

Boston Pepper OAIC Annual Directory 2016

Section I. Description of Center

The Boston OAIC is unique in its thematic focus on Function Promoting Therapies (FPTs) and its positioning across the entire spectrum of translational science from mechanism elucidation, preclinical proof-of-concept studies, biomarker validation, epidemiologic investigation to randomized trials of FPTs. The Boston OAIC integrates 19 NIH-funded studies of function promoting therapies, 3 Research Education Component projects, 3 pilot projects, and 3 developmental projects into an interdisciplinary program that is supported by a Leadership and Administrative Core, a Research Education Component (REC), a Pilot and Exploratory Studies Core (PESC), and 3 resource cores (Function Assessment Core, Preclinical Discovery Core, Biostatistical and Data Analysis Core). Our REC and PESC candidates include several rising stars in Geriatrics and Gerontology, including 3 Beeson and K grant awardees. The REC will recruit the most promising stars from a vast reservoir of talent at Harvard, Tufts and BU, and train them through a didactic education and mentored research program. Integration will be achieved by the PROMOTE Program that includes a research concierge service, research meetings, annual retreats, a website and a newsletter. The Boston OAIC is well integrated with the the Harvard Geriatrics and Gerontology research community and programs, including its T32 training grant, Harvard Clinical Translational Science Institute, the Roybal Center, The New England Geriatrics Research Clinical Education Center, and the Glenn Foundation Center for Biology of Aging.

Boston OAIC's unique strengths include its focus on Function Promoting Therapies, emphasis on translation and commercialization, access to a large pool of talented young investigators, its extension across the entire spectrum of translational research, and its infrastructure for developing intellectual property and companies, and supporting several seminal randomized trials of FPTs.

Programs and Components of the Boston OAIC			
LEADERSHIP AND ADMINISTRATIVE CORE (Leader: Bhasin)	RESEARCH EDUCATION CORE (Leader: Lipsitz)	RESOURCE CORES AND DEVELOPMENTAL PROJECTS (Leader: Jette)	PILOT AND EXPLORATORY SCIENCE (Co-Leaders: Montano, Kiel)
<ul style="list-style-type: none"> • Executive Committee • Internal Advisory Board • External Advisory Board • PROMOTE Program • LINK Program • Evaluation Unit • Dissemination and Community Outreach 	<ul style="list-style-type: none"> • Leadership Team • Advisory Committee • Mentoring Team • Training Program • The FARM REC Candidates (Mentors) • Sinha (Wagers, Bhasin) • Kim (Marcantonio, Lipsitz) • Lustgarten (Fielding) 	<ul style="list-style-type: none"> • RC1. Function Assessment Core (Leaders: Fielding, torer) • RC2. Preclinical Discovery Core (Leader: Jasuja) • RC3. Biostatistical Design and Analytical Core (Leader: Travison) Developmental Projects (DP) Leader: Jette • DP1. Determination of MCIDs for Late Life Function and Disability Index: Latham, Jette • DP2. Using 7T MR Spectroscopy to Assess Muscle Function, Quality and Energetics: Balschi, Mukundan • DP3. Novel Randomization Schemes for Cluster Randomized Trials; Travison, Allore 	<ul style="list-style-type: none"> • PES1. MicroRNAs as predictors of anabolic response (Rivas) • PES2. Home-based Exercise to Improve Functional Status after Trans-catheter Aortic Valve Replacement (Kim) • PES3. Optimization of Transcranial Brain Stimulation to Improve Physical Function in Older Adults (Manor)

Section II. Research, Resources and Activities

A. Cores

- a. Function Assessment Core
- b. Preclinical Discovery and Small Animal Phenotyping Core
- c. Biostatistical Design and Analysis Core

