

June 6, 2024

Change Request for OMB #0923-0041: National Amyotrophic Lateral Sclerosis (ALS) Registry

Justification/Brief Explanation for the Change Request

This is a nonmaterial/non-substantive change request for the National ALS Registry (OMB Control No. 0923-0041 (expiration date: May 31, 2026)).

We are requesting OMB approval to update the current consent form to include language for collaboration to federal interagency data exchange between the NIH (ALL ALS) group and the National ALS Registry. Modifications have been Appendix D: Consent Form in track changes and clean. Congress has passed Public Law 117-79, Accelerating Access to Critical Therapies for ALS Act, which tasks the Department of Health and Human Services (HHS) to award grants to eligible entities for scientific research utilizing data from expanded access to investigational ALS treatments for individuals who are not otherwise eligible for clinical trials. The National Institutes of Health (NIH) issued a grant to two institutions, referred to as ALL ALS, to establish a comprehensive network of 34 ALS clinics around the country that will enroll current and newly diagnosed patients in order fulfill this objective. The National ALS Registry, established by Public Law 110-73, ALS Registry Act, tasks the Centers for Disease Control and Prevention (CDC) to determine the epidemiology of ALS as well as the identification of risk factors and possible etiologies. Both of these Congressional mandated programs will allow researchers to better understand and identify mechanisms of disease progression, genetics, and possible treatments. NIH's ALL ALS will be updating their consent forms to allow the sharing of patient information with the CDC's National ALS Registry. The sharing of data will be voluntary. The Registry in turn will update their own consent form to share patient data with the NIH. Data sharing will be voluntary. The benefits of data sharing are multifold. First, this will allow the capture of cases from both systems to ensure maximum catchment as well as reduction of duplicative cases and reduce patient burden by enrolling in a single system. This will also reduce overall public burden for the ALS community.

Additionally, the National ALS Registry (Registry) is proposing the launch of a pilot incentives project. The Agency for Toxic Substance and Disease Registry (ATSDR) endeavors to improve the completeness, representativeness, and accuracy of the Registry data over time. Enrollment rates for those self-enrolling in the Registry have been lower than expected based on census and prevalence data estimates. Thus, a small incentive will help increase enrollment and participation in the risk factor surveys. The goal of the incentive pilot project will be measured in two parts. The first goal is to increase participation in the Registry. The second goal is to improve risk factor survey completion rates for all 18 surveys. Because the incentive will be provided in two parts, this will incentivize individuals who have registered to also complete risk factor surveys. This pilot will assess the benefits of providing a small monetary incentive on the enrollment and survey completion rates for the Registry. This pilot project proposal, along with the sign-up form is being added as a new appendix (Appendix U and U2 - New).

These changes have been approved by IRB for the protocol for the National ALS Registry. The overall number of respondents and requested burden hours remain the same for the Registry program.

SUPPLEMENTAL DOCUMENTS

National ALS Registry – Consent Form – Update

Appendix D- Consent Form – track changes

Appendix D – Consent Form – clean

CDC/ATSDR National ALS Registry Incentives Pilot Project

Appendix U - Proposal for National ALS Registry Incentives Pilot Project

Appendix U2 - Incentive Project - Sign Up Form

SSA National ALS Registry - track

SSA National ALS Registry - clean