MCKNIGHT BRAIN RESEARCH FOUNDATION (MBRF)
Meeting of the Research Committee
of the Board of Trustees

Tuesday, July 6, 2021
5:00 pm EDT – 6:00 pm EDT
Conference Call # 855-417-2207
Conference Id 6434672

Members Attending:	Dr. Madhav Thambisetty, Chair; Dr. Patricia Boyle; Dr. Richard Isaacson; Dr. Sue Pekarske; and Dr. Mike Dockery, MBRF Chair
Also Attending:	Ms. Amy Porter, Ms. Melanie Cianciotto

AGENDA

5:00 pm EDT	1.	Call to Order/Roll Call	Dr. Thambisetty
ACTION	2.	Approval of Minutes, January 29, 2021	Dr. Thambisetty
	3.	Updated Activity Timeline	Dr. Thambisetty
	4.	Current Grants/Programs a. Status – Pilot "Harnessing Optimal Mechanisms of Exercise for Cognitive Gains" PIs Dr. Joyce Gomes-Osman and Dr. Eric Porges	Dr. Thambisetty
		b. Status - MBRF Innovators Awards in Cognitive Aging and Memory Loss	
		c. Status – MBRF Clinical Translational Research Scholarship in Cognitive Aging and Age-Related Memory Loss	
ACTION		d. Request – Final Reserve & Resilience Collaboratory Workshop. Yaakov Stern, PhD	
ACTION	5.	New Program Concepts/Requests a. Request – "Centralized, Telephone-Based, Computer-Assisted Assessment of Age-Related Cognitive Decline in Spanish" Ron Lazar, PhD, and Bonnie Levin, PhD	Dr. Thambisetty
ACTION		b. Request – "Investing in Our Future" UM MBI	Dr. Mike Dockery
6:00 pm EDT **ACTION**	4.	Adjourn	Dr. Thambisetty All

MINUTES
MCKNIGHT BRAIN RESEARCH FOUNDATION (MBRF)
RESEARCH COMMITTEE
CONFERENCE CALL
January 29, 2021

The Research Committee of the MBRF was called to order at 4:30 pm EST on January 29, 2021, by Dr. Madhav Thambisetty.

The following members were present:

Dr. Madhav Thambisetty, Chair of the Research Committee, Trustee
Dr. Richard Isaacson, Trustee
Dr. Robert Krikorian, Advisory Member
Dr. Sue Pekarske, Trustee
Dr. Patricia Boyle, Trustee
Dr. Mike Dockery, MBRF Chair

Others attending:

Ms. Melanie Cianciotto, Corporate Trustee
Ms. Amy Porter, Executive Director
Ms. Valeria Patmintra, Senior Communications Director

1. Call to Order/Roll Call

Dr. Thambisetty welcomed the members of the committee and Ms. Porter called roll.

2. Minutes of the June 15, 2020, Meeting

The minutes of the June 15, 2020, Research Committee will be sent out after the call for review and approval by email.

Action Item 1: Ms. Cianciotto will send out the minutes of the June 15, 2020, Research Committee (Attachment 1) after the call for review and approval by email.

3. Current Grants/Programs

a. Review of the Pilot Grant Applications and Reviewers' Comments

Dr. Thambisetty shared with the committee that there were challenges, probably due to the pandemic, of securing interest and the RFA had to be posted twice. Dr. Thambisetty asked the committee for feedback regarding the overall quality of the applications (Attachment 2). The consensus was the applications were okay but not overly impressive, there appeared to be a

discrepancy in scoring one applicant and most felt that the pilot grants are intended for junior investigators and senior researchers should be discouraged from applying. The committee recommends the RFA structure for these pilot grants be reviewed prior to the next cycle and that it should be specified the grants are targeted towards junior investigators. Ms. Porter will obtain a copy of the current RFA from Dr. Levin. A motion was made to recommend to the Board that the top three (3) highest ranked applications be funded. The top three highest ranked applications are from Dr. Lazar, Dr. Hernandez and Dr. Gomes-Osman.

Action Item 2: A motion was made to recommend to the Board that the top three (3) highest ranked applications should be funded. The top three highest ranked applications are from Dr. Lazar, Dr. Hernandez and Dr. Gomes-Osman.

Action Item 3: Ms. Porter will obtain a copy of the current RFA from Dr. Levin so the structure may be reviewed prior to the next cycle and specify the RFA should be targeted towards junior investigators.

b. McKnight Clinical Translational Research Scholarship

a. The committee received information about the 2021 Scholars and their project proposals for information (Attachment 3).

b. The committee received a complete list of Scholars and Mentors for information (Attachment 4).

c. Ms. Porter provided the committee an update on the draft agreement for the 2022 -2027 program renewal (Attachment 5). The draft agreement received from the ABF has been modified from the original agreement and Ms. Porter asked Mr. Raattama and Ms. Cianciotto to review and provide feedback.

   i. ABF response to the MBRF's request for Advertising and Application was to assure the MBRF that the current advertising and application process would be continued.
   ii. ABF response to the MBRF's Review Request was to assure the MBRF that the MBRF reviewers will be allowed to see all applications being reviewed.

4. Report on Outreach to Possible Partners for the MBRF Mid-Career Research Award in Cognitive Aging and Memory Loss

Ms. Porter provided the committee with an update on outreach to possible partners for the MBRF Mid-Career Research in Cognitive Aging and Memory Loss (Attachment 6). The most promising possible partner is the American Federation for Aging Research (AFAR). AFAR can do everything required to advertise, promote and manage the grant awards. They are developing a proposal for the MBRF to consider.

5. Adjourn

Dr. Thambisetty asked if there was any further discussion. Hearing none, he called for adjournment of the meeting at 5:20 p.m. EST.

