Ed and Ethel Moore Alzheimer's Disease Research Program

Funding Opportunity Announcement

FY 2019-20

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Ed and Ethel Moore Alzheimer's Disease Research Program
Funding Opportunity: FY 2019-20

All awards in response to this Funding Opportunity are subject to the availability of funds and spending authority provided by the Florida Legislature. By submitting a grant application pursuant to this Funding Opportunity, all applicants acknowledge and consent to this condition.

Direct all questions about the online application process and related issues to:

Florida Department of Health
Public Health Research Unit
Division of Community Health Promotion
4052 Bald Cypress Way Bin A24
Tallahassee, Florida 32399-1725
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Website: https://peernet.orau.org/Intake/Submission/948b695c-ad96-e911-8142-0050568131c9

I. OVERVIEW

1. Introduction

The Ed and Ethel Moore Alzheimer's Disease Research Program (hereafter referred to as the "Program"), is established in section 381.82, Florida Statutes. The purpose of the Program is to fund research leading to prevention of, or a cure for, Alzheimer's disease by pursuing the following goals:

1. Improve the health of Floridians by researching better prevention and diagnoses of, and treatments and cures for, Alzheimer's disease.

2. Expand the foundation of knowledge relating to the prevention, diagnosis, treatment, and cure of Alzheimer's disease.

3. Stimulate economic activity in Florida in areas related to Alzheimer's disease research.

Funding is available for research grants awarded in FY 2019-2020. This document will provide the detailed information needed for completing a Letter of Intent and the grant application.

2. Priority Areas

The purpose of this Funding Opportunity Announcement (FOA) is to stimulate research relating to the prevention, diagnosis, treatment, care management, and cure of Alzheimer's disease (AD) that is of the highest priority and potential benefit to the people of Florida. This program anticipates this will be achieved by supporting research in the following five priorities:

Priority Area 1:

Objectives: This FOA aims to stimulate the discovery and validation of a broad spectrum of potential therapeutic strategies for dealing with the behavioral and social needs of persons with AD and their caregivers. The major overall goal of this FOA is to foster novel ideas relating to underdeveloped/underfunded areas of research that will then lead to transformative advances and major funding from the National Institutes of Health (NIH), not-for-profit foundations, or in some cases licensing of a technology by a for-profit entity. The FOA is designed to support grants ranging from pilot research to more mature projects that are attempting to advance a therapeutic approach or concept. Consortium grants are encouraged for maximum return on results.

Background: The current national portfolio for AD research is focused primarily on the biomedical aspects of AD and related dementias. The National Alzheimer's Project Act specifically includes two goals related to behavioral and social aspects of care: Goal 2: Enhance Care Quality and Efficiency; and Goal 3: Expand Support for People with Alzheimer's Disease and Their Families. Further, there is a desperate need for research into changes in care processes that will lead to improvement in the lives of people with AD and related

dementias, and their caregivers. This FOA Priority is designed to encourage novel studies that can lead to transformative advances in care.

Focus Areas: (The applicant must state clearly, which of these areas the proposal addresses.)

Focus Area 1.1 Behavioral. "Behavioral expressions," formally called psychiatric manifestations of dementia, are common and difficult problems. Often, these lead to caregiver exhaustion and the transfer of care to institutional care facilities. The antipsychotic, anti-seizure, anti-anxiety, and antidepressant medications may not be effective treatment options or may have serious side effects, including death. Centers for Medicare and Medicaid Services, partnered with state and federal agencies, special memory care facilities, community agencies and programs (in-home or in-facility), respite care services, and volunteer programs, improve the quality of care and life of diagnosed persons and their caregivers. While many such resources were initially developed to reduce the use of antipsychotic medications, the national partnership's main goal is to encourage the use of non-pharmacological approaches and person-centered dementia care practices to optimize the functioning of persons with Alzheimer's disease and related dementias, reduce caregiver stress, and provide person-centered care practices. Although many facilities have developed special units for managing persons with these problems, there has been limited research into their effectiveness. Consortium partnerships of such programs and services with research institutions to examine effectiveness is strongly encouraged for maximum return on results. High priority will be given to research on:

- Evaluation of antecedents and triggers of "behavioral expressions"
- Testing of non-pharmacological interventions (e.g., physical exercise, group activities, music, diet, bright light therapy, play therapy, replacement therapy, pet therapy, massage, Snoezellen rooms) for "behavioral expressions."
- Comparative evaluations of different types of facilities, such as memory care units or geropsych units, for clinical outcomes and cost-effectiveness.
- Proof of concept proposal demonstrating a community model for the evaluation and treatment of individuals with cognitive impairment and acute psychiatric/behavioral disturbances.
- Demonstration project providing alternatives to utilizing the Baker Act in the setting of acute agitation/behavioral disturbances.
- Demonstration project providing alternative and novel pharmacological approaches to treat agitation/behavioral disorders.
- Development of more specific and sensitive screening tools to diagnose people with psychiatric disorders who present with AD and related disorders.

Focus Area 1.2 Social. The social environment for people with AD plays an important role in disease management, progression, and health care costs. The scope of this focus area includes interventions to reduce caregiver burden and to improve the quality of care across various settings including individuals, families, and communities through resource improvement or education.

1.2.1 Resources: Sometimes individuals are diagnosed with AD or other types of dementias but do not receive referral information to community-based resources. Some communities, particularly rural communities, have few services available such as support groups, respite care,

or caregiver education. Consortium work is encouraged for maximum return on results. High priority will be given to research on:

- Technological interventions for assisting people with Alzheimer's or caregivers (e.g., application development, use of robotics, sensors, locator devices, reminders, virtual reality related technology)
- Technological assistance for improving quality of care in adult day care or other residential settings in rural places where there may be few or no existing resources
- Interventions to help caregivers navigate the interface of formal and informal care and acquire seamless care coordination
- Barriers to access and utilization of long-term care resources including home and community-based services such as adult day care services, foster/group homes, nursing homes, memory care programs, assisted living facilities, hospice care services
- Memory rehab programs
- Research on disparities in quality of care received amongst diverse racial, ethnic and sociodemographic settings secondary to lack of opportunities
- Analysis of alternative environmental design to promote greater independence and reduce adverse behaviors (e.g., dementia-friendly housing, communities and gardens, as well as, person-centered care such as Eden Alternative)
- Transportation barriers, driving related issues seen with Alzheimer's disease and related dementias
- Developing useful resources to help caregivers with planning ahead such as financial and legal planning, emergency back-up plans, etc.

1.2.2 Education: There are important cultural differences in caregiving. Many people with AD have acknowledged the "stigma" of the diagnosis. The lack of attention to these types of factors contributes to adverse health outcomes and high costs of care. Consortium work is encouraged for maximum return on results. High priority will be given to research on:

- Applied research into different types of AD caregiver training (e.g., The Best Friends Approach and Dementia Care Mapping)
- Best methods for communicating the diagnosis to people with AD and related dementias
- Methods of assessing surrogate decisions for continued care and their fidelity with the wishes and preferences of the diagnosed person
- Best practice curricula for educating and training first responders and similar community health and service providers who address acute behavioral emergencies in people with AD and related dementias
- Education and training related to planning ahead such as financial and legal planning, emergency back-up plans such as for weather emergencies or for when the caregiver is temporarily or no longer able to provide care

Focus Area 1.3 Palliative and End-of-Life Care. AD and related dementias are the sixth leading cause of death (COD) in America, and recent estimates suggest it is the third leading

COD in those over age 65 due to underreporting. Because of an improvement in early diagnosis, patients live many years with AD before they die.

1.3.1 Advance Care Planning: While the other common causes of death are associated with preservation of cognition, often until the very end of life, persons with AD and related dementias typically lose the ability to direct their own care long before the time of death. Surrogate decision-making is the norm. Some studies have shown that family caregivers have a low to moderate agreement with persons with diagnosed persons on preferences for end of life treatment. This highlights how planning for care at the end of life is affected by uncertainty, even when the caregiver and person with dementia may perceive the care-giving/receiving relationship to be sound and satisfactory. Little is known about the status of personal advance care planning for caregivers of diagnosed persons, and its relationship with advance care planning for persons with dementia. Advance care planning is known to improve end of life care and patient and family satisfaction and it reduces stress, anxiety, and depression in surviving family members and caregivers. Consortium work is encouraged for maximum return on results. High priority will be given to research on:

- Promotion and best practices for conducting Advance Care Planning (ACP) discussions in persons with AD and/or caregivers of persons with AD (e.g., Engage with Grace – The One Slide Project, The Conversation Project, Caring Conversations, ACP Decisions videos, Go Wish Cards, Five Wishes, Aging with Dignity)
- The use of online advance directives in persons with early AD and/or caregivers of persons with AD (e.g., PrepareForYourCare.org, MyDirectives.com, the Letter Project form, Five Wishes, Aging with Dignity)
- Effective approaches to promote advance care planning (discussions and completion) as part of primary care services for persons with early AD and/or for caregivers of persons with AD.

1.3.2 Multimorbidity: There is high prevalence of comorbid conditions in people with dementia. Neuropsychiatric symptoms (NPS) are known to increase with cumulative comorbidity burden. The presence of dementia may confound clinical care for other conditions and challenge the ability to manage their chronic conditions. Little is known or has been explored about systems and processes currently in place for the care of people with dementia who have comorbid medical conditions, and about the experiences of people with dementia who have comorbid medical conditions and their family caregivers. There is a need for more research looking at the ways in which having dementia influences clinical care for other conditions and how systems, processes of care, and different services adapt to the needs of people with dementia and multiple comorbid conditions. In addition, coordination and planning for the management of multiple comorbid conditions in a person with moderate to advanced dementia, in keeping with the person's personal goals of care while balancing potential benefits with recognized harms, can be a challenge. Consortium work is encouraged for maximum return on results. High priority will be given to research on:

- Analysis of methods for decision-making on discontinuing treatments of co-morbid conditions in advanced AD, for example, based upon goals of care, life expectancy, time to benefit, treatment targets, and balance between potential benefits and potential or recognized harms of treatments.

- Application of recommendations from the Choosing Wisely campaign that promotes conversations between clinicians and diagnosed persons choose care that is supported by evidence, not duplicative of other tests or procedures already received, free from harm, and truly necessary (e.g., American Geriatrics Society Choosing Wisely Campaign: Ten Things Clinicians and Patients Should Question)

1.3.3 Palliative Care: Progressive Dementia is a life limiting condition with mounting prevalence and multifaceted needs. Palliative care needs of persons with dementia are often not recognized or inadequately addressed. Symptoms, such as pain, are under treated while these persons are over subjected to burdensome interventions with often additional accumulation of symptoms or distress or functional compromise related to the burdensome interventions. Palliative care can be described as person and family centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care, throughout the continuum of illness, involves addressing physical, intellectual, emotional, social and spiritual needs, as well as, facilitating their autonomy, access to information, and choices of the person with the diagnosis.

The delivery of palliative care can be differentiated from the delivery of hospice care. Palliative care is delivered as inter-professional care that aims to relieve physical and emotional suffering, improve quality of life, optimize function, and assist with decision making for people with advanced illness and their families/care partners. It is offered simultaneously with all other disease-modifying medical treatments, either by the primary medical team or in conjunction with a palliative care consultant. Hospice services in the United States are considered to be specialized palliative care limited to people who meet two criteria: a) their life expectancy is <6 months if their disease takes its natural course, and b) they (or their proxies) have elected to focus on comfort measures and forgo curative treatment. Consortium work is encouraged for maximum return on results. High priority will be given to research on:

- Best practices for palliating symptoms in persons with moderate to advanced AD
- Best methods for providing palliative care education or hospice training for AD care providers of diagnosed persons
- Inter-professional palliative care education or hospice training for care providers of diagnosed persons
- Effective approaches for transition in care for a person with advanced AD to palliative care or hospice care, including optimal processes for communication (e.g., based on the applicable components of the 7 C's of the Gold Standard Framework: communication, coordination, control of symptoms, continuity, continued learning, caregiver support, and care of the dying).

Priority Area 2:

Objectives: This FOA aims to stimulate a) the discovery and validation of a broad spectrum of potential therapeutic targets or novel therapeutic strategies, b) provide novel insights into the pathophysiology of AD, and c) identify novel biomarkers. The major overall goal of this FOA is to foster novel ideas relating to underdeveloped/underfunded areas of research that will then lead to transformative advances and major funding from the National Institutes of Health, not-for-profit foundations, or in some cases licensing of a technology by a for-profit entity. The

FOA is designed to support grants ranging from pilot research to more mature projects that are attempting to advance a therapeutic concept or approach.

Background: The current national portfolio for AD research is rather conservative and many questions about the pathophysiology of AD remain poorly explored. Further, there is a desperate need to develop novel therapeutic approaches and strategies. This FOA is designed to encourage novel studies that can lead to transformative advances.

