APPENDIX D

Forms for all TSNRP Awards

PHS 398

			1- & 2- &			_ 11 11		_
		Novice	3-Year	Pilot	EBP	Fellowship	Graduate	Pages
	TSNRP forms	$\sqrt{}$	\checkmark	$\sqrt{}$	$\sqrt{}$	V	√	C4-7
	Face Page Form Page 1	\checkmark	\checkmark	\checkmark	\checkmark	$\sqrt{}$	\checkmark	D-3
	Form Page 2 Description,					\checkmark	\checkmark	
	Sites	\checkmark	\checkmark	\checkmark	\checkmark			D-4
	Form Page 2 continued Key						,	
	Personnel, Other Contributors	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	D-5
	Form Page 3 Table of							
	Contents	\checkmark	\checkmark	\checkmark	\checkmark		\checkmark	D-6
	Form Page 4 Detailed Budget							
∞	Initial	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	D-7
398	Form Page 5 Budget for the							
PHS	Entire Period	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	D-8
PF	Biographical Sketch	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	\checkmark	\checkmark	\checkmark	D-9
	Resources	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	\checkmark	\checkmark	\checkmark	D-10
	Checklist	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	\checkmark	D-11
	Personal Data	$\sqrt{}$	$\sqrt{}$	$\sqrt{}$	\checkmark	\checkmark	\checkmark	D-12
	Other Support					√		D-13
	CDA Substitute Form Page 3:							
	Table of Contents					\checkmark		D-15
	Continuation	·		·				
	Format Page					$\sqrt{}$		D-16

Department of Health and Human Services Public Health Services

LEAVE BLANK-	FOR PHS USE ON	LY.		
Туре	Activity	Number		
Review Group		Formerly		
Council/Board (Month, Year)		Date Received		

Crant Annli	nation	review Group		Cillicity		
Grant Applio Do not exceed character length restr	Council/Board (Mon	Council/Board (Month, Year)				
TITLE OF PROJECT (Do not exceed 81 chara	acters, including spaces and	punctuation.)				
RESPONSE TO SPECIFIC REQUEST FOR A (If "Yes," state number and title) Number: Title:	APPLICATIONS OR PROGR	AM ANNOUNCEMEN	T OR SOLICIT	TATION NO	YES	
3. PROGRAM DIRECTOR/PRINCIPAL INVESTI	New Investigator	□ No □	Yes			
3a. NAME (Last, first, middle)		3b. DEGREE(S)		3h. eRA Commo	ns User Name	
3c. POSITION TITLE		3d. MAILING ADDR	RESS (Street, o	city, state, zip code)	
3e. DEPARTMENT, SERVICE, LABORATORY, C	PR EQUIVALENT					
3f. MAJOR SUBDIVISION						
3g. TELEPHONE AND FAX (Area code, number	and extension)	E-MAIL ADDRESS:				
TEL: FAX:						
4. HUMAN SUBJECTS RESEARCH ☐ No ☐ Yes	4a. Research Exempt No Yes	If "Yes," Exemption	No.			
4b. Federal-Wide Assurance No.	4c. Clinical Trial No Yes	4d. NIH-defined Phase III Clinical Trial No Yes				
5. VERTEBRATE ANIMALS No Yes	3	5a. Animal Welfare	Assurance No.			
DATES OF PROPOSED PERIOD OF SUPPORT (month, day, year—MM/DD/YY)	7. COSTS REQUESTE BUDGET PERIOD	D FOR INITIAL		REQUESTED FOR OF SUPPORT	RPROPOSED	
From Through	7a. Direct Costs (\$)	7b. Total Costs (\$)	8a. Direct Co		ıl Costs (\$)	
9. APPLICANT ORGANIZATION		10. TYPE OF ORGA	ANIZATION			
Name		Public: → L	Public: → ☐ Federal ☐ State ☐ Local			
Address		Private: → [Private Nor	nprofit		
		 ' -	For-profit: → ☐ General ☐ Small Business			
			Woman-owned Socially and Economically Disadvantaged 11. ENTITY IDENTIFICATION NUMBER			
		III. ENIIIT IDENI	IFICATION INC	JIVIDER		
		DUNS NO. Cong. District				
12. ADMINISTRATIVE OFFICIAL TO BE NOTIFIE Name	ED IF AWARD IS MADE	13. OFFICIAL SIGN Name	IING FOR APP	LICANT ORGANIZ	ZATION	
Title	Title					
Address		Address				
Tel: FAX:		Tel:		FAX:		
E-Mail:	D ACCEDTANCE: 1	E-Mail: SIGNATURE OF OI	EEICIAI NIANAF	ID IN 12	DATE	
14. APPLICANT ORGANIZATION CERTIFICATION AN the statements herein are true, complete and accurate to accept the obligation to comply with Public Health Servic is awarded as a result of this application. I am aware the statements or claims may subject me to criminal, civil, or	(In ink. "Per" signatu			DATE		

