

AMERICAN BRAIN FOUNDATION Research Advisory Committee July 27, 2018

3:00 p.m. EST/2:00 p.m. CST/1:00 p.m. MST/12:00 p.m. PST

Call-in number: 866-740-1260 Access code: 9286317

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Committee Members			Robert Griggs, MD, Chair; Raymond Roos, MD, Vice Chair; Carsten Bonnemann, MD; Merit Cudkowicz, MD; Mark Mehler, MD; John Morris, MD; Ralph Sacco, MD; Ira Shoulson, MD; Eugene Scharf, MD; Natalia Rost, MD; Christy Phelps, Deputy ED AAN; Catherine Rydell, CAE		
		Staff	Jane Ransom, Shelly Collins Rucks, Suzi Sherman, Natalie Baumgartner		
	AG	ENDA ITEM		PRESENTED BY	
	1.	Approve May 25, 2018	Minutes (pg. 2)	Dr. Griggs	
10 min	2.	Crowdfunding Marketi	ng Update (pg. 4)	Stephanie Olson	
20 min	3.	. Research Program (pg. 5)		Suzi Sherman	
5 min	4.	RAC Recruitment Upda	ate (pg. 9)	Dr. Griggs	
5 min	5.	Science Committee Meeting Debrief (pg. 19)		Dr. Roos	
5 min	6.	Alzheimer's Association International Conference Debrief		Suzi Sherman	
5 min	7.	'. XPRIZE Update (pg. 20)		Dr. Morris	
5 min	8.	. New LBD awards (pg. 21)		Dr. Morris	
5 min	9.	Research Program Upo Applications" attachme a. Deeb applicati b. Harrington applicati c. Sharma applicati d. Nariai applicati e. Patel applicati f. Pehlivan applicati g. Nicholson app	on olication ation ion on cation	Suzi Sherman	
	Adjou	ırn			



American Brain Foundation Research Advisory Committee Meeting May 25, 2018 3:00 p.m. ET/ 2:00 p.m. CT/ 1:00 p.m. MT/ 12:00 p.m. PT Conference Call

Meeting Minutes

In attendance: Robert Griggs, MD, Chair; Raymond Roos, MD, Vice Chair; Merit Cudkowicz, MD; Mark Mehler, MD; John Morris, MD; Eugene Scharf, MD; Ira Shoulson, MD

Staff: Jane Ransom, Shelly Collins Rucks, Suzi Sherman, Natalie Baumgartner,

Excused: Carsten Bonnemann, MD; Sue Rodmyre, Director ED AAN; Natalia Rost, MD; Ralph Sacco, MD; Christine Phelps, Deputy ED AAN

Dr. Griggs welcomed the Committee.

 RAC recruitment update: The Research Advisory Committee has appointed a vice chair based on performance and active involvement. Dr. Roos will act as Vice Chair of this Committee.

2. Annual Meeting Debrief:

- a. Research Program Luncheon: There were presentations by the CRTS and CSDA recipients, showcasing over 20 people. They had enough time for presentations and one or two questions. All the funding partners were in attendance. It was a great event.
- b. ELA Stage Presentation: Dr. Mehler presented on the new crowdfunding site. There were about 20 people in attendance. Attendees asked if they could include their salary as part of the project proposal. According to its policy, the Foundation allows researchers to include up to 10% of the total project budget for indirects. Ms. Sherman will send the policy to the Committee for review. They asked if they could mix and match grant applications on the same topic. Dr. Mehler told them that they could.

Dr. Mehler discussed the Crowdfunding initiative as a new platform that might be better served by raising funds for specific disease areas rather than individual researchers and their projects. Crowdfunding is very personal. Dr. Griggs acknowledged this topic and explained that marketing the crowdfunding site has been ongoing for four months, and there will be a lot of discussion about crowdfunding moving forward.

c. Research Symposium: Dr. Scharf presented at the Innovation Hub and the Research Career Symposium. The presentation at the Innovation Hub was not well attended, but this could be because the name and time were wrong by 30minutes. The primary questions were around idea theft. The presentation at the Research Career Symposium was well attended with over 60 people. Some questions were around international investigators, projects that are underfunded, salary support, and idea theft.

The Committee agreed that idea theft has not been discussed during these calls, but the consensus was that this was an issue for most grants. The language on the website is also vague enough that it is not a practical concern, and idea theft would be difficult to accomplish.

3. American Brain Foundation's statement on mental illness: The mental illness statement written by Dr. Mehler is going to be put into practice. Ms. Sherman drafted a memo proposing to create a new disease category on the crowdfunding site "Neuropsychiatry". The FAQs for the crowdfunding site will include the mental illness statement. It will be up to the researcher to prove how neurology and psychiatry meet in their project. Dr. Roos will present the mental illness statement at the upcoming AAN Science Committee meeting.

The Committee agreed that a term such as "Mental Illness" or "Mental Health in Neurological Diseases" should be a category title. Ms. Sherman will come up with the best category based on this feedback. There is overlap between psychiatry and neurology, and psychiatrists should be notified of the crowdfunding site becoming available to their proposals.

- 4. Lewy Body Dementia (LBD) Subcommittee meeting: This subcommittee will be designing two awards: 1) a career development award for an early stage investigator in LBD; and 2) a larger award designed to support the research of an established investigator. LBD bridges several disciples, so many people can apply. The subcommittee will be looking at other awards in the field, and the Committee would need to approve the overall awards.
- 5. **Donor Advised Fund:** The Foundation has Donor Advised Funds. These funds go through the Research Advisory Committee for approval, when it does not go through the AAN process. The Committee is sometimes asked to recommend research funding opportunities to the Foundation, and the Foundation would like to have documentation in place about what is required for an investigator to submit a project for this money.

Approval of March 23, 2018 Meeting Minutes.

Approved. (Unanimous)

Adjourn 2:45 p.m. (Central).



TO: American Brain Foundation Research Advisory Committee

FROM: Stephanie Olson, Marketing & Communications Manager

DATE: July 27, 2018

SUBJECT: Crowdfunding Marketing Plan

Dear Research Advisory Committee,

In May the Board of Directors approved to move forward with the Foundation's recommended business strategy for the crowdfunding platform. Below is an overview of the strategy that the Foundation has begun executing.

Please feel free to reach out to Jane with any questions.

Thank you, Stephanie

Pipeline Marketing Approach

The Foundation staff that supports crowdfunding has spent the last three months solidifying a marketing strategy for the crowdfunding platform. The strategy we are moving forward with closely mirrors the traditional crowdfunding model. Armed with a robust marketing guide, toolkit and consultation from our marketing manager, researchers will lead the marketing efforts for their projects. In most cases, the Foundation will function as a platform and our focus will be on building a pipeline of researchers to flow through the crowdfunding site, contributing to greater awareness of the Foundation. Select projects through the year will qualify for full-fledged marketing support from the Foundation in the form of a marketing campaign activated on the American Brain Foundations marketing channels. Projects that receive this support will meet stringent criteria, including: projects that have mass appeal, are timely and relevant to the general population, the researcher has an institution that is willing to engage in marketing activities, we have pre-arranged funding to seed the project for success, etc. We are confident in this approach as it balances industry trends while being realistic about the Foundation's current resources.



TO: American Brain Foundation Research Advisory Committee

FROM: Suzi Sherman, Program Officer, Research & Digital Grants

DATE: July 27, 2018

SUBJECT: Research Program Strategy

Dear Research Advisory Committee,

The Foundation has ambitious goals for its crowdfunding site and cornerstone research program to continue supporting 20 Clinical Research Training Scholarships and Clinician Scientist Development Awards. To achieve these goals the Foundation must overcome several challenges, including getting approval from institutions to allow their researchers to crowdfund on our site and affording the administrative/program costs for the CRTS/CSDA awards. To date, 2 researchers have rescinded their crowdfunding applications because of their institutions' restrictions and the administrative costs for the 2018 CRTS/CSDA awards is roughly \$93,000. The American Brain Foundation requests the assistance of the RAC to address these issues.

Crowdfunding restrictions at institutions:

The Foundation has had conversations with several other crowdfunding organizations, including Diabetes Research Connection and Consano. Based on our discussions we have determined that we need to have conversations with institutions' development/grant departments to answer questions and alleviate any concerns they have about crowdfunding. These conversations should illustrate the value crowdfunding adds to the institution and its researchers.

We would like to start with the institutions that we have a connection to and so we ask that each Research Advisory Committee member connects us with your institution's development or grants department to schedule a meeting. Eventually, we would like to list all of the institutions we work with on our crowdfunding website.

