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14. ABSTRACT This registry initiates a program of epidemiological assessments of PS among Alaska Native people to study the natural history and clinical management of PS, and establishes a database of Alaska native people with PS for public health, research and educational purposes. As feasible, the prevalence of PS in Alaska Native people may be estimated as well. This registry not only will facilitate future research into PS etiology, but also guide health care planning and community education efforts in this population. The proposal takes advantage of a case control study of PS that is ongoing in the same population. The registry was designed in two phases. Phase 1 is a developmental period and is well underway at this time. During this phase, we established the data collection and dissemination protocols and developed a surveillance protocol that received IRB approval. The electronic registry database is complete, surveillance has begun in Anchorage. Phase 2 has just begun in Southeast AK where tribal board approval was recently obtained. Phase 2 is a period of educational outreach and active statewide data collection on prevalent and incident cases of PS. After Phase 2 ends, the registry will be sustained through the Alaska Native Medical Center.					
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A. Introduction

Parkinsonism (PS) is a syndrome characterized by tremor, rigidity, slowness of movement, and problems with walking and balance. Parkinson's disease is the most common form of PS, accounting for about 1% of the U.S. population over age 50 years. Little information is available about trends in PS, particularly in Alaska Native people.

This registry initiates a program of epidemiological assessments of PS among Alaska Native people to study the natural history and clinical management of PS, and establishes a database of Alaska Native people with PS for public health, research and educational purposes. As feasible, the prevalence of PS in Alaska Native people may be estimated as well. This registry will not only facilitate future research into PS etiology, but will also guide health care planning and community education efforts in this population. The proposal takes advantage of a case control study of PS that is commencing in the same population.

The registry is designed in two phases. Phase 1 is complete in Anchorage. During phase 1, data collection and dissemination protocols were established, necessary approvals for the registry were obtained, and surveillance began in Anchorage. Phase 2 is a period of educational outreach and active statewide data collection on prevalent and incident cases of PS. Phase 2 is currently ongoing.

B. Body

A transfer of the registry project from the AK Native Tribal Health Consortium to the Parkinson's Institute was initiated June 23, 2011 and finalized August 25, 2011. The aims of this project are:

Specific Aim 1: Identify cases of parkinsonism among Alaska Native people and populate a secure electronic registry database.

Specific Aim 2: Provide education on parkinsonism and its treatment to primary care physicians and other health care providers.

SCOPE OF WORK

The funding provides personnel and travel support to initiate and populate the registry in Anchorage and regions outside of Anchorage.

Data collection and registry population was initiated in Anchorage immediately after all regulatory approvals for Anchorage were obtained. The work underway to populate the registry in Anchorage and regions outside of Anchorage is as follows:

Specific Aim 1: Identify cases of parkinsonism among Alaska Native people and populate a secure electronic registry database. To achieve this aim in a) Anchorage and b) regions outside of Anchorage, the following tasks will be accomplished.

a) Population of registry database in Anchorage

Task 1 – Obtain and submit to the AK Area Institutional Review Board (AAIRB) the SouthCentral Foundation (SCF) privacy consult approval. This is the last known contingency to meet the AAIRB approval requirements.

Task 2—Obtain AAIRB approval for the registry surveillance protocol.

Task 3 - Submit the AAIRB approved surveillance protocol to the Western Institutional Review Board, the IRB for the Parkinson's Institute, for approval.

Task 4— Submit all approval documents to initiate the registry in Anchorage to the U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office.

Milestone: Fulfill the remaining regulatory requirements to initiate population of the registry in the Anchorage service unit. **Status:** Complete. The surveillance protocol was approved by the AK Area IRB, the 2 tribal boards in Anchorage, and their respective privacy officers. The protocol was then approved by Western Institutional Review Board, the IRB providing oversight for the Parkinson's Institute coordination of the project. Upon approval by Western Institutional Review Board, all approval documents were submitted to and approved by the U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office. We then initiated population of the registry in the Anchorage service unit. To date, 48 cases of PD have been abstracted into the surveillance database in Anchorage.

b) Population of registry database in regions outside of Anchorage

Task 1 – Prepare written requests for approval to initiate the registry to regional tribal boards that regulate research outside of Anchorage.

Milestone: Submit regional tribal board requests. **Status:** This activity is well underway. We have submitted to 9 of the 10 regional tribal boards outside of the Anchorage service unit. The full status of those submissions and approvals is summarized in Section G of this report.

Task 2 – Travel to each region outside of Anchorage to conduct an in-person presentation describing the registry project to the convened tribal board reviewing the project, or participate in the convened tribal board meetings via conference call. Once approval is obtained, meet annual reporting requirements as required by each region. If approval is not initially obtained, address concerns and submit modifications/clarifications until approval is obtained.

Milestone: Obtain approval from tribal boards to populate the registry in regions outside of Anchorage. **Status:** We continue to have ongoing discussions with medical staff and representatives of the statewide tribal boards to familiarize them with the

registry project. In order to maximize cost-effectiveness, this effort is spearheaded by co-investigator Dr. Brian Trimble during his routine statewide neurology field visits to regional clinics and when possible, during travel related to the ongoing case control study of PS.

Task 3 – Travel to rural and hub clinics to abstract medical records and populate the registry with data from regions outside of Anchorage.

Milestone: Initiate travel for data collection to regions outside of Anchorage. **Status:** Data collection/abstraction will be initiated September 12, 2013 in the areas covered by the Southeast Area Regional Health Consortium, the first regional tribal board to document their approval of this project. As we receive approval from additional regional tribal boards, data collection/abstraction will be initiated in those regions.

Task 4 – Prepare registry data from Anchorage and regions outside of Anchorage for dissemination and publication.

Milestone: Registry data will be prepared for dissemination and publication for Anchorage and regions outside of Anchorage. **Status:** This activity is pending tasks outlined above.

Task 5 – Submit all publication proposals to the Anchorage based review committee and regional tribal boards outside of Anchorage for approval to publically disseminate summaries and/or findings.

Milestone: Proposals for public dissemination of registry data summaries and/or findings will be approved in Anchorage and regions outside of Anchorage. **Status:** This activity is pending tasks outlined above.

Task 6 – Submit approved registry findings and manuscripts to tribal organizations, conferences and journals for publication.

Milestone: Dissemination and publication of approved registry findings from Anchorage and regions outside of Anchorage. **Status:** This activity is pending tasks outlined above.

Specific Aim 2: Provide education on parkinsonism and its treatment to primary care physicians and other health care providers.

Task 1: Leverage the time spent in Anchorage and the regions while obtaining approvals and abstracting data by presenting medical education seminars to health care providers.

Milestone: Investigators will present Parkinson's disease-related education seminars in each of the regional clinics and at the Alaska Native Medical Center in Anchorage.

Status: General Parkinson's disease educational presentations and presentations qualifying for Continuing Medical Education credits have been presented and will continue during the Neurology field clinic visits and at Anchorage facilities.

C. Key Research Accomplishments

- Achieved approval for the surveillance protocol from Western Institutional Review Board and U.S. Army Medical Research and Materiel Command, Office of Research Protections, Human Research Protection Office.
- Initiated population of the registry in the Anchorage service unit. To date, 48 cases of PD have been abstracted into the surveillance database in Anchorage.
- The surveillance protocol was submitted to 9 regional tribal boards
- Investigators presented an educational seminar in Juneau, AK for local clinicians and tribal board representatives which lead to the successful approval of the surveillance protocol by the Southeast Area Regional Health Consortium.

D. Reportable Outcomes

The Parkinson's Institute is leading the effort in obtaining approvals necessary to begin data collection and population of the registry database statewide. Until statewide data has been collected, we will not have reportable outcomes.

E. Conclusions

This project is well underway. We have succeeded in developing the surveillance database, and we have made significant progress toward obtaining regulatory approval. We obtained all regulatory approvals to allow us to initiate database population in Anchorage, and are phasing in regional sites on a continuing basis as individual tribal board approvals are received. Following the completion of statewide data collection and analysis, we will summarize and report scientific data pursuant to study aims and deliverables.

F. References

None

G. Appendices - Alaska Native PS Registry IRBs and Tribal Boards

Table 1. Institutional Review Boards

Institution	Review Board	Status
Alaska Native Medical Center	AK Area IRB	Approved
Parkinson's Institute	Western Institutional Review Board (WIRB)	Approved
US Army Medical Research and Material Command	Office of Research Protections	Approved

Anchorage basin Tribal Board submissions completed:

1. Southcentral Foundation (SCF) (Anchorage) - APPROVED
2. Alaska Native Tribal Health Consortium (ANTHC) (Anchorage) - APPROVED

Regional Tribal board submissions in the following regions:

1. Southeast Alaska Regional Health Corp - APPROVED
2. Metlakatla Indian Community - SUBMITTED
3. Ketchikan Indian Corp – SUBMITTED
4. Tanana Chiefs Conference - SUBMITTED
5. Arctic Slope Native Assoc - SUBMITTED
6. Maniilaq Association - SUBMITTED
7. Norton Sound Health Corp - SUBMITTED
8. Yukon-Kuskokwim Health Corp - PENDING
9. Bristol Bay Area Health Corp – SUBMITTED
10. Kodiak Area Native Assoc - SUBMITTED