

1K23CA93566-01A1

Fax

JUST IN TIME

The Bunting Family - The Family of Jacob and Hilda Blaustein Building
Division of Medical Oncology
1650 Orleans Street
Suite 186
Baltimore, MD 21231

Date: 7-3-02

To: Mr. Leo F. Buscher, Jr.

Fax: 301-435-3376

Phone: _____

From: Gail Jackson

Fax: 410-955-0125

Phone: 410-955-8838

Pages: This cover sheet plus _____ pages to follow.

Comments:

Please see Dr. Daniel Laheri's K23 response to
your June 21 letter requesting additional information

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**The Bunting ♦ Blaustein Cancer Research Building**

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Email: laherda@jhmi.edu

Daniel A. Laheru, M.D.
Instructor in Oncology

July 2, 2002

Mr. Leo F. Buscher, Jr.
Chief, Grants Management Officer
National Cancer Institute
Grants Administration Branch
Executive Plaza South, Suite T-42
Bethesda, Maryland 20892

RE: Mentored Patient-Oriented Research Career Development Award 1K23CA093566-01A1

Dear Mr. Buscher:

In response to your letter dated June 21, 2002 regarding the above referenced K23 award, I am providing you with additional requested information. This supplemental information includes:

- 1) Active Other Support for all key personnel (PHS 398 other support page). This would include support sheets from my co-mentors Dr. Elizabeth Jaffee and Dr. Steven Piantadosi.
- 2) A detailed budget for the initial budget period (PHS Format Page 4)
- 3) A budget for the entire proposed period of support (PHS Format page 5)
- 4) A completed checklist (PHS checklist form page)

Please call me with any questions.

Sincerely,

Daniel A. Laheru, M.D.
Instructor in Medical Oncology

Rosalie Wollett
Administrator
Sidney Kimmel Comprehensive
Cancer Center at Johns Hopkins



A Comprehensive Cancer
Center Designated by the
National Cancer Institute

Principal Investigator/Program Director:
(Last, first, middle)

OTHER SUPPORT

Daniel A. Laheru, M.D.

Project Number (Principal Investigator) Source Title of Project (or Subproject)	Dates of Approved/Proposed Project Annual Direct Costs	Percent Effort
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ACTIVE

No Project Number available (Schulick)	1/1/2002 – 12/31/2002	20%
NIH	\$150,000	
GM-CSF Enhanced Autologous Colon Cancer Vaccine		

The main goal of this study is to evaluate the safety of the vaccination with autologous colorectal carcinoma cells administered with a GM-CSF producing bystander cell line.

No Project Number available (Laheru)	7/1/2002 – 6/30/2003	10%
OSI Pharmaceuticals, Inc. (Sponsored)	\$284,976	
A Randomized Placebo Controlled Study of OSI-774 (Tarceva™) Plus Gemcitabine in Patients with Locally Advanced, Unresectable or Metastatic Pancreatic Cancer		

The main goal of this study is to evaluate the clinical benefit of a molecular targeted drug administered with standard chemotherapy versus chemotherapy alone in patients with metastatic pancreatic cancer.

No Project Number available (Laheru)	7/1/2002 – 6/30/2003	30%
Cell Genesys, Inc.	\$275,698	
A Phase II Trial of CG 8020 and CG 2505 in Patients with Nonresectable or Metastatic Pancreatic Cancer		

The main goal of this study is to evaluate safety of two GM-CSF secreting allogeneic pancreatic carcinoma cell lines used as a vaccine in patients with local-regional advanced unresectable or metastatic pancreatic cancer.

No Project Number available (Abrams)	2/1/2002 – 1/31/2004	5%
Eli Lilly	\$70,000	
A Phase I/II Study Using Gemcitabine and Cisplatin with Radiation Therapy in Patients with Locally Unresectable Pancreatic or Non-Pancreatic Periampullary Adenocarcinoma		

The main goal of this study is to evaluate the safety and efficacy of gemcitabine and cisplatin in combination with radiation therapy in patients with locally advanced pancreatic cancer.