Summary of Action Items:

Respectfully Submitted,

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Melanie A. Cianciotto
Corporate Trustee

Research Committee Activity Timeline
For the One-Year Period July 1, 2021, to June 30, 2022
Updated July 6, 2021

Duty (from Committee Charter)	Activity/Action	Outcome	Date	Comments
"Encourage and assess research at the McKnight Brain Institutes (MBIs)"	Review of the Annual Reports of the MBIs	Information for scientific review includes: scientific achievements, publications, presentations, collaborations	DONE February 5, 2020 DONE June 15, 2020 DONE Review took place at Feb. 26, 2021 Meeting	Reviewers presented at Feb Trustees Meeting. Follow up letters were written and sent to each of the MBIs. All Requests of MBIs were addressed. MBRF/MBI Task Force was established April 2021 to streamline Annual Report
	Review of all New Funding Requests from MBIs	UM submitted a request for $200,000 for Neurocognitive Post-Doctoral Fellowship over the next two years Christian Agudelo, MD, was selected	October 23, 2019 Trustees voted to fund -- payable over two years. Position Start Date – July 2020 February 25, 2021 Trustees Meeting A Funding Request was submitted in late April by Dr. Ron Lazar	The notification letter mentioned that future funding should come from other sources. No New Funding Requests were submitted by MBIs. This request will be reviewed by the Research Cmte at their summer 2021 meeting.
		UA submitted a request for $244,400 for UM's participation in the Precision Aging Demonstration Pilot	The proposal was reviewed and approved by the Trustees on Feb 5, 2020. The budget was revised and approved June 2020	Dr. Mike Dockery notified UA of the Trustees' approval. Trustees were notified of the revised budget and approved no-cost revisions

Duty (from Committee Charter)	Activity/Action	Outcome	Date	Comments
"Encourage and assess research at the McKnight Brain Institutes (MBIs)" continued	Review of Travel Award Fund: Originally established to fund research scholars and faculty to visit other McKnight institutions.	Few applications for travel. The funds allocated for travel have been used to fund the activities of focus groups: Epigenetics, MRI standardization and cognitive test battery working group	Reviewed at each Trustees' Meeting ON HOLD DUE TO UNIVERSITY TRAVEL RESTRICTIONS	Approved in 2009 In the amount of $100,000 Approximately $30,000 remains in the fund
	Inter-institutional Block Grants	Cognitive Aging Core Working Groups	N/A	5 Areas: Brain and Cognitive Health Cognitive Aging & Memory Cognitive Testing Battery Epigenetics MRI standardization
	Inter-institutional Block Grants	Bio-Informatics Core (Epigenetics)	Funding period: 9/1/2013-8/31/2015	Tom Foster, UF still lead scientist. $76,276.49 still unexpended funds
	Inter-institutional Block Grants	Neuroimaging Core	Funding period: 1/1/2015 to 12/31/2017 $931,759.00	Remaining balance: $514,229.21
	Inter-institutional Block Grants	Cognitive Assessment and Brain Registry Core	Funding period: 9/1/2015-8/31/2017 Request for another extension was approved at the Feb 5, 2020, Trustees' meeting.	Remaining Balance: $101,275.15 No-cost Extension Request submitted for April 30, 2021. Trustees approved the extension.

Duty (from Committee Charter)	Activity/Action	Outcome	Date	Comments
	Review of Pilot Grants (Funding Requests and Progress Reports)	A Novel Invention Tool – Levin	Funding Period: 5/1/2018-4/30/2020	Funding for 2-years for total of $120,000
		Revitalizing Cognition in Older Adults – Bowers	Funding period: 5/1/2018-4/30/2020	Funding for 2-years for total of $120,000 No-cost Extension Request submitted for April 30, 2021. Trustees approved the extension.
		Transcutaneous Vagal Nerve Stimulation and Cognition Training – Williamson/Alexander	Approved July 2019 Funding period: 10/1/2019-9/30/2021	Funding for 2-years for total of $120,000
	Applications for 2021 Pilot Grants Check RFA for 2022 before it's posted to be sure it stresses Junior Faculty	5 Letters of Intent were Submitted	Deadline was extended Research Cmte Reviewed Jan. 29, 2021 Trustees approved 3 grants on Feb. 26, 2021	Bonnie Levin and Ron Lazar forwarded applications and reviewers comments. Research Cmte recommended 3 awards be granted
"Identify opportunities…to foster greater interest in cognitive aging and age-related memory loss (in the scientific community)"	Research Partnership with the Foundation for NIH and the NIA. 1st cycle-2009, 2nd cycle 2014, 3rd cycle approved 2019 to begin Spring of 2020	Fund balance of $1 million from 2nd five-year partnership returned to MBRF Report received on all FNIH/MBRF activities RFA posted: "Network for Identification, Evaluation, and Tracking of Older Persons with	DONE August 2019 FNIH Report in October 2019 had error. A corrected report resubmitted on Feb. 5, 2020. Posted Feb 2020; Deadline LOI Sept. 1; Application October 1, 2020	History: Established 2009 $5 M over 5 years from MBRF; match from NIA and partners was $23 M for total of $28 M (17 five-year grants funded). 2014 Partnership renewal funded one 5-year project for $15 million with $5 M from MBRF and $10 M from NIA RFA was shared with Communications Working Group

Duty (from Committee Charter)	Activity/Action	Outcome	Date	Comments
	Research Partnership with the Foundation for NIH and the NIA (continued)	Superior Cognitive Performance for Age" FNIH Report submitted For information only	October 14, 2020 First Payment was made to FNIH by March 31, 2021. Will continue until 2025	for posting and with Leadership Council. Valerie connected with Julie Wolf-Rodda and Molly Wagster on promoting STARRS study. NIA will provide $14M to be pooled with MBRF $5 M. A 2.8 Match. Julie Wolf-Rodda is setting a date for lunch with Amy and Molly Wagster in August, 2021.
"Identify opportunities…to foster greater interest in cognitive aging and age-related memory loss (in the scientific community)" (continued)	MBRF Innovators Awards in Cognitive Aging and Memory Loss	Program was Approved by the Trustees Potential administrative and/or funding partners were approached American Federation of Aging Research (AFAR) was identified as an excellent partner organization. AFAR presented a proposal and draft contract for review Revised Agreement signed	October 14, 2020 December 2020 January 2021 February 2021 May 2021 July 15, 2021 August 2021 Mid Oct. 2021 Dec. 15, 2021	The McKnight Brain Research Foundation committed $4.5 million over the next five years to support outstanding mid-career scientists committed to researching the basic biological mechanisms underlying cognitive aging and memory loss. Trustees approved AFAR as the MBRF Partner on the mid-career award Announcement for the Innovators Awards is finalized and posted. LOI Deadline LOI Review Application Deadline Award Announcement

