



STATE OF VERMONT
JOINT FISCAL OFFICE

MEMORANDUM

To: Joint Fiscal Committee members
From: Daniel Dickerson, Fiscal Analyst *DWD*
Date: July 23, 2019
Subject: Grant Request – JFO #2968

Enclosed please find one (1) item, which the Joint Fiscal Office has received from the Administration.

JFO #2968 – \$60,000 from the Association of Public Health Laboratories (APHL) to the VT Dept. of Human Services – Department of Health. The department will utilize the funding to offset the purchase of an additional graphite furnace atomic absorption spectrometer, an upgrade to the existing spectrometer's controlling PC system, in addition to software to ensure compatibility between the two instruments. The Department will utilize the equipment to enhance the childhood blood lead testing program. While the equipment purchase has not been put out to bid, an estimated equipment cost of \$68,730.11 was provided in the grant package. Any funds needed over the \$60,000 grant application will be funded by the department's Global Commitment Investments fund. This is a one-time purchase request and there will be no additional cost to the State for the equipment.

[JFO received 7/15/19]

Please review the enclosed materials and notify the Joint Fiscal Office (Daniel Dickerson at (802) 828-2472; ddickerson@leg.state.vt.us) if you have questions or would like an item held for legislative review. Unless we hear from you to the contrary by August 6, 2019, we will assume that you agree to consider as final the Governor's acceptance of these requests.



JFO 2968

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Agency of Administration
JUL 15 2019
JOINT FISCAL OFFICE

State of Vermont
Department of Finance & Management
109 State Street, Pavilion Building
Montpelier, VT 05620-0401
[phone] 802-828-2376
[fax] 802-828-2428

STATE OF VERMONT
FINANCE & MANAGEMENT GRANT REVIEW FORM

Grant Summary:	Funding to Begin or Enhance an Existing Childhood Blood Lead Testing Program ; one-time third party funding for 2 ³ pieces of lab equipment				
Date:	5/29/2019 [Funding is 1X and related to equipment replacement] 7/15/19 by DFM				
Department:	Agency of Human Services – Department of Health				
Legal Title of Grant:	Funding to Begin or Enhance an Existing Childhood Blood Lead Testing Program				
Federal Catalog #:	N/A				
Grant/Donor Name and Address:	Association of Public Health Laboratories (APHL) 8515 Georgia Ave., Suite 700 Silver Spring, MD 20910				
Grant Period:	From:	7/1/19	To:	12/31/19	
Grant/Donation	\$60,000				
	SFY 20	SFY 2	SFY 3	Total	Comments
Grant Amount	\$60,000			\$60,000	
Position Information	# Positions		Explanations/Comments		
	0				
Additional Comments	See attached grant abstract				

Department of Finance & Management		(Initial)
Secretary of Administration		(Initial)
Sent to Joint Fiscal Office	7/15/19	Date



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Funding Abstract

Funding to Develop or Enhance an Existing Childhood Blood Lead Testing Program

APHL is a non-profit membership organization that works to safeguard the public's health by strengthening laboratory systems in the United States and globally. APHL is organized under the laws of the District of Columbia, with its headquarters office in Silver Spring, MD. APHL's members include state and local laboratories, state environmental and agricultural laboratories, and other governmental laboratories that conduct public health testing. APHL is recognized as tax exempt in the United States under Section 501(c)(3) of the U.S. Internal Revenue Code. Its work on behalf of public health laboratories spans more than 60 years.

APHL, with funding support from the Centers for Disease Control and Prevention (CDC) is pleased to offer funds to one or more state, local or territorial laboratories to develop or enhance an existing childhood blood lead testing program.

The selected applicant(s) will be expected to enhance their childhood blood lead testing program in their laboratory, or to help start a program. Funding can be used for initiatives to begin or enhance a program, including but not limited to:

- Equipment, reagents, proficiency test challenges and/or certified reference materials
- Partial payment towards an analytical instrument
- Instrument service agreement
- Instrument interface to laboratory information management system (LIMS)
- Specimen collection materials and outreach
- Specimen transport
- Communication materials

Vermont's proposed work plan would use funding to:

The VDH laboratory is requesting funding to support the purchase of ^{one}~~two~~ new graphite furnace atomic absorption spectrometers. In order to maximize the efficient installation and operation of within the laboratory's workflow it is proposed to purchase the Perkin Elmer PinAAcle model 900Z with the corresponding cooling and control systems 9,10. An additional benefit to replacing the existing Perkin Elmer equipment with updated models from the same manufacturer is that any IT work to integrate with the VDH laboratory information system (LIMS) will be minimized.

Because the funding is one-time and related to an equipment purchase, there are no new position requests.

STATE OF VERMONT REQUEST FOR GRANT (*) ACCEPTANCE (Form AA-1)

BASIC GRANT INFORMATION				
1. Agency:	Agency of Human Services			
2. Department:	Department of Health			
3. Program:	Childhood Blood Lead Program			
4. Legal Title of Grant:	Funding to Begin or Enhance an Existing Childhood Blood Lead Testing Program			
5. Federal Catalog #:				
6. Grant/Donor Name and Address:	Association of Public Health Laboratories (APHL)			
7. Grant Period:	From:	7/1/2019	To:	12/31/2019
8. Purpose of Grant:	See attached summary.			
9. Impact on existing program if grant is not Accepted:	None			
10. BUDGET INFORMATION				
	SFY 1	SFY 2	SFY 3	Comments
Expenditures:	FY 20	FY	FY	
Personal Services	\$0	\$	\$	
Operating Expenses	\$60,000	\$	\$	
Grants	\$0	\$	\$	
Total	\$60,000	\$	\$	
Revenues:				
State Funds:	\$0	\$	\$	
Cash	\$0	\$	\$	
In-Kind	\$0	\$	\$	
Federal Funds:	\$0	\$	\$	
(Direct Costs)	\$0	\$	\$	
(Statewide Indirect)	\$0	\$	\$	
(Departmental Indirect)	\$0	\$	\$	
Other Funds:	\$	\$	\$	
Grant (source)	\$60,000	\$	\$	
Total	\$60,000	\$	\$	
Appropriation No:		Amount:	\$	
	3420021209		\$60,000	
			\$	
			\$	
			\$	
			\$	
			\$	
		Total	\$60,000	

902
7/1/19

STATE OF VERMONT REQUEST FOR GRANT (*) ACCEPTANCE (Form AA-1)

PERSONAL SERVICE INFORMATION

11. Will monies from this grant be used to fund one or more Personal Service Contracts? Yes No
 If "Yes", appointing authority must initial here to indicate intent to follow current competitive bidding process/policy.


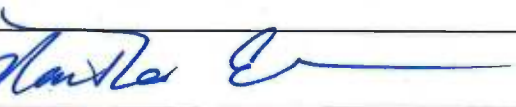
Appointing Authority Name: _____ Agreed by: _____ (initial)

12. Limited Service Position Information:	# Positions	Title
Total Positions		

12a. Equipment and space for these positions: Is presently available. Can be obtained with available funds.

13. AUTHORIZATION AGENCY/DEPARTMENT

I/we certify that no funds beyond basic application preparation and filing costs have been expended or committed in anticipation of Joint Fiscal Committee approval of this grant, unless previous notification was made on Form AA-1PN (if applicable):

Signature: 	Date: 6/16/19
Title: Commissioner of Health	
Signature: 	Date: 7/1/19
Title: Interim Secretary, AHS	

14. SECRETARY OF ADMINISTRATION

Approved: _____ (Secretary or designee signature) Date: 7/3/19

15. ACTION BY GOVERNOR

Check One Box: Accepted
 Rejected
 _____ (Governor's signature) Date: July 11, 2019

16. DOCUMENTATION REQUIRED

- Required GRANT Documentation**
- | | |
|---|---|
| <input checked="" type="checkbox"/> Request Memo | <input type="checkbox"/> Notice of Donation (if any) |
| <input type="checkbox"/> Dept. project approval (if applicable) | <input type="checkbox"/> Grant (Project) Timeline (if applicable) |
| <input checked="" type="checkbox"/> Notice of Award | <input type="checkbox"/> Request for Extension (if applicable) |
| <input type="checkbox"/> Grant Agreement | <input type="checkbox"/> Form AA-1PN attached (if applicable) |
| <input checked="" type="checkbox"/> Grant Budget | |

End Form AA-1

(*) The term "grant" refers to any grant, gift, loan, or any sum of money or thing of value to be accepted by any agency, department, commission, board, or other part of state government (see 32 V.S.A. §5).



April 23, 2019

Dominic Reynolds, PhD, MBA
Program Chief - Inorganic Chemistry
Vermont Department of Health Laboratory

Dear Dr. Dominic Reynolds,

Congratulations! The Association of Public Health Laboratories (APHL) is pleased to inform you that the Vermont Department of Health Laboratory has been selected to receive a funding award of \$60,000 to enhance its childhood blood lead program. Your proposal was selected from a highly competitive pool of applicants. The funding for this award will be administered through a contract agreement with APHL.