Administrative/Program costs for CRTSs/CSDAs:

The Foundation has a grant from the American Academy of Neurology to help fund the costs of the CRTSs/CSDAs. The Foundation anticipates expending that grant by 2022. Enclosed is a forecast of the costs associated with the CRTSs/CSDAs for 2018-2022. As you can see, as the Foundation spends more of the AAN's grant each year, the amount of money the Foundation is responsible for raising increases. The biggest issue we face is raising funds to support our administrative (aka program) costs to administer and manage the CRTS/CSDA program. From 2018 to 2022 we anticipate the admin costs increasing from \$93K to \$133K.



In order to sustain our program goals, the Foundation needs admin support. As leaders at your institutions, you're no stranger to this issue that we are facing and **ask for suggestions on how to address this issue**.

One approach the Foundation will take in 2019 to address this issue is to strengthen current and prospective partnerships. We will focus on 6 organizations in 2019,

- 1. American Brain Tumor Association currently trying to jointly fundraise to support a CRTS and one of the ABTA's research awards, but no historical partnership with them
- 2. Lewy Body Dementia Association currently engaging them with the development of two new awards in LBD, but no historical partnership with them
- 3. Alzheimer's Association longstanding partnership with them to fund CRTS's
- 4. The ALS Association longstanding partnership with them to fund CRTS's & CSDA's
- 5. McKnight Brain Research Foundation new partnership (since 2018) to fund 10 CRTS's
- 6. The Mary E. Groff Charitable Trust new partnership (since 2018) to fund CRTS's in DLB/LBD

As noted, some of these are prospects, some are brand new partners, and some are longstanding partners. The objective of this narrowed focus is to create new and expand on existing partnerships with the hope that each organization will either fully fund the CRTS/CSDA and/or fund a portion or all of our administrative costs for their specific award(s).

We will execute the following actions to strengthen these relationships:

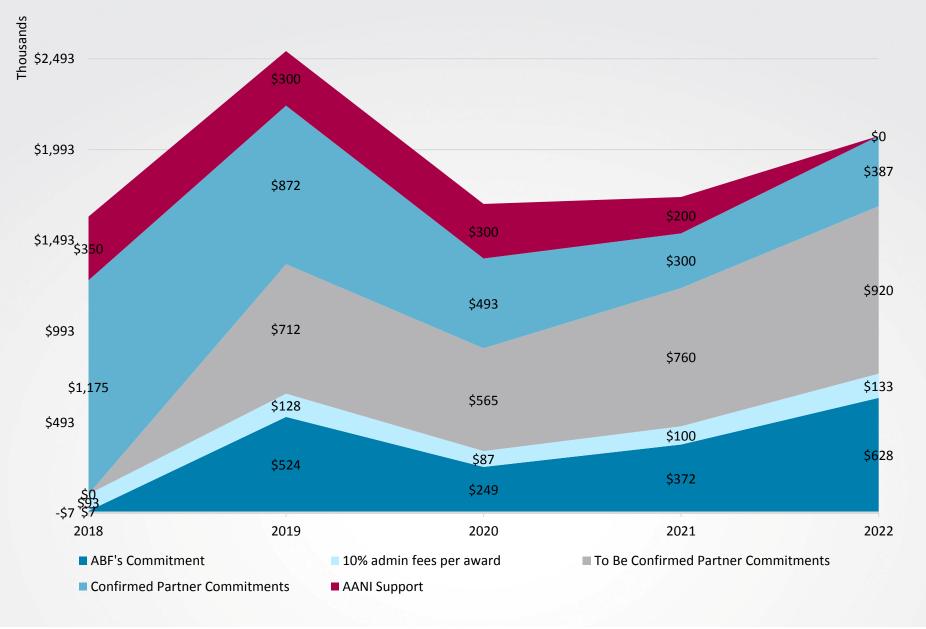
- Send them special invitations to any ABF events in 2019, including the CRTS/CSDA
 breakfast/lunch event held at the Annual Meeting and our Commitment to Cures event
- Plan to travel to their offices for a face-to-face meeting
- Exhibit/attend their annual conferences
- Periodically send them ABF updates, e.g. our annual report, and check-in with them

We appreciate your insight and suggestions on these issues.

Thank you, Suzi

February 2018 Forecast

5 Year Research Program Forecast



	2018	2019	2020	2021	2022
Research Program Total	\$1,624,700	\$2,534,700	\$1,694,200	\$1,732,200	\$2,068,000

Assumptions:

- 1. YTD AANI support is \$1.15M and the ABF is forecasting to use \$350,000 in 2018, \$300,000 in 2019 & 2020, and \$200,000 in 2021.
- 2. In cases where the ABF has more than one award with a partner in any given year, AANI admin fee is \$5K total (per partnership) instead of per award
- 3. 2018 is based on actual commitments, 2019 is based on projections, and 2020-2022 is based on benchmarks agreed upon with AANI
 - a) 2018 = 11 total: 9 CRTS's/2 CSDA's;
 - b) 2019 = 15 total: 11 CRTS's/4 CSDA's;
 - c) 2020 = 11 total: 9 CRTS's/2 CSDA's;
 - d) 2021 = 11 total: 9 CRTS's/2 CSDA's;
 - e) 2022 = 12 total: 9 CRTS's/3 CSDA's
- 4. In 2019, the cost of a CRTS increased to \$150,000
- 5. Hearst Foundation's grant to support the research program is included in the "Confirmed Partner Commitments" in 2018, \$90,000 of the \$100,000 is included. The remaining \$10,000 is budgeted in under "Unrestricted" to cover overhead.
- 6. "10% admin fees" includes MBRF's \$30K/yr (2018-2022) and ALS's \$13K/yr (2019 & 2020)



BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors. Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME: Zee, Phyllis C.

eRA COMMONS USER NAME (credential, e.g., agency login): PHYLLISZEE

POSITION TITLE: Professor

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Mills College, Oakland, CA	B.A.	06/1976	Biology
Chicago Medical School, North Chicago, IL	Ph.D.	06/1980	Physiology
Chicago Medical School, North Chicago, IL	M.D.	06/1983	Medicine
Northwestern University Medical School	Residency	06/1987	Neurology
Northwestern University Medical School	Postdoctoral	06/1989	Neurobiology& Physiology
University of Chicago	Fellowship	06/1990	Sleep Medicine

A. Personal Statement

I have expertise and extensive experience in basic, translational research and clinical trials in the area of sleep and circadian biology. I am currently the Director of the Center for Circadian and Sleep Medicine (CCSM) and the Chief of the Division of Sleep Medicine in the Department of Neurology at Northwestern University Feinberg School of Medicine; and, Associate Director of the Center for Sleep and Circadian Rhythms at the Evanston campus of Northwestern University. My research focuses on understanding the mechanisms that link alterations in sleep, circadian rhythms and sleep disorders, such as in pregnancy, aging, and neurodegenerative and cardio-metabolic disorders. Our group has also prioritized research to develop treatments for sleep and circadian based disturbances in populations at risk. I am the principal investigator of a P01 on the role of circadian clocks in metabolic aging that includes basic animal and human translational mechanistic studies. I also sever as PI or collaborator in several NIH funded studies to understand the mechanisms linking sleep quality and circadian alignment with neurocognitive impairment, mood, cardiovascular and metabolic risk in populations at risk for sleep and circadian disorders, such pregnant women and older adults. Although my research currently focuses on pre-clinical and clinical studies, I have substantial experience in basic sleep and circadian research using animal models. My laboratory has maintained an active animal sleep and circadian research facility. My career as a translational scientist brings an integrative perspective to interdisciplinary research on understanding the mechanisms linking sleep and circadian rhythms with neurologic and cardiometabolic health. In addition to my scientific expertise and experience, I have substantial experience as a mentor for pre-doctoral students and post-doctoral students, and I have served as primary mentor for four K23 Junior Faculty awardees.

- a. Sheward WJ, Naylor E, Knowles-Barley S, Armstrong JD, Brooker GA, Seckl JR, Turek FW, Holmes MC, Zee PC, Harmar AJ. Circadian control of mouse heart rate and blood pressure by the suprachiasmatic nuclei: behavioral effects are more significant than direct outputs. PLoS One. 2010 Mar 22;5(3):e9783. PMID: 20339544; PMCID: PMC2842429
- b. Mander BA, Reid KJ, Davuluri VK, Small DM, Parrish TB, Mesulam MM, Zee PC, Gitelman DR. Sleep deprivation alters functioning within the neural network underlying the covert orienting of attention. Brain Res. 2008 Jun 27;1217:148-56. PMID: 18511023; PMCID: PMC2528837

- c. Mander BA, Reid KJ, Baron KG, Tjoa T, Parrish TB, Paller KA, Gitelman DR, Zee PC. EEG measures index neural and cognitive recovery from sleep deprivation. J Neurosci. 2010 Feb 17;30(7):2686-93. PMID: 20164352; PMCID: PMC2835412.
- d. Cheung IN, Zee PC, Shalman D, Malkani RG, Kang J, Reid KJ. Morning and Evening Blue-Enriched Light Exposure Alters Metabolic Function in Normal Weight Adults. PLoS One. 2016 May 18;11(5):e0155601. PMID: 27191727; PMCID: PMC4871543.