Duty (from Committee Charter)	Activity/Action	Outcome	Date	Comments
	Cognitive Aging Conference (**CAC) 2020** Cognitive Aging Conference (CAC) 2022	MBRF requested information about sponsoring a panel and/or poster session reception Registration is at cac.gatech.edu	April & July 2019 No proposals were received. CAC 2020 Mtg CANCELED Will be held April 7 – 10, 2022	MBRF sponsored a successful panel at Cognitive Aging Conference May 2018 The Conference coordinator is Christopher Hertzog. cogagingconference@gmail.com
	Reserve & Resilience Workshop 2019 Reserve & Resilience Workshop Pilot Grants 2020 Final Reserve & Resilience Workshop 2021	Over 300 Attendees (8 MBI researchers) Organizers requested $30,000 to support (1 – 3) pilot grants	September 9 and 10th, 2019 Bethesda In-Person Meeting CHANGED TO VIRTUAL MTG September 14 and 15, 2020; Report Submitted Jan. 2021 Oct 31/Nov 1 Bethesda	This is an outcome from Cog. Aging Summit III held in 2017. Research Committee approved support in first and second years. Dr. Stern requested support for the Final R & R Workshop to take place Oct. 31/Nov. 1 in Bethesda. He did not request a specific amount but support MBRF provided last year was $30,000.
"Encourage young investigators in this area of research"	McKnight Brain Research Foundation Clinical Translational Research Scholarship with American Academy of Neurology (AAN) and American Brain Foundation (ABF)	Reviewers are Dr. Krikorian, Drs. Thambisetty, Isaacson, and O'Brien (Duke)	Reviewers meet in Dec. Two Scholars are selected and alternates were identified. Awardees are notified in January. Funding starts July 1 of each cycle	First Scholarships Awarded January 2018 (McConnell, Albert) Second Scholarships Awarded January 2019 (Camargo, Sedaghat) Third Scholarships Awarded January 2020 (Baxter, Getz)

Duty (from Committee Charter)	Activity/Action	Outcome	Date	Comments
	McKnight Brain Research Foundation Clinical Translational Research Scholarship with American Academy of Neurology (AAN) and American Brain Foundation (ABF) (continued)		Edits to 2021 RFA were made and approved by Research Cmte. RFA has been posted as of July 4, 2020, on AAN site. Was added prominently to MBRF site in July. Advertising followed 2019 Plan for 2020 Award and begin in August, 2020. 8 applications for 2021 were received. October 14, 2020, Renewal for next five years was approved by the Trustees	Fourth Scholarships were Awarded in January 2021 to Dr. Wendy Yau Wai-Ying (Brigham and Women's) and Dr. Matthew Burns (UF) Publicly announced in April 2021 UPDATE: Dr. Matthew Burns (UF) received a K-Award from NIA and had to decline the McKnight Scholarship. First Alternate Dr. Reem Waziry was offered and accepted the 2021 Scholarship Fifth Scholarships will be advertised in summer of 2021; deadline Oct. 1, 2021, and awarded in January ABF presented report on the program and request for renewal for 2023 – 2027 was approved by the Trustees
"Encourage young investigators…" Continued	Poster Reception at 2019 Society for Neuroscience annual meeting		October 20, 2019	First Poster Reception held in 2008. (50 submissions received) Sponsored by MBRF. Hosted by Directors of MBIs. Submissions open to researchers at MBIs and invited guests only

Duty (from Committee Charter)	Activity/Action	Outcome	Date	Comments
	Poster Reception at 2020 Society for Neuroscience (SfN) annual meeting in DC October 24 – 28, 2020 SfN 2020 Meeting was canceled due to DC pandemic closing guidelines SfN 2021 50th Annual Meeting	Wagster and Jon King of NIH. Proposal submitted and reviewed and approved by MBRF Trustees MBI Leadership Council considered but ruled out a virtual poster session	Feb 5 2020 Trustees meeting Hotel was canceled at no cost to MBRF November 8 – 11 virtually and Nov. 13 – 16 at McCormick Place Convention Center in Chicago	Vicki Hixon has been asked the organizers' thoughts on the McKnight poster session.

CURRENT GRANTS/PROGRAMS

4a. Status – Pilot "Harnessing Optimal Mechanisms of Exercise for Cognitive Gains"

Dr. Joyce Gomes-Osman, grantee of a 2021 MBRF pilot grant, has taken a new position at Linus Health as Director of Interventional Therapy. She will no longer be conducting the approved pilot. Dr. Rundek will talk with the MBI committee to ascertain whether they would recommend that the pilot grant be given to another applicant. We expect to hear from the committee before the July 28 Trustees' Meeting.

4b. Status – MBRF Innovators Awards in Cognitive Aging and Memory Loss

The award announcement is posted along with the forms and application submission form on AFAR's website at www.afar.org/grants/mcknight-award#annual%20meeting . LOIs are due July 15 and will be reviewed in late August. The application deadline will be mid October and the award is expected to be announced by December 15.

4c. Status – MBRF Clinical Translational Research Scholarship in Cognitive Aging and Age-Related Memory Loss

The announcement for the 2022 McKnight CTRS Program is posted and should link to the PDF that was edited for the scholarship program. The link did not include our PDF on Friday, July 2, but we requested that it be corrected. Advertising will take place in August and September to encourage applications. https://www.aan.com/education-and-research/research/aan-research-program/mcknight-clinical-translational-research-scholarship-in-cognitive-aging-and-age-related-memory-loss/

4d. Request - Final Reserve & Resilience Collaboratory Workshop

Please see Dr. Stern's recent email – next page. Dr. Stern did not request a specific amount but asked that the MBRF renew its support for the workshop. The MBRF provided $25,000 and $30,000 respectively in 2019 and 2020. The meeting will be held October 31/November 1 in Bethesda. I have requested a specific amount but I have not received any further information.

REQUEST – FINAL RESERVE & RESILIENCE WORKSHOP

From: Yaakov Stern <ys11@cumc.columbia.edu>
Date: June 25, 2021 at 11:55:58 AM EDT
To: Amy Porter <aporter@mcknightbrf.org>
Subject: Final Reserve and Resilience Collaboratory workshop
Reply-To: ys11@columbia.edu

Hi Amy:
I hope all is well with you.
The Reserve and Resilience Collaboratory has made very good progress. The main accomplishment is a consensus "Framework" that defines three key concepts and provides operational definitions for how to research them. I have held numerous zoom meetings with investigators to get input and edits. Right now the close-to-final version is posted on the website (reserveandresilience.com) in order to get final comments from as many people as possible.

"Ratifying" this Framework and discussing its implications for human and non-human research in the field will be the major theme of the 3rd and final upcoming Workshop, which will take place in Bethesda on October 31/November 1. I already have over 20 key experts agree to attend in person. The workshop will be hybrid, allowing people who can't make it in person to participate remotely.

