

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: Brain Tumor Registry Program at the McKnight Brain Institute/Florida Center for Brain Tumor Research
2. Date of Submission: 01/04/2016
3. House Member Sponsor(s): W. Perry

4. DETAILS OF AMOUNT REQUESTED:

- a. Has funding been provided in a previous state budget for this activity? Yes
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? 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: A | B | C | 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: | 500,000 | 0 | 500,000 | 500,000 | 0 | 0 | 0 |

- 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: William A. Friedman, M.D.
- b. Organization: McKnight Brain Institute
- c. Email: friedman@neurosurgery.ufl.edu
- d. Phone #: (352)273-9000

6. Organization or Name of Entity Receiving Funds:

- a. Name: McKnight Brain Institute at the University of Florida
- b. County (County where funds are to be expended) Alachua
- c. Service Area (Counties being served by the service(s) provided with funding) Statewide

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.)

Purpose: This project is a brain tumor bank/data registry that provides highest-quality tumor samples, DNA, plasma/serum samples, and annotated clinical data to Florida's brain tumor researchers for the conduct of basic, translational, and clinical research on brain tumors in order to

? Establish a coordinated effort among the state's public and private universities and hospitals and the biomedical industry to discover brain tumor cures and develop brain tumor treatment modalities;

? Develop and maintain a brain tumor registry that is an automated, electronic, and centralized database of individuals with brain tumors;

? Foster collaboration with brain cancer research organizations and other institutions, providing a central repository for brain tumor biopsies from individuals throughout the state, improving and monitoring brain tumor biomedical research programs within the state, facilitating funding opportunities, and fostering improved technology transfer of brain tumor research findings into clinical trials and widespread public use;

? Expand the state's economy by attracting biomedical researchers and research companies to the state.

The project was founded by the Florida Legislature in 2006 (381.853FS).

How the funds requested will be spent: Of the direct costs, approximately \$200,000 will be spent to run the bank (salaries, supplies, shipping, database registry program, etc.) and \$250,000 will be distributed to Florida's brain tumor scientists for the most promising scientific projects as judged by an out-of-state, impartial panel of experts. Please see the attached budget with a 10% indirect cost rate. The research grants are enhanced each year by contributions from Accelerate Brain Cancer Cure (ABC2), a non-profit organization dedicated to funding research aimed at finding the fastest possible route to a cure for brain cancer. ABC2 contributes from \$75 to \$100,000 each year and empanels the expert reviewers. ABC2 is also supporting research by underwriting whole exome sequencing of brain cancer specimens as part of a research project conducted by Duane Mitchell, MD, PhD, State of Florida Endowed Cancer Research Chair and

Director, University of Florida Brain Tumor Immunotherapy Program.

Who is served: This is a statewide project that serves brain tumor researchers throughout the entire state independent of whether they directly contribute to the bank. The Scientific Advisory Council includes University of Florida, University of Miami, Cleveland Clinic Weston, Scripps Florida, Mayo Jacksonville, Tallahassee Neurological Clinic, UFHealth ? Orlando Health Cancer Center, and Moffitt. 1,328 patients have been enrolled in the bank. 10,764 specimens have been collected and include brain tumor, blood, DNA and cerebrospinal fluid samples. More than 3,023 samples have been distributed for research to investigators from the University of Miami; the University of Florida; MD Anderson Cancer Center Orlando; the University of Central Florida; Johns Hopkins University in collaboration with UF investigators; The Cancer Genome Atlas (TCGA) project, National Institutes of Health (NIH); the Chordoma Foundation; University of Colorado in collaboration with an investigator from UF; Jackson Laboratories in collaboration with an investigator from UF; and Arresto Biosciences.

Bringing federal research dollars to Florida: In the past few years, \$13,119,857 has been awarded to researchers who either leveraged FCBTR/ABC2 funding to conduct pilot data used in the federal award application or utilized tissue and data to obtain grants from federal agencies and private foundations.

Federal grants received by Florida researchers include:

R-15 NIH/NINDS (PI: Eric Laywell, Ph.D.)

Adaptive EdU Therapy for Brain Tumors

Dates of Award: 7/1/13 to 6/30/16

Grant Award from NIH: \$430,586

1R01CA195563 (PI: Duane Mitchell, M.D., Ph.D.)

NIH/NCI

Enhancing Adoptive Immunotherapy Targeting Pediatric High-Grade Gliomas

Dates of Award: 6/1/15 ? 5/31/20

\$2,855,413

1R01NS067037 (PI: Duane Mitchell, M.D., Ph.D.)

NIH/NINDS

Reversal of CMV Immune Deficits in Patients with Glioblastoma

(9/15/09 ? 6/30/15)

\$1,695,925

W81XWH-10-0089 (PI: Duane Mitchell, M.D., Ph.D.)

Department of Defense

Adoptive Cellular Therapy Targeting Recurrent Pediatric Brain Cancers During Hematopoietic Recovery from High-Dose Chemotherapy and Autologous Stem Cell Transplantation

(4/1/10 ? 3/31/16)

\$3,798,300

1R01CA134844 (PI: Duane Mitchell, M.D., Ph.D.)