PENDING

1K23CA93566-01A1 (Laheru)	6/30/1997 – 7/1/2002	75%
NIH	\$837,903	
Gene Modified Cell Lines as vaccine for pancreatic cancer		

The main goal is to test a pancreatic tumor vaccine for safety and efficacy in 60 patients with stage 1, 2 or 3 pancreatic cancer and to test the vaccine with immune modulating doses of chemotherapy for metastatic pancreatic cancer.

Project Number not yet available (Wahl)	12/01/2002 – 11/30/2005	10%
NIH	\$193,640	
Radioimmunotherapy of pancreatic cancer with humanized PAM4		

The main goal is to test the safety and efficacy of a yttrium labeled humanized PAM4 immunoglobulin in pancreatic cancer.

Principal Investigator/Program Director:
(Last, first, middle)

OTHER SUPPORT

Piantadosi, Steven

Project Number (Principal Investigator) Source Title of Project (or Subproject)	Dates of Approved/Proposed Project Annual Direct Costs	Percent Effort
The major goals of this project are...		

ACTIVE

P50 OAT00437 (Dobs/Piantadosi) NIH Johns Hopkins Center for Cancer Complementary Medicine (CAM) The major goals of this project will be to provide internally recognized state-of-the art scientific expertise and a powerful interdisciplinary infrastructure.	09/01/00 – 08/31/05 \$75,894	10%
N01-HR-76119 (Piantadosi) NHLBI Clinical Coordinating Center for National Emphysema Treatment Trial: A Multi-Center Assessment and Prospective Patient Surgery The major goals of this project are to determine whether LVRS, along with intensive medical therapy, will improve quality of life, reduce respiratory symptoms, increase exercise capacity maximum workload.	12/20/96 – 12/19/03 \$390,710	21%
01-CN-85129-MAO (Carducci) NIH/NCI A Randomized Controlled Phase II Clinical Trial of Modulation of Intermediate Endpoint Biomarkers of Chemoprevention Agents in Patients with Clinically Localized Prostate Cancer and High Grade The main goal of this project is to evaluate celecoxib in men pre-prostatectomy.	09/30/99 – 09/29/03 \$239,927 (Salary support only)	2%
830229 (Dicello) NSBR/NASA Radiation Effects: Core Project The major goal of this project are to examine mammary-tumor induction in Sprague-Dawley Rats Exposed to Photons, Protons and Iron Mass.	12/01/99 – 09/30/02 \$66,315 (Salary support only)	5%
N01 CN8508357 (Forastiere) NIH/NCI Phase II Clinical Studies of Celecoxib in Barrett's Dysplasia The major goals of this project are to establish a multi-center collaboration to perform two clinical trials testing the efficacy of a cyclooxygenase inhibitor (Celecoxib) for the prevention of esophageal cancer.	09/30/98 – 09/29/03 \$4,186,719 (Salary support only)	5%
1P01 CA79862 (Williams) NIH Mechanism-Based Radiotherapy The major goals of this project are to test the central concept that the use of a new cellular radiosensitivity (alpha-omega) model offer the potential for improving the outcome of radiotherapy in a number of tumors.	07/01/99 – 04/30/04 \$82,599 (Salary support only)	2%
P01 HL65608 (Becker) NIH Oxidants and Nitric Oxide in Post-Ischemic Heart Injury This Program Project focuses on cellular mechanisms underlying post-ischemic myocardial inflammation.	05/17/99 – 06/30/05 \$1,199,925 (Salary support only)	10%
R01-AG-95477 (Breitner) NIA Prevention of Alzheimer Dementia & Cognitive Disease This project sets out to determine if sustained use of NSAID Ibuprofen and/or COX-2 inhibitor (celecoxib) reduce the incidence of alzheimer's disease and age related cognitive decline.	01/01/00 – 12/31/04 \$3,783,928 (Salary support only)	10%

Principal Investigator/Program Director:
(Last, first, middle)

OTHER SUPPORT
PIANTADOSI, Steven (Continued)

2U01 CA62475 (Grossman)	01/01/98 – 08/31/02	2%
NIH/NCI	\$184,486	
New Approaches to Brain Tumor Therapy CNS Consortium		

The major goal of this study are to improve the therapeutic outcome for adults with primary brain tumors.