Once again I am turning to the McKnight foundation to ask for your continued support. This time the "ask" is for funds to support food at the meeting. As you know, NIA funds cannot be used for food. You provided this support at the 1st Workshop, but we also had support from the Alzheimer's Association and AARP. Although I will ask them again, I'm not optimistic. I think that they have both been hit pretty hard by the pandemic, and they did not contribute to last year's Workshop.I'd be glad to discuss this with you, or to provide estimates for the anticipated costs.

By the way, one of the pilot awards last year went to your McKnight professor Tom Foster along with a postdoc of his. They have already prepared a paper for submission based on their results. I think Tom could explain to you very well how the Collaboratory process has helped guide his research on reserve and resilience.

All the best,
Yaakov

ReplyForward

NEW PROGRAM CONCEPTS/PROPOSALS

5.a. on the Meeting Agenda
REQUEST "Centralized, Telephone-Based Computer-Assisted Assessment of Age-Related Cognitive Decline in Spanish"

---------- Forwarded message ---------
From: **Lazar, Ronald M** <rlazar@uabmc.edu>
Date: Fri, Apr 16, 2021 at 5:24 PM
Subject: Spanish Cognitive Testing Project: UAB and UM
To: Amy Porter <aporter@mcknightbrf.org>
Cc: Barber, Susan <shbarber@uabmc.edu>

Dear Amy,
I hope this note finds you well.
You hopefully recall that we had a conversation last summer about the lack of Hispanics in our McKnight studies, which I thought was a major gap in our research. It is my recollection that you then brought this matter to the attention of some of the Trustees, and your feedback to me was that they would welcome a proposal. With all the challenges of initiating research in the era of COVID-19, I was finally able with the collaboration of the UMiami EMBI to fashion a proposal for your consideration, which is attached.

I look forward to the feedback from the Trustees and would be glad to discuss any aspect of this project with them.

Best regards,

Ron

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Ronald M. Lazar, PhD, FAHA, FAAN|UAB
Evelyn F. McKnight Endowed Chair
Professor of Neurology and Neurobiology
Director, Evelyn F. McKnight Brain Institute at UAB
Director, Division of Neuropsychology

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Centralized, Telephone-Based, Computer-Assisted Assessment
of Age-Related Cognitive Decline in Spanish

Ronald M. Lazar, PhD, MPI (Contact)
UAB McKnight Brain Institute

Bonnie Levin, PhD (MPI)
Univ of Miami McKnight Brain Institute

A. Executive Summary

The McKnight Brain Research Foundation has an exemplary record in funding research at its Evelyn F. McKnight Brain Institutes over the past 20 years, focused on age-related memory and cognitive decline. Nearly all of these projects, however, have derived their data on English-speaking populations. With Spanish-speaking populations representing the fasting growing cohort in the United States, there is a significant need to address age-related changes in memory in the language which will most validly assess their level of function. In a one-year collaboration between two E.F. McKnight Brain Institutes, UAB and Miami, we are proposing here to develop and validate a multiple-domain, telephone-based cognitive examination in Spanish that is administered centrally at UAB and capable of assessing participants not only at the four MBIs, but anywhere in the United States.

B. Background and Context

The McKnight Brain Research Foundation has as its mission to better understand and alleviate age-related cognitive decline and memory loss. In the ensuing years since its founding in 1999, the MBRF has supported state-of-the-art research at its four affiliated institutions. The work it has underwritten has appeared in world-class, peer-reviewed journals and has influenced thinking about cognitive aging in the absence of brain disease. The matter arises, however, as to the generalizability of this research to the rapidly changing demographics in the US, especially Spanish-speaking groups, a population that has more than quadrupled since 1980 with a 43% increase in the decade between 2000 and 2010 (US Census Bureau, 2010). In 2019, Census data indicate that there were 60.5 million Hispanic/LatinX subjects residing in the US, representing 18% of the population (US Census Bureau, 2019). To our knowledge, all of the data to date, including the MBAR project, have been acquired in English. The purpose of this proposed project is to address this gap for multi-site studies by adapting and validating the use cognitive measures for Spanish-speaking individuals.

There are screening measures of cognition that have been translated into Spanish, such as the Mini-Mental State Examination[1], the Telephone Interview of Cognitive Status[2], and the Montreal Cognitive Assessment[3], which are often used in population-based studies. These tests, however, were predominantly designed to diagnose severe cognitive impairment and not to identify subtle age-related cognitive decline that would help to identify those at greatest risk of future decline and may be amenable to a restorative or preventive therapy. Rather, the gold standard for the clinical assessment of cognitive function in research settings is the neuropsychological examination, comprised of tests of multiple cognitive domains.

There have been few large-scale, NIH-funded epidemiological studies of cognition among US-based Hispanic populations. Among them is the NINDS-funded Northern Manhattan Stroke Study (NOMAS), a single-site project comprised of 63% Hispanics in which memory, processing speed, language, and executive function has been assessed face to face.[4] The NIA-funded Hispanic Community Health Study/Study of Latinos (HCHS/SOL) administered four face-to-face neurocognitive tests across the Bronx, Chicago, Miami and San Diego, comprised of the

Spanish-English Verbal Learning Test, Word-list generation for the letter F, A, and S, respectively, word list generation for animals, and the Symbol-Digit Substitution Test.[5] Each clinical site was responsible for its own assessments, resulting in four duplicate test operations, which required constant monitoring of inter-site variability.

In a collaboration between two E.F. McKnight Brain Institutes, we are proposing here to develop and validate a multiple-domain, telephone-based cognitive examination in Spanish that is administered centrally at UAB and capable of assessing participants not only at the four MBIs, but anywhere in the United States. We will leverage the infrastructure already in place in the Survey Research Unit (SRU) in the UAB School of Public Health, and the extensive Spanish-speaking population served by the Neuropsychology Division in the Univ of Miami Department of Neurology. This assessment model was first used at UAB in the REasons for Geographic And Racial Differences in Stroke (REGARDS) study, a project with 30,000 participants largely in the Southeast US. Computer-assisted for standardized administration and data entry, and audio recorded, this approach has been the basis of over 30 peer-reviewed published reports, including formal evaluation for the validity of the telephone assessments,[6] assessing the impact of incident stroke on cognitive decline,[7] and showing associations between cognition and risk factors in a stroke-free population.[8]

In 2012, the Carotid Revascularization and Medical Management for Asymptomatic Carotid Stenosis Trial (CREST-2) adapted and extended the test battery to more closely follow the harmonization guidelines for the assessment of vascular cognitive impairment[9] and the updated NINDS Common Date Elements 2.0[10]. This study involves 140 clinical sites throughout North America. The assessment, taking 20-25 minutes on average, probes attention (Digit Span[11]) , learning (CERAD word list registration[12]), memory (CERAD delayed recall)[12], executive function (word list generation for animals and the letters, F, A and S[13], respectively, and Oral Trail Making[14]), and depression via a brief screen[15] used as a covariate. The success of this process is such that the CREST-2 battery is now being used in the ARCADIA-CSI study for the effects of heart disease on silent brain infarction (83 US sites), and the joint UAB/UM Family Study of Atherosclerosis and Vascular Cognitive Dysfunction. Collectively, there have been more than 90,000 administrations of this test battery, importantly corresponds closely to that in HSHS/SOL, and stands ready for Spanish translation, standardization and validation, and incorporated into future EMBI studies.

