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Award Number: W81XWH-07-1-0261

TITLE: California's Parkinson's Disease Registry Pilot Project - Coordination Center

and Northern California Ascertainment

PRINCIPAL INVESTIGATOR: Caroline M. Tanner, M.D., Ph.D.

CONTRACTING ORGANIZATION: The Parkinson's Institute

Sunnyvale, CA 94085-2934

REPORT DATE: March 2011

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command

Fort Detrick, Maryland 21702-5012

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REPORT DOCUMENTATION PAGE					Form Approved OMB No. 0704-0188			
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Parkinson's disease (PD) registry in the state of California. This study is one of two linked research programs								
with the goals of establishing and using California PD registry data. The Parkinson's Institute was funded to								
serve as the coordinating center for the pilot project (including maintaining a secure data enclave), conduct								
ascertainment work in Santa Clara County and explore utilization of registry data. To date, approximately								
5,000 parkinsonism cases have been identified in Santa Clara County via legally mandated reporting sources,								
including physicians and health care facilities. With the majority of case-finding work accomplished, project								
effort is being directed to investigate possible associations between PD and toxicant exposure using state								
databases, to define disease prevalence and care patterns among registrants, and to assess the value of the								
registry to stakeholders.								
15. SUBJECT TERMS								
Parkinson's disease, disease registry, pilot feasibility study, toxicant exposures.								
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON			
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A. Introduction

This project consists of a pilot study conducted in partnership with the California Department of Public Health (CDPH) and the University of California-Los Angeles School of Public Health (UCLA) to implement a legally mandated statewide population-based Parkinson's disease (PD) registry in California to serve health surveillance and research aims. As the coordinating center for the surveillance activities, the Parkinson's Institute has achieved multiple milestones. including the development of data collection tools, staff training materials, a secure database, and policies and procedures for registry operations. Case ascertainment activities by the PI and UCLA have been underway in the four target counties in northern and southern California for more than two years with approximately 10,000 PD cases identified to date. As the database grows, we are applying systematic de-duplication procedures to ensure unique entries, validating registry content (i.e. confirmation of diagnosis and other qualifying criteria) and evaluating the quality and completeness of registry data using census, Medicare and death certificate data. Other analyses considered include assessing differences in PD prevalence and patterns of care across different groups, exploring associations between toxicant exposure and PD patterns utilizing state hazardous substances databases, determining the value of the registry to key stakeholder groups, and evaluating the cost of registry operation.

B. Body

The goals of this project are to conduct a feasibility study for the legally mandated California statewide population-based PD registry and utilize pilot registry data to explore trends in PD prevalence, patterns of care, possible relationship to the distribution of environmental toxicants, stakeholder priorities and cost efficiency of operations. This project is linked with a USAMRMC-funded project based at UCLA (Award Number W81XWH-07-1-0005, Principal Investigator: Beate Ritz), under which case ascertainment in Southern California and exploratory analyses are being performed.

The initial phase of this project focused on the establishment of a secure, high quality registry database, and launch of health surveillance activities, including active case ascertainment and clinical abstraction. This initial project phase encountered significant administrative and regulatory delays. As a result, we have requested and been granted a project extension (copy of request and approval attached) in order to be able to carry out the next phase of the project, which involves ongoing organization and compilation of data and initiating analyses.

C. Key Accomplishments

- 1. <u>Deputization status from the CDPH as designated agents for creation of a state registry:</u> Zero-dollar contracts between CDPH and PI were developed, and signed in October, 2007.
- 2. <u>Approval from Institutional Review Boards:</u> Human subjects research waivers for the initial surveillance-oriented work were obtained from the Army Medical Research and Materiel Command Office of Research Protections Human Research Protection Office, the State of California Committee for the Protection of Human Subjects (CPHS), the Kaiser Permanente Northern California Institutional Review Board and the UCLA Office for Protection of Research Subjects. CPHS has also authorized work to link registry data

