospital For Special Surgery 535 East 70th Street New York, NY 10021

CONTACT: Ms. Reesa Kaufman, Senior Director, Foundation Relations

PHONE: 212-774-7120

PAYEE OTHER THAN ADDRESSEE:

AMOUNT REQUESTED: \$100,000 **NATURE OF REQUEST:** Toward biomechanics research being conducted by Dr. Timothy Wright, F.M. Kirby Chair in Orthopaedic Biomechanics

GRANT HISTORY

LAST GRANT DATE: 9/17/2018 LAST GRANT AMOUNT: \$80,000 AFS DATE: 4/5/2019

2013	\$125,000	9/23/2013	For: Continued support of biomechanics research
2014	\$100,000	12/15/2014	For: Support of research directed toward better treatment and
			prevention of osteoarthritis
2015	\$100,000	12/11/2015	For: Support of additional pilot projects aimed at better treatment
			and prevention of osteoarthritis
2017	\$80,000	9/15/2017	For: Support of research directed toward better treatment and
			prevention of osteoarthritis
2018	\$80,000	9/17/2018	For: Support of research directed toward better treatment and
			prevention of osteoarthritis

See site visit report attached.

DLK COMMENTS: HSS has consistently made advances in surgical technology for joint replacement. I found their personalized approach to treating ACL injuries fascinating and was impressed by longevity of the NIH Ruth L. Kirschstein National Research Service Award training program, now in its 41st year! HSS continues to lower its debt/equity ratio and has a strong balance sheet. The F.M. Kirby Chair endowment will provide approximately \$134K in income for 2019, to be used at the direction of Dr. Wright. Financial analysis attached. All good.

ECC COMMENTS: This request very closely follows the presentation SDK and I received at our site visit in late June, so the attached site visit report covers most of our response to these updates. I'd just like to highlight two aspects of the request: 1) Dr. Maher, the studies directed by whom have received much of our support, has developed a novel approach for treatment of damaged cartilage, which has no intrinsic capacity for healing and leads to severe arthritic problems later in life. Her device includes a load-carrying "core" designed to integrate seamlessly with the remaining cartilage. This device is what sparked HSS's first spin-off company, AGelity Biomechanics, the primary mission of which is to further develop this device for clinical use; 2) The seed funding provided by the FMKF has been leveraged into current annual NIH grants totaling over \$1.8 million* to support biomechanics research and education.

APPLICANT: Hospital For Special Surgery

Overall, I'm very impressed with the work produced so far and very confident in Dr. Wright's leadership of the Biomechanics Department. I recommend the budgeted \$80K for support of research directed toward better treatment and prevention of osteoarthritis.

SDK COMMENTS: Cannot add much here besides site visit comments. I will say Ms. Kaufman is top notch in stewardship.

*Of course, overall NIH funding of Dr. Wright's team is much more than that.

APPLICANT: Hospital For Special Surgery

FM KIRBY FOUNDATION Financial Statement Analysis

Grantee Name: Prepared By:	Hospital for Special Surgery DLK	Date:		8/21/2019
Grant Request Amt. Budgeted Amt.	\$ 100,000 \$ 80,000	Type of Financial Report Submitted		Audit
		Period Covered in Financial Report		12/31/2018
Audit Firm Opinion	Ernst & Young, LLP Present Fairly	Date of Report		4/5/2040
Basis of Acctg.	GAAP	Issuance	,	4/5/2019
Current Ratio (Liquidity Ratio/Working Capital Ratio)		Amount of Unrestricted Net Assets (Operating		
	4.03	Reserve)	\$	721,468,000

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	12/31/2018 (thousands)	%	Must Read Financial Statement Notes
A. Operating Expenses	\$ 1,169,519	86%	Ideally program expenses should be
B. Research Operations	\$ 184,457	14%	at least 70% of total budget.
D. Total Expenses	\$ 1,353,976	100%	

Comments/ Notes:

<u>Budget</u>: The Restoring Mobility: Novel Solutions for Joint Restoration project is budgeted at \$1.4M, with the Kirby request totaling 7% of the total project budget. HSS's operating budget is projecting a \$51M surplus and 7% increase in expenses from prior year actuals. The F.M. Kirby Chair will provide approximately \$134K in income to be used at the direction of Dr. Wright.

Audit: HSS had a \$50.0M operating surplus as of December 31, 2018 vs a \$70.8M surplus in 2017. Operating revenues increased by \$77M (7%) but were offset by increased operating expenses of \$91K (8%). The Hospital has lowered its debt to equity ratio from 0.77 (2016) to 0.74 (2017) to 0.64 (2018). HSS provided \$185M of community benefit activities, of which \$13.1M was charity care. Approximately 19% of the Hospital's net patient service revenue was derived from the Medicare and Medicaid programs. HSS had investments of \$516M, of which \$202.6M were endowment related.

Overall, there were no red flags as a result of my review.

APPLICANT: Hospital For Special Surgery

DISPOSITION:

()	Rejection						
()	Hold for review on/about:						
(xx)	Approval for: \$80,000						
(xx)	Hold for Board Review						
(xx)	Insert Information: For: Support of research directed toward better treatment and prevention of osteoarthritis						
()	Other:						
	Initials: Date: Date:						

SITE VISIT REPORT

Report No: 15

Grantee:

Hospital For Special Surgery 535 East 70th Street New York, NY 10021

Program Area: Health

Most Recent Grant Amount and Date: \$80,000.00 - 9/17/2018

Primary Contact: Ms. Reesa Kaufman, Senior Director, Foundation Relations

Phone: 212-606-1321

Met With: Ms. Ressa Kaufman, Senior Director, Foundation Relations; Dr. Tim Wright;

Dr. Carl Imhauser

Location: Same as above

Date Visited: June 27, 2019

F. M. Kirby Foundation Representative: S. Dillard Kirby, President; Erin C. Clifford, Communications and Program Associate

Comments: As we typically do with this grantee, we've eliminated the matrix for this report given that our support is really focused on work being pursued by the Laboratory for Biomechanics within the Department of Orthopaedic Surgery.