C. Proposed Methods

Specific Aims

Specific Aim 1: To develop a cognitive testing protocol in Spanish, using previously validated translations of cognitive tests and incorporating them into a telephone-based, computer-assisted Spanish testing protocol.

Specific Aim 2: To validate the Spanish protocol by enrolling participants previously tested in-person within the past year, administering the telephone-based battery, and comparing scores within similar domains between the in-person and telephone-based administrations.

C.1. General Study Procedures: After the UAB testing protocol is translated into Spanish, we propose to enroll Spanish-speaking individuals with stable neurological conditions who had been given comprehensive in-person neurocognitive examinations within the past year comprised of domain measures comparable to the telephone battery. After study participants sign informed consent, the UAB Survey Research Unit will then administer the Spanish,

telephone-based cognitive examination by a single, certified, Spanish-speaking test administrator. The tests will be scored and then compared statistically to the in-person test batteries. Our criterion for validation of the phone battery will be a concordance of 70%.

C.2. Study Population: We propose to enroll 60 monolingual Spanish or bilingual-Spanish predominant speakers, ages 45 to 90 years old, who had been tested in-person within the past year in the U Miami Neuropsychology Clinic with a comprehensive test battery. We will target those with stable neurological conditions, including those with mild cognitive impairment, mild traumatic brain injury, well controlled temporal lobe epilepsy, and mild stroke (NIHSS <5 with minimal aphasia and minimal weakness). We will stratify enrollment so that 12 individuals will be enrolled in each of the age ranges of 45-49, 50 – 59, 60 – 69, 70 – 79 and 80 – 89 years old. Exclusions will include those who have known clinical worsening over the past year, significant changes in medication, or interval cognitive testing in another clinical or research setting. All participants will be assigned a unique study number, and we will collect information regarding age, education and race.

C.3. The Test Battery and Spanish Translation: The current English test battery takes 20-25 minutes and uses well-validated measures in an aural format that can be administered in standardized fashion to participants. The domains will be the same as those used in CREST-2, and encompass learning (CERAD Word List Learning), attention (Digit Span), memory (CERAD Delayed Recall), and executive function (word fluency for animals and letters), Oral Trail Making). We also include the abbreviated (4 question) Center for Epidemiologic Studies Depression Scale (CES-D), which will serve as a covariate for depressive symptoms. There are already comparable tests that are administered in Spanish, which we will compare to the proposed Spanish test battery. Test instructions and the introductory script, however, will be adapted in Spanish to the telephone format by Dr. Rey, co-Investigator at U Miami, who has extensive experience in English to Spanish test adaptation, and who was responsible for the Spanish version of the well-known Multi-Lingual Aphasia Examination and other cognitive tests in Dr. Arthur Benton's Neuropsychology Laboratory. As per contemporary standards, Dr. McInerney, co-Investigator at U Miami, will blindly back-translate into English to ensure reliability. The Spanish testing script will then be sent to the UAB School of Public Health where Michael Tyler will write the Spanish code into the computer program for test administration.

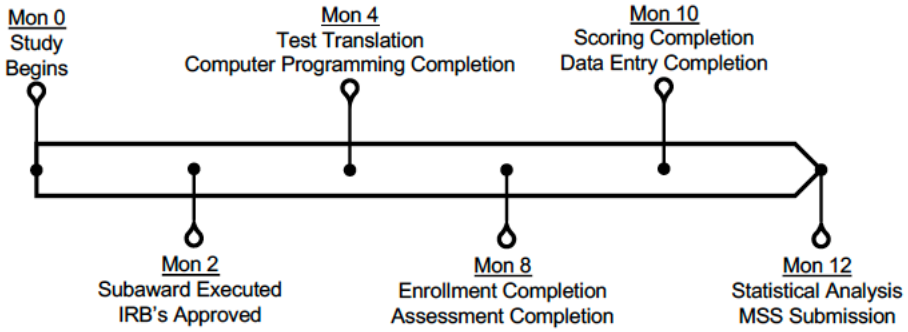
C.4. Test Administration. Study participants will be tested in the U Miami Neuropsychology Clinic. To ensure that the UAB test administrator will be available, Drs. Rey, McInerney and Kaur will use the UAB Survey Research Unit Reservation System to enter the study number, date and time of the anticipated assessment. On the assigned day and time, the study participant will be led into a quiet room with a telephone and a member of the study team will call the UAB test administrator and leave the room, whereupon the test will be administered.

C.5. Test Scoring and Data Entry. The computer software automatically scores the learning and memory tasks, digit span and the time to complete Oral Trail Making. The results are then automatically entered into a RedCap database stored in a secured server at UAB. Word fluency for animal names and for letters, however, have to be manually scored. Dr. Rey, McInerney and Kaur, all experienced neuropsychologists, will be given access to the server where audio recordings of the word list generation can be heard, and they will enter scores in the UAB database. To help maintain objectivity in these tabulations, the scorers will not listen to participants for whom they had conducted the in-person clinic examinations. The U Miami Research Assistant will then enter the scores from their respective in-person examinations into the study database.

D. Statistical Analysis Plan

On measures are identical instruments utilized for both in-person and phone based evaluations (i.e., Animal fluency, phonemic fluency using the letters P-T-M, and digit span forward and backwards) a direct comparison of raw scores will be performed and analyzed with Pearson Correlation Coefficient which yields a value between +1 and −1. A value of +1 is total positive linear correlation, 0 is no linear correlation, and −1 is total negative linear correlation. For those cognitive domains where the measures utilized for in-person evaluations differ from the proposed phone based instruments, correlational validation will be performed by comparing normatively derived Standard Scores for the respective instruments. Specifically, Standard Scores on the Miami Attention and Memory Instrument Verbal Learning Test (MAMI-VLT) total learning and delayed recall will be correlated with normatively derived Standard Scores for the CERAD total learning and delayed recall respectively. Similarly, Oral Trails A and B normatively calculated Standard Scores will be correlated with the corresponding for the paper-pencil scores obtained in the in-person visit. As indicated previous a correlational value of 70% has been established as criterion for concordance, which would represent nearly 50% shared variance between the instruments.

