

Department of Health and Human Services Public Health Services <h2 style="margin: 0;">Grant Application</h2> <p style="font-size: small; margin: 0;"><i>Do not exceed character length restrictions indicated.</i></p>		<b>LEAVE BLANK—FOR PHS USE ONLY.</b>			
		Type	Activity	Number	
		Review Group		Formerly	
		Council/Board (Month, Year)		Date Received	
1. TITLE OF PROJECT ( <i>Do not exceed 81 characters, including spaces and punctuation.</i> ) <b>The effects of insulin on laboratory rats</b>					
2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAM ANNOUNCEMENT OR SOLICITATION <input checked="" type="checkbox"/> NO <input type="checkbox"/> YES <i>(If "Yes," state number and title)</i> Number: _____ Title: _____					
3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR			New Investigator <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes		
3a. NAME (Last, first, middle) Schumacher, Kenneth		3b. DEGREE(S) MD		3h. eRA Commons User Name	
3c. POSITION TITLE Principal Investigator		3d. MAILING ADDRESS ( <i>Street, city, state, zip code</i> )  , USA  E-MAIL ADDRESS: kenneths@university.edu			
3e. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT Engineering					
3f. MAJOR SUBDIVISION Biology Department					
3g. TELEPHONE AND FAX ( <i>Area code, number and extension</i> ) TEL: 510/555-1111 FAX: _____					
4. HUMAN SUBJECTS RESEARCH No <input checked="" type="checkbox"/> Yes <input type="checkbox"/>		4b. Human Subjects Assurance No.		5. VERTEBRATE ANIMALS <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	
		4c. Clinical Trial <input type="checkbox"/> No <input type="checkbox"/> Yes	4d. NIH-defined Phase III Clinical Trial <input type="checkbox"/> No <input type="checkbox"/> Yes	5a. If "Yes," IACUC approval Date	
4a. Research Exempt No <input type="checkbox"/> Yes <input type="checkbox"/>		If "Yes," Exemption No.			
6. DATES OF PROPOSED PERIOD OF SUPPORT ( <i>month, day, year—MM/DD/YY</i> ) From 01/01/05 Through 12/31/09		7. COSTS REQUESTED FOR INITIAL BUDGET PERIOD 7a. Direct Costs (\$) \$75,000		8. COSTS REQUESTED FOR PROPOSED PERIOD OF SUPPORT 7b. Total Costs (\$) \$100,500 8a. Direct Costs (\$) \$510,150 8b. Total Costs (\$) \$652,650	
9. APPLICANT ORGANIZATION Name PeopleSoft University Address 4305 Hacienda Dr Pleasanton, CA 94588 USA		10. TYPE OF ORGANIZATION Public: → <input type="checkbox"/> Federal <input type="checkbox"/> State <input type="checkbox"/> Local Private: → <input type="checkbox"/> Private Nonprofit For-profit: → <input checked="" type="checkbox"/> General <input type="checkbox"/> Small Business <input type="checkbox"/> Woman-owned <input type="checkbox"/> Socially and Economically Disadvantaged			
		11. ENTITY IDENTIFICATION NUMBER 123 DUNS NO. 18915 Cong. District			
12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE Name Title Address  Tel: _____ FAX: _____ E-Mail: _____		13. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION Name Title Address  Tel: _____ FAX: _____ E-Mail: _____			
14. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.		SIGNATURE OF PI/PPD NAMED IN 3a. <i>(In ink. "Per" signature not acceptable.)</i>		DATE	
15. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.		SIGNATURE OF OFFICIAL NAMED IN 13. <i>(In ink. "Per" signature not acceptable.)</i>		DATE	

Principal Investigator/Program Director (Last, First, Middle): Schumacher, Kenneth

DESCRIPTION: See instructions. State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the **mission of the agency**). Describe concisely the research design and methods for achieving these goals. Describe the rationale and techniques you will use to pursue these goals.

**In addition**, in two or three sentences, describe in plain, lay language the relevance of this research to **public** health. If the application is funded, this description, as is, will become public information. Therefore, do not include proprietary/confidential information. **DO NOT EXCEED THE SPACE PROVIDED.**

Report on the Major goals has been completed

Submitted with all of the required details

PERFORMANCE SITE(S) (organization, city, state)

EGV05 - Miami, FL, Miami, FL

Principal Investigator/Program Director (Last, First, Middle): Schumacher, Kenneth

KEY PERSONNEL. See instructions. Use continuation pages as needed to provide the required information in the format shown below. Start with Principal Investigator. List all other key personnel in alphabetical order, last name first.

Name	eRA Commons User Name	Organization	Role on Project
Schumacher, Kenneth			PI

OTHER SIGNIFICANT CONTRIBUTORS

Name	Organization	Role on Project
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Human Embryonic Stem Cells  No  Yes

If the proposed project involves human embryonic stem cells, list below the registration number of the specific cell line(s) from the following list: <http://stemcells.nih.gov/registry/index.asp>. Use continuation pages as needed.

If a specific line cannot be referenced at this time, include a statement that one from the Registry will be used.

Cell Line

Disclosure Permission Statement. Applicable to SBIR/STTR Only. See instructions.  Yes  No

The name of the principal investigator/program director must be provided at the top of each printed page and each continuation page.

RESEARCH GRANT
TABLE OF CONTENTS

Page Numbers

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Description, Performance Sites, Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells ..... 2
Table of Contents .....
Detailed Budget for Initial Budget Period (or Modular Budget) .....
Budget for Entire Proposed Period of Support (not applicable with Modular Budget) .....
Budgets Pertaining to Consortium/Contractual Arrangements (not applicable with Modular Budget) .....
Biographical Sketch – Principal Investigator/Program Director (Not to exceed four pages).....
Other Biographical Sketches (Not to exceed four pages for each – See instructions) .....
Resources .....

Research Plan.....

Introduction to Revised Application (Not to exceed 3 pages) .....
Introduction to Supplemental Application (Not to exceed one page) .....
A. Specific Aims .....
B. Background and Significance .....
C. Preliminary Studies/Progress Report/ Phase I Progress Report (SBIR/STTR Phase II ONLY) .....
D. Research Design and Methods.....
E. Human Subjects.....
Protection of Human Subjects (Required if Item 4 on the Face Page is marked "Yes") .....
Inclusion of Women and Minorities (Required if Item 4 on the Face Page is marked "Yes" and is Clinical Research) .....
Targeted/Planned Enrollment Table (for new and continuing clinical research studies) .....
Inclusion of Children (Required if Item 4 on the Face Page is marked "Yes") .....
Data and Safety Monitoring Plan (Required if Item 4 on the Face Page is marked "Yes" and a Phase I, II, or III clinical trial is proposed) .....
F. Vertebrate Animals .....
G. Literature Cited .....
H. Consortium/Contractual Arrangements.....
I. Resource Sharing .....
J. Letters of Support (e.g., Consultants) .....
Commercialization Plan (SBIR/STTR Phase II and Fast-Track ONLY) .....

(Items A-D: not to exceed 25 pages\*)
\* SBIR/STTR Phase I: Items A-D limited to 15 pages.

Checklist.....

Appendix (Five collated sets. No page numbering necessary for Appendix.)

Appendices NOT PERMITTED for Phase I SBIR/STTR unless specifically solicited.....

