

McKnight Brain Research Foundation
University of Florida Foundation, Inc.
University of Florida College of Medicine
Evelyn F. and William L McKnight Brain Institute of the University of Florida
University of Florida College of Public Health and Health Professions

Memorandum of Understanding

This Memorandum of Understanding ("MOU") is entered into as of the 11 day of November, 2010, by and between the **McKNIGHT BRAIN RESEARCH FOUNDATION** ("MBRF") and **THE UNIVERSITY OF FLORIDA FOUNDATION** ("Foundation") on behalf of and for the benefit of **THE COLLEGE OF MEDICINE** ("COM") of **THE UNIVERSITY OF FLORIDA** ("UNIVERSITY"), **THE EVELYN F. AND WILLIAM L. McKNIGHT BRAIN INSTITUTE OF THE UNIVERSITY OF FLORIDA** ("MBI-UFL") and **THE UNIVERSITY OF FLORIDA COLLEGE OF PUBLIC HEALTH and HEALTH PROFESSIONS** ("College of PHHP").

WHEREAS the MBRF, the College, the Foundation, the University and MBI-UFL entered into a Gift Agreement on the 28th day of April 2000;

WHEREAS the MBRF, the College, the Foundation, the University, Institute on Aging (IOA) and MBI-UFL amended the Gift Agreement on the 20th day of October 2009 (the "First Amendment");

WHEREAS, the MBRF, the College, the Foundation, the University, IOA and MBI-UFL amended the Gift Agreement a second time on July 1, 2015 (the "Second Amendment");

WHEREAS, the Gift Agreement, the First Amendment and the Second Amendment are collectively referred to as the Gift Agreement;

WHEREAS, the defined terms and words in the Gift Agreement shall have the same meaning in this MOU; and

WHEREAS, the Parties understand that the MOU does not modify the Gift Agreement, but instead expresses the current understanding of the Parties regarding implementation of the CAM Center and re-structuring of the CAM-CTRP.

Purpose

The parties hereto believe it would be in the best interest of all to enter into this MOU to provide flexibility for the development and structuring of the Cognitive Aging and Memory Clinical Translational Research Program (CAM-CTRP) and the implementation of a Center for Cognitive Aging and Memory Clinical Translational Research (the "CAM Center"). Instead of entering into a formal gift agreement amendment at this time, this MOU will provide general guidelines. After the structure, relationships, and function of the CAM-CTRP and CAM Center are better understood, it is intended that a formal gift agreement amendment reflecting the structure and relationships will be entered into. Exhibit I is a schematic showing the relationship of the CAM Center and CAM-CTRP. It is understood that the structure now envisioned, the locations, and participants may change. The purpose of the MOU is to set forth the current understanding of the Parties and to give the parties flexibility to allow for change so that the final product is as good as it can be. The CAM-CTRP is the research program funded by a portion of the Cognitive Aging and Memory Research Fund. The CAM-CTRP was fully described in Schedule 11 of the 1st Amendment and 2nd Amendment, and is attached as Exhibit IV. Reference to CAM-CTRP includes the activities described in Exhibit IV. This program is housed within the CAM Center, which is a formal designation made by the University as part of its academic and research governance structure. The CAM Center will have a Director in accordance with University policy; the CAM Center Director administers the CAM-CTRP. The position formerly referred to as the CAM-CTRP Director is now included in the responsibilities of the CAM Center Director.

1. Cognitive Aging and Memory Research Fund

A. The disbursements from the Cognitive Aging and Memory Research Fund (f/k/a/ the Research Grant Fund) ("CA&MR Fund") shall be allocated one-half to the CAM-CTRP and one-half to the MBI-UFL. Exhibit I.

B. The disbursement to MBI-UFL shall be used under the oversight of the UF Senior Vice President for Health Affairs ("SVPHA") to support ongoing research and other academic activities related to cognitive aging and age-related memory loss in the McKnight Brain Institute, such as faculty recruitment, post-doctoral fellowships, clinical research scholars and basic science research scholars, intra-mural grant awards and visiting scholars and scientists.

C. The one-half disbursed to the CAM-CTRP shall continue to be used to fund CAM-CTRP, now within the CAM Center. The CAM Center Director shall establish a budget for the use of the CAM-CTRP disbursement by the CAM Center for the CAM-CTRP activities. The budget process will develop a detailed schedule of expenditures that will not exceed the CAM-CTRP Fund disbursement. Exhibit II

2. Center for Cognitive Aging and Memory Clinical Translational Research.

The CAM Center was approved as of February 1, 2017. University Centers may include faculty from one or more academic departments and colleges. See Exhibit III. The departmental affiliation of a faculty member should be that which provides his or her optimal academic home in terms of commonality of discipline, commonality of research interests of other faculty members, access to graduate students, and a sophisticated grasp of the faculty member's scientific methods and subject area. The departmental chair will provide and promote professional development, an academic environment that will lead to departmental faculty endorsement of junior faculty for promotion and tenure, and an appropriate place to hold and administer external research grants.