E. Study Timeline



Study Timeline and Milestones

F. Budget

UAB					
Personnel:					
Name	**Role in Project**	**Effort (%)**	**Base Salary**	**Fringe**	**Total Salary**
Ronald M. Lazar, PhD	**Principal Investigator (Contact PI)**	1%	266,343	24.7%	3,321
Michael Crowe, Ph.D.	**Co-Investigator**	1%	128,757	24.7%	1,606
Michael Tyler	**Computer Programmer**	15%	86,465	35.3%	17,548
Biostatistician	TBN			24.7%	12,500
Terina Myers	**Study Coordinator**	15%	50,000	35.3%	10,148
			Total Personnel		**40,196**
OTPS					
UAB SRU Testing Fee	@175. (x 60 participants)				10,500
UAB OnCore Management System					1,000
			Total OTPS		11,500
			Total UAB		**51,696**
U Miami					
Bonnie Levin	**Principal Investigator**	0%		0.0%	
Gustavo Rey	**Co-Investigator**	20.0%	163,995	24.0%	40,671
Katalina McInerney	**Co-Investigator**	10.0%	85,000	24.0%	10,540
Sonya Kaur	**Co-Investigator**	5.0%	85,000	24.0%	5,270
TBD	**Coordinator/Res Asst**	15.0%	48,000	37.4%	9,893
			Total Personnel		**66,374**
OTPS					
IRB continuation fee + closing report fee					2,387
Compliance fee					350
IRB Continuation fee + closing report fee					2,387
Participant Incentive	@100 (x 60 participants)				6,000
					11,424
			Total Miami		**77,498**
			Total Project		**129,194**

G. Budget Justification

University of Alabama at Birmingham

Personnel:

Ronald M. Lazar, PhD (UAB Principal Investigator, 1% salary effort): Dr. Lazar holds the Evelyn F. McKnight Endowed Chair in Learning and Memory in Aging in the UAB Department of Neurology, where he is Professor of Neurology and Neurobiology, Director of the UAB McKnight Brain Institute, and Director of the Neuropsychology Division. Prior to joining the faculty in the UAB School of Medicine in 2017, he served as Professor of Neuropsychology in Neurology and Neurological Surgery in the Department of Neurology at the Columbia University College of Physicians & Surgeons, and Director of the Richard & Jenny Levine Cerebral Localization Laboratory at the Neurological Institute of New York. For more than 25 years, funding from NINDS, NICHD, NHLBI, NIA and NIDDK has enabled Dr. Lazar and his teams at Columbia and UAB to have a long and successful history of examining the cognitive effects of cerebrovascular disease and its comorbidities, and aging, including cognitive effects of stroke, carotid artery disease, heart disease, systemic sources of neuroinflammation, and endocrine abnormalities on brain function.

Michael Crowe, PhD (Co-Investigator, 1% salary effort). Dr. Crowe is Professor of Psychology with a specialty in cognitive aging. He oversees cognitive assessments by the UAB Survey Research Unit for the NIH-funded REGARDS study, which has administered more than

90,000 test batteries to date. He is PI of an NIH-funded study on in Puerto Rico that is using a similar Spanish language cognitive battery.

Michael Tyler, BS (Programmer, 15% effort) Based in the UAB School of Public Health, Mr. Tyler will be writing the code that will adapt the cognitive core battery administered by the UAB SRU to the needs of this project, including setting up the reservation system for cognitive testing by the SRU, computer scripting for the test administration by SRU staff, and encryption and transfer of data from the SRU to the study database.

Biostatistician (TBN) This individual, who will be the only unblinded investigator who will have access to both in-person and telephone-based cognitive scores, will be responsible for all data analyses.

Terina Myers, BA (Clinical Coordinator, 15% Effort) Ms Myers will be responsible for coordinating the reservation system and troubleshooting problems in the administration of the cognitive batteries. She will be blinded with respect to in-person neuropsychology test results.

Susan Barber, **BA (UAB Grants Administrator, 3% effort)** Ms. Barber will serve as administrative liaison between UAB and the University of Miami.

Other than Personnel Service:

UAB SRU Testing Fee. Each of the study participants will undergo one cognitive test administrations @ $175 per administration. This is the standard charge by the UAB Survey Research Unit for comparable studies.

UAB OnCore Management System Fee. Every UAB clinical study using any procedure is administered by this unit at an annual fee of $1,000.

University of Miami

Personnel:

Bonnie Levin, PhD (Miami Principal Investigator, No Salary Requested). Based in the Department of Neurology and a senior faculty member of the University of Miami McKnight Brain Institute, Dr. Levin will oversee all project activities at the Miami site.

Gustavo Rey, PhD (Co-Investigator, 20% Effort). Based in the Department of Neurology, Dr. Rey is an expert in English to Spanish translation of neuropsychological tests. He will be responsible for translating the instructions read by the Spanish-speaking SRU test administrator, and for recruiting the major of participants for this project.

Katalina McInerney, PhD, (Co-Investigator, 10% Effort). Based in the Department of Neurology, Dr. McInerney will recruit Spanish speaking subjects from the Miami Neuropsychology Clinic.

Sonya Kaur, PhD (Co-Investigator, 5% Effort). Based in the Department of Neurology, Dr. McInerney will recruit Spanish speaking subjects from the Miami Neuropsychology Clinic.

TBD (Research Coordinator, 15% effort). This individual will coordinate all recruitment activities at the Miami site and will be responsible for data entry for all participants.

Other than Personnel Service

IRB New Study FEE. U Miami's fee for the IRB review.

Compliance Fee. U Miami standard fee for new studies

Participant Incentive. Each of the 60 participants will receive $100 for undergoing cognitive examination.

H. References

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4. Wright CB, Gardener H, Dong C, et al. Infectious Burden and Cognitive Decline in the Northern Manhattan Study. *J Am Geriatr Soc.* 2015;63(8):1540-1545.