Positions and Honors.

RESEARCH AND PROFESSIONAL EXPERIENCE

1983 – 1987	Internal Medicine and Neurology Residency at Northwestern University Medical School
1987 – 1989	Postdoctoral Fellow at Northwestern Univ., Neurobiology and Physiology Dept.
1989 – 1996	Assistant Professor of Neurology, Neurobiology and Physiology, Northwestern University
1990 – Present	Director, Northwestern Memorial Hospital Sleep Disorder Center
1996 – 2001	Associate Professor of Neurology, Neurobiology and Physiology, Northwestern University
2001 – Present	Professor of Neurology, Neurobiology and Physiology, Northwestern University
1990 – Present	NIH (NICHD, NIA, NHLBI, NCI) ad hoc special emphasis and study section review panels
1998 – 2005	NIH PRDP Study Section Member
2001	Howard Hughes Medical Institute Fellowship Committee
2002 – 2004	Chair, CRSD International Classification of Sleep Disorders Manual Revision Committee
2003 – 2009	Board of Directors, National Sleep Foundation
2004 - Present	DSMB member NIH/NHLBI
2005 – 2012	Director, Sleep Medicine Fellowship, Northwestern University
2005 – 2009	Member Sleep Disorders Research Advisory Board, NIH
2006 – 2009	Chair, Sleep Disorders Research Advisory Board, NIH
2007 – 2013	Board of Directors, Sleep Research Society
2011 – 2012	President, Sleep Research Society
2012 – 2013	President, Sleep Research Society Foundation
2013 – 2014	Association of Professional Sleep Societies Program Committee Member
2014 - Present	Director, Center for Circadian and Sleep Medicine, Feinberg School of Medicine
2015 - Present	National Heart, Lung and Blood Advisory Council
2016 - Present	Chief, Division of Sleep Medicine, Dept. of Neurology, Feinberg School of Medicine

CERTIFICATION

- 1984 Diplomate of the National Board of Medical Examiners, parts I, II, III
- 1988 Diplomate of the American Board of Psychiatry and Neurology (Neurology)
- 1990 Diplomate of the American Board of Sleep Disorder Medicine and Clinical Polysomnography
- 2008 Diplomate American Board of Psychiatry and Neurology (Sleep Medicine)
- 2018 Diplomate American Board of Psychiatry and Neurology (Sleep Medicine)

HONORS AND AWARDS

1994	Brookdale National Fellow
1997	Sleep Academic Award (NIH)
2005 - 2017	Best Doctors in America

2012 American Academy of Neurology Sleep Science Award

2014 American Academy of Sleep Medicine William C. Dement Academic Achievement Award

C. Contribution to Science

1. Aging and its effects on sleep and circadian systems in animals

Our early studies, initiated while I was a postdoctoral fellow (1987), demonstrated that aging had important effects on the circadian clock system and how these changes were related functional impairment in animals. Among the most notable findings were that aging: 1) increased the fragmentation of circadian rhythms; 2) decreased the response of the central circadian clock to both photic and non-photic stimulus, and 3) altered light-induced gene expression in the circadian clock. This early work led to the recognition that age-related changes in circadian rhythms may be potential targets for delaying common age-related cognitive and physical impairments.

- a. Rosenberg, RS, Zee, PC and Turek, FW, Phase response curves to light in young and old hamsters, *Am J Physiol*, 261 (1991) R491-5. PMID: 877706
- b. Zee, PC, Rosenberg, RS and Turek, FW, Effects of aging on entrainment and rate of resynchronization of circadian locomotor activity, *Am J Physiol*, 263 (1992) R1099-103. PMID: 1443228
- c. Labyak, SE, Turek, FW, Wallen, EP and Zee, PC, Effects of bright light on age-related changes in the locomotor activity of Syrian hamsters, *Am J Physiol*, 274 (1998) R830-9. PMID: 9530252
- d. Benloucif S, Green K, L'hermite-Baleriaux M, Weintraub S, Wolfe LF, Zee PC. Responsiveness Of the aging circadian clock to light. *Neurobiol Aging*, 2005. PMCID: PMC1866218

2. Effects of aging on circadian and sleep regulation in humans

Our work in animals opened up new avenues for understanding the relationship between dysregulation of the circadian system and sleep with increased risk for cognitive and cardio-metabolic disorders in older adults. Furthermore, we developed behavioral, environmental and pharmacologic approaches for improving sleep and circadian-related function in older adults.

- a. Naylor, E, Penev, PD, Orbeta, L, Janssen, I, Ortiz, R, Colecchia, EF, Keng, M, Finkel, S and Zee, PC. Daily social and physical activity increases slow-wave sleep and daytime neuropsychological performance in the elderly, Sleep, 23 (2000) 87-95. PMID: 10678469
- b. Baehr, E, Ravelle, R, Eastman, C and Zee, PC. Circadian phase shifting effects of nocturnal exercise in older compared with young adults. *Am. J. Physiol.* 284: R 1542-R1550, 2003. PMID: 12573982
- c. Benloucif S, Green K, L'hermite-Baleriaux M, Weintraub S, Wolfe LF, Zee PC. Responsiveness of the aging circadian clock to light. *Neurobiol Aging*, 2006. PMCID: PMC1866218
- d. Westerberg CE, Florczak SM, Weintraub S, Mesulam MM, Marshall L, Zee PC, Paller KA. Memory improvement via slow-oscillatory stimulation during sleep in older adults. Neurobiol Aging. 2015. Sep;36(9):2577-86. PMID: 26116933; PMCID: PMC4523433.

3. Sleep and circadian rhythm disorders and their impact on health

One of the goals of my career is to translate the basic animal and human science on sleep and circadian rhythms to clinical practice and to help develop evidence based practice guidelines on circadian rhythm disorders. I served as chair of the Circadian Rhythm Sleep Disorders Section of International Classification for Sleep Disorders (2005; 2013). We are one of the leading programs in clinical circadian medicine, research and education. Our group has made significant contributions to the concept that circadian timing is critical for health.

- a. Mundey K, Benloucif S, Harsanyi K, Dubocovich ML, Zee PC. Phase-dependent treatment of delayed sleep phase syndrome with melatonin. *Sleep* 28(10):1271-8, 2005. PMID: 16295212
- b. Dawson D, Zee P. Work hours and reducing fatigue-related risk: good research vs good policy. *JAMA*. Sep 7:294 (9):1104-6, 2005, PMID: 16145032
- c. Reid, KJ, Chang, AM, Dubocovich, ML, Turek, FW, Takahashi, JS and Zee, PC. Familial advanced sleep phase syndrome, *Arch Neurol*, 58 (2001) 1089-94. PMID: 11448298
- d. Videnovic A, Klerman EB, Wang W, Marconi A, Kuhta T, Zee PC. Timed Light Therapy for Sleep and Daytime Sleepiness Associated With Parkinson Disease: A Randomized Clinical Trial. JAMA Neurol. 2017 Apr 1;74 (4): 411-418. PMID: 28241159.

4. Timing of sleep, feeding and light exposure impact weight and metabolic regulation

Our modern lifestyle is accompanied by self-imposed sleep deprivation, later sleep and feeding times and light exposure at night. The circadian system and sleep play important roles in regulating the timing of physiological and behavioral circadian rhythms such as rest and activity patterns, alertness, hunger/appetite, and blood glucose and insulin sensitivity. Our group demonstrated a relationship between later feeding and caloric intake with increased appetite for unhealthy foods and higher body weight. In addition, moderate to bright light exposure later in the day when compared to the morning was associated with higher body mass index. These results add to the emerging evidence that it's not just about the calories, but also the timing of consumption that is important for metabolic regulation.