Input box for Appendix inclusion

Check if Appendix is Included

Number of publications and manuscripts accepted for publication (not to exceed 10)

Other items (list):

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY					FROM 01/01/2005	THROUGH 12/31/2005	
PERSONNEL <i>(Applicant organization only)</i>		TYPE APPT. <i>(months)</i>	% EFFORT ON PROJ.	INST. BASE SALARY	DOLLAR AMOUNT REQUESTED <i>(omit cents)</i>		
NAME	ROLE ON PROJECT				SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Schumacher, Kenneth	Principal Investigator	12	100.0	40,000	40,000	8,000	48,000
		0	0.0	0	0	0	
<b>SUBTOTALS</b> →					<b>40,000</b>	<b>8,000</b>	<b>48,000</b>
CONSULTANT COSTS							0
EQUIPMENT <i>(Itemize)</i> : \$500.00. : \$9050.00.							9,550
SUPPLIES <i>(Itemize by category)</i> Diabetic supplies: \$12000.00.							12,000
TRAVEL							0
PATIENT CARE COSTS		INPATIENT					0
		OUTPATIENT					0
ALTERATIONS AND RENOVATIONS <i>(Itemize by category)</i>							0
OTHER EXPENSES <i>(Itemize by category)</i> Mice: \$5450.00.							5,450
CONSORTIUM/CONTRACTUAL COSTS				DIRECT COSTS		0	
<b>SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD</b> <i>(Item 7a, Face Page)</i>						<b>\$ 75,000</b>	
CONSORTIUM/CONTRACTUAL COSTS				FACILITIES AND ADMINISTRATIVE COSTS		0	
<b>TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD</b>						<b>\$ 75,000</b>	
<b>SBIR/STTR Only: FEE REQUESTED</b>							0

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

BUDGET CATEGORY TOTALS		INITIAL BUDGET PERIOD (from Form Page 4)	ADDITIONAL YEARS OF SUPPORT REQUESTED			
			2nd	3rd	4th	5th
PERSONNEL: <i>Salary and fringe benefits. Applicant organization only.</i>		48,000	48,000	48,000	48,000	198,000
CONSULTANT COSTS		0	0	0	750	0
EQUIPMENT		9,550	0	7,500	7,275	3,575
SUPPLIES		12,000	15,650	10,000	8,500	8,500
TRAVEL		0	0	450	0	0
PATIENT CARE COSTS	INPATIENT	0	0	0	0	0
	OUTPATIENT	0	0	0	0	0
ALTERATIONS AND RENOVATIONS		0	0	0	0	0
OTHER EXPENSES		5,450	5,800	5,500	7,975	11,675
CONSORTIUM/ CONTRACTUAL COSTS	DIRECT	0	0	0	0	0
<b>SUBTOTAL DIRECT COSTS</b> (Sum = Item 8a, Face Page)		75,000	69,450	71,450	72,500	221,750
CONSORTIUM/ CONTRACTUAL COSTS	F&A	0	0	0	0	0
<b>TOTAL DIRECT COSTS</b>		75,000	69,450	71,450	72,500	221,750
<b>TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD</b>						<b>\$ 510,150</b>
<b>SBIR/STTR Only Fee Requested</b>		0	0	0	0	0
<b>SBIR/STTR Only: Total Fee Requested for Entire Proposed Project Period</b> (Add Total Fee amount to "Total direct costs for entire proposed project 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.)						<b>\$</b>

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

<b>BUDGET JUSTIFICATION PAGE MODULAR RESEARCH GRANT APPLICATION</b>						
	<b>Initial Period</b>	<b>2<sup>nd</sup></b>	<b>3<sup>rd</sup></b>	<b>4<sup>th</sup></b>	<b>5<sup>th</sup></b>	<b>Sum Total (For Entire Project Period)</b>
<b>DC less Consortium F&amp;A</b>	<i>(Item 7a, Face Page)</i>					<i>(Item 8a, Face Page)</i>
<b>Consortium F&amp;A</b>						
<b>Total Direct Costs</b>						<b>\$</b>

**Personnel**

**Consortium**

**Fee (SBIR/STTR Only)**

## RESOURCES

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**FACILITIES:** Specify the facilities to be used for the conduct of the proposed research. Indicate the performance sites and describe capacities, pertinent capabilities, relative proximity, and extent of availability to the project. Under "Other," identify support services such as machine shop, electronics shop, and specify the extent to which they will be available to the project. Use continuation pages if necessary.

Laboratory:

Clinical:

Animal:

Computer:

Office:

Other:

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**MAJOR EQUIPMENT:** List the most important equipment items already available for this project, noting the location and pertinent capabilities of each.



**CHECKLIST**

**TYPE OF APPLICATION** (Check all that apply.)

- NEW application. (This application is being submitted to the PHS for the first time.)
- REVISION of application number: \_\_\_\_\_  
(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: \_\_\_\_\_
- CHANGE of Grantee Institution. Name of former institution: \_\_\_\_\_
- FOREIGN application     Domestic Grant with foreign involvement    List Country(ies) Involved: \_\_\_\_\_
- SBIR Phase I     SBIR Phase II: SBIR Phase I Grant No. \_\_\_\_\_     SBIR Fast Track
- STTR Phase I     STTR Phase II: STTR Phase I Grant No. \_\_\_\_\_     STTR Fast Track

**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.)

In signing the application Face Page, the authorized organizational representative agrees to comply with the following policies, assurances and/or certifications when applicable. Descriptions of individual assurances/certifications are provided in Part 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 Research, Including Human Gene Transfer Research; •Financial Conflict of Interest (except Phase I SBIR/STTR); •Smoke Free Workplace; •Prohibited Research; •Select Agents
- STTR ONLY: Certification of Research Institution Participation.

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

- DHHS Agreement dated: 05/03/2005     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.)

a. Initial budget period:	Amount of base \$ _____	x Rate applied <u>0.00%</u>	= F&A costs \$ _____
b. 02 year	Amount of base \$ _____	x Rate applied <u>0.00%</u>	= F&A costs \$ _____
c. 03 year	Amount of base \$ _____	x Rate applied <u>0.00%</u>	= F&A costs \$ _____
d. 04 year	Amount of base \$ _____	x Rate applied <u>0.00%</u>	= F&A costs \$ _____
e. 05 year	Amount of base \$ _____	x Rate applied <u>0.00%</u>	= F&A costs \$ _____
TOTAL F&A Costs			\$ <span style="border: 2px solid black; display: inline-block; width: 100px; height: 20px; vertical-align: middle;"></span>

\*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.):

Principal Investigator/Program Director (Last, First, Middle): Schumacher, Kenneth

Place this form at the end of the signed original copy of the application.  
Do not duplicate.

### PERSONAL DATA ON PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR

The Public Health Service has a continuing commitment to monitor the operation of its review and award processes to detect—and deal appropriately with—any instances of real or apparent inequities with respect to age, sex, race, or ethnicity of the proposed principal investigator/program director.

To provide the PHS with the information it needs for this important task, complete the form below and attach it to the signed original of the application after the Checklist. **Do not attach copies of this form to the duplicated copies of the application.**

Upon receipt of the application by the PHS, this form will be separated from the application. This form will **not** be duplicated, and it will **not** be a part of the review process. Data will be confidential, and will be maintained in Privacy Act record system 09-25-0036, "Grants: IMPAC (Grant/Contract Information)." The PHS requests the last four digits of the Social Security Number for accurate identification, referral, and review of applications and for management of PHS grant programs. Although the provision of this portion of the Social Security Number is voluntary, providing this information may improve both the accuracy and speed of processing the application. Please be aware that no individual will be denied any right, benefit, or privilege provided by law because of refusal to disclose this section of the Social Security Number. The PHS requests the last four digits of the Social Security Number under Sections 301(a) and 487 of the PHS Acts as amended (42 U.S.C 241a and U.S.C. 288). All analyses conducted on the date of birth, gender, race and/or ethnic origin data will report aggregate statistical findings only and will not identify individuals. If you decline to provide this information, it will in no way affect consideration of your application. Your cooperation will be appreciated.

DATE OF BIRTH (MM/DD/YY)	01/01/05	SEX/GENDER	
SOCIAL SECURITY NUMBER (last 4 digits only)	XXX-XX- 65010	<input type="checkbox"/> Female	<input checked="" type="checkbox"/> Male

#### ETHNICITY

1. Do you consider yourself to be Hispanic or Latino? (See definition below.) Select one.

**Hispanic or Latino.** A person of Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino."

- Hispanic or Latino
- Not Hispanic or Latino

#### RACE

2. What race do you consider yourself to be? Select one or more of the following.

- American Indian or Alaska Native.** A person having origins in any of the original peoples of North, Central, or South America, and who maintains tribal affiliation or community attachment.
- Asian.** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent, including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam. (Note: Individuals from the Philippine Islands have been recorded as Pacific Islanders in previous data collection strategies.)
- Black or African American.** A person having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black" or African American."
- Native Hawaiian or Other Pacific Islander.** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
- White.** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.
- Check here if you do not wish to provide some or all of the above information.