A. **Mission.** The overarching mission of the CAM Center is to advance understanding of cognitive and brain aging with the goal of developing approaches that will help people to age successfully with optimal cognitive and functional capacity throughout the lifespan. Consistent with the CAM Center Mission, the CAM Center will:

1. Engage in cutting-edge interdisciplinary clinical neuroscience and translational research on age-associated cognitive, behavioral and emotional functioning, factors that contribute to impairments and functional decline, and future avenues for intervention.
2. Translate basic science discoveries into clinical application in order to slow, avert or restore age-related cognitive decline and sensory loss.
3. Conduct clinical trials to test promising clinical applications to achieve the stated goals.

This 2A and all of its parts, shall be the "CAM-CTRP Mission". The CAM-CTRP is part of and subsumed by the CAM Center Mission.

(See Exhibit III – Cognitive Aging and Memory – Clinical Translational Research Center – February 1, 2017)

B. **Location of the CAM Center:** The CAM Center research headquarters will be located in the MBI-UFL. Adequate space shall be designated to house the staff and administrative functions of the CAM Center. Space and staff shall be adequate to permit the growth and success of the CAM Center with expanded opportunities through the interdisciplinary research collaborations throughout the University, and may be housed in other appropriate locations as needed and as determined by the SVPHA, in consultation with the

MBRF. Faculty members will be located in their respective departments of academic appointment.

C. **CAM Center Director.** The SVPHA will periodically name a qualified person of national prominence as the CAM Center Director, who will be responsible for the implementation and supervision of the CAM Center. The occupant of the CAM Center Director position will be a full-time member of the University faculty. The UF recognizes the MBRF's strong preference for the CAM-Center Director to be appointed to a COM clinical department and UF commits to use its best efforts to achieve that goal. It is recognized, however, that the appointment of the Center Director who is best qualified to accomplish the Mission and Purpose, as defined, may not be in a COM clinical department. It is agreed that UF will not name a CAM Center Director whose appointment is not in the COM without approval of MBRF, which approval will not be unreasonably withheld. In all events UF commits to consulting with MBRF as part of the process of naming a CAM Center Director.

In the event the CAM Center Director does not fulfill the Purpose, as defined in the Gift Agreement, or does not carry out CAM Center Mission, the MBRF may request the removal and naming of another CAM Center Director. The ultimate removal of the CAM Center Director and naming of a successor will be at the discretion of the Senior Vice for Health Affairs according to the University's standing policies and procedures.

The first CAM Center Director is Ronald A. Cohen, Ph.D. who has served as the Director of the CAM-CTRP and is the occupant of the Evelyn F. McKnight Chair for Clinical Translational Research in Cognitive Aging (the "Clinical Translational Chair"). The CAM Center Director will report to his or her department chair and to the MBI-UFL Executive Director, who in turn reports to the SVPHA. Exhibit I

D. Additional Faculty. Efforts will continue to recruit additional faculty members including physician research/clinical scientists (e.g. a neurologist or a psychiatrist), who will become members of the CAM Center and may participate in the CAM-CTRP but have a faculty appointment in a department that is consistent with his or her discipline.

3. Cognitive Aging and Memory Clinical Translational Research Program.

A. Activities and Operations of CAM-CTRP. The CAM-CTRP activities and operations will continue as they presently exist including the overall goal of CAM-CTRP, which is to develop a highly competitive cutting-edge interdisciplinary clinical translational research program, which translates basic science discoveries regarding cognitive aging and memory into clinical applications to slow, avert or restore age-related cognitive decline and memory loss. See Exhibit IV.

B. Scientific Director. The position of Scientific Coordinator will be abolished.

C. Administration of the CAM Center and the CAM-CTRP. Overall administration of the CAM Center and the CAM-CTRP shall be the responsibility of the SVPHA. The budget will be prepared by the Director of the CAM Center with the assistance of the Health Science Center Vice President for Administration (HSC VPA) who will then present the proposed budget for final review and approval by the executive director of the MBI-UFL and SVPHA. After approval of the proposed budget by the SVPHA, the HSC VPA will coordinate the release and distribution of funds for CAM-CTRP.

A committee consisting of the SVPHA, the MBI-UFL Executive Director, and the Deans of any other appropriate colleges (currently COM and the College of PHHP) will assess progress of the research efforts of the CAM-CTRP to determine the allocation of funds in that year for the CAM-CTRP portion of the distribution from the Cognitive Aging and Research Fund (see

Exhibit I) and discuss with the MBRF the recommended allocation that would best advance the above stated purpose. The MBRF agrees that this is a consultative arrangement on its part.

The University shall be responsible for all expenses connected with the operation of the CAM Center exceeding those expenses required for the operation of the CAM-CTRP.