B. Research

External Projects

Boston OAIC Projects and Their Relation to Research Platforms of FPT Development				
	PI	Title	Specific Aims	Core Utilization
Elucidation of Mechanisms/ Target Identification/ Biomarker Development				
P1.	Bhasin/ 5R01AG03719	Mechanisms of Androgen Action on Skeletal Muscle	Mechanisms that mediate androgen action on muscle progenitor cell differentiation	PDC
P2.	Fielding/ USDA 58- 1950-51000- 062-01A	Effects of Nutrient Modulation on Skeletal Muscle in Aging Animals	A USDA-supported program to conduct molecular and intervention studies of effects of diet on age-related loss of muscle mass and function	PDC BDAC
P3.	Rivas / 1K01AG0472 47	Role of microRNAs in age-related muscle loss	To determine the role of microRNAs in mediating the loss of muscle mass with aging	PDC
P4	Wagers/ 5R01AG3350 3	Reversing age-related dysfunction of muscle stem cells	To characterize juvenile protective factors which can reverse age-related skeletal muscle dysfunction	PDC, BDAC
P5.	Wagers/ 1R01AG0489 17	The role of GDF11 in development and aging	To determine the anti-geronic effects of GDF11 during development and aging	PDC
Intervention Trials of FPTs				
P6.	Lipsitz/ 2R01AG0250 37	Health Outcomes of Tai Chi In Subsidized Senior Housing	To determine the effects of Tai Chi on functional performance, health care utilization and costs in poor, elderly residents of low income housing facilities	FAC, BDAC
P7.	Pahor, Fielding/ U01AG05049 9	The ENRGISE Study (Pahor overall PI; Fielding Tufts Site PI)	A pilot study to investigate effects of anti-inflammatory agents on serum cytokine levels and mobility.	FAC
P7.	Wang/ 1R01 AT006367	Tai Chi & Aerobic Exercise for Fibromyalgia	The effects of Tai Chi and aerobic exercise on physical function and wellbeing in patients with fibromyalgia	FAC; BDAC
P8.	Bhasin/ 1R01AG3754 7	Optimizing Protein Intake In Older Americans	Protein requirements for optimal anabolic response to FPTs in older adults with mobility limitation	FAC; BDAC
P9.	Bhasin/ 1U01	A Randomized Trial of a Fall Injury Prevention Strategy	To determine effectiveness of individually-tailored, risk factor-based fall injury prevention strategy	FAC
P10.	Manson/ 1U01- CA138962,S1 S2	Vitamin D and OMEGA-3 TRIAL (VITAL)	The effects of vitamin D and omega-3 fatty acids on physical function and cardiovascular outcomes	FAC
P11.	Fielding /PI of Tufts site	Nitrite Supplementation for Improving Physiological Function in Older Adults	To examine to examine the role of nitrite supplementation on vascular function and physical functioning in older at risk adults	FAC; BDAC
P12.	Fielding/ USDA 58- 1950-51000-	Nutrition, Exercise Physiology, and Sarcopenia	This USDA program studies effects of exercise and diet on age-related loss of muscle mass and function.	FAC, BDAC

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P1 3.	Bhasin/ 1UO1NR	A Prostate-sparing SARM in men with prostate cancer	To determine the efficacy of a prostate sparing SARM in improving physical function, fatigue, anemia, and sexual symptoms in men with prostate cancer.	FAC, BDAC
Biomarkers/ Methods Development/Outcomes Assessment Necessary for FPAT Trials				
P1 4.	Jette/ 3U01AR05792 9	Patient Reported Outcomes for Persons with Disabilities	Transform data collection technology for assessing function and disability in persons with disabilities	FAC; BDAC
P1 5.	Bhasin/ R01 AG037547- S1	D3-creatinine for measuring muscle mass	Validate the measurement of muscle mass in older adults with mobility limitation using D3- creatinine	FAC; BDAC
P1 6.	Montano/ 1R01DA36444	Biomarkers of muscle function and aging in HIV infection	To validate biomarkers of functional decline in chronic HIV infection and aging	FAC, BDAC
Epidemiological Studies of Age-related Changes in Physical Function, Functional Limitations and Disability				
P1 7.	Bhasin/ 1 U01 AG051421-01	Muscle mass and strength Cutpoints for Mobility Disability	Secondary analyses of data from epidemiologic studies and RCTs of FPTs to determine cutpoints of muscle mass and strength associated with mobility limitations	BDAC
P1 8.	Lipsitz/ 1R01AG0417 85	Vascular Mechanisms of Slow Gait and Falls in MOBILIZE Boston	To examine the relationships between cerebral blood flow regulation and the development of slow gait and falls in elderly participants of MOBILIZE Boston Study.	FAC, BDAC
P1 9.	Kiel/ R01 AR41398	Risk Factors for Age Related Musculoskeletal Loss	Mechanisms that mediate effect of visceral adipose tissue on bone microarchitecture and muscle quality	BDAC