**Targeted/Planned Enrollment Table****This report format should NOT be used for data collection from study participants.**Study Title: StudyTotal Planned Enrollment: 6

<b>TARGETED/PLANNED ENROLLMENT: Number of Subjects</b>			
<b>Ethnic Category</b>	<b>Sex/Gender</b>		
	<b>Females</b>	<b>Males</b>	<b>Total</b>
Hispanic or Latino	0	0	
Not Hispanic or Latino	3	3	6
<b>Ethnic Category: Total of All Subjects *</b>	3	3	6
<b>Racial Categories</b>			
American Indian/Alaska Native	0	0	
Asian	0	0	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	0	
White	3	3	6
<b>Racial Categories: Total of All Subjects *</b>	3	3	6

\* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

**Inclusion Enrollment Report****This report format should NOT be used for data collection from study participants.**

**Study Title:** Study \_\_\_\_\_

**Total Enrollment:** \_\_\_\_\_ **Protocol Number:** \_\_\_\_\_

**Grant Number:** \_\_\_\_\_

<b>PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race</b>				
<b>Ethnic Category</b>	<b>Sex/Gender</b>			<b>Total</b>
	<b>Females</b>	<b>Males</b>	<b>Unknown or Not Reported</b>	
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (individuals not reporting ethnicity)				
<b>Ethnic Category: Total of All Subjects*</b>				*
<b>Racial Categories</b>				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or Not Reported				
<b>Racial Categories: Total of All Subjects*</b>				*
<b>PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)</b>				
<b>Racial Categories</b>	<b>Females</b>	<b>Males</b>	<b>Unknown or Not Reported</b>	<b>Total</b>
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or Not Reported				
<b>Racial Categories: Total of Hispanics or Latinos**</b>				**

\* These totals must agree.

\*\* These totals must agree.

Use this substitute page for the Table of Contents of Research Career Development Awards. Type the name of the candidate at the top of each printed page and each continuation page.

RESEARCH CAREER DEVELOPMENT AWARD
TABLE OF CONTENTS
(Substitute Page)

Page Numbers

Letters of Reference\* (attach unopened references to the Face Page)

Section I: Basic Administrative Data

Table listing administrative data items and their page numbers: Face Page (Form Page 1) - 1, Description, Performance Sites, Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells (Form Page 2) - 2, Table of Contents (this CDA Substitute Form Page 3), Budget for Entire Proposed Period of Support (Form Page 5), Biographical Sketches (Candidate, Sponsor[s],\* and Key Personnel\*—Biographical Sketch Format page) (Not to exceed four pages), Other Support Pages (not for the candidate), Resources (Resources Format page).

Section II: Specialized Information

Introduction to Revised Application\* (Not to exceed 3 pages)

1. The Candidate

Table listing candidate information: A. Candidate's Background, B. Career Goals and Objectives: Scientific Biography, C. Career Development/Training Activities during Award Period, D. Training in the Responsible Conduct of Research. Includes a bracketed note: (Items A-D included in 25 page limit).

2. Statements by Sponsor, Co-Sponsor(s),\* Consultant(s),\* and Contributor(s)\*

3. Environment and Institutional Commitment to Candidate

Table listing environment and institutional commitment items: A. Description of Institutional Environment, B. Institutional Commitment to Candidate's Research Career Development.

4. Research Plan

Table listing research plan items: A. Specific Aims, B. Background and Significance, C. Preliminary Studies/Progress Report, D. Research Design and Methods, E. Human Subjects Research (Targeted/Planned Enrollment Table for new and continuing clinical research studies), F. Vertebrate Animals, G. Literature Cited, H. Consortium/Contractual Arrangements\*, I. Resource Sharing. Includes a bracketed note: (Items A-D included in 25 page limit).

Checklist

Appendix (Five collated sets. No page numbering necessary.)

Check box for Appendix inclusion: [ ] Check if Appendix is included

Number of publications and manuscripts accepted for publication (not to exceed 5)

Note: Font and margin requirements must conform to limits provided in the Specific Instructions.

\*Include these items only when applicable.

CITIZENSHIP

Citizenship options: [X] U.S. citizen or noncitizen national, [ ] Permanent resident of U.S. (If a permanent resident of the U.S., a notarized statement must be provided by the time of award.)

# CAREER DEVELOPMENT AWARD REFERENCE REPORT GUIDELINES (Series K)

**Title of Award:**

**Type of Award:**

**Application Submission Deadline:** \_\_\_\_\_

**Name of Candidate (Last, first, middle):**

**Name of Respondent (Last, first, middle):**

The candidate is applying to the National Institutes of Health for a Career Development Award (CDA). The purpose of this award is to develop the research capabilities and career of the applicant. These awards provide up to five years of salary support and guarantee them the ability to devote at least 75–80 percent of their time to research for the duration of the award. Many of these awards also provide funds for research and career development costs. The award is available to persons who have demonstrated considerable potential to become independent researchers, but who need additional supervised research experience in a productive scientific setting.

We would appreciate receiving your evaluation of the above candidate with special reference to:

- potential for conducting research;
- evidence of originality;
- adequacy of scientific background;
- quality of research endeavors or publications to date, if any;
- commitment to health-oriented research; and
- need for further research experience and training.

Any related comments that you may wish to provide would be welcomed. These references will be used by PHS committees of consultants in assessing candidates.

Complete the report in English on 8-1/2 x 11" sheets of paper. Return your reference report to the candidate sealed in the envelope as soon as possible and in sufficient time so that the candidate can meet the application submission deadline. References must be submitted with the application.

We have asked the candidate to provide you with a self-addressed envelope with the following words in the front bottom corner: "DO NOT OPEN—PHS USE ONLY." Candidates are not to open the references. Under the Privacy Act of 1974, CDA candidates may request personal information contained in their records, including this reference. Thank you for your assistance.

Type the name of the principal investigator/program director at the top of each printed page and each continuation page. (For type specifications, see PHS 398 Instructions.)

**INSTITUTIONAL RUTH L. KIRSCHSTEIN NATIONAL RESEARCH SERVICE AWARD  
(Substitute Page)**

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<b>Table of Contents (this Kirschstein-NRSA Substitute Form Page 3)</b> .....	_____
<b>Detailed Budget for Initial Budget Period (Kirschstein-NRSA Substitute Form Page 4)</b> .....	_____
<b>Budget for Entire Proposed Period of Support (Kirschstein-NRSA Substitute Form Page 5)</b> .....	_____
<b>Biographical Sketch—Principal Investigator/Program Director (Not to exceed four pages)</b> .....	_____
<b>Other Biographical Sketches (Not to exceed four pages for each)</b> .....	_____
<b>Resources</b> .....	_____

**Research Training Program Plan**

Introduction to Revised Application, <i>if applicable</i> (Not to exceed 3 pages) .....	_____
Introduction to Supplemental Application, <i>if applicable</i> (Not to exceed one page) .....	_____
A. Background .....	_____
B. Program Plan .....	_____
1. Program Administration .....	_____
2. Program Faculty .....	_____
3. Proposed Training .....	_____
4. Training Program Evaluation .....	_____
5. Trainee Candidates .....	_____
C. Minority Recruitment and Retention Plan .....	_____
D. Plan for Instruction in the Responsible Conduct of Research .....	_____
E. Progress Report (Competing Continuation Applications Only) .....	_____
F. Human Subjects .....	_____
G. Vertebrate Animals .....	_____
H. Consortium/Contractual Arrangements .....	_____

(Items A-D: not to exceed 25 pages, excluding tables\*)

**Checklist** .....

**Appendix** (Five collated sets. No page numbering necessary for Appendix.)

Check if Appendix is included

\* Font and margin requirements must conform to limits provided in PHS 398 Specific Instructions.