- a. Dewan K, Benloucif S, Reid K, Wolfe LF, Zee PC. Light-Induced Changes of the Circadian Clock of Humans: Increasing Duration is More Effective than Increasing Light Intensity. Sleep. 2011 May 1;34(5):593-9. PMCID: PMC3114508
- b. Baron KG, Reid KJ, Kern AS, Zee PC. Role of Sleep Timing in Caloric Intake and BMI. Obesity (Silver Spring). 2011 Jul;19(7):1374-81. PMID: 21527892

- c. Reid KJ, Santostasi G, Baron KG, Wilson J, Kang J, Zee PC. Timing and intensity of light correlate with body weight in adults. PLoS One. 2014 Apr 2;9(4):e92251. PMCID: PMC3973603
- d. Reid KJ, Baron KG, Zee PC. Meal timing influences daily caloric intake in healthy adults. Nutr Res. 2014 Nov; PMID: 25439026. PMCID: PMC4794259

5. Sleep and circadian rhythms and adverse pregnancy outcomes

Data regarding the impact of short sleep duration and circadian misalignment on pregnancy outcomes is limited. In 2009, we demonstrated that poor sleep quality and short sleep duration is common in pregnancy. We went on to show that snoring and insufficient sleep increases the risk of gestational diabetes. Because sleep disturbances are potentially modifiable risk factors for adverse pregnancy outcomes, this area of research has significant public health impact.

- a. Facco FL, Kramer J, Ho KH, Zee PC, Grobman WA. Sleep disturbances in pregnancy. *Obstet Gynecol.* 2010 Jan;115(1):77-83. PMID: 20027038
- b. Facco FL, Liu CS, Cabello AA, Kick A, Grobman WA, Zee PC. Sleep-Disordered Breathing: A Risk Factor for Adverse Pregnancy Outcomes? Am J Perinatol. 2012 Apr;29(4):277-82. PMID: 22105436
- c. Facco FL, Ouyang DW, Zee PC, Strohl AE, Gonzalez AB, Lim C, Grobman WA. Implications of sleep-disordered breathing in pregnancy. Am J Obstet Gynecol. 2014 Jun;210(6):559.e1-6. PMID: 24373947; PMCID: PMC4511595
- d. Facco FL, Grobman WA, Reid KJ, Parker CB, Hunter SM, Silver RM, Basner RC, Saade GR, Pien GW, Manchanda S, Louis JM, Nhan-Chang CL, Chung JH, Wing DA, Simhan HN, Haas DM, Iams J, Parry S, Zee PC. Objectively measured short sleep duration and later sleep midpoint in pregnancy are associated with a higher risk of gestational diabetes. Am J Obstet Gynecol. 2017 Oct;217(4):447.e1-447.e13. PMID: 28599896; PMC5783638.

List of published work: http://www.ncbi.nlm.nih.gov/pubmed/?term=phyllis+zee

D. Research Support

1U10 HL119992 Grobman (PI)

08/24/2013 - 08/30/2018

NICHD

Pregnancy as a Window for Future Cardiovascular Health

NICHD is currently conducting a large study that looks for tests to identify the risk of developing pregnancy problems in women who are pregnant for the first time. In this new study, the same women in the current study will be tested again at approximately two years after they give birth to see if there are early signs of heart disease in those who had problem pregnancies. Information from this follow-up study will be used to improve the health of women using their experiences during pregnancy.

Role: Sleep Group Lead and Co-I

R01HL114529 (Ong)

09/1/2012 - 06/30/2019 (NCE)

NIH/NHLBI

Multidisciplinary Treatment for Obstructive Sleep Apnea and Insomnia \$278,500

The purpose of this research project is to determine the efficacy of a multidisciplinary treatment model for patients with OSA and comorbid insomnia. The specific aims are to determine the efficacy of a treatment model combining CBT and CPAP for individuals with OSA and comorbid insomnia and to determine if there are relative benefits in the sequence of treatment initiation.

Role: Co-I

R01HL134015-01 (Pack)

08/15/2016 - 04/30/2020

NIH/NHLBI

Approaches to Genetic Heterogeneity of Obstructive Sleep Apnea

Obstructive sleep apnea (OSA) is a common disorder with multiple adverse consequences. It is known that OSA has a genetic basis, but to date no convincing gene variants have been identified. This study uses state of the art approaches to identifying relevant genes based on a very large sample of patients with OSA obtained from multiple institutions in the United States. It is by far the largest study ever proposed for identifying genes for this common sleep disorder.

Role: Site PI

P01 AG011412-18A1 (Zee)

09/15/2017 - 05/31/2022

National Institute on Aging

Alterations of Sleep and Circadian Timing in Aging

The proposal focuses on the interactions between peripheral tissue clocks, sleep and centrally regulated circadian rhythms in the age-related increase in metabolic disease. A multi-disciplinary and multi-institutional approach combining basic (Project 1), translational and clinical (Projects 2 & 3) studies will employ genetic, biochemical, molecular and integrative physiologic approaches to determine the role of age-related clock system disruption on the deterioration of cardiometabolic health, sleep and circadian rhythms in aging. Role: Principal Investigator

R01 HL140580-01 (Zee)

09/15/2017 - 05/31/2022

National Heart, Lung and Blood Institute

Strengthening Circadian Signals to Enhance Cardiometabolic Function

The overall goal of this study is to elucidate the physiological and molecular mechanisms that underlie the relationship between circadian dysregulation and obesity associated cardiometabolic disease risk. This will be accomplished by strengthening the amplitude of circadian metabolic signals via extended overnight fasting and enhancement of nocturnal circadian signaling with exogenous melatonin in overweight and obese middle aged and older adults.

Role: PI

Completed Research Support (Selected, Past 3 Years)

Dixon Research Grant Zee (PI) 01/01/2013 - 12/31/2017

Northwestern Memorial Foundation

Sleep Disturbance & Metabolic Syndrome

The overall goal of this project is to determine the ability of sub-threshold acoustic stimulation to enhance slow wave sleep, blood pressure and glucose regulation in patients with metabolic syndrome.

Role: PI

R01 HL105549 Zee and Grobman (MPI)

06/01/2011 - 10/30/2016

NIH/NHLBI

Sleep Disturbance and risk for adverse pregnancy outcomes

The overall goal of this proposal is to form the basis for future studies to determine whether screening for and treatment of sleep disturbances during pregnancy is an effective strategy to improve pregnancy outcomes.

Role: Principal Investigator

UM1HL112856 Carley, Radulovacki & Zee (MPI) 05/15/2012 - 06/30/2016

NIH/NHLBI

Cannabimimetic Treatment of Obstructive Sleep Apnea: A Proof of Concept Trial

The overall goal of this project is to identify novel treatments for obstructive sleep apnea (OSA) that would be of great public health significance, because fully effective and acceptable OSA treatments are lacking. A critical need remains for NIH supported, mechanistically driven proof-of-concept clinical studies to evaluate novel therapeutic strategies.

Role: Principal Investigator

P01 AG11412 Van Cauter (PI)

05/15/2009 - 03/31/2016

NIH/NIA/ University of Chicago

"Alterations of Sleep and Circadian Timing in Aging" Project 1: Insomnia and cardiometabolic risk
The overall goal is to define the sleep and cardio-metabolic phenotypes of individuals with the most common types of age-related insomnia

Role: Institution PI

BIOGRAPHICAL SKETCH DO NOT EXCEED FIVE PAGES.

NAME: Cavazos, Jose E.

eRA COMMONS USER NAME (credential, e.g., agency login): cavazosi

POSITION TITLE: Assistant Dean & Professor of Neurology, Neuroscience and Physiology

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Completion Date MM/YYYY	FIELD OF STUDY
Instituto Tecnológico de Monterrey (ITESM),	M.D.	10/1987	Physician and Surgeon,
Monterrey, México			(Cum Laude)
University of Wisconsin at Madison	Ph.D.	08/1993	Neuroscience
University of Wisconsin at Madison	Internship	06/1993	Internal Medicine
Duke University, Durham, NC	Residency	06/1996	Neurology
Duke University, Durham, NC	Fellowship	06/1997	Clinical Neurophysiology & Epilepsy
University of Texas at San Antonio	Graduate Certificate	08/2016	Business of Health