NIH/NCI

Adoptive Immunotherapy for GBM During Hematopoietic Recovery from Temozolomide
(9/30/09-8/31/14) Extension to 2016

\$1,245,000

Research Agreement (PI: Duane Mitchell, M.D., Ph.D.)

Immunomic Therapeutics

\$76,257

R24NS086554-01 (PI: Brent Reynolds, Ph.D.)

NIH/NINDS

(2014 ? 2017)

Establishment of a Human Grade IV Glioma Stem Cell Line Bank

\$1,007,828

Foundation Grants received by Florida researchers for projects involving brain tumor specimens have included:

Pediatric Cancer Foundation (PI: Duane Mitchell, M.D., Ph.D.)

Engineering Tumor-Specific Central Memory T Cells

(11/01/14 ? 10/31/15)

\$100,000

American Cancer Society (Co-Investigator: Brent Reynolds, Ph.D.)

Identifying and Targeting Therapy Resistant Cells in Glioblastoma

(2013 ? 2016)

\$720,000

Hyundai Hope on Wheels Award (PI: Elias Sayour, M.D.)

Personalized RNA-nanoparticle vaccines.

(1/15 ? 12/16)

\$250,000

Alex's Lemonade Stand Young Investigator's Award (PI: Catherine Flores, Ph.D.)

Stem Cell Therapy in Pediatric Brain Cancer

(07/15 ? 06/17)

\$100,000

Ocala Royal Dames for Cancer Research (PI: Jeffery Harrison, Ph.D.)

CXCR4, VEGFR, and TGFbeta inhibitors for GBM therapy.

(07/14 ? 06/16)

\$50,000

Bristol-Myers Squibb (PI: Jeffery Harrison, Ph.D.)

Anti-CXCR4 antibody with or without Avastin for GBM

(12/14 ? 12/15)

\$46,548

American Cancer Society (PI: Matthew Sarkisian, Ph.D.)

Identifying And Targeting Therapy Resistant Cells In Glioblastoma

(1/2013 - 12/2016)

\$720,000

Medtronic (PI: Chelsey Simmons, Ph.D.)

Characterization of brain tumor tissue with custom multiscale indenter.

(08/15-07/16)

\$24,000

? Provision of best brain cancer care bringing patients to Florida for treatment

Malignant brain tumors are one of the most virulent forms of cancer. Patients who suffer from the most malignant type, glioblastoma multiforme (GBM), survive on average only 12 to 15 months, a prognosis that has not significantly improved over the past 50 years. Only very recently have there been some modestly promising new treatments such as Novocure, a product that delivers tumor-treating fields, which are locally or regionally delivered treatments that produce electric fields within the human body to disrupt the rapid cell division exhibited by cancer cells. The device was approved by the FDA in November 2014. Dr. David Tran, M.D., Ph.D., recently recruited to Florida, was one of the researchers who conducted the clinical trials leading to approval by the FDA.

Although still in clinical trials, brain tumor immunotherapy is showing impressive results. This type of immunotherapeutic treatment for many types of cancer was identified as the Breakthrough of the Year 2013 by Science Magazine. Patients have been sent to Florida from the most prestigious academic institutions in America [Stanford, MD Anderson, Children's Hospital of Pennsylvania (CHOP), and Duke] for ground-breaking experimental trials.

? Jobs for healthcare workers in Florida

Researchers and physicians, recruited to Florida, have hired nurses, nurse practitioners, physician assistants, research coordinators, regulatory specialists, lab managers, lab technicians, office assistants, database managers, as well as graduate assistants and post-doctoral scientists.

In addition to bringing millions of dollars of research funding to the state, a biomedical business has been started as well (please see attached letter).

? Prestige for Florida within the scientific community, which has helped in the recruitment of the best physicians and scientists throughout the U.S. and the world to Florida

Florida's Cancer Centers of Excellence program is a milestone in Florida's rise to becoming a top destination for cancer care and research. Bringing the best possible care to those fighting cancer in Florida will also attract the most talented medical professionals to our state. The Florida Center for Brain Tumor Research is an integral part of that effort.

Because of the Florida Center for Brain Tumor Research, Florida was able to participate in The Cancer Genome Atlas (TCGA) project, a collaborative research

effort jointly funded and managed by the National Cancer Institute and the National Human Genome Research Institute (NHGRI). Participation in TCGA put Florida on the ?research map? for identifying the genome of glioblastoma multiforme and low-grade gliomas. Samples from Florida were part of the basis of the article published in Cell, a high impact journal: The somatic genomic landscape of glioblastoma. Cell. 2013 Oct 10;155(2):462-77 and for the recently published Comprehensive, Integrative Genomic Analysis of Diffuse Lower-Grade Gliomas. The Cancer Genome Atlas Research Network. N Engl J Med 2015; 372:2481-2498 June 25, 2015. FCBTR is also participating in a project evaluating recurrent low-grade gliomas being run by Jill Barnhart-Sloan, Ph.D., at Case Western Reserve. Dr. Kenna Shaw, Ph.D., past Director of TCGA, was a keynote speaker at the 2014 Brain Tumor Biomedical Technology Summit held in Orlando May 16-17, 2014.

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

Federal: 0

State: 500,000 (Excluding the requested Total Amount in #4d, Column G)

Local: 0

Other: 100,000

9. Is this a multi-year project requiring funding from the state for more than one year?

Yes