**Kirschstein-NRSA Initial Budget  
Period Substitute Page**

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

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY (Kirschstein-NRSA Substitute Page)	FROM	THROUGH
<b>STIPENDS</b>		<b>DOLLAR TOTAL</b>
PREDOCTORAL		
	No. Requested:	
POSTDOCTORAL <i>(Itemize)</i>		
	No. Requested:	
OTHER <i>(Specify)</i>		
	No. Requested:	
<b>TOTAL STIPENDS</b> _____ →		
TUITION, FEES, AND INSURANCE <i>(Itemize)</i>		
TRAINEE TRAVEL <i>(Describe)</i>		
TRAINEE RELATED EXPENSES		
<b>TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD</b> <i>(Also enter on Face Page, Item 7)</i>		<b>\$</b>



**BUDGET FOR ENTIRE PROPOSED PERIOD OF SUPPORT  
DIRECT COSTS ONLY (Kirschstein-NRSA Substitute Page)**

BUDGET CATEGORY TOTALS	INITIAL BUDGET PERIOD <i>(from Form Page 4)</i>		ADDITIONAL YEARS OF SUPPORT REQUESTED							
	No.		2nd		3rd		4th		5th	
	No.		No.		No.		No.		No.	
PREDOCTORAL STIPENDS										
POSTDOCTORAL STIPENDS										
OTHER STIPENDS										
<b>TOTAL STIPENDS</b>										
TUITION, FEES, AND INSURANCE										
TRAINEE TRAVEL										
TRAINEE RELATED EXPENSES										
<b>TOTAL DIRECT COSTS</b>										

**TOTAL DIRECT COSTS FOR ENTIRE PROPOSED PROJECT PERIOD** *(Item 8a, Face Page)*

**\$**

JUSTIFICATION. For all years, explain the basis for the budget categories requested. Follow the instructions for the Initial Budget Period and include anticipated postdoctoral levels. No explanation is necessary for Training-Related Expenses.

<b>BUDGET of RESEARCH INSTITUTION (STTR ONLY)</b>	FROM	THROUGH
---	------	---------

NAME AND ADDRESS OF RESEARCH INSTITUTION

PERSONNEL		TYPE APPT. <i>(months)</i>	% EFFORT ON PROJ.	INST. BASE SALARY	DOLLAR AMOUNT REQUESTED <i>(omit cents)</i>		
NAME	ROLE ON PROJECT				SALARY REQUESTED	FRINGE BENEFITS	TOTAL
	Principal Investigator						

**SUBTOTALS** →

		<b>\$</b>
--	--	-----------

CONSULTANT COSTS

EQUIPMENT *(Itemize)*

SUPPLIES *(Itemize by category)*

TRAVEL

PATIENT CARE COSTS	INPATIENT
	OUTPATIENT

ALTERATIONS AND RENOVATIONS *(Itemize by category)*

OTHER EXPENSES *(Itemize by category)*

**TOTAL DIRECT COSTS** (also enter as Consortium/Contractual Costs on Budget Page of Small Business Concern) **\$**

**FACILITIES and ADMINISTRATIVE COSTS (show calculation)** (also enter as Consortium/Contractual Costs on Budget of Small Business Concern) **\$**

**CERTIFICATION OF RESEARCH INSTITUTION PARTICIPATION.** Through the signature below of the duly authorized representative of the research institution on this "Certification of Research Institution" page, and by way of the signature of the official signing for applicant organization (small business concern) on the Face Page of the application, the small business concern and the research institution certify *jointly* that: (1) the proposed STTR project will be conducted jointly by the small business concern and the research institution in which not less than 40 percent of the work will be performed by the small business concern and not less than 30 percent of the work will be performed by the research institution ("cooperative research and development"); (2) the proposed STTR project is a cooperative research or research and development effort to be conducted jointly by the small business concern and the research institution in which not less than 40 percent of the work will be performed by the small business concern and not less than 30 percent of the work will be performed by the research institution ("performance of research and analytical work"); and (3) regardless of the proportion of the proposed project to be performed by each party, the small business concern will be the primary party that will exercise management direction and control of the performance of the project. If the research institution is a contractor-operated federally funded research and development center, the duly authorized representative of the contractor-operated federally funded research and development center certifies, *additionally*, that it: (4) is free from organizational conflicts of interests relative to the STTR program; (5) did not use privileged information gained through work performed for an STTR agency or private access to STTR agency personnel in the development of this STTR grant application; and (6) used outside peer review, as appropriate, to evaluate the proposed project and its performance therein.

Signature of Duly Authorized Representative	Printed Name	Title	Date of Signature
---	--------------	-------	-------------------

## **Certification of Research Institution for Small Business Technology Transfer Grants**

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Through the signature below of the duly authorized representative of the research institution on this "Certification of Research Institution" page, and by way of the signature of the official signing for applicant organization (small business concern) on the Face Page of the application, the small business concern and the research institution certify *jointly* that:

- (1) the proposed STTR project will be conducted jointly by the small business concern and the research institution in which not less than 40 percent of the work will be performed by the small business concern and not less than 30 percent of the work will be performed by the research institution ("cooperative research and development");
- (2) the proposed STTR project is a cooperative research or research and development effort to be conducted jointly by the small business concern and the research institution in which not less than 40 percent of the work will be performed by the small business concern and not less than 30 percent of the work will be performed by the research institution ("performance of research and analytical work"); and
- (3) regardless of the proportion of the proposed project to be performed by each party, the small business concern will be the primary party that will exercise management direction and control of the performance of the project.

If the research institution is a contractor-operated federally funded research and development center, the duly authorized representative of the contractor-operated federally funded research and development center certifies, *additionally*, that it:

- (4) is free from organizational conflicts of interests relative to the STTR program
- (5) did not use privileged information gained through work performed for an STTR agency or private access to STTR agency personnel in the development of this STTR grant application; and
- (6) used outside peer review, as appropriate, to evaluate the proposed project and its performance therein.

---

Signature of Duly Authorized Representative

Date of Signature

---

Printed Name and Title of Duly Authorized Representative

**Research Institution Total Costs =**  
(Direct costs + F&A Costs)

**DO NOT SUBMIT UNLESS REQUESTED**

**Competing Continuation Applications  
KEY PERSONNEL REPORT**

**All Key Personnel for the Current Budget Period**

Name	Degree(s)	SSN (last 4 digits)	Role on Project (e.g. PI, Res. Assoc.)	Date of Birth (MM/DD/YY)	Annual % Effort

# ***Mailing address for application***

*Use this label or a facsimile*

**All applications and other deliveries to the Center for Scientific Review must come either via courier delivery or via the United States Postal Service (USPS.) Applications delivered by individuals to the Center for Scientific Review will no longer be accepted.**

**Applications sent via the USPS EXPRESS or REGULAR MAIL should be sent to the following address:**

**CENTER FOR SCIENTIFIC REVIEW  
NATIONAL INSTITUTES OF HEALTH  
6701 ROCKLEDGE DRIVE  
ROOM 1040 – MSC 7710  
BETHESDA, MD 20892-7710**

**NOTE: All applications sent via a courier delivery service (non-USPS) should use this address, but CHANGE THE ZIP CODE TO 20817**

The telephone number is 301-435-0715. C.O.D. applications will not be accepted.

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## ***For application in response to RFA***

*Use this label or a facsimile*

IF THIS APPLICATION IS IN RESPONSE TO AN RFA, be sure to put the RFA number in line 2 of the application face page. In addition, after duplicating copies of the application, cut along the dotted line below and staple the RFA label to the bottom of the face page of the original and place the original on top of your entire package. Failure to use this RFA label could result in delayed processing of your application such that it may not reach the review committee on time for review. **Do not use** the label unless the application is in response to a specific RFA. Also, applicants responding to a specific RFA should be sure to follow all special mailing instructions published in the RFA.

**RFA No.** \_\_\_\_\_

# **RFA**

# ***Mailing address for application***

*Use this label or a facsimile*

**All applications and other deliveries to the Center for Scientific Review must come either via courier delivery or via the USPS. Applications delivered by individuals to the Center for Scientific Review will no longer be accepted.**

**Applications sent via the USPS EXPRESS or REGULAR MAIL should be sent to the following address:**

<p><b>CENTER FOR SCIENTIFIC REVIEW NATIONAL INSTITUTES OF HEALTH 6701 ROCKLEDGE DRIVE ROOM 1040 – MSC 7710 BETHESDA, MD 20892-7710</b></p>
--

**NOTE: All applications sent via a courier delivery service (non-USPS) should use this address, but CHANGE THE ZIP CODE TO 20817**

The telephone number is 301-435-0715. C.O.D. applications will *not* be accepted.