A. Personal Statement

I am a Clinician-Scientist-Educator in Epilepsy with substantial activity in each of these endeavors. Every week, I see Epilepsy patients, interpret Clinical Neurophysiological studies, and participate in our Epilepsy Surgical Case conference. With another clinical partner, we have built the largest clinical Epilepsy center in Texas with 9 clinical epileptologists, 2 epilepsy surgeons, 2 neuropsychologists, and 14 epilepsy monitoring beds. I direct our clinical neurophysiology fellowship with 3 fellows per year. As a clinician-scientist, I critically evaluate clinical practice and have participated in many clinical trials in Epilepsy. I recently took a bench hypothesis about synergistic mechanisms of action of antiepileptic drugs, and evaluated how to combine medications in a 94 Million health care claim database. Until 2016, I also kept an active bench research laboratory at the VA Medical Center, where I examined the role of hippocampal circuit plasticity as mechanism of epileptogenesis in experimental models of epilepsy. I now work with a team of 3 talented PhD Faculty trying to understand mechanisms of post-traumatic epilepsy in a novel animal model with two DoD awards, and I am a co-Investigator in both awards. Given my passion for remaining a triple- threat academic physician, I couldn't pass up the opportunity of becoming the Director of the MD/PhD Program in 2011, and mentoring 35-40 future clinician scientists at any given time. I have graduated 28 students with their PhD degrees including 21 students with both MD and PhD degrees. For the past 7 years, I have been responsible for recruitment, admissions, curriculum, mentoring, student affairs, financials, and development in the Dean's offices of the Graduate and Medical Schools as it pertains to the MD/PhD Program. At the same time, I mentored several junior faculty members who have successfully obtained independent funding, including one becoming a NRC Senior Research Associate). For 3 years (2014-17), I also had the opportunity of using my mentoring experience to support the development of junior faculty in the CTSA KL2 Program overseeing 25 junior faculty. I embraced the opportunity to mentor and support the career development of clinician-scientists at all stages as they develop into independently funded investigators. Since May 2016, I returned full-time to my University positions to focus my efforts in these critical missions for a robust institutional clinician-scientist workforce while remaining active as an investigator, clinician and educator. I am committed to mentor and sponsor the next generation of physician scientists at the UT Health San Antonio. I have shown passion, commitment and dedication to these goals.

Positions and E	Employment
1997-2000	Assistant Professor of Neurology - University of Colorado Health Sciences Center (UCHSC)
1999-2000	Assistant Professor of Neuroscience – UCHSC, Denver, CO
2000-2008	Assistant Professor of Neurology and Pharmacology – Univ. of Texas Health Science
	Center at San Antonio (UTHSCSA), San Antonio, TX
2001-2016	Staff Physician (6/8th) - Audie L. Murphy Veterans Administration Hospital (ALM VAH)
2001-2010	Director of the Epilepsy Center – ALM VAH, San Antonio, TX
2001-2012	Director of Research – South Texas Comprehensive Epilepsy Center, UTHSCSA
2005-Present	Clinical Neurophysiology Fellowship Director (ACGME accredited, PGY5), UTHSCSA
2005-2012	Co-Director – South Texas Comprehensive Epilepsy Center, UTHSCSA
2006-2010	Director of the Neurodiagnostic Center – ALM VAH
2008-2011	Associate Professor (with Tenure) of Neurology, Pharmacology and Physiology – UTHSCSA
2009-Present	Co-Founder and Consultant, LGCH, Inc. (DBA: Brain Sentinel), San Antonio, TX
2010-2016	Director of the San Antonio VA Epilepsy Center of Excellence (ECoE) – ALM VAH
2011-2012	Interim Director – MD/PhD Program – UTHSCSA
2011-Present	Professor (with Tenure) of Neurology, Neuroscience and Physiology – UTHSCSA
2012-Present	Assistant Dean and Director, MD/PhD Program – SOM/GSBS – UTHSCSA
2014-2015	Acting Chief, Neurology Section, ALM VAH for 12 months acted as Chief of Neurology
2014-2017	CTSA Mentored Research Career Development (KL2) Program Director – UTHSCSA
Other Experience	ce and Professional Memberships
1995-1996	Chief Resident of Neurology - Duke University/Durham VA Hospital
1998-2006	American Epilepsy Society (AES) Student and Resident Education Committee – Member
	('98), Vice-chair ('99), Chair ('00-'03), Ex-officio ('03-'06).
1998-2000	Faculty Senator – Univ. of Colorado Health Science Center
1998-2000	Finance committee – Dept. of Neurology – Univ. of Colorado Health Science Center
1999-2003	Co-Chair – TOP Scholar program at the annual meeting of the AES
2000-2010	AES – Council of Education - member ('00-'06; '08-'10)
2002-2003	Brain Disorders & Clinical Neuroscience-1(BDCN-1) NIH study section; Ad-hoc ('02),
	member ('03)
2003-2006	Clinical Neuroscience and Disease (CND) NIH study section – Member ('03-'06)
2005-2011	AES Technology / Webcontent committee – Chair ('06-'09), Ex-officio ('10-'11)
2006, 2013	Wellcome Trust, UK – Ad-hoc reviewer
2006-2009	CURE Foundation – Ad-hoc reviewer
2006-2012	AES International Affairs committee – Member ('06-'12)
2006-2010	Medical Research Council (Singapore) – Ad hoc reviewer
2008-2008	NINDS Fellowships Review NIH Study Section – Ad hoc reviewer
2007-2017	Latin American Education Task Force – North American Region of International League
	Against Epilepsy (ILAE), member (2007-2013), Chair (2013-17)
2007-2010	AES Scientific Program Committee – member ('07-'08), Vice-Chair ('09), Chair (2010)
2007-2010	AES Annual Meeting Committee – member ('07-'10)
2007-2012	AES Operation Giveback Task Force - member ('07-'12)
2007-2018	Medical School Admissions Committee – UTHSCSA
2008	Brain Disorders and Clinical Neuroscience- 3 (Member conflict) NIH Study sec. – Ad-hoc
2008, 2010	ILAE Visiting Professor – Partnering of Epilepsy Centers in the Americas
2008-2011	GME Internal Review panel – program director representative – UTHSCSA
2008-2012	NST-2 Fellowship Review NIH Study Section – Member
2009-2011	AES Council of Communication - Member
2009-2019	Editorial Board Member, Epilepsy Research (Elsevier)
2009-2010	American Academy of Neurology, Editorial board member of Science section of AAN.com
2010-2014	Finance committee member – Dept. of Neurology - UTHSCSA
2010-2019	Editorial Board Member, Epilepsy and Behavior (Elsevier)
2010, 2018	PCNS Federal Drug Administration (FDA) Advisory Panel member (Ezogabine, Phenytoin
2010 2011	IV, Cannabidiol)
2010-2011	MD/PhD Promotions Committee Chair – UTHSCSA
2012-2014	HHMI Med Fellows Program review committee Membership committee American Clinical Neurophysiology Society (ACNS)
2012-2019	Membership committee, American Clinical Neurophysiology Society (ACNS)

2013 2013 2013-2017 2014 2015-2017 2015-2020 2016-2019 2017-2020	FDA Neurological Devices Advisory Panel, voting member (Neuropace) NIH Fogarty International Brain Disorders Study Section (BDCN-N-55) Elected as a Board member and Treasurer for North American Commission of ILAE ('13-'17) NIH/NIGMS T32 Special Emphasis Panel (Member Conflict MSTP) AES Finance Committee ('15-'17) Science Committee, American Academy of Neurology (AAN) AAMC MD/PhD Section of GREAT – elected steering committee member AES Spanish Symposium Committee
Honors	7.20 Opariion Oymposiam Committee
1987	M.D. with "Mención Honorífica" (Cum Laude), ITESM
1995	Honorary Fellow in Epilepsy - University of Wisconsin at Madison
1997	Junior Faculty Award – Howard Hughes Medical Institute/Univ. of Colorado SOM
1998-2001	NRSA – K-08 Award from NINDS
2009	Elected Fellow of the American Academy of Neurology (AAN)
2009	Elected Fellow of the American Neurological Association (ANA)
2009-2018	America's Top Doctors, Neurology, Castle Connolly
2010-2018	US News & World Report Top Doctors, Neurology, Epilepsy & Clinical Neurophysiology
2012-2014	Ambassador to Mexico and Latin America, American Academy of Neurology (AAN)
2013	Elected Fellow of the American Clinical Neurophysiology Society (ACNS)
2014	Honorary Fellow Mexican Chapter of the ILAE (CAMELICE)
2014	Honorary Fellow Mexican Academy of Neurology
2015	Honorary Fellow Guatemalan Society for Neurology

Board Certifications

2016 2017

Neurology (ABPN) 5/1997-12/2027 (Recertified 4/2007, 10/2017)

Elected Fellow of the American Epilepsy Society (AES)

American Epilepsy Society - Distinguished Service Award

Clinical Neurophysiology (ABPN) 4/1999-12/2019 (Recertified 8/2009)