D. Location of CAM-CTRP. The appointment of the current faculty of the CAM-CTRP will be transferred to the academic office of the department where each such faculty member resides. The administrative office space for the faculty of the CAM-CTRP will be located in the college in which the CAM Center Director resides (currently the College of PHHP) which will be adequate to permit the expected growth and success of the program. The research components of the CAM-CTRP will be transferred to dedicated research space on the ground floor of the MBI-UFL. Clinical and laboratory facilities will be shared resources throughout the relevant clinical departments. Space on the ground floor of the MBI-UFL will be renovated for the ongoing research studies and other academic activities directly related to CAM-CTRP. Until the renovated space is available, the research studies will be performed in space in the Clinical Translational Research Institute. Space allocated for the CAM-CTRP shall be adequate to permit the expected growth and success of the program with anticipation all components of the CAM-CTRP will ultimately reside within the MBI-UFL.

4. The Endowed Chair for Clinical Translational Research in Cognitive Aging ("Clinical Translational Chair").

A. Administration of Clinical Translational Chair: In accordance with University policy, the responsibility for the management and administration of the Clinical Translational Chair shall be under the College of PHHP for as long as it is occupied by Ronald A. Cohen, Ph.D. and his faculty appointment resides in the Department of Clinical and Health Psychology. When and if the Clinical Translational Chair is no longer occupied by Dr. Cohen, then in accordance with University policy, the responsibility for the management and

administration of the Clinical Translational Chair shall be under a clinical department in the COM.

C. Naming of the Clinical Translational Chair: When and if the Clinical Translation Chair is vacant, a qualified person of national prominence will be named to the Clinical Translational Chair, in accordance with University policy. The occupant of the Clinical Translational Chair will be a full-time member of the University Faculty.

All appointments to the Clinical Translational Chair shall be limited to a maximum of five years, renewable each year during that term. Appointments may be extended with the recommendation of the Dean of the COM and the SVPHA, with consultation with the MBRF. The Clinical Translational Chair will not remain vacant for more than (1) year without approval of the MBRF. In the event the Clinical Translational Chair does not fulfill the Purpose or other duties outlined in schedule 11.4 (Second Amendment) the MBRF may request the removal and naming of another chairperson to occupy the Clinical Translational Chair. The ultimate removal of the Clinical Translational Chair occupant and the naming of the occupant of the Clinical Translational Chair will be at the discretion of the Dean of the COM according to the University's standing policies and procedures of the University. The COM agrees the appointment of subsequent Clinical Translational Chairs shall be made in consultation with the MBRF. References herein to the Clinical Translational Chair shall mean either the occupant of the Chair or the Chair, as context dictates.

5. Collaborating/Visiting Professors: The MBI-UFL, the COM, the College of PHHP, and the University will endeavor to identify research scientists involved in similar research in other institutions who would collaborate with faculty at the University to complement or augment the CAM-CTRP, the CAM Center, and the research initiatives of the Chair, if it is anticipated such collaboration will be beneficial.

6. Annual Reports. At least annually, the CAM Center Director shall prepare, and present to the MBRF for discussion, a report that describes the operations of the CAM Center, including CAM-CTRP, the performance and activities of the Clinical Translational Chair, and the ongoing research and other academic activities related to cognitive aging and age-related memory loss including results of ongoing and recently completed research. In addition to the annual report, in order to keep the MBRF reasonably informed about the CAM-CTRP activities, the SVPHA will report significant events to the MBRF when they occur.

The MBRF agrees that this discussion is a consultative arrangement on its part. The annual report from the CAM Center Director shall include an affirmative statement that the operations funded by the MBRF of the CAM Center, the CAM-CTRP, the Clinical Translational Chair and ongoing research and other academic activities related to cognitive aging and age-related memory loss in the McKnight Brain Institute, further the Purpose and that no portion of the CAM-CTRP Fund was used for a Prohibited Purpose or other than in support of the Purpose. A suggested template for the annual report is at Schedule 10.2. First Amendment.

7. Consultation. The operations of the CAM-CTRP, the CAM Center, and the Clinical Translational Chair, will be within the sole discretion of the SVPHA and appropriate deans. However, the COM, the College of PHHP and the MBI-UFL shall discuss the operations of the CAM-CTRP, the CAM Center and the performance of the Clinical Translational Chair with the MBRF at least annually in a consultation mode and shall take into consideration the MBRF's input regarding activities. In addition to the annual report, in order to keep the MBRF reasonably informed about the CAM-CTRP activities, the COM the College of PHHP, and the MBI-UFL will report significant events to the MBRF when they occur. The MBRF acknowledges that notwithstanding its various rights to consult, confer, and advise on various matters under this MOU and Gift Agreement, the ultimate decision-making authority regarding

staffing, appointments, research initiatives, and related institutional decisions lies with the University as vested in the SVPHA.