- with Medicare data from the Center for Medicare and Medicaid Services (CMS), in order to evaluate the efficiency of the registry ascertainment methods utilizing capture-recapture analytic methods. A joint TPI-UCLA application to conduct exploratory analyses (evaluating diagnostic validity, linkage to toxicant databases, defining patterns of PD care) has been approved by CPHS.
- 3. Notification of case reporting sources and professional organizations of registry implementation, as required by the California Parkinson's Disease Registry Act: A formal notification letter was developed in conjunction with CDPH, and mailed on January 2008 to the state Medical Board and the Board of Pharmacy, professional organizations representing potential case reporting sources (pharmacists, physicians and health care facilities) and public health officers in the project target counties. Inquiries from reporting sources/organizations about the registry have been addressed via email, telephone and in public and scientific gatherings.
- 4. <u>Conduct outreach to stakeholders:</u> A public stakeholders' meeting was convened in March, 2006. A free-standing website (<u>www.capdregistry.org</u>) and email box were created and launched in March, 2008. Requests for information about the registry from patients, colleagues and the public have consistently been answered within several days of receipt. A public fact sheet and informational brochure were developed and have been utilized in mailings, at patient-oriented events and are also posted on the website.
- 5. Convene a Stakeholders' Advisory Committee: Under the direction of its leaders, Mr. Greg Wasson, Ms. Anne Wasson and Mr. Mark Siegel, a committee is acting to create a forum and network in which registry stakeholders can be informed of project activities, provide valuable input to the project and strategize about future funding and expansion opportunities for the registry. In addition, two new members, Dr. James Wong and Dr. Ronald Kobayashi have joined the committee. In the past year, a Stakeholder's Committee Teleconference meeting was conducted on March 9, 2010. Email communication was used otherwise to review project strategies and project output.
- 6. <u>Define case ascertainment strategies:</u> Investigators at the PI and UCLA initiated case ascertainment activities by approaching physician offices (neurology practices in particular), medical groups and large health care facilities, to enhance the willingness of these high-yield sources to cooperate with the reporting requirements.
- 7. <u>Creation of tools and instruments for data collection:</u> A data collection form and Microsoft Access database was developed and pilot-tested by staff (both physicians and non-physicians) at the PI. The form includes fields for obtaining information on basic demographics, key clinical parameters and characterization of data collection feasibility.
- 8. <u>Establishment of a secure registry database</u>: A secure, non-networked data repository was established in a dedicated room with access limited to trained project personnel.
- 9. Develop policies and procedures for ensuring data confidentiality, quality and appropriate use: Policies and procedures have been developed, together with staff training materials. TPI and UCLA project employees have attended group training sessions in September and October, 2008 and again in June and July of 2009. With the launch of field data collection in October, 2008, weekly conference calls have been held to keep all field staff updated on progress and the latest standard operating procedures on safe data collection/transmission and storage. In addition, all registry staff members are required to complete Information Security training in a yearly basis.

- 10. <u>Hiring and training staff:</u> Registry staff members have been hired and trained in communication with potential reporting sources, project security procedures, data collection and clinical abstraction. In addition, weekly conference calls between TPI and UCLA staff members and principal investigators have continued to keep all registry staff updated on progress and the latest standard operating procedures for field work and data safety.
- 11. Active case ascertainment and data collection in designated counties: The cumulative data collection accomplishments from October, 2008 through March 2011, are shown in the Reportable Outcomes section. The table shows the total number of patients reported to us as well as the total number of unique cases identified after systematic de-duplication procedures have been applied. All reported cases have basic identifying data and some demographic information available. Detailed clinical information has been collected directly from medical records on a random subsample of cases for diagnosis validation purposes.
- 12. <u>Development of systematic de-duplication procedures</u>: Because cases are being ascertained from multiple reporting sources, some cases are reported more than once. Utilizing the CDC's LinkPlus software platform, procedures have been developed to compare all new incoming data against existing registry data to identify duplicate cases in the database. This ensures a more accurate estimate of the cases within the designated reporting areas.
- 13. <u>Activation of voluntary patient self registration</u>: A mechanism for self registration has been established. Interested patients can print a registration form directly from the registry website (http://www.capdregistry.org/NewPatient.html).
- 14. <u>Application for external validation data</u>: Assessment of registry validity and ascertainment efficiency can be accomplished through linkage with external datasets listing Parkinson's disease cases. Applications have been filed for Medicare data with the University of Minnesota Research Data Assistance Center/CMS, and with the California Vital Statistics Advisory Committee/CPHS for death certificate data. Both applications have been approved and datasets have been received, however receipt of Medicare data from CMS was significantly delayed due to administrative barriers on the part of CMS. The Medicare dataset was recently obtained in February 2011 and work is now underway.
- 15. <u>Assessment of surveillance efficiency:</u> We have initiated collaborative planning with Dr. Lorene Nelson (Stanford University) for the capture-recapture analytic work to evaluate registry data collection efficiency. However, due to the unforeseen delays in receiving the Medicare data files, much of this work has been on hold until recently.