SDK and ECC met Reesa, Dr. Wright, and Dr. Imhauser in a conference room of the Department of Biomechanics in the Hospital's Dana Center. Reesa has been with HSS for about 17 years, Dr. Wright for 43 years, and Dr. Imhauser for 13 years and completed his post-doc with the Hospital, as well.

As Dr. Suzanne Maher was unable to join us, Dr. Wright presented on her work to develop new biomaterials for joint restoration. (See the PowerPoints for both Dr. Maher and Dr. Imhauser's work attached.) The demand is certain: osteoarthritis affects 27 million Americans (with a 6% growth rate per year) and total joint replacement is the second most expensive Medicare service with 860K per year at an aggregate cost of \$22.6 billion. Dr. Maher has developed a novel approach for treatment of damaged cartilage, which has no intrinsic capacity for healing and leads to severe arthritic problems later in life. Her device includes a load-carrying "core" surrounded by a porous titanium base (affixed to the surrounding bone) and a porous outer layer to integrate with

remaining cartilage. Studies are being continued to develop a layer of phosphonates to lubricate the exterior of the device and encourage integration with the surrounding cartilage and bone; there has been much success with this "modified polymer" approach and, while this addition is not yet ready for clinical translation, publications are being prepared to share with the wider scientific community. This device is what sparked HSS's first spin-off company, AGelity Biomechanics, the primary mission of which is to further develop this device for clinical use. So far, a sheep study has been successfully completed, patents have been filed to strengthen the hydrogel-metal interface, and investors are being approached. Importantly, AGelity has reached Phase II of a NIH Small Business grant, an encouraging investment towards making the product commercially available. The device is anticipated to be "first-in-man" in 2022.

We continued onto Dr. Imhauser's presentation, which synthesized his work regarding personalized ACL reconstruction and mechanisms of knee laxity (how loose or tight the joint is). Statistically, there are about 150K ACL reconstructions per year (one of the most common joint injuries, especially among young women) at an average of \$10K per surgery. Even if the torn ligament is repaired shortly after injury, graft failure rates, depending on the study, are as high as 18%, and repeated tears or injuries left unrepaired lead to early-onset osteoarthritis and longer-term complications down the line. Dr. Imhauser hypothesized that more personalized ACL reconstruction could prevent these rejections and graft tears. Though a simplified description, he explained that no two injuries or knees are the same, meaning there is no best generalized solution that applies to all patients. Essential to understanding the best solution for each patient is understanding the differences between individual knee mechanics and knee laxity. Currently, a surgeon performs a surface exam to "feel" the laxity of the knee, resulting in very subjective analyses that shift from doctor to doctor. Dr. Imhauser has developed an apparatus to test the laxity, mechanics, and load-bearing ability of a patient's knee, all of which is transmitted to a computer which can then develop a computational model and subsequent simulation. To build on this, after several years of applying and reapplying, he's received a \$275K, two-year NIH grant to research the subject-specific mechanisms of knee laxity, as well as a \$2M, four-year NIH grant to research the reproducibility in simulations of knee mechanics (i.e. development of manipulatable computer models) in collaboration with four other clinics (Cleveland Clinic, University of Auckland, University of Denver, and Cleveland State). Furthermore, he's established a partnership with Professor Bruce Beynnon at the University of Vermont to leverage an existing database of risk factors for ACL tears and reinjury in order to understand the cause of higher rates in some sects of the population, as opposed to the correlations already identified.

Relevant to the future of the aforementioned research, Dr. Wright informed us of a partnership between HSS and LimaCorporate to construct a 3D-printing lab for custom complex implants, the first design and additive manufacturing facility on a hospital campus. This collaboration will set the stage to substantially increase the availability and speed of personalized orthopedic care, avoid the "one size fits all" implants, and increase efficiency of joint surgeries.

As far as education and career-development activities, the HSS Perry Initiative, which encourages young women to pursue careers in science, orthopedic surgery and mechanical engineering and is led by Dr. Maher, is in its 9th year, and the West Point summer immersion program is going into its fourth summer with two cadets interested in biomechanical engineering training. (Interestingly, ACL injuries are extremely high in the military.)

Following the meeting, Reesa shared with us that "the F.M. Kirby Chair in Orthopaedic Biomechanics is fully endowed with over \$2 million raised (for which the FMKF funded \$500K in 2005). As of May 30, 2019, the market value for the endowment supporting the Chair was approximately \$2.8 million, and the 2019 spendable income is projected to be \$134,000. This income is expended to help seed novel biomechanics research and support the education of future leaders in the field." She also said she'll follow up with specifics of NIH funding for the Department which we'll add here. (ECC Note: Reesa later informed us through email that "seed funding provided by the FM Kirby Foundation has been leveraged into current annual NIH grants totaling over \$1.8 million to support biomechanics research and education.")

Overall, the conversation was very insightful and enjoyable. The longevity of Dr. Wright's career has spanned significant developments in the field of biomechanics and there is a definite sense of anticipation as the Department works towards clinical translation of developed products. There was no specific guidance on Wright's retirement plans, but we would guess over the next 3-5 years (although he lacked no energy on this day!). All three were sure to express gratitude for our funding and the foresight to contribute seed funding towards the development of proven data that can be leveraged for NIH dollars further down the line, an approach HSS has evidently had some success at. We'll look for their request around the first week of August to be considered at our September Board Meeting.