McKNIGHT BRAIN RESEARCH FOUNDATION

By J. Lee Dockery
J. Lee Dockery, MD, Trustee

By Michael L. Dockery
Michael L. Dockery, MD, Trustee

By Richard I. Isaacson
Richard I. Isaacson, MD, Trustee

By Nina Ellenbogen Raim
Nina Ellenbogen Raim, MD, JD, Trustee

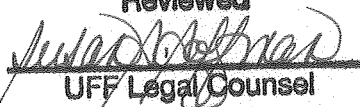
By Gene G. Ryerson
Gene G. Ryerson, MD, Trustee

By Madhav Thambisetty
Madhav Thambisetty, MD, PhD, Trustee

By Robert M Wah
Robert M Wah, MD, Trustee

SUNTRUST BANK, CORPORATE TRUSTEE

By Melanie A. Cianciotto
Melanie A. Cianciotto, First Vice
President, Foundations & Endowments Specialty Practice

Reviewed

UFF Legal Counsel

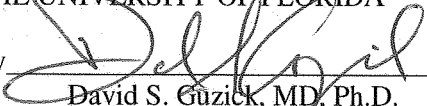
THE UNIVERSITY OF FLORIDA FOUNDATION,
INC.

By 
Thomas J. Mitchell, Executive Vice
President

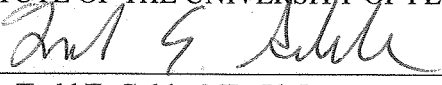
THE UNIVERSITY OF FLORIDA COLLEGE OF
MEDICINE

By 
Michael L. Good, MD.
Dean, College of Medicine

THE UNIVERSITY OF FLORIDA

By 
David S. Guzick, MD, Ph.D.
Senior Vice President for Health Affairs
President, UF Health
University of Florida

EVELYN F. and WILLIAM L. McKNIGHT BRAIN
INSTITUTE OF THE UNIVERSITY OF FLORIDA

By 
Todd E. Golde, MD, Ph.D.
Executive Director
Evelyn F. and William L. McKnight Brain
Institute of the University of Florida

By 
Ronald A. Cohen, Ph.D.
The Clinical Translational Chair and
Director, Center for Cognitive Aging and
Memory Clinical Translational Research

THE UNIVERSITY OF FLORIDA COLLEGE OF
PUBLIC HEALTH AND HEALTH PROFESSIONS

By 
Michael Perri, Ph.D.
Dean, College of Public Health and
Health Professions

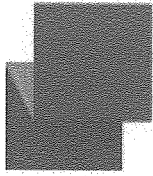
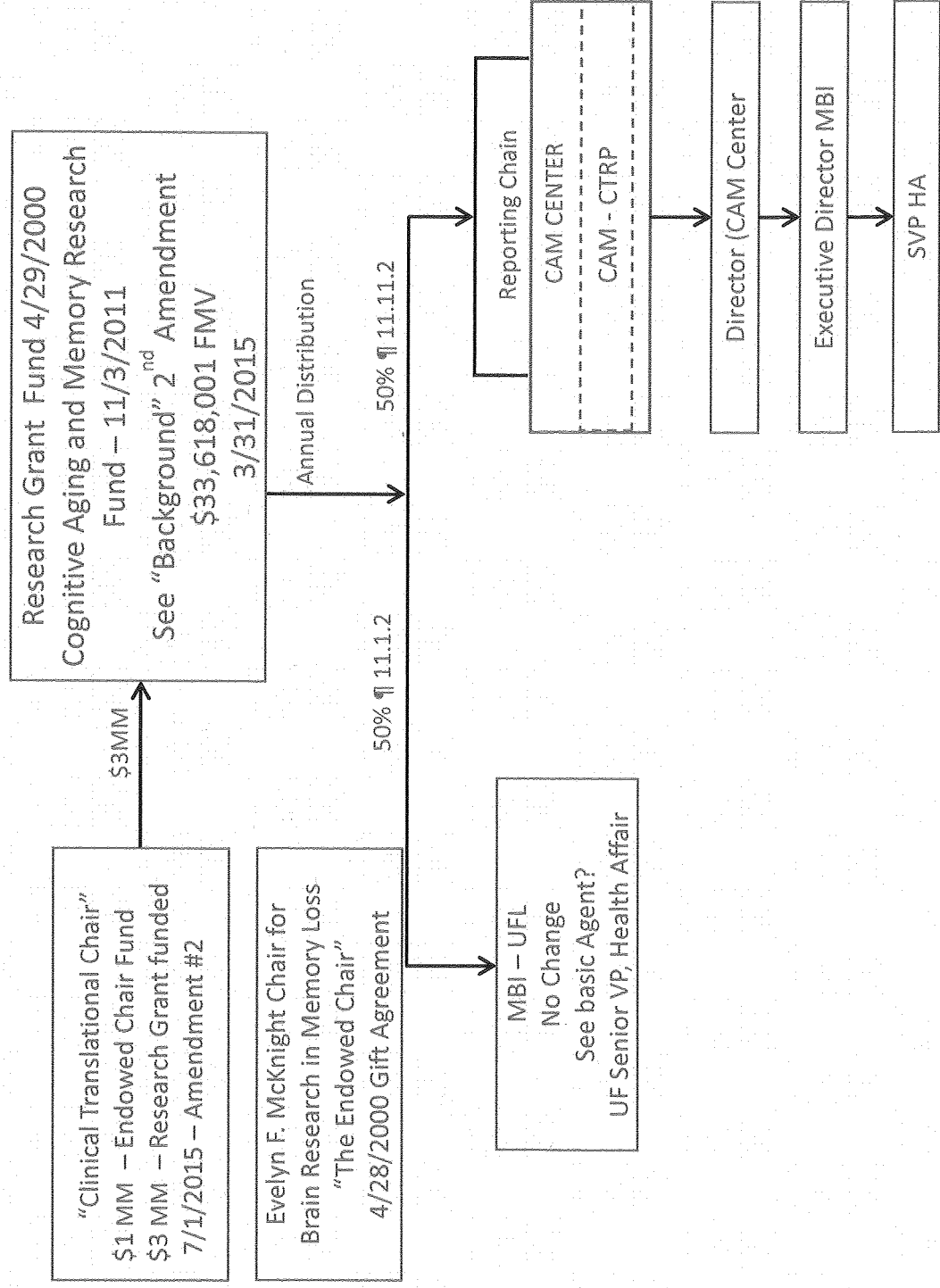
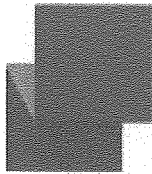


