Budget Detail Request - Fiscal Year 2016-17

Your request will not be officially submitted unless all questions and applicable sub parts are answered.

- 1. Title of Project: <u>UF Center for Translational Research in Neurodegenerative Disease</u>
- 2. Date of Submission: <u>01/06/2016</u>
- 3. House Member Sponsor(s): Jason Brodeur

4. DETAILS OF AMOUNT REQUESTED:

- a. Has funding been provided in a previous state budget for this activity? <u>Yes</u> If answer to 4a is ?NO? skip 4b and 4c and proceed to 4d
- b. What is the most recent fiscal year the project was funded? $\underline{2015-16}$
- c. Were the funds provided in the most recent fiscal year subsequently vetoed? No
- d. Complete the following Project Request Worksheet to develop your request (Note that Column E will be the total of Recurring funds requested and Column F will be the total Nonrecurring funds requested, the sum of which is the Total of the Funds you are requesting in Column G):

FY:	Input Prior Year Appropriation for this project for FY 2015-16 (If appropriated in FY 2015-16 enter the appropriated amount, even if vetoed.)			Develop New Funds Request for FY 2016-17 (If no new Recurring or Nonrecurring funding is requested, enter zeros.)			
Column:	А	В	С	D	E	F	G
Funds Description:	Prior Year Recurring Funds	Prior Year Nonrecurring Funds	Total Funds Appropriated (Recurring plus Nonrecurring: Column A + Column B)	Recurring Base Budget (Will equal non- vetoed amounts provided in Column A)	INCREASED or NEW Recurring Requested	TOTAL Nonrecurring Requested (Nonrecurring is one time funding & must be re-requested every year)	Total Funds Requested Over Base Funding (Recurring plus Nonrecurring: Column E + Column F)
Input Amounts:	0	1,000,000	1,000,000	0	0	2,000,000	2,000,000

- e. New Nonrecurring Funding Requested for FY 16-17 will be used for:
 ☑Operating Expenses □Fixed Capital Construction □Other one-time costs
- f. New Recurring Funding Requested for FY 16-17 will be used for: □Operating Expenses □Fixed Capital Construction □Other one-time costs

5. Requester:

- a. Name: <u>Todd Golde</u>
- b. Organization: UF Center for Translational Research in Neurodegenerative Disease (CTRND)
- c. Email: tgolde@ufl.edu
- d. Phone #: (352)273-9456

6. Organization or Name of Entity Receiving Funds:

- a. Name: UF College of Medicine
- b. County (County where funds are to be expended) <u>Alachua, Broward, Miami-Dade</u>
- c. Service Area (Counties being served by the service(s) provided with funding) <u>Statewide</u>

7. Write a project description that will serve as a stand-alone summary of the project for legislative review. The description should summarize the entire project?s intended purpose, the purpose of the funds requested (if request is a sub-part of the entire project), and most importantly the detail on how the funds requested will be spent - for example how much will be spent on positions and associated salaries, specifics on capital costs, and detail of operational expenses. The summary must list what local, regional or statewide interests or areas are served. It should also document the need for the funds, the community support and expected results when applicable. Be sure to include the type and amount of services as well as the number of the specific target population that will be served (such as number of home health visits to X, # of elderly, # of school aged children to receive mentoring, # of violent crime victims to receive once a week counseling etc.)

Florida is an epicenter of the Alzheimer's disease epidemic with ~10% of all cases of Alzheimer's disease in the country. The total economic toll of Alzheimer's in the state is estimated to be \$20 billion dollars a year - more than either heart disease or cancer. As age is the major demographic risk factor, with its large population of elderly Florida, the toll that Alzheimer's will wreak both socially and economically is only going to increase over the coming decades. Our only hope to reduce these costs is research that will ultimately lead to therapies that modify the disease course or, perhaps more immediately, research that will enable us to better handle patients with dementia within health care systems.

The CTRND, which is now in its 6th year, has recruited a core of 12 new faculty who study Alzheimer's disease and other neurodegenerative disorders. We have developed a portfolio of extramural funding of ~\$9M/yr, which has increased nearly 50% from last year. We remain poised to steadily increase this funding over the next few years, and these funds from the State will be essential for maintaining that trajectory.

The funds from the State have been a huge factor in our success and future funds will be used to leverage the ADRC such that we will become the preeminent center in the Southeast for neurodegenerative research and translation to improved clinical outcomes. In collaboration with Mt. Sinai Medical Center in Miami, we have successfully competed for a NIH funded P50 Alzheimer's Disease Research Center. Notably, this award also involves faculty at FAU, FIU and U of Miami. We hope that the infrastructure provided by the ADRC will also increase funding in AD to those institutions. We will also continue to work with our colleagues at USF to synergize our efforts in AD research.

ADRCs serve a role much like national cancer center designations. The 1Florida ADRC that we have now renamed the 1Flordia ADRC enables us to create infrastructure that supports clinical care for patients with Alzheimer's Disease. ADRCs also serve as hubs of translational science that are necessary to advance the science in order to reach our shared goal of preventing or treating Alzheimer's Disease. They are essential to increasing enrollment from industry sponsored clinical trials and also for ensuring that advances in the science and care of Alzheimer's disease are efficiently and rapidly disseminated to the wider community. By enhancing clinical trial capacity in Alzheimer's disease, we project that we will enroll an additional 200 clinical trial participants per year in the state of Florida resulting in an additional \$2 million per year. This increase will ramp up over the course of the grant. The vast majority of these funds for clinical trials would be from the pharmaceutical industry. Notably, the head of Alzheimer's disease research at a major pharmaceutical company views Florida with its huge number of elderly as an underdeveloped opportunity for enrolling the large number of elderly subjects needed to advance promising Alzheimer's drugs.