If your laboratory accepts this award, please send me an email at brianna.carey@aphl.org by COB on Friday, April 26, 2019 indicating your acceptance.

Thank you for your proposal and your laboratory's dedication to public health blood lead initiatives.

Sincerely,

A handwritten signature in black ink that reads "Brianna Carey".

Brianna Carey, MPH
Associate Specialist, Environmental Health
Association of Public Health Laboratories

APHL Funding to begin or enhance an existing childhood blood lead testing program proposal.

Vermont Department of Health Laboratory (VDHL)

The VDH Laboratory's need for funding

Since 1993 the Vermont Department of Health (VDH) Laboratory has operated a program for the analysis of lead in blood, with samples being collected from children at 12 and 24 months of age, though a range of client ages are seen in practice. In order to support the community through the national and statewide public health blood lead initiatives¹ the laboratory needs to update its equipment used for blood lead analysis – both to ensure the reliability of its program and to continue to improve services by lowering the detection limits reported to meet the demands associated with the observed trend of declining levels of lead in blood².

In addition to providing blood lead screening and confirmation results directly to clients, the VDH Laboratory's blood lead analysis program supports a broader public health purpose through the ongoing compilation and reporting of data to monitor trends which then allows health professionals to target parts of the community for action. The Healthy Homes Lead Poisoning Prevention Programs in the State of Vermont and New Hampshire both receive blood lead results from our laboratory.

The technology currently employed at the VDH Laboratory uses graphite furnace atomic absorption spectrometry (GFAAS) instruments which have proven to be reliable and robust throughout the life of the program and have so far provided the required sensitivity. While it would be desirable to move towards the introduction of inductively coupled plasma – mass spectrometry (ICP-MS) instruments in the analysis of lead in blood, the use of GFAAS as a 'high complexity reference method' is well established and, with developments in instrumentation, have become even more sensitive while remaining affordable to many laboratories.

In comparison, even entry level ICP-MS systems can be cost prohibitive (~\$200,000) and require modification of methods and laboratory practices, though offering the advantage of lower limits of detection and the ability to analyze multiple elements simultaneously. The VDH laboratory uses ICP-MS instruments extensively in its drinking water and chemical threat analysis programs, and these instruments will soon be at capacity when the statewide lead in school drinking water project commences.

The VDH Laboratory operates two GFAAS instruments exclusively for blood lead analysis which are nine and thirteen years old; both now outside of the manufacturer's support period. The maintenance of these instruments is increasingly problematic and the preventive maintenance contracts can no longer guarantee a repair when parts break down. There is no funding in the laboratory's current budget to replace either instrument, and with laboratory funding becoming tighter there is a need for critical equipment to be more reliable and require less operator interaction, which also results in more efficient use of staff resources.

Maintaining this obsolete equipment incurs significant cost to the laboratory when greater value could be provided to the community by a similar investment in new instruments, particularly when the laboratory is aiming to service the customer with an acceptable analytical turnaround time.

The current equipment issues also include;

- An instrument with obsolete PC system software (Windows XP), with no support and no security updates,
- older analytical software that is less efficient and less flexible,
- decreased instrument sensitivity compared to more recent models,
- increased background noise and contamination
- increasing problems with instrument stability – must ‘baby sit’ each analytical run

In addition to the limitations posed by the current fleet of equipment detailed above, there are changes occurring in the public health recommendations for levels of lead observed in childhood blood samples. The current reference level⁴ for lead at of 5 micrograms per deciliter (ug/dL) blood was set in 2012 based upon the 97.5th percentile value from the previous two NHAMES surveys, these are now due to be revised with updated NHAMES values and a new lower level projected³ to be 3.48ug/dL. With these values decreasing there is a need to use more sensitive equipment to ensure the validity of results at these lower levels and achieving these lower limits is more problematic with an aging instrument.

The CLIA error acceptability criteria of $\pm 4\text{ug/dL}$ (or 10%) in the reporting of sample results for lead concentrations of 40ug/dL will also need to be revised for these lower concentrations. To ensure meaningful results, an error acceptability of $\pm 2\text{ug/dL}$ (or 10%) has been recommended as an achievable goal^{5,8}.

The lower limits will present challenges in the analysis of blood lead, particularly for the low volume capillary samples typically used in screening of children as the reference level approaches the limit of reporting for the technique and instrumentation being used in the laboratory. It can be expected that older, less sensitive instruments will struggle to comply with these increased requirements for sensitivity and accuracy.

Many clinics that previously used the VDH Laboratory for childhood blood lead analysis have installed their own equipment in the past few years to conveniently provide screening results on site, in particular the LeadCare 2 analyzer system. With a revised reference level potentially approaching the manufacturer’s limit of reporting of 3.3 ug/dL, the LeadCare 2 analyzer may no longer be deemed appropriate which will likely result in a noticeable increase in samples coming to the laboratory. Due to the known issues⁶ with false positive results from screening requiring venous blood confirmations performed on high complexity reference instruments, such as GFAAS or ICP-MS, an increase in confirmation samples received at the laboratory may be observed in the future⁷, necessitating the use of reliable and sensitive analytical instrumentation.

The New Hampshire Division of Public Health Services, an existing client of the VDH laboratory, is now required to notify every parent of a child with an elevated blood lead level greater than 3 ug/dL, lowered from 5 ug/dL which requires the laboratory to provide verifiable results at this level.

Description of VDH Laboratory's current childhood blood testing program

The Vermont Department of Health Laboratory (VDHL) has a thriving childhood blood lead testing program, currently serving state-wide health care providers (49 different providers in 2018), medical centers and twelve VDH district offices through their WIC (Women, Infants and Children) programs.

While the total number of samples received annually has decreased since the program began in 1993, a total of 34,000 samples were analyzed in the period 2011 to 2018. The laboratory routinely performs approximately 2300 blood lead analyses annually, varying between 50 and 80 samples a week depending on client needs.

As Vermont law requires all children to be screened for lead there remains a continued need within the community to maintain this testing service; a 2018 VDH survey showed that some medical practices in Vermont have greater than 50% of one-year-old and two-year-old children requiring blood lead testing.

The proportion of VDH blood lead testing patients with insurance coverage has declined from 42% to 33% in the period 2011-2018. These costs are not recovered by the VDH laboratory resulting in significant 'in kind' costs provided to the community in order to ensure the screening of children takes place.

The VDH Laboratory also supports patients who reside outside of Vermont but use medical facilities within the state. Therefore, childhood blood lead samples are submitted from a small but steady number of residents of Massachusetts, New Hampshire and New York, who might otherwise find it difficult to attend a clinic in their home state (Table 1). The Healthy Homes Lead Poisoning Prevention Programs in the State of Vermont and New Hampshire also receive blood lead results from the laboratory.

Table 1- Top four blood lead sample submission origins in 2018

State	MA	NH	NY	VT	Total
Number of samples	15	53	115	2088	2271

The VDH blood lead testing staff consists of three trained chemists rotating through a twice weekly analysis schedule to consistently achieve a seven day turn-around-time for reporting results to clients. These staff possess science bachelors' degrees and have up to 25 years' experience at the VDH laboratory. All staff are also HIPAA trained/ compliant and receive annual ethics and integrity training updates.

As part of accreditation and quality system requirements, as well as individual career development, each staff member is required to undergo annual technical competency assessment and successfully participate in appropriate proficiency test challenges, such as provided by the CDC LAMP and Wisconsin State Laboratory of Hygiene (WSLH) blood lead programs. The VDH Laboratory analytical methods are fully validated and the blood lead analysis area is CLIA approved for high complexity testing. Other test areas of the VDH Laboratory are accredited under TNI/ NELAC and ISO 12025, demonstrating the laboratory's commitment to quality.

At the facilities and operational levels, the laboratory is located in a new (2015) state of the art laboratory facility and resources have been committed to streamline analytical and reporting procedures – for example analytical instruments have automated upload interfaces to the laboratory LIMS system (StarLims) to reduce potential errors in data handling and to increase efficiency.

Other programs within the laboratory support the scientific basis of the blood lead testing program, including the Vermont statewide school and day care center lead in drinking water project, in which the laboratory provides analytical services and support, as well as the laboratory's biomonitoring work.

Description of VDH Laboratory's proposed program enhancements

The VDH laboratory proposes to use the available funding to update the critical GFAAS analytical equipment within its existing program to newer models from the same manufacturer (Perkin Elmer). This would allow the laboratory to leverage its existing knowledge and experience in the use of the instruments to significantly upgrade the laboratory's capacity and capability while minimizing the costs of installation as the required services -gas supply, power and computer network connections - are already in place and operating optimally. The training requirement for the new instruments is also significantly reduced.

In addition, acquiring new instruments while the older ones are still functioning, would allow us to focus on all the initial testing and method validation requirements for a new instrument and have no break in service for clients relying on the timely reporting of blood lead results. The VDH laboratory staff can both test and implement the new instrument while continuing to provide the same dependable analysis and turnaround times.