EXHIBIT I

McKnight Research Grant Fund Schematic

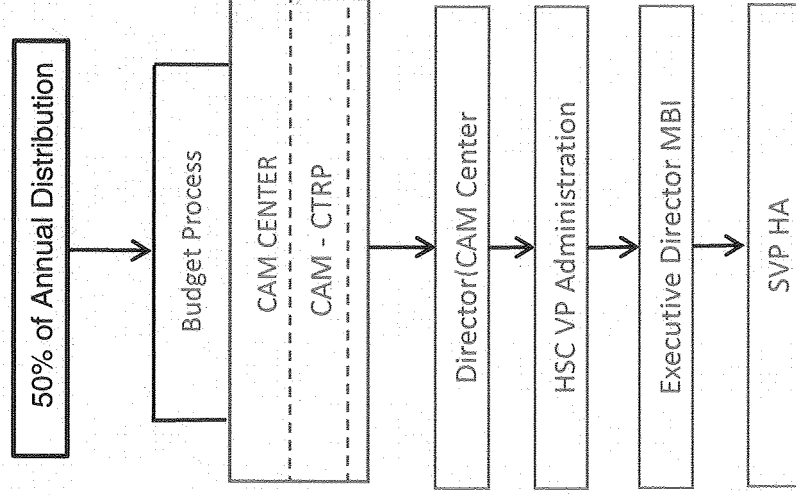


12/22/2016



McKnight Research Grant Fund Schematic

EXHIBIT II



12/22/2016

40264833;2

EXHIBIT III



Office of the Provost and Senior Vice President

235 Tigert Hall
PO Box 113175
Gainesville, FL 32611-3175
352-392-2404 Tel
352-392-8735 Fax

February 1, 2017

MEMORANDUM

TO: Ronald Cohen, Ph.D., Proposed Center Director

FROM: Joseph Glover, Provost and Senior Vice President for Academic Affairs
David Norton, Vice President for Research 

SUBJECT: Center for Cognitive Aging and Memory-Clinical Translational Research Center

We are pleased to inform you that your request to establish the Center for Cognitive Aging and Memory-Clinical Translation Research Center at the University of Florida has been approved. This note will also confirm that the 7.5% indirect cost return that is distributed to a center shall be divided equally at 3.75% between the Cognitive Aging and Memory-Clinical Translational Research Center and the McKnight Brain Institute at the University of Florida.

JG/DN/rjh

cc: David Guzick, Senior Vice President for Health Affairs
Michael Perri, Dean, College of Public Health and Health Professions
Marie Zeglen, Director, Institutional Planning & Research

41070089

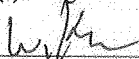
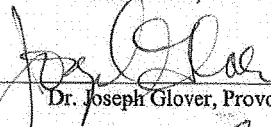
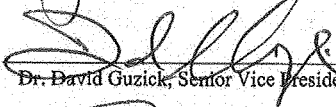
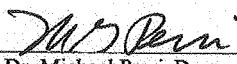
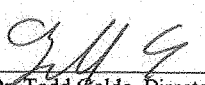
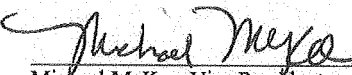
The Foundation for The Gator Nation
An Equal Opportunity Institution

Form 1

Cognitive Aging and Memory – Clinical Translational Research Center

(January 1, 2017)

The submission and signing of a proposal to initiate a State of Florida institute/center or the establishment of a University institute/center constitutes a commitment by the university(ies) to ensure that the institute/center's activities support the stated mission(s) and goals of the institution(s).