---

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## ***For application in response to SBIR/STTR***

*Use this label or a facsimile*

IF THIS APPLICATION IS IN RESPONSE TO AN SBIR/STTR Solicitation, be sure to put the SBIR/STTR Solicitation number in line 2 of the application face page. In addition, after duplicating copies of the application, cut along the dotted line below and staple the appropriate SBIR or STTR label to the bottom of the face page of the original and place the original on top of your entire package. If this SBIR or STTR application is in response to an RFA, be sure to also include the RFA No. in the space provided below.

**SBIR**

RFA No. \_\_\_\_\_ (if applicable)

**STTR**

RFA No. \_\_\_\_\_ (if applicable)

# ***Mailing address for application***

*Use this label or a facsimile*

**All applications and other deliveries to the Center for Scientific Review must come either via courier delivery or via the USPS. Applications delivered by individuals to the Center for Scientific Review will no longer be accepted.**

**Applications sent via the USPS EXPRESS or REGULAR MAIL should be sent to the following address:**

<p><b>CENTER FOR SCIENTIFIC REVIEW NATIONAL INSTITUTES OF HEALTH 6701 ROCKLEDGE DRIVE ROOM 1040 – MSC 7710 BETHESDA, MD 20892-7710</b></p>
--

**NOTE: All applications sent via a courier delivery service (non-USPS) should use this address, but CHANGE THE ZIP CODE TO 20817**

The telephone number is 301-435-0715. C.O.D. applications will *not* be accepted.

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## ***For application in response to SBIR/STTR***

*Use this label or a facsimile*

IF THIS APPLICATION IS IN RESPONSE TO AN SBIR/STTR Solicitation, be sure to put the SBIR/STTR Solicitation number in line 2 of the application face page. In addition, after duplicating copies of the application, cut along the dotted line below and staple the appropriate SBIR or STTR label to the bottom of the face page of the original and place the original on top of your entire package. If this SBIR or STTR application is in response to an RFA, be sure to also include the RFA No. in the space provided below.

**SBIR**

RFA No. \_\_\_\_\_ (if applicable)

**STTR**

RFA No. \_\_\_\_\_ (if applicable)

### BIOGRAPHICAL SKETCH

Provide the following information for the key personnel and other significant contributors in the order listed on Form Page 2.  
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME Schumacher, Kenneth		POSITION TITLE Principal Investigator	
eRA COMMONS USER NAME			
EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY
Georgetown University	MD	1997	Medicine

#### A. Positions and Honors.

Experience:

Honors:

Memberships:

Institute of Directors, 1999-11-09 to 2003-01-01

#### B. Peer-reviewed Publications.

Publications:

1. The Effect of Diabetes on Rats

Journal of Medicine, 2000-12-10, 3:5

#### C. Research Support.

Ongoing Research Support:

Schumacher, Kenneth (PI) 10/01/04-09/30/09

National Institute of Health

The effects of insulin on laboratory rats

The effects of insulin on laboratory rats with an insatiable appetite for chocolate

Role: Principal Investigator



Facilities and Administration Costs for Entire Proposed Project Period.

Project #	F & A Rate Type	Budget F & A Period Base	Amount of Base	Effective Date	Rate Applied	F & A Costs
000000000000165	On Campus	1 MTDC	\$30000	07/01/2001	40%	\$12000
000000000000165	On Campus	1 MTDC	\$30000	07/01/2005	50%	\$15000
000000000000165	On Campus	2 MTDC	\$63000	07/01/2005	50%	\$31500
000000000000165	On Campus	3 MTDC	\$58000	07/01/2005	50%	\$29000
000000000000165	On Campus	4 MTDC	\$56500	07/01/2005	50%	\$28250
000000000000165	On Campus	5 MTDC	\$56500	07/01/2005	50%	\$28250

Department of Health and Human Services  
Public Health Services

Review Group	Type	Activity	Grant Number
Total Project Period			
From: 10/01/2001		Through: 09/30/2006	
Requested Budget Period			
From: 10/01/2001		Through: 09/30/2002	

# Grant Progress Report

1. TITLE OF PROJECT <b>The effects of insulin on diabetic rats</b>	
2a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR (Name and address, street, city, state, zip code)  <b>Schumacher, Kenneth,</b>	3. APPLICANT ORGANIZATION (Name and address, street, city, state, zip code)  <b>PeopleSoft University. 4305 Hacienda Dr Pleasanton, CA 94588 USA</b>
2b. E-MAIL ADDRESS <b>kenneths@university.edu</b>	4. ENTITY IDENTIFICATION NUMBER <b>123</b>
2c. DEPARTMENT, SERVICE, LABORATORY, OR EQUIVALENT <b>Engineering</b>	5. TITLE AND ADDRESS OF ADMINISTRATIVE OFFICIAL           E-MAIL:
2d. MAJOR SUBDIVISION  <b>Research and Development</b>	

6. HUMAN SUBJECTS		7. VERTEBRATE ANIMALS	
<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes	6a. Research Exempt <input type="checkbox"/> No <input type="checkbox"/> Yes	<input type="checkbox"/> No <input type="checkbox"/> Yes	7a. If "Yes," IACUC approval Date
If Exempt ("Yes" in 6a): Exemption No.	6b. Human Subjects Assurance No.	7b. Animal Welfare Assurance No.	
If Not Exempt ("No" in 6a): IRB approval date	6c. NIH-Defined Phase III Clinical Trial <input type="checkbox"/> No <input type="checkbox"/> Yes  <input type="checkbox"/> Full IRB <u>or</u> <input type="checkbox"/> Expedited Review		

8. COSTS REQUESTED FOR NEXT BUDGET PERIOD		9. INVENTIONS AND PATENTS	
8a. DIRECT \$ <b>336,500</b>	8b. TOTAL \$ <b>500,000</b>	<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes If "Yes,"	<input type="checkbox"/> Previously Reported <input type="checkbox"/> Not Previously Reported

10. PERFORMANCE SITE(S) ( <i>Organizations and addresses</i> )  <b>EGV03 - Pleasanton, CA, Pleasanton, CA.</b>	11a. PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR ( <i>Item 2a</i> )	TEL <b>510/555-1111</b>
		FAX
	11b. ADMINISTRATIVE OFFICIAL NAME ( <i>Item 5</i> )	TEL
		FAX
11c. NAME AND TITLE OF OFFICIAL SIGNING FOR APPLICANT ORGANIZATION ( <i>Item 14</i> )		
NAME		
TITLE		
TEL		FAX
E-MAIL		

12. Corrections to Page 1 Face Page

13. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR ASSURANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties. I agree to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of this application.	SIGNATURE OF PI/PD NAMED IN 2a. ( <i>In ink. "Per" signature not acceptable.</i> )	DATE
14. APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with Public Health Services terms and conditions if a grant is awarded as a result of this application. I am aware that any false, fictitious, or fraudulent statements or claims may subject me to criminal, civil, or administrative penalties.	SIGNATURE OF OFFICIAL NAMED IN 11c. ( <i>In ink. "Per" signature not acceptable.</i> )	DATE

DETAILED BUDGET FOR NEXT BUDGET PERIOD – DIRECT COSTS ONLY		FROM 10/01/2001	THROUGH 09/30/2002	GRANT NUMBER		
PERSONNEL (Applicant organization only)		TYPE APPT. (months)	% EFFORT ON PROJ.	DOLLAR AMOUNT REQUESTED (omit cents)		
NAME	ROLE ON PROJECT			SALARY REQUESTED	FRINGE BENEFITS	TOTALS
Schumacher, Kenneth	Principal Investigator	12	100.0	40,000	8,000	48,000
<b>SUBTOTALS</b> →				<b>40,000</b>	<b>8,000</b>	<b>48,000</b>
CONSULTANT COSTS						
: \$180000.00.						
						180,000
EQUIPMENT (Itemize)						
: \$18500.00.						
						18,500
SUPPLIES (Itemize by category)						
						0
TRAVEL						
						0
PATIENT CARE COSTS						
INPATIENT						0
OUTPATIENT						0
ALTERATIONS AND RENOVATIONS (Itemize by category)						
						0
OTHER EXPENSES (Itemize by category)						
: \$60000.00.						
						60,000
<b>SUBTOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD</b>						<b>\$ 306,500</b>
CONSORTIUM/CONTRACTUAL COSTS		DIRECT COSTS				30,000
		FACILITIES AND ADMINISTRATIVE COSTS				3,000
<b>TOTAL DIRECT COSTS FOR NEXT PROJECT PERIOD (Item 8a, Face Page)</b>						<b>\$ 339,500</b>

<b>BUDGET JUSTIFICATION</b>	GRANT NUMBER
-----------------------------	--------------

Provide a detailed budget justification for those line items and amounts that represent a significant change from that previously recommended. Use continuation pages if necessary.