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To:
Michael L. Dockery, M.D.
Madhav Thambisetty, MD; PhD
Patricia A. Boyle, Ph.D.
Allison Brashear, M.D., M.B.A
Richard I. Isaacson, M.D.
Susan Pekarske, MD
J. Lee Dockery, M.D. Emeritus
Melanie A. Cianciotto
Trustees, The Evelyn F. McKnight Brain Research Foundation, Inc.
SunTrust Bank
Mail Code 886-73-17-50
333 S. Garland Avenue, 17th Floor,
Orlando, FL 32801

UNIVERSITY OF MIAMI

July 1, 2021

Dear Trustees,

We want to thank you for your generous support that allowed us to demonstrate and establish success in research training of cognitive neurologists. Though your recommendation was that your initial funding was for a pilot, our success has propelled us to ask for your partnership again.

We respectfully request that the McKnight Brain Research Foundation consider an additional gift of $3 million to establish a dedicated program for endowed clinical scholars focusing on age-related changes in memory and cognition. **The Evelyn F. McKnight Neurocognitive Training Fund in Brain Health and Aging** would create:

- **The Evelyn F. McKnight Neurocognitive Junior Faculty Clinical Research Scholar and**
- **The Evelyn F. McKnight Neurocognitive Post Doctoral Clinical Scholar**

For this new commitment, we have already secured a matching gift of $4 million from our long-time supporters and Advisory Council members, Judy and Robert Cornfeld. Their gift will establish the Judy and Robert Cornfeld Neuroimaging Research Center in the McKnight Brain Institute. It is particularly important to this program since it will give us the capability to use this support for neuroimaging research for all MBI research and training activities by our MBI scholars and other MBI investigators.

Our MBI is deeply committed to research education and training of next generation of clinician-scientist capable of performing clinical and translational research in age-related memory loss and cognitive aging and of rapid translation of new discoveries into clinical practice. **The *proposed research training program for clinicians is a unique signature of our MBI. Through this partnership we would be able to cement a strong focus on research in cognitive aging in clinical neurology training and education, and its translation to clinical practice.*** It will offer a unique approach to advancing innovative research training by enhancing our mutual educational goals in the field of neurocognitive disorders and brain health for our junior faculty and post-doc physicians and clinician-scientists.

We are grateful for this opportunity and for the ongoing support of the Evelyn F. McKnight Brain Research Foundation. Should you have any questions please feel free to contact us. Thank you so much for your consideration.

Yours truly,

Ralph L. Sacco, M.D., M.S.
Executive Director
Evelyn F. McKnight Brain Institute

Tatjana Rundek, M.D., Ph.D.
Scientific Director
Evelyn F. McKnight Brain Institute

cc: Amy Porter

Investing in our Future

The Evelyn F. McKnight Neurocognitive Training Fund in Brain Health and Aging

UNIVERSITY OF MIAMI

Presented to the

Evelyn F. McKnight Brain Research Foundation

July 2021

Request for Endowed Funding - $3 Million

We respectfully request that the McKnight Brain Research Foundation expand its investment in the University of Miami's Evelyn F. McKnight Brain Institute with an additional gift of $3 million to establish **The Evelyn F. McKnight Neurocognitive Training Fund in Brain Health and Aging**, to continue our strength in training the next generation of neurocognitive clinician scientists.

For this new commitment, we have a matching gift of $4 million from our long-time supporters and Advisory Council members, Judy and Robert Cornfeld. Their gift will establish the Judy and Robert Cornfeld Neuroimaging Research Center in the McKnight Brain Institute.

Our MBI has been successful in research training of cognitive neurologists and this new commitment would continue this success**. The *proposed research program for clinicians is a unique signature of our MBI. This commitment would allow us to partner to cement a strong focus on research in cognitive aging in clinical neurology training and education, and its translation to clinical practice.***

Evelyn F. McKnight Neurocognitive Training Fund in Brain Health and Aging

Evelyn F. McKnight Neurocognitive Junior Faculty Clinical Research Scholar — $1 Million

The funds generated annually by this endowed gift will offer **one junior faculty member each year** dedicated time to focus on their neurocognitive research initiatives, under the mentorship of the MBI leadership. This grant will move the MBI collaborative research project pipeline forward and provide a research opportunity to advance their academic career in age-related memory loss and cognitive decline.

Evelyn F. McKnight Neurocognitive Post-Doctoral Clinical Scholar — $2 Million

The funds generated annually by this endowed gift will be used to provide **one fully funded two year fellowship** focused on clinical and translational research and patient care. Under the direction of Drs. Sacco and Rundek, this award will help recruit and train scholars to excel in academic medicine and become leaders in the field of cognitive aging, neurocognitive disorders, and brain health.

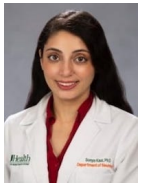
The University of Miami Miller School of Medicine recognizes the importance in investing in our future physician-scientists. Through the MBI's mentorship program our brilliant faculty are dedicated to the encouragement of creative thought, interdisciplinary research endeavors and clinical translational investigations in cognitive neurology and neurosciences. Our goal is to create and develop a centralized core of outstanding physician scientists who are focused on problems of great importance to neurocognitive and brain health.

PROPOSAL: EVELYN F. MCKNIGHT NEUROCOGNITIVE JUNIOR FACULTY CLINICAL RESEARCH SCHOLAR $1 MILLION

Our MBI launched the McKnight Brain Institute Small Pilot Grant in 2017, with a vision to help junior faculty members with promising potential to become successful investigators in age-related memory loss and cognitive decline by providing them with small grant/pilot funding. This opportunity supported their research and considerably help in advancing the MBI collaborative research project pipeline.

Joyce Gomes-Osman, PT, PhD

Sonya Kaur, PhD



Sarah Getz, PhD

Joyce Gomes-Osman, PT, PhD was the first recipient of this small pilot grant to develop a precision medicine approach to the delineation of effective exercise dose to achieve maximal cognitive benefits for older adults. This project examined the influence of a 4-week aerobic exercise regimen on cognition and neuroplasticity. The study results were published in *Neurology Clinical Practice.* Utilizing the experiences learned from the MBI Small Pilot Grant, Dr. Joyce Gomes-Osman received the prestigious KL2 CTSI award funded by NCATS. She also received Training for Grantsmanship in Rehabilitation Research award funded by the NIH, which recognizes outstanding young investigators with high promise for success in the Rehabilitation Research Community. Dr Gomes-Osman has now accepted a leadership position at Linus Health as Director of R&D for mobile technology and brain health, and continues working with us as a Voluntary Faculty in the Department of Neurology.