Program D	irector/Principal	Investigator	(Last,	First,	Middle)):

PROJECT SUMMARY (See instructions):					
RELEVANCE (See instructions):					
PROJECT/PERFORMANCE SITE(S) (if additional	al space is nee	ded, use F	Project/Performance Site Fo	ormat Page)
Project/Performance Site Primary Location					
Organizational Name:					
DUNS:					
Street 1:			Street 2:		
City:		County:			State:
Province:	Country:			Zip/Postal	Code:
Project/Performance Site Congressional Districts:					
Additional Project/Performance Site Location					
Organizational Name:					
DUNS:					
Street 1:			Street 2:		
City:		County:			State:
Province:	Country:	•		Zip/Postal	•
Project/Performance Site Congressional Districts:					
DLIQ 000 (D-11 44 (07)		D	- 0		

SENIOR/KEY PERSONNEL. See instruction Start with Program Director(s)/Principal	uctions. Use continuation pages as nee Investigator(s). List all other senior/key	ded to provide the required integration personnel in alphabetical orde	formation in the format shown below. er, last name first.
Name	eRA Commons User Name	Organization	Role on Project
OTHER SIGNIFICANT CONTRIBUTOR	28		
Name	Organization	Rol	e on Project
Human Embryonic Stem Cells	□ No □ Yes		idia and the day form the full code of the
If the proposed project involves human http://stemcells.nih.gov/research/re			ific cell line(s) from the following list:
If a specific line cannot be referenced at the	is time, include a statement that one from	the Registry will be used.	
Cell Line			

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

RESEARCH GRANT TABLE OF CONTENTS

_			Page Numbers			
De	ce Pagescription, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributo d Human Embryonic Stem Cells	rs,				
	ble of Contentsble					
	Detailed Budget for Initial Budget Period					
	dget for Entire Proposed Period of Support					
	dgets Pertaining to Consortium/Contractual Arrangements		 -			
	ographical Sketch – Program Director/Principal Investigator (Not to exceed four pages each)					
Oth	her Biographical Sketches (Not to exceed four pages each – See instructions)					
Re	sources					
Ch	ecklist					
Re	search Plan					
1.	Introduction to Resubmission Application, if applicable (Not to exceed three pages.), or Introduction to Revision Application, if applicable (Not to exceed one page.)					
2.	Specific Aims					
3. 4.	Background and Significance					
5.	Research Design and Methods		·			
6.	Inclusion Enrollment Report (Renewal or Revision applications only)					
7.	Bibliography and References Cited/Progress Report Publication List		·			
8.	Protection of Human Subjects					
9.	Inclusion of Women and Minorities					
10.	Targeted/Planned Enrollment Table					
11.	Inclusion of Children					
12.	Vertebrate Animals					
13.	Select Agent Research					
14.	Multiple PD/PI Leadership Plan					
15.	Consortium/Contractual Arrangements		·			
16.	Letters of Support (e.g., Consultants)					
17.	Resource Sharing Plan (s)					
Ар	pendix (Five identical CDs.)		Check if Appendix is Included			

DETAILED BUDGET DIRECT COSTS ONI	FROM	ר	THROU	JGH					
PERSONNEL (Applicant org	ganization only)	Months	s Devoted to	o Project		DOLLAR AMO	OUNT REQ	UESTE	D (omit cents)
NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST.BASE SALARY		FRING BENEF	GE	TOTAL
	PD/PI								
			$\Gamma_{\underline{}}$	$\top_{\underline{}}$				_	
						=			
	SUBTOTALS	3			<u> </u>				
CONSULTANT COSTS									
EQUIPMENT (Itemize) SUPPLIES (Itemize by cate	- 4								
SUPPLIES (ROTHIZE Sy Suit	·gory)								
TRAVEL									
ŀ	INPATIENT OUTPATIENT								
ALTERATIONS AND RENO		egory)							
OTHER EXPENSES (Itemiz	ze by category)								
CONSORTIUM/CONTRACT	TUAL COSTS					DIRE	ECT COST	S	
SUBTOTAL DIRECT	COSTS FOR INITIAL	BUDGE	ET PERI	OD (Item	7a, Face Pag	e)		\$	
CONSORTIUM/CONTRACT	TUAL COSTS			FA	CILITIES AND	D ADMINISTRATI	IVE COST	S	
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD \$					\$				