<b>CURRENT BUDGET PERIOD</b>	FROM 10/01/2001	THROUGH 09/30/2002
------------------------------	--------------------	-----------------------

Explain any estimated unobligated balance (including prior year carryover) that is greater than 25% of the current year's total budget.

Principal Investigator/Program Director (Last, First, Middle): Schumacher, Kenneth

<b>PROGRESS REPORT SUMMARY</b>	GRANT NUMBER	
	PERIOD COVERED BY THIS REPORT	
PRINCIPAL INVESTIGATOR OR PROGRAM DIRECTOR Schumacher, Kenneth	FROM 10/01/2001	THROUGH 09/30/2002
APPLICANT ORGANIZATION PeopleSoft University		
TITLE OF PROJECT (Repeat title shown in Item 1 on first page) The effects of insulin on diabetic rats		
A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	<input checked="" type="checkbox"/> No Change Since Previous Submission	<input type="checkbox"/> Change

SEE PHS 2590 INSTRUCTIONS.

**WOMEN AND MINORITY INCLUSION: See PHS 398 Instructions. Use Inclusion Enrollment Report Format Page and, if necessary, Targeted/Planned Enrollment Format Page.**

GRANT NUMBER \_\_\_\_\_

**CHECKLIST****1. PROGRAM INCOME (See instructions.)**

All applications must indicate whether program income is anticipated during the period(s) for which grant support is requested. 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.)**

In signing the application Face Page, the authorized organizational representative agrees to comply with the following policies, assurances and/or certifications when applicable. Descriptions of individual assurances/certifications are provided in Part III of the PHS 398. 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 Research, Including Human Gene Transfer Research • Financial Conflict of Interest (except Phase I SBIR/STTR) • Prohibited Research • Select Agents  
• STTR ONLY: Certification of Research Institution Participation.

**3. FACILITIES AND ADMINISTRATIVE (F&A) COSTS**

Indicate the applicant organization's most recent F&A cost rate established with the appropriate DHHS Regional Office, or, in the case of for-profit organizations, the rate established with the appropriate PHS Agency Cost Advisory Office.

F&A costs will **not** be paid on construction grants, grants to Federal organizations, grants to individuals, and conference grants. Follow any additional instructions provided for Research Career Awards, Institutional National Research Service Awards, Small Business Innovation Research/Small Business Technology Transfer Grants, foreign grants, and specialized grant applications.

DHHS Agreement dated: \_\_\_\_\_  No Facilities and Administrative Costs Requested.

No DHHS Agreement, but rate established with \_\_\_\_\_ Date \_\_\_\_\_

**CALCULATION\***

Entire proposed budget period: Amount of base \$ \_\_\_\_\_ x Rate applied 0.00% = F&A costs \$ \_\_\_\_\_

Add to total direct costs from Form Page 2 and enter new total on Face Page, Item 8b.

\*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*):

**KEY PERSONNEL REPORT**

GRANT NUMBER

Place this form at the end of the signed original copy of the application. Do not duplicate.

**All Key Personnel for the Current Budget Period (do not include Other Significant Contributors)**

Name	Degree(s)	SSN (last 4 digits)	Role on Project (e.g. PI, Res. Assoc.)	Date of Birth (MM/DD/YY)	Annual % Effort
Schumacher, Kenneth		107		01/01/56	

<b>NEXT BUDGET PERIOD</b> <i>(Follow instructions carefully)</i>	<b>FROM</b>	<b>THROUGH</b>	<b>GRANT NUMBER</b>
<b>ITEMIZE DIRECT COSTS REQUESTED FOR NEXT BUDGET PERIOD</b>			<b>DOLLAR AMOUNT REQUESTED (omit cents)</b>
PREDOCTORAL STIPENDS			No. Requested: \$
POSTDOCTORAL STIPENDS <i>(Itemize)</i>			No. Requested: \$
OTHER STIPENDS <i>(Specify)</i>			\$
<b>TOTAL STIPENDS</b>			\$
TUITION, FEES, AND INSURANCE <i>(Itemize)</i>			\$
TRAINEE TRAVEL <i>(Describe)</i>			\$
TRAINEE RELATED EXPENSES			\$
<b>TOTAL DIRECT COSTS FOR NEXT BUDGET PERIOD</b> <i>(Also enter on Page 1, Item 8a)</i>			\$



**Summary of Trainees**

GRANT NUMBER

**Complete for trainees who have left the program or who have completed their training** (during this reporting period)

Name	Degree Earned	Current Position

**Complete for all trainees for this reporting period.**

**Distribution of Trainees According to Category: Use the table on the "Inclusion Enrollment Report Format Page." See PHS 398.**

**Targeted/Planned Enrollment Table****This report format should NOT be used for data collection from study participants.**Study Title: TestTotal Planned Enrollment: 19

<b>TARGETED/PLANNED ENROLLMENT: Number of Subjects</b>			
<b>Ethnic Category</b>	<b>Sex/Gender</b>		
	<b>Females</b>	<b>Males</b>	<b>Total</b>
Hispanic or Latino	0	0	
Not Hispanic or Latino	11	8	19
<b>Ethnic Category: Total of All Subjects *</b>	11	8	19
<b>Racial Categories</b>			
American Indian/Alaska Native	0	0	
Asian	2	0	2
Native Hawaiian or Other Pacific Islander	5	5	10
Black or African American	0	0	
White	4	3	7
<b>Racial Categories: Total of All Subjects *</b>	11	8	19

\* The "Ethnic Category: Total of All Subjects" must be equal to the "Racial Categories: Total of All Subjects."

## Inclusion Enrollment Report

**This report format should NOT be used for data collection from study participants.**

Study Title: Test  
 Total Enrollment: 19 Protocol Number: \_\_\_\_\_  
 Grant Number: \_\_\_\_\_

<b>PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race</b>				
Ethnic Category	Sex/Gender			Total
	Females	Males	Unknown or Not Reported	
Hispanic or Latino	0	0		**
Not Hispanic or Latino	11	8	0	19
Unknown (individuals not reporting ethnicity)	0	0	0	
<b>Ethnic Category: Total of All Subjects*</b>	11	8		19 *
<b>Racial Categories</b>				
American Indian/Alaska Native	0	0		
Asian	2	0	0	2
Native Hawaiian or Other Pacific Islander	5	5		10
Black or African American	0	0	0	
White	4	3	0	7
More Than One Race	0	0	0	
Unknown or Not Reported	0	0	0	
<b>Racial Categories: Total of All Subjects*</b>	11	8		19 *
<b>PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)</b>				
Racial Categories	Females	Males	Unknown or Not Reported	Total
American Indian or Alaska Native	0	0	0	
Asian	0	0	0	
Native Hawaiian or Other Pacific Islander	0	0	0	
Black or African American	0	0	0	
White	0	0	0	
More Than One Race	0	0	0	
Unknown or Not Reported	0	0	0	
<b>Racial Categories: Total of Hispanics or Latinos**</b>				**

\* These totals must agree.

\*\* These totals must agree.