Budget and justification

The VDH laboratory is requesting funding to support the purchase of two new graphite furnace atomic absorption spectrometers. In order to maximize the efficient installation and operation of within the laboratory's workflow it is proposed to purchase the Perkin Elmer PinAAcle model 900Z with the corresponding cooling and control systems^{9,10}. An additional benefit to replacing the existing Perkin Elmer equipment with updated models from the same manufacturer is that any IT work to integrate with the VDH laboratory information system (LIMS) will be minimized.

If funding is only available for the purchase of one new instrument it is proposed that one of the existing instruments will have upgrades to the controlling PC system and software to ensure compatibility between the two instruments and minimize training requirements.

The new instruments are supplied with a 12-month warranty as standard, after this initial period the laboratory would enter into a service agreement with the manufacturer for the ongoing maintenance of the equipment at the laboratory's expense as with all other equipment currently operating at the VDH laboratory facility. The laboratory would also take responsibility for the purchase of necessary consumables required for the daily operations and sample analysis.

The costs for supply of a single GFAAS instrument supplied and installed by Perkin Elmer are detailed in Table 2 below; if two instruments are purchased at the same time further discounts may be negotiated for delivery and installation, also parts and consumables would be shared between the two compatible units.

Table 2 – Quote for supply of a single GFAAS instrument

Part Number	Quantity	Description	Unit Price	Total
N3200060	1	PinAAcle 900Z THGA Only with Cooling Sys	\$ 56,400.00	\$ 56,400.00
N1010307	1	Dell Windows 10 AA System Controller	\$ 3,536.00	\$ 3,536.00
N9306345	1	Oil Free Air Compressor 115V 60Hz for AA	\$ 2,025.00	\$ 2,025.00
9421085	1	BROTHER HL-5000D 120V B/W Laser Printer	\$ 505.00	\$ 505.00
N0231014	1	AA Installation and Familiarization	\$ 990.00	\$ 990.00
N3050157	1	Lumina Hollow Cathode 2 Lamp - Pb	\$ 621.00	\$ 621.00
B0504033	1	THGA Standard Graphite Tubes, Pkg. 20	\$ 2,796.00	\$ 2,796.00
REGDELAA	1	Regular Delivery	\$ 1,857.11	\$ 1,857.11
Total				\$ 68,730.11

References

1. <https://www.healthypeople.gov/2020/topics-objectives/topic/environmental-health/objectives> accessed 5th April 2019
2. McClure LF, Niles JK, Kaufman HW. Blood Lead Levels in Young Children: US 2009-2015. *Journal of Pediatrics*. 2016; 175, 173-181
3. https://www.cdc.gov/nceh/lead/acclpp/blood_lead_levels.htm accessed 10th April 2019
4. Caldwell KL, Cheng P-Y, Jarrett JM, et al. Measurement Challenges at Low Blood Lead Levels. *Pediatrics*. 2017, 140(2): e20170272
5. https://www.cdc.gov/nceh/lead/acclpp/final_document_030712.pdf accessed 5th April 2019
6. Wang A, et al. Rates of False Positive Capillary Blood Lead Tests. *Journal of Public Health Management and Practice*. Jan/ Feb 2019, 25 (1 supp) S44
7. Mason J, et al. Response to the US FDA LeadCare Testing Systems Recall and CDC Health Alert. *Journal of Public Health Management and Practice*. Jan/ Feb 2019, 25 (1 supp) S91-50
8. Caldwell KL, et al. LAMP: A CDC Program to Ensure the Quality of Blood-Lead Laboratory Measurements. *Journal of Public Health Management and Practice*. Jan/ Feb 2019, 25 (1 supp) S23
9. <http://www.perkinelmer.com/CMSResources/Images/Determination%20of%20Lead%20in%20Blood.pdf> accessed 5th April 2019
10. <https://www.perkinelmer.com/lab-solutions/resources/docs/PinAAcleBloodLeadbyGFAAAppNote.pdf> accessed 5th April 2019



SUBAWARD AGREEMENT

This Subaward Agreement, dated May 31, 2019, is made by and between APHL and the Subrecipient to authorize and provide a subaward of financial assistance to the Subrecipient for the Project. All capitalized terms are defined in Section 1 Below.

Background

- I. Under the Cooperative Agreement, APHL has been approved to conduct the Project as part of the overall scope of programs to be financed or provided under the terms of the Notice(s) of Award from the Funding Agency for the current Cooperative Agreement funding year.
- II. The Subrecipient has requested financial assistance from APHL for the Project, and, in accordance with APHL's subgrant and procurement requirements for a matter of this size, APHL selected the Subrecipient to receive financial support in connection with the Project.
- III. The Parties agree that the financial assistance to the Subrecipient for the Project will be subject to the terms and conditions specified in this Subaward Agreement.

Agreement on Project Terms and Conditions

1. Definitions.

- A. The following definitions apply to capitalized terms used in this Subaward Agreement:

<u>Capitalized Term</u>	<u>Meaning</u>
<u>"Agreement"</u>	Collectively, this Subaward Agreement and any Cooperative Agreement Funding Conditions, together with any other attachments, exhibits or appendices incorporated into this Subaward Agreement by reference
<u>"APHL"</u>	The Association of Public Health Laboratories, Inc., a nonprofit corporation organized under the laws of the District of Columbia
<u>"Confidential Information"</u>	Economic and financial information, information and materials obtained from interviews or surveys, membership and donor lists, business procedures, solicitation or contact methods, and any other information regarding the business of APHL; the term does not include information that: (i) is or becomes available from public sources through no wrongful act of the Subrecipient; (ii) is already lawfully in the Subrecipient's possession prior to the date of this Subaward Agreement without an obligation of confidentiality, except

<u>Capitalized Term</u>	<u>Meaning</u>
	for information disclosed during discussions related to this Subaward Agreement; (iii) is rightfully disclosed to the Subrecipient by a third party with no obligation of confidentiality; (iv) is independently developed by the Subrecipient; or (v) is required to be disclosed pursuant to any valid court or regulatory order served on the Subrecipient
<u>"Cooperative Agreement"</u>	Cooperative Agreement Number NU60OE000103 (formerly 1U60OE000103; CFDA #93.322) with the Centers for Disease Control and Prevention (CDC) of DHHS
<u>"Cooperative Agreement Funding Conditions"</u>	All of the Cooperative Agreement funding conditions imposed by the Funding Agency as specified on Exhibit A to this Subaward Agreement
<u>"End Date"</u>	June 30, 2020
<u>"FFATA"</u>	The Federal Funding Accountability and Transparency Act of 2006 (Pub. L. 109-282), as amended
<u>"Final Report Due Date"</u>	March 31, 2020
<u>"Funding Agency"</u>	Centers for Disease Control and Prevention (CDC)
<u>"Materials"</u>	All articles, reports, and other materials produced by the Subrecipient pursuant to this Agreement
<u>"Maximum Assistance Amount"</u>	The maximum amount of financial assistance payable by APHL to the Subrecipient in support of the Project as specified in Section 5.A of this Subaward Agreement is \$60,000
<u>"Parties" or "Party"</u>	Collectively, APHL and the Subrecipient, and individually, either APHL or the Subrecipient
<u>"Period of Performance"</u>	The entire time period of the Project, beginning with the Start Date and concluding on the End Date
<u>"Project"</u>	Funding to enhance an existing childhood blood lead testing program.
<u>"Start Date"</u>	June 1, 2019
<u>"Subrecipient"</u>	Vermont Department of Health Laboratory, a governmental entity or administrative unit of Vermont
<u>"Uniform Guidance"</u>	The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards of 2 CFR 200 and, if applicable, the

Capitalized Term

Meaning

Department of Health and Human Services' implementing guidelines found at 45 CFR 75

B. Other capitalized terms used in this Agreement have the meaning given to those terms in the Cooperative Agreement Funding Restrictions.

2. Project Term; Specific Terms and Conditions of the Project.

A. The term of this Agreement will begin on the Start Date and will conclude on the End Date.

B. The Parties will fulfill their respective obligations in accordance with the specifications and other terms and conditions contained in the Agreement.

C. In the event that the component documents that make up the Agreement contain conflicting terms or conditions, the following priority will apply:

i. The terms and conditions specified in the Cooperative Agreement Funding Restrictions will prevail over this Subaward Agreement and any other attachment, exhibit or appendix; and

ii. The terms and conditions specified in this Subaward Agreement will prevail over any other attachment, exhibit or appendix.

3. Financial Assistance.

A. APHL awards financial assistance to the Subrecipient to support the Project in an amount not to exceed the Maximum Assistance Amount specified in Section 1. These funds will be paid on a flat-fee basis, and subject to the conditions listed below.

B. The cost must be allowed to APHL by the Funding Agency. For further information, see the Uniform Guidance (an electronic copy of which is currently available at <http://www.ecfr.gov/cgi-bin/text-idx?SID=7423d2aa8c6a9e55a691805dd2bb7c54&mc=true&node=pt2.1.200&rgn=div5>).