BUDGET FOR ENTIRE PROPOSED PROJECT PERIOD DIRECT COSTS ONLY

BUDGET	CATEGORY	INITIAL BUDGET PERIOD	ADDI	TIONAL YEARS OF S	UPPORT REQUESTED	
	OTALS	(from Form Page 4)	2nd	3rd	4th	5th
	Salary and fringe cant organization					
CONSULTAN	T COSTS					
EQUIPMENT						
SUPPLIES						
TRAVEL						
PATIENT CARE	INPATIENT					
COSTS	OUTPATIENT					
ALTERATIONS RENOVATION						
OTHER EXPE	NSES					
CONSORTIUM/ CONTRACTUAL DIRECT COSTS						
SUBTOTAL DIRECT COSTS (Sum = Item 8a, Face Page)						
CONSORTIUM CONTRACTUM COSTS						
TOTAL DIRE	ECT COSTS					
TOTAL DIRE	ECT COSTS FOR	ENTIRE PROPOSED	PROJECT PERIOD	,	\$	

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

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	POSITION TITL	-E			
eRA COMMONS USER NAME (credential, e.g., agency login)					
EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)					
INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY		

Please refer to the application instructions in order to complete sections A, B, and C of the Biographical Sketch.

Program Director/Principal Investigator (Last, First, Middle):
RESOURCES
FACILITIES: Specify the facilities to be used for the conduct of the proposed research. Indicate the project/performance sites and describe capacities, pertinent capabilities, relative proximity, and extent of availability to the project. If research involving Select Agent(s) will occur at any performance site(s), the biocontainment resources available at each site should be described. 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:
MAJOR EQUIPMENT: List the most important equipment items already available for this project, noting the location and pertinent capabilities of each

		CHECKLIS	T				
TYPE OF APPLICATION (Che	ck all that apply.)						
NEW application. (This application is being submitted to the PHS for the first time.)							
	RESUBMISSION of application number: (This application replaces a prior unfunded version of a new, renewal, or revision application.)						
RENEWAL of grant number: (This application is to extend a funded grant beyond its current project period.)							
REVISION to grant number	er:		_				
	ditional funds to supplement a cu	urrently funded gra	ant.)				
CHANGE of program direct	tor/principal investigator.						
Name of former program	director/principal investigator:	-					
CHANGE of Grantee Instit	tution. Name of former institution.						
FOREIGN application	Domestic Grant with foreign		List Country(ies) Involved:				
INVENTIONS AND PATENTS	(Renewal appl. only) No	Yes					
		If "Yes,"	Previously repo	orted Not previous	sly reported		
	instructions.) hether program income is anticip w to reflect the amount and sour		eriod(s) for which	grant support is request	t. If program income is		
Budget Period	Anticipated Am			Source(s)			
listed in the application instructi	TIONS (See instructions.) Page, the authorized organizatio ons when applicable. Descriptior fy compliance, where applicable.	ns of individual as	surances/certifica	tions are provided in Pa			
3. FACILITIES AND ADMINST	RATIVE COSTS (F&A)/ INDIRE	CT COSTS. See	specific instruction	ons.			
DHHS Agreement dated:			No F	Facilities And Administra	tive Costs Requested.		
DHHS Agreement being no	egotiated with			Regional Office.			
No DHHS Agreement, but	rate established with			 Date			
CALCULATION* (The entire gr	rant application, including the Ch	ecklist, will be rep	roduced and prov	vided to peer reviewers a	as confidential information.)		
a. Initial budget period:	Amount of base \$	x Rate	applied	% = F&A costs	\$		
b. 02 year	Amount of base \$	x Rate	applied	% = F&A costs	\$		
c. 03 year	Amount of base \$	x Rate	applied	% = F&A costs	\$		
d. 04 year	Amount of base \$	x Rate	applied	% = F&A costs	\$		
e. 05 year	Amount of base \$	x Rate	applied	% = F&A costs	\$		
•				TOTAL F&A Costs	\$		
*Check appropriate box(es):							
Salary and wages base	Modified total dir	rect cost base	[Other base (Explain	in)		
Off-site, other special rate	, or more than one rate involved	(Explain)					
Explanation (Attach separate s	heet, if necessary.):						
	N STATEMENT: If this applicati						
	name, address, telephone numb ested in contacting you for furthe				Yes No		

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

PERSONAL DATA ON PROGRAM DIRECTOR(S)/PRINCIPAL INVESTIGATORS)(

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 program director(s)/principal investigator(s).