Standard Form 1034 (EG) Department of the Treasury 1 TFM 4-2000 1034-121	<b>PUBLIC VOUCHER FOR PURCHASES AND SERVICES OTHER THAN PERSONAL</b>	VOUCHER NO.  PC-00020938 07
U.S. DEPARTMENT, BUREAU, OR ESTABLISHMENT LOCATION National Institute of Health Science Scully, Dana 6701 Rockledge Drive Room 1040-MS7710 Bethesda MD 20892-7710	DATE VOUCHER PREPARED <p style="text-align: center;"><b>09/07/1999</b></p> CONTRACT NUMBER AND DATE <p style="text-align: center;"><b>Airlines</b></p> REQUISITION NUMBER AND DATE	SCHEDULE NO.  PAID BY
<b>INVOICE</b>		DATE INVOICE RECEIVED  DISCOUNT TERMS  PAYEE'S ACCOUNT NUMBER
United States  Administration Building 100 College St. San Francisco CA United States		GOVERNMENT B/L NUMBER
<b>Award: UNITEDAIR1</b>		
SHIPPED FROM	TO	WEIGHT
NUMBER AND DATE OF ORDER	DATE OF DELIVERY OR SERVICE	ARTICLES OR SERVICES <small>(Enter description, item number of contract or Federal supply schedule, and other information deemed necessary)</small>
		QUANTITY
		UNIT PRICE COST      PER
		AMOUNT  (1)
		\$500.00
	Michele Barnes	
(Use continuation sheet(s) if necessary) <b>(Payee must NOT use the space below)</b> <b>TOTAL</b>		\$500.00
PAYMENT: <input type="checkbox"/> PROVISIONAL <input type="checkbox"/> COMPLETE <input type="checkbox"/> PARTIAL <input type="checkbox"/> FINAL <input type="checkbox"/> PROGRESS <input type="checkbox"/> ADVANCE	APPROVED FOR BY 2 TITLE	EXCHANGE RATE = \$1.00
	= \$	= \$1.00
		DIFFERENCE S
		Amount verified; correct for (Signature or initials)
Pursuant to authority vested in me, I certify that this voucher is correct and proper for payment.		
(Date)	(Authorized Certifying Officer) 2	(Title)
ACCOUNTING CLASSIFICATION		
<b>P</b> <b>A</b> <b>I</b> <b>D</b>	CHECK NUMBER      ON ACCOUNT OF U.S. TREASURY  CASH      DATE	CHECK NUMBER      ON (Name of bank)  PAYEE 3
		PER
		TITLE
<small>1 When stated in foreign currency, insert name of currency.</small> <small>2 If ability to certify and authority to approve are combined in one person, one signature only is necessary; otherwise approving officer will sign in space provided, over official title.</small> <small>3 When a voucher is receipted in the name of a company or corporation, the name of the person writing the company or corporate name, as well as the capacity in which he signs, must appear. For example: "John Doe Company, per John Smith, Secretary", or "Treasurer", as the case may be.</small>		

Standard Form 1035 (EG)  
4 Treasury FRM 2000  
1035-110

**PUBLIC VOUCHER FOR PURCHASES AND SERVICES OTHER THAN PERSONAL**

VOUCHER NO.  
PC-00020938 07  
SCHEDULE NO.  
SHEET NO.

CONTINUATION SHEET

U.S. DEPARTMENT, BUREAU, OR ESTABLISHMENT

NUMBER AND DATE OF ORDER	DATE OF DELIVERY OR SERVICE	ARTICLES OR SERVICES (Enter description, item number of contract or Federal supply schedule, and other information deemed necessary)	QUANTITY	UNIT PRICE		AMOUNT
				COST	PER	
<b>INVOICE</b>						
	Administration Building 100 College St. San Francisco CA United States	Invoice Date: 09/07/1999 Sponsor Award: Airlines Award Period: 09/01/1999 - 08/31/2002 Award Amount: \$600,000.00				
		Bill Amount 08/01/1999 Thru 08/31/1999			Cumulative Amount	
	*****THANK YOU FOR YOUR ORDER!*****					
	We appreciate the opportunity to do business with you. If you have any questions about your order, please call our tol free hotline: 1-800-380-HELP.					
			0.00			500.00
	Equipment		0.00			312.50
	Personnel		500.00			1,750.00
	Supplies Expense		0.00			1,672.00
	5032		0.00			419.51
	<b>SUBTOTAL:</b>		500.00			4,654.01
	<b>TOTAL AMOUNT DUE :</b>		500.00			

<b>REQUEST FOR ADVANCE OR REIMBURSEMENT</b>  <small>(see instructions)</small>		Approved by Office of Management and Budget, No. 80-R0183		Page 1	of 1 pages
		1. TYPE OF PAYMENT REQUESTED		a. "X" one, or both boxes ADVANCE REIMBURSEMENT X b. "X" the applicable box FINAL PARTIAL X	
3. FEDERAL SPONSORING AGENCY AND ORGANIZATIONAL ELEMENT TO WHICH THIS REPORT IS SUBMITTED National Institute of Health Science		4. FEDERAL GRANT OR OTHER IDENTIFYING NUMBER ASSIGNED BY FEDERAL AGENCY Airlines		2. BASIS OF REQUEST CASH X ACCRUAL	
6. EMPLOYER IDENTIFICATION NUMBER 860128764		7. RECIPIENT'S ACCOUNT NUMBER OR IDENTIFYING NUMBER UNITEDAIR1		8. PERIOD COVERED BY THIS REQUEST FROM (month, day, year) 08/01/1999 TO (month, day, year) 08/31/1999	
9. RECIPIENT ORGANIZATION Administration Building 100 College St. San Francisco CA		10. PAYEE (Where check is to be sent if different than item 9)			
<b>11. COMPUTATION OF AMOUNT OF REIMBURSEMENT/ADVANCES REQUESTED</b>					
PROGRAMS/FUNCTIONS/ACTIVITIES		(a)	(b)	(c)	TOTAL
<small>(As of Date)</small>					
a. Total program outlays to date		\$ 4,154.01	\$	\$	
b. Less: Cumulative program income		0.00			
c. Net program outlays (Line a minus line b)		4,154.01			
d. Estimated net cash outlays for advance period		0.00			
e. Total (Sum of lines c & d)		4,154.01			
f. Non-Federal share of amount on line e		0.00			
g. Federal share of amount on line e		4,154.01			
h. Federal payments previously requested		3,654.01			
i. Federal share now requested (Line g minus line h)		500.00			
j. Advances required by month, when requested by Federal grantor agency for use in making prescheduled advances		1st month			
		2nd month			
		3rd month			
<b>12. ALTERNATIVE COMPUTATION FOR ADVANCES ONLY</b>					
a. Estimated Federal cash outlays that will be made during period covered by the advance					
b. Less: Estimated balance of Federal cash on hand as of beginning of advance period					
c. Amount requested (Line a minus line b)					
<b>13. CERTIFICATION</b>					
I certify that to the best of my knowledge and belief the data above are correct and that all outlays were made in accordance with the grant conditions or other agreement and that payment is due and has not been previously requested.		SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL			DATE REQUEST SUBMITTED
		TYPED OR PRINTED NAME AND TITLE Michele Barnes			09/07/1999  TELEPHONE (AREA CODE, NUMBER, EXTENSION) 510-225-4949

# INVOICE

**Please Remit To:**

Administration Building  
 100 College St.  
 San Francisco CA  
 United States

Page:

1

Invoice No:

PC-00020939 07

Invoice Date:

09/07/1999

Customer Number:

10006

Payment Terms:

Net 30

Due Date:

10/07/1999

**Sponsor:**

California University  
 John Black  
 100 College Avenue  
 Walnut Creek CA 94596  
 United States

Award: UNITEDAIR1

AMOUNT DUE:

500.00 USD

Sponsor Award: Airlines  
 Award Amount: \$600,000.00

Paul Lambert

For billing questions, please call Frank G. Joyce at 408-641-CORP

Description	Bill Amount 08/01/1999 Thru 08/31/1999	Cumulative Amount
*****THANK YOU FOR YOUR ORDER!*****		
We appreciate the opportunity to do business with you. If you have any questions about your order, please call our tol free hotline: 1-800-380-HELP.		
Facilities and Admin	0.00	500.00
Modified Total Direct Costs	500.00	3,422.00
Non-Modified Total Direct Co	0.00	312.50
<b>SUBTOTAL:</b>	<b>500.00</b>	<b>4,654.01</b>

<b>TOTAL AMOUNT DUE :</b>	<b>500.00</b>
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PeopleSoft BI  
INVOICE PRINT SUMMARY - SELECTED BILLS

Report ID: GMIVCPN  
Report Action: INVOICE

Page No. 1  
Run Date 09/07/1999  
Run Time 08:37:29

<u>Business Unit</u>	<u>Number of Bills</u>	<u>Total Invoice Amount</u>	<u>Currency</u>
EDGVT	1	1,654.01	USD

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Total number of bills printed: 1



## SALARY DETAIL

Sponsor Award #: JRS005  
Invoice Date : 04/22/1999  
Invoice #: PC-00020980  
From/To Date: 03/01/1999 03/31/1999