Epilepsy (ABPN) 10/2014-12/2024 Clinical Neurophysiology (ABCN) 4/1998-4/2008

Medical Licenses

US: Texas: 2000-Present; NC: 1995-2005; CO: 1997-2005

Mexico: 1987-Present

C. Contribution to Science [Out of 45 publications and 18 patents – 6084 citations by Google Scholar]

- 1. My early publications reflect my PhD dissertation studies on Mossy Fiber Sprouting and Hippocampal Cell Loss in experimental models of Epilepsy. The direction of the laboratory changed as I performed some control experiments that showed surprising results. I participated in the planning, execution and interpretation of these experiments aimed to explain that surprising result. I wrote the first-author publications. These series of papers are part of 12 publications where I described the physiopathology of how the mossy fiber pathway of the dentate gyrus reorganized in response to progressive deafferentation in the inner molecular layer of the dentate gyrus caused by hilar polymorphic neuronal death.
 - a. Sutula T, He XX, Cavazos J, Scott G."Synaptic Reorganization in the Hippocampus Induced by Abnormal Functional Activity." Science 1988 Mar 4; 239(4844):1147-50. [882 citations] PMID:2449733
 - Cavazos JE, Sutula TP. "Progressive Neuronal Loss Induced by Kindling: A Possible Mechanism for Mossy Fiber Synaptic Reorganization and Hippocampal Sclerosis." Brain Res. 1990 Sep 10; 527(1):1-6. [383 citations] PMID:2282474
 - c. **Cavazos JE**, Golarai G, Sutula TP. "Mossy Fiber Synaptic Reorganization Induced by Kindling: Development, Progression, and Permanence." J. Neurosci. 1991 Sep;11(9):2795-803. [531 citations] PMID:1880549
 - d. Cavazos JE, Das I, Sutula TP. "Neuronal loss induced in limbic pathways by kindling: evidence for induction of hippocampal sclerosis by repeated brief seizures." J. Neurosci. 1994 May;14 (5 Pt 2):3106-21. [473 citations] PMID:8182460
- 2. The next set of publications occurred mostly during my residency and fellowship, where I contributed to several observations of clinical relevance that expanded my PhD dissertation work into a translational

context. In these observations, I played a major role collecting data, executing experiments, interpreting results and writing manuscripts. Of note, I did Hippocampal Volumetric analysis of Brain MRIs in "d".

- a. Sutula T, Cascino G, **Cavazos J**, Parada I, Ramirez L. "Hippocampal Synaptic Reorganization in Partial Complex Epilepsy: Evidence for Mossy Fiber Sprouting in Epileptic Human Temporal Lobe." Ann. Neurol. 1989 Sep; 26(3):321-330. [1090 citations] PMID:2508534
- b. Cavazos JE, Caress JB, Chilukuri VR, Devlin T, Gray L, Hurwitz BJ. "Sumatriptan-Induced Stroke in Sagittal Sinus Thrombosis." Lancet 1994 Apr 30;343(8905):1105-6. [54 citations, changed FDA label for Imitrex/Sumatriptan] PMID:8182460
- c. **Cavazos JE,** Bulsara K, Caress J, Osumi A, Glass JP. "Pure motor hemiplegia including the face induced by an infarct of the medullary pyramid" Clin Neurol Neurosurg 1996 Feb; 98(1): 21-23. PMID: 8681473 [16 citations]
- d. VanLandingham KE, Heinz ER, **Cavazos JE,** Lewis DV. "Magnetic Resonance Imaging Evidence of Hippocampal Injury after Prolonged Focal Febrile Convulsions." Ann. Neurol. 1998 Apr; 43:413-26. [481 citations—**primary inspiration for the NIH P50 FEBSTAT study**] PMID: 9546321.
- 3. The next set of my contributions to science came from the establishment of my research laboratory in the Audie L. Murphy VA Medical Center investigating morphological plasticity beyond the Mossy Fiber Pathway of the Dentate Gyrus utilizing anatomical and physiological techniques to understand their effect increasing excitability in experimental animal models. I was supported by K08 award and a VA Merit award as the principal investigator proposing the ideas, executing the experiments and writing the manuscripts.
 - a. **Cavazos JE**, Jones SM, Cross DJ. "Sprouting and Synaptic Reorganization in the Subiculum and CA1 Region of the Hippocampus in Acute and Chronic Models of Partial-Onset Epilepsy." Neuroscience 2004; 126(3):677-88. [109 citations] PMID: 15183517
 - b. **Cavazos JE**, Cross DJ. "The role of synaptic reorganization in mesial temporal lobe epilepsy." Epilepsy Behav. 2006 May;8(3):483-93. Epub 2006 Feb 24. [109 citations] PMID: 16500154
 - c. Cross DJ, **Cavazos JE.** "Synaptic reorganization in subiculum and CA3 after early-life status epilepticus in the kainic acid rat model. Epilepsy Res. 2007 Feb;73(2):156-65. Epub 2006 Oct 27. [53 citations] PMID: 17070016
 - d. Tolstykh GP, **Cavazos JE.** "Potential mechanisms of sudden unexpected death in epilepsy". Epilepsy Behav. 2013 Mar; 26(3):410-4. [36 citations] PMID: 23305781
- 4. The next set of my contributions to science came from my clinical interest in the practice of clinical epilepsy in the Audie L. Murphy VA Medical Center. These included the participation in the VA Cooperative Study of treatment of Seizures in the Elderly as well as collaborations developing the Neuro-QOL tool, validating it in patients with Epilepsy and exploring other health care outcome databases as Senior investigator.
 - a. Rowan AJ, Ramsay RE, Collins JF, Pryor F, Boardman KD, Uthman BM, Spitz M, Frederick T, Towne A, Carter GS, Marks W, Felicetta J, Tomyanovich ML; VA Cooperative Study 428 Group (Cavazos JE, et al.). New Onset Geriatric Epilepsy: A Randomized Study of Gabapentin, Lamotrigine and Carbamazepine. Neurology, 2005 Jun 14;64(11):1868-73. [489 citations] PMID:15955935
 - b. Pugh MJ, Copeland LA, Zeber JE, Cramer JA, Amuan ME, **Cavazos JE**, Kazis LE. "The Impact of Epilepsy on health status among younger and older adults." Epilepsia, 2005 Nov; 46(11):1820-7. [100 citations] PMID:16302863
 - c. Victorson D, **Cavazos JE**, Holmes GL, Reder AT, Wojna V, Nowinski C, Miller D, Buono S, Mueller A, Moy C, Cella D. "Validity of the Neurology Quality-of-Life (Neuro-QoL) measurement system in adult epilepsy". Epilepsy Behav. 2014 Feb; 31:77-84. [18 citations] PMID: 24361767
 - d. Margolis JM, Chu BC, Wang ZJ, Copher R, Cavazos JE. "Effectiveness of antiepileptic drug combination therapy for partial-onset seizures based on mechanisms of action." JAMA Neurol. 2014 Aug; 71(8):985-93. [37 citations] PMID: 24911669
- 5. The final set of my contributions to science and clinical practice stem from my initial consulting to a start-up company that became LGCH, Inc. (I am the "C") aiming to develop a seizure alert utilizing surface electromyography (sEMG). After raising \$47 Million of venture capital, I own about 1.6% of this company. I was the PI of four clinical studies including a pivotal controlled multicenter double-blinded comparison of a sEMG detection with an algorithm as compared to video EEG determination of classic Generalized Tonic

Clonic Seizures enrolling 199 patients in 11 sites. The studies have led to 18 patents and 2 manuscripts leading to FDA clearance on 2/16/17. I practiced my art to take a concept to FDA clearance in less than 9 years along with a very talented team. The clearance is for an innovating *De-Novo* class II device that has an automated diagnostic algorithm within a device for alerting and diagnosing convulsive seizures. Since 2010, the FDA has only granted 16 *De-Novo* (out-of-the box) technologies per year for all health applications, for which they need to create a new category in their classification. This is the newest technology for aiding in the identification of seizures in people with epilepsy since the 1970's when video was added to EEG.

- a. Szabó CÁ, Morgan LC, Karkar KM, Leary LD, Lie OV, Girouard M, **Cavazos JE**. Electromyography-based seizure detector: Preliminary results comparing a generalized tonic-clonic seizure detection algorithm to video-EEG recordings. *Epilepsia*.2015 Sep; 56(9):1432-7.[20 citations]PMID: 26190150
- b. Halford JJ, Sperling MR, Nair DR, Dlugos DJ, Tatum WO, Harvey J, French JA, Pollard JR, Faught E, Noe KH, Henry TR, Jetter GM, Lie OV, Morgan LC, Girouard MR, Cardenas DP, Whitmire LE, Cavazos JE. Detection of generalized tonic-clonic seizures using surface electromyographic monitoring. Epilepsia. 2017 Nov;58(11):1861-1869. PMID: 28980702

Complete List of Published Work in MyBibliography:

- http://www.ncbi.nlm.nih.gov/myncbi/browse/collection/45484074/?sort=date&direction=descending
- https://scholar.google.ca/citations?user=mhsqiNoAAAAJ

D. Additional Information: Research Support and/or Scholastic Performance

Ongoing Research Support

NIH 1T32GM113896-01A1 Cavazos, JE (PI) 07/01/18-06/30/23

South Texas Medical Scientist Training Program (STX-MSTP) Effort: 40%

The major goal of this pre-doctoral T32 training grant award is to expand the Medical Scientist Training Program (MSTP) at the University of Texas Health San Antonio from 5 to 7 students per year, increasing and supporting capacity to 56 MD/PhD students.