D. Reportable Outcomes

Number of Reported Cases, October 2008 - March 2011								
	Northern California Ascertainment (TPI)	Southern California Ascertainment (UCLA)						
County	Santa Clara	Fresno	Kern	Tulare	Total			
Total Population (Census) Population >65 (Census)	1,764,499 192,330	909,153	800,458 72,041	426,276 40,922	3,900,386			
Physicians Reporting	18	15	16	7	56			
Medical Groups and Facilities Reporting	6	5	7	6	24			
Total Patients Reported	5078	2145	1814	1587	10624			
Total Records w/ queries in progress*	-	1939	-	1413	3352			
Total Unique Patients Reported**	4413	76	623	131	5243			

^{*}Data records w/ queries under investigation

An abstract has been accepted by the American Academy of Neurology (AAN). A poster will be presented at the AAN meeting taking place April 9-16, 2001 in Honolulu, Hawaii. The poster will include information on the history and start-up of the surveillance project, as well as prevalence and demographic characteristics of registry PD cases.

E. Conclusions

Since our last annual progress report, most milestones in the project's primary specific aims, including developing methods for active ascertainment and registration of cases with PD and parkinsonism have been successfully achieved. Establishment of the registry now enables us to transition our effort to organizing the data and addressing the exploratory aims of the project which will utilize the registry data. Important next steps for the project include the following:

- 1. Ongoing data cleaning and application of systematic de-duplication methods to ensure unique entries in registry database from multiple reporting sources
- 2. Ongoing case ascertainment and clinical abstraction.
- 3. Review and rectification of discrepant diagnosis information reported for cases within and across data sources.

^{**}Unique cases after duplicates reported from multiple sources have been removed

- 4. Diagnosis validation comparing source-reported cases with detailed clinical information abstracted from medical records
- 5. Compile and summarize demographic characteristics of reported cases
- 6. Carry out capture-recapture validation analysis to assess the efficiency of data collection approaches using census, Medicare and California death certificate data.
- 7. Implement projects analyzing patterns of PD prevalence and care, and exploring the feasibility of assessing possible associations between toxicant exposure and PD.
- 8. With Stakeholders' Advisory Committee, continue outreach and assess stakeholders' priorities for the registry.
- 9. Conduct ongoing meetings with project staff at TPI and UCLA and convene Working Group and Stakeholder's Committee meetings, as necessary.

F. References

None.

G. Appendices

- 1. Abstract accepted by AAN
- 2. Project extension request letter and amendment/modification of contract (following pages) with a new project end date of February 28, 2013.

The California Parkinson's Disease Registry Pilot Project in Santa Clara County, CA

CM Tanner, SA Jewell, P English, M Siegel, DF Roucoux, G Wasson, AJ Wasson, SK Van Den Eeden, C Meng, K Comyns, K Albers, SM Goldman, LM Nelson, B Topol, J Bronstein, JW Langston, B Ritz

OBJECTIVE: To describe the characteristics of Parkinson's disease (PD) and identify the best methods for case ascertainment in Santa Clara County.