Sonya Kaur, PhD, in 2020, received MBI support for protected time to explore research into sleep and its effects on cognition in the Hispanic population, Her manuscript, "Differential pathways by age and sex for the association between combined sleep disordered breathing and sleep duration with neurocognitive decline in Hispanic/Latino adults: the Hispanic Community Health Study/Study of Latinos (HCHS/SOL)." has been recently published in *Alzheimers Dementia*. She is now pursuing a K-like award with the AHA and AAN.

Sarah Getz, PhD, in 2020, became the AAN McKnight Clinical Translational Research Scholar in Cognitive Aging and Age-Related Memory Loss for her research project "Uncovering Risk Profiles of Deception and Mitigating Susceptibility to Scamming in Midlife and Older Age: A Novel Intervention Tool". She is now actively pursuing the study enrollment and planning for the a larger K or K-like award.

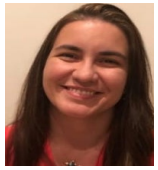
Receiving a grant like the above - MBI Small Pilot or becoming the AAN McKnight Scholar - offered protected time and collaborative mentorship to pursue innovative research. It allowed Drs. Gomes-Osman, Kaur and Getz to focus creativity and time on performing groundbreaking research. The creation of an ***Evelyn F. McKnight Neurocognitive Junior Faculty Clinical Scholar*** *would* allow our MBI to offer in perpetuity, to one promising junior faculty member, each year, protected time for research. It would also formally enable additional training and critical mentorship from a multi-disciplinary group of established researchers needed for successful career in age-related cognitive research.

Endowed scholarships/fellowships are essential to the fulfillment of the University of Miami Miller School of Medicine's academic mission. A fellowship provides the resources to fund a young physician or clinical cognitive scientist's work, reward academic achievement, and enable them to pursue innovative areas of research. Fellowships are often the reason UM can retain the brightest post-docs and young scholars.

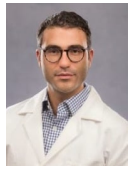
Drs. Camargo, Saporta and Agudelo have been appointed our MBI scholars and have shown special success. They each obtained a broad education in the clinical, neuropsychological, and radiological aspects of age-related cognitive function and neurodegenerative disorders. Their focus was on normal brain changes in aging by attending and actively participating in cognitive clinics, seminars and research projects across departments, Centers and Institutes, and across disciplines. Our cross-disciplinary co-mentorship approach stimulated collaborative research and provided the best clinical training opportunities.

Christian Camargo, MD

Anita Saporta, MD



Christian Agudelo, MD



Christian Camargo, MD was our first clinical neurologist and research MBI fellow in cognitive neurology who completed his training in June 2018 under Drs. Sacco's and Rundek's mentorship. He was recruited as faculty in the UM Department of Neurology Cognitive Division. He continues to be an integral collaborator of our MBI. He was the recipient of the McKnight Clinical Translational Research Scholarship in Cognitive Aging and Age-Related Memory Loss, funded by the MBI Foundation through the American Brain Foundation and the American Academy of Neurology. He is currently completing this award, which was delayed due to the Covid-19 pandemic.

Anita Seixas Dias Saporta, MD was enrolled, under guidance of Dr. Rundek as the second MBI research fellow in July 2019, Dr. Saporta has a strong clinical background in MRI and electrophysiology with a particular research interest in multimodality brain imaging and aging. She continued her fellowship through 2020 to improve her skills in clinical care and enhance her research area. Dr. Saporta is a great example of integrating the MBI and neuro-imaging center as her previous research in brain neuroimaging was funded by the Judy and Robert Cornfeld Neuro-Imaging Research Center endowed gift, housed in our MBI.

Christian Agudelo, MD was awarded, the first ***Evelyn F. McKnight Neurocognitive Post-Doctoral Scholar*** in July 2020. Dr. Agudelo is a neurologist and sleep specialist, and very productive member of our MBI team with several publications in the area of sleep and cognitive decline. The second year of his fellowship will end in June 2022, and he will join our Department as an Assistant Professor of Clinical Neurology in Sleep Division, where he will pursue a combined research and clinical care for patients with sleep and cognitive disorders.

Because of UM's special clinical and translational research expertise and clinical neurology training success we are asking the Foundation to create a fully funded 2-year fellowship, in perpetuity, to ensure the opportunity for young post-doctoral trainees to study age-related memory loss and cognitive decline. We have demonstrated our ability to train our fellows to excel in research and clinical care in preparation for a primarily academic career and to become leaders in the field of neurocognitive disorders and brain health. Preference will continue to be given to MDs in neurology and behavioral neurology, but we will consider PhD candidates in neuroscience, neuropsychology, bioengineering or other related disciplines who are also engaged in clinical care and services.

Extraordinary gifts, such as this, provides the Department of Neurology an opportunity to embark on various momentous undertakings that will demonstrate we are firmly committed to the goal of translating neuroscience discoveries into therapies and cures that can help transform lives. We would be deeply honored if you would consider this most significant gift to benefit the University of Miami's Evelyn F. McKnight Brain Institute and their trainees and scholars to develop into the next generation of clinician-scientist needed to improve brain health and care for a vast number of patients with age-related cognitive disorders in south Florida.

5.b. on the Meeting Agenda

REQUEST "Investing in Our Future"

From: **Fox-Rosellini, Susan Eva** <sfoxrose@med.miami.edu>
Date: Fri, Jul 2, 2021 at 12:09 PM
Subject: Re: [EXTERNAL] Proposal
To: Amy Porter <aporter@mcknightbrf.org>, Cianciotto, Melanie <Melanie.Cianciotto@truist.com>
Cc: Sacco, Ralph L <rsacco@med.miami.edu>, Rundek, Tatjana <TRundek@med.miami.edu>, Koorse, Lena <l.koorse@med.miami.edu>

Happy Friday Amy and Melanie:

Thanks so much for your guidance. You do make us feel as true partners.

Please find attached our request for T**he Evelyn F. McKnight Neurocognitive Training Fund in Brain Health and Aging.** The proposal briefly speaks to our unique strength and success of all our past and current trainees. Currently not only Christian Agudelo, MD but those who have received the AAN/MBRF support Christian Camargo, MD and Sara Getz, PhD. We also included the successes of those who received MBRF pilot grants and our own MBI support.

Should the Foundation have commitments that would allow you not to commit immediately please remember our current scholar is funded till June 2022. We would be happy to work with you on timing over 5 years or new funding could kick in on a cash basis for both proposed scholars until such time as you would be able to fund the endowment.

If you have any questions please feel free to reach out.
Happy July 4th. Enjoy the weekend. Wish us luck as the reality of hurricane season rears its ugly head.

With much appreciation.

Best regards,

Susan

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