5P30 CA06973-36 (Abeloff/Piantadosi)	05/01/01 – 04/30/06	5%
NIH/NCI	\$336,333	

Regional Oncology Research Center - Biostatistics

This project is aimed toward the ultimate goal of reducing cancer incidence, morbidity, and mortality.

5P50 CA58236/08/S3 (Piantadosi)	06/01/02 – 05/31/03	10%
NIH	\$65,100	

Prostate SPORE – Biostatistics Core

The SPORE application (P-50) is to support a highly interactive and multidisciplinary study at the Johns Hopkins Medical Institutions to impact on control of human prostate cancer.

P01 CA15396 (Jones)	07/13/01 – 02/28/06	12%
NIH	\$117,622	

Bone Marrow Transplantation in Human Disease

The major goal is to improve the antitumor activity of BMT, and translate strategies into the clinic setting.

PENDING

P01 CA70970 (Civin)	04/01/02 – 03/31/07	5%
NIH/NCI	\$1,159,685 (Salary support only)	

Hematopoietic Stem Cells for Transplantation

The major goal of this study is to discover and develop uses of stem cells in human transplantation.

5P50 CA58184 (Baylin/Piantadosi)	09/30/96 – 12/31/02	5%
NIH/NCI	\$39,689	

SPORE Grant in Lung Cancer

This SPORE proposes to test patients with inherited predisposition to colorectal carcinoma due to replication error (RER) phenotype from germline FCC .

7012-03 (Civin)	07/01/02 – 06/30/08	5%
LLS	\$74,000	

Immunologic Therapies for Hematologic Malignancies: Research Administration and Data Analysis

Core A will provide the SCOR with central leadership, administrative management, and biostatistical planning and data analysis.

(Ambinder / Piantadosi)	09/01/02 – 10/30/07	10%
NIH	\$347,101	

SPORE in Lymphoma Cancer

The major goal of the Biostatistics Core will have an integral role in the scientific development, execution and analysis of all projects in the SPORE, including the clinical trials.

OVERLAP

Potential commitment overlap for Dr. Piantadosi if pending projects are funded the following will be reduced (N01-HR-76119, R01-AG-95477-01) and effort discontinued on (P01-HL-65608)

Principal Investigator/Program Director:
(Last, first, middle)

OTHER SUPPORT

Elizabeth Jaffee, M.D.

Project Number (Principal Investigator) Source Title of Project (or Subproject)	Dates of Approved/Proposed Project Annual Direct Costs	Percent Effort
The major goals of this project are...		

ACTIVE

1R01CA79685-01A1 (Jaffee)	12/01/00 – 11/31/04	10%
NIH/NCI	\$165,123	
Identification of CD8+T cell targets on renal cancer.		

The main goal of this study is to identify new target antigens for renal cell cancer.

1R01CA88058-01 (Jaffee)	07/01/00 – 06/30/04	20%
NIH/NCI	\$298,708	
A Phase II Clinical Trial Testing the Efficacy of a GM-CSF Secreting Allogeneic Pancreatic Tumor Vaccine for the Treatment of Pancreatic Adenocarcinoma		

The main goal of this study is to identify new target antigens for pancreatic adenocarcinoma.

2U19CA72108 (Jaffee)	09/01/00 – 04/30/04	20%
NIH/NCI NCDDG	\$451,252	
Antigen-specific vaccines for breast cancer		

The main goal of this study is to identify new target antigens for breast cancer.

1P50CA88843-01 (Davidson/Jaffee)	09/30/00 – 09/29/05	10%
SPORE in Breast Cancer	\$285,870	
Vaccines: A New Paradigm for Breast Cancer Prevention		

As part of the breast SPORE Grant, the goals of the study are to use vaccine strategies using known breast cancer antigens as prevention in patients at high risk for breast cancer.

No Project Number available (Jaffee)	06/01/00 – 05/31/03	10%
Cell Genesys, Inc.	\$171,624	
Development of vaccine strategies potent enough to activate low affinity T cells.		