Focus Areas: (The applicant must state clearly which of these areas the proposal addresses.)

Focus Area 2.1 Novel therapeutic targets and strategies. The development of novel therapeutics aimed at slowing and eventually preventing the progression of AD remains a critically important public health goal. Further, there is a need for better therapies that can improve symptoms or alter the disease course even at later stages of the disease. High priority will be given to novel therapeutic approaches. These may include novel approaches to target known factors (e.g., amyloid, tau), identification of new targets, evaluation of combination therapies, non-pharmacologic interventions, or even non-traditional interventions (e.g., nutraceutical interventions and chair yoga). Studies may range from pure target discovery to high throughput screening campaigns to preclinical proof of concept studies to pilot or small clinical trials. For more advanced technologies, initial, small, PI-initiated Investigational New Drug (IND) enabling studies may be proposed.

Focus Area 2.2 Mechanisms of neurodegeneration. There is considerable evidence that AD is a complex proteinopathy in which accumulation of Abeta and tau proteins and other proteins play a pivotal role. However, we have a relatively poor understanding of how these proteinopathies cause neurodegeneration. High priority will be given to applications that provide novel insights into cellular pathways and other mechanisms of neurodegeneration. These proposals, for example, may address questions such as: 1) How does Abeta trigger tau pathology? 2) What is a dystrophic neurite? 3) Why are some populations of neurons vulnerable? 4) What is the role of innate immune activation? 5) What early changes in neurochemistry predispose to developing Alzheimer's disease or related dementias and implications for therapies? Studies should expand beyond current paradigms (such as primary culture toxicity of Abeta) to address these questions.

Focus Area 2.3 Understanding co-morbidities and other factors that contribute to progression of AD. There is increasing evidence that co-morbidities may dramatically alter the course of AD. Further, other events such as infection, surgery, acute or repeated head traumas, and hospitalization, appear to accelerate cognitive decline. Conversely, there are factors that may slow progression (e.g., physical exercise). High priority will be given to applications that can provide fundamental insights into how co-morbidities and other potentially modifiable risk-factors contribute to cognitive decline and dysfunction.

Focus Area 2.4 Novel biomarkers. Novel biomarker approaches, especially those that may identify biomarkers of AD risk or AD progression (as opposed to state dependent biomarkers) will be given high priority for funding.

Focus Area 2.5 Biological basis of novel genetic risk factors in Alzheimer's Disease.

Applications that explore the biological mechanism of genetic risk factors, identified by Genome Wide Association Studies (GWAS), genomic sequencing, or other genomic approaches associated with AD and related dementias will be given high priority. These studies should focus on novel loci (e.g., not APP, APOE, PSEN1, or PSEN2). Studies may range from attempts to identify the functional variants within a genetic locus, to evaluating the biological impact of genes within established genetic loci.

Priority Area 3:

Objectives: This FOA aims to stimulate a consortium of clinical centers to conduct high quality clinical research studies of greater breadth than described in Priority 2, Focus Area 2.1. The consortium should involve partnerships to be developed among investigators across Florida, in such fields as neuromedicine (i.e. neurology, psychiatry, neuroimaging, neuropsychology, etc.), neuroengineering, neurotechnology, geriatrics, gerontology, pharmacology, nutrition, physical therapy, occupational therapy, speech pathology, nursing, and clinical social work. The consortium should develop common clinical protocols using electronic databases to address one or more areas of research interest and to support the exploration of the focus areas listed within Priority Area 3. Grants may range from pilot research to more mature projects that are attempting to advance a therapeutic approach or concept.

Background: There are several academic medical centers in Florida that have developed their own infrastructure for conducting high quality clinical and diagnostic projects and have received federal, state and private foundation grants to support these activities. However, many clinical organizations and Memory Disorder Clinics (MDC) in Florida have an interest in conducting studies in the fields of AD, Mild Cognitive Impairment (MCI) and normal cognitive aging but lack such an infrastructure. In an effort to promote the development of the infrastructure to support such clinical research studies, applications may be submitted by any university or established research institute in Florida, with existing infrastructure and clinical and behavioral research protocols to collaborate with MDCs and other clinical organizations without such existing infrastructure. This will promote the development of a consortium of clinical centers to conduct high quality clinical research studies. An application submitted by any existing or established university or research institute, that collaborates with a clinical organization or community-based or hospital-based, free-standing Memory Disorder Clinic/Center must show a clear and high-quality research relationship, collaboration, infrastructure, and protocol in the application.

Focus Areas: (The applicant must state clearly which of these areas the proposal addresses.)

Focus Area 3.1 Risk factors for cognitive decline. These risk factors may include exposure to stress, anesthesia, surgery, acute and repeated head traumas, chronic health conditions such as cardiovascular conditions, and lifestyle factors.

Focus Area 3.2 Underlying pathophysiology. Providing a better understanding of the pathophysiology underlying those at high risk for AD (e.g., the interaction of cytokines and inflammation to cerebrovascular disease and neurodegeneration detected on imaging such as structural and functional MRI).

Focus Area 3.3 Treatment protocols. The development of novel treatment protocols.

Focus Area 3.4 Evaluating the influence of changes in brain structure. Evaluating the relationships of psychiatric and cognitive features of the disease to regional changes in brain structure and function.

Focus Area 3.5 Expert diagnosis system. Developing a valid expert diagnosis system to improve and validate diagnoses of AD by health care professionals across Florida. The expert system could have both electronic and human expert components.

Focus Area 3.6 Comprehensive protocol for care management with links to support services over the course of decline. Providing a careful diagnosis is important and as important is providing the person with the diagnosis and the caregiver(s) with educational information and referrals to community resources. Along the course of decline, educational handouts and internet links may provide practical tips and guidelines for the family to plan ahead for changes over the course of the disease, referrals for health and social services and accessible resources in the community such as senior center activities, day (health) care centers for daily or occasional use, and support groups. Studies of protocols for diverse populations such as racially, ethnically, or culturally different or rural Floridians or programs such as at community centers or staffed with volunteers at civic or religious organizations may provide models of best and cost-effective practices for long-term quality of life during ongoing decline.

Focus Area 3.7 Normative neuropsychological database. Developing a Normative Neuropsychological Database for the purpose of developing standards for neuropsychological diagnosis, accounting for age, primary language, race, ethnicity, educational achievement, occupation, cognitive reserve, socioeconomic status, and other lifestyle factors. The ethnic diversity in Florida provides both a challenge for neuropsychological diagnosis as well as an opportunity to provide the nation with invaluable normative data. Priority will be given to applications that involve populations that have been historically underrepresented in research.

Priority Area 4:

Objectives: This FOA includes priorities in the area of epidemiology to address the needs of Florida's diverse population. This FOA will fund epidemiologic studies that improve our understanding of genetic, epigenetic, and acquired neurodegenerative and vascular disorders that result in cognitive impairment and dementia and how these conditions affect Floridians.

Background: The population of older adults in Florida continues to grow through the aging of its population and the influx of older adults from other parts of the U.S. and abroad. Minorities, especially the Hispanic and African American populations, are growing demographics and the risk factors, prevalence and incidence in Florida, course, and outcomes of neurocognitive disorders that are specific to these groups are not well understood. Vascular disease is both preventable and treatable, but studies are needed that focus on identifying populations at risk and clarifying the risk factors to be targeted in specific groups. Access to care is limited for many Floridians, including those in both urban and rural areas and each of these populations has special needs.

Focus Areas/Themes: (The applicant must state clearly which of the following areas the proposal addresses.)

Focus Area 4.1 Health disparities. Studies that include fluid and pathologic biomarkers of the diseases to understand health disparities are a priority. The FOA encourages the inclusion of Hispanics, African Americans, and those in rural areas. An overarching goal of studies in this focus area is to identify genetic, environmental, and other factors that influence disease incidence, presentation, and course. Studies that incorporate life course methods to assess the contributions of particular risk factors are encouraged.

Focus Area 4.2 Cardiovascular contributions to neurocognitive disorders. Increasing evidence suggests that cardiovascular problems, endothelial dysfunction, and amyloid angiopathy play critical roles in the development and progression of AD and cardiovascular dementia and little is known about the interaction of cardiovascular factors in other neurodegenerative dementias. Epidemiological studies that examine these interrelationships and include biomarkers such as vascular brain imaging, fluid biomarkers of inflammation and vascular risk, cardiac health risk factors, and markers of the underlying neurodegenerative process will be given high priority. Studies that incorporate non-invasive markers of cardiovascular injury are encouraged.

Focus Area 4.3 Early detection. Pathological studies suggest that amyloid deposition and proteinopathies occur decades before cognitive symptoms begin in AD and the role of environmental and potentially modifiable factors at the earliest stages is not well understood. Epidemiologic studies using novel methods to detect the earliest cognitive, functional, and endophenotypic changes (e.g., brain imaging, fluid biomarkers) of AD and other neurocognitive disorders are encouraged. Studies that make use of community engagement methods to include at-risk populations not normally involved in research will be prioritized.

Priority Area 5:

Objectives: This FOA aims to provide clinical, patient-oriented research fellowship training that stimulates a) novel insights into the brain-mediated function and dysfunction related to AD, b) discovery and validation of novel diagnostic strategies related to symptomatology of AD, and c) discovery and validation of novel treatment and care management strategies of AD. Organizations must have a certified fellowship-training program or an established training program for health professionals to be considered eligible. Submission of a competitive National Institutes of Health (NIH) K Award application or comparable grant application is a required grant deliverable in the final grant year.

Background: The current national opportunities for clinical fellowship training of physicians and PhDs and comparable terminal degrees in patient-centered AD research is rather limited leading to a paucity of experts and research mentors available to address the many challenges for accurate diagnosis and care management over the long course of decline. A major public health goal is to promote healthy brain function and prevent the onset or progression of AD. There is a desperate need to develop novel therapeutic approaches and strategies that can be adapted to individual variation in the presentation of symptoms as well as the training of medical and other health-related experts in effective diverse protocols for accurate diagnosis, treatment, and care strategies. The gap of expertise in addressing the impacts of AD also has led to the

inadequacy of community resources to help patients maintain optimal quality of care in a community-based setting. Of special need are underserved populations dealing with AD. This FOA is designed to support physician or PhD (or comparable terminal degree) in postdoctoral fellowship training that fosters and advances clinical research training (e.g., clinical service, evaluation, neurochemistry, neurosciences, neuromedicine, neurotherapeutics, neuropharmacology, neuropathology) to develop expert health provider research skills focused on people with AD and to encourage attention to the challenges of diverse and underserved people dealing with AD.

Focus Areas: (The applicant must state clearly which of the following areas the proposal addresses.)

Focus Area 5.1 Novel training to address inadequate number of highly trained patient-centered researchers. The postdoctoral research training occurs in an underdeveloped/underfunded specialty area of patient-centered research on AD. Research fellowship training will lead to transformative advances in patient-centered evaluation, diagnosis (including clinical diagnosis and/or post-mortem neuropathological diagnosis), treatment, assistive technology, and care management skills and research. An outcome of the training is preparation of an application for major funding, for example, from the NIH, other federal agency, or not-for-profit foundation.

The research fellowship training involves learning how to: review the literature on basic or brain-mediated areas of function and dysfunction; develop hypotheses and the methodology to test these hypotheses on diagnosed persons, family members, care partners, and control subjects based on their willingness to volunteer for the research; develop a protocol that receives Institutional Review Board (IRB) approval from the research institution; recruit volunteer participants as subjects (with double informed consent, as appropriate, provided by people with AD); collect data; analyze results; present the data and write articles for presentations at professional meetings; write up results for refereed professional journals; and translate results into information for lectures, appropriate treatments, caregiving strategies, and for simple practical informational handouts or suggestions for people diagnosed with AD and related dementias, family and professional caregivers/care partners, health and social service providers, and the general public.

Focus Area 5.2 Understanding brain-mediated function and dysfunction and therapeutic strategies. The postdoctoral research training fellowship covers scientific research and must be related to parameters of AD. The parameters may include brain-mediated function, assessment tools, diagnostic techniques, therapeutic interventions, care management strategies, assistive technology, and support services for people suffering from AD. Basic clinical or translational research may involve basic brain-mediated behavior studies based in the clinical setting and may deal with deficits in memory, attention, language, visual-spatial functions, movement problems, and related cognitive dysfunctions that are experienced by people with symptoms of decline related to AD.

Focus Area 5.3 Novel diagnostic procedures, tools, and strategies. The development of novel diagnostic evaluation procedures, may involve assessment tools, treatments, and therapeutic strategies to slow decline, optimize function (especially cognitive function), and nurture as much independence as possible in the person with the diagnosis of AD.