Role: Program Director and PI

PR141246P3 J.D. Lechleiter and M. Shapiro (Co-Pl's) 07/01/15-06/30/18

DOD-CDMRP Investigator-Initiated grant Effort: 5%

Novel Strategies Targeting Signaling Molecules of Neurons and Astrocytes to Prevent Acquired Epilepsies.

The major goals of this project are to investigate the potential synergistic effects of treating mice suffering TBI and preventing the development of epilepsy.

Role: Co-Investigator

Completed Research Support

NIH 5KL2TR001118 Clark et al. (Pls) 05/01/13-04/30/18

Institute for Integration of Medicine & Science: a Partnership to Improve Health

This is one of the NIH awards that are part of our Clinical Translational Science Awards (CTSA) and that aims to provide faculty support for 5 KL-2 Scholars at our institution. The grant supported 10% of my FTE providing salary support as the director of the KL-2 Program.

Veterans Administration Cavazos (PI) 10/01/14-04/30/16

San Antonio VA Epilepsy Center of Excellence

The major goal of this project is to advance research, education, and clinical care activities in the diagnosis and treatment of epilepsy, and in particular, post-traumatic epilepsy. I was the director of the local site.

NIH 1F31NS083160 - 01 Barron (PI) 06/01/13-05/30/14

Quantification of Thalamic Atrophy and Connectivity in Medial Temporal Lobe Epilepsy

Role: Co-Mentor

VA Mentored VISN Award Tolstykh (PI) 10/01/11–09/30/13

Properties of Cardiovascular Afferent Inputs During Epileptogenesis

The major goal of this project is to examine the anatomy and physiology of the Nucleus of the Tractus Solitarius in the Kainic Acid model of Temporal Lobe Epilepsy as possible dysregulation inducing SUDEP (Sudden Death in Epilepsy).

Role: Mentor

Presentation to AAN's Science Committee

The American Brain Foundation was invited to present to the AAN's Science Committee on June 21, 2018. Dr. Raymond Roos presented on the behalf of the Foundation's Research Advisory Committee. Below is a summary of what was presented and any discussions that took place related to the presentation.

Meeting Summary:

Dr. Roos provided an update on what the Foundation has been working on over the last year, including its accomplishments. His presentation included information on the following:

- Number of contracts signed to date with partners to fund the 2019 and 2020 Clinical Research
 Training Scholarships and Clinician Scientist Development Awards, including any pending
 contracts
- Update on the success of the crowdfunding site to date, including
 - How much the Foundation has granted out through crowdfunding projects
 - How many projects have been posted on the site and how many project applications we have received
 - Overview of the two crowdfunding marketing campaigns that ran in January and March and the Foundation's new marketing approach going forward to use a "pipeline"
- The Foundation's new position to support mental illness research projects and the implications this has on its Research Program
- The Foundation's involvement with the XPRIZE Foundation to develop a new XPRIZE in Alzheimer's Disease
- The development of two new awards, one senior level and one junior level, focused on Lewy Body Diseases

Discussion:

- Dr. Nina Schor expressed concern about the review process for the crowdfunding projects and potential message the Foundation is sending to donors – that a cure will be found if they support the project.
 - Jane and Dr. Roos addressed her concerns by discussing in detail the 2-stage review process for each application and the project description that talks about the *potential* impact this research project could have on the neurologic community, never claiming to provide a cure.

XPRIZE in Alzheimer's Update

The American Brain Foundation had a call with one of the founders of the XPRIZE in Alzheimer's disease on July 2, 2018 to discuss the potential for collaboration in the development, execution, and management of the XPRIZE. Below is a summary of the discussion.

Attendees:

- Ric Edelman Founder and benefactor of XPRIZE in Alzheimer's Disease
- Robert Griggs, MD Chair of the American Brain Foundation Research Advisory Committee
- John Morris, MD Member of the American Brain Foundation Research Advisory Committee
- Jane Ransom, Executive Director, American Brain Foundation
- Suzi Sherman, Program Officer, Research & Digital Grants, American Brain Foundation

Meeting Minutes:

- XPRIZE Foundation is currently in search of a new CEO so the development of the XPRIZE in Alz's is on hold; they anticipate launching the campaign in 4-5 months
- Ric and his wife Jean have committed \$25M for the XPRIZE with \$10M designated for the prize and \$15M designated for operational/administration expenses, but they are still determining if \$25M is enough as XPRIZEs are typically \$50M-\$100M
- Ric welcomes the American Brain Foundation's involvement with the development of the prize; we will reconvene once the new CEO is hired
- Ric is also intrigued by the Foundation's crowdfunding site and has invited the American Brain
 Foundation to be a guest on his national radio show to talk promote the crowdfunding site and
 Foundation in general
 - o His show reaches 50,000 people a week
 - Would be willing to have us on periodically
 - American Brain Foundation staff will follow up with Ric to discuss logistics of this opportunity

Research Funding Opportunity

Request for Proposals to Improve Recognition and Diagnosis of

Lewy Body Dementia

Lewy Body Dementia Biomarkers Funding Opportunity

Purpose

The American Brain Foundation (ABF) and partners [LIST FUNDING PARTNERS, IF ANY] seek(s) to support breakthrough research on the recognition and diagnosis of Lewy Body Dementia (LBD), specifically through the discovery of biomarker(s) of the disease. We are offering a 5-year award of up to \$5 million (no more than \$1 million per year) to support discovery, development and validation of biomarkers for LBD. Projects can address disorders across the LBD spectrum and may target all disease stages, from preclinical to advanced symptomatic disease.

Background

The current lack of validated biomarkers (objectively measured characteristics that indicate an underlying biological or pathological process) for Lewy Body Dementia (LBD) results in delayed or missed diagnosis and impedes pertinent clinical and translational research, including drug discovery efforts.

[ASK COMMITTEE MEMBER(S) TO ADD MORE CONTENT HERE, ABOUT WHAT THE AVENUES OF RESEARCH HAVE BEEN AND THE GAPS IN KNOWLEDGE/DISCOVERY.]

Eligibility

- Applicants must be a member of the faculty at the rank of Assistant Professor (or its equivalent) or higher at an academic institution or nonprofit medical research institution
- Applicants must have a MD, PhD, or MD-PhD degree
- Both United States and international investigators are eligible
- Institutions must be nonprofit entities with charitable purpose

Deadlines

- Letters of interest due with required background information due: [DATE]
- Full proposal invitations: [DATE]
- Full proposals (by invitation only) due: [DATE]
- Project selection: [DATE]
- Anticipated start of funding: [DATE]
- Annual Progress and Financial Reports due: [DATES]

<u>Letter of Interest (LOI) Instructions & Required Materials</u>

The following must be submitted:

Title Page

- Project Title
- Name of the Principal Investigator (with contact information)
- Affiliation
- Institutional official (name, contact information) responsible for grant administration

Abstract of Proposed Research Project (500-word limit)

- Specific Aims
- Background
- Approach
- Prospective Collaborators
- Significance and Overall Impact
- Project Duration

Budget

- Summary 5-year budget
- Special technology needs and cost
- No more than 10 percent in indirects

Principal Investigator (PI)

- PI's NIH formatted biosketch
- Institution
- Mailing address
- Email
- Phone
- Listing of the applicant's current and anticipated overlapping support, including pending overlapping support

Reference

• Letter of support from Department Chair/Dean

Full Proposal Instructions & Required Materials

Full proposals are to be submitted by invitation only, and should include, in no more than 6 pages:

I. Executive Summary

- a. Purpose
- b. Approach
- c. Overall significance

II. Project Goals

III. Project Design

- a. Approach and specific plan
- b. Study methods
- c. Preliminary data if possible
- d. Collaborators
- e. Milestones
- f. Timeline
- g. Technology

IV. Budget Narrative (for attached 5-year budget)

- a. Case for budget needs with allowable cots:
 - i. Salary and fringe benefits for Principal Investigator, key personnel, and other essential personnel
 - ii. Equipment and supplies
 - iii. Consultant costs
 - iv. Alterations and renovations
 - v. Publications and miscellaneous costs
 - vi. Contract services
 - vii. Consortium costs
 - viii. Facilities and Administrative costs (indirect costs)
 - ix. Travel expenses

x.