C. The cost must be within the amounts and categories set forth in the Project budget in Exhibit B.

D. Expenses incurred before the Start Date or after the End Date are not eligible for reimbursement.

E. Indirect costs are eligible for reimbursement at the Subrecipient's federally negotiated rate of N/A of N/A costs.

F. Reimbursement of travel expenses is limited to the rates and standards authorized by APHL's policy governing travel by its staff.

G. Payment will be made in response to reimbursement requests submitted by the Subrecipient. The Subrecipient will submit reimbursement requests on a quarterly basis, with the first request submitted by June 28, 2019. Each reimbursement request must include (i) a detailed statement of actual expenses incurred for the quarter, and (ii) cumulative cost totals for each budget category. In the event any cost was incurred using a foreign currency, the Subrecipient must report that cost in U.S. Dollars using the exchange rate at the time the reimbursement request is submitted to APHL. The Subrecipient must include the following certification on each reimbursement request:

By signing this invoice, the Subrecipient certifies that: (1) all information provided in the accompanying financial report is accurate, (2) it remains eligible to receive the requested funds, (3) its certifications in the Subaward Agreement remain valid, (4) all costs were actually incurred for the activities supported by the Subaward Agreement and are allowable, allocable, and reasonable, and (5) it remains in compliance with the Subaward Agreement and the Cooperative Agreement Funding Conditions.

H. The Subrecipient will send reimbursement requests to:

Julianne Nassif, MS
Director, Environmental Health
APHL
8515 Georgia Avenue, Suite 700
Silver Spring, MD 20910
P: 240.485.2737
F: 240.485.2700
E: julianne.nassif@aphl.org

I. APHL will review and approve or reject each request. APHL may withhold reimbursement for a cost until the Subrecipient provides adequate documentation to substantiate the cost as allowable or proper. The undisputed portion of each reimbursement request will be paid within 30 days after APHL's receipt of the request.

J. The Subrecipient must submit all reimbursement requests to APHL no later than the Final Report Due Date so that the Subrecipient's expenses may be included in APHL's final report to the CDC. **By signing below, the Subrecipient releases APHL from and waives all claims of any**

nature for non-payment based upon the Subrecipient’s failure to submit all reimbursement requests by this date.

K. APHL is not responsible for payment of any amount other than the financial assistance specified in this Subaward Agreement.

L. In the event a cost reimbursed under this Agreement is later determined to be unallowable under the Cooperative Agreement, then the Subrecipient will reimburse APHL for that cost.

4. Responsibilities of the Subrecipient.

A. The Subrecipient will carry out the Project as described in Exhibit B.

B. The Subrecipient will assign these staff members to the Project: (i) N/A.

C. The Subrecipient will provide APHL with progress and financial reports according to the schedule in the table below. The Subrecipient will submit one electronic copy and, if requested by APHL, one bound paper copy or unbound copy of each report. The Subrecipient will prepare reports using a format and software programs agreed to in advance by APHL and will produce all reports in English.

Report	Submission Due Date
Receipts for materials purchased with the funding received.	March 31, 2020
Brief (2 page) write up of the materials bought with the funding received, as well as the impact that it has made on the laboratory’s childhood blood lead testing program.	March 31, 2020
<p>One electronic copy of a final Project report that, at a minimum, includes the following:</p> <ol style="list-style-type: none"> 1. Statement of progress made toward the achievement of the Project’s originally stated aims 2. Description of the results (positive or negative) considered significant 3. A list of publications resulting from the Project, with plans, if any, for further or future publication 	By the Final Report Due Date
A complete inventory of all major equipment acquired or furnished under this Project with a unit acquisition cost of	By the Final Report Due Date

<p>USD 5,000 or more. The inventory list must include the following:</p> <ol style="list-style-type: none"> 1. A description of each item 2. A manufacturer serial and/or identification number for each item 3. The acquisition date and cost for each unit 4. The percentage of Cooperative Agreement funds used in the acquisition of each item 5. Current condition or location of each item 	
<p>A final invention statement utilizing the form found at http://grants1.nih.gov/grants/hhs568.pdf. If no inventions were conceived under the Project, a negative report is required.</p>	<p>By the Final Report Due Date</p>

D. The Subrecipient will not make any change in the Project that might affect its program or budget without APHL’s prior written approval. These types of changes include:

- i. a change in the project activities or goals;
- ii. either a change in the individuals serving in the project roles listed above or a reduction in the amount of time an individual will devote to the project;
- iii. a change in the project budget;
- iv. use of the funds provided by APHL for a different cost;
- v. a change in the project schedule; or
- vi. a transfer of the funds provided by APHL to another organization (except for the purchase of goods or services for use by the Subrecipient).

E. The Subrecipient will perform all of its obligations in a timely manner during the Period of Performance, and will comply with APHL’s instructions regarding the closeout process.

F. The Subrecipient may communicate with the Funding Agency about the Project only through APHL and will not communicate directly with the Funding Agency. In the event the Subrecipient desires to communicate with the Funding Agency about one or more topics, the Subrecipient will summarize the topics in a written notice to APHL and APHL will then pass on to the Funding Agency those topics it deems, in its sole discretion, advisable, appropriate or necessary.

G. The Subrecipient will provided data that is free of identifiers that would permit linkages to individuals and free of variables that could lead to deductive disclosure of the identity of the individual subjects.

H. The Subrecipient will comply with all applicable laws in the performance of its project. The Subrecipient will comply with federal, state, and local health and safety standards applicable to its operations, and will establish and implement necessary measures to minimize its employees' risk of injury and illness in activities related to this Subaward. If the Subrecipient is conducting activities outside the United States of America under this Agreement, the Subrecipient will coordinate as necessary with appropriate government authorities and will obtain appropriate licenses, permits, and approvals. The Subrecipient will ensure that it and its officers, directors, employees, agents, and contractors (regardless of nationality) (i) avoid any action that violates or appears to violate any governmental rule relating to ethics and integrity, (ii) avoid any corrupt practice (for example, offering or accepting bribes), and (iii) avoid any fraudulent practice (for example, falsifying financial records). The Subrecipient will immediately inform APHL of any violation of this provision, and will cooperate with APHL in taking corrective action. APHL will have the express right, in its sole and exclusive discretion, to require cessation of all work on the Project until these corrective actions have been taken by the Subrecipient.

5. **Consequences of Noncompliance.** If the Subrecipient fails to comply with the terms and conditions of this Subaward Agreement or the Cooperative Agreement Funding Restrictions, APHL (in its sole and exclusive discretion) may take one or more of the following actions:

- A. temporarily withhold reimbursements;
- B. deny reimbursement of a noncompliant cost;
- C. demand a refund of noncompliant costs already reimbursed;
- D. suspend or terminate this Subaward; or
- E. take any other remedy that may be legally available.

6. **Examination of Records; Ongoing Monitoring of Subaward.**

A. The Subrecipient will cooperate with APHL in the audit of APHL that is required by the Uniform Guidance audit requirements and, if the Funding Agency is a part of the Department of Health and Human Services, as may be contained in the Department of Health and Human Services' Grants Policy Statement (dated January 1, 2007), as supplemented by any addenda in effect as of July 1, 2017 (an electronic copy of which is currently available at <https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf>). The Subrecipient acknowledges that the standards set forth in 2 CFR Part 200 Subpart F will apply to audits of fiscal years beginning on or after 26 December 2014. The Comptroller General of the United States, the Funding Agency and the federal department to which it belongs, APHL, and their representatives have the right to access and examine any books, documents, papers, and records of the Subrecipient that involve transactions related to this Agreement, for the purpose

of audit and making excerpts and transcriptions. The Subrecipient will maintain auditable records for at least four (4) years following the close of the Cooperative Agreement (currently expected to end June 30, 2020). Further, the Subrecipient will permit these representatives access to its facilities and personnel for the purpose of on-site inspections, and will provide information, as requested, to determine compliance with the Cooperative Agreement Funding Restrictions.

B. The Subrecipient will provide APHL with a copy of any and all written communications received by the Subrecipient from an auditor related to Subrecipient's internal control over financial reporting requirements and communication with those charged with governance (including those in compliance with or related to Statement of Auditing Standards (SAS) 112 Communicating Internal Control related Matters Identified in an Audit and SAS 114 The Auditor's Communication with Those Charged With Governance). The Subrecipient will send APHL a copy of this written communications no more than five days after the Subrecipient receives the communication (or the Subrecipient may instruct any auditor it employs to deliver copies of this written communications to APHL at the same time copies are delivered to the Subrecipient, in which case the Subrecipient will promptly verify that APHL has received a copy).

C. The Subrecipient will also cooperate with APHL in its ongoing oversight and monitoring of the Project during the Period of Performance. In the event that APHL selects the Project or the Subrecipient for an inspection or audit during the Period of Performance, the Subrecipient will make its key staff available to APHL during normal business hours and upon reasonable notice for inspection or auditing purposes.