List of Development Projects: Innovation and Relevance to FPTs			
Project Title	Investigators	Innovation/ Application to Other OAIC Projects	Cores
DP1. Minimal Clinically Important Difference of the Late-Life Function Instrument	PI: Jette (PROs, disability), Latham (Rehab, PT); Co-I: Beuchamp (Outcomes assessment)	To use anchor and distribution-based approaches to determine MCID of LLFI in older adults using data from the STRIDE study; these data will be useful in projects P6, P7, P9, P13	FAC
DP2. Functional Microscopy of Muscle Using 7T Magnetic Resonance Imaging and Spectroscopy	PI: Mukundan (Muscle Imaging, Spectroscopy); Jasuja (Muscle Biology; Biophysical Engineering)	Validate a novel method for quantitative assessment of myofibrillar space, muscle perfusion, O2 uptake, and fatigability using 7T MRI and Spectroscopy; of value to P1, P2, P3, P4	PDC
DP3. A Novel Randomization Strategy for Cluster- Randomized Trials	PI: Trivison (Biostatistics); Allore (Biostatistics, Yale)	To develop a novel method for randomization in cluster randomized trials	BDAC
FAC, Function Assessment Core; PDC, Preclinical Discovery Core; BDAC, Biostatistical Design and Analytical Core			

C. Pilot and Exploratory Science Projects

PES1. MicroRNAs as predictors of anabolic response (Rivas)

PES2. Home-based Exercise to Improve Functional Status after Trans-catheter Aortic Valve Replacement (Kim)

PES3. Optimization of Transcranial Brain Stimulation to Improve Physical Function in Older Adults (Manor)

Section III. Research Education Component (REC) Projects: Provide names and funding subsequent to Pepper pilot funding.

1. Michael S. Lustgarten, PhD; The Effect of Prebiotic Supplementation on Lean Mass and Physical Function in Older Adults. *Current Position*: Scientist III, Exercise Physiology and Sarcopenia Laboratory, Jean Mayer USDA HNRCA, Tufts University. *Mentor*: Roger Fielding, PhD.

2. Caroline A. Kim, MD, MPH, SD candidate; Functional Status Trajectories After Transcatheter Aortic Valve Replacement. *Current Position*: T32 Postdoctoral Fellow and Geriatrician (The candidate will have assumed a faculty position as Instructor in Medicine early next year), Beth Israel Deaconess Medical Center and Harvard Medical School, *Mentors*: Edward Marcantonio, MD and Lewis Lipsitz, MD

3. Indranil Sinha, MD, Increased cyclooxygenase-2 activity mediates aging-associated decrease in skeletal muscle regeneration. Instructor in Surgery, Brigham and Women's Hospital and Harvard Medical School. *Mentors*: Shalender Bhasin, MD, and Amy Wagers, PhD

Section IV. Publications: Provide only those that are a direct result of Pepper Center resources and list publications published in the 2015-2016 years only.

1. Snyder PJ, Bhasin S, Cunningham GR, Matsumoto AM, Stephens-Shields AJ, Cauley JA, Gill TM, Barrett-Connor E, Swerdloff RS, Wang C, Ensrud KE, Lewis CE, Farrar JT, Cella D, Rosen RC, Pahor M, Crandall JP, Molitch ME, Cifelli D, Dougar D, Fluharty L, Resnick SM, Storer TW, Anton S, Basaria S, Diem SJ, Hou X, Mohler ER 3rd, Parsons JK, Wenger NK, Zeldow B, Landis JR, Ellenberg SS; Testosterone Trials Investigators. Effects of Testosterone Treatment in Older Men. *N Engl J Med*. 2016 Feb 18;374(7):611-24.
2. Basaria S, Harman SM, Travison TG, Hodis H, Tsitouras P, Budoff M, Pencina KM, Vita J, Dzekov C, Mazer NA, Coviello AD, Knapp PE, Hally K, Pinjic E, Yan M, Storer TW, Bhasin S. Effects of testosterone administration for 3 years on subclinical atherosclerosis progression in older men with low or low-normal testosterone levels. *JAMA* 2015;314(6):570-81.
3. Huang G, Wharton W, Bhasin S, Harman SM, Pencina KM, Tsitouras P, Li Z, Hally KA, Asthana S, Storer TW, Basaria S. Effects of long-term testosterone administration on cognition in older men with low or low-to-normal testosterone concentrations: a prespecified secondary analysis of data from the randomised, double-blind, placebo-controlled TEAAM trial. *Lancet Diabetes Endocrinol*. 2016 Aug;4(8):657-65.
4. Cunningham GR, Stephens-Shields AJ, Rosen RC, Wang C, Bhasin S, Matsumoto AM, Parsons JK, Gill TM, Molitch ME, Farrar JT, Cella D, Barrett-Connor E, Cauley JA, Cifelli D, Crandall JP, Ensrud KE, Gallagher L, Zeldow B, Lewis CE, Pahor M, Swerdloff RS, Hou X, Anton S, Basaria S, Diem SJ, Tabatabaie V, Ellenberg SS, Snyder PJ. Testosterone Treatment and Sexual Function in Older Men With Low Testosterone Levels. *J Clin Endocrinol Metab*. 2016 Aug;101(8):3096-104.
5. Guo W, Schmidt PJ, Fleming MD, Bhasin S. Effects of Testosterone on Erythropoiesis in a Female Mouse Model of Anemia of Inflammation. *Endocrinology*. 2016 Jul;157(7):2937-46.
6. Storer TW, Bhasin S, Travison TG, Pencina K, Miciek R, McKinnon J, Basaria S. Testosterone Attenuates Age-Related Fall in Aerobic Function in Mobility Limited Older Men With Low Testosterone. *J Clin Endocrinol Metab*. 2016 Jun;101(6):2562-9.
7. Travison TG, O'Donnell CJ, Bhasin S, Massaro JM, Hoffmann U, Vasan RS, D'Agostino RB Sr, Basaria S. Circulating Sex Steroids and Vascular Calcification in Community-Dwelling Men: The Framingham Heart Study. *J Clin Endocrinol Metab*. 2016 May;101(5):2160-7.