BACKGROUND: Population-based characteristics of PD are not well defined. In late 2004, California legislation (AB 2248) was passed making PD and parkinsonism reportable conditions in the state. A pilot project was initiated in 4 counties; results reported here are for one of those, Santa Clara County.

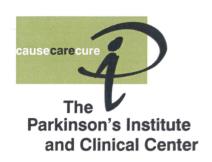
METHODS: Individuals with care service dates between 1/1/2006 and 7/1/2010 for one or more ICD-9 codes or diagnoses of interest (Parkinson's disease (332.0), secondary parkinsonism (332.1), other diseases of the basal ganglia (333.0), and dementia with Lewy body disease (LBD) (331.82)) were actively ascertained from medical facilities and physician practices in Santa Clara County. Age, race, ethnicity, sex, reporting physician, and diagnosis or service date were reported. About 5% of medical records were reviewed in detail.

RESULTS: 4,211 cases were reported, representing 3,632 unique individuals, from 17 individual physicians and 7 medical facilities or large groups. 72.8% of reported cases had PD, 6.4% parkinsonism, 2.8% secondary PD, 3.2% dementia with LBD, and 14.8% had more than one diagnosis. Estimated crude prevalence of PD in 2007 was 203.5 per 100,000 population. Cases of PD and parkinsonism had a mean age of 76.5 years and 76.8 years, respectively and were more likely to be male (55.6% PD, 56.4% parkinsonism) and White race (67.4% PD, 71.4% parkinsonism). 86.2% of cases were reported by medical facilities/large groups, 11.1% by individual physicians and 2.7% were reported from both.

CONCLUSIONS: Active ascertainment of PD is feasible when reporting is legally mandated. Recent legislation promoting national surveillance of PD and other neurological disorders (HR 1362) highlights the importance of these surveillance efforts. The concurrent tracking of environmental toxicants in California will allow for future assessment of risk factors.

Word Count = 300 of 300

Support: USAMRAA W81XWH-07-1-0261



Dana Herndon USAMRAA 820 Chandler Street Fort Detrick, MD 21702-5014

August 5, 2010

RE: Project Extension Request for Award Number: W81XWH-07-1-0261

TITLE: California's Parkinson's Disease Registry Pilot Project – Coordination Center and

Northern California Ascertainment

PRINCIPAL INVESTIGATOR: Caroline M. Tanner, MD, PhD.

Dear Ms. Herndon,

The Parkinson's Institute would like to request an extension of the period of performance concerning the above referenced grant for two years and supplemental funds in the amount of \$258,000. If granted, the revised project end date would be February 28, 2013. This extension is needed to complete the statement of work. We have encountered unexpected regulatory requirements which have delayed our work. We will also need to assume analytic tasks that the State of California Department of Public Health will no longer be able to perform. Despite these delays, much has been accomplished, and we fully anticipate achieving our project goals as originally envisioned.

The original and ongoing purpose of this project was to serve as the coordination center for the PD registry and ascertain cases in Santa Clara County. The Parkinson's Institute has made substantial progress towards these goals and continues to achieve milestones that satisfy the original aims of this project. Since active case ascertainment has begun, we have identified 6385 unique cases with parkinsonism and are continuing analysis of additional cases. We have received clearance to access Medicare data, which will allow us to assess the completeness of registry data. Although we expected to receive the Medicare files in early 2010, the data have not yet been received. Initiating this analysis will not be possible until the Medicare files are received. Following this, we will be able to assess differences in PD prevalence and patterns of care across different groups, explore possible associations between toxicant exposure and PD patterns and assess the efficiency of data collection approaches. These will be the first population-based data of this type for PD in the US.

To support the completion of the study goals during the extended period of performance, we request supplementary project funds of \$258,000 (\$173,972 direct, \$84,028 indirect at 48.3%), as detailed in the attached budget. This represents a 19% increase in the total award and is the minimum figure we could calculate to achieve the project goals.

