SUPPORTING STATEMENT FOR 2900-0649
VA COOPERATIVE STUDIES PROJECT NUMBER 500A, NATIONAL REGISTRY OF VETERANS WITH AMYOTROPHIC LATERAL SCLEROSIS (ALS)
VA FORMS OF THE 10-21047 SERIES

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

1. Provide a numerical estimate of the potential respondent universe and describe any sampling or other respondent selection method to be used. Data on the number of entities (e.g., households or persons) in the universe and the corresponding sample are to be provided in tabular format for the universe as a whole and for each strata. Indicate expected response rates. If this has been conducted previously include actual response rates achieved.

The Potential Respondent Universe includes all living veterans with ALS.

***Prevalence*.** The expected annual prevalence of ALS is 5-9 per 100,000 persons. Extrapolating to the population of U.S. veterans (25,349,000 in FY 2001), we expected a prevalence of 1,270-2,280. We have also used VA outpatient data to estimate a more specific prevalence of ALS among veterans. During FY 2001, there were 1,417 veterans with an ICD-9 code of 335.20 (ALS). There are known limitations to using this ICD-9 code to ascertain cases of ALS. Specifically, a false positive rate of 19% has been documented. During previous studies on Gulf War Veterans, approximately 40% of verified cases of ALS were identified via sources other than VA records (i.e., no ALS-related ICD-9 code was found in inpatient or outpatient databases). Using this information, we estimated 1,800 prevalent ALS cases at any time. This estimated prevalence falls approximately in the middle of the expected prevalence (1,270-2,280) in a population the size of all U.S. veterans.

Incidence. The expected incidence of ALS within the general population is 1-2 per 100,000 persons per year. Extrapolating to the population of U.S. veterans, we would expect the annual incidence of ALS to be approximately 450. However, some of these veterans are already enrolled in the Registry, and we have adjusted our projections accordingly.

Expected Response Rates. Estimated response rates are based on prior years of the study. Specifically, of those screened, about 50% were eligible and consented to participate. We anticipate response rates will be similar for succeeding years of the project.

2. Describe the procedures for the collection of information, including:

- **Statistical methodology for stratification and sample selection**
- **Estimation procedure**
- **Degree of accuracy needed**
- **Unusual problems requiring specialized sampling procedures**
- **Any use of less frequent than annual data collection to reduce burden**

All living veterans with ALS will be sought for participation. There are no sampling procedures or stratification. Patients are identified through a variety of commonly used methods in clinical research. The two primary means of identification of participants are: 1.) Use of VA medical databases to identify patients with ALS diagnoses and 2.) A nation-wide solicitation for veterans with ALS, publicized through various ALS and veterans organizations. Once individuals are identified, a thorough review of medical records is conducted to accurately determine whether an individual is

eligible for the ALS registry. Baseline and biannual assessments are administered to all individuals who are eligible for the registry. Biannual follow-up was selected because of the rapidly progressive nature of ALS.

3. Describe methods to maximize response rate and to deal with issues of non-response. The accuracy and reliability of information collected must be shown to be adequate for intended uses. For collections based on sampling, a special justification must be provided for any collection that will not yield "reliable" data that can be generalized to the universe studied.

The baseline and biannual assessments are conducted by telephone and are brief. While it is important to periodically assess the health status of registry participants, interviews are purposely kept short to minimize respondent burden and maximize response rates. All interviews are approximately thirty minutes long and are scheduled at the participants' convenience. For follow-up interviews, as many attempts as necessary are made to contact the participant. During the screening questionnaire, contact information for another friend/family member who lives at another residence but who will always know how to reach the participant (i.e., in case of a move) is obtained. By collecting this information, the ability to maintain contact with participants is enhanced. To date, less than 1% of participants have been "lost-to follow-up" (i.e., could not be contacted) or withdrew.

4. Describe any tests of procedures or methods to be undertaken. Testing is encouraged as an effective means of refining collections to minimize burden and improve utility. Tests must be approved if they call for answers to identical questions of 10 or more individuals.

Main components of the telephone interviews are military history questions (established and required by the Department of Veterans Affairs Cooperative Studies Program) and the ALS Functional Rating Scale (ALSFRS). The ALSFRS is a validated scale and is the most frequently used functional rating instrument in studies of ALS patients. Studies have shown the ALSFRS correlates well with objective measures of strength and pulmonary function, has high internal consistency and test-retest reliability, and shows sensitivity to change in health status.

5. Provide the name and telephone number of individuals consulted on statistical aspects of the design and the name of the agency unit, contractor(s), grantee(s), or other person(s) who will actually collect and/or analyze the information for the agency.

Cynthia Coffman, PhD and Jennifer H. Lindquist, MS were consulted on statistical aspects of the registry design. Dr. Coffman and Ms. Lindquist are both statisticians at the Epidemiologic Research and Information Center at the Durham VA Medical Center. Both of these individuals are permanent members of the Registry team and will be responsible for any statistical analyses conducted throughout this project. The primary data collection site will be the Durham VA Medical Center. Ms. Barbara Norman will be the primary person responsible for data collection, under the direction of Dr. Eugene Z. Oddone, the principal investigator. All of the above individuals can be reached at the following address:

ERIC (152)
VA Medical Center
508 Fulton Street
Durham, NC 27705
919-286-6936