University of Florida	 1/31/2017 Dr. W. Kent Fuchs, President Date
University Center	 1/28/17 Dr. Joseph Glover, Provost Date
Type of Center/Institute	 1/19/17 Dr. David Guzik, Senior Vice President Health Affairs Date
January 1, 2017	 1/20/17 Dr. David Norton, Vice President for Research Date
Proposed Implementation Date	
51	
Associated Discipline (2-digit CIP)	 1/19/17 Dr. Michael Perri, Dean Date College of Public Health and Health Professions
 01/18/2016 Proposed Center Director Date Dr. Ronald Cohen, Director	 1/15/17 Dr. Todd Golde, Director Date McKnight Brain Institute
 1/23/17 Michael McKee, Vice President and Date Chief Financial Officer	

Form 2

Institute/Center Data

Directory Information

I/C Name: Center for Cognitive Aging and Memory - Clinical Translation Research Center			
I/C Code:		University: University of Florida	I/C Type: Center
I/C Director: Ronald Cohen, Ph.D., ABPP, ABCN			Discipline(s) (2-Digit CIPs): 51
I/C Address: 1225 Center Drive, Gainesville, FL 32611			
I/C Telephone: 352-294-5830		I/C E-Mail Address: CAM@php.ufl.edu	
I/C SUNCOM:		I/C Web Site Address: TBD	
I/C FAX:		Affiliated Universities:	

Mission and Areas of Focus

Mission Statement: (No more than 120 words)	The overarching mission of the center is to advance understanding of cognitive and brain aging with the goal of developing approaches that will help people to age successfully with optimal cognitive and functional capacity throughout the lifespan. Consistent with this mission, the CAM will: ☐ Engage in cutting-edge interdisciplinary clinical neuroscience and translational research on age-associated cognitive, behavioral and emotional functioning, factors that contribute to impairments and functional decline, and future avenues for intervention. ☐ Translate basic science discoveries into clinical applications in order to slow, avert or restore age-related cognitive decline and memory loss. ☐ Conduct clinical trials to test promising clinical applications to achieve these goals.
	Key Terms:

Form 3

I/C Code:		I/C Name: Center for Cognitive Aging and Memory - Clinical Translational Research Center				
Prepared By: Tina Lacy		Date: 12/16/2016	Telephone: 352-294-5841			
Estimated Expenditures for the Institute/Center		FISCAL YEAR: 2017				
		Budgetary Unit:* UF HSC				
		SUS Appropriated Funds	Contracts and Grants	Fees for Services	Private & Other (Specify)	Total
Salaries & Benefits	Faculty, TEAMS, & USPS	0	541,947	0	223,242	765,189
Other	Housestaff	0	0	0	0	
Personal	Graduate Assistants	0	0	8	21,528	21,528
Services	Other	0	101,100	0	21,568	122,668
Expenses		0	916,075	0	72,172	988,247
Operating Capital Outlay		0	0	0	100,000	100,000
Total Expenditures		0	1,559,122	0	438,509	1,997,631

Positions and Rate	SUS Appropriated Funds	Contracts and Grants	Fees for Services	Private & Other (Specify)	Total
Faculty Positions (FTE in Personyears)	0.00	27.96	0.00	8.04	36.00
TEAMS and USPS Positions (FTE in Personyears)	0.00	23.40	0.00	12.60	36.00
Total Positions (FTE in Personyears)	0.00	51.36	0.00	20.64	72.00
Sum of Salary Rates for These Faculty Positions	0	326,598	0	110,714	437,312
Sum of Salary Rates for These TEAMS and USPS Positions	0	107,423	0	68,007	175,430
Sum of Salary Rates for Faculty, TEAMS, and USPS Positions	0	434,021		178,721	612,742

* Budgetary Unit: Specify E&G, IFAS, or UF-HSC

Projected Space Requirements (in square feet)

Projected Space Required by Source	Office	Laboratory	Conference Rooms	Other
From Existing Inventory	360 + 120 (480)	0	0	~430
Rented				
New Construction		~900+~120 (~1020)	~180	

Current Office Space (CHP): 3 x 120 sq. ft. (Faculty offices)

CAM Administrator Office (Tina Lacy) : ~ 120 sq. ft.

Current Shared RA Workspace: 3 x ~144

Clinical Research Space in MBI (renovation): ~900 sq. ft.

The projected space requirements for the near term are as indicated in the table. A detailed plan of the new construction has been provided previously, and is being used for architectural blueprints. The CAM research space will include clinical assessment and intervention rooms located on the ground floor of the MBI, next to the new Prisma scanner. In addition, a room that is approximately 12 x10 sq ft. will be renovated to serve as a phlebotomy and freezer area for storing biospecimens.