The main goals of the study are to develop strategies to identify and isolate immunodominant epitopes for cancer vaccine development.

CA93714 (Jaffee)	12/01/01 – 11/30/06	20%
NIH		
Chemotherapy plus vaccine for breast		

The main goals of the study are to test the safety of a breast cancer vaccine in metastatic disease using a number of selected breast cancer antigenic peptides.

OTHER SUPPORT**Jaffee, Elizabeth (Continued)**

P50CA62924 (Jaffee)	10/01/93 – 06/30/02	10%
NIH-RFA	\$158,025	
SPORE in Gastrointestinal Cancer		

As part of the Gastrointestinal SPORE Grant, the goals of the study are to identify and isolate immunodominant peptides in GI malignancies that can be as targets for vaccine therapies.

PENDING

No Project Number available (Jaffee)	10/01/02 – 09/30/05	10%
Avon	\$1,250,000	
The Avon Baltimore/Seattle Breast Cancer Immunotherapy Collaborative		

The main goals of this study are to identify new target antigens for breast cancer.

Principal Investigator/Program Director (Last, first, middle):

Laheru, Dan 1K23CA093566-01A1

**DETAILED BUDGET FOR INITIAL BUDGET PERIOD
DIRECT COSTS ONLY**

FROM 07/01/02 THROUGH 06/30/03

PERSONNEL (Applicant organization only)		TYPE APPT. (MONTHS)	% EFFORT ON PROJ	INST. BASE SALARY	DOLLAR AMOUNT REQUESTED (omit cents)		
NAME	ROLE ON PROJECT				SALARY REQUESTED	FRINGE BENEFITS	TOTALS
Laheru, Daniel A.	Principal Investigator	12.00	86%	\$104,000	\$89,440	\$25,938	\$115,378
Jaffee, Elizabeth	Sponsor	12.00	10%	\$0	No Cost to Project		
Steven Piantadosi	Co-Sponsor	12.00	5%	\$0	No Cost to Project		
Tartakovsky, Irena	Sr.Prog.Coord. Data Mgr.	12.00	20%	\$42,000	\$8,400	\$2,436	\$10,836
Onners, Beth	Research Nurse	12.00	25%	\$57,500	\$14,375	\$4,169	\$18,544
SUBTOTALS					\$112,215	\$32,542	\$144,757

CONSULTANTS COSTS		
EQUIPMENT	(Itemize)	
SUPPLIES	(Itemize by category)	
TRAVEL		\$1,646
PATIENT CARE COSTS	INPATIENT	
	OUTPATIENT	
ALTERATIONS AND RENOVATIONS	(Itemize by category)	
OTHER EXPENSES	(Itemize by category)	

SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD		\$146,403
CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	
	FACILITIES AND ADMINISTRATION COSTS	
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD (ITEM 7A, FACE PAGE)		\$146,403

Principal Investigator/Program Director (Last, first, middle):

LaHeru, Dan 1K23CA093566-01A1

**BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD
DIRECT COSTS ONLY**

BUDGET CATEGORY TOTALS		INITIAL BUDGET PERIOD <i>(from Form Page 4)</i>	ADDITIONAL YEARS OF SUPPORT REQUESTED			
			2nd	3rd	4th	5th
PERSONNEL <i>Salary and fringe benefits. Applicant organization only</i>		\$144,757	\$150,547	\$158,569	\$162,832	\$169,345
CONSULTANT COSTS						
EQUIPMENT						
SUPPLIES						
TRAVEL		\$1,646	\$1,646	\$1,646	\$1,646	\$1,646
PATIENT CARE COSTS	INPATIENT					
	OUTPATIENT					
ALTERATIONS AND RENOVATIONS						
OTHER EXPENSES						
SUBTOTAL DIRECT COSTS		\$146,403	\$152,193	\$158,215	\$164,478	\$170,991
CONSORTIUM/ CONTRACTUAL COSTS	DIRECT					
	F&A					
TOTAL DIRECT COSTS		\$146,403	\$152,193	\$158,215	\$164,478	\$170,991
TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD (Item 8a, Face Page)						\$792,281
SBIR/STTR Only Fixed Fee Requested						
SBIR/STTR Only: Total Fixed Fee Requested for Entire Proposed Phase II Period (Add Total Fixed Fee amount to "Total direct costs for entire proposed period" above and Total F&A/indirect costs) from Checklist Form page, and enter these as "Costs Requested for Proposed Period of Support on Face Page, Item 8b.						