Further, there is a need for better therapies to improve symptoms, to prevent cognitive dysfunction by optimizing a healthy lifestyle, or to alter the disease course even at later stages of the disease. High priority will be given to novel therapeutic approaches.

Focus Area 5.4 Understanding co-morbidities and other factors that contribute to progression of AD. There is increasing evidence that co-morbidities may dramatically alter the course of AD. Further, other events, such as infection, surgery, acute and repeated head traumas, and hospitalization, appear to accelerate cognitive decline. Conversely, there are factors that may slow progression (e.g., physical exercise, good nutrition, appropriate hydration, avoidance of anticholinergics and benzodiazepines, treatment of cardiovascular conditions, and healthy sleep). High priority will be given to applications that can provide fundamental insights into how co-morbidities and other potentially modifiable risk-factors contribute to cognitive decline and dysfunction.

3. Grant Categories

The Florida Department of Health (Department) anticipates making awards from the following types of grant categories:

- **Consortium Grant:** Stimulate a consortium of clinical, basic or translational research centers to conduct high quality grant-supported research. The consortium should involve partnerships to be developed among investigators across the State of Florida, with the award made to the lead organization. The lead organization of the consortium must perform a substantive role in conducting the planned research including providing oversight of all scientific, programmatic, financial, and administrative matters related to the grant. The collaborating organizations must have well-defined roles that contribute to the common scientifically rigorous research goals, and include sound background information, hypotheses, protocols, and promising practices that address clearly one or more areas of research interest. A letter of commitment from all collaborating organizations is required. The consortium must support the exploration of the focus areas listed within Priority Areas 1 and 3. Grants may range from discovery science to more mature projects that are attempting to advance a therapeutic approach or concept.

    - Research organizations are eligible to **apply for no more than one Consortium Grant.**
    - The PI must be a full-time faculty member at the lead institution.
    - The application must include at least **three** collaborating institutions. The lead institution must be an existing established university or research institute.
    - Maximum award amount will be up to $500,000 per award.
    - Maximum duration to complete the grant will be up to four years. **Grant duration is contingent upon legislative spending authority from fiscal year to fiscal year.**

- **Standard Grant:** Research projects that are fully developed, scientifically rigorous, and include sound background information, hypotheses, and promising preliminary results or supporting data.

    - Research organizations are eligible to **apply for no more than seven Standard Grants** that address the five priority areas listed in Section 2, Priority Areas.

Organizations choosing to submit more than one Standard Grant application may have **no more than three applications in a single Priority Area**.

- Maximum award amount will be up to $250,000 per award.
- Maximum duration to complete the grant will be up to four years. **Grant duration is contingent upon legislative spending authority from fiscal year to fiscal year.**

- **Pilot Grant:** Exploratory, novel studies that break new ground or extend previous discoveries toward new directions or applications. No preliminary data are required but may be included if available.
  - Research organizations are eligible to **apply for no more than four Pilot Grants** that address one of the five Priority Areas listed in the previous section. If an institution submits more than one Pilot Grant application, **no more than two applications may be submitted within the same Priority Area.**
  - Maximum award amount will be up to $100,000 per award.
  - Maximum duration to complete the grant will be up to two years. **Grant duration is contingent upon legislative spending authority from fiscal year to fiscal year.**
- **Postdoctoral Research Fellowship Grant:** Supports the career development of individuals who have made a commitment to focus their research endeavors on research oriented to clinical service, evaluation, neurochemistry, neurosciences, neuromedicine, neurotherapeutics, neuropharmacology, neuropathology, etc.
  - Research organizations are eligible to apply for **no more than three Postdoctoral Research Fellowship Grants**. Organizations choosing to submit two or more Postdoctoral Research Fellowship Grant **applications must assure that they address different focus areas (1-4) listed under Priority Area 5**.
  - Maximum award amount will be up to $100,000 per award.
  - Maximum duration to complete the grant will be up to two years. **Grant duration is contingent upon spending authority from fiscal year to fiscal year.**

The **maximum total number of applications an organization may submit is 15** in the following categories:

- **Consortium Grant:** One application (in Priority Area 1 and 3; only **one** application per institution)
- **Standard Grant:** Seven applications (no more than **three** applications per Priority Area)
- **Pilot Grant:** Four applications (no more than **two** applications per Priority Area)
- **Postdoctoral Research Fellowship Grant:** Three applications (in Priority Area 5)

All applications must be different. Organizations may not submit the same application in different grant categories. For example, organizations may not submit the same project for a Standard Grant and a Pilot Grant.

Institutions must specify the appropriate grant Category and Priority Area for each application. Applications submitted in incorrect Priority Areas will be ineligible for funding or peer-review.

4. Highlights

- **All awards in response to this FOA are subject to the availability of funds and spending authority provided by the Florida Legislature. By submitting a grant application pursuant to this FOA, all applicants acknowledge and consent to this condition.**

- Applications conducting research with Department data must include a letter of support from the program office that houses the data. For example, an applicant conducting research using data from the Bureau of Vital Statistics must include a letter of support from that Bureau.

- Applications will only be accepted through the online application system.

- There is a defined question and answer timeframe as indicated in Table 1. Schedule of Important Dates. To ensure equal access by all applicants to questions and answers, all questions must be submitted in writing. Answers to questions will be published according to the schedule indicated in Table 1. Questions that are received after the timeframe deadlines as indicated in Table 1 will not be answered.

- For research, especially involving human or animal participants, grantees are required to obtain and maintain approval or receive a signed waiver from an Institutional Review Board (IRB) accredited by the Association for Accreditation of Human Research Protection Programs (AAHRPP), or from an Institutional Animal and Core Use Committee (IACUC) within 60 days of notice of award. Grantees should be prepared to start the regulatory review process at their institution immediately upon being notified of an award. Grantees are required to follow Department policies for reporting unanticipated problems and non-compliance involving research to the Department. Department policies comply with Title 45 Code of Federal Regulations, Part 46. For more information about reporting requirements, refer to the U.S. Department of Health and Human Services' Office of Human Research Protections website at http://www.hhs.gov/ohrp/.

- Projects which include research participant incentives must receive approval from the Florida Department of Health Institutional Review Board (IRB). For these projects, the Florida Department of Health IRB must be the IRB of Record. There is no cost associated with the Department's IRB for grants awarded by the Department. This includes initial application, modification, and annual renewals.

- The Program will pay a proportional percentage of the base salary (based on effort) of any personnel named on the grant application. The **maximum annual base salary** used in calculating these payments must not exceed the Executive Level II annual salary rate of the Federal Executive Pay Scale that is in effect as of the application submission date. See Section II. Eligibility and Application Requirements, 7. Definitions, for more information about the Federal Executive Pay Scale.

- Applicants are encouraged to check the Program website (http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity.html) regularly throughout the application, peer review, and award processes for Program announcements, addendums, and answers to programmatic questions.

- All materials submitted to the Department are subject to the provisions of Article 1, Section 24, Florida Constitution and Chapter 119, Florida Statutes, Florida's public records law. These laws grant a right to inspect any public record to anyone upon request. All Program materials, including applications, are public record. Refer to Section II. Eligibility and Application Requirements, 6. Requirements for Protecting Intellectual Property, for instructions on how to properly identify confidential/proprietary information.

- The Grant Manual is an important reference document for grant awardees. It contains Department policies as well as the procedures necessary for compliance with those policies, and is organized around a typical grant lifecycle. The Grant Manual can be found at http://www.floridahealth.gov/provider-and-partner-resources/research/grant-programs-resources/forms-library.html

- After awards are made, each grantee must sign a contract, called the "Terms and Conditions," agreeing to certain legal requirements of the award. The "Terms and Conditions" are non-negotiable and acceptance is required as part of the grant award process. The Department reserves the right to change or modify the "Terms and Conditions" as needed. By submitting a grant application pursuant to this FOA, all applicants acknowledge this requirement. The "Terms and Conditions" also include the post-award schedule of deliverables.

Schedule of Important Dates

Table 1. Schedule of Important Dates		
ACTIVITY	**DATES**	**IMPORTANT INFORMATION**
Funding Opportunity announced	July 1, 2019	Located on the Program website at: http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity.html.
Written questions accepted	Questions may be submitted any time from July 1 until 5:00 p.m. EST on July 22, 2019	Email questions to: research@flhealth.gov
Answers posted to written questions	Anticipated Date for final responses to questions: July 25, 2019	Answers to questions will be published on the Program's website in two groups as they come in until the deadline. The first round of answers

		will be posted on July 11th. The final round of questions will be answered and posted on July 25th.
Letter of Intent due (required)	Letter of Intent must be submitted by July 29, 2019 5:00 p.m. EST	Letter of Intent must be submitted in the online system located on the Program website (http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity.html). The letter must answer all 11 requirements beginning on page 20 of the FOA. Applications without a Letter of Intent will not be accepted.
Application system opens	Anticipated Date: August 5, 2019	Applications must be submitted in the online system located on the Program website.
Applications due	Applications must be submitted before 5:00 p.m. EST, September 6, 2019	Applications must be submitted using the online system available on the Program website (https://peernet.orau.org/Intake/Submission/948b695c-ad96-e911-8142-0050568131c9). Applications must be submitted on or before the deadline. Applications will not be accepted after the deadline.
Awards announced	Anticipated date: December 15, 2019	Award letters and Terms & Conditions will be emailed to the Administrative Official and the Principal Investigator.
Institutional reviews due (if applicable)	Immediately after award notification, grantees should submit application(s) for all institutional authorizations including, but not limited to, the Institutional Animal Care and Use Committee (IACUC), IRB, and Radiation Safety Review. Project work may not begin until documentation of all approvals is provided. The documentation of institutional approval(s) must have the same project title as the application project title and must be signed by the Review Board	Grantees should be prepared to start the regulatory review process at their institutions immediately upon being notified of award. Grantees are required to obtain and maintain approval or receive a signed waiver from an IRB or from an IACUC within 60 days of notice of award. For more information, see Section 4. Highlights, on page 13.

	chairperson or organizational representative.	
Grants begin	Anticipated date: February 1, 2020	Contingent on verification of all eligibility requirements and regulatory approvals.

Changes to dates or other requirements will be posted to the Program website. Applicants should monitor the program website (http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity.html) for changes and announcements.

II. ELIGIBILITY AND APPLICATION REQUIREMENTS

1. Alzheimer's-Relatedness

All applicants must clearly demonstrate how the proposed project is relevant to AD. Proposals that do not or cannot demonstrate a close relationship with advancing progress toward etiology, prevention, diagnosis, treatment, care management, and cure of AD will not be funded.

2. Eligibility Requirements

A. Eligible Applicants

According to section 381.82(2)(b), Florida Statutes, applications for AD research funding under the Program may be submitted by a Principal Investigator from any university or established research institute in Florida. Established research institutes, as defined on page 28 of this Funding Opportunity Announcement, do not include Veteran's Administration (VA) hospitals. Although the Principal Investigator submitting the application may not be a (full-time or part-time) employee of a VA hospital, the grant application may list collaborators such as a Co-Principal Investigator from a VA hospital among the key personnel.

The Principal Investigator must have the skills, knowledge and resources necessary to carry out the proposed research as well as possess personal interest, commitment and expertise consistent with the goals of the Ed and Ethel Moore Alzheimer's Disease Research Program. The Principal Investigator (PI) must hold a research or health professional doctoral level degree, i.e. a MD, PhD, MD/PhD, DO/PhD, DO, DNS/DNS(c) (Doctor of Nursing Science) or equivalent. The PI must be in good standing and judged to have the appropriate training, level of authority and responsibility to direct the research program or project outlined in the grant application to the Ed and Ethel Moore Alzheimer's Disease Research Program. The PI is responsible to ensure the proper conduct of the research program or project, comply with all of the requirements of the Ed and Ethel Moore Alzheimer's Disease Research Program, and submit all required reports. The PI is the one individual designated by the applicant organization to direct the project to be supported by the grant, is responsible and accountable to the applicant organization officials for the proper conduct of the project. The PI must have research experience and the time commitment so as to supervise the project directly and in person.

An application submitted by any existing established university or research institute which collaborates with a clinical organization or community-based or hospital-based, free-standing Memory Disorder Clinic/Center must show a clear and high quality research relationship, collaboration, infrastructure, and protocol in the application. Such an application must identify clearly who is the one Principal Investigator designated by the applicant organization as legally responsible to direct the grant project. The Principal Investigator is responsible and accountable to the applicant organization officials for the project's scientific and technical direction as well as the proper conduct of the project. There may be multiple collaborators on a project, but there must be only one Principal Investigator.