As center grants, ADRCs support both research and clinical trial activity. After 5 years, one can expect an additional >\$2.5 million per year of research grant support (commercial, public sector, private philanthropy /foundations).

These ADRCs serve as hubs for both established STEM employees as well as training centers for those interested in STEM jobs. ADRCs will result in medical tourism, as they represent a sign of clinical and scientific excellence to the outside world. ADRCs also provide a basis for many private-public partnerships in the battle to cure Alzheimer's disease - infrastructure developed for the ADRCs would also be used to compete for other programmatic grants that provide a similar level of extramural funding.

With the UF Center for Movement Disorder and Neuro-Restoration we will continue to compete for an NIH funded P50 Morris Udall Parkinson's Disease Research Center of Excellence. We have submitted two applications in recent years and were competitive, but missed the funding line. These centers are similar to ADRC and serve as hubs for Parkinson's research. By helping us to address issues raised in previous reviews, we believe that we can successfully compete for the Udall center award. Again, like the ADRC, the total award is ~\$1.5M/yr for five years and once obtained are much more easily renewed for another 5 years.

The CTRND has recruited over 12 faculty to the University and we have engaged over 30 other faculty to participate in our research efforts. The primary faculty publish >50 high impact manuscripts a year. As our work is thematically related and we work extremely well together, we are well positioned to successfully compete for programmatic NIH funding through the P01 mechanisms. This mechanism is distinct from the P50 mechanisms as these are investigator-initiated awards. We are currently developing two P01 grants related to AD, PD, stroke, ALS and neuro-inflammation. We believe that we can successfully compete for these awards over the next 3 years. Again, each grant is funded for 5 years at ~\$1.5M/yr. U01 awards are designed to move a therapeutic lead from the bench to patients. We have two novel therapeutic approaches to AD that will enable us to compete for U01 awards within the next three years. These grants typically provide \$1-1.5M/yr for five years of funding and, importantly, if successful will lead to licensing of technologies.

Collectively, from a purely financial ROI perspective, we have been able to use the previous state allocations (\$1.25M in 2013-14 and 2014-15) to garner grants worth over \$20M. These grants have supported an additional 15-20 STEM FTE positions.

These funds also have other intangible ROI. First and foremost is the unmet medical need. There are no disease modifying therapies for Alzheimer's disease or, for that matter, any other neurodegenerative disease that we study and our mission is to contribute to the development of such therapies. If we are successful, then we will have made an impact on the field and helped those who suffer from these disorders. We insure that we protect our inventions so that we can license the technologies for additional ROI.

From the UF preeminence perspective, we believe that these funds have and will continue to dramatically increase the visibility of UF nationally and internationally. By obtaining an ADRC and, hopefully in the future, an Udall Parkinson?s center we would be one of the few institutions to have both of these awards (others include John Hopkins, Columbia, Mayo Clinic).

Further, these new NIH funds have pushed the UF Neuroscience program into one of the Top 10 funded NIH Neuroscience departments in the US.

The NIH has increased funding for Alzheimer?s disease by ~\$350,000,000 this year. Already, the NIH/NIA has announced pay lines for AD research will be ~60-70% higher than for other grants. Our growing team of outstanding Alzheimer?s disease researchers will, thus, be well positioned to enhance funding as the likelihood of success for obtaining grants from the NIH that relate to AD is dramatically increased.

Finally, we have recruited two outstanding clinical AD investigators to UF. With their arrival and our ADRC grant, we can envision future recruitment of faculty in this area to provide the critical mass and intellectual capital to become one of the preeminent centers for Alzheimer?s and other neurodegenerative research in the world. Again, State funds will provide critical support for our future efforts in this area.

In short, the UF CTRND is emerging as a preeminent international Alzheimer?s and Neurodegenerative disease research program. We have provided excellent ROI and expect to further leverage the State funds in the future.

Previous allocations of funds were not tied to specific budgets but rather general support of the CTNRD. It was precisely this flexibility that enabled us to provide an excellent return on investment from the previous state funds. We invested the funds into research avenues likely to lead to new federal funding. The major shift in our plans for expenditures this year from salary support and research expenditures as in the past year stem from needing to support the ADRC grant that was awarded in August 15th 2015. This grant, much like a National Cancer Center designation, leverages a lot of internal resources. Indeed, in the state of Arizona, the Arizona ADRC award from the NIH is matched by State of Arizona funding every year with a nearly one to one match. To support the ADRC efforts ~\$200,000 are need to support our data basing and other IT needs. Of importance, we are building a database for clinical research in AD that we plan to distribute throughout the state. We hope that in the future all institutions who clinical AD research utilize the database so we have a shared resource that serves not just the institutions affiliated with our ADRC, but other institutions in the state (E.g. USF, UCF, FSU). The other funds will be used to support research efforts (personnel, operating expenses, etc) that are most likely to lead to new funding. From the allocations to date of \$3.5M we have garnered over \$29M of new funds.

8. Provide the total cost of the project for FY 2016-17 from all sources of funding:

Federal: <u>6,900,000</u> State: <u>0</u> (Excluding the requested Total Amount in #4d, Column G) Local: <u>1,000,000</u> Other: <u>1,000,000</u>

9. Is this a multi-year project requiring funding from the state for more than one year? <u>Yes</u>