Thank you for your continued support and consideration of this request. We are hopeful that we will be able to obtain a period of performance extension and additional funding to complete this very important work in California. If you have any questions regarding this matter, please contact Julia Roudabush at (408)542-5650 or by e-mail at jroudabush@thepi.org.

Sincerely,

Caroline M. Tanner, MD PhD

Cc: Stephen J. Grate, DVM

Program Manager, Neurotoxin Exposure Treatment Research Program Telemedicine and Advanced Technology Research Center (TATRC/MRMC)

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT				1. CONTRACT ID CODE		PAGE OF PAGES	
AMENDMENT OF SOLICITA	ATION/MODIF	ICATION OF CONTRACT		S		1 8	
2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.			5. PROJEC	T NO.(Ifapplicable)	
P00004	27-Feb-2011	SEE SCHEDULE					
6. ISSUED BY CODE	W81XWH	7. ADMINISTERED BY (If other than item 6)		COI	DE W81	XWH	
US ARMY MEDICAL RESEARCH ACQUISITION ACT		USA MED RESEARCH ACQ ACTIVITY ATTN: ELENA BANE					
DIRECTOR		301-619-6871					
820 CHANDLER STREET FORT DETRICK MD 21702-5014		ELENA.BANE@US.ARMY.MIL FORT DETRICK MD 21702-5014					
8. NAME AND ADDRESS OF CONTRACTOR PARKINSON'S INSTITUTE	(No., Street, County, S	State and Zip Code)		9A. AMENDM	ENT OF S	OLICITATION NO.	
675 ALMANOR AVE SUNNYVALE CA 94085-2934				9B. DATED (SI	EE ITEM 1	11)	
			X 10A. MOD. OF CONTRACT/ORDER NO. W81XWH-07-1-0261				
		10B. DATED (SEE ITEM 13) X 01-Mar-2007					
CODE 1VUD0	FACILITY COL			01-Mar-2007			
		PPLIES TO AMENDMENTS OF SOLIC	_				
The above numbered solicitation is amended as set forth	in Item 14. The hour and	date specified for receipt of Offer		is extended,	is not ext	ended.	
Offer must acknowledge receipt of this amendment prior	•						
(a) By completing Items 8 and 15, and returning	_ -	tt; (b) By acknowledging receipt of this amendme				;	
or (c) By separate letter or telegram which includes a re RECEIVED AT THE PLACE DESIGNATED FOR TH					IO BE		
REJECTION OF YOUR OFFER. If by virtue of this an	endment you desire to cha	nge an offer already submitted, such change may b	e ma	de by telegramor let	ter,		
provided each telegramor letter makes reference to the	solicitation and this amend	ment, and is received prior to the opening hour a	nd da	ate specified.			
12. ACCOUNTING AND APPROPRIATION DA	ATA (If required)						
See Schedule							
		O MODIFICATIONS OF CONTRACTS					
A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.							
B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(B).							
C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:							
X D. OTHER (Specify type of modification and	authority)						
Mutual Agreement - See Recipient's Itr and GOR Approval dtd 8/5/2010.							
E. IMPORTANT: Contractor X is not,	is required to sig	n this document and return	cop	oies to the issuing	g office.		
14. DESCRIPTION OF AMENDMENT/MODIFI	CATION (Organized	by UCF section headings, including solic	itati	on/contract subj	ect matter		
where feasible.)	277						
Modification Control Number: ebane1112277 The Durages of this Modification is to extend the period of performance from 31 March 2011 to 31 March 2013 (Research and 29 Esh 2013)							
The Purpose of this Modification is to extend the period of performance from 31 March 2011 to 31 March 2013 (Research ends 28 Feb 2013) and to add funds in the amount of \$258,000.00 to complete the pilot study for the Parkinson's disease California registry, in accordance with							
supplemental SOW dated 1/14/2011.							
Total Grant Award and funded amount: \$1,613,813.00							
See SUMMARY of CHANGES							
Except as provided herein, all terms and conditions of the do	ocument referenced in Item	9A or 10A, as heretofore changed remains unchar	ged -	and in full force and	effect		
15A. NAME AND TITLE OF SIGNER (Type or			_			e or print)	
1372 TANIE AND TITLE OF SIGNER (Type of	PAMELA NEVELS / ACCOUNT MANAGER	ME AND TITLE OF CONTRACTING OFFICER (Type or print) vels/account manager					
		TEL: 301-619-8802		EMAIL: pamela.nev	els@us.army.r	mil	
15B. CONTRACT OR/OFFEROR	15C. DATE SIGNEI	1 1 12 12 12			I .	6C. DATE SIGNED	
(C:						04-Feb-2011	
(Signature of person authorized to sign)	1	(Signature of Contracting Of	ııcer)	1		