7. Assurance. If APHL, in good faith, has reason to believe that the Subrecipient does not intend to, is unable to or discontinues performing material obligations under this Subaward Agreement, APHL may demand in writing that the Subrecipient give a written assurance of its intent to perform. Failure by the Subrecipient to provide written assurance within the number of days specified in APHL's demand may, at APHL's option, be the basis for terminating this Subaward Agreement.

8. Termination of Cooperative Agreement. If (i) funds are not appropriated or otherwise made available for the continued performance of the Cooperative Agreement, (ii) the Cooperative Agreement is terminated or (iii) the Cooperative Agreement funds are reduced or eliminated for the Project, APHL may terminate this Subaward Agreement without penalty upon written notice to the Subrecipient.

9. Prohibition against Lobbying. No part of the Cooperative Agreement funds may be used for:

A. Publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation, designed to support or defeat the enactment of legislation before the Congress or any state or local legislature or legislative body, except in presentation of the Congress or any state or local legislature itself, or designed to support or defeat any proposed or pending

regulation, administrative action, or order issued by the executive branch of any state or local government itself.

B. Paying the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive Order proposed or pending before the Congress or any state government, state legislature or local legislature or legislative body, other than normal and recognized executive-legislative relationships or participation by an agency or officer of a state, local or tribal government in policymaking and administrative processes within the executive branch of that government.

C. Any activity to advocate or promote any proposed, pending, or future Federal, state or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including, but not limited to the advocacy or promotion of gun control.

10. Certifications. By signing this Subaward Agreement, the Subrecipient certifies the statements listed below. These certifications are material representations of facts upon which APHL relied when it agreed to provide the financial assistance to the Project.

A. Debarment, Suspension, Ineligibility and Voluntary Exclusion (not applicable to foreign governments or governmental entities, public international organizations, or foreign-government-owned or -controlled entities). The Subrecipient certifies that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency.

B. Lobbying. The Subrecipient certifies that:

i. No Federal appropriated funds have been paid or will be paid, by or on behalf of the Subrecipient, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

ii. If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the Cooperative Agreement supporting this

Subaward, the Subrecipient will complete and submit Standard Form-LLL, "Disclosure of Lobbying Activities," in accordance with its instructions.

C. No Delinquency on US Government Debts. The Subrecipient certifies that it is not indebted to the United States government (including any unpaid Federal tax liability that has been assessed and for which all judicial and administrative remedies have been exhausted or have lapsed), nor does it have a judgment lien filed against it.

D. Recent Felonies. The Subrecipient certifies that it has not been convicted (nor has any of its officers or agents acting on behalf of the Subrecipient been convicted) of a felony criminal violation under any Federal or State law within the preceding twenty-four (24) months.

11. Cap on Extramural Salaries. The Consolidated Appropriations Act of 2012 (Pub. L. 112-74), as amended, limits the salary amount that may be awarded or charged to the Cooperative Agreement. None of the Federal Agency funds payable to the Subrecipient for Project may be used to pay the salary of an individual, through a grant, contract or other extramural mechanism, at a rate in excess of \$187,000 (the Executive Level II salary in the Federal Executive Pay scale in effect when the Cooperative Agreement was awarded by the Federal Agency). This salary limitation also applies to any subawards issued by the Subrecipient for the Project under this Subaward Agreement. The salary limitation does not limit how much salary the Subrecipient may pay an individual; it merely limits the amount that may be paid with Federal funds.

12. Whistleblower Protections.

A. This Subaward Agreement and employees of the Subrecipient working on the Project will be subject to the whistleblower rights and remedies in the pilot program in the Pilot Program for Enhancement of Contractor Employee Whistleblower Protections established at 41 U.S.C. §4712 by Section 828 of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112-239) and the Federal Acquisition Regulation §3.908.

B. The Subrecipient will inform its employees in writing, in the predominate language of the workforce, of employee whistleblower rights and protections under 41. U.S.C. §4712, as described in §3.908 of the Federal Acquisition Regulation.

C. The Subrecipient will insert the substance of this Section, including this subsection (iii), in all sub-subawards or subcontracts over the simplified acquisition threshold.

13. Conflicts of Interest. The Subrecipient, to the to the best of its knowledge and belief at this time, certifies that either (i) there no relevant facts or circumstances which could give rise to an organizational conflict of interest, as defined in FAR Subpart 9.5 or (ii) the Subrecipient has disclosed all such relevant information as of the Agreement Date, and that it will disclose any actual or potential organizational conflict of interest that is discovered on or after the Agreement Date. During the Period

of Performance, the Subrecipient will not enter into other contracts, awards or arrangements or otherwise engage in work that will conflict with the Subrecipient's obligations under this Subaward Agreement.

14. FFATA Reporting Requirements. In compliance with the requirements imposed under FFATA, the Subrecipient will complete and return Exhibit C.

15. Copyright & Intellectual Property Rights.

A. The Subrecipient retains all copyright rights to materials developed by it with the funding provided under this Agreement, subject to terms of (i) the Cooperative Agreement Funding Conditions and (ii) Section 6.B. below.

B. The Subrecipient hereby grants to APHL a royalty-free, non-exclusive, and irrevocable right to reproduce, publish, and otherwise use publications, data, and other copyrightable works developed by the Subrecipient under this Agreement for the purpose of furthering the general objectives of the Cooperative Agreement and meeting APHL's obligations under it.

16. Indemnification. The Subrecipient will defend and indemnify APHL against all claims, liabilities, damages and expenses (including reasonable attorney's fees) arising out of any act, omission, negligence, misconduct or breach of this Subaward Agreement by the Subrecipient, its directors, officers, employees, subcontractors or agents while engaged in the performance of the Project.

17. Insurance. Unless prohibited from doing so pursuant to state law or regulation, the Subrecipient will maintain with a reputable insurance company policies of insurance providing an adequate level of coverage for all risks which may be incurred by the Subrecipient as a result of its performance of the Subaward Agreement (including death, personal injury or loss of or damage to property). Upon reasonable request from APHL, the Subrecipient will provide APHL with copies of such insurance policies or other evidence confirming the existence and extent of the coverage given by those policies.

18. Confidentiality. The Subrecipient will maintain in strict confidence any Confidential Information of APHL that the Subrecipient reviews, receives, or acquires in the performance of this Subaward. APHL will make efforts to clearly identify, preferably in writing, any Confidential Information. The Subrecipient may disclose Confidential Information to its accountants, counsel, and other financial and legal advisors with a need to know. If disclosure to a sub-subrecipient is necessary in order to carry out the Subrecipient's work, the Subrecipient must obtain the sub-subrecipient's agreement to abide by this confidentiality provision prior to disclosure.

19. Representatives. The following will act as a representative authorized to administer this Subaward Agreement on behalf:

APHL	The Subrecipient
[Julianne Nassif, MS Director, Environmental Health] APHL 8515 Georgia Avenue, Suite 700 Silver Spring, MD 20910 P: 240.485.2737 F: 240.485.2700 E: julianne.nassif@aphl.org	Paul Daley Director of Finance 108 Cherry Street Suite 202 Burlington, VT 05401 P: 802.863.7589 F: N/A E: ahs.vdhfedgrantoperations@vermont.gov

20. **Notices.** Any notice or request under this Agreement must be in writing **and must reference the APHL Agreement Number identified at the top of each page.** A Party may send notices (i) personally, (ii) by mail, with first class postage prepaid, certified and return receipt requested, or (iii) by delivery through a nationally recognized overnight delivery service, with confirmed delivery and charges prepaid or billed to shipper. A notice or request must be sent to addressees shown below, unless a different address or addressee is specified in writing by the receiving Party. On the same day that a notice is placed in the mail or with an overnight delivery service, a complete copy will also be transmitted by the sending Party to the receiving Party via email or facsimile.

APHL	The Subrecipient
Scott J. Becker, MS, Executive Director APHL 8515 Georgia Avenue, Suite 700 Silver Spring, MD 20910 P: 240.485.2745 F: 240.485.2700 E: scott.becker@aphl.org <i>With a copy to:</i> Troy Willitt, General Counsel APHL 8515 Georgia Avenue, Suite 700 Silver Spring, MD 20910 P: 240.485.2716 F: 240.485.2700 E: troy.willitt@aphl.org	Paul Daley Director of Finance 108 Cherry Street Suite 202 Burlington, VT 05401 P: 802.863.7589 F: N/A E: ahs.vdhfedgrantoperations@vermont.gov

21. **Survival.** The obligations and rights of the Parties which by their nature would continue beyond the termination or expiration of this Subaward Agreement will survive beyond the termination or expiration of this Subaward Agreement and remain in full force and effect. These obligations and rights include those set forth in the Sections entitled “Consequences of Noncompliance” and “Indemnification”.