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. When multiple PDs/PIs are proposed, complete a form for each. **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 BI	RTH (MM/DD/YY)	SEX/GENDER			
SOCIAL SEC	CURITY NUMBER XXX-XX-	Female Male			
ETHNICIT	·Y				
1. Do you	consider yourself to be Hispanic or Latino? (See definition	n below.) Select one.			
	<i>Hispanic or Latino.</i> A person of Mexican, Puerto Rican, Cuba or origin, regardless of race. The term, "Spanish origin," can be				
	Hispanic or Latino				
	Not Hispanic or Latino				
RACE					
2. What ra	ace do you consider yourself to be? Select one or more of	the following.			
	American Indian or Alaska Native. A person having origins in America, and who maintains tribal affiliation or community attact				
	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 "Haitian" or "Negro" can be used in addition to "Black" or Africa				
	Native Hawaiian or Other Pacific Islander. A person having Samoa, or other Pacific Islands.	origins in any of the original peoples of Hawaii, Guam,			
	White. A person having origins in any of the original peoples of	of Europe, the Middle East, or North Africa.			
	Check here if you do not wish to provide some or all of the abo	ve information.			

For New and Renewal Applications (PHS 398) – DO NOT SUBMIT UNLESS REQUESTED For Non-competing Progress Reports (PHS 2590) – Submit only Active Support for Key Personnel

PHS 398/2590 OTHER SUPPORT

Provide active support for all key personnel. Other Support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Training awards, prizes, or gifts do not need to be included.

There is no "form page" for other support. Information on other support should be provided in the *format* shown below, using continuation pages as necessary. *Include the principal investigator's name at the top and number consecutively with the rest of the application.* The sample below is intended to provide guidance regarding the type and extent of information requested.

For instructions and information pertaining to the use of and policy for other support, see Other Support in the PHS 398 Part III, Policies, Assurances, Definitions, and Other Information.

Note effort devoted to projects must now be measured using person months. Indicate calendar, academic, and/or summer months associated with each project.

Format

NAME OF INDIVIDUAL ACTIVE/PENDING		
Project Number (Principal Investigator) Source Title of Project (or Subproject)	Dates of Approved/Proposed Project Annual Direct Costs	Person Months (Cal/Academic/ Summer)
The major goals of this project are		

OVERLAP (summarized for each individual)

Samples

ANDERSON, R.R.

<u>ACTIVE</u>

2 R01 HL 00000-13 (Anderson) 3/1/1997 – 2/28/2002 3.60 calendar

NIH/NHLBI \$186,529

Chloride and Sodium Transport in Airway Epithelial Cells

The major goals of this project are to define the biochemistry of chloride and sodium transport in airway epithelial cells and clone the gene(s) involved in transport.

5 R01 HL 00000-07 (Baker) 4/1/1994 – 3/31/2002 1.20 calendar

NIH/NHLBI \$122.717

Ion Transport in Lungs

The major goal of this project is to study chloride and sodium transport in normal and diseased lungs.

R000 (Anderson) 9/1/1996 – 8/31/2002 1.20 calendar

Cystic Fibrosis Foundation \$43,123

Gene Transfer of CFTR to the Airway Epithelium

The major goals of this project are to identify and isolate airway epithelium progenitor cells and express human CFTR in airway epithelial cells.

PENDING

DCB 950000 (Anderson) 12/01/2002 – 11/30/2004 2.40 calendar

National Science Foundation \$82,163

Liposome Membrane Composition and Function

The major goals of this project are to define biochemical properties of liposome membrane components and maximize liposome uptake into cells.

D-13

OVERLAP

There is scientific overlap between aim 2 of NSF DCB 950000 and aim 4 of the application under consideration. If both are funded, the budgets will be adjusted appropriately in conjunction with agency staff

RICHARDS, L.