Account Number	Employee Name	Current Invoice	Cumulative
4001 Local grants and contracts8001	Schumacher, Simon	0.00	24,463.25
4001 Local grants and contracts8006	Tiger, Ben Wild	0.00	18,809.36
4001 Local grants and contracts8058	Bukau, Hans	0.00	14,441.21
4001 Local grants and contracts8060	Nelson, Jennifer Free Willy	897.33	2,296.10
4001 Local grants and contractsBING	Crosby, Bing	0.00	3,453.06
Sub Total		<hr/> 897.33	<hr/> 63,462.98
Grand Total		<hr/> 897.33	<hr/> 63,462.98

End of Report

State University  
389 Pine Street  
Pleasanton, CA 97879  
Letter of Credit Sponsor 10020, Department of Health & Human Services

Letter of Credit Number MELANIE  
Draw Date 08/03/1999  
From Date 01/01/1900  
Thru Date 08/03/1999

Document #	Federal Award	Project/Grant	Funding	Previously Billed	Unbilled Amount	Allowable Draw
<b>SUMMARY</b>						
Document1			200,000.00	2,500.00	850.00	850.00
Document2			200,000.00	1,000.00	1,000.00	1,000.00
Document2			100,000.00	1,250.00	1,200.00	1,200.00
<b>GRAND TOTAL</b>				<b>4,750.00</b>	<b>3,050.00</b>	<b>3,050.00</b>
<b>DETAILS</b>						
Document1	NIH PSAWDR01	MSAWDR01	200,000.00	2,500.00	850.00	850.00
Sub-Total Doc # Document1				2,500.00	850.00	850.00
Document2	NIH PSAWDR01	MSAWDR01-2	200,000.00	1,000.00	1,000.00	1,000.00
Sub-Total Doc # Document2				1,000.00	1,000.00	1,000.00
Document2	NIH PSAWDR02	MSAWDR02	100,000.00	1,250.00	1,200.00	1,200.00
Sub-Total Doc # Document2				1,250.00	1,200.00	1,200.00
<b>GRAND TOTAL</b>				<b>4,750.00</b>	<b>3,050.00</b>	<b>3,050.00</b>

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

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### BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.  
Follow the sample format for each person. **DO NOT EXCEED FOUR PAGES.**

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NAME	POSITION TITLE
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EDUCATION/TRAINING <i>(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)</i>			
INSTITUTION AND LOCATION	DEGREE <i>(if applicable)</i>	YEAR(s)	FIELD OF STUDY

Ben Tiger  
, Professor  
100 Main St. #120  
San Mateo CA 90101  
USA

## Pending

Unit	Proposal	Version	Project	Begin Date	End Date	Effort %	Amount	Role	Sponsor/Title
EDGVT	DALE_FRI2	V1	DALE_FRI2	07/01/1999	06/30/2000	100.00	246,000.00	PI	California University Dale's Friday Proposal
EDGVT	DALE_FRI2	V1	DALE_FRI2B	07/01/1999	06/30/2000	75.00	246,000.00	PI	California University Dale's Friday Proposal
EDGVT	DALE_FRI2	V1	DALE_FRI2C	07/01/1999	06/30/2000	100.00	246,000.00	PI	California University Dale's Friday Proposal
EDGVT	DALE_FRI3	V1	DALE_FRI3	07/01/1999	06/30/2000	100.00	100,000.00	PI	California University Third Proposal
EDGVT	DALE_FRI4	V1	DALE_FRI4	07/01/1999	06/30/2000	100.00	198,000.00	PI	California University Dale's Friday Proposal
EDGVT	DALE_FRI4	V1	DALE_FRI4B	07/01/1999	06/30/2000	75.00	198,000.00	PI	California University Dale's Friday Proposal
EDGVT	DALE_FRI4	V1	DALE_FRI4C	07/01/1999	06/30/2000	100.00	198,000.00	PI	California University Dale's Friday Proposal

## FEDERAL FINANCIAL REPORT

(Follow form instructions)

1. Federal Agency and Organizational Element to Which Report is Submitted  National Institute of Health		2. Federal Grant or Other Identifying Number Assigned by Federal Agency (To report multipls grants, us FFR Attachment)		Page	Of
				1	1
3. Recipient Organization (Name and complete address including Zip code) 4305 Hacienda Dr , Pleasanton, CA, 94588					
4a. DUNS Number  144709193	4b. EIN  0000000000000000000649310000	5. Recipient Account Number or Identifying Number (To report multiple grants, use FFR Attachment)  <b>SIR</b>	6. Report Type  Annual	7. Basis of Accounting  Accrual	
8. Project/Grant Period From: (Month, Day, Year)  2009-08-24			To: (Month, Day, Year)  2010-08-23		9. Reporting Period End Date (Month, Day, Year)  2010-08-23
10. Transactions			Cumulative		
<i>(Use line a-c for single or multiple grant reporting)</i>					
Federal Cash (To report multiple grants, also use FFR attachment):					
a. Cash Receipts			40,400.00		
b. Cash Disbursements			13,500.00		
c. Cash on Hand (a minus b)			26,900.00		
<i>(Use lines d - o for single grant reporting)</i>					
Federal Expenditures and Unobligated Balance:					
d. Total Federal funds authorized			13,500.00		
e. Federal share of expenditures			13,500.00		
f. Federal share of unliquidated obligations			0.00		
g. Total Federal share (sum of lines e and f)			13,500.00		
h. Unobligated balance of Federal funds (line d minus g)			0.00		
Recipient Share:					
i. Total recipient share required			1,000.00		
j. Recipient share of expenditures			0.00		
k. Remaining recipient share to be provided (line i minus j)			1,000.00		
Program Income:					
l. Total Federal income earned			2,000.00		
m. Program income expended in accordance with the deduction alternative			400.00		
n. Program income expenses in accordance with the addition alternative			600.00		
o. Unexpended program income (line l minus line m or line n)			1,000.00		
11. Indirect					
• Type of Rate (Place "X" in appropriate box)					
<b>Pre-determined</b>					
Expense	b. Rate: 0	c. Base: 0	d. Total Amount: 4500	e. Federal Share: 4,500.00	
12. Remarks: Attach any explanation deemed necessary or information required by Federal sponsoring agency in compliance with governing legislation: SIR REPORT					
13. Certification: By signing this report, I certify that this is true, complete, and accurate to the best of my knowledge. I am aware that any false, fictitious or fraudulent information may subject me to criminal, civil, or administrative penalties. (U.S.Code, Title 218, Section 1001)					
a. Typed or Printed Name and Title of Authorized Certifying Official <b>Schumacher, Kenneth Administrative Assistant</b>			c. Telephone (Area code, number and extension) <b>510/555-1111</b>		
			d. Email address <b>kenneths@university.edu</b>		
b. Signature of Authorized Certifying Official			e. Date Report Submitted (Month, Day, Year) <b>2010-08-23</b>		
14. Agency use only:					

Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget Paperwork Reduction Project \_\_\_\_\_, Washington, DC 20503.

## FEDERAL FINANCIAL REPORT ATTACHMENT

(For reporting multiple grants)

<b>1. Federal Agency and Organization (Element to Which Report is Submitted (Box 1 on Page 1))</b> <b>National Institute of Health</b>		<b>2. Recipient Organization (Box 3 on Page 1)</b> <b>4305 Hacienda Dr , Pleasanton, CA, 94588</b>	
<b>3a. DUNS Number (Box 4a on Page 1)</b> <b>144709193</b>	<b>4. Reporting Period End Date (Box 9 on Page 1) (Month, Day, Year)</b> <b>2010-08-23</b>		<b>Page 1 of 1</b>
<b>3b. XEF (Box 4b on Page 1)</b> <b>00000000000000000000000649310000</b>			
<b>5. List information below for each grant covered by this report. Use additional pages if more space is required.</b>			
Federal Grant Number	Recipient Account Number	Cumulative Federal Cash Disbursement	
<b>TOTAL (Should correspond to the amount on Line 10b on Page 1)</b>			<b>\$ 0.00</b>

Public reporting burden for this collection of information is estimated to average 1 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget Paperwork Reduction Project \_\_\_\_\_, Washington, DC 20503.