22. **Non-Discrimination.** The Parties will not discriminate against any employee or applicant for employment because of race, color, religion, sex, age, national origin, sexual orientation, gender identity, disability, genetic information, citizenship status, veteran status or any other classification protected by applicable law or regulation.
23. **Governing Law.** This Subaward Agreement is governed exclusively by the laws of the District of Columbia.
24. **Governing Language.** In the event that this Subaward Agreement is produced in English and one or more foreign languages, this English language version of this Subaward Agreement is the official version and will govern if there is a conflict between this English language version and one or more of the foreign translations.
25. **Dispute Resolution.** The Parties agree that the sole jurisdiction and venue for any litigation arising from this Subaward Agreement is the appropriate federal or District court located in the District of Columbia. The Parties hereby waive trial by jury in any action arising out of this Agreement. If a dispute arises, the Parties will make a good faith attempt to resolve the dispute through dialogue and negotiation prior to pursuing court action.
26. **Independent Contractors.** The relationship between the Parties to this Agreement is that of independent contractors. This Agreement is not intended to create any association, partnership, joint venture, or agency relationship between the Parties.
27. **Assignability.** The Subrecipient will not assign this Agreement, or any interest in this Agreement, without the prior written consent of APHL.
28. **Successors.** This Agreement will be binding upon, and will inure to the benefit of, the Parties and their respective permitted successors and assigns.
29. **Sole Agreement.** This document contains the entire agreement between the Parties concerning the subject matter of this Agreement. It supersedes all prior and contemporaneous oral and written understandings.
30. **Amendment.** Except as is described in the following sentence, no amendment of this Agreement will be valid unless in writing and signed by both Parties. In the event the Parties seek to make a ministerial or non-substantive modification to this Agreement (such as a no-cost extension to the Period of Performance), APHL will send an email to the Subrecipient stating the terms of the proposed modification and, upon APHL's receipt of a reply email from the Subrecipient that confirms the Subrecipient's agreement with and consent to the proposed modification, the modification will be deemed approved and will be enforceable as if it were a formal written amendment to this Agreement.

31. Waiver. A Party's waiver of a breach is not to be deemed a waiver of any subsequent breach of the same term or of any other term. No waiver will be valid unless in writing and signed by the waiving Party.

32. Severability. If any provision of this Subaward is held to be invalid, only that provision will be modified and the remaining provisions of this Subaward Agreement will not be affected and will continue in full force and effect. The invalid provision is to be deemed modified to the least degree necessary to remedy the invalidity.

33. Interpretation. When used in this Subaward Agreement, the terms "include" or "including" are not limiting (such that the terms should be read as if stating "include without limitation" or "including without limitation" as applicable).

34. Section Headings. The captions or headings in this Subaward Agreement are made for convenience and general reference only and should not be construed to describe or limit the scope or the intent of the provisions of this Subaward Agreement.

35. Drafting Party. The Parties have participated jointly in the negotiation and drafting of this Subaward Agreement and each Party has had the opportunity to consult with, and to get assistance from the counsel and other advisors that Party deemed appropriate. In the event an ambiguity or question of intent or interpretation arises, this Subaward Agreement will be construed as jointly drafted by the Parties, and no presumption or burden of proof will arise favoring or disfavoring any Party by virtue of the authorship of any provision of this Subaward Agreement.

36. Counterparts. The Parties may execute this Subaward Agreement in counterparts, each of which is deemed an original and all of which taken together constitute one original.

37. Signatures/E-delivery. A manually signed copy of this Subaward Agreement delivered by facsimile, email or other means of electronic transmission will be deemed to have the same legal effect as delivery of an original signed copy of this Subaward Agreement.

38. Other Project Specific Terms and Conditions. For purposes of this Subaward, the Parties make the following modifications, amendments, or substitutions to the Standard Terms and Conditions. Unless expressly modified, amended, or replaced in this Section 38 below, the Project Terms and Conditions remain in full force and effect.

i. *Definitions.* The following clause is added to the term "Confidential Information":

a. (vi) required by law.

- ii. *Indemnification.* Section 16 of the Subaward Agreement is deleted in its entirety.
- iii. *Insurance.* Section 17 of the Subaward Agreement is deleted in its entirety.
- iv. *Confidentiality.* Section 18 of the Subaward Agreement is deleted in its entirety and replaced with the following language:
 - a. The Subrecipient will maintain in strict confidence any Confidential Information of APHL that the Subrecipient reviews, receives, or acquires in the performance of this Subaward. APHL will make efforts to clearly identify, preferably in writing, any Confidential Information. The Subrecipient may disclose Confidential Information if required by law, as well as to its accountants, counsel, and other financial and legal advisors with a need to know. If disclosure to a sub-subrecipient is necessary in order to carry out the Subrecipient's work, the Subrecipient must obtain the sub-subrecipient's agreement to abide by this confidentiality provision prior to disclosure.
- v. *Governing Law.* Section 23 of the Subaward Agreement is deleted in its entirety.
- vi. *Dispute Resolution.* Section 25 of the Subaward Agreement is deleted in its entirety and replaced with the following language:
 - a. The Parties agree that if a dispute arises out of this Agreement, the Parties will make a good faith attempt to resolve the dispute through dialogue and negotiation prior to pursuing court action.

[Remainder of page intentionally left blank; signatures on the following page.]

Each Party represents to the other Party that the individual signing below has the legal capacity and proper authority to do so and that, once signed on behalf of the Party, this Agreement will be enforceable against the Party in accordance with its terms and conditions.

THE ASSOCIATION OF PUBLIC HEALTH LABORATORIES, INC.

By: 
Name: Carol Clark, MS, CPA
Title: Chief Operating Officer

VERMONT DEPARTMENT OF HEALTH LABORATORY


By:  Date: 6/20/19
Name: Mark A. Lewis
Title: Commissioner of Health

EXHIBIT A

Cooperative Agreement Funding Conditions

Please see the attached Cooperative Agreement Funding Conditions.

EXHIBIT B
The Project and Budget

See attached.

EXHIBIT C
FFATA Reporting Requirement

Contractor/Award Recipient's Name: Vermont Department of Health Laboratory

Amount of Award (obligated amount): \$60,000

Funding Agency: Centers for Disease Control and Prevention

CFDA Number: See the definition of the "Cooperative Agreement" in the Work Order.

Program Source: EH Program – 56300-200-010-19

Award Title Descriptive of the Purpose of the Funding Action: Funding to enhance and existing childhood blood lead testing program.

Contractor/Award Recipient's Location:

108 Cherry Street
Suite 202
Burlington VT, 05401

Contractor/Award Recipient's Congressional District: VT-ALL

Contractor/Award Recipient's Place of Performance:

SAME AS LOCATION

Contractor/Award Recipient's Place of Performance Congressional District: VT-ALL

Contractor/Award Recipient's Unique Identifier (DUNS #): 809376155

Contractor/Award Recipient's Unique Identifier of Parent Organization, if applicable (DUNS #):

N/A

In order to determine whether you are required to provide executive compensation data, answer the following question(s):

1. In your business or organization's preceding completed fiscal year, did your business or organization (the legal entity to which this specific CCR record, represented by a DUNS number, belongs) receive:

a. 80 percent or more of your annual gross revenues in U.S. federal contracts, subcontracts, loans, grants, subgrants, and/or cooperative agreements?

Yes No

b. \$25,000,000 or more in annual gross revenues from U.S. federal contracts, subcontracts, loans, grants, subgrants, and/or cooperative agreements?

Yes No

If you selected 'Yes' for both a. and b. in question 1 please go to question 2. If you selected 'No' for either or both a. and b. in question 1 you are done completing the form.

2. Does the public have access to information about the compensation of the executives in your business or organization (the legal entity to which this specific CCR record, represented by a DUNS number, belongs) through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended (15 U.S.C. §§78m(a), 78o(d)), or section 6104 of the Internal Revenue Code of 1986, as amended (26 U.S.C. §6104)? Yes No

If you selected 'Yes' to question 2 you are done completing the form. If you selected 'No' to question 2 please provide the names and total compensation for your five highest compensated executives (i.e. officers, managing partners, or any other employees in management positions):

Name: _____ Total Compensation: \$ _____

Name: _____ Total Compensation: \$ _____

Name: _____ Total Compensation: \$ _____

Name: _____ Total Compensation: \$ _____

Name: _____ Total Compensation: \$ _____



COOPERATIVE AGREEMENT
FUNDING CONDITIONS

FOR COOPERATIVE AGREEMENT #5NU60OE000103

(formerly #1U60OE000103) (CFDA NO. 93.322)

with the U.S. Centers for Disease Control and Prevention (CDC)

These Cooperative Agreement Funding Conditions (the "Funding Conditions") have been attached as Exhibit A to a Project Agreement (as defined in Section 1 of these Funding Conditions) between APHL (as defined in the Project Agreement) and the Counterparty (as defined in Section 1 of these Funding Conditions) and have been incorporated into that Project Agreement by reference. These Funding Conditions, together with the Project Agreement and, if the Project Agreement is a Work Order, the Standard Terms and Conditions, make up the entire Agreement (as defined in the Project Agreement) between the Parties (as defined in the Project Agreement).