V. Outcomes & Impact

- a. Desired outcomes for this project
- b. Significance and potential impact

Junior Investigator Award in Lewy Body Dementia Diagnostics

This award aims to recognize the importance of good clinical research and to encourage early-career investigators to focus on research in Lewy Body Dementia diagnostics. It is expected that one award of \$75,000 [PLEASE WEIGH IN ON THIS AMOUNT. IS IT ENOUGH TO ACCOMPLISH SOMETHING?] per year for two-years, will be awarded (one-time, continuing).

Eligibility

- Applicants must have a MD, PhD or MD-PhD degree
- Both United States and international investigators are eligible

Annual and Final Progress Reports

An annual progress report is due in the spring of the first year. Renewal of the award in year two is contingent upon satisfactory progress in the first year. Additionally, a final research report and a final expenditure report are due within 60 days following the close of the grant term. The final expenditure report must be prepared by the institution's financial office.

Materials for Application

The following must be submitted:

- Letter of nomination from the chair of the applicant's department, including assurance that clinical service responsibilities will be restricted to no more than 20 percent of the recipient's time.
- Three-page Research Plan, including brief statements of aims, background, and the planned methodological approaches. The research plan should be written by the applicant and should represent his/her original work. However, the applicant is expected and encouraged to develop this plan based on discussions with the proposed mentor. It is appropriate but not required for the proposal work to be specifically related to the mentor's ongoing research.
- Applicant's NIH Biosketch.
- Two letters of reference supporting the applicant's potential for a clinical research career and qualifications for the scholarship.
- Listing of the applicant's current, pending and overlapping support, including pending overlapping support using NIH format.
- Letter from proposed mentor detailing his/her support of and commitment to the applicant and the proposed research and training plan. The letter should specifically indicate the mentor's role in the applicant's career development to include:
 - o How the proposed research fits into the mentor's research program

- Expertise and experience in the area of research proposed and the nature of the mentor's proposed time commitment to the supervision and training of the applicant
- Mentor's prior experience in the supervision, training and successful mentoring of clinician scientists
- Potential for applicant's future research career and comparison of applicant among other residents
- Proposed mentor's NIH Biosketch, including listing of mentor's current and pending support.
- Plans and arrangments for formal course work including quantitative clinical epidemiology, biostatistics, study design, data analysis, and ethics.

Review Committee

Applications will be reviewed by a committee made up of LBD experts, which includes scientific advisors at the Lewy Body Dementia Association, Michael J. Fox Foundation, and American Academy of Neurology.



TO: American Brain Foundation Research Advisory Committee

FROM: Suzi Sherman, Program Officer, Research & Digital Grants

DATE: July 27, 2018

SUBJECT: Crowdfunding and Research Program Summary to date

Dear Research Advisory Committee,

Below is a summary of the progress for the crowdfunding site and research program as of July 13, 2018. Once a project is approved for the crowdfunding site an overview of the research project will be provided to the RAC. Please direct any questions about this information to Suzi Sherman, ssherman@americanbrainfoundation.org or 612-928-6315.

Thank you,

Suzi

Crowdfunding Summary

Projects live on the site:

- Using skin stickers to detect tics in Tourette syndrome NEW AS OF 7/3/18, 2018 CRTS recipient, see overview attached
- Studying specific cells that may prevent neurodegeneration in MS patients NEW AS OF 7/3/18,
 2018 CSDA recipient, see overview attached
- 3. Protective effects of endogenous cannabinoids in stroke NEW AS OF 5/17/18
- 4. Unlocking the secrets of the immune system
- 5. Increasing accuracy of current diagnostics in MS
- 6. Genetics of Familial Gliomas
- 7. Improving concussion awareness
- 8. A new approach to treating dementia
- 9. High-tech imaging of Alzheimer's brain
- 10. Reducing pain in breast cancer treatment
- 11. Detection of brain swelling

Projects recently removed from site:

1. Comparative studies of RNA toxicity in myotonic dystrophy – 2017 CRTS recipient



- 2. New treatments for patients with Friedreich's Ataxia 2017 CRTS recipient
- 3. Wearable devices and smartphone apps in Parkinson's 2017 CRTS recipient
- 4. Reducing cardiovascular hospitalizations 2017 CRTS recipient
- 5. Roles of social & behavioral factors in Alzheimer's 2017 CRTS recipient
- 6. A toolbox for diagnosing epilepsy in Alzheimer's 2017 CRTS recipient
- 7. Impact of immigration status on stroke
- 8. Virtual reality to improve stroke rehabilitation
- 9. Treating childhood brain cancer

Projects in the pipeline:

Approved but waiting to post on crowdfunding site until marketing campaign has been confirmed and approved

- 1. Development and validation of a risk-factor based clinical app predicting outcomes in patients with multiple sclerosis **NEW AS OF 5/4/18**, see overview attached
- 2. High-frequency oscillations (HFOs): A specific biomarker of pharmaco-resistant epilepsy **NEW AS OF 7/1/18, 2018 CRTS recipient, see overview attached**
- Investigating Patterns of Care for Dementia with Lewy Bodies in Florida NEW AS OF 7/1/18,
 2018 CRTS recipient, see overview attached
- 4. Elucidating the genetic etiology of neuromuscular disorders using high-throughput sequencing NEW AS OF 7/1/18, 2018 CRTS recipient, see overview attached
- Early Markers of Disease in C9ORF72 ALS NEW AS OF 7/1/18, 2018 CRTS recipient, see overview attached
- 6. Teleneurology Assessment Program for Creutzfeldt-Jakob disease

Approved, but waiting to receive requirements from researcher before posting on the site:

None at this time.

Declined applications

- 1. A simple blood test approach for stroke etiology: metabolomics of cardioembolic and atherothrombotic stroke
- 2. Neurorehabilitation for functional movement disorders: novel insights into neural, endocrine and immunological mechanisms
- 3. Machine learning system to diagnose movement disorders

LOI is approved, waiting for approval from Expert Review Panel:

1. Narcolepsy genetic marker HLA DQB1 and daytime alertness in patients with Parkinson's disease treated with dopaminergic agents



LOI is approved, waiting for researcher to submit full application:

- 1. Cognition in aging adults with multiple sclerosis
- 2. Serotonin and catecholamine signaling in cigarette smoking-associated ischemic stroke
- 3. and visual arts education program for high school students
- 4. Understanding how certain individuals are naturally resisting the symptoms of Alzheimer's pathology
- 5. Promoting remyelination to treat multiple sclerosis
- 6. A big data approach to solve insomnia
- 7. Treating dizziness in athletes with concussion
- 8. GEMSTONE: Gastrointestinal microbiome and stroke outcomes network
- 9. Nociceptin system: a potential therapeutic target of opioid-seeking behavior and relapse in an adolescent rat model
- 10. In vivo metabolic regulation in malignant brain tumors using 13C isotopomer technology
- 11. Discovery of novel migraine therapeutic targets by single-cell RNA sequencing

Research Program Summary

Confirmed 2018 awards:

- 1. CRTS in ALS
- 2. CRTS in Dementia with Lewy Bodies
- 3. CRTS in Epilepsy
- 4. CRTS in Muscular Dystrophy
- 5. CRTS in Neuromuscular Disease
- 6. CRTS in Tourette's
- 7. CRTS in Cognitive Aging and Age Related Memory Loss
- 8. CRTS in Cognitive Aging and Age Related Memory Loss
- 9. CSDA in Interventional Neurology
- 10. CRTS in Stroke
- 11. CSDA in Multiple Sclerosis

Confirmed 2019 awards:

- 1. CRTS in Cognitive Aging and Age Related Memory Loss
- 2. CRTS in Cognitive Aging and Age Related Memory Loss
- 3. CRTS in Stroke
- 4. CSDA in Myasthenia Gravis
- 5. CRTS in Muscular Dystrophy
- 6. CRTS in Epilepsy
- 7. CRTS in Alzheimer's



- 8. CRTS in Parkinson's disease
- 9. CRTS in Parkinson's disease
- 10. CRTS in Multiple Sclerosis
- 11. CRTS in Headache
- 12. CRTS in ALS
- 13. CSDA in ALS
- 14. CSDA in Multiple Sclerosis (NMSS)
- 15. CSDA in Interventional Neurology (SVIN)
- 16. CRTS in Tourette

Pending 2019 awards:

- 1. CRTS in Neuromuscular Disease
- 2. CRTS in Neuromuscular Disease

Confirmed 2020 awards:

- 1. CRTS in Alzheimer's
- 2. CRTS in Cognitive Aging and Age Related Memory Loss
- 3. CRTS in Cognitive Aging and Age Related Memory Loss
- 4. CRTS in Parkinson's disease
- 5. CRTS in ALS
- 6. CSDA in ALS
- 7. CRTS in LBD