8. Guo W, Miller AD, Pencina K, Wong S, Lee A, Yee M, Toraldo G, Jasuja R, Bhasin S. Joint dysfunction and functional decline in middle age myostatin null mice. *Bone*. 2016 Feb;83:141-8.
9. Basaria S, Travison TG, Alford D, Knapp PE, Teeter K, Cahalan C, Eder R, Lakshman K, Bachman E, Mensing G, Martel MO, Le D, Stroh H, Bhasin S, Wasan AD, Edwards RR. Effects of testosterone replacement in men with opioid-induced androgen deficiency: a randomized controlled trial. *Pain* 2015;156:280-8.
10. Jasuja GK, Bhasin S, Reisman JI, Berlowitz DR, Rose AJ. Ascertainment of Testosterone Prescribing Practices in the VA. *Med Care*. 2015 Sep;53(9):746-52.
11. Cesari M, Fielding R, Bénichou O, Bernabei R, Bhasin S, Guralnik JM, Jette A, Landi F, Pahor M, Rodriguez-Manas L, Rolland Y, Roubenoff R, Sinclair AJ, Studenski S, Travison T, Vellas B. PHARMACOLOGICAL INTERVENTIONS IN FRAILTY AND SARCOPENIA: REPORT BY THE INTERNATIONAL CONFERENCE ON FRAILTY AND SARCOPENIA RESEARCH TASK FORCE. *J Frailty Aging*. 2015;4(3):114-120.
12. Dawson-Hughes B, Harris SS, Palermo NJ, Gilhooly CH, Shea MK, Fielding RA, Ceglia L. Potassium Bicarbonate Supplementation Lowers Bone Turnover and Calcium Excretion in Older Men and Women: A Randomized Dose-Finding Trial. *J Bone Miner Res* 2015 Nov;30(11):2103-11.
13. Mavros Y, O'Neill E, Connerty M, Bean JF, Broe K, Kiel DP, Maclean D, Taylor A, Fielding RA, Fiatarone Singh MA. Oxandrolone Augmentation of Resistance Training in Older Women: A Randomized Trial. *Med Sci Sports Exerc* 2015 Nov;47(11):2257-67.
14. Zakharov MN, Bhasin S, Travison TG, Xue R, Ulloor J, Vasani RS, Carter E, Wu F, Jasuja R. A multi-step, dynamic allosteric model of testosterone's binding. *Mol Cell Endocrinol* 2015;399:190-200.
15. O'Connell KE, Guo W, Serra C, Beck M, Wachtman L, Hoggatt A, Xia D, Pearson C, Knight H, O'Connell M, Miller AD, Westmoreland SV, Bhasin S. The effects of an ActRIIb receptor Fc fusion protein ligand trap in juvenile simian immunodeficiency virus-infected rhesus macaques. *FASEB J* 2015;29:1165-75.
16. Buendia JR, Bradlee ML, Singer MR, Moore LL. Diets higher in protein predict lower high blood pressure risk in Framingham Offspring Study adults. *Am J Hypertens*. 2015;28(3):372-9.
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18. Wang C, McAlindon T, Fielding RA, Harvey WF, Driban JB, Price LL, Kalish R, Schmid A, Scott TM, Schmid CH. A novel comparative effectiveness study of Tai Chi versus aerobic exercise for fibromyalgia: study protocol for a randomized controlled trial. *Trials* 2015;16:34.
19. Huang G, Pencina KM, Coady JA, Beleva YM, Bhasin S, Basaria S. Functional voice testing detects early changes in vocal pitch in women during testosterone administration. *J Clin Endocrinol Metab* 2015;100:2254-60.
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22. Jang H, Bhasin S, Guarneri T, Serra C, Schneider M, Lee MJ, Guo W, Fried SK, Pencina K, Jasuja R. The Effects of a Single Developmentally Entrained Pulse of Testosterone in Female Neonatal Mice on Reproductive and Metabolic Functions in Late Life. *Endocrinology*. 2015 Oct;156(10):3737-46.
23. Corcoran MP, Chui KK, White DK, Reid KF, Kirn D, Nelson ME, Sacheck JM, Folta SC, Fielding RA. Accelerometer Assessment of Physical Activity and Its Association with Physical Function in Older Adults Residing at Assisted Care Facilities. *J Nutr Health Aging*. 2016;20(7):752-8.
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29. Rivas DA, McDonald DJ, Rice NP, Haran PH, Dolnikowski GG, Fielding RA. Diminished anabolic signaling response to insulin induced by intramuscular lipid accumulation is associated with inflammation in aging but not obesity. *Am J Physiol Regul Integr Comp Physiol*. 2016 Apr 1;310(7):R561-9.
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33. Fielding RA. A Summary of the Biological Basis of Frailty. *Nestle Nutr Inst Workshop Ser*. 2015;83:41-4.
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35. Reid KF, Price LL, Harvey WF, Driban JB, Hau C, Fielding RA, Wang C. Muscle Power Is an Independent Determinant of Pain and Quality of Life in Knee Osteoarthritis. *Arthritis Rheumatol*. 2015 Dec;67(12):3166-73

