

July 19, 2021

## **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: January 31, 2023)).

We are requesting OMB approval to update prices for postmortem specimens from the National ALS Part C- National ALS Biorepository Postmortem Sample Request Form as part of the National Amyotrophic Lateral Sclerosis (ALS) Registry Research Application Form. There are two types of updates. First, the revised form will incorporate tissue types and prices that were inadvertently omitted from the original form. The ALS Registry has historically collected non-motor cortex (1g), CSF, muscle, and bone, but the price list did not provide information for these tissue types. This error will be corrected on the revised form. Second, all prices will be updated to reflect current costs. The price list was originally established in 2015. Since that time, costs have increased, and we are requesting approval to make appropriate adjustments.

In addition, the National ALS Registry and Biorepository research team created a document to inform the OMB and IRB office of the plan that was created to minimize risk and exposure and safely restart participant sample collections. Briefly, on March 11, 2020, the Registry paused Biorepository specimen collections to protect the health of the Biorepository participants and members of their household. The Biorepository staff canceled all collection appointments scheduled until further review of the pandemic. Restarting the Biorepository collections will require that precautions be put in place to ensure that staff and participants and their caretakers/household members are protected from COVID-19. This plan is based on interim CDC guidance for non-COVID public health activities that require face-to-face interaction during the COVID-19 pandemic and will be used to outline practices for conducting Biorepository project activities.

Changes in the Biorepository procedures are proposed to reduce or eliminate close contact (within 6 feet) between project staff and participants when possible to prevent the spread of COVID-19 during collection activities. The precautions and personal protective equipment (PPE) recommended in this plan will be reevaluated monthly and more often as needed to ensure they are still in line with CDC COVID-19 guidelines and may be revised to add or remove precautions as needed. The full details of this plan can be found in the supplemental materials.

The overall number of respondents and requested burden hours remain the same.

### **SUPPLEMENTAL DOCUMENTS**

#### **National ALS Part C – National ALS Biorepository Postmortem Sample Request Form – Price Change**

Attach\_11A-ALS Registry Research Application Form revised 12022020

Attach\_11A-ALS Registry Research Application Form

Researcher Application Webpage\_Changes highlight

#### **Biorepository COVID-19 Safety Procedures and Restart Plan**

Appendix S – ALSBiorepository\_Protocol-Amendment 6- v2 clean

Appendix S – ALSBiorepository\_Protocol-Amendment 6- v2 track changes

Appendix B6b COVID-19 Restart Plan 04062021  
Appendix B6b COVID-19 Biorepository Information Sheet