To be eligible as a Principal Investigator at an eligible institution**,** the individual must be a full-time faculty member or researcher employed by the lead institution by the time the application is submitted and may have a joint appointment by more than one research institution that totals full time employment. Temporary faculty members/researchers, even though full-time, are not eligible to apply. The license of the Principal Investigator must be up to date and in good standing in the State of Florida. Only U.S. citizens or permanent residents may be principle or co-principle investigators.

Non-principle investigators may be employed on the grant with an authorized visa (i.e., J-1 visa). Unauthorized aliens shall not be employed pursuant to §274A(e) of the Immigration and Naturalization Act (8 U.S.C. 1324a), section 101 of the Immigration Reform and Control Act of 1986, and Florida Executive Order 11-02.

Grant applications failing to meet the eligibility requirements will be disqualified.

B. Letter of Intent

Submission of a Letter of Intent (LOI) is required prior to submission of an application. The LOI must be submitted by the applicant in the online application system. Applicants must obtain an approval letter from their Office of Research (or Sponsored Research). This letter must state that the LOI has been reviewed and approved by the Office of Research and include the signature of the Sponsored Research Official. Applicants will then upload a scanned copy of the approval letter to the online application system when they submit their LOI. For collaborative applications, the applicant from the lead organization is required to submit the LOI. The information in the LOI allows Department staff to estimate the potential review workload and plan for the review. Applications will not be accepted if the applicant has not submitted a LOI by the deadline listed in Table 1. However, applicants who submit a LOI are not bound to submit an application, and a decision to submit a LOI and not submit an application will not affect eligibility for future funding opportunity announcements or be considered by peer reviewers in future funding applications. Researchers must submit an application under the same title that was specified in the LOI. In addition, the PI may not change between the LOI and the application.

Prospective applicants must submit a LOI through the online system that includes all of the following items of information:

1. Name, address, telephone number, email address of the Principal Investigator

2. Names of other research personnel

3. Name, address, telephone number, email address of the Sponsored Research Official
4. Lead organization
5. Collaborating institutions and collaborating research personnel, if any
6. Descriptive title of proposed research
7. Research Priority Area
8. Grant category
9. General Audience Abstract (no more than 500 words)
10. Key Words (no more than five words)
11. Signed Approval Letter from the Principal Investigator's Office of Sponsored Research

C. Guidelines for Alzheimer's Disease Research Grant Advisory Board Member Participation

The Florida Alzheimer's Disease Research Grant Advisory Board (Board) has statutory conflict of interest obligations regarding the participation of its members in Ed and Ethel Moore Alzheimer's Disease Research Program grants and grant applications.

Board members shall not:

- Participate in any discussion or decision of the Board or a panel with respect to a research proposal by any firm, entity, or agency with which the member is associated as a member of the governing body or as an employee or with which the member has entered into a contractual arrangement.
- Receive any form of financial compensation from a Program grant award.
- Participate in any named role on a proposed Program grant project in this FOA.
- Advise applicants regarding the preparation of a specific Program grant application.
- Answer any programmatic questions (eligibility, content of the FOA, competition procedures, etc.).
- Violate any provision of Chapter 112, Part III, Florida Statutes.

Violations of these restrictions may result in the disqualification of an applicant for this competition. For a list of Board members, refer to the program website.

D. Types of Applications and Overlap Limits

The Department will accept the following types of applications:

- **New application:** An application that has not been submitted to the Program in a previous competition.

- **Revised application:** An application that was submitted to the Ed and Ethel Alzheimer's Disease Research Program, but not funded. Applications must identify areas that have been revised from the initial submission.

Applicants must ensure that their proposed project does not duplicate or significantly overlap, scientifically or financially, with other projects in which they or any key personnel are involved. Overlap, whether scientific or financial, or commitment of a project member's effort greater than 100 percent is prohibited.

The Principal Investigator may:

- Serve as a co-PI or other role on other applications.

The Principal Investigator shall not:

- Submit the same project/research to the Program that is also being submitted by another investigator regardless of the grant mechanism.

- Submit an application that was reviewed during a previous funding cycle and did not receive funding unless the applicant has followed the instructions for submitting a revised application outlined above.

- Submit two or more applications in which they are listed as the PI to the Program during the same FOA.

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3. Required Grant Application Components

A complete Grant application package must contain all required items listed in Table 2.

Table 2. Application Components The online application will prompt applicants of required fields and word limits for each section.	
Category	**Comment**
General Project Information	Required. Identifies general project information, the applicant organization, and the principal investigator.
Fellowship Plan	Required (if applicable). Describe a plan: (1) that shows a logical progression from prior research and training experiences to the patient-centered clinical and research career development experiences that will occur during the award period and then to independent investigator status; and (2) that justifies the need for further career development to become an independent investigator.
Human Subjects	Required (if applicable). Describe protections for human subjects involved in the research.
Vertebrate Animals	Required (if applicable). Describe protections for animals involved in the research.
Recombinant DNA Molecules	Required (if applicable). Describe use of recombinant DNA molecules involved in the research.
Survey Instruments	Required (if applicable). Survey Instruments must be uploaded as a single document.
Table, Image, or Graph	Optional. Upload a single document containing images, graphs, and figures. (There is no page limit on the number of images, graphs, and figures). Images, graphs, and figures cannot appear in the text of the application, but must be uploaded separately in this section. Figure legends need to be included in the document.
Budget Template	Required. The budget must explain the planned spending. See appendix for template. The budget module must be edited and submitted within the online application system. When applications involve collaborations with different universities or research institutions, the lead institution should complete the budget form and include collaborating institutions as a contractual expense.
Collaborator Information	Required. Identifies all key personnel.
Biographical Sketch	Required. Bio-sketches of key personnel must be uploaded as a single document in the format specified in the online system.
Consultants	Required (if there are consultants). Letters from all consultants confirming their roles in the project, including the rate/charge for consulting services, must be uploaded as a single document.
Research/Project Plan	Required. Describe the specific aims including the significance, innovation, and approach. Provide a bibliography of any references cited and list facilities and other resources.

Table 2. Application Components The online application will prompt applicants of required fields and word limits for each section.	
Category	**Comment**
General Audience Abstract	Required. Explains the proposed project in lay terms, including its relationship to the Priority Areas listed in this FOA.
Scientific Abstract	Required. This is the scientific description of the project.
Health Impact	Required. Applications must describe how the proposed project impacts the health of Floridians. Health impact means the ability of the research to reduce morbidity and mortality from AD. Applications must describe how the results of the research can provide information and evidence for changes in policy, or improve health service delivery and quality of care, or improve disease prevention through improvements in health literacy and changes in behavior within a certain amount of time. Do not consider possible long-range effects of applying knowledge gained in the research or the ability of the research to support future research grant applications or publications or patents as a health impact that may result from the research.
Alzheimer's-Relatedness	Required. Provides a clear explanation of how the project is related to Alzheimer's Disease.
Letters of Support	Required. (if applicable) If applying for a fellowship grant, signed letters of support confirming participation and describing specific roles must be uploaded. If applying for a grant involving Department data, a signed letter of support from the program office, which houses the data, must be uploaded. Upload as a single document. (There is no page limit on the number of letters of support).
Reportable Financial Interests	Required. The Principal Investigator must disclose any financial interests that the researcher, the researcher's immediate family, or any other personnel on the project (sub-investigators and research staff) and their immediate families, have related to the research.
Applicants are discouraged from submitting information considered proprietary unless it is deemed by the applicant to be essential for proper evaluation of the application. If the application contains information that the applicant believes constitutes trade secrets or proprietary information or is protected by a specific statutory exemption; it should be limited to the Research Project Plan section. The applicant must CLEARLY identify the information with [brackets] and a footnote that specifies the law that makes the document or information exempt from the public records laws. If a public records request is made involving documents with declarations of confidentiality, the Department will notify the applicant so that he/she may defend the claim in circuit court. The Department will not provide legal representation to assert a confidentiality claim when a public record request is made.	

4. Allowed and Disallowed Costs

The following information explains direct and indirect costs allowed by the Department, as well as disallowed costs.

A. Allowed Direct Costs

Allowed direct cost expenses must be directly related to the project and may include:

- Salaries, including up to a three percent increase per year
- Tuition (documentation of courses must be submitted with quarterly financial expenditure report)
- Fringe benefits
- Supplies
- Equipment, including CT, MRI, or other imaging systems, and improvements to existing systems. For the purposes of this FOA, "equipment" refers to items with a purchase price of over $1,000.00 and with a useful life of over one year.
- Lab services
- Travel will be reimbursed at no more than the state of Florida travel reimbursement rates. Current state of Florida reimbursement rates can be found in section 112.061, Florida Statutes. In order to implement appropriations in the General Appropriations Act for state travel and notwithstanding s. 112.061, Florida Statutes, costs for lodging associated with a meeting, conference, or convention organized or sponsored in whole or in part by a state agency or the judicial branch may not exceed $150 per day.)
- Consultant costs, provided they do not exceed 10 percent of the total budget
- Patient-care costs
- Animal-care costs
- IRB or IACUC fees
- Consortium or contractual costs
- Fees to obtain data from a health registry (e.g. vital statistics)
- Research Participant Incentives including promotional items (such as t-shirts, hats, water bottles), food and food coupons, and payment for travel expenses. Any incentive for food, food coupons, or travel expenses may not exceed the limitations in 112.061 F.S.

Administrative costs *may* be included in direct cost categories, but only under two conditions:

- the services, functions, or activities are directly necessary for this grant, and
- these administrative costs have not been included in the calculation of the indirect costs.

The Program does not prohibit administrative costs as part of direct costs, but to be allowable, they must meet both of the above conditions. All direct costs must be specifically and directly related to the project, necessary for the project's completion, and adequately justified. Pay particular attention to these criteria with costs such as copying charges, telephone and Internet charges, maintenance contracts, etc.

Maximum Annual Base Salary Calculations:

The Program will pay a proportional percentage of the base salary (based on effort) of any personnel named on the application for this grant. The maximum annual base salary used in calculating these payments must not exceed the Executive Leve II annual salary rate of the Federal Executive Pay Scale that is in effect as of the application submission date. See Section II. Eligibility and Application Requirements, 7. Definitions, for more information about the Federal Executive Pay Scale. This salary cap excludes fringe benefits, facilities and administrative (F&A) expenses; and excludes any income that an individual may be permitted to earn outside of the duties to the applicant organization. This provision is consistent with the NIH salary limitations on grants, cooperative agreements, and contracts.

Work Must Occur in Florida:

Activities funded through this competition must occur in Florida. All work (effort) must occur and funds must be spent in Florida at the applicant organization and any collaborating entities. However, the Department may make exceptions if the service is essential and only provided outside the state, and if the amount is less than 10 percent of the requested amount.

B. Allowed Indirect Costs

Indirect costs (also referred to as IDC, F&A, or administrative costs) are limited to 15 percent of the direct costs requested. Indirect costs are those costs that are incurred for the joint or common benefit of several separate organizational or financial components (cost centers) of an organization, which specifically or readily cannot be identified to a particular cost center, project, or program.

C. Disallowed Costs

All direct costs must be specifically and directly related to the project, necessary for the project's completion, adequately justified, and made during the active grant period. Any other costs are disallowed. Additionally, the following items shall NOT be paid for with grant funds:

- Department personnel
- Construction, renovation, or remodeling
- International travel (including Canada)
- Vehicles
- Entertainment
- Employment subsidies
- Dues/Membership fees
- Lobbying
- Meals/Food (other than as part of travel costs)
- Malpractice insurance premiums

5. Inquiries and Contacts

A. Programmatic Questions about This Funding Opportunity

This FOA is issued by the Department. The Public Health Research Unit manages the FOA and is responsible for answering all applicant questions. Applicants and persons acting on their behalf may contact the Department in writing via email as indicated below regarding programmatic issues. Applicants who attempt to contact the Alzheimer's Disease Research Program Grant Advisory Board members regarding this FOA may have their applications disqualified.

To ensure equal access by all applicants to questions and answers, all programmatic questions must be submitted in writing via email to research@flhealth.gov. Answers to questions will be available on the program website. Answers to submitted questions will be posted in groups as they are received and published on the website, according to the schedule in Table 1. Schedule of Important Dates.

B. Technical Questions about the Online Application

Direct all questions about the online application process and related issues (e.g. username and password problems) to research@flhealth.gov.

The Department recommends that applications be submitted early. Applications submitted past the deadline will not be considered, regardless of the reason.

6. Requirements for Protecting Intellectual Property

Submitted materials are subject to the provisions of Article I, Section 24, Florida Constitution and Chapter 119, Florida Statutes, Florida's public records law. These laws grant the right to any person to inspect any public record. Some documents and information that are exempt from the public records laws. All application materials are public record unless the applicant can show how they are exempt.