SECTION SF 30 BLOCK 14 CONTINUATION PAGE

SUMMARY OF CHANGES

SECTION 00010 - SOLICITATION CONTRACT FORM

The total cost of this contract was increased by \$258,000.00 from \$1,355,816.00 to \$1,613,816.00. The 'administered by' organization has changed from

USA MED RESEARCH ACQ ACTIVITY ATTN: DANA HERNDON 301-619-7140 DANA.HERNDON@US.ARMY.MIL FORT DETRICK MD 21702 to USA MED RESEARCH ACQ ACTIVITY ATTN: ELENA BANE 301-619-6871 ELENA.BANE@US.ARMY.MIL FORT DETRICK MD 21702-5014

The contractor organization has changed from

THE PARKINSONS INSTITUTE 1170 MORSE AVENUE SUNNYVALE CA 94089-1605 to PARKINSON'S INSTITUTE 675 ALMANOR AVE SUNNYVALE CA 94085-2934

CLIN 0001

The CLIN extended description has changed from Period of Performance: 1 March 2007 to 31 March 2009 (Research ends 28 February 2009) to Period of Performance: 1 March 2007 to 31 March 2013 (Research ends 28 February 2013).

The estimated/max cost has increased by \$258,000.00 from \$1,355,816.00 to \$1,613,816.00. The total cost of this line item has increased by \$258,000.00 from \$1,355,816.00 to \$1,613,816.00.

SUBCLIN 000102 is added as follows:

W90ERG

ITEM NO SUPPLIES/SERVICES QUANTITY UNIT UNIT PRICE AMOUNT 000102 \$0.00

Supplemental Funding for CLIN 0001

COST

Mod P00004 to incorporate supplemental SOW dated 1/14/2011, Pilot Study for

PD California Registry

FOB: Destination

MILSTRIP: W23RYX0347N602

PURCHASE REQUEST NUMBER: W23RYX0347N602

ESTIMATED COST \$0.00

ACRN AC \$258,000.00

CIN: W23RYX0347N6020001

DELIVERIES AND PERFORMANCE

The following Delivery Schedule item for CLIN 0001 has been changed from:

DELIVERY DATE QUANTITY SHIP TO ADDRESS UIC

POP 01-MAR-2007 TO N/A USA MED RESEARCH AND MATERIEL W23RYX 31-MAR-2011 COM

JUANITA LIVINGSTON 504 SCOTT STREET

FORT DETRICK MD 21702-5012

FOB: Destination

To:

DELIVERY DATE QUANTITY SHIP TO ADDRESS UIC

POP 01-MAR-2007 TO N/A USA MED RESEARCH MAT CMD

31-MAR-2013 TMED AND ADV TECH RSRCH CTR

TATRC

504 SCOTT STREET

FORT DETRICK MD 21702-5012

FOB: Destination

INSPECTION AND ACCEPTANCE

The following Acceptance/Inspection Schedule was added for SUBCLIN 000102:

INSPECT AT INSPECT BY ACCEPT AT ACCEPT BY N/A N/A Government

The following have been modified: