Supporting Statement of the Request for OMB Review and Approval of Promotion of the National Amyotrophic Lateral Sclerosis (ALS) Registry to Non-referral Centers

0923-NEW

(Part B: Justification)

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B. Collection of Information Employing Statistical Methods

This project will employ varying statistical methods for the purpose of sampling respondents and analyzing data for the different types of project activities as described below.

Project Component Process Evaluation
Counts of the number of phone calls, faxes, and mailing pieces will be described. The Continuing Medical Education registration and completion rates will be reviewed to identify any increases that could be attributed to the CME flier included in the mailing.

Registry Self-enrollment
To analyze the change in registry self-enrollment, enrollment rates will be compared between Groups 1, 2, 3, and 4 (comparison group). The comparison group will be utilized to control possible threats to internal validity of this study design, as this will help to evaluate any natural history effects of other Registry promotion activities. Neurologists in the 44 states in Group 4 will not be contacted. Persons with ALS self-enrollment rates in Group 4 will be monitored for comparison and statistical purposes on a monthly basis. Descriptive statistics will be used to describe the differences, if any, between and among the four groups. This information will be used to describe changes in Registry enrollment rates.

Key Informant Interview (KII)
The KII transcripts will be analyzed looking for common themes or categories across the interviewee's responses. Established methods for analyzing focus group data will be used, including exploring the frequency, extensiveness, intensity, and consistency of responses. For example, reliability analysis will focus on the consistency of responses among the participants and concordance rates among the independent assessments of different observers (the two Program Coordinators). Examining the pattern of responses is important in determining the generalizability of the data. Consistency and responses suggest that factors may be generalizable across all neurologists with similar characteristics or circumstances and not simply any idiosyncratic viewpoint or alternatively whether that concept is worth further exploration. While other themes might emerge from the data, the project team anticipates summarizing responses according to the themes outlined in the KII interview guide. A manuscript of the results of the KIIs will characterize the overall themes and subthemes with de-identified quotations, where appropriate.

1. Respondent Universe and Sampling Methods

Selection of State Sites
The respondent universe for project will include the state sites selected to participate in Group 1 **(**refer to table 1) previously participated in the ALS Surveillance Projects. Existing relationships with providers in the Group 1 states will be leveraged and a possible bias exists; therefore Group 2 and 3 will include two state sites that did not participate in Surveillance Projects. Groups 2 and 3 will each include two states that have current enrollment rates in the National ALS Registry, geographic make-up, and demographic distributions similar to the Group 1 state sites (as further described below and in Table 1). Group 4 will serve as a comparison group (include remaining 44 states), and will not receive any outreach materials or phone calls.

To select the participating states in Groups 2 and 3, a combination of state population, demographic distributions, and previous Surveillance Project participation were considered. Utilizing the 2013 American Community Survey (http://factfinder.census.gov/faces/nav/jsf/pages/index.xhtml) population estimates for all states were ranked from highest to lowest population. California (ranked 1), Texas (ranked 2), Illinois (ranked 5), Pennsylvania (ranked 6), Georgia (ranked 8), Michigan (ranked 9),

Maryland (ranked 19), and Nevada (ranked 35) were not eligible to participate based on previous participation in Surveillance Projects.

Table 1: Demographic Characteristics of Selected State Sites*

	Group 1		**Group 2**		**Group 3**	
	FL	**NJ**	**NY**	**VA**	**OH**	**WA**
Total Population	19,552,860	8,899,339	19,651,127	8,260,405	11,570,808	6,971,406
Rank of Population Compared with Other States	4	11	3	12	7	13
% Male	48.9%	48.8%	48.5%	49.2%	48.9%	49.9%
% Over Age 60 Years	24.7%	20.1%	20.2%	19.1%	21.4%	19.8%
% White	76.2%	68.2%	64.6%	69.3%	82.5%	78.0%
% Black/African American	16.1%	13.7%	15.7%	19.3%	12.1%	3.7%

** Data from 2013 American Community Survey*

Group 1: Florida (FL) and New Jersey (NJ), two states that participated in the Surveillance Projects, are selected as the Group 1 state sites because the highest percentage of expected cases were collected in these states during the Surveillance Projects.

Group 2: New York (NY) and Virginia (VA) are the two states selected as the Group 2 state sites. These states have Registry self-enrollment rates similar to that of FL and NJ. In addition the population sizes, percentage of population over the age of 60, and percentage of minorities is similar to the Group 1 state sites.

Group 3: Ohio (OH) and Washington (WA) are the two states selected as the Group 3 state sites. These states have Registry self-enrollment rates similar to that of FL and NJ. In addition the population sizes, percentage of population over the age of 60, and percentage of minorities is similar to the Group 1 state sites.

Train-the-trainer (TTT) Sampling Frame
Neurologists in Group 1 (Florida and New Jersey) that currently or would diagnose and/or care for ALS patients will be eligible for a TTT session (**Appendix L1**). A cluster sampling technique will be used to select a sample of 5-15% of these neurologists. Florida has been divided into four geographic regions (Panhandle, North, Central, and South) and each neurologist will be placed into one of these regions based on their main practice location's county. In NJ, practices will be placed into one of three geographic regions (North, Central, and South) based on primary practice location's county. For further details of the sampling frame see page 14 of the Protocol (**Attachment 5**).

Key Informant Interview (KII) Sampling Frame
Neurologists in Group 1 (Florida and New Jersey) that currently or would diagnose and/or care for ALS patients in FL and NJ will be eligible for the key informant interview site visits. The same regionalized cluster sampling technique used to identify practices for the train-the-trainer will be utilized to determine a sample of 12-16 neurologists in both FL and NJ for a total of 24-32 KIIs. Neurologists that participated in the TTT are eligible to be selected for the KII. Typically qualitative research does not begin with an a priori hypothesis or predefined sample size, as is the case on most quantitative studies of a priori hypotheses. In qualitative research, "small purposeful samples are ideally suited to qualitative inquiry."[1]

This sample size was selected to provide adequate responses to reach saturation.

Neurologists in Groups 2 and 3 will not be eligible for a KII.

2. Procedures for the Collection of Information

Initial Phone Call to Determine Provider Status
For Groups 1 & 2, a trained project team member will conduct a six minute phone call using a checklist (**Appendix A**). These calls will classify neurologists either "Yes", "No, But Would", or "No" in regards to their diagnosis and/or care of persons with ALS. Any neurologist that reports currently diagnosing and/or caring for at least one person with ALS will be classified as a "Yes" provider. Those neurologists that report not currently diagnosing and/or caring for persons with ALS, but would if one presented will be classified as "No, But Would" provider. All other neurologists will be classified as "No" providers

During the initial phone call, practice name, all neurologists at the practice, and practice contact information will be confirmed. Neurologists' provider status group will be identified, as well as the number of persons with ALS seen annually by the neurologist(s) at each practice. A point of contact for the practice will be identified. Based on the response to the question about number of patients seen annually, each practice will be categorized for groups for the number of recruitment materials they will be mailed. For more details, refer to page 10 of the protocol (**Attachment 5).**

Follow-up phone call #1
For Groups 1 & 2, a trained project staff member will conduct phone calls using a checklist (**Appendix D**). These calls will determine if the mailing was received. Group 3 will not receive this phone call.

Follow-up phone call #2
For Groups 1 & 2, a trained project staff member will conduct phone calls using a checklist (**Appendix H**). These calls will determine if the mailing was received and if neurologists are promoting the Registry. Group three will not receive this phone call. For more details, refer to page 13 of the protocol (**Attachment 5**).

KII Site Visits
The purpose of the KIIs is to better understand neurologists' knowledge, attitudes, and beliefs about the Registry, and to gather additional information about the currently deployed Registry materials. KIIs will follow a semi-structured interview guide. KIIs will be digitally recorded and later transcribed. Once a neurologist is selected, a Participant Invitation Letter (**Appendix N**) and KII Informed Consent Form (**Appendix O**) will be sent to the neurologist and a project staff member will contact via phone (**Appendix P**) the neurologist to determine if the neurologist will participate. If a neurologist refuses to participate a replacement neurologist from that region will be randomly selected. Program Coordinators will identify a mutually agreeable day/time to conduct the KII site visit at the primary practice location. Information will be stored in a spreadsheet. A Participant Confirmation Letter (**Appendix Q**) will be sent to the neurologist, with a copy also sent to the point of contact. The letter will include a reminder of the purpose of the KII, the day, time, and location of the KII, and the interviewer's contact information. See page 15 of the protocol (**Attachment 5**) for further information.

Consent will be obtained prior to the commencement of the interview. For the key informant interviews, transcripts reviewed by two team members. Information will be clarified during the interview as needed; no respondents will be re-contacted during the quality assessment/quality control processing of the transcripts. The information collected will be stored in a spreadsheet.

3. Methods to Maximize Response Rates and Deal with Non-response

In order to identify neurologists who are eligible for the project we will implement a proven methodology similar to that used during the ALS Surveillance Projects to identify non-referral/center neurologists in Groups 1, 2, and 3. Further, methods that were employed in the Surveillance Projects to discern whether neurologists do or would diagnose and/or care for ALS patients will be replicated in Groups 1 and 2. Based on the Surveillance Projects, we expect a response rate over 90% for the initial phone calls and follow-up phone calls. Project staff will make up to five attempts to complete the initial and follow up phone calls with supplemental faxes to increase the response rate. Because no information is collected during unsuccessful attempts, only successful contacts will be counted toward burden. All neurologists meeting project criteria will be contacted during the initial and follow-up phone calls.

We expect a 90% participation rate for the TTT and KII. The project team will coordinate with the neurologists to determine a day and time that is most convenient for them for the TTT and KII. The project team will travel to the neurologists' offices to conduct the TTT and KII. If a neurologist refuses to participate in the TTT or KII, a replacement neurologist from the same region of the refusal region will be randomly selected. The project has a letter of support from ATSDR that will be including with all mailings. Selected neurologists will be encouraged to participate in the TTT and KII through recruitment letters explaining the benefits of the Registry. To assist with the completing the KIIs, a token of appreciation will be available to neurologists in the amount of $100.

The decision to include $100 for completing the KII was based on the successful reporting in the Surveillance Projects (OMB No. 0923-0043, Expiration Date 04/30/14). Very few neurologists declined compensation for a form that averaged 15 minutes to complete during the Surveillance Projects. Finally, the typical hourly salary for a neurologist is $105.22 and we are asking for 90 minutes of their time to complete the KII. For more details, refer to pages 15 and 16 of the protocol (**Attachment 5**).

Neurologists will be selected for the KII and TTT using a stratified (by geographic location) sampling technique. This will ensure a representative sample across each state will be selected. This method was chosen due to the heterogeneity of neurologists in different regions across states.

All phone calls, TTT sessions and KII interviews will be completed by a trained project team member.

4. Tests of Procedures or Methods to be Undertaken

The methods used for recruitment and eligibility determination have been previously undertaken, tested and proven successful in the Surveillance Projects. Staff will practice these phone calls again beforehand.

Project staff will practice the TTT to ensure the session can be completed in 30 minutes, with 30 additional minutes available for recruitment and Q&A. In addition, project staff will practice the KII to ensure the interview can be complete in 60 minutes. No further procedures or methods are needed at this time.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Individuals consulted on statistical aspects:

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