**CDC Newborn Screening Quality Assurance Program – Spinal Muscular Atrophy (SMA) Proficiency Testing (PT) Pilot**

OSTLTS Generic Data collection Request

OMB No. 0920-0879

## Supporting Statement – Section B

Submitted: 6/15/2020

**Program Official/Project Officer**

John Bernstein, MS, PMP

Quality Manager

Newborn Screening and Molecular Biology Branch

4770 Buford Highway, Atlanta, GA 30341

770.488.0973

Yfj5@cdc.gov

### Table of Contents

[Section B – Data collection Procedures 3](#_Toc413847910)

[1. Respondent Universe and Sampling Methods 3](#_Toc413847911)

[2. Procedures for the Collection of Information 3](#_Toc413847912)

[3. Methods to Maximize Response Rates Deal with Nonresponse 4](#_Toc413847913)

[4. Test of Procedures or Methods to be Undertaken 4](#_Toc413847914)

[5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data 4](#_Toc413847915)

[LIST OF ATTACHMENTS – Section B 5](#_Toc413847916)

### Section B – Data collection Procedures

#### Respondent Universe and Sampling Methods

It is expected that there will be 40 participants. These participants are clinical laboratory technologists/technicians from public health labs that perform newborn screening and/or develop newborn screening tests. PHLs that have contacted CDC in the past 12 months inquiring about a SMA PT service will be invited to participate.

#### Procedures for the Collection of Information

Respondents will be recruited through an invitation email (see **Attachment D – Pilot SMA PT Email Invitation**) to the respondent universe. Respondents will have 2 weeks to indicate their willingness to participate. Two business days before shipment, respondents who request to participate will receive a notification email that will explain:

* The purpose of the data collection, and why their participation is important
* Instructions for participating
* Method to safeguard their responses
* That participation is voluntary
* The expected time to complete the instruments
* Contact information for the project team

Data will be collected via electronic spreadsheets (see **Attachment A – Pilot SMA PT Reporting Form** and **Attachment B – Pilot SMA PT Feedback Form**) sent as attachments to an email notification (see **Attachment G – Pilot SMA PT Email Packet**) 2 days before shipment of PT panels. Participants will have 4 weeks to complete and return the data. A reminder email (see **Attachment F – SMA Pilot PT Email Reminder**) will be sent to participants who have not submitted data 1 week before the participation deadline.

Data analysis will involve simple as well as categorical statistics. Individual respondents will receive an evaluation of their performance (actual versus expected outcome per PT specimen). This evaluation will not be shared with any other participant. All participants will receive an event summary report containing aggregate statistical data (aggregate PT outcomes). The use of custom Lab IDs known only to CDC and respondent maintains confidentiality of the data. A summary report of the aggregate interval scale feedback will be provided to CDC program staff in order to inform program improvements.

#### Methods to Maximize Response Rates Deal with Nonresponse

Although participation in the data collection is voluntary, the project team will make every effort to maximize the rate of response. Labs that had previously requested and/or shown interest in this service are included as participants in the pilot, which is expected to increase response rates. The data collection instruments were designed to limit questions to collect only required information with the minimum number of free-response questions, thereby minimizing response burden.

Two business days before shipping the PT panels, an email notification will be distributed (see **Attachment G – Pilot SMA PT Email Packet**) containing the data reporting form (see **Attachment A – Pilot SMA PT Data Reporting Form**), customer service feedback form (see **Attachment B – Pilot SMA PT Feedback Form**) and instruction sheet (**see Attachment C – Pilot SMA PT Instructions**)**.** Respondents will have 20 business days to complete the instrument. Those who do not respond within 15 business days will receive a reminder email (see **Attachment F – Pilot SMA PT Email Reminder**) urging them to complete the instruments. Those who do not respond within 5 business days from the reminder email will be considered non-responders.

#### Test of Procedures or Methods to be Undertaken

**Pilot SMA PT Data Collection Form**

The estimate for burden hours is based on a pilot test of the Data Reporting Form (**Attachment A**) by 2 of public health professionals. In the pilot test, the average time to complete the instrument including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 8.6 minutes (range: 7 –10). For the purposes of estimating burden hours, the upper limit of this range (i.e., 10 minutes) is used.

**Pilot SMA PT Feedback Form**

The estimate for burden hours is based on a pilot test of the Feedback Form (**Attachment B**) by 2 of public health professionals. In the pilot test, the average time to complete the instrument including time for reviewing instructions, gathering needed information and completing the instrument, was approximately 2.5 minutes (range: 2 –3). For the purposes of estimating burden hours, the upper limit of this range (i.e., 3 minutes) is used.

#### Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Miyono Hendrix

Research Biologist

CDC: Newborn Screening and Molecular Biology Branch

4770 Buford Highway, Atlanta GA 30341

770.488.4767

zuj7@cdc.gov

Nicolle Baird

Biologist

CDC: Newborn Screening and Molecular Biology Branch

4770 Buford Highway, Atlanta GA 30341

404.498.5701

mmy1@cdc.gov

John Bernstein

Quality Manager

4770 Buford Highway, Atlanta GA 30341

770.488.0973

Yfj5@cdc.gov

Suzanne Cordovado, PhD

Lab Chief

4770 Buford Highway, Atlanta GA 30341

770.488.4048

Snc4@cdc.gov

### LIST OF ATTACHMENTS – Section B

Note: Attachments are included as separate files as instructed.

1. **Attachment A – Pilot SMA PT Data Reporting Form**
2. **Attachment B – Pilot SMA PT Feedback Form**
3. **Attachment C – Pilot SMA PT Instructions**
4. **Attachment D – Pilot SMA PT Email Invitation**
5. **Attachment F – Pilot SMA PT Email Reminder**
6. **Attachment G - Pilot SMA PT Email Packet**