We anticipate the need for a small conference room and The conference room is not an immediate need, but will be necessary longer term.

A MBI office for Tina Lacy apparently already exists, but may require renovation. This will need to be determined in conjunction with the planned move of the MBI administrative offices.

Additional office space for future faculty recruits may be necessary.

There has been discussion about eventually moving the current CAM-CTRC faculty and staff to offices in the MBI depending on future space developments in the MBI.

Form 1a
Indirect Cost Return for Proposed Center

For UF Internal Use Only

The indirect cost return for a center in a college is subtracted from that received by the college. This is because all indirect costs are now returned to the colleges, minus costs of running central programs. This form is to establish what percentage (7.5% maximum), if any, the proposed center or institute will receive in indirect cost return.

INDIRECT COST ASSIGNMENT

Date: 01/13/2016

The 7.5% indirect cost return that is distributed to a center **shall be divided equally** at 3.75% between the Cognitive Aging and Memory – Clinical Translational Research Center and the McKnight Brain Institute at the University of Florida.

Institute or Center: Cognitive Aging and Memory – Clinical Translational Research (CAM) Center

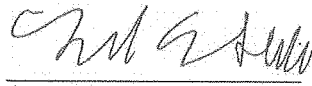
Indirect Cost Return: YES x % Return (max 7.5%) 3.75%
NO _____

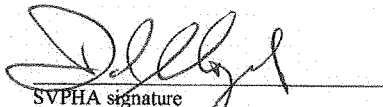
Institute or Center: McKnight Brain Institute, Senior Vice President for Health Affairs.

Indirect Cost Return: YES x % Return (max 7.5%) 3.75%
NO _____

Director's Agreement:

Sr. VP, Health Affairs Agreement:


Director's signature


SVPHA signature

EDC/cl

Exhibit IV

Schedule 11.1

Cognitive Aging and Memory Clinical Translational Research Program – CAM-CTRP Concept and Strategic Executive Plan

Approximately 1 in 7 adults age >65 years experiences moderate to severe cognitive and memory impairment, both of which adversely impact independence. Clinical and translational research on interventions to remediate or prevent these highly prevalent age-related conditions is in its early stage.

Creating a novel Cognitive Aging and Memory Clinical Translational Research Program (CAM-CTRP) addresses this critical gap in research. The CAM-CTRP is intended to capitalize on the existing strengths of the Institute on Aging/Pepper Center Cores in clinical and basic research, of the UF McKnight Brain Institute, of the Departments of Neurology, Neurosciences, Psychiatry and Aging and Geriatric Research, of other UF institutes and colleges, and of the extremely rich UF grant funding portfolio in the arena of aging, brain, cognition and memory. The CAM-CTRP is intended to be fully integrated into the newly NIH funded Clinical Translational Sciences Institute (CTSI) of which the Institute on Aging is one of the eight Clinical Research Units. The CAM-CTRP is designed to be positioned at the forefront of the national arena of aging, cognition and memory research by using an interdisciplinary approach that traverses the entire spectrum of biomedical investigation.

The primary goal of the CAM-CTRP is to develop a highly competitive cutting-edge interdisciplinary clinical translational research program, which translates basic science discoveries regarding cognitive aging and memory into clinical applications to slow, avert or restore the age-related cognitive decline and memory loss.

The specific research goals include but are not limited to the following:

- Translate into clinical applications discoveries from basic research.
- Conduct community- and patient-based clinical trials to test the efficacy of interventions to slow, avert or restore age-related cognitive decline and memory loss. Such interventions may include lifestyle modification, behavioral, pharmacological, hormonal, nutraceuticals and regenerative medicine approaches.
- Assess the impact of such interventions on quality of life, and cognitive and physical independence of older adults.
- Conduct ancillary studies focused on cognition and memory in ongoing and future clinical trials of interventions aimed at averting age-related conditions.

- Conduct community- and patient-based epidemiologic and mechanistic studies to assess modifiable biological and behavioral risk factors of age-related cognitive decline and memory loss, which could be targeted in intervention clinical trials.
- Conduct secondary data analyses in existing databases of epidemiologic studies and clinical trials to generate preliminary data for planning the above mentioned clinical studies.
- Translate into human studies concepts and models developed in basic and translational research in the McKnight Brain Institute focused on aging brain plasticity and reprogramming, and in other areas.
- Translate findings from brain development and repair into new paradigms for protecting and restoring at-risk higher forebrain circuitry that contributes to age-related memory and learning loss.
- Translate into effectiveness and implementation studies the efficacious interventions tested in clinical trials.

