2021-12-21

Request for Developmental Funds
Spinal Muscular Atrophy Implementation Pilot Expenses

Executive Summary

- The Iowa Newborn Screening Program (INSP) conducted an implementation assessment for Spinal Muscular Atrophy (SMA)
- The Congenital and Inherited Disorders Advisory Committee (CIDAC) reviewed the implementation assessment and approved SMA for addition to the Iowa panel of newborn screening disorders, pending a successful pilot on April 19, 2019
- Assay development began at the State Hygienic Laboratory (SHL) immediately after CIDAC recommended addition of SMA to the Iowa panel, pending a successful pilot
- The INSP applied for and received funding from Cure SMA for assay development costs beginning June 30, 2019
- Due to the need for SHL to build capacity and capability for SMA screening to meet a July 1, 2020 pilot start date, expenses in the amount of $82,246.37 were incurred
- Expenses were incurred prior to receipt of funds from Cure SMA
- SHL requests developmental funds for SMA screening implementation in the amount of $82,246.37

Summary and Request

Following submission and review of an implementation assessment for SMA by the INSP Newborn Screening Executive Team, CIDAC approved addition of SMA to the Iowa panel of disorders, pending a successful pilot. To meet an implementation deadline of July 1, 2020, SHL began building capacity and capability for SMA screening after CIDAC approval on 04/19/2019.

To reduce costs for SMA implementation, SHL submitted a grant to Cure SMA for assay development expenses. The grant was awarded with a project period of 06/30/2019 to 07/01/2020. Funding in the amount of $ 150,000 was received which covered personnel, reagents, consumables, and instrument upgrades for completion of assay development, assay validation, and staff training.

However, since SHL had a 07/01/2020 deadline for SMA pilot screening and since receipt of funding from Cure SMA was not guaranteed, SHL spent $82,246.37 for SMA implementation that was not covered by Cure SMA funding.

As the contract laboratory for the INSP, SHL is tasked with adding testing capacity and capability as directed by the Center for Congenital and Inherited Disorders (CCID) with the assistance of CIDAC. Thus, the expenses incurred by SHL for SMA implementation were under the direction of CCID and CIDAC. For this reason, SHL requests reimbursement for SMA pilot expenses in the amount of $82,246.37.

Expenses incurred for SMA development between 04/19/2019 and 06/30/2019:

Category	**Amount**
Personnel	
salary	$7,903.83
fringe	$3,247.68
Total Personnel	$11,151.51
General Expenses	
vehicle rental/fuel	$290.09
consumables/reagents	$55,740.77
capital equipment	$14,628.00
freight	$436.00
Total General Expenses	$71,094.86
Grand Total	**$82,246.37**