1. Definitions.

A. The term "Counterparty" is used in these Funding Conditions to refer to either (i) the Contractor under the Work Order or (ii) the Subrecipient under the Subaward Agreement, as applicable.

B. The term "Maximum Amount" is used in these Funding Conditions to refer to either (i) the Maximum Compensation Amount under the Work Order or (ii) the Maximum Assistance Amount under the Subaward Agreement, as applicable.

C. The term "Project Agreement" is used in these Funding Conditions to refer to either (i) the Work Order or (ii) the Subaward Agreement, as applicable, to which these Funding Conditions are attached as Exhibit A.

2. Compliance with Funding Conditions. This project is funded through the Cooperative Agreement (as defined in the Project Agreement) between APHL and the Centers for Disease Control and Prevention ("CDC"). The Counterparty will comply with the terms and conditions of the Cooperative Agreement.

3. Uniform Administrative Requirements. The US Office of Management and Budget's Uniform Administrative Requirements (the "UAR") found at 2 CFR Part 200, as implemented by the US Department of Health and Human Services ("DHHS") at 45 CFR Part 75, apply to the terms of the Agreement. An electronic copy of DHHS' UAR is currently available at <http://www.ecfr.gov/cgi-bin/text-idx?node=pt45.1.75> and the Counterparty will ensure that it has reviewed the applicable provision and will conduct the Project (as defined in the Project Agreement) in compliance with the UAR terms.

4. HHS Grants Policy Statement. The Cooperative Agreement is subject to the terms of the DHHS Grants Policy Statement (dated January 1, 2007), as supplemented by any addenda in effect as of July 1, 2016. An electronic copy of which is currently available at <https://www.hhs.gov/sites/default/files/>

[grants/grants/policies-regulations/hhsgps107.pdf](#) and the Counterparty will ensure that it has review the applicable provisions and will conduct the Project in compliance with its terms.

5. **Lower Tier Transactions.** The Counterparty will include the provisions of these Funding Conditions as conditions of any subcontract or sub-subaward (with the subcontractor or sub-subrecipient agreeing to comply with these provisions as if it is the Counterparty). These provisions must be conditions of any subcontract, sub-subcontract, etc., governing a lower tier transaction.

6. **Public Policy Requirements.** The Counterparty will comply with each of the following laws and regulations as applicable to the Cooperative Agreement:

- A. Byrd Anti-Lobbying Amendment (31 U.S.C. §1352);
- B. Debarment and Suspension (Executive Orders 12549 and 12689);
- C. Equal Employment Opportunity regulations (Executive Order 11246, as amended by Executive Order 11375 and as supplemented by 41 CFR Part 60);
- D. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, as amended (42 U.S.C. §§201 et seq.);
- E. Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, as amended (USA PATRIOT Act) (Pub. L. 107-56); and
- F. Non-Discrimination Acts, including: (a) Title VI of the Civil Rights Act of 1964, as amended (42 U.S.C. §§2000d et seq.) which prohibits discrimination on the basis of race, color or national origin (not applicable to foreign (non-US) organizations); (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §§1681-1683, and 1685-1686), which prohibits discrimination on the basis of sex (not applicable to foreign (non-US) organizations); (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. §794), which prohibits discrimination on the basis of handicap (not applicable to foreign (non-US) organizations); (d) the Age Discrimination Act of 1975, as amended (42 U.S.C. §§6101 et seq.), which prohibits discrimination on the basis of age (not applicable to foreign (non-US) organizations); (e) the Drug Abuse Office and Treatment Act of 1972 (Pub. L. 92-255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (Pub. L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§523 and 527 of the Public Health Service Act of 1912, as amended (42 U.S.C. §§290 dd-3 and 290 ee-3), relating to confidentiality of alcohol and drug abuse patient records; and (h) any other nondiscrimination provisions in the specific statute(s) under which the Cooperative Agreement was made, or any other nondiscrimination statute(s) which may otherwise apply to the Cooperative Agreement.

7. **Bayh-Dole Act.** Inventions conceived or first actually reduced to practice by the Counterparty in the performance of experimental, developmental, or research work under the Agreement are subject to the Bayh-Dole Act (37 CFR Part 401) and the standard patent right clauses (37 CFR Part 401.14).

8. **Equipment & Products.**

A. Purchases of equipment and products under the Agreement are subject to the Buy American Act of 1933, as amended (41 U.S.C. §§8302 *et seq.*), which requires the purchase of American-made equipment and products to the greatest extent practicable.

B. The CDC defines “equipment” as tangible non-expendable personal property (including exempt property) charged directly to the Project Agreement having a useful life of more than one year and an acquisition cost of \$5,000 or more per unit but the Counterparty is permitted to have a lower threshold consistent with its policies. The Counterparty will provide APHL with information or documentation regarding its procurement policies if it has established a lower threshold.

9. **Travel.** Travel within and outside the US under the Agreement is subject to the Fly America Act, as amended (49 U.S.C. §40118), which requires utilization of US-flag carriers to the greatest extent practicable (generally regardless of cost, convenience, and personal travel preferences).

10. **Publications and Publicity.**

A. Any (a) publication, paper or journal article relating to or (b) press release, article, report, or other material publicizing or resulting from the Counterparty’s work or services under the Agreement must include an acknowledgment that the Project was supported by CDC. The Counterparty will use the following disclaimer and acknowledgment of support:

“This publication (journal article, etc.) was supported by the Cooperative Agreement Number 5NU600E000103, funded by the Centers for Disease Control and Prevention through the Association of Public Health Laboratories. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of the Centers for Disease Control and Prevention, the Department of Health and Human Services, or the Association of Public Health Laboratories.”

B. When issuing statements, press releases, requests for proposals, bid solicitations and other documents describing the Project (as a project funded in whole or in part with federal money) such documents must clearly state:

- i. the percentage of the total costs of the project which will be financed with Federal money;
- ii. the dollar amount of Federal funds for the project or program; and

iii. the percentage and dollar amount of the total costs of the project that will be financed by non-governmental sources.

C. The US Government has a royalty-free, non-exclusive, and irrevocable right to reproduce, publish, and otherwise use publications, data, and other copyrightable works developed by the Counterparty under the Agreement. The US Government may also grant a sublicense of these rights to others to do so for Federal purposes.

D. For the purposes of this Section 10 of these Funding Conditions, “data” means recorded information, regardless of the form or media on which it may be recorded, and includes writings, films, sound recordings, pictorial reproductions, drawings, designs or other graphic representations, procedural manuals, forms, diagrams, work flow charts, equipment descriptions, data files, data processing or computer programs (software), statistical records, and other research data.

11. Copyright Interests.

A. Pursuant applicable federal grant regulations and the CDC’s Public Access Policy, the Counterparty will submit into the National Institutes of Health (NIH) Manuscript Submission (“NIHMS”) system an electronic version of the final, peer-reviewed manuscript (as defined below) of the work developed under or in connection with the Agreement upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. Also at the time of submission, the Counterparty or the Counterparty’s submitting author must specify the date the final manuscript will be publicly accessible through PubMed Central (“PMC”). The Counterparty or the Counterparty’s submitting author must also post the manuscript to PMC within 12 months of the publisher’s official date of final publication; however the Counterparty is strongly encouraged to make the subject manuscript available as soon as possible. The Counterparty must obtain prior written approval from APHL (who, in turn, must obtain prior approval from CDC) for any exception to this provision.

B. For purposes of this Section 11 of these Funding Conditions, the “final, peer-reviewed manuscript” is defined as the final version accepted for journal publication, and includes all modifications from the publishing peer review process, and all graphics and supplemental material associated with the article. The Counterparty and its submitting authorized working under the Agreement are responsible for ensuring that any published or copyright agreements concerning submitted articles reserve adequate right to fully comply with this provision and the licensing reserved by the CDC. The manuscript will be hosted in both PMC and the CDC Stacks institutional repository system. In progress reports for the Project, the Counterparty must identify publications subject to the CDC Public Access Policy by using the applicable NIHMS identification number for up to three months after the publication date and the PMC identification number (PMCID) number thereafter.

12. Limitations on an Individual’s Salary. The Consolidated Appropriations Act of 2012 (Pub. L. 112-74), as amended, limits the salary amount that may be awarded or charged to the Cooperative

Agreement. Cooperative Agreement funds may not be used to pay the salary of an individual at a rate in excess of \$185,100 (the Executive Level II salary in the Federal Executive Pay scale for 2016). Such amount reflects an individual's base salary exclusive of fringe and any income that an individual may be permitted to earn outside of his or her duties to the Counterparty. Such salary limitation also applies to any subcontracts or sub-subawards issued by the Counterparty for services to or work on the Project under the Project Agreement. The salary limitation does not limit how much salary the Counterparty may pay an individual, but simply limits the amount that may be awarded or charged to Cooperative Agreement funds.

13. Whistleblower Protections. In the event that the Maximum Amount is equal to or greater than \$100,000, the following provisions will apply.