JUSTIFICATION. Follow the budget justification instructions exactly. Use continuation pages as needed.

Principal Investigator/Program Director (Last, first, middle):

CHECKLIST

TYPE OF APPLICATION (Check all that apply.)

- NEW application. (This application is being submitted to the PHS for the first time.)
 - SBIR Phase I SBIR Phase II: SBIR Phase I Grant No. _____
 - STTR Phase I STTR Phase II: STTR Phase I Grant No. _____
- SBIR Fast Track
- STTR Fast Track
- REVISION of application number: 1K23CA093566-01A1
(This application replaces a prior unfunded version of a new, competing continuation, or supplemental application.)
- COMPETING CONTINUATION of grant number: _____
(This application is to extend a funded grant beyond its current project period.)
- SUPPLEMENT to grant number: _____
(This application is for additional funds to supplement a currently funded grant.)
- CHANGE of principal investigator/program director.
Name of former principal investigator/program director: _____
- FOREIGN application or significant foreign component.

- INVENTIONS AND PATENTS**
(Competing continuation appl. and Phase II only)
- No
 - Previously reported
 - Yes. If "Yes," Not previously reported

1. PROGRAM INCOME (See instructions.)
All applications must indicate whether program income is anticipated during the period(s) for which grant support is request. If program income is anticipated, use the format below to reflect the amount and source(s).

Budget Period	Anticipated Amount	Source(s)

2. ASSURANCES/CERTIFICATIONS (See instructions.)

The following assurances/certifications are made and verified by the signature of the Official Signing for Applicant Organization on the Face Page of the application. Descriptions of individual assurances/certifications are provided in Section III. If unable to certify compliance, where applicable, provide an explanation and place it after this page.

- Human Subjects; •Research Using Human Embryonic Stem Cells
- Research on Transplantation of Human Fetal Tissue •Women and Minority Inclusion Policy •Inclusion of Children Policy •Vertebrate Animals

- Debarment and Suspension; •Drug- Free Workplace (applicable to new [Type 1] or revised [Type 1] applications only); •Lobbying; •Non-Delinquency on Federal Debt; •Research Misconduct; •Civil Rights (Form HHS 441 or HHS 690); •Handicapped Individuals (Form HHS 641 or HHS 690); •Sex Discrimination (Form HHS 639-A or HHS 690); •Age Discrimination (Form HHS 680 or HHS 690); •Recombinant DNA and Human Gene Transfer Research; •Financial Conflict of Interest (except Phase I SBIR/STTR) •STTR ONLY: Certification of Research Institution Participation.

3. FACILITIES AND ADMINISTRATIVE COSTS (F&A) INDIRECT COSTS. See specific instructions.

- DHHS Agreement dated: 03/24/99
- No Facilities And Administrative Costs Requested.
- DHHS Agreement being negotiated with _____ Regional Office.
- No DHHS Agreement, but rate established with _____ Date _____

CALCULATION* (The entire grant application, including the Checklist, will be reproduced and provided to peer reviewers as confidential information.)

	Amount of base \$	x Rate applied	% = F&A costs	\$
a. Initial budget period:	146,403	0.08	% = F&A costs	11,712
b. 02 year	152,193	0.08	% = F&A costs	12,175
c. 03 year	158,215	0.08	% = F&A costs	12,657
d. 04 year	164,478	0.08	% = F&A costs	13,158
e. 05 year	170,991	0.08	% = F&A costs	13,158
TOTAL F&A Costs \$				63,382

*Check appropriate box(es):

- Salary and wages base
- Modified total direct cost base
- Other base (Explain)
- Off-site, other special rate, or more than one rate involved (Explain)

Explanation (Attach separate sheet, if necessary.):

4. SMOKE-FREE WORKPLACE Yes No (The response to this question has no impact on the review or funding of this application.)