Resources

The following resources are necessary to successfully address the Program goals:

Human resources

- Program director: must have an MD or MD, PhD degree, must qualify for the appointment at the full professor level, and must have proven extensive experience in: (1) cognitive aging/memory related clinical and interdisciplinary research funded by the NIH or other peer-reviewed federal funding; (2) leadership and administration; and (3) mentoring and recruiting innovative and productive researchers.
- Two associate/assistant professor faculty members with expertise in the area of clinical trials, epidemiology and/or interdisciplinary research in aging, cognition and/or memory
- Two post-doctoral fellows
- One administrative manager
- One clinical research study manager
- One research study coordinator

Space and equipment

- Office: Approximately 1,500 sq. ft. of office space for faculty and staff

- Shared resources:
 - **Clinical research assessment** facility specialized in assessments relevant to cognition, memory and performance outcomes. A research study drugs dispensing and storage area to be used for clinical trials.
 - **Biological specimens processing and repository.** A laboratory for processing, tracking and storing biological samples to be adjacent to the clinical research area. The samples will be available for analysis in other shared resources, including the Genomics and Biomarkers core of the Institute on Aging, the Genetics Institute and the Cell and Tissue Analysis Core (CTAC) and Adult Stem Cell Engineering and Therapeutic (ASCEnT) core in the McKnight Brain Institute that offers state of the art analysis of at-risk tissues and cells, as well as bioassays for high-throughput screening of new cell and molecular therapeutics for age-related memory loss.
 - **Recruitment and retention** of study participants presents unique challenges in older and frail participants regarding accessibility, transportation, caregiver involvement and communication barriers. This resource includes a telephone screening area, a mass-mailing area, a transportation van and interview rooms for screening.
 - **Behavioral and lifestyle modification** intervention facility for implementing intervention studies that involve cognitive training, physical activity, diet, and behavioral counseling resources. This area includes a walking track, physical exercise devices, activity rooms and counseling meeting rooms.
 - **Laboratory of epidemiology.** The laboratory maintains electronic data sets of epidemiological studies, clinical trials and administrative databases involving older adults, which are available for data analyses by affiliated researchers. These resources are particularly useful for generating preliminary data for planning clinical research studies to improve the cognition and memory of the aging community.
 - **Magnetic Resonance Imaging** capability, to complement existing 3T and large T MRIs in the McKnight Brain Institute for functional and morphologic studies.
 - **Interdisciplinary cognitive aging and memory clinic** which provides specialized consult care. The outpatient resources are used for testing the diffusion and implementation of clinical research findings and for recruitment of research study participants.

Seed funds for pilot studies

Although seed funding is not the primary focus of the CAM-CTRP, seed funds for pilot studies are needed to generate preliminary data to be competitive for larger independently funded grants, and to foster interdisciplinary collaborations in the area of cognitive aging and memory across the UF campus. The distribution of such funds ought to be publicized by internal request for applications and is subject to formal internal peer review according to explicit criteria. Such

criteria must include clear plans for designing larger independently funded studies, and other factors to ensure future funding success.

Accurate tracking of progress of the pilot studies, as well as success in independent funding is planned to ensure accountability for the return on investment in pilot studies.

Program governance and reporting

Because the focus of the CAM-CTRP is cross-campus and interdisciplinary, it's governance ought to be under an interdisciplinary institute. To ensure the full accountability, responsiveness to the goals, adherence to set timelines and success in reaching the benchmarks, the CAM-CTRP Director reports to a single Program Supervisor and Coordinator (ideally the Director of the Institute on Aging or the Executive Director of the McKnight Brain Institute) who receives the input from the chairs and directors of the collaborating departments and institutes, and who is ultimately responsible of the overall success and administrative oversight of the Program.

The CAM-CTRP Director keeps the Trustees of the McKnight Brain Research Foundation apprised of progress with the Program, and submits to them an annual progress report regarding success in achieving the benchmarks.

The faculty members of the program are appointed in the departments related to their parent discipline or to their scientific focus (Aging-geriatrics, Neurology, Psychiatry, Neurosciences, others) with cross-appointments with other relevant departments.

Timeline and benchmarks

- **Year 1.** During the first year of appointment each of the senior faculty members submits at least one NIH R01 or equivalent grant, and each of the junior faculty members submits at least one small grant or a career development grant.
- **Year 2.** In the second year of appointment the Program Director submits a program project or equivalent NIH programmatic grant related to clinical translational research in cognitive aging and memory, and the grants submitted during the first year are resubmitted if they have not been funded in the first place.
- **Year 3.** The Program generates the first independent NIH funded grants and submits new grants or resubmits revised grants.
- **Year 4.** Additional grants previously submitted are funded and new grants are submitted.
- **Year 5.** The program project grant is funded and external grants provide full support of direct costs of the Program. In the fifth year all faculty members support at least 75% of their effort by means of independently funded grants. Infrastructure and administrative costs of the program continue to be supported by means of recurrent funds.

It is expected that the members of the Program collaborate on existing grants in the Institute on Aging, such as for example the Pepper Center or the Testosterone Trial, and other grants in the McKnight Brain Institute.

It is expected that the Program participates in the training, mentoring and research career development of junior investigators