A. The Agreement and employees of the Counterparty working on the Agreement will be subject to the whistleblower rights and remedies in the pilot program in the Pilot Program for Enhancement of Contractor Employee Whistleblower Protections established at 41 U.S.C. §4712 by Section 828 of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112-239) and Federal Acquisition Regulation ("FAR") §3.908.

B. The Counterparty will inform its employees in writing, in the predominate language of the workforce, of employee whistleblower rights and protections under 41. U.S.C. §4712, as described in §3.908 of FAR.

C. The Counterparty will insert the substance of this Section, including this subsection (C), in all subcontracts over the simplified acquisition threshold.

14. Examination of Records. The Counterparty will cooperate with APHL in the audit of APHL that is required by the UAR audit requirements found at 2 CFR Part 200 Subpart F or contained in the HHS Grants Policy Statement. The Counterparty acknowledges that the standards set forth in 2 CFR Part 200 Subpart F will apply to audits of fiscal years beginning on or after 26 December 2014. The Comptroller General of the United States, DHHS, CDC, APHL, and their representatives have the right to access and examine any books, documents, papers, and records of the Counterparty that involve transactions related to the Agreement, for the purpose of audit and making excerpts and transcriptions. The Counterparty will maintain auditable records for at least four years following the close of the Cooperative Agreement (currently expected to end June 30, 2020). Further, the Counterparty will permit these representatives access to its facilities and personnel for the purpose of on-site inspections, and will provide information, as requested, to determine compliance with the Cooperative Agreement terms and conditions.

15. Termination of Cooperative Agreement. If (i) funds are not appropriated or otherwise made available for the continued performance of the Cooperative Agreement, (ii) the Cooperative Agreement is terminated or (iii) the Cooperative Agreement funds are reduced or eliminated for the Project, APHL may terminate the Agreement without penalty upon written notice to the Counterparty.

16. Prohibition on Lobbying. No part of the Cooperative Agreement funds may be used for:

A. Publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation, designed to support or defeat the enactment of legislation before the Congress or any state or local legislature or legislative body, except in presentation of the Congress or any state or local legislature itself, or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any state or local government itself.

B. Paying the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any state government, state legislature or local legislature or legislative body, other than normal and recognized executive-legislative relationships or participation by an agency or officer of a state, local or tribal government in policymaking and administrative processes within the executive branch of that government.

C. Any activity to advocate or promote any proposed, pending, or future Federal, state or local tax increase, or any proposed, pending, or future requirement or restriction on any legal consumer product, including its sale or marketing, including, but not limited to the advocacy or promotion of gun control.

D. In addition, the Cooperative Agreement is subject to the additional lobbying restrictions and provisions of CDC's Anti-Lobbying Restrictions for CDC Grantees (an electronic copy of which is currently available at http://www.cdc.gov/grants/documents/Anti-Lobbying_Restrictions_for_CDC_Grantees_July_2012.pdf).

17. Federal Information Security Management Act. The Counterparty will ensure that all information systems, electronic or hard copy, that contain federal data are protected from unauthorized access and will comply with the Federal Information Security Management Act (FISMA), Title III of the E-Government Act of 2002, as amended (Pub. L. 107-347).

18. Gun Control Prohibition. None of the funds made available under the Project Agreement may be used, in whole or in part, to advocate or promote gun control.

19. Needle Exchange. No funds made available under the Project Agreement may be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

20. Blocking Access to Pornography. No funds made available under the Project Agreement may be used to maintain or establish a computer network unless this network blocks the viewing, downloading and exchanging of pornography. Nothing in this Section 20 will limit the use of funds necessary for any federal, state, tribal or local law enforcement agency or any other entity carrying out criminal investigations, prosecution or adjudication activities.,

21. Trafficking in Persons. If the Counterparty is either a for-profit organization or a nonprofit organization, including any nonprofit institution of higher education, hospital, or most US tribal organizations then the following provisions apply.

- A.** The Counterparty, its employees, any subcontractors under the Agreement, and any subcontractor's employees may not:
- i.** Engage in severe forms of trafficking in persons during the period of time that the Agreement is in effect;
 - ii.** Procure a commercial sex act during the period of time that the Agreement is in effect; or
 - iii.** Use forced labor in the performance of the Project or any work performed by approved subcontractors under the Agreement.

22. Meetings and Conferences; Logo Use for Conferences and Other Meetings. If the Project Agreement involves or is related to a meeting, conference or seminar, then the following provisions apply.

- A.** The Counterparty will include the following statement on conference or meeting materials, including promotional materials, agenda and internet sites:

“Funding for this conference was made possible (in part) by the U.S. Centers for Disease Control and Prevention. The views expressed in written conference materials or publications and by speakers and moderators do not necessarily reflect the official positions of the U.S. Department of Health and Human Services, nor does the mention of trade names, commercial practices or organizations imply endorsement by the U.S. Government.”

- B.** Neither the DHHS nor the CDC logo may be displayed if such display would cause confusion as to the conference source or give false impression of U.S. Government endorsement. Use of the DHHS logo is governed by U.S.C. §1320b-10, which prohibits misuse of the DHHS name and emblem in written communication. The Counterparty is prohibited from using the DHHS name or logo except as governed by U.S.C. §1320b-10. The appropriate use of the DHHS logo is subject to the review and approval of the DHHS Office of the Assistant Secretary for Public Affairs. Moreover, the Office of the Inspector General has the authority to impose civil monetary penalties for violations (see 42 CFR Part 1003). Neither the DHHS nor the CDC logo can be used on conference materials without the expressed, written consent of APHL (who, in turn, must receive such consent from the CDC).

23. Certifications. By signing the Project Agreement, the Counterparty certifies the statements listed below. These certifications are material representations of facts upon which APHL relied when it entered into this transaction.

A. Debarment, Suspension, Ineligibility and Voluntary Exclusion. The Counterparty certifies that neither it nor its principals is presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any Federal department or agency.

B. Lobbying. The Counterparty certifies that:

i. No Federal appropriated funds have been paid or will be paid, by or on behalf of the Counterparty, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

ii. If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the Cooperative Agreement supporting this Agreement, the Counterparty will complete and submit Standard Form-LLL, "Disclosure of Lobbying Activities," in accordance with its instructions.

C. No Delinquency on US Government Debts. The Counterparty certifies that it is not indebted to the US government, and does not have a judgment lien filed against it.

D. Recent Felonies. The Counterparty certifies that it has not been convicted (nor has any of its officers or agents acting on behalf of the Counterparty been convicted) of a felony criminal violation under any Federal or State law within the preceding 24 months.

E. Equal Opportunity Employer. The Counterparty certifies that it is an Equal Opportunity Employer in accordance with US law and regulation in effect as of the date of this Agreement.

EXHIBIT B
The Project and Budget

See attached.

APHL Funding to begin or enhance an existing childhood blood lead testing program proposal.

Vermont Department of Health Laboratory (VDHL)

The VDH Laboratory's need for funding

Since 1993 the Vermont Department of Health (VDH) Laboratory has operated a program for the analysis of lead in blood, with samples being collected from children at 12 and 24 months of age, though a range of client ages are seen in practice. In order to support the community through the national and statewide public health blood lead initiatives¹ the laboratory needs to update its equipment used for blood lead analysis – both to ensure the reliability of its program and to continue to improve services by lowering the detection limits reported to meet the demands associated with the observed trend of declining levels of lead in blood².

In addition to providing blood lead screening and confirmation results directly to clients, the VDH Laboratory's blood lead analysis program supports a broader public health purpose through the ongoing compilation and reporting of data to monitor trends which then allows health professionals to target parts of the community for action. The Healthy Homes Lead Poisoning Prevention Programs in the State of Vermont and New Hampshire both receive blood lead results from our laboratory.

The technology currently employed at the VDH Laboratory uses graphite furnace atomic absorption spectrometry (GFAAS) instruments which have proven to be reliable and robust throughout the life of the program and have so far provided the required sensitivity. While it would be desirable to move towards the introduction of inductively coupled plasma – mass spectrometry (ICP-MS) instruments in the analysis of lead in blood, the use of GFAAS as a 'high complexity reference method' is well established and, with developments in instrumentation, have become even more sensitive while remaining affordable to many laboratories.

In comparison, even entry level ICP-MS systems can be cost prohibitive (~\$200,000) and require modification of methods and laboratory practices, though offering the advantage of lower limits of detection and the ability to analyze multiple elements simultaneously. The VDH laboratory uses ICP-MS instruments extensively in its drinking water and chemical threat analysis programs, and these instruments will soon be at capacity when the statewide lead in school drinking water project commences.

The VDH Laboratory operates two GFAAS instruments exclusively for blood lead analysis which are nine and thirteen years old; both now outside of the manufacturer's support period. The maintenance of these instruments is increasingly problematic and the preventive maintenance contracts can no longer guarantee a repair when parts break down. There is no funding in the laboratory's current budget to replace either instrument, and with laboratory funding becoming tighter there is a need for critical equipment to be more reliable and require less operator interaction, which also results in more efficient use of staff resources.