Applicants are strongly discouraged from submitting information considered proprietary unless it is deemed by the applicant to be essential for proper evaluation of the application. If the application contains information that the applicant believes constitutes trade secrets, intellectual property, proprietary information, or information protected by a specific statutory exemption, it should be limited to the Main Application Body. The applicant must clearly identify the confidential information with [brackets].

If a public records request is made involving documents with declarations of confidentiality, the Department will notify the applicant so that he/she may substantiate and defend the claim. The Department will not provide legal representation to assert a confidentiality claim.

7. Definitions

Alzheimer's Disease: According to the National Institutes of Health, "Alzheimer's disease is an irreversible, progressive brain disorder that slowly destroys memory and thinking skills, and eventually the ability to carry out the simplest tasks. In most people with Alzheimer's, symptoms first appear in their mid-60s. [. . .] Alzheimer's disease is currently ranked as the sixth leading cause of death in the United States, but recent estimates indicate that the disorder may rank third, just behind heart disease and cancer, as a cause of death for older people."

Alzheimer's Disease Research Grant Advisory Board (The Board): The Alzheimer's Disease Research Grant Advisory Board was created per Section 381.82(3), Florida Statutes. According to statute, the Board "shall consist of two geriatric psychiatrists, two geriatricians, two neuroscientists, and three neurologists." Board members "must have experience in Alzheimer's disease or related biomedical research." The board shall consider applications for program funding, and make recommendations to the State Surgeon General by December 15 of each year.

Business entity: Per Section 606.03(1), Florida Statutes, this means any form of corporation, partnership, association, cooperative, joint venture, business trust, or sole proprietorship that conducts business in Florida.

Collaborator: An individual involved with the Principal Investigator in the scientific development or execution of the project. These individuals typically devote a specific percent of effort to the project and are identified as key personnel. The collaborator may be employed by, or affiliated with, either the Grantee institution or an institution participating in the project under a consortium or contractual agreement.

Commercialization: The process of developing markets and producing and delivering products or services for sale (whether by the originating party or by others). As used by the Program, commercialization includes both government and non-government markets.

Consortium or Contractual Agreement: An agreement whereby a project is carried out by the Grantee and one or more other organizations that are separate legal entities. In this arrangement, the Grantee contracts for the performance of a substantial and/or a significant portion of the activities to be conducted under the grant. These agreements typically involve a specific percent of effort from the consortium's Principal Investigator and a breakdown of costs by category, such as personnel, supplies, and other allowable expenses, including indirect costs.

Consultant: An individual hired to give professional advice or services for a fee, normally not as an employee of the hiring entity. Consultants may also include firms that provide paid professional advice or services.

Community-Based Participatory Research (CBPR): A collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community (which can be self-defined, regional, or by interest) and has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities.

Cooperative Agreement: A support mechanism that will have substantial scientific and/or programmatic involvement. Substantial programmatic involvement means that after award, scientific or project staff will assist, guide, coordinate, or participate in programmatic activities beyond the normal stewardship responsibility in the administration of grants. Proposed cooperative agreements will be published as policy announcements, program announcements, or requests for applications.

Department: The Florida Department of Health works to protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts.

Development: The systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

Eligible Institution: Any public university, non-public institution, or established research institute (see specific definitions of each) in Florida.

Established Research Institute: An established research institute eligible for Program funding is an organization that is any Florida nonprofit covered under Chapter 617, Florida Statutes, with a physical location in Florida, whose stated purpose and powers are scientific, biomedical or biotechnological research and/or development and is legally registered with the Florida Department of State, Division of Corporations. For purposes of this competition, federal government and nonprofit medical and surgical hospitals including Veteran's Administration hospitals are not considered eligible research institutes.

Feasibility: The practical extent to which a project is capable of being successfully performed within the requested time and for the awarded money.

Federal Executive Pay Scale, Executive Level 2: The U.S. Office of Personnel Management establishes executive pay schedules each year normally around the first month of the calendar year. To view the current Executive Level 2 pay scale, visit the website of the U.S. Office of Personnel Management at http://www.opm.gov/oca/ and search for executive schedule.

Full-time Equivalent (FTE): The definition of a Full-time Equivalent must be in accordance with the institution's policy, used consistently by the institution regardless of the source of support, and may be different in terms of actual months per year or days per week at the applicant institution.

Full-time Faculty: Full-time Faculty positions are defined as teaching, clinical, and research appointments carrying classroom teaching, laboratory teaching, clinical teaching or service, or research assignments equal to at least nine months per fiscal year or 0.75 FTE. This includes tenured, tenure-track, and non-tenure track appointments.

Health Disparities: According to The Centers for Disease Control and Prevention, health disparities are, “preventable differences in the burden of disease, injury, violence, or opportunities to achieve optimal health that are experienced by socially disadvantaged populations. Populations can be defined by factors such as race or ethnicity, gender, education or income, disability, geographic location (e.g., rural or urban), or sexual orientation. Health disparities are inequitable and are directly related to the historical and current unequal distribution of social, political, economic, and environmental resources.”

Institutional Base Salary: The annual compensation that the applicant institution pays for an employee’s appointment, whether that individual’s time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of duties to the applicant institution. Base salary may not be increased as a result of replacing institutional salary funds with grant funds.

Institutional Review Board (IRB): A committee that reviews research involving human subjects to determine if research complies with law, including but not limited to 45 CFR 46, and 21 CFR 50, 56, 312 and 812 as applicable.

Key Personnel: Key personnel are defined as, and should be limited to, individuals who contribute to the scientific development or execution of the project in a substantive way, whether or not salaries are requested. Only U.S. citizens or permanent residents may be principle or co-principle investigators. Non-principle investigators may be employed on the grant with an authorized visa (i.e., J-1 visa).

Nonpublic Institutions: Nonpublic institutions in Florida operating under Chapter 1005, Florida Statutes, are eligible. For the purposes of the Program, any branch campuses, centers, or other affiliates of a nonpublic institution are considered one and the same with that institution. Where the number of applications is limited, the institution and its branch campuses, centers, or other affiliates must coordinate submission(s) in order to comply with the limitation.

Overlap, Commitment: Commitment overlap occurs when any project staff has time commitments exceeding 100 percent. This is the case whether or not the grant includes salary support for the effort. While information on other support is only requested for the Principal Investigator, no individual on the project may have combined commitments in excess of 100 percent.

Overlap, Financial: Financial overlap occurs when duplicate or equivalent budget items (e.g., equipment, salary) are requested in an application but are already funded or provided for by another source.

Overlap, Scientific: Scientific overlap occurs when: a) substantially the same research is funded by two or more different funding sources, or b) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more awards, regardless of the funding source.

Principal Investigator: The Principal Investigator (PI) must have the skills, knowledge and resources necessary to carry out the proposed research as well as possess personal interest, commitment and expertise consistent with the goals of the Ed and Ethel Moore Alzheimer's Disease Research Program. The PI must hold a research or health professional doctoral level degree, i.e. a MD, PhD, MD/PhD, DO/PhD, DO, DNS/DNS(c) (Doctor of Nursing Science) or equivalent. The PI must be in good standing and judged to have the appropriate training, level of authority and responsibility to direct the research program or project outlined in the grant application to the Ed and Ethel Moore Alzheimer's Disease Research Program. The PI is responsible to ensure the proper conduct of the research program or project, comply with all of the requirements of the Ed and Ethel Moore Alzheimer's Disease Research Program, and submit all required reports. The PI is the one individual designated by the applicant's organization to direct the project to be supported by the grant and is responsible and accountable to the applicant's organization officials for the proper conduct of the project. The PI must have research experience and the time commitment so as to supervise the project directly and in person. The PI is responsible and accountable to the applicant's organization officials for the project's scientific and technical direction as well as the proper conduct of the project. There may be multiple collaborators on a project, but there must be only one PI. To be eligible as a PI at an eligible institution**,** the individual must be a full-time faculty member or researcher employed by the lead institution by the time the application is submitted and may have a joint appointment by more than one research institution that totals full time employment. Temporary faculty members/researchers, even though full-time, are not eligible to apply. The license of the PI must be up to date and in good standing in the state of Florida. Only U.S. citizens or permanent residents may be principle or co-principle investigators. Non-principle investigators may be employed on the grant with an authorized visa (i.e., J-1 visa). Unauthorized aliens shall not be employed pursuant to §274A(e) of the Immigration and Naturalization Act (8 U.S.C. 1324a), section 101 of the Immigration Reform and Control Act of 1986, and Florida Executive Order 11-02.

Program: In this context, "Program" refers to the Ed and Ether Moore Alzheimer's Disease Research Program. established in section 381.82, Florida Statutes. The purpose of the Program is to fund research leading to prevention of, or a cure for, Alzheimer's disease by pursuing the following goals: a) Improve the health of Floridians by researching better prevention and diagnoses of, and treatments and cures for, Alzheimer's disease; b) Expand the foundation of knowledge relating to the prevention, diagnosis, treatment, and cure of Alzheimer's disease; and c) Stimulate economic activity in Florida in areas related to Alzheimer's disease research.

Public University: A public (state) university is defined in section 1000.21, Florida Statutes*,* except as otherwise specifically provided in that Statute; are the 12 named public, postsecondary institutions and any branch campuses, centers, or other affiliates of the institution. For purposes of the Program, any branch campuses, centers, or other affiliates of a public university are considered one and the same with that university. Where the number of applications is limited, the university and any branch campuses, centers, or other affiliates must coordinate submission(s) in order to comply with the limitation.

III. INSTRUCTIONS FOR APPLICATION PREPARATION AND SUBMISSION

Applications will only be accepted through the online application system found on the Program's website: http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity.html.

Application materials not submitted in the specified manner and in the specified format will be disqualified from competition.

Required signature pages such as budgets and letters of support, must be included in the appropriate section of the application as indicated in the online system. Online applications without scanned copies of these pages will be disqualified.

Other documentation and materials such as biographical sketches and other support must be converted to electronic format and placed in the appropriate section of the online application.

Applications will be evaluated on the materials in the application, and other sources of information will not be considered.

A. Online Registration and Application Submission

The online system will be available to accept applications for this FOA on the date published in Table 1. Schedule of Important Dates.

To complete the online application process:

1. Applicants must register to access the online application and forms. Register for an online application on the program website (https://peernet.orau.org/Intake/Submission/948b695c-ad96-e911-8142-0050568131c9) and complete the brief project profile. Registration will be acknowledged with an email message containing login instructions and a username and password. Reference http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity.html for frequently asked questions (FAQs) and additional information.

2. Complete the online application form. Deviations may be grounds for the Program to reject the entire application. Special formatting, scientific notation, pictures, and objects may be included in these documents. However, within the online application form fields such as the Project Title, General Audience Abstract and the Scientific Abstract, use only conventional alphanumeric letters and numbers (i.e. ASCII text) with no drawings, special characters, or symbols.

3. An application cannot be changed after an application is submitted. Errata sheets or replacement files will not be accepted once an application is submitted.

B. General Application Guidelines

1. Applications must be in English.

2. The entire text of all documents uploaded into the online application must be single spaced in an easily readable font. Use standard 11-point type for the text, and no less than 10-point type for tables figures and legends. Margins on all applicant created documents should be at least one inch (excluding required headers and footers). Do not use photo reduction for scanned items. Use black type for all text. The application must contain only materials that, when scanned or converted to PDF format, are clear, sharp, and easy to read.

3. All applications must be self-contained within specified page limits. Unless otherwise specified in this document, Internet website addresses (URLs) may not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites.

4. Before it can be submitted, the application must contain all of the required sections identified in Table 2. Application Components. Uploaded files should be titled by the categories listed in the table.

5. Applications must comply with space limitations specified in the online application. Appendices are not allowed.

IV. AFTER APPLICATION SUBMISSION

1. Changes to a Submitted Application

It is the responsibility of the applicant to ensure that a complete application is submitted by the applicant before the date and time specified in Table 1. Schedule of Important Dates. The Department does not allow submitted application files or data to be replaced or changed after an application is submitted. This decision will help ensure no applicants receive an unfair advantage. Before submitting the application, please check it for completeness, accuracy, quality, and readability. This should include verifying that all graphic elements, including tables, charts, and images, converted properly when saving the original documents in PDF format as required.

2. Evaluation of Applications

The Department will use a multi-step evaluation process before making award determinations for all applications submitted in response to this FOA. The Department will consider the outcome of each of these evaluation steps in making final funding recommendations to the State Surgeon General.

A. Administrative Review

Application materials not received according to the date, time, and location specified in Table 1. Schedule of Important Dates, will be disqualified.

Each application submitted by the deadline indicated in Table 1 will receive an administrative review verifying mandatory eligibility requirements and the completeness of the application. The administrative review does not include review of the overall scientific impact.