NONE

HERNANDEZ, M.

ACTIVE

5 R01 CA 00000-07 (Hernandez) 4/1/1995 – 3/31/2002 3.60 academic

NIH/NCI \$110,532

Gene Therapy for Small Cell Lung Carcinoma

The major goals of this project are to use viral strategies to express the normal p53 gene in human SCLC cell lines and to study the effect on growth and invasiveness of the lines.

5 P01 CA 00000-03 (Chen) 7/1/2000 – 6/30/2002 1.80 academic NIH/NCI \$104,428 (sub only) 3.00 summer

Mutations in p53 in Progression of Small Cell Lung Carcinoma

The major goals of this subproject are to define the p53 mutations in SCLC and their contribution to tumor progression and metastasis.

BE 00000 (Hernandez) 9/1/1996 – 8/31/2002 1.80 academic

American Cancer Society \$86,732

p53 Mutations in Breast Cancer

The major goals of this project are to define the spectrum of p53 mutations in human breast cancer samples and correlate the results with clinical outcome.

OVERLAP

Potential commitment overlap for Dr. Hernandez between 5 R01 CA 00000-07 and the application under consideration. If the application under consideration is funded with Dr. Hernandez committed at 3.60 person months, Dr. Hernandez will request approval to reduce her months on the NCI grant.

BENNETT, P.

ACTIVE

Investigator Award (Bennett) 9/1/1999 – 8/31/2002 9.00 calendar

Howard Hughes Medical Institute \$581,317

Gene Cloning and Targeting for Neurological Disease Genes

This award supports the PI's program to map and clone the gene(s) implicated in the development of Alzheimer's disease and to target expression of the cloned gene(s) to relevant cells.

OVERLAP: None

D-14

CDA TOC Substitute Page

Candidate (Last, first, middle):

Use this Table of Contents for Research Career Development Awards. Include candidate's name on each page.

RESEARCH CAREER DEVELOPMENT AWARD TABLE OF CONTENTS (Substitute Page)

Page Numbers

Letters of Reference* (attach unopened references to the Face Page)					
Basic Administrative Data					
Face Page (Form Page 1)		1			
Description, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors, and Human Embryonic Stem Cells (Form Page 2)					
Table of Contents (this CDA Substitute Form Page 3)					
Budget for Entire Proposed Period of Support (Form Page 5)					
Biographical Sketches (Candidate, Mentor[s],* Key Personnel and Other Signif—Biographical Sketch Format page) (Not to exceed four pages)					
Other Support Pages (for mentor(s)only)					
Resources (Resources Format page)					
Career Development Plan					
The Candidate					
Candidate's Background)				
Career Goals and Objectives: Scientific Biography	. (Items included in 25 page limit)	J			
Career Development/Training Activities during Award Period	<u>-</u>	ጎ			
Training in the Responsible Conduct of Research	J	L			
Statements by Mentor, Co-Mentor(s),* Consultant(s),* and Contributor(s)*					
Environment and Institutional Commitment to Candidate					
Description of Institutional Environment					
Institutional Commitment to Candidate's Research Career Development					
Research Plan					
1. Introduction to Resubmission Application* (Not to exceed 3 pages)					
2. Specific Aims]	ر			
3. Background and Significance	(Items 2-5 included in 25 page limit)	J			
4. Preliminary Studies/Progress Report		<u> </u>			
5. Research Design and Methods					
Inclusion Enrollment Report (Renewal or Revision Applications only)					
7. Bibliography and References Cited/Progress Report Publication List					
8. Protection of Human Subjects					
9. Inclusion of Women and Minorities					
10. Targeted/Planned Enrollment Table					
-	11. Inclusion of Children				
12. Vertebrate Animals		-			
13. Select Agents					
14. Multiple PD/PI Leadership Plan (Not applicable. Do not include.)					
15. Consortium/Contractual Arrangements*					
16. Letters of Support/Consultants		-			
17. Resource Sharing Plan(s)					
Checklist					
Appendix (Five identical CDs.)	Check if Appendix is included				
Note: Font and margin requirements must conform to limits provided in the Spe	ecitic Instructions.				
*Include these items only when applicable.					
CITIZENSHIP					
U.S. citizen or non-citizen national Permanent resident of U.S. (If a permanent resine notarized statement must be provided by the time					

Continuation Page