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Section V. External Advisory Board Members Names, Institutions and Years of service

Thomas Gill, MD, Yale University, New Haven, CT 2009-present

Marco Pahor, MD, University of Florida, Gainesville, FL, 2013-present

Andrew Goldberg, MD, University of Maryland, Baltimore, MD, 2009-present

Please also send two additional and separate documents:

1. Recognition and Awards

Honors and awards received by OAIC Investigators and Trainees	
OAIC Investigator/ Role in OAIC	Honors
Shalender Bhasin, Boston OAIC Director	Clinical Investigator Award of the Endocrine Society 2015; Research Mentor in Women's Health Award of the Endocrine Society 2015
Roger Fielding, OAIC Associate Director, Director, FAC	Olof Johnell Science Award for Excellence in Musculoskeletal Research, International Osteoporosis Foundation; Section editor, Calc Tissue Int; Associate Editor, J Gerontol Med Sci
Lewis Lipsitz, OAIC Associate Director, REC Director	Joseph T. Freeman Award, Gerontological Society of America, 2010; William Silen Lifetime Achievement in Mentoring Award, 2009-2010
Alan Jette, Director, Developmental Projects	Elected to Institute of Medicine, 2014; <i>John Maley Award, American Physical Therapy Association 2014</i> ; McMillan Lectureship Award, APTA 2012; Charles M. Magistro Distinguished Service Award, Foundation for Physical Therapy 2014, Excellence in the Rehabilitation of Aging Persons Award, GSA 2011
Edward Marcantonio, Assoc. Director, REC	Outstanding Scientific Achievement in Clinical Investigation Award, American Geriatrics Society
Amy Wagers, Assoc Director, REC	Howard Hughes Early Career Investigatorship; Robertson Prize for translational stem cell research
Douglas Kiel, Co-Director, PESC	A. Clifford Barger Excellence in Mentoring Award in Geriatrics, HMS, 2013; Elected President, American Society of Bone Mineral Research
Jasuja, former PESC Awardee; now PDC Director	Patent on free testosterone calculator
Monty Montano, former PESC awardee, now PESC Director	Charter member, AIDS Clinical and Epidemiology Study Section; patent for biomarkers of anabolic response; Launched Biosyntax, LLC; Authored a book on Translational Medicine
Tuhina Neogi (RCDC Awardee, now an REC Faculty Mentor)	Osteoarthritis Research Society Young Investigator Award; Evans Junior Investigator Award; Panelist for developing treatment guidelines; appointed chair of FDA Advisory Committee
Chen Chen Wang (RCDC Awardee)	Appointed to Advisory Council of NCAAM; Appointed Chief of Department of Integrative Medicine

2. Minority Research:

Donato Rivas, Ph.D. received K08 award to study the Potential for microRNAs to serve as predictors of anabolic response to exercise. He was an RCDC candidate supported by a minority supplement.