Any application failing to meet all administrative requirements may be ruled ineligible for funding in response to this FOA and not entitled to further consideration and will not undergo peer review.

The Department reserves the right to disqualify any and all applications or to waive minor irregularities when doing so would be in the best interest of the State of Florida. A minor irregularity is defined as a variation from the specifications of this FOA that does not give any applicant an advantage or benefit not enjoyed by other applicants, does not affect the cost of the application, nor adversely affects the interests of the State. At its option, the Program may correct minor irregularities, but is under no obligation to do so.

B. Scientific Merit Review

Scientific merit review will be assessed by the Ed and Ethel Moore Alzheimer's Disease Research Program Grant Advisory Board, or when appropriate, ad hoc reviewers with appropriate expertise in the area of the research application and recommended by the Advisory Board with follow-up by the DOH staff. Advisory Board members will be assigned to review applications based on member expertise and the absence of indicated conflicts of interest for the proposed project. Advisory Board members will review and rate applications, including assessing Alzheimer's-relatedness, novelty of ideas, research approach, quality of the science and research design, health impact, budget request, and level of support necessary to complete the work. Advisory Board members are required to disclose any possible conflicts of interests to the Department, and the Department will determine if any disclosed interests are conflicts of interests. Advisory Board members are not allowed to review applications with any related conflict of interest.

Overall Impact Score:

Similar to the National Institutes of Health, Board members will use a standard rating format:

(1) Exceptional – Exceptionally strong with essentially no weaknesses

(2) Outstanding – Extremely strong with negligible weaknesses

(3) Excellent – Very strong with only some minor weaknesses

(4) Very Good – Strong but with numerous minor weaknesses

(5) Good – Strong but also at least one moderate weakness

(6) Satisfactory – Some strengths and some moderate weaknesses

(7) Fair – Some strengths but with at least one major weakness

(8) Marginal – A few strengths and a few major weaknesses

(9) Poor – Very few strengths and numerous major weaknesses

Board members will rate all proposals for overall impact on the following criteria:

- Significance: the importance of the topic being addressed.
- Investigators: the qualifications of the key personnel contributing to the project.
- Innovation: the potential for the project to shift current paradigms.
- Approach: the appropriateness of the planned strategy, methodology, and analyses.
- Environment: the suitability of institutional support, equipment, and physical resources.
- Health impact on the people of Florida.

Other Review Considerations:

Separately, Board members will rate the relationship of the project to the advancement toward cause, prevention, diagnosis, treatment, and/or cure of AD. Board members will be asked the question “Has the applicant made a compelling case for a strong AD relationship?”

Board members will also identify any concerns regarding the proposed budget or apparent scientific or budgetary overlap with active or pending support. Board member concerns regarding protection of human and/or animal subjects will be considered.

C. Programmatic Review

The Department and the Alzheimer’s Disease Research Program Grant Advisory Board will consider the scientific merit review scores in a manner that eliminates or appropriately manages any conflicts of interest. Other programmatic interests, such as the availability of funds, and Program goals and preferences, will be used to form a funding recommendation to the State Surgeon General.

3. Notification of Funding Decision

The applicant organization and Principal Investigator will receive written notification of the funding decisions as indicated in Table 1. Schedule of Important Dates. All awards in response to this FOA are subject to the availability of funds and spending authority provided by the Florida Legislature. By submitting a grant application pursuant to this Funding Opportunity, all applicants acknowledge and consent to this condition.

4. Requests for Re-Consideration

All funding decisions of the State Surgeon General are final.

5. Grantee Requirements

A. Terms and Conditions

After awards are made, each grantee must sign a contract, called the "Terms and Conditions," agreeing to certain legal requirements of the award. The "Terms and Conditions" are non-negotiable and acceptance is required as part of the grant award process. The Department reserves the right to change or modify the "Terms and Conditions" as needed. The "Terms and Conditions" include the post-award schedule of deliverables.

B. Grantee Reporting Requirements

If the applicant's proposal is funded, the Grantee must respond to Department requests for information for a period of five (5) years after the end of the grant period, including any no cost extensions. The requested information may include but is not limited to long-term outcomes based on the funded project, including the value of additional grant awards for AD research, a list of AD presentations, a list of AD publications in peer-reviewed journals, commercialization results and any invention disclosures, patent filings, and patents received.

C. Open Innovation and Sharing of Publication-Related Materials, Data, and Software

Publishing a scientific paper is a transaction whereby the author(s) receive credit and status in exchange for sharing their scientific findings. Authors have a responsibility to make available materials, databases, and software integral to their findings so that others may validate or refute the results and/or extend them in new directions. Grantees funded through the Department are encouraged to use material transfer agreements to make materials, data and databases, and software that result from this funding and which is integral to their research findings, freely and promptly available upon request for research use by other scientists.

In accord with the National Institutes of Health notice NOT-OD-08-033, Grantees shall submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication, in a manner consistent with copyright law. This applies to all publications resulting from the Department funded projects/research. For more information on the NIH Open Access Policy visit http://publicaccess.nih.gov/. A copy of the electronic version of final, peer-reviewed, published manuscripts must be submitted to the Department when submitting the current quarterly progress report.

V. APPENDIX

1. Reportable Financial Interests

**Sample. Subject to revisions.

Florida Department of Health Financial Conflict of Interest in Research

Principal Investigator: _____

Title of project: _____

Grant number: _____

Step 1: Use the following tests to determine if the researcher and the researcher's immediate family, or any other personnel on the grant (sub-investigators and research staff) and their immediate families, have any of the following financial interests related to the research:

"Immediate Family" means spouse, domestic partner, children, and dependents.

"Financial Interest Related to the Research" means financial interest in the sponsor, product or service being tested, or competitor of the sponsor.

☐ Ownership interest, stock options, or other financial interest of any value related to the research. Does not include mutual funds or companies publicly traded on a stock exchange.
☐ Compensation of any value related to the research.
☐ Proprietary interest related to the research of any value including, but not limited to, a patent, trademark, copyright or licensing agreement.
☐ Board or executive relationship in a company (such as a startup company but including publicly traded companies) related to the research, regardless of compensation.
☐ Any arrangement where the value of the ownership interests will be affected by the outcome of the research. For example, an arrangement has been made where the value of stock options given to the researcher by a startup company will vary depending on the outcome of the research.
☐ Any other interest that could be affected by the outcome of the research

If any of the following above conditions are met, provide a description of financial interests related to the research:

☐ The grantee has no financial interests requiring disclosure

Signed _____ Dated _____

Failure to disclose financial interests related to the research, and failure to provide an updated disclosure at least at the time of the continuation request or if the financial interests of the researcher and personnel on the grant change, may result in:

- Immediate termination of the grant.
- Financial consequences, including repayment of all grant funds.
- Any other action required by state law.

2. Budget Template Form

ED AND ETHEL MOORE ALZHEIMER'S DISEASE RESEARCH PROGRAM
BUDGET BREAKDOWN BY CATEGORY

INSTITUTION: **FDOH GRANT #**

PRINCIPAL INVESTIGATOR (NAME):

GRANT PERIOD: **FROM:** **TO:**

CATEGORY	BUDGET YEAR 1 PERIOD	BUDGET YEAR 2 PERIOD				TOTAL BUDGET FOR GRANT PERIOD
						0.00
a. Personnel						0.00
b. Fringe Benefits						0.00
c. Travel						0.00
d. Equipment						0.00
e. Supplies						0.00
f. Contractual						0.00
g. Patient Care Costs						0.00
h. Other						0.00
i. SUB-TOTAL						0.00
j. Indirect						0.00
k. TOTAL						

**NOTE: The total budget may not exceed the award amount.*

GRANTEE
Signature of Authorized Official:

Name:

Date:

DEPARTMENT OF HEALTH
Signature of Authorized Official:

Name:

Date:

**Sample. Subject to revisions.

3. Budget Narrative Form

Justify each entry by describing how it is related to the project. Where appropriate, include details that show how the estimated cost was calculated. Use additional sheets as necessary.

Name	Role on Project	Type of Appt. (months)	% Effort on Project	Base Salary	Fringe	Project Salary (% effort x base salary)	Project Fringe (% effort x fringe)	Total
				TOTAL PERSONNEL:				

Personnel:

Consultants:

Consortium /Contractual:

Equipment:

Supplies:

Travel:

Patient Care:

Other Expenses:

**Sample. Subject to revisions.

4. Terms and Conditions Template

Sample. Subject to revisions

Florida Department of Health

Ed and Ethel Moore Alzheimer's Disease Research Program

Terms and Conditions

The Florida Department of Health ("Department") requires that a Grant recipient ("Grantee") for the Ed and Ethel Moore Alzheimer's Disease Research Program agree to certain legally enforceable terms and conditions. "Grantee" refers to both the eligible institution and its authorized agents.

The Funding Opportunity Announcement ("FOA"), including any FOA addendums, and the application submitted by the Grantee in response thereto ("application"), are hereby incorporated by reference as part of this agreement:

- Ed and Ethel Moore Alzheimer's Disease Research Program Funding Opportunity Announcement: Fiscal Year 2019-20.

  Grant Category:

  1. Standard Grants will be effective: Date of Execution – (2 year)
  2. Pilot Grants will be effective: Date of Execution – (2 year)
  3. Postdoctoral Research Fellowship Grants will be effective: Date of Execution – (2 year)

- Grantee must comply with the provisions outlined in those documents, all applicable federal and State of Florida laws, rules, and regulations, and with the following terms and conditions to receive and maintain grant awards.

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1. **Grant Period and Award:** The Grant titled, (GRANT TITLE), total award amount, a description of the project funded by this grant, and other specific information about this grant are shown in Attachment I. The grant period will include the original term of the grant and all approved extensions. In the case of multi-year grants, annual continuation is not automatic and continuation requests must be submitted according to the schedule in Attachment II. The Department may grant an extension of the grant period without additional funds (no-cost extension) at the sole discretion of the Department. Awards, continuations, extensions, renewals, and payments will be made contingent upon satisfactory project performance and compliance with the grant terms and conditions. The Department's performance and obligation to pay under this grant agreement are contingent upon annual appropriation by the Legislature, and/or the availability of funds.

2. **Starting the Grant Project:** This Grant may begin only with an approved budget, an approved conflict of interest, management plan, when appropriate, Institutional Review Board (IRB) approvals, and Institutional Animal Care and Use Committee (IACUC) approvals.

   a. 30 Day Updates: Grantee must update the Department, in writing, every 30 days after the start date of the grant period regarding the status of all applicable regulatory approvals. Failure to keep the Department

informed will result in either a financial consequences of a reduction of ten percent per invoice, or grant termination. Once applicable regulatory approvals are received, the Grantee will no longer need to provide the 30 day update.

b. Starting the Project: If the project has not started 90 days after the start date of the Grant period, the Department will impose either a financial consequences of a ten percent reduction per invoice, or grant termination.

c. The Grant Manual is an important reference document for grant awardees. It contains Department policies as well as the procedures necessary for compliance with those policies, and is organized around a typical grant lifecycle. The Grant Manual can be found at http://www.floridahealth.gov/provider-and-partner-resources/research/grant-programs-resources/forms-library.html.

d. IRB and IACUC Approval: If the research requires human or animal participants the Grantee must submit application(s) for all institutional authorizations included, but not limited to the Institutional Animal Core and Use Committee (IACUC) and Institutional Review Board (IRB) and Radiation Safety Review. The Grantee may request in writing to the Grant Manager authority to begin a portion of the project pending regulatory approvals.

3. Scope of Work and Project Adjustments:

a. The Grantee must complete the work as described in the application.

b. Any changes or adjustments in the designs, aims, or research plans as proposed in the application; any changes requiring IRB and/or IACUC approval; and any change that may result in a conflict of interest, must be submitted in writing and are subject to Department approval prior to the change taking place. Failure to obtain prior written approval from the Department will result in financial consequences of 10 percent per invoice.

4. Required Documentation: The Grantee will provide reports to the Department describing the impact of the research on health outcomes; scientific impact such as publications in peer review journals, presentations, patents; and any subsequent additional grant funding related to the subject research. Failure to comply with all deliverables required will result in either a financial consequence of a ten percent reduction per invoice, or grant termination.

a. Grantee must prepare and submit to the Department within 30 days of the end of each quarter; financial status reports, narrative progress reports that include a description of the impact of the research on health outcomes, and the deliverables as outlined in Attachment II. Reports must be prepared in the format specified by the Department.

b. The Grantee will make all reasonable efforts to assist the Department in gathering data required for reporting to the Legislature and Governor pursuant to section 381.82, Florida Statutes, and other laws, as applicable, both during and after the grant period. Upon request, Grantee will report a description of all outcomes resulting from this grant, including but not limited to a description of the impact of the research on health outcomes, publications, presentations, published reports, databases, additional grants and monies received, patents, invention disclosures, and copyrights to the Department.

5. Financial Consequences: Failure to provide all documentation required will result in either a financial consequence of a reduction of ten percent per invoice, and/or grant termination.

6. Quarter: There are four quarters in a fiscal year, consisting of three months each. The quarters are as follows: Quarter 1 is July through September; Quarter 2 is October through December; Quarter 3 is January through March; Quarter 4 is April through June.

7. **Payment:** This Grant has a fixed payment schedule as shown in Attachment II. Payments will be contingent on Grantee compliance with these Terms and Conditions and all other grant requirements.

   a. Total per annum payments to the Grantee must not exceed the total per annum allocation as shown in Attachment I, and cannot exceed the total award amount.

   b. Grantee must request payment using the Department's invoice form. Expenses will be reviewed for allow-ability.

   c. The Grantee will only be paid for satisfactory and timely deliverables. Payment of the final invoice for this grant will take place after the end of the Grant period once all required documentation and deliverables have been received and approved.

8. **Key Personnel Requirements and Adjustments:** Project key personnel include the Principal Investigator, Project Director, Mentor, and other project personnel noted as such in the grant application.

   a. Commitment of any individual's effort greater than 100 percent is not permitted.

   b. The Grantee must establish a system to track work effort commitments of all key personnel. Effort certification documentation shall indicate the committed/actual work effort expended on the grant during the Grant period as well as percent effort for all other duties/tasks/projects. All effort assigned to this Grant must be for work directly related to the project.

   c. Prior Department approval is required for Project Director, Principal Investigator, and Mentor changes.

   d. Reductions in Project Director or Principal Investigator effort are not allowed within the first year and may not be decreased more than ten percent within any one year of the grant period. The amount of effort of the Project Director and/or Principal Investigator must remain above the minimum percent required in the Call.

9. **Budget Adjustments:** The approved Budget Form is the annual budget approved by the Department at the beginning of the grant period and annually thereafter and includes any approved budget adjustments.

   a. The Department will reimburse the Grantee for allowable, reasonable, and necessary costs as detailed in the line item budget.

   b. The Department must review and approve any deviation from the approved budget. Any overspending in the personnel, equipment, or travel budget categories must be justified to and pre-approved by the Department. Any revisions to the Budget Form in excess of ten percent of the total amount of any one budget category being revised must be submitted to the Grant Manager on the Budget Revision Form reflecting the changes and justification. Revisions will become effective upon approval by the Department and signature by the Grantee and Department.

   c. The Department reserves the right to: a) require further justification, b) reject any disallowed costs, and c) request new/revised budgets as it deems necessary.

10. **No-Cost Extensions:** Extension of a grant period without additional funds.

    a. No-cost extensions are contingent upon spending authority.

    b. All no-cost extension requests must be received in writing in the form provided by the Department no less than three months prior to the ending date of the grant or date defined in Attachment II.

    c. No-cost extension requests are subject to review and approval or disapproval from the Department.

    d. The Grant will not be eligible for more than one six month no-cost extension.

11. **Property/Equipment:** Property and equipment is defined as non-expendable, tangible property having a useful life of more than one year. All property and equipment purchased with grant funds must be (a) necessary to carry out the proposed research; (b) justified to and pre-approved by the Department; (c) inventoried and tracked throughout the grant period; and (d) protected with sufficient insurance and security safeguards.

    a. All approved property and equipment must be purchased and received prior to the last 90 days of the grant period, unless prior written approval from the Department has been obtained.

    b. All equipment purchased with grant funds is the property of the eligible institution, and is subject to Chapter 273, Florida Statutes, dealing with state-owned tangible personal property and the disposition thereof.

12. **Fiscal Accountability:** The Grantee must establish and maintain books, records, and documents (including electronic storage media) in accordance with generally accepted accounting procedures and practices, which sufficiently and properly reflect all revenues and expenditures of funds provided by the Department.

    a. The Grantee must not commingle grant funds with other personal or business accounts. The Grantee must not use grant funds to supplant or replace funds from other resources.

    b. The Grantee must maintain and electronically submit to the Department on a quarterly basis, sufficient documentation of all grant expenditures as proof that such expenditures are allowable, reasonable, and necessary for the work performed under this agreement. The Grantee will not charge the Department for the value of donated goods, services, or facilities; however, donations may be used to meet any required match.

    c. The Grantee must develop and use a system for tracking all project costs incurred. All expenses paid with grant funds must be directly related to the project. Any grant funds utilized for purposes outside of the budget will be considered an overpayment and must be returned to the Department.

    d. The Department will not be responsible for any project costs incurred before or after the grant period. Only project costs incurred during the grant period are eligible for payment. All project costs are subject to Department audit, and only those required for this project during the grant period will be allowed.

    e. Per Section 112.061, Florida Statutes, reimbursement for allowed travel must be at or below the current state of Florida travel rates. Travel will be reimbursed at no more than the state of Florida travel reimbursement rates. Current state of Florida reimbursement rates can be found in section 112.061, Florida Statutes. In order to implement appropriations in the General Appropriations Act for state travel and notwithstanding s. 112.061, Florida Statutes, costs for lodging associated with a meeting, conference, or convention organized or sponsored in whole or in part by a state agency or the judicial branch may not exceed $150 per day.)

13. **Matching Funds:** If matching funds are a condition of this grant per the Funding Opportunity Announcement, the Grantee agrees it will specifically provide at a minimum the funds or other consideration as outlined in the application. Grantees may match more than the minimum required amount. If the Grantee does not contribute the agreed-to match amount, the total award amount may, at the discretion of the Department, be reduced proportionately to maintain the required matching ratio.

14. **Return of Funds:** This grant is a fixed payment grant, which provides a specific level of quarterly support without regard to actual costs incurred. The final invoice is based on a reconciliation of all costs associated with the project not to exceed the fixed amount indicated in Attachment II. The Grantee must return to the Department any overpayment of grant funds related to disallowed expenditures, funds unaccounted for due to non-submission of required deliverables, or other unused grant funds at the end of the grant period. If the Grantee or its independent auditor identifies that overpayment has been made, the Grantee must repay the overpayment within 90 calendar days of grant end date. In the event that the Department first discovers an

overpayment has been made, the Department will notify the Grantee of such a finding. Should repayment not be made in a timely manner, the Department may withhold the amount of the overpayment from any future payments under this or any other agreement. This provision will not be a limitation on any remedies at law or equity available to the Department.

15. **Monitoring:** The Grantee must permit persons duly authorized by the Department to inspect any records, papers, documents, facilities, and/or goods and services of the Grantee that are relevant to this grant, and/or interview any clients, subcontractors, and employees of the Grantee to assure the Department of satisfactory performance of the terms and conditions of this grant. Monitoring may take place at any time during the grant period or records retention period with reasonable advance notice during normal business hours. Following such evaluation, the Department may deliver to the Grantee a written report of its findings and may include written recommendations with regard to the Grantee's performance of the terms and conditions of this grant. The Grantee will correct all noted deficiencies identified by the Department within the specified period of time set forth in the recommendations. The Grantee's failure to correct noted deficiencies may, at the sole and exclusive discretion of the Department, result in any one or a combination of the following: (a) the Grantee being deemed in breach or default of this agreement; (b) the withholding of payments to the Grantee by the Department under this or any other agreement; (c) and/or the termination of this grant.

16. **Access to Records:** All records related to this Grant or Grant Project will be subject at all reasonable times to inspection, review, or audit by federal, state, or personnel duly authorized by the Department. Persons duly authorized by the Department will have full access to and the right to examine any of the Grantee's grant and related records and documents, regardless of the form in which kept, at all reasonable times for as long as records are retained. Upon termination of the grant, and at the request of the Department, the Grantee will cooperate with the Department to facilitate the duplication and transfer of any said records or documents during the required retention period. The Department unilaterally reserves the right to terminate this grant if the Grantee refuses to allow public access to all documents, papers, letters, or other materials subject to provision of Chapter 119, Florida Statutes, made or received by the Grantee or its contractor in conjunction with this grant.

17. **Retention of Records:** The Grantee must retain all client records, financial records, supporting documents, statistical records, and any other documents (including electronic storage media) pertinent to this grant for a period of six years after the end of the grant period. If an audit has been initiated and audit findings have not been resolved at the end of the six years, the records must be retained until resolution of the audit findings or litigation, which may be based on the terms of this grant. Upon completion or termination of the grant and at the request of the Department, the Grantee will cooperate with the Department to facilitate the duplication and transfer of any said records or documents during the required retention period as specified.

18. **Financial, Scientific, Commitment Overlap and Other Support:** Financial overlap occurs when duplicate or equivalent budget items (e.g., equipment, salary) are requested in an application but are already funded or provided for by another source. Financial overlap is defined as accepting financial compensation from one or more other support sources for the same or substantially similar scientific aims/projects that are funded by the Department. Financial overlap is not permitted. Scientific overlap occurs when substantially the same research is funded by two or more different funding sources, or a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more awards, regardless of the funding source. Commitment overlap occurs when any project staff has time commitments exceeding 100 percent. This is the case whether or not the grant includes salary support for the effort. While information on other support is only requested for the Corresponding Principal Investigator, no individual on the project may have combined commitments in excess of 100 percent. Other Support is defined as all financial resources, whether federal, state or private, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards (not included are training awards, prizes, or gifts).

The Grantee is responsible for monitoring changes in other support for project key personnel to avoid overlap. The Grantee is responsible for notifying the Department of such changes and for resolving overlap or requesting an amendment to prevent overlap. If overlap is due to receipt of an award from another funding source during the grant period, the Grantee must immediately notify the Department and resolve the overlap by: a) modifying at least one of the awards to eliminate the overlap or b) relinquishing one of the awards. Updated information on other support may be requested by and shall be provided to the Department at any time during the grant period.

19. **Financial Conflict of Interest:** Grantee must report to the Department any interest in the list of reportable interests specified in Attachment III, regardless of any conflict of interest procedures at the Grantee's institution, at the time of the application and before the grant starts. The Grantee must have in place an administrative process to identify and resolve financial conflicts of interest that may affect the objectivity of the proposed research. The Grantee must inform the Department of any conflict of interest management plan required by the Grantee's institution prior to starting research. The Department may require an additional management plan if the plan developed by the Grantee institution is not acceptable to the Department. If a reportable interest as defined by the Department arises after the grant starts, the Grantee must immediately notify the Department within 48 hours.

20. **Assignment and Sub grants:** The Grantee will neither assign the responsibility of this grant to another party nor subcontract for any of the work contemplated under this grant without prior written approval of the Department. Any sub-license, assignment, subcontract, or transfer otherwise occurring will be null and void. No sub grants will be authorized that involve researchers outside the state of Florida. The Grantee will be responsible for all work performed and all expenses incurred for this grant and for ensuring compliance with these terms and conditions. If the Department permits the Grantee to subcontract part of the work contemplated under this grant, including entering into subcontracts with vendors for services and commodities, the Department will not be liable to the subcontractor for any expenses or liabilities incurred under the subcontract and the Grantee will be solely liable to the subcontractor for all expenses and liabilities incurred under the subcontract. To the extent permitted by Florida law, the Grantee, at its expense, will defend the Department against such claims.

21. **Confidentiality:** The Grantee will maintain confidentiality of all data, files, documents, papers, electronic storage media, and records, including client records, and shall protect the privacy of human subjects related to this grant and all services provided. The Grantee must not use or disclose any information concerning human subjects under this grant for any purpose not in conformity with applicable state and federal law or regulations (including but not limited to 45 CFR 46, 160, 162, and 164, and 21 CFR 56.111 and 45) and Department Institutional Review Board policies, except upon written consent of the recipient, or his or her responsible parent or guardian, when authorized by law. Grantee must report any breach of confidentiality to the Department within 48 hours of an allegation being made.

22. **Publications, Presentations or Printing of Reports:** Any publications, presentations, printed reports, or resulting research findings related to this grant must acknowledge the appropriate funding source: Florida Department of Health, Ed and Ethel Moore Alzheimer's Disease Research Program. Grantee shall notify the Department of all publications, presentations, printed reports, and resulting research findings created for this project both during the grant period and for a period of six years after the grant period.

23. **Public Access:**

    a. Upon publication of their work, grantees funded through this Program are encouraged to make materials, data and databases, and software that result from this funding and which is integral to their publication,

freely and expeditiously available upon request for research use by other scientists, utilizing materials transfer agreements.

b. In concert with the National Institutes of Health (NIH) notice NOT-OD-08-033, the Grantee will submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication, in a manner consistent with copyright law.

24. Patents, Copyrights, and Royalties: Notwithstanding the provision at Section I.T of the Standard Contract, the following provisions will apply to all inventions, including intellectual property, created under this grant:

a. All inventions will be the property of the Grantee or business partner if a written agreement has been executed; and Grantee will retain the entire right, title and interest to such.

b. The Department will have a fully paid up, non-exclusive, non-transferable, irrevocable license to practice or have practiced or to use or have used the invention for or on behalf of the State of Florida.

c. Grantee will disclose all inventions to the Department within two months of patent application and/or any licensing event, and will subsequently report on commercialization progress regarding patenting (filing dates and issue dates), licensing, and commercialization events.

d. Grantee will make reasonable efforts to commercialize such invention through patenting and licensing and will make reasonable efforts to give preference to Florida-based companies.

e. If the Grantee seeks to apply for copyright, trademark or patent when commercially reasonable for any property created, developed or invented as a result of services provided under this grant, the Grantee will furnish the Department with a description of said property and a copy of any licensing obtained.

f. Grantee will report to the Department, upon request, any progress in securing or exploiting such inventions, trademarks, copyrights, or patents both during and after the grant period.

g. It is expressly agreed that neither Grantee nor Department transfers by operation of this Agreement to the other party any right in or license to any patents, copyrights, or other proprietary right owned as of the commencement date of the Agreement or arising outside of the research conducted under this Agreement.

25. Policy Regarding Scientific Misconduct: The following provisions will apply to ensure research integrity and manage scientific misconduct.

a. Applicants for, and recipients of, grants must promptly inform the Department of any notices of scientific misconduct or suspensions. If an administrative action for scientific misconduct is imposed by the Department of Health and Human Services (HHS), by his/her own institution, or by any other regulatory agency, the Grantee must notify the Department within 48 hours. Grantee must provide a copy of the final notice of the administrative action (i.e. after the disposition of any appeal) to the Department either at the time of application or within thirty (30) days of the imposition of the administrative action.

b. Each eligible institution that receives or applies for a grant must certify establishment of administrative policies consistent with 42 CFR 50, Subpart A, "*Responsibilities for PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science," and 42 CFR 94, "Public Health Service Standards for the Protection of Research Misconduct Whistleblowers.*"

26. Human Subjects: The following provisions will apply if the project involves human subjects:

a. Grantee must comply with all applicable federal and state laws and regulations, including 45 CFR 46, 45 CFR 160 and 164, and 21 CFR 50, 56, 312, 812, and other applicable regulations when research is covered by regulations or the organization has committed to applying federal regulations or equivalent protections to all research.

b. Grantee is responsible for safeguarding the rights and welfare of human subjects in Department-supported projects. Grantees proposing to involve human subjects in nonexempt research must provide, upon request, a copy of the organization's Assurance of Compliance with the Office of Human Research Protections (OHRP), and must establish and maintain appropriate policies and procedures for the protection of human subjects.

c. Grantees are required to obtain and maintain approval from an IRB within 60 days of notice of award. Grantees are required to follow Department policies for reporting unanticipated problems and non-compliance involving the research to the Department.

d. When appropriate, Grantee agrees to define the arrangements for medical care for research-related injury before the research starts and communicate it to prospective research participants. This does not require any particular party to be responsible for such care; it requires that it be made clear to participants through the informed consent document/process who will provide medical care and who will be responsible to pay for it should a participant experience a research-related injury.

e. Grantee agrees to report to the Department within 48 hours any expiration of IRB approval, serious or continuing non-compliance, unanticipated problems involving risks to participants or others, and any suspension or termination of IRB approval. The Grantee IRB agrees to report to the Department when reporting to federal officials any serious, continuing non-compliance or unanticipated problem involving risks to participants or others.

f. Projects which include research participant incentives must receive approval from the Florida Department of Health Institutional Review Board (IRB). For these projects, the Florida Department of Health IRB must be the IRB of Record. The online system is found at https://flhealth.my.irbmanager.com/

g. During the time that one or more IRB approval(s) is expired, all activities covered by the expired IRB approval(s) must stop until approval is obtained, and expenses for those activities during the expired period will be disallowed.

h. Grantee must comply with the "*NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research*."

27. Vertebrate Animals: If this project involves the use of vertebrate animals, the following terms apply.

a. Grantee is responsible for the humane care and use of animals in Department-supported research activities. Grantee must abide by the Animal Welfare Act as amended (7 USC 2131-2159) and other Federal statutes and regulations relating to animals.

b. Grantee must obtain, maintain, and provide to the Department active verification or certification of Institutional Animal Care and Use Committee (IACUC) approval before project work can begin. The verification must include principal investigator name, project name, approval and expiration dates, and signature of the approving authority chairperson.

c. Grantee agrees to report within 48 hours to the Department any expiration of IACUC approval, serious or continuing non-compliance, and any suspension or termination of IACUC approval.

d. During the time that the IACUC approval is expired, all activities covered by the expired IACUC approval must discontinue until a renewal is obtained, and expenses for those activities during the expired period will be disallowed.

28. Recombinant DNA: All research involving recombinant DNA techniques must meet the requirements of NIH Notice NOT-OD-02-052, "*NIH Guidelines for Research Involving Recombinant DNA Molecules.*"

29. **Stem Cells:** All research involving human stem cells must meet the requirements of the "National Institutes of Health Guidelines for Human Stem Cell Research."

30. **Lobbying:** Pursuant to sections 11.062 and 216.347, Florida Statutes, no portion of grant funds will be used for lobbying.

31. **Insurance:** The Grantee must provide adequate liability insurance coverage on a comprehensive basis at all times during the grant period. Upon execution of this grant, unless it is a public college or university as identified in Chapter 1004, F.S., the Grantee accepts full responsibility for identifying and determining the type(s) and extent of liability insurance necessary to provide reasonable financial protections for the Grantee and the clients to be served under this grant, if any. Upon execution of this grant, upon request the Grantee must furnish the Department written verification supporting both the determination and existence of such insurance coverage. A self-insurance program established and operating under the laws of the State of Florida may provide such coverage. The Department reserves the right to require additional insurance where appropriate. Insurance must be secured from a company licensed to do business in the State of Florida.

32. **Florida Single Audit Act Financial Audit:** The Grantee must comply with the provisions of the Florida Single Audit Act, section 215.97, Florida Statutes, as applicable. The following provisions apply:

    a. The Grantee is required to maintain separate accounting of revenues and expenditures of funds and maintain sufficient documentation of all expenditures incurred (e.g., invoices, canceled checks, payroll detail, bank statements, etc.) under this contract that evidences that expenditures are:

        i. Allowable under the contract and applicable laws, rules, and regulations;

        ii. Reasonable; and

        iii. Necessary in order for the Grantee to fulfill the obligations under these Terms and Conditions.

    b. The aforementioned documentation is subject to review by the Department and/or the State Chief Financial Officer and the Grantee will comply timely with any requests for documentation.

33. **Termination:** Regardless of the cause of termination, the Grantee must comply with the terms and conditions of this grant at all times during and after the grant period. The Grantee may be reimbursed for allowable costs incurred and any irrevocable charges through the date of termination up to the total award amount.

    a. This grant may be terminated by the Grantee upon no less than 30 calendar days notice in writing, without cause, at no additional cost.

    b. This grant may be terminated by the Department upon no less than 30 days notice, without cause, at no additional cost, unless a different notice period is mutually agreed upon by the parties or outlined elsewhere herein. The provisions herein do not limit the Department's right to any legal remedies.

    c. In the event funds to finance this grant become unavailable, the Department may terminate this grant upon no less than 24 hours notice in writing to the Grantee. The notice will be delivered by certified mail, return receipt requested, or in person with proof of delivery. The Department will be the final authority as to the availability and adequacy of funds.

    d. In the event of research non-compliance or violation of the terms of this agreement, the Department may terminate this research grant upon no less than 24 hours notice in writing to the Grantee.

34. **Indemnification:** Unless the Grantee is an agency or subdivision of the State of Florida or a public college or university as identified in Chapter 1004, Florida Statutes, the Grantee will be liable for and will indemnify,

defend, and hold harmless the State of Florida, its officers, employees and agents to the full extent allowed by law from all losses, expenses, claims, damages, actions, suits and judgments, consequential or otherwise and including attorneys' fees and costs, arising out of any act, actions, neglect, or omissions by the Grantee, its agents, subcontractors, or employees during the performance or operation of this grant, whether direct or indirect, and whether to any person or tangible or intangible property. Only adjudication or judgment after highest appeal is exhausted specifically finding the Grantee not liable will excuse performance of this provision.

Nothing in this grant agreement is intended to serve as a waiver of sovereign immunity, nor will anything in this grant agreement be construed as consent by a state agency or political subdivision of the State of Florida to be sued by third parties in any matter arising out of this grant agreement. If the Grantee is an agency or subdivision of the State of Florida, the Grantee agrees to be fully responsible for its acts of negligence, or its agents' acts of negligence when acting within the scope of their employment or agency, and agrees to be liable for any damages resulting from said negligence. Nothing herein is intended to serve as a waiver of sovereign immunity by any Grantee to whom sovereign immunity may be applicable.

35. Dispute, Dispute Resolution, and Renegotiation:

a. Failure of this agreement to cite all applicable state and federal laws and regulations does not waive compliance requirements.

b. Failure of the Department to declare any default immediately upon the occurrence thereof, or delay in taking any action in connection therewith, does not waive such default. The Department shall have the right to declare any default at any time and take such action as might be lawful or authorized hereunder, in law or in equity. No Department waiver of any term, provision, condition or covenant hereof will be deemed to imply or constitute a further Department waiver of any other term, provision, condition or covenant hereof, and no payment by the Department will be deemed a waiver of any default hereunder.

c. Modifications of provisions of this agreement will only be valid when they have been reduced to writing and duly signed by both parties.

d. The Department will be entitled to assign or transfer, in whole or part, its rights, duties, or obligations under this agreement to another governmental agency in the State of Florida upon giving prior written notice to the Grantee.

36. Contact:

a. All correspondence relating to contractual matters should be directed to Research@flhealth.gov or via mail to Florida Department of Health, Office of Public Health Research, 4052 Bald Cypress Way, Bin A-24, Tallahassee, FL 32399-1749. The Department requires original signatures for all grant contract matters (invoices, budgets, and reports). These documents must be mailed to the above address.

b. A Vendor Ombudsman has been established within the Department of Financial Services, whose duties include acting as an advocate for Grantees who may be experiencing problems in obtaining timely payment from a state agency. The Vendor Ombudsman may be contacted at (850) 413-5516 or (800) 342-2762, the State of Florida Chief Financial Officer's Hotline.

I have read the above Terms and Conditions and understand each section.

The parties hereto have caused these Terms and Conditions to be executed by their undersigned officials as duly authorized.

GRANTEE:

Signature of Authorized Official	Date
Typed or Printed Name of Authorized Official	Eligible Institution Name

FLORIDA DEPARTMENT OF HEALTH:

Signature of Authorized Official	Date
	Florida Department of Health

Attachment I

Florida Ed and Ethel Moore Alzheimer's Disease Research Programs

Terms and Conditions

Program:	
Program CSFA #:	
Grant ID:	
Type of Grant:	
Institution:	
Principal Investigator:	
Project Title:	
General Audience Abstract:	
Grant Period:	
Total Grant Award:	
Year One Amount:	
Year Two Amount:	

***** Grant duration is contingent upon spending authority from fiscal year to fiscal year.**

Attachment II

Florida Ed and Ethel Moore Alzheimer's Disease Research Program

Terms and Conditions

Schedule of Deliverables and Payments

Deliverable	Period Covered	Due Dates
YEAR ONE		
• 1st Quarter Progress Summary Report • 1st Quarter Financial Report • 1st Quarter Expenditure Summary Report • Invoice for $		
• 2nd Quarter Progress Summary Report • 2nd Quarter Financial Report • 2nd Quarter Expenditure Summary Report • Invoice for $		
• Continuation Cumulative Progress Report		
• 3rd Quarter Progress Summary Report • 3rd Quarter Financial Report • 3rd Quarter Expenditure Summary Report • Invoice for $		
• 4th Quarter Progress Summary Report • 4th Quarter Financial Report • 4th Quarter Expenditure Summary Report • Invoice for $		
YEAR TWO		
• 1st Quarter Progress Summary Report • 1st Quarter Financial Report • 1st Quarter Expenditure Summary Report • Invoice for $		
• 2nd Quarter Progress Summary Report • 2nd Quarter Financial Report • 2nd Quarter Expenditure Summary Report • Invoice for $		
• 3rd Quarter Progress Summary Report • 3rd Quarter Financial Report • 3rd Quarter Expenditure Summary Report • Invoice for $		
• Final Cumulative Progress Report • Final Financial Report • Final Expenditure Summary Report		
• Final Invoice is based on a reconciliation